SNAP MOP - Chapter 2
Recruitment Activities
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2. Recruitment Activities

2.1. INTRODUCTION

The recruitment goal for the Study of Novel Approaches for Prevention (SNAP) is to randomize 600 participants over a two-year period. Participants will be recruited from two centers and randomly assigned to one of three groups: control (N=200), self-regulation with small changes (N=200) or self-regulation with large changes (N=200). Participants will be recruited in cohorts of 60 (20 randomized to each group) at the centers. There will be five cohorts at each center.

2.2. RECRUITMENT STRATEGIES

2.2.1. General Information

The general recruitment strategy for SNAP will be to use a multi-method strategy including advertisements in local media (television, newspapers, Internet, radio, etc.), direct mailings to young adults, and site-specific recruitment at locations where the target population likely live and work. These site-specific recruitment strategies include attending local meetings of young adult groups and making presentations or providing information to target specific worksites and universities in the metropolitan area of each study site.

In order to reach SNAP recruitment goals, each SNAP clinic should develop clinic-specific recruitment plans. As a start, each SNAP clinic should attempt to determine the number of eligible participants who reside in their catchment area. Each SNAP center should design a comprehensive recruitment plan after careful assessment of its local community. A single strategy is rarely sufficient to reach recruitment goals. Numerous recruitment strategies and methods that should be considered when developing a local SNAP recruitment plan are included in sections that follow.

Since SNAP is a long-term study, clinic staff must do their best to identify potential participants who will be able to maintain their commitment to the study. Motivational enhancement techniques, along with other SNAP screening procedures, can help in this regard. The local clinic behaviorist should organize efforts to build skill in using motivational interviewing among recruitment staff as well as other staff and investigators who have contact with participants. The members of the site team (e.g., intervention staff and clinic staff) should also take part in discussions of potential participants prior to randomization.

2.2.2. General Guidelines

Patient recruitment is of prime importance to the success of this study. Listed below are points to consider on recruiting participants.

1. Emphasize the importance of the trial. Emphasize the services provided. The trial provides a system of follow-up, which parallels the participant's private care, but does not conflict with it. This programmatic approach includes cooperation in general matters pertaining to medical care, special attention to risk factors, and the provision of health information. Approach potential participants more than once, if necessary.
2. Be courteous and pleasant, and potential participants will respond positively.
3. Be professional and show interest and enthusiasm in the study.
4. Make sure that the potential participant fully understands the potential risks and benefits of the study. Explain all aspects of the study detailed in the participant brochure and informed consent document. Assure that the participant understands the information in the documents. Allow the participant sufficient time to consider and sign the informed consent document.
5. Potential participants may be told, "We don't know the answers, but here is a chance to help medical science."
6. Some potential participants will be motivated by stressing that the results may benefit their children and that they may have a chance to help society as well as themselves. Other advantages would be close follow-up from experts in relevant disciplines and increased knowledge and sense of involvement in their long term health.

2.2.3. Specific Recruitment Strategies and Tools

Included below are a number of strategies for each site to draw upon in developing a tailored local recruitment plan.

2.2.3.1. Inform the Healthcare Community

In order to foster a supportive partnership with health care providers in the community, it is essential that individual practitioners be informed about the SNAP objectives and participant eligibility criteria in advance of announcements to the media and potential participants.

Potential participants may consult their health care providers before or during the SNAP screening process for guidance or approval of SNAP participation.

Health care providers need to be assured that SNAP will not interfere with the existing relationship with their patients.

Health care provider referrals can be a source of participants. Decisions about which health care professionals to inform about SNAP and the method of informing them should be made after consideration of the cost effectiveness of each method. Health professionals to be informed might include:

- primary care providers
- medical residents and interns
- primary care providers' assistants
- nurse practitioners and registered nurses
- registered nutritionists
- exercise physiologists and physical therapists
- pharmacists
- any other healthcare providers who may be deemed appropriate by an individual center.

a. Colleague Letters

Clinics may want to send a "Dear Colleague" letter that includes a statement about the rationale for SNAP. A protocol summary that gives a brief description of the study design, the sponsors, the dates of the start of recruitment, site-specific information about personnel (PI, co-PIs, Program Coordinator), the clinic location, and the phone number for more information should be included with the letter. A SNAP study brochure could also be enclosed with the Dear Colleague letter and a fact sheet that provides background information about SNAP, study interventions, and eligibility criteria.

b. In-Person Contacts

Face-to-face contacts between the Principal Investigator or Co-Investigators and members of the medical community should be scheduled before recruitment begins. These may include:

1. SNAP presentations at regularly scheduled meetings of medical groups and professional organizations.
2. Presentations hosted by the SNAP centers.

3. SNAP displays at national or regional medical conferences, conventions, etc.
4. More informal discussions within the medical community of the SNAP design and goals may be as effective as formal presentations.

c. Articles

Articles describing SNAP should be submitted to journals and other professional publications that are distributed nationally, statewide, or locally (e.g., local medical society newsletters). Articles submitted to national publications will be coordinated centrally, but sites should pursue local publications.

d. Contact Information

"Pocket" cards or Rolodex cards with SNAP information, eligibility criteria, site location and phone number can be given to health care professionals for easy reference.

2.2.3.2. Inform or Prepare Community at Large

One of the greatest challenges of recruiting participants for SNAP will be to create a general awareness and understanding of the importance of this clinical trial. This effort may directly increase the number of volunteers making contact with SNAP staff, and broad-based community education about the trial will also increase the likelihood that volunteers may make contact SNAP when prompted by other methods. In addition, community knowledge about the importance of the trial facilitates support for the trial from family and friends of prospective participants. This effort will necessitate a public education campaign about weight gain among young adults -- its prevalence, the role of excessive body fat in the pathogenesis of the disease, its cardiovascular complications, and the importance of SNAP in answering important questions about the advisability of preventing weight gain in young adults.

Because of the distinct differences in locations and target populations at the SNAP clinical centers, the most effective and expedient means of achieving community awareness will vary from site to site. The process of community assessment and the development of partnerships within the local community should be followed as part of planning recruitment strategies that are critical to achieving the SNAP recruitment goals.

Some of the key strategies to create public awareness and support that will enhance SNAP recruitment efforts are:

a. Announcements

Send letters announcing and describing SNAP to business and professional organizations, service organizations (Rotary, Lions Club, sororities/fraternities, etc.), business owners and leaders, worksites and community groups. Ready-to-publish news articles about SNAP or related topics (i.e., diet, exercise, obesity, etc.) suitable for inclusion in newsletters or lay journals directed towards the study population and/or distributed by any of the above are another effective means of raising awareness and interest. Include the phone number and address of the local SNAP clinic where potential participants may learn more about SNAP.

b. Presentations

Make presentations to the groups listed above. Topics may include diabetes, exercise strategies, weight control and obesity, etc.

c. Community Coalition

Form a SNAP community coalition, advisory committee, or advisory network whose members can be spokespersons for the local SNAP site or can act as liaisons to the targeted population.

2.2.3.3. Inform Potential Participants

Potential participants should receive repeated recruitment messages about SNAP through a variety of media. An important key to successful recruitment is to develop "layered strategies" that deliver a repeated message to a targeted audience with a planned timeline. Volunteers are often unlikely to respond to a single message but may respond after hearing the same message a number of times.

a. Mass Mailings

A mailing sent to potential participants may include a cover letter from the local SNAP PI and/or a SNAP study brochure or flyer and a business reply card that requests more information about SNAP. Whenever feasible, sites are encouraged to limit mass mailings to "enriched" or "targeted" lists, although the site may also elect to send mass mailings to the general population as well.

Sources of lists include:

1. Commercially -prepared purchased lists which may target potential volunteers by age, sex, ethnicity, weight, geographic location, etc. (Businesses that contract to prepare large mailings can obtain lists

for a fee. Cost is typically based on the number of names provided and the criteria requested, e.g., age and gender.)

2. Department of Motor Vehicles lists which may be useful in identifying individuals who are age-eligible who reside within clinics' geographic catchment areas.
3. Voter registration lists, which may also be useful in selecting age- and geographic-eligible participants.

Sources of "enriched" lists (lists that are comprised of names of individuals who have a high likelihood of being interested in and/or eligible for SNAP are considered enriched lists, although some of the organizations controlling these lists may not release names directly to SNAP staff, requiring staff to work through the organization to send information to individuals) may include:

1. Medical practices
2. HMOs, MCOs
3. Medical chart reviews
4. Mail order pharmacies
5. Special populations - age, gender, ethnicity - may be obtained from special interest groups.

b. Print and Electronic Media

Print media, television and radio may also be effective avenues of communication to potential SNAP participants. The effectiveness of these methods as well as the specific print and electronic media selected may depend on the site-specific media market. The use and placement of various types of media can vary, such as:

1. Study-wide or local brochures that give basic information about SNAP design and rationale which can be distributed through a variety of means, e.g., door-to-door, with existing publications, through worksites, etc.
2. Posters containing SNAP logo, eligibility criteria, clinic-specific information which can be posted throughout community at health care service facilities (e.g., provider/clinic offices, pharmacies) and high-traffic areas.

3. Flyers (8.5" x 11" duplicates of posters described above) can be distributed through the mail or at community events.
4. Free advertising such as PSAs (public service announcements) may be placed at no cost on TV, radio, and in newspapers and magazines at the discretion of the owner of the media source. Other free advertising includes the informational pieces about SNAP generated through interviews, news releases (local or national) or articles written by SNAP personnel. These may also appear in church or organizational bulletins or newsletters.
5. Paid advertisements which can appear on TV, radio, in newspapers, magazines, on bus billboards, walkboards (a small version of a billboard that can be seen by pedestrians), billboards, inside buses and subways.

c. Presentations

Oral presentations about SNAP to any and all groups of interested people can generate numerous inquiries from potential participants.

Word-of-mouth is an effective means of obtaining volunteers. Screenees, randomized participants, and individuals who are contacted through other means (e.g., community talks at civic groups, health fairs, etc.) should be encouraged to tell others about SNAP throughout the recruitment period. Extra SNAP study brochures should be readily available for screenees to take to other potential participants.

d. Community Events

Community events can be an effective means of raising awareness of diabetes and its risk factors and enlisting volunteers who may qualify. By providing free information, community events provide an opportunity to reach a large number of people in a short time. However, these events may require a significant amount of time and staff to plan, implement and follow-up, and actual participant yield may be low.

Materials distributed at community events may include:

- the SNAP brochure
- educational handouts on diet
- educational handouts on exercise.

Sites may include:

- health fairs at community events or worksites

- local gyms
- supermarkets
- drugstores
- places of worship
- work-sites.

e. Community Events

Miscellaneous advertising opportunities may include:

1. SNAP information booths or displays at seminars, conferences, meetings
2. Payroll or bill stuffers - 8.5" x 3” information enclosure with payroll checks or bills (utilities, etc.)
3. Institutional e-mails
4. Brochures included in informational packets when the local center's participation in an event is not appropriate or feasible.
5. Home page on Internet describing SNAP and giving address and phone for SNAP sites (the study’s centralized home page will screen potential participants on relative eligibility criteria and location and forward appropriate information to clinical centers).
6. Point-of-purchase displays at health care providers’ offices, pharmacies, etc.

2.3. RECRUITMENT MATERIALS

Recruitment materials include flyers, posters, brochures, small items with SNAP logos, and dedicated e-mail address. Incentive items may include small items such as hats, T-shirts, or similar. Participants are compensated for their time and effort to participate in the study.

2.4. DEVELOPING A RECRUITMENT PLAN

Recruitment is challenging and vitally important to the success of SNAP. Retaining the participants for the remainder of the study begins in the recruitment phase by enrolling the right participants. Following is a brief description regarding development of a recruitment plan. Each clinic should create and adapt their recruitment plan to ensure they are meeting recruitment goals.

1. Identify staff involved with recruitment, review their responsibilities, and set regular meeting times.
2. Prepare an outline of your plan (brief but descriptive) in order to meet your designated randomization goal. Determine the number of patients needed to screen per week in order to successfully enroll the specified amount (consider the number of people predicted to refuse or be ineligible).
3. Decide on the best system(s) at your site to promote referrals **FROM WITHIN** your office/clinic/institution:
    a. Promote SNAP among staff
    b. Promote SNAP among patients
    c. If available, use computer lists of your patients. Call, send letters, or flag charts for upcoming appointments.
4. Decide on the best system(s) at your site to promote referrals **FROM OUTSIDE**.
5. Discuss your plan with your Project Coordinator and Study Team, as they can provide extra assistance as needed.
6. Monitor your recruitment progress and revise your plan as needed.
    a. Meet weekly as a team to discuss actual progress of your weekly goals. Determine what is working and what is not. Review barriers and problems. Revise the plan as necessary.
    b. Maintain a screening log for all patients screened.
7. Stay involved and motivated – keep the momentum going! Keep your Study Team informed. Share your ideas and problems. Keep your staff informed of your site's progress and thank them for their support and help. Recognize contributions of successful staff members.

2.5. RECRUITMENT GOALS AND MONITORING AND ASSISTANCE

2.5.1. Recruitment Goals

Multiple factors will contribute to variation in randomization rates. Size of the potentially eligible population will be a major factor as will the degree to which potential participants at sites may encounter barriers to participation. Each center may have considerable variation in randomization rates from month-to-month based on local factors. Nonetheless, during the two-year randomization period, participants will be recruited in cohorts of 60 (20 randomized to each group) at the centers. There will be five cohorts at each center.

The National Institutes of Health (NIH) is the funding agency for SNAP and requires annual reporting of enrollment by ethnicity, race and gender. For these purposes, ethnicity is reported as either Hispanic or Latino ***OR*** Not Hispanic or Latino. Race is reported to the NIH as American Indian/Alaskan Native; Asian; Native Hawaiian or Other Pacific Islander; Black or African American; and/or White. SNAP proposes to recruit at least 25% minorities. SNAP proposes to recruit at least 25% men.

2.5.2. Recruitment Monitoring

2.5.2.1. Local Monitoring

The prescreening process will contribute valuable information regarding the initial phase of recruitment activities study-wide and at each center. Each center will capture potential participant information during screening via the completion of the Pre-Screening Form, the Telephone Screening Form, the Orientation Visit, and two Screening Visits. The information generated by these forms will be entered into the study website. Each center is encouraged to use the study website and available online dynamic reports to guide their local recruitment strategies. This information will be helpful in assisting with strategies to facilitate randomization.

2.5.2.2. Central Monitoring

Beginning with pre-screening, information gathered on each potential participant will be captured centrally by the coordinating center and tracked. Web-based reports may be generated at any time to provide up-to-date recruitment totals and rates. Additional reports will be generated by the coordinating center, as needed, such as local reports of screening efforts. These reports may be particularly useful in gauging screening progress if sites lag behind in contacting potential participants and/or entering screening information. The integrity of these reports will depend on clinics entering data in a timely manner.

2.5.3. Processing and Reporting

To facilitate the processing, reporting and problem-solving elements of the recruitment process, the study recruitment reports will be reviewed regularly on study calls. Discussion will include reviewing reports and providing feedback concerning the study's progress toward achieving their recruitment goals. Other purposes of this discussion are to lend support and encouragement to the center and to summarize lessons learned from sites for dissemination to the other site. It will be the responsibility of each center to facilitate this process by providing center-specific summaries of their screening and recruitment activities.

2.6. RESPONSES TO RECRUITMENT PROBLEMS

Strategies for solving recruitment problems will be center-specific based on individual site and study-wide recruitment data. These strategies will be defined and implemented through a series of hierarchical responses that will begin one month after the start of recruitment and will be applied study-wide. The stepped response is designed to address more serious recruitment problems with more aggressive assistance.

The following responses serve mainly as a process to approach recruitment problems and considerable flexibility will be required in the implementation of the responses. The Executive Committee will determine the actual shortfall from recruitment goals that will trigger a response on a continuing basis, depending upon center-specific factors and study-wide recruitment progress. If both centers fail to meet recruitment goals, it may be necessary to reassess study-wide recruitment strategies and develop recommendations to enhance overall SNAP recruitment.

2.7. INFORMED CONSENT

The SNAP informed consent process is designed to meet the ethical obligations to the participant and improve retention by fostering a progressive understanding of the program by the participant as well as the development of a positive relationship between the participant and clinic staff. It is an interactive and conversational process, the ultimate goal being maximum understanding of SNAP and its impact upon the participant's life. The understanding includes what the responsibility of the participant is to the trial, and the responsibility of the investigators to the participant. It is anticipated that one result of this process will be maximized retention of participants in SNAP. This informed consent process is integrated with the screening and enrollment process and is described in Chapter 5.

2.8. RETENTION ISSUES DURING SCREENING

Retention of SNAP volunteers is covered in Chapter 8 of the Manual of Procedures, which contains many useful techniques for improving attendance and compliance of the SNAP volunteers throughout screening and during follow-up. Nonetheless, an essential aspect of retention occurs at the same time of recruitment and screening. Volunteers who have significant barriers to participation should be identified during the screening process, and the extent to which these barriers threaten active participation should be assessed thoroughly prior to randomization. Despite the need to meet recruitment goals, it is essential that all staff recognize that enrolling participants who have significant challenges to active participation may compromise study objectives.

The clinic and intervention staff should be actively involved in the screening and randomization process: helping all staff and investigators who have contact with volunteers build skills in motivational interviewing, discussing potential participants prior to randomization, and meeting with potential participants to assess potential barriers to success in SNAP. A number of "red flags" may be considered to identify enrollees for which adherence may be particularly difficult:

- Motivation to participate not clear
- Reservations about randomization (i.e., really wants only one arm of the study)
- Doesn't fully understand commitment (i.e., long duration of study, life-style, time and effort requirements)
- Missed visits during screening
- Adherence problems during screening
- Lack of family support for participation
- Current family crisis or transition
- Frequent job changes
- Cultural issues that mitigate against protocol adherence
- Emotional problems (including low self-esteem).

We hear from staff in other clinical trials that many retention problems can be traced back to issues identifiable during screening. Needless to say, it is impossible to catch all retention problems prior to randomization, but "an ounce of prevention is worth a pound of cure," so careful attention during screening to the indicators listed above will likely save many problems later. Unfortunately, a minority of participants who present retention problems often take up a majority of staff time, emphasizing the need to be careful when screening participants.

Once potential participants have been identified, clinic staff may consider adopting the following approaches to address potential adherence problems:

- Clarify motivation for participation in SNAP
- Fully explore willingness to be randomized. This is a good opportunity to use motivational interviewing. In pre-randomization the goal is to help potential participants decide if SNAP is right for them, given all the things that are going on in their lives. This approach is likely to reduce potential participants' defensiveness.
- Fully explore understanding of SNAP participation commitment (including having participant go over schedule for next few months and talk about how

potential demands of SNAP would be accommodated). Here again, motivational interviewing techniques may be useful.

- Discuss the schedule of visits during study and emphasize necessity for consistent long-term attendance.
- Discuss adherence problems during screening in context of continuing need to adhere during study and maintain records.
- Discuss family support for participation in SNAP and any current or imminent family crises or transitions.
- Discuss job and school situation in context of potential problems transitions may create for SNAP participation.
- Discuss cultural issues that might facilitate or hamper SNAP participation.

Hold full discussions among all staff to discuss potential participants for whom serious questions arise, even if the person assures staff that SNAP participation will not be a problem.

2.9. MOTIVATIONAL ENHANCEMENT METHODS

Participants volunteer to participate in a clinical trial for many different reasons, including health improvement and altruism. SNAP staff should help potential participants identify their personal motivation for participating in the trial. Once identified, these reasons can guide efforts to maintain the motivation of SNAP volunteers for continued participation. The appropriate staff at each SNAP clinical center should develop a program to help staff and investigators incorporate motivational enhancement methods into their interactions with participants. This training program should emphasize using:

- Reflective listening to help participants identify personal reasons for participation as well as barriers to participation.
- Problem solving methods to help participants overcome identified barriers to active participation.

SNAP MOP - Chapter 3
Eligibility
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3. Eligibility

3.1. OVERVIEW OF STUDY POPULATION

The goal of the eligibility inclusion and exclusion criteria is to identify participants who are at moderate or high risk of weight gain over time where weight gain prevention seems to be an appropriate message. The following section will describe the rationale used to select the eligibility criteria for this trial. This section of the MOP is provided as background for SNAP staff so that they can respond to questions that may be asked by a potential participant. See Chapter 6, Screening for detailed information about how to operationalize these eligibility criteria.

SNAP will recruit 600 participants from 2 clinical centers. The initial goal is for each center to have an equal share in recruitment (300 participants from each clinical center). Participants will be recruited in cohorts of 60. There will be five cohorts recruited at each clinical center.

3.2. INCLUSION CRITERIA

3.2.1. Body Mass Index

Participants with a BMI between 21 - 30 kg/m² are eligible. A BMI of 21 kg/m^2 was selected as the lower end of the eligibility criteria because these individuals are able to lose 5-10 pounds and still remain within the normal weight range. The upper criteria was selected since individuals with BMI > 30 kg/m^2 are considered obese and weight loss, rather than weight gain prevention, is more appropriate for these individuals.

3.2.2. Gender

Men and women are eligible. SNAP plans to recruit approximately 25% men. Women may be more likely to choose to participate in clinical trials, especially trials related to weight gain prevention. The gender distribution will be monitored by the Coordinating Center.

3.2.3. Age

Participants must be 18-35 years of age to be eligible for SNAP. This age group was selected because young adults have the greatest risk of weight gain over time and prevention strategies implemented at this time may be important for lowering the risk of future weight gain and cardiovascular risk factors. Age 18 was selected as the lower limit to in hopes that the young adults were no longer living at home with their parents and thus would be less responsible for their food choices. Additionally, concerns about the reported effects of the development of

eating disorders are greater in younger people. Age 35 was selected as an upper limit because weight gain appears less common after this age. If an individual is 35 years old when he/she begins the screening process, but turns 36 prior to randomization, he/she will be allowed to continue in the study as long as all screening visits were conducted within the appropriate window.

3.2.4. Ethnicity

All ethnic groups are eligible for SNAP. The goal of SNAP is to recruit 25% of the study cohort from all minority groups but with special emphasis on African Americans, Hispanic Americans, and American Indians, who are disproportionately affected by obesity and experience larger weight gains during young adulthood. The Coordinating Center will monitor each clinic's recruitment and study-wide recruitment to help the study achieve the goals for minority recruitment.

3.2.5. Willingness to Participate

To be eligible, individuals must be willing to be randomly assigned to any of the three programs.

3.3. EXCLUSION CRITERIA

3.3.1. Exclusions That May Limit Adherence to Intervention or Affect the Conduct of the Trial

Since participants may be randomized to a lifestyle intervention requiring participation in a group treatment and ongoing efforts to lose or maintain weight, participants who do not appear to be able to perform these activities will be excluded. Specific exclusions related to these criteria are described below.

3.3.1.1. Have lost and maintained a weight loss of 10 pounds or more within the past 6 months

Such individuals may have difficulty losing additional weight and may be at an increased risk of experiencing weight gain during the intervention.

3.3.1.2. Trying to gain weight at this time

The goal of the intervention groups is weight loss or maintenance, so individuals trying to gain weight would be inappropriate for a weight loss or weight maintenance intervention.

3.3.1.3. Hospitalization for depression or other psychiatric disorder within the past 12 months

These individuals are at risk for subsequent hospitalizations and may find the requirements of the intervention overwhelming.

3.3.1.4. History of schizophrenia, manic depression or bipolar disorder

Such illnesses may limit the individual's ability to adhere to the interventions and may increase the risk of behavioral difficulties, which could cause disruption to the group. In addition, medications used to treat these problems may cause weight gain.

3.3.1.5. Past diagnosis of or treatment for a DSM-IV-TR eating disorder or meeting criteria for anorexia or bulimia nervosa

The SNAP intervention is not appropriate for individuals with a history of or currently displaying symptoms of eating disorders.

3.3.1.6. Past diagnosis of or current symptoms of alcohol abuse or substance dependence

Individuals with heavy alcohol consumption may be less likely to adhere, consume more calories and may be difficult to retain in the trial.

3.3.1.7. Have had surgery for weight loss

The SNAP interventions are designed to assess large and small changes in behaviors. Individuals who have had surgery for weight loss must follow specific dietary guidelines and eating practices which may be contraindicated in the intervention. In addition, individuals who have had weight loss surgery may be different from the population that SNAP is studying which makes the results harder to generalize.

3.3.1.8. Chronic steroid use

Individuals who use steroids chronically are excluded because these drugs are associated with weight gain. Hormone replacement therapy (HRT) and oral contraceptives are allowed. Topical and inhaled preparations are allowed since they are not well absorbed systemically and do not significantly cause weight gain. Examples of common steroids include: betamethasone, dexamethasone, hydrocortisone, methyl prednisone, prednisolone, and mednisone.

3.3.1.9. Currently using steroid pills/gel/shots for muscle mass or weight gain

Individuals who use steroids for muscle mass or weight gain are excluded because this conflicts with the SNAP intervention. If the individual is willing to discontinue the use of steroids, they are eligible to participate.

3.3.1.10. Currently pregnant, pregnant within the past 6 months or planning to become pregnant within the next 6 months

Individuals who are currently pregnant are excluded due to possible risks of recommending caloric restriction. (These individuals can be re-contacted for screening after delivery.)

3.3.1.11. Currently participating in a weight loss program

If the participant is unwilling to stop participation in the weight loss program, they are ineligible, as the weight loss program would conflict with the SNAP intervention and make assessing the results difficult.

3.3.1.12. Taking weight loss medications

This includes both prescription and over-the-counter weight loss products. Weight loss medications will interfere with the intervention. If the individual is willing to stop taking the medications, they are eligible to participate.

3.3.1.13. Currently participating in another weight loss or physical activity study that would interfere with this study

In the event that an individual says he/she is in another study, clinic staff must determine whether the other study will interfere with SNAP. Depending on the other study's goals, it may be allowable to participate in both SNAP and the other study.

3.3.1.14. Not able to read, write or speak English

The intervention and all study forms were designed to be presented in English therefore individuals not able to read, write or speak English would not be able to complete the study as outlined in the protocol.

3.3.1.15. Perceived inability to attend the intervention and assessment visits

If the participant plans to move from the area within the next 6 months, they should be excluded as they will be unable to attend the active intervention phase and assessment visits as outlined in the protocol. If the participant plans to move from the area in the next 1 - 3 years the clinic

should probe to identify whether the participant will be coming back at regular intervals in order to meet the study visit schedule.

If the participant reports that they will be away for weeks or months at a time during the next 6 months, the clinic should probe in order to determine whether the participant would be able to attend orientation, screening visits and the initial 4-month interventions sessions as outlined in the protocol.

If a participant reports that the timing of the group meeting is not convenient for their schedule, the person should be excluded, but can be re-screened at a later time.

These individuals may be unable to fully participate in the intervention and will likely be lost to follow-up. Based on the discussion between the participant and the clinic staff, the person may be eligible for SNAP, or may be able to be re-screened at a later time.

3.3.1.16. Residence or work further than 30 miles from the intervention site

The intervention site may not be convenient for these participants and they may be unable to fully participate in the intervention and will likely be lost to follow-up. The clinic staff should probe in order to determine whether the person would be able to attend the visits as outlined. Based on the discussion between the participant and the clinic staff, the person may be eligible for SNAP.

3.3.1.17. Another member of the household (or roommate) is a participant or staff member on SNAP

Only one member per household (excluding group living arrangements such as dorms or sorority/fraternity houses), may be randomized. Participation is limited to one person per household since behavior changes in one member of the house might affect others in the house.

3.3.1.18. Does not have internet access on a regular basis

Participants will be asked to complete SNAP study forms online and to use the intervention website on a regular basis. Regular internet access is necessary to have access to all study materials.

3.3.1.19. Reasons to suspect that the participant would not adhere to the study intervention or assessment

A behavioral interview and staff review should include discussion regarding staff impressions of the person’s ability to adhere to the SNAP study intervention and assessment. If staff members do not feel this

person would be a good candidate for participation, they should be excluded. Care should be taken by clinic staff to document reasons for exclusions using detailed examples. For example, participant reports drinking six beers per day and not willing to give this up for the duration of the study.

3.3.2. Exclusion Criteria for Underlying Diseases Likely to Limit Lifespan and/or Affect the Safety of the Interventions

3.3.2.1. Type 1 diabetes

These individuals are excluded because their disease may affect their body weight and their ability to follow the lifestyle intervention.

3.3.2.2. Type 2 diabetes treated with insulin or oral medications that may cause hypoglycemia

These individuals are excluded because their disease may affect their body weight and their ability to follow the lifestyle intervention.

3.3.2.3. Report of a heart attack or stroke

Individuals reporting a history of heart attack or stroke are excluded because these conditions may affect their ability to follow the physical activity intervention.

3.3.2.4. HIV

There are insufficient data available to judge the potential health risk of the intervention for persons with HIV. Furthermore, AIDS is likely to lead to weight loss, which would be indistinguishable from voluntary weight loss which is the study intervention.

3.3.2.5. Active tuberculosis

These individuals are excluded due to involuntary weight loss associated with this disease.

3.3.2.6. Cancer with the past 5 years (except non-melanoma skin cancers or early stage cervical cancer)

Such individuals are excluded because these diseases may limit life span and produce involuntary weight loss and the intervention may be counter indicated for their treatment regimen.

3.3.2.7. Chronic hepatitis B or C

These individuals are excluded because their disease may affect their weight and their chance of surviving the length of the trial. It is important

to keep in mind that many health professionals will have antibodies for hepatitis B or C. These individuals would not be excluded unless they reported “chronic” or “active” problems with hepatitis.

3.3.2.8. Thyroid disease

These individuals are excluded due to weight fluctuations associated with this disease.

3.3.2.9. Liver disease

These individuals are excluded because their disease may affect their weight and their chance of surviving the length of the trial.

3.3.2.10. Renal disease

These individuals are excluded because they may be too ill to participate in the lifestyle intervention and may be unlikely to survive the length of the trial.

3.3.2.11. Inflammatory bowel disease requiring treatment within the past year

These individuals are excluded because their disease may affect their body weight and their ability to follow the lifestyle intervention.

3.3.2.12. Hospitalization for asthma in the past year

Such individuals are excluded because these diseases may not allow them to follow the physical activity intervention.

3.3.2.13. Other disease

In the event that an individual says he/she has another disease, clinic staff must determine whether the other disease will interfere with SNAP. Depending on the disease, it may be a disease which would be allowable in SNAP.

3.3.2.14. Chest pain during periods of activity or rest

Such individuals are excluded because these diseases may not allow them to follow the physical activity intervention.

3.3.2.15. Loss of consciousness

Such individuals are excluded because these diseases may not allow them to follow the physical activity intervention.

3.4. CONDITIONS REQUIRING MD CONSENT PRIOR TO PARTICIPATING

Individuals with the following conditions are eligible for participation in SNAP if their primary care physician agrees. These conditions may impact the participant's ability to follow their lifestyle intervention; however the SNAP intervention is an appropriate initial treatment for these medical issues. The physician must give permission and indicate that they will continue to manage these risk factors.

3.4.1. Type 2 Diabetes that is Not Treated with Insulin or Oral Medications That May Cause Hypoglycemia

Weight loss is an appropriate intervention for individuals with type 2 diabetes if they are not taking any medications that could lead to hypoglycemia.

3.4.2. Hypertension, Hyperlipidemia

Weight loss is an appropriate initial treatment for these types of medical issues. If the SNAP study identifies hypertension or Hyperlipidemia this with study measurements, the study will provide the participant with the values so that the participant can contact their physician in order to ensure that participation in SNAP is appropriate.

3.4.3. Heart Disease or Heart Problems

Physician consent is required for participants who report heart disease, heart problems or abnormal pulse rate in order to ensure that the physical activity intervention involved in SNAP is appropriate for this participant.

3.4.4. Doctor currently prescribing drugs for un-controlled blood pressure or major heart condition

Physician consent is required for participants who report being prescribed drugs for blood pressure or a major heart condition in order to ensure that the physical activity intervention involved in SNAP is appropriate for this participant.

3.4.5. Bone or Joint Problems

Physician consent is required for participants who report bone or joint problems in order to ensure that the physical activity intervention involved in SNAP is appropriate for this participant.

3.4.6. Health Problems Which May Influence the Ability to Walk for Physical Activity or Other Reasons Why a Person Should Not Do Physical Activity

Physician consent is required for participants who report health problems that may impact their ability to do physical activity. The physician should determine whether involvement in SNAP is appropriate for this participant.

SNAP MOP - Chapter 4
General Procedures
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4. General Procedures

4.1. GENERAL GUIDELINES

The following sections provide information on staffing certification, assignment of staff ID's, clinic ID's and standard procedures that will be used for all forms during the data collection visits in the SNAP study.

4.2. CERTIFICATION OF STUDY STAFF

Each clinical center will be responsible for designating staff to carry out data collection. These individuals will be centrally trained or trained by someone who was centrally trained. Certification is required for individuals conducting study measurements (e.g., blood pressure, blood drawing, height, weight, impedance measures, data entry and safety reporting). In addition, the Lifestyle interventionist(s) will also be certified. An individual may be certified in multiple study components.

The Project Coordinator at each site will be responsible for making sure the certification of staff is current. Quality control checks will be performed by the Coordinating Center to assure that all study measurements are being conducted by certified personnel.

The rationale for certification is that data should be collected in the same way on each participant at each site. All data collectors in SNAP should establish how they will collect data and how they will respond to questions from participants. Sometimes unimportant factors, such as the order of forms, the setting, or the mood of the data collector can impact the quality of data. The same data collection methods should be used at all SNAP sites during the course of the study. Clinics should not have staff collect data that are not certified. Should this happen, it will be considered a violation of the protocol. Multiple staff should be trained and certified so that back-ups are available. When a new staff member is added, they must be trained by a certified individual at the local clinic site or centrally trained at a SNAP training session.

4.3. ASSIGNMENT OF CLINIC STAFF CODES

Staff ID's (personnel codes) will be assigned to SNAP staff members by the web-based data management system. The staff ID is assigned at the time certification is complete and is recorded as part of the user profile on the SNAP web site. The Staff ID is a five-digit number. A list of all active and inactive staff IDs at each clinic can be obtained from the data management system. Notify Letitia Perdue at the

Coordinating Center in the event of staff resignation; their staff ID will be closed out of the system.

4.4. ASSIGNMENT OF CLINIC CODES

Each clinic site is assigned a clinic number. This number will be used for multiple reports in identifying individual clinics. The Clinic Codes are listed below.

CLINIC NAME	CLINIC CODE
PROV - Providence (Brown University)	1
CH - Chapel Hill (University of North Carolina)	2
WFU - Winston-Salem	9

4.5. SNAP FORMS

SNAP study forms are will accessible via the study web site. There are two different types of forms, staff-entered forms and participant-entered forms. Staff-entered forms should be completed on the paper versions and then data entered into the SNAP web site. For participant-entered forms, participants may enter information directly on the participant web-site or clinics may download and make copies of the study forms. There are several advantages to having forms available via the SNAP web site:

- The correct version of each form is immediately accessible
- Reduce the need for storage of large boxes of forms at each site
- Allows each site to choose whether to copy on both sides or only one side of the paper
- Reduce expensive shipping costs to the study.

Staff members are encouraged to test your abilities in downloading forms as soon as possible before you need these forms for a participant exam.

4.5.1. Downloading Forms from the SNAP Websites

Over the course of the study, changes will be made to the study forms. A date of issue and version number will appear as the footer on all study forms. Forms can be located on the study web site and printed locally for reproduction. Study forms are located on the SNAP web site under Documents > Forms. Click on the selected form to open and print the necessary number of forms.

All SNAP forms have a standard header that includes the following: Patient ID; Date Form Completed; Administration Type; and Visit Code. A description of these items is provided below.

4.5.2. Participant Identifiers and Key Information

A log of all participants screened will be maintained in the SNAP web based data management system. After a pre-screening form has been completed and submitted on the website, a PID and ACROSTIC will be assigned to the participant. All study forms should be entered into the SNAP data base on a weekly basis.

4.5.2.1. The Patient Identification (ID) Number

The participant ID is a five digit number. This five-digit ID is assigned to each person who completes a pre-screen interview. The ID number is unique for that individual; that is, it will never be assigned again. As the participant continues through the study, he or she will keep the same assigned ID number.

Participants will also be identified by a code called the acrostic that represents their full name. This six-letter alphabetic code will serve as a second check of the Participant ID. The acrostic is comprised of the first three letters of the participant's last name, the first two letters of his/her first name, and his/her middle initial. For example, the acrostic for Mary Jane Doe would be DOEMAJ. If the participant's last name is comprised of fewer than three letters, or if the participant has no middle name, a dash will be used by the computer to fill in each blank space. For example, John Smith (no middle name) would have an acrostic of SMIJO-.

Even if a participant changes their name during the course of the study, their acrostic will remain the same. If an error is made in assigning the acrostic at the beginning of the trial and discovered later, the acrostic should <u>NOT</u> be corrected.

4.5.2.2. Date Form Completed

Clearly enter the date the form was completed in the header of the forms. This will be the date the participant comes in for their clinic visit or the date the participant fills out the forms. The website will automatically fill in this date if entry is completed online via the SNAP website.

4.5.2.3. Administration Type

The three types of form administration are self-administered (web), self-administered (paper), or staff-administered. If a paper form is being used,

record either a 2 for self-administered (paper) or a 3 for staff-administered in the space provided. For forms filled out on the website this field will automatically be generated as option 1, self-administered (web).

4.5.2.4. Visit Code

The visit code is a three digit character Please refer to the following codes when filling in the visit code.

Pre-Screening	PRE
Telephone Screening	TEL
Orientation Visit	ORT
Screening Visit 1	SV1
Screening Visit 2	SV2
4 Month Follow-up	4MO
1 Year Follow-up	1YR
2 Year Follow-up	2YR
3 Year Follow-up	3YR
4 Year Follow-up	4YR
As Needed	PRN

Special use forms such as Study Termination, Serious Adverse Events require a visit code of PRN.

4.5.3. General Rules for the Completion of Forms

The following general information should be discussed with each participant prior to their completion of questionnaires. These same rules should be adhered to by staff that is completing forms and questionnaires.

1. Print in BOLD LETTERS. Much information is garbled simply by sloppy handwriting. This can result in inaccurate data or time lost in data entry.
2. Print clearly and use a pen.
3. Clearly enter all dates numerically for month, day, and year using leading zeros as necessary. For example: July 5, 2010 would appear as 07 05 10.
4. Record all numerical values carefully in the boxes provided, using leading zeros as necessary. In those rare cases where a value is not available,

draw a line through the space(s) to indicate that the item is missing intentionally, and write NA (Not Answered) beside the response.

5. All corrections should be made by marking through the error and writing the correct information above it. The individual making the correction should sign her or his initials next to the corrected entry and date it. Do not attempt to erase or write over any entry. Do not use correction fluid.
6. Certain fields require dates. Participants may not always know the exact date of a procedure or event. When you know the year, but not the month or day, enter 06-15 and the year.

Once a participant has completed the self-administered forms, a staff member should check all forms immediately to ensure that they are complete and legible throughout.

For forms and questionnaires completed by staff, another staff member should review the forms immediately following the clinic visit. The staff member that completed the form should clarify illegible sections.

4.5.4. Study Charts

There are no specific requirements in SNAP on the structure of study charts. Specifically, because SNAP is not a drug trial, clinic staff will not be required to keep a separate chart of “source documents” unless they wish to do so or are required to do so by their IRB. (In drug trials, FDA regulations require that case histories of patients’ eligibility and course of therapy be developed independent of the study forms to support the validity of the data collection process.)

Study charts must be stored in a secure location, accessible only to study staff. During non-clinic hours, the files should be locked. These requirements are necessary to protect the confidentiality of the participant data.

All SNAP clinic visit material should be accurate, detailed, signed, and dated. Clinic staff may keep two participant study charts, one for clinic information including study forms and one for intervention. If two charts are used, it is best if these are different colors. For example, visit checklist charts are red and study form charts are green. If clinic staff elects to use one study chart, then source documentation should appear on the left side and study forms on the right side. Each clinic should follow their own institution’s guidelines for charting requirements. It is understood that clinics will need flexibility in preparing their study charts. The clinic chart should be labeled with the Participant ID and acrostic. Each study form and other clinic material should include the participant ID and acrostic.

Examples of Clinic Visit materials include, but are not limited to the following:

1. Participant identification and demographics such as: name, address, phone, date of birth, age, race and gender.
2. Information on the contact information sheet.
3. All informed consents which should be signed and dated. Some IRB's may require the time that the informed consent was signed. In some situations, there will be multiple informed consents. If the participant refuses certain parts of the study, this should be noted.
4. Some IRB's will require information on women's reproductive potential; you might include this information in the comment section of the clinic visit checklist.
5. Print outs of SNAP laboratory reports, blood pressure, etc.
6. Eligibility worksheet with inclusion/exclusion criteria, or clinic flow chart or clinic checklist of completed procedures.
7. Information on Adverse Events, Serious Adverse Events should include details of the event, the date(s) of the event, and copies of materials collected for event verification if needed.
8. Clinic visit information on general medical history, current medications, behaviors, dates of visits, randomization and group assignments. Any documentation of noncompliance, missed visits, telephone calls to or from the participant, etc. Clinic notes include notes written by the physician, nurse, or other clinic staff.

SNAP MOP - Chapter 5
Informed Consent Guidelines
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5. Informed Consent Guidelines

5.1. INTRODUCTION

The success of every clinical trial depends on the cooperative participation of its subjects. For SNAP to succeed, the participants will be required to complete the screening visits, consent to enrollment in their assigned study arm, return for all follow-up visits as indicated, and report any side effects that may develop. To aid in meeting these objectives, it is critical to obtain truly informed voluntary consent. If the consent process is simply a mechanical ritual, the trial could be jeopardized by a large number of early dropouts, poor adherence to interventions, and confusion about study protocol.

5.2. BASIC ELEMENTS OF INFORMED CONSENT

The Department of Health and Human Services (DHHS) guidelines set forth eight essential elements of informed consent:

5.2.1. Statement That The Study Involved Research

Participants must be advised that the study involves research. An explanation must be given regarding the purposes of the research, the expected duration of the subject's participation and a description of the procedures to be followed, including identification of any experimental procedures.

It is essential that the participant understand that he or she will not necessarily be participating in an active intervention and that his or her treatment assignment may be determined by chance. The participant will be randomized to one of three possible groups: self-regulation, self-regulation with small behavior changes, or self-regulation with large behavior changes. The participant will have an equal chance of being assigned to one of these groups.

It is important that participants be given a clear understanding of the purpose of the Self-Regulation group. An explanation of the scientific approach to the study and the need to control as many variables as possible should be provided. By emphasizing the importance of the Self-Regulation group, attention is called to the fact that this is primarily a study, rather than a therapeutic program specifically designed for an individual participant.

Clinic staff should carefully explain that the participant, the doctor, and the individuals administering the tests do not know which treatment group the participant is assigned to. To allay anxiety, it is important to note that those individuals involved in safety monitoring will be able to identify the participant's treatment assignment. A panel of national experts will be continually informed as

to what is happening to each treatment group. If an active treatment group proves to be significantly harmful, the study may be stopped, at least for those who might be harmed. Experts who have access to all the data from the trial are in the best position to judge the relative effectiveness or harm of active treatment to the participants or special subgroups of the participants.

Participants should be told that they are expected to attend the formal screening/eligibility visits. During the first visit they will have their blood pressure measured; blood will be collected for a variety of tests; and participants will complete one questionnaire. They will leave with instructions on how to complete a variety of questionnaires about their health, family history, medical history and the medications they are taking. They will be given armbands to measure their physical activity on a daily basis. If they are still eligible for the SNAP study and agree to participate, they will be asked to return for a second screening visit. At the second screening visit, they will have their height, weight and waist circumference measured; the armband and questionnaires will be reviewed; they will have their body composition measured using the biological impedance test and possibly the BOD POD; they will be interviewed by a behavioral interventionist; and they will complete additional questions about their physical activity. If they remain eligible, they will be contacted by phone and asked to come to the first group session.

All participants will be requested to attend all screening visits, a general educational session, and follow-up visits and all visits associated with their group assignment. Participants should have a clear idea of the time demands of the study for all three groups, the clinic visits and time required to complete study forms. To avoid misunderstanding, it should be made clear that the study is expected to last for two to four years, depending on when they start the study.

5.2.2. Attendant Discomforts and Risks Must Be Described

Participants should be notified of any foreseeable risks or discomforts they may experience. There may be uncommon or previously unknown risks and in these situations, participants should be told to report any problems to the researcher.

There are no major risks associated with the intervention itself or data collection visits. However, all medical tests and care may involve some minor risks or discomforts. Every attempt will be made to closely monitor all participants. To reduce the risks, we have purposely excluded patients for whom the study is contraindicated.

However, in spite of our precautions, participants may experience risks and discomfort which include the following:

Risks of Blood Draw

While rare, the risks of drawing blood for the study include the possibilities of brief pain, becoming faint during the blood draw or developing a bruise or bump following the blood draw, and there is a slight risk of infection at the site where blood was drawn.

Blood Pressure Assessment

A participant may experience temporary discomfort during blood pressure recordings due to the pressure of the blood pressure cuff on your arm or ankle.

Risks of Increasing Physical Activity

Risks involved with increasing the level of physical activity include, but are not limited to, injuries to the muscles, ligaments, tendons and joints of the body. Other risks include abnormal blood pressure, fainting, dizziness, disorders of heart rhythm, and very rare instances of heart attack, stroke, or even death. To help ensure the safety of the participants, the study will follow guidelines and safety recommendations for physical activity set forth by the American College of Sports Medicine and by the participant's doctor.

Risks of Wearing the Activity Monitor

Some people may experience mild skin irritation at the site where the activity monitor is worn. One cause of skin irritation has already been identified in people who wear the armband for extensive periods of time (i.e., more than 24 hours). Specifically, the build-up of sweat that can be trapped between the skin and the armband can cause pink pustules or pimples to appear. This condition is named miliaria, or prickly heat. This condition is common and occurs in 10% to 25% of people (10 to 25 out of 100 people) that wear the armband. To help to prevent this condition, participants should be advised to clean his or her arm using rubbing alcohol before putting on the activity monitor, to use soap and water to clean the elastic strap that attaches the monitor to your arm before each use, and to wipe off the monitor using rubbing alcohol and allow this to dry before putting it on his or her arm.

Risks of Bioelectrical Impedance Analysis (BIA)

Use of the bioelectrical impedance analysis machine may cause a participant to experience skin irritation or skin redness from the electrodes being placed on his or her skin. The risk of this happening is likely because this occurs in more than 25% of people (more than 25 out of 100 people).

Risks of Air Displacement Plesthymography

In selected clinics, assessment of body composition will be performed using a measurement tool called the BodPod. Participants may feel slight discomfort from wearing the required clothing to get accurate measurements, which include a swim cap plus spandex shorts for men and swim cap plus swim suit or spandex shorts and a sports bra for women. Despite the large glass window in the BodPod chamber, if a participant is sensitive to being in small spaces, he or she may experience claustrophobia from being confined to the BodPod for the completion of the five minute test.

5.2.3. Anticipated Benefits of the Trial Must Be Explained to Participants

Many participants appreciate the opportunity to be involved in relevant research and to contribute to medical knowledge. In the SNAP trial, the knowledge gained may or may not be specifically applicable to participants in the study. Results from the study will provide knowledge about whether making small behavior changes or large behavior changes are effective methods of preventing or reducing the amount of weight an individual may gain.

SNAP participants may benefit from this program by being able to prevent or reduce the amount of weight they gain, but there is no guarantee that they will achieve this benefit. A participant may also benefit from the information they will learn through classes or newsletters about healthy eating and physical activity.

Participants will have blood tests done at baseline and month 24 relating to cardiovascular diseases and its complications. With signed consent, results of all medical tests about blood sugar control, blood pressure, and lipids will be given to participant and sent to their doctor.

This study may help doctors find out whether making small behavior changes versus large behavior changes are effective over the long term. The researchers also will learn more about the problems that might occur with these approaches to weight gain prevention, so that this information can be provided to people and the medical community.

There is no way of knowing in advance whether a particular participant will personally benefit from active treatment during the course of the trial. This will depend on whether the interventions are effective and whether the participant is assigned to the active treatment group. Care should be taken not to suggest that participants will benefit from active treatment simply by entering the trial. The study may show that participants in the Self-Regulation group do as well or better than participants either of the two intervention arms.

5.2.4. Appropriate Alternative Procedures That Might Be Advantageous for the Subject Must Be Disclosed

This mandate is often overlooked in written consent forms. It means that the participant should be told what options exist if he or she elects not to participate in the trial. The participant should be told that the alternate treatment available would include talking to their doctor about the benefits of weight control and exercise and other programs to lose weight or prevent weight gain. The participant can continue with his or her usual health care, whether they join the study or not.

5.2.5. The Extent to Which Confidentiality of Records Identifying the Participant Will Be Maintained Must Be Described

Confidentiality of all participant information is assured in all participating centers. No unauthorized personnel should have access to participant records or results of interviews or tests. Additionally, all records will be stored in a locked storage room and on protected web servers.

It may be useful to explain that in studies of this nature, numerical and alphabetic codes are assigned by which central study files may be linked to individual participants. Participants are not identified by name in any reports or publications.

5.2.6. Medical Treatment or Compensation for Injuries That Occur As A Result of Participation in the Study

Prospective subjects must be advised of the availability or non-availability of medical treatment or compensation for physical injuries incurred as a result of participation in the study, and, if available, what they consist of, or where further information may be obtained.

It may be useful to distinguish between providing study treatment and follow-up free of charge and financial compensation for injuries incurred. The Federal Government is prohibited by law from committing funds that have not yet been appropriated by Congress, and no funds have been allocated for compensating injured subjects in trials such as SNAP. The only recourse for such participants is to seek compensation through the courts or through negotiation with the clinical center involved.

Reimbursing the cost of medical treatment for a research-induced injury is a separate issue. Every effort will be made by the Project Office and the cooperating centers to reimburse injured subjects for their medical expenses if the participants are required to pay such costs out of their own pockets. Any such problems will be dealt with on a case-by-case basis.

Policies regarding compensation and reimbursement vary from institution to institution, so there is not a standard approach for all participating centers. Staff members should stress the fact that the chance of serious injury in SNAP is small but the government requires that compensation be discussed with participants if there is any risk at all. Legal terms and concepts should be translated into lay person's language, and the ideas should be made relevant to the SNAP study, not simply to research in general. Comments regarding compensation should be as brief as possible.

5.2.7. Contacts

Persons responsible for the study must offer an explanation of who to contact for answers to pertinent questions about the research and the participant's rights, and who to contact in the event of the development of side effects, a medical emergency or a research related injury to the participant.

Prospective subjects should be handed the names of these people on a card when they are first approached. If no names are provided, they may ask questions of persons not knowledgeable about the study and be given unclear answers or misinformation. We suggest that one or more persons associated with the trial be available to answer relevant questions while participants are contemplating participation.

Once they are enrolled in the study, we recommend that participants receive written information regarding whom to contact at any time about possible side effects during therapy or rights as a volunteer in the study.

5.2.8. Voluntary Participation and Right to Withdraw

Participants must be told that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which he or she is otherwise entitled.

It is hoped that each participant will remain in the study until the trial is completed, but they have the right to withdraw at any time. This must be communicated to participants without luring them into the trial on a probationary "look and see" basis. Hesitant participants should be carefully evaluated in order to screen out those who are likely to withdraw early.

The right to withdraw from a trial is compromised if such behavior invokes penalties. This is the reason for the phrase, "without penalty or loss of benefits," and the idea should be explained to participants. If they drop out of the trial, the act of dropping out will not jeopardize their regular care.

The eight requirements of informed consent in the DHHS guidelines above refer primarily to categories of information that enable participants to make rational decisions regarding participation in clinical trials. Except for the stipulation that participant inquiries should be answered, these basic elements do not refer to the process of obtaining informed consent.

5.3. THE PROCESS OF OBTAINING CONSENT

Various studies indicate that the circumstances under which consent is obtained in clinical trials can have a profound influence on the participant's interpretation of information communicated during the consent discussion and on the freedom of participants to make their own decisions.

It is recommended that the following guidelines be followed to ensure that the consent obtained will be as informed and voluntary as possible:

5.3.1. Informed

Participants should be fully informed about the study and have adequate time to evaluate the pros and cons of participation. The Project Coordinator should review the informed consent with the participant and answer any questions. The Informed Consent form may then be sent home with the participant so that he or she may more carefully review it if necessary.

5.3.2. Open Discussion

Participants should be encouraged to discuss the study with anyone they wish, particularly family and friends who might be affected. Close associates of the participant may raise questions and considerations that the participant has overlooked, and questions that concern the family are better answered sooner than later. Furthermore, there is evidence to suggest that family support for studies of this kind increases the probability of participant cooperation during the course of the research.

5.3.3. Open Discussion

To be eligible for participation in the SNAP study, participants must have the capacity to give their own informed consent. If a participant is incapable of understanding what is expected of him or her as a subject in the study, it is not permissible to obtain informed consent from a guardian. The study requires daily responsibilities that cannot be easily assumed by other persons. The participant is also free to discuss participation with his or her personal physician.

5.3.4. Setting

The setting in which consent is obtained should be as private as possible so participants can freely ask questions without embarrassment. If extraneous parties can hear the conversation, participants may be reluctant to ask appropriate questions.

To avoid pressuring the participant, only one person associated with the study should be present when the participant reviews the consent forms. If a second witness is required, he or she should be as unobtrusive and non-committal as the situation permits.

5.3.5. Copy of Informed Consent

The participant should be given a copy of the informed consent forms after they are signed, dated and witnessed. Participants should be encouraged to keep the consent forms. The consent forms contain useful information about the study which participants may want to review from time to time. After the participant has signed the consent form, forward the consent form to the Principal Investigator for his signature.

Even though participants are free to withdraw from the study at anytime, the consent form spells out the obligations to the participant and the participant's obligations to the study while he or she is a subject.

5.3.6. Witness Signature and Source Documentation

Anyone who signs a consent form should personally date it. If consent is obtained the same day that the participant's involvement in the study begins, the participant's medical records should document that consent was obtained prior to participation in the research. A general statement for source documentation should be included, such as, "All the required elements of informed consent were presented to the patient. Voluntary consent was obtained and the patient's questions were answered prior to initiation of any research procedures."

5.4. REPORTING REQUIREMENTS FOR INFORMED CONSENTS AND IRB APPROVAL

The Coordinating Center needs a copy of each clinic site’s Approved Consent Form(s) and the copy of the IRB approval of the study protocol letter. The annual approval letter should be provided to the Coordinating Center. Whenever changes are made to the consent form, a new, approved consent form and the letter of approval should be forwarded to the Coordinating Center. Confirmation that this process is being followed will occur at the site visits at which time the site visit team

will check that the approved and currently used informed consent forms are the same as those on file at the Coordinating Center.

Signed original consent forms stay at the clinic. A copy is provided to the participant.

5.4.1. Study Forms (Database) for Tracking Consent

The SNAP study has multiple consent forms. In order to track the informed consent process, clinic staff should use the SNAP Orientation form. There are check boxes for the following:

- Consent for full study obtained
- Consent for DNA obtained
- Consent for storage samples obtained (if required)

Note that a separate indication of verbal screening consent is not denoted.

5.5. TRAINING IN THE PROTECTION OF HUMAN SUBJECTS

The National Institutes of Health (NIH) now requires training in the protection of human research participants for all investigators who submit NIH applications for grants or contracts, as well as those investigators who receive new or non-competing awards for research involving human subjects. This requirement applies to SNAP. For more information please see the following web site: http://grants.nih.gov/grants/policy/hs and http://grants.nih.gov/grants/policy/hs_educ_faq.htm.

5.6. GENERAL GUIDELINES

Remember that Informed consent is not just a form. Rather, it is a process that involves the following steps:

- Giving a participant adequate information about the study
- Providing adequate opportunity for the participant to consider all options
- Responding to the participant's questions
- Ensuring the participant has comprehended the information
- Obtaining the participant's voluntary agreement to enter the study
- Continuing to provide information as the participant or situation requires.

In order to be effective, the process should provide ample opportunity for the investigator and the participant to exchange information and ask questions.

Use of the first person (e.g., "I understand that ...") can be interpreted as suggestive, may be relied upon as a substitute for sufficient factual information, and can constitute coercive influence over a participant. Use of scientific jargon and legalese is not appropriate. Think of a consent document as a teaching tool, not as a legal instrument.

A copy of the consent document must be provided to the participant and the original signed consent should be retained in the study records.

Below are some frequently asked questions about the consent process:

Who can obtain consent from potential participants?
Some sponsors and IRBs require the clinical investigator to conduct the consent interview. Regardless, the person who conducts the consent interview should be knowledgeable about the study and able to answer questions. If someone other than the investigator obtains consent, the clinical investigator should formally delegate this responsibility and the person so delegated should have the appropriate training to perform this activity.

21 Code of Federal Regulations (CFR) 50.27(a) requires that a copy of the consent document be given to the person signing the form. Does this have to be a photocopy of the form with the participant's signature affixed?
No. The regulation does not require the copy of the form given to the participant to be a copy of the document with the participant's signature, although this is strongly encouraged. It must, however, be a copy of the IRB approved document that was given to the participant to obtain their consent.

Do you have to have a witness to the consent process?
An impartial witness is only required if the participant cannot read, if the participant is incapable of understanding the consent document, or if the participant does not speak English. Otherwise, a witness is not required.

When a witness is required, must they observe the entire consent interview or only the signature of the participant?
When a witness is required, they must be present throughout the entire consent interview. The intended purpose is to have the witness attest to the accuracy of the presentation and the apparent understanding of the participant, not just the validity of the participant's signature.

How do you obtain informed consent from someone who speaks and understands English but cannot read?
Illiterate persons who understand English may have the consent read to them and

"make their mark," if appropriate under applicable state law. Federal regulations do permit the use of a short form for patients that cannot read. A short form is a document that states that the elements of informed consent as required by the Code of Federal Regulations have been presented orally to the participant. When this method is used, there must be an impartial witness to the oral presentation. Also, the IRB should approve a written summary of what is to be said to the participant. The participant must sign the short form. However, the witness must sign both the short form and a copy of the IRB approved summary. A copy of the summary and short form must be given to the participant. If you encounter an illiterate participant, consult with your IRB Chair to discuss your local guidelines.

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Screening
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6. Screening

6.1. OVERVIEW

This chapter describes the screening activities for SNAP and the collection of screening measures. Details are provided on how participant eligibility is determined. The protocol allows for flexibility in scheduling visits and in the order data may be collected. This chapter's description of how these aspects of the protocol are conducted is provided as a guide, which may be tailored to the specific needs of clinic staff and individuals.

6.2. OVERVIEW OF SCREENING STEPS

The SNAP screening process consists of multiple contacts related to screening prior to participant randomization. Potential participants will complete an online pre-screening questionnaire, a telephone screening, an orientation visit, and two clinic screening visits and, if eligible, will receive a randomization phone call.

6.3. PRE-SCREENING QUESTIONNAIRE

The initial phase of screening will be by completion of an online pre-screening form by individuals. The Pre-Screen Questionnaire may also be administered over the phone or face-to-face by clinic staff, but must be entered into the SNAP website in order for a participant ID to be assigned and to initiate the screening process. Specific instructions on the Pre-Screen Questionnaire are provided in Section 6.13.1. The goal of pre-screening is to determine interest in the SNAP study and to identify ineligible individuals as early as possible in order to inform them that they are ineligible. Identifying those who are ineligible at an early stage is helpful to both individuals so they will not waste time making a trip to the clinic; and to the clinic, so that resources (*i.e.,* staff time, lab assays) are not being incurred for ineligible individuals.

Potential participants should be directed to www.snapstudy.org to learn more about the study and complete the Pre-Screening Questionnaire by clicking the "SIGN ME UP!" button. The SNAP recruitment website provides individuals with a brief description of the study including details of what will be expected if they participate, benefits of participation, and where the clinical centers are located. If the individual is interested in participating, they will be asked to provide initial screening information via the website. If they choose not to complete the online form, they can contact a SNAP clinic and a SNAP team member can complete the form for the individual.

All ten questions on the Pre-Screening Questionnaire should be completed for each individual screened. This allows SNAP to capture information on several important characteristics of those screened including age, gender, ethnicity, height, weight, basic weight history, and location. Individuals are not required to indicate their gender, race or ethnicity at the time of submitting the Pre-Screening Questionnaire, however all other questions must be answered in order for the form to be submitted. Gender, race and ethnicity can be captured later on the Telephone Screening Form.

Individuals will not be notified by the system of their eligibility. Upon successful completion of a SNAP Pre-Screen Questionnaire, the system will notify the individual of a successful submission and send an automatic e-mail to the individual notifying them that they will be contacted by a SNAP clinic within two weeks. The system will also automatically e-mail the appropriate clinic, as part of a daily digest e-mail. It is the responsibility of the clinic staff to call each individual and notify them of their eligibility. If an individual is not eligible, the clinic staff may wish to refer them to another study or a weight loss program.

Potential participants who identify themselves as close to the Chapel Hill clinic, and are ineligible based upon a higher BMI, will be notified of their ineligibility status and will be supplied with information about the CITY program. With this exception, ineligible participants will not be notified of their eligibility status *via* the data entry system.

If the individual is eligible, the clinic staff should complete the Telephone Screening Form with the individual.

Staff members will see Question 11 on the Pre-Screening Questionnaire. This question can be used to indicate that an individual has been notified of their eligibility results from the Pre-Screening Questionnaire. Individuals can be notified of their eligibility via the phone, e-mail or letter.

The Pre-Screening Questionnaire data can be updated by SNAP clinic staff up until the time the individual is randomized.

6.4. TELEPHONE SCREENING

If an individual meets the basic criteria set on the Pre-Screening Questionnaire, the clinic staff will call the individual to complete the Telephone Screening Form. Specific instructions on the Telephone Screening Form are provided in Section 6.13.2. The Telephone Screening Form allows the clinic to provide more information about the SNAP study to potential participants and obtain information about the individual's medical history and other general information.

6.4.1. Participant Tracking for Telephone Screening

The telephone screening status and e-mail contact questions in the header of the Telephone Screening Form can be used to indicate to all SNAP clinic staff that an individual has been contacted, but the Telephone Screening Form was not able to be completed. For example, the telephone screening status question allows staff members to indicate that they have left a message, were unable to contact the individual, or that the individual refused to continue. Using this field is helpful to ensure all staff members are familiar with where the participant is in the process. Similarly, the e-mail contact question allows staff members to track the number of times an individual has been contacted *via* e-mail. Specific notes about good times to call the individual or notes to other staff members can be recorded in the comment field.

All questions on the Telephone Screening Form should be answered. If it is determined that the individual is ineligible, the clinic staff should continue completing the form as this provides important information on exclusion which will be useful for SNAP manuscripts. In addition, the individual may be eligible to be re-screened at a later time (see details in section 6.12). However, if, at the beginning of a call, prior to completion of the Telephone Screening Form, an individual indicates that they have a medical condition that will make them ineligible (*i.e.*, I have type 1 diabetes, will that make me ineligible?), the Telephone Screening Form does not have to be completed in its entirety. In order to not waste the individual's time, the staff member can skip over other questions and select the appropriate response. In order for a Telephone Screening Form to be submitted, the date form completed field must be answered.

6.4.2. Eligibility Status Check on Telephone Screening Form

In order to assess eligibility, **the 'telephone screening status' field must be blank but all other** questions on the Telephone Screening Form must be answered.

After successful completion of the Telephone Screening Form, and data entry of the form, the system will score the form and notify the staff that the individual is either: 1) eligible; 2) ineligible; or 3) pending. If the individual is determined to be eligible, the staff will be directed to the Telephone Screening Form, Part II: Eligible Participants and the orientation visit should be scheduled. If the individual is ineligible, the staff will be directed to the Telephone Screening Form, Part II: Ineligible Participants and the clinic staff can refer the individual to another study or weight loss program, if desired.

The Eligibility Tracking System can be used to indicate that eligibility has been assessed by completing a Telephone Screening Form and that the individual has been notified of their eligibility results, as well as used for further tracking regarding orientation scheduling (if eligible) or mailing of packet with information about other weight control programs (if ineligible).

6.4.2.1. Pending Status

The eligibility status may not be able to be determined at the time of completion of the Telephone Screening Form if the clinic staff needs to get more information (*i.e.*, determine whether having a disease not listed on the Telephone Screening Form will impact the individual's ability to participate) or if the Telephone Screening Form had to be stopped before all questions had been answered. If the individual's eligibility is pending because more information is needed to make a decision, the lead project coordinator at the clinic should review the form, collect all needed data and then update the system by changing the answer to the question from 'pending' to the appropriate response (*i.e.,* 'yes' or 'no') depending on whether the clinic staff believes the individual can participate in this study and notify the individual of their eligibility.

Based upon a potential participant's answers to some questions on the Telephone Screening Form, it may be necessary for the potential participant's primary care physician to consent to their participation in SNAP. If this is necessary, the individual should be notified this will be required and they will be given this form at their orientation visit. The signed MD consent must be received no later than screening visit 2 and must be received prior to randomization (see Section 6.11 for further information about MD consent).

6.4.2.2. Eligible Participants

Based on the answers to the Telephone Screening Form, if an individual is determined to be eligible for participation in SNAP the clinic should mail or e-mail an orientation packet to the individual. The packet should include a letter with the orientation date and time and a map with directions to where the orientation is taking place.

6.4.2.3. Ineligible Participants

Based on the answers to the Telephone Screening Form, if an individual is determined to be ineligible for participation in SNAP the staff member should ask the individual if they would like to receive a mailing with further information about other weight control programs. Based upon an individual's responses, the individual can either be permanently or temporarily ineligible.

When notifying the participant of their ineligibility, staff members should let the individual know that if the staff believes they could be eligible at a later date, they may contact them if they believe they could now be eligible for participation in the SNAP study.

The Telephone Screening Form data can be updated by SNAP clinic staff up until the time the individual is randomized.

6.5. ORIENTATION AND CONSENT PROCEDURE

Individuals who appear eligible for the study after completion of the telephone screening should be scheduled for an orientation session. This session may be conducted individually or in small groups. The study must be presented to the potential participants in detail and the individual's questions must be addressed. A video describing SNAP may be shown. Following this, individuals are asked to review and sign the informed consent form. (See Chapter 5, Informed Consent Guidelines.) An emergency contact should be identified at this time, and this information should be stored for future reference.

In preparation for orientation visits, clinics should review the Orientation Script (Appendix A); review the online "Orientation Listings" report to note number of individuals who are scheduled for the orientation visit; make copies of informed consent forms, MD consents (Appendix B) and SNAP Orientation Forms; and ensure that a digital scale and wall-mounted stadiometer are easily accessible.

Potential participants must sign the consent before the clinic staff can complete the Orientation Form or take any measurements. After the individual has signed the SNAP consent form, clinic staff should complete the SNAP Orientation Form which captures whether the potential participant attended the visit, completed the consent process, and allows a place to record information required for programming the armbands (i.e., handedness, smoking status, weight, height).

The participant's BMI must be confirmed at orientation visit. Their BMI must be between 21 - 30 kg/m^2. Individuals do not need to be in gowns for these measurements. The height and weight taken at the orientation visit will not serve as the baseline measurements, but will be used to determine if a participant is eligible. If the participant's BMI is borderline eligible, a screening visit 1 can be scheduled and the participant must be re-weighed. The screening visit 1 weight should be data entered into the Orientation Form in order to update the eligibility BMI. If the participant will be re-weighed at the Screening Visit 1, the weight and height at orientation should be entered into the form and the staff should select 'BMI ineligible reweigh at SV1.' This box should be unselected after the participant's BMI has been determined (either at Orientation or Screening Visit 1).

If an individual is deemed to be eligible based upon their BMI and they consent to participate, screening visit 1 should be scheduled. The clinic staff should provide verbal and written instructions about screening visit 1 (location, time, fasting requirements).

6.6. SCREENING VISIT 1

6.6.1. Overview of Screening Visit 1

In preparation for an individual's Screening Visit 1, clinics should print out a copy of each form to be completed at this visit (Blood Specimen Collection, Screening Blood Pressure and CES-D); program the armband based on information recorded on the individual's Orientation Form; prepare handout for instructions on wearing the armband and instructions for login to the SNAP website for form completion; and ensure that all necessary blood collection and shipping supplies, and blood pressure supplies are easily accessible.

Screening Visit 1 should take place in the morning and must be a fasting visit (at least eight hours). The baseline blood specimen and storage collection and baseline blood pressure will be taken during this visit. Clinic staff will administer the following forms: Center for Epidemiologic Studies Depression Scale (CES-D), Blood Specimen Collection Form, and Screening Blood Pressure Individuals will leave with a SenseWear armband, and the instructions for wearing the SenseWear armbands, as well as instructions for logging onto the SNAP website and completing the online questionnaires (Appendix D). At the conclusion of Screening Visit 1, Screening Visit 2 should be scheduled. Screening Visit 2 should be scheduled at least eight days after Screening Visit 1. The clinic staff should provide verbal and written instructions about screening visit 2 (location, time, fasting requirements).

6.6.2. Blood Pressure and Blood Collection

Blood pressure should be measured following the study blood pressure protocol as outlined in Chapter 11, Physical Measurements. Blood pressure must be less than 140/90 mmHg. Pulse must be 110 beats per minute or less. If the blood pressure or pulse equals or exceeds these levels, the individual must receive consent from their primary care physician to participate in SNAP.

Blood collection should occur when the individual has been fasting for at least eight hours. Three blood collection tubes should be collected (see Chapter 10, Specimen Collection):

1. 1 tiger-top SST (7.5 ml)
2. 1 pearl-top PPT (5 ml)

3. 1 yellow-top tube (8.5 ml)

The following criteria must be met: glucose ≤ 126 mg/dl, LDL-C ≤ 160 mg/dl and triglycerides ≤ 500 mg/dl. If the glucose, LDL-C, or triglycerides levels are found to be elevated, the individual must receive consent from their primary care physician to participate in SNAP. In general, clinics will be notified of lab values within 48 hours of receipt of sample at the laboratory.

6.6.3. Armband Instructions

Based on the information collected at orientation, clinic staff will program and distribute a SenseWear armband and instructions for its use (see Chapter 12, Physical Activity and Sedentary Behavior). Individuals will be instructed to wear the armband for seven days (in order to be eligible, they must wear the armband for eight hours a day, for at least 4 days). Depending on the scheduling of Screening Visit 2, individuals will be asked to mail in the armband or to bring it with them to Screening Visit 2.

6.6.4. Form Completion at Screening Visit 1

Clinic staff will administer the CES-D form to each individual during Screening Visit 1. At the conclusion of the visit, individuals will be given a document outlining the list of forms to be completed prior to coming for Screening Visit 2 with instructions on how to access the forms (Appendix D). Participants will be directed to the SNAP study website (https://www.snapstudy.phs.wfubmc.edu) and provided their username. A clinic staff member should activate the participant and instruct participants that they will receive an e-mail with login instructions, as well as their password (see Appendix E for instructions on participant activation). Participants will be asked to complete the forms prior to Screening Visit 2.

6.6.5. Review of Blood Pressure and Blood Results for MD Consent

Based on the results from Screening Visit 1, the clinic staff should review the blood pressure and lab reports to determine whether a specific MD consent is required (Appendix C). The following will require MD consent prior to an individual being considered eligible for participation in SNAP:

1. Blood Pressure: SBP>140 and/or DBP >90
2. Pulse >110
3. Fasting glucose > 126 mg/dl
4. LDL-C > 160 mg/dl
5. Triglycerides ≥ 500 mg/dl

If a specific MD consent is required, the clinic staff should e-mail or mail the MD consent to the potential participant and the potential participant should take the consent to their primary care physician for signature. The signed consent should be brought to Screening Visit 2.

6.7. SCREENING VISIT 2

6.7.1. Overview of Screening Visit 2

In preparation for an individual's Screening Visit 2, clinics should print out a copy of each form to be completed at this visit (Screening Physical Measurements, Impedance, and Exercise Habits), review the individual's armband data (if available), review completeness of data entry of the SNAP forms, and ensure that a digital scale, wall-mounted stadiometer, Gulick tape measure, BIA machine and the BOD POD (if applicable) are easily accessible.

Screening Visit 2 should take place in the morning and must be a fasting visit (at least four hours). In addition to fasting, the individual should refrain from alcohol for at least 12 hours prior to the visit, and should refrain from moderate or vigorous physical activity or sauna at least 8 hours prior to the visit.

Baseline weight, height and waist circumference will be taken during this visit. Clinic staff will administer the Exercise Habits (Paffenbarger) Form. Completion of the BOD POD, impedance test, and the behavioral interview will occur during Screening Visit 2.

6.7.2. Physical Measurements

Individuals must have their height, weight and waist circumference measured following the protocols outlined in Chapter 11, Physical Measurements. Individuals should be supplied with hospital gowns. The measurements taken during Screening Visit 2 will serve as the individual's baseline measurements.

6.7.3. Review of Armband, Bod Pod and Impedance Test

While there is not specific eligibility criteria related to the armband, Bod Pod, or the impedance test, clinic staff are responsible for review of each of these measures. If the participant does not complete these measures appropriately, this should be considered when making the final staff decision regarding eligibility prior to randomization.

The SenseWear armbands provide an objective assessment of physical activity. Individuals are instructed to wear the armband for seven days; however, in order to be eligible, they must wear the armband for at least 8 hours for at least 4 days.

The Bod Pod assessment and impedance test provide individuals with results regarding their body composition. The Bod Pod assessment is only completed at participating clinics (Chapel Hill).

6.7.4. Form Completion and Review

Clinic staff will administer the Exercise Habits (Paffenbarger) Form to each individual during Screening Visit 2 (see Chapter 12, Physical Activity and Sedentary Behaviors).

The individual should have completed all forms as outlined below *via* the SNAP website. Clinic staff should review missing forms and/or fields and direct individuals to an available computer at the clinic in order to complete forms.

The AUDIT and EDA score will be displayed to clinic staff once the participant has entered these forms as part of the Eligibility Tracking Report. Clinic staff should review the individual's scores for the AUDIT and the EDA. Individuals who score ≤ 8 on the AUDIT are eligible for participation in SNAP. If an individual scores between 9-15 on the AUDIT, a behavioral psychologist or interventionist at the clinic must review the form with the individual and provide approval before they can be considered to be eligible for this criteria. If an individual scores ≥ 16, they are ineligible for participation in SNAP.

Clinic staff should check the eligibility/participant tracking system to ensure that all other SNAP forms are completed (see Appendix F for complete list of study forms).

<u>Forms to be completed online by the participant prior to randomization</u>

Questions about myself and my family

1. Demographics
2. Contact Information
3. Life Events
4. Weight History of Friends and Family
5. Perception of Program

Questions about my mood and behavior

1. Eating Inventory
2. TSRQ
3. PSS (Perceived Stress Scale)

Questions about my diet

1. BLOCK

Questions about my health and health behaviors

1. Health Behaviors
2. Medication Use
3. AUDIT
4. Weight History
5. Smoking and Tobacco Behaviors
6. Quality of Life Questionnaire

Questions about my lifestyle

1. EDA (Eating Disorder Assessment)
2. Weight Management Strategies
3. Self-Weighing Questionnaire
4. Sedentary Behaviors
5. Sleep Patterns
6. Physical Activity Neighborhood Environment

6.7.5. Behavioral Screening

All potential participants should be scheduled to be seen by a behavioral psychologist or interventionist during Screening Visit 2. The purposes of this interview are:

1. to ensure that participants understand what is required if assigned to any of the three groups;
2. to determine whether there are significant competing life stressors that would make adherence to SNAP difficult;
3. to determine whether the individual is appropriate for a group intervention; and
4. to determine whether there are major problems with depression, binge eating, or alcohol that would make adherence difficult.

A behavioral guide and checklist are available that can be used to direct staff through this process (Appendices G and H). After completion of the interview, the behavioral psychologist or interventionist should make a recommendation on

inclusion or exclusion of this individual in the SNAP study and record their recommendation on the SNAP website.

6.7.6. Review of Participant

After completing all of the above, each individual should be reviewed by the local study team to determine whether there is general consensus that the individual is appropriate to be randomized to the study.

During the screening process, if the study team uncovers discrepant information related to eligibility, the participant is ineligible. If the individual completed the questionnaires with many missing fields, the staff should use their discretion in determining if the study results could be compromised by missing data or if they suspect adherence would be a problem for the individual. If the team does not feel that the person would be a good SNAP participant, they are able to mark the participant ineligible via the randomization checklist on the SNAP website.

Historically, many studies have found that clinic and intervention staff has a good 'gut instinct' about those individuals who would be appropriate to participate as well as those who are inappropriate.

The randomization checklist has several sections that must be completed by the clinic before the individual can be randomized. These include, a section for clinic sign off for the AUDIT (if the score is ≥ 9); a drop-down box for whether each type of MD consent was received (if applicable); a drop-down for approval based on the behavioral interview; a drop-down to indicate the individual is not pregnant (if female; to be asked of potential participant right before randomization over the randomization phone call), a drop-down box for whether the meeting time works for the potential participant (to be confirmed over the randomization phone call); and a final drop-down box for the staff to sign off on all areas.

6.8. RANDOMIZATION PHONE CALL

Procedures for the randomization are described in Chapter 7. The randomization phone call must occur within two months of Screening Visit 2, where the baseline physical measurements have been obtained. If a potential participant falls out of the two month window, clinic staff must re-do the physical measurements, including re-entry of the Baseline Physical Measurement Form.

Clinic staff should call the potential participant and confirm the meeting time availability still works with their schedule, and if the potential participant is female, they should confirm that the individual is not pregnant. After these two things have been confirmed, the clinic staff should select 'eligible' or 'ineligible' based on their final review and submit. If the participant is eligible, the clinic staff should select the

appropriate cohort and click 'Randomize.' The system will display the group assignment for the participant.

The clinic staff will not reveal the group assignment during the randomization phone call, but only identify the date and time of the first group session the participant should attend. Group assignment will be revealed at the first group session. After a participant has been randomized, clinic staff will be unable to modify any of the screening forms.

If the participant is ineligible, the data will be saved, but the 'Randomize' button will not appear.

6.9. SUGGESTED SCHEDULE

There are a number of different approaches to organizing the screening and baseline assessments. The suggested sequence detailed in this chapter is summarized below:

1. Pre-screen by internet
2. Telephone screening
3. Orientation and Consent
4. Screening Visit 1: baseline blood pressure and blood collection; give participants armband and instructions for online form completion; CES-D
5. Screening Visit 2: review armband and online form completion; baseline BOD POD; baseline impedance test; baseline weight, height and waist circumference; behavioral screening; Exercise Habits
6. Review of Participant
7. Randomization Phone Call
8. First Group and notification of group assignment

6.10. ELEMENTS REQUIRED FOR SCREENING

- Pre-screening Form
- Telephone Screening Form
- Orientation Form
- Informed Consent
- Blood Pressure /Pulse
- Blood Collection and lab results

- Physical Measurements (height, weight, waist)
- AUDIT
- EDA
- Behavioral Interview
- MD consent (if applicable)
- Confirm meeting availability
- Confirm not pregnant (if female)
- Randomization within 2 months of Screening Visit 2
- Staff Review/Final Decision

6.11. MD CONSENT

Consent from a participant's primary care physician may be required based on responses to questions on the Telephone Screening Form (type 2 diabetes and taking insulin or other medications that could lead to hypoglycemia; hypertension; hyperlipidemia; heart disease or heart problems; bone or joint problems; currently being prescribed drugs for blood pressure or heart condition; physical activity restrictions; or health problems that may influence the ability to walk); blood pressure (>140/90 mmHg), pulse (>110) and/or blood work results (fasting glucose > 126 mg/dl, LDL-C > 160 mg/dl or triglycerides ≥ 500 mg/dl). Participants can continue through the screening process if they are waiting to receive consent from their primary care physician, but cannot be randomized until consent has been obtained.

There are two types of MD consent form, a general consent and a specific consent. The general MD consent can be used if MD consent is needed based on responses from the Telephone Screening Form. If MD consent is required because of blood pressure, pulse or blood work results, the specific MD consent is required. SNAP staff should notify the PCP of the specific results obtained if the specific consent is required. If a participant needs MD consent for both the specific and general questions, if the specific consent is signed, this is sufficient for enrollment in the SNAP study.

6.12. RE-SCREENS (TEMPORARY EXCLUSIONS)

There are several exclusion criteria that may provide an opportunity for re-screening due to temporary exclusions. If, upon re-screening, the individual now meets the eligibility criteria, the appropriate form(s) should be updated and he/she may continue through the screening process.

Re-screening should ideally occur within 4 months of the Screening Visit 1. If the individual is re-screened and is within the four-month window between SV1 and randomization, the only item that needs to be re-done is the item in question. Consequently, the screening forms do not need to be repeated; only the item in question should be repeated and recorded on the appropriate screening form. Baseline weight (from the SV2) will have to be repeated if outside of the 2 months window prior to randomization. Draw a line through the original value, record the new value above it then initial and date the corrections. The corrected data should then be data entered. The same ID number should be used if the participant is re-screened.

If the participant's SV1 visit occurred more than 4 months prior to the date of randomization, the SV1 and SV2 visits should be repeated, including all forms, tests and measurements.

See Table 1 below for potential reasons for re-screen.

Table 1. Temporary exclusion criteria for which one re-screening is allowed

Exclusion criteria	Re-screen interval	Location to record Re-screening results
Age < 18 years	May be re-screened at age 18	Pre-Screening Questionnaire (#4) and/or Telephone Screening Form (#5)
18 kg/m^2 < BMI < 20 kg/m^2 or 31 kg/m^2 < BMI < 33 kg/m^2 or	May be re-screened when BMI 20-30 kg/m^2	Pre-Screening Questionnaire (#8 and #9), Telephone Screening Form (#6) and/or Orientation Form (#7)
More than10 pounds weight loss over the previous 6 months	May be re-screened in 6 months	Telephone Screening Form (#6)
Treatment for cancer (except non-melanoma skin cancer or early stage cervical cancer), within past 5 years	May be re-screened when time since treatment or hospitalization ≥ 5 years	Telephone Screening Form (#7i)
Hospitalization for depression, treatment for inflammatory bowel diseases; or hospitalization for asthma with past 1 year	May be re-screened when time since treatment or hospitalization ≥ 1 year	Telephone Screening Form (#7j, 7r, 7s)
Currently pregnant, pregnant within the past 6 months or planning to becoming pregnant	May be re-screened 6 months after delivery	Telephone Screening Form (#15) and/or Randomization Checklist

Exclusion criteria	Re-screen interval	Location to record Re-screening results
Trying to gain weight, participating in another weight loss program, using steroids for muscle mass or weight gain, taking weight loss medications, or participating in another weight loss or physical activity study	May be re-screened if choose to stop these weight management practices	Pre-Screening Questionnaire (#10), Telephone Screening Form (#16, 17)
Availability for meetings (planning to move, live or work more than 30 miles away, away for periods of time, household member or roommate in study, no regular internet access)	May be re-screened if living situation or circumstances change for the participant	Telephone Screening Form (#19, 20, 21, 22, 23)
Evening meetings do not work	May be re-screened if meeting time availability changes, either at the clinic or individual level	Telephone Screening Form (#24) and/or Randomization Checklist

6.13. USE OF THE SCREENING FORMS

6.13.1. Pre-Screening Form

These questions will be completed by the individual online or can be asked by an interviewer to a potential participant either on the telephone or face-to-face. Each question must be answered. Regardless of whether an answer makes an individual ineligible, all questions will be answered. Individuals will not be notified of their eligibility by the SNAP website, with the exception of participants who identify themselves as close to the Chapel Hill clinic and are ineligible based upon a higher BMI. A staff member of the clinic closest to the individual will contact the individual to let them know whether they are eligible for participation in SNAP.

Question-by-Question Instructions

1. **Choose the clinic you are closest to**

   The individual responds by identifying the clinic location that is closest to him/her, selecting either Providence, RI or Chapel Hill, NC. This response dictates which clinic staff is notified of the submission.

2. **Name**

   The individual's responds with his/her name. First name and last name are required. Middle initial and suffix are recorded if appropriate

3. **Contact Information**

   The individual responds by providing his/her contact information in order to allow the SNAP clinic to contact the individual.

   Phone

   Phone numbers must include the area code, and contain ten digits. Participants may enter a home, cell and/or work phone number. At least one phone number must be entered.

   Which contact number is preferred?

   The individual selects one preferred contact number (home, cell or work).

   Which days and times are best to contact you?

   The individual indicates the best day(s) and time(s) to contact him/her.

   E-mail

   A valid e-mail address must be entered twice. The entered e-mail addresses must match exactly.

   Which days and times are best to contact you?

   The individual indicates the best day(s) and time(s) to contact him/her.

4. **How old are you?**

   The individual responds by giving his/her current age at the time the form is completed. Individuals must be between the ages of 17 and 35 in order for the date entered on the Pre-Screening Questionnaire to save. Individuals who are 17 can be contacted by the SNAP clinic in order to determine when they will turn 18, at which time they may be eligible for participation in SNAP.

5. **Gender**

   The individual responds by identifying his/her gender.

6. **Are you of Hispanic or Latino origin?**

   The individual responds 'yes' if he/she considers himself/herself to be of Hispanic or Latino origin.

7. **Which of the following best describes you? (You may check more than one.)**

   The individual responds by selecting the race that he/she feels best describes them. More than one race may be selected. If the participant selects 'Other,' further clarification is requested.

8. **What is your height?**

   The individual provides his/her height. Height is recorded in feet and inches.

9. **What is your weight?**

   The individual provides his/her weight. Weight is recorded in pounds.

   Based on the responses to questions 8 and 9, the system will calculate the participant's BMI. The individual's BMI must be between 20 and 31 kg/m^2 to be considered eligible for completion of the Telephone Screening Form. If the individual's BMI is very close to the eligible range, the SNAP clinic can verify the BMI at the orientation visit. If the individual's BMI is not within the SNAP criteria, they may be re-screened at a later time.

10. **Are you trying to gain weight at this time?**

    The individual responds as to whether he/she is trying to gain weight at the time the form is completed. If an individual is trying to gain weight, they cannot participate in SNAP. If the individual later decides they don't want to try to gain weight, they can be re-screened at a later time.

Staff Use Only

11. **Has the participant been notified of the eligibility status?**

    The clinic staff should check 'Yes' when the participant has been notified of his/her eligibility or ineligibility for the SNAP program.

6.13.2. Telephone Screening Form

These questions will be asked by an interviewer either on the telephone or face-to-face for the purpose of determining the initial eligibility of the person responding to the recruitment efforts. Standardized interviewing practices as discussed in Chapter 4 must be followed.

The interviewer script identifies the interviewer, gives a brief introduction to the study, and allows the individual to request a more convenient time to call back. If asked how long the interview will take, staff should respond that it usually takes ten to fifteen minutes.

If at any point in the questionnaire the individual is found to be ineligible, the interview continues. Unless the individual wishes to stop the interview, all questions should be answered. Individuals may not change their answers to become eligible. However, in some cases, the individual may be re-screened at a later date. At the conclusion on the telephone screening form, the individual will be identified as eligible, ineligible, or pending review. Some responses require that an individual receive consent from his/her primary care physician before participation in SNAP can begin. These individuals should still have the orientation visit scheduled and are considered eligible, but the SNAP clinic must receive the consent from the individual's primary care physician before the individual can be randomized.

Question-by-Question Instructions

The interviewer must complete the "date form completed" field or the form will not be saved. Administration type for the telephone screen will always be "staff-administered." The telephone screening status field should be used if the interview interviewer is unable to contact the individual, if they leave a message for the individual, if the individual refuses, or if the telephone screening form is not able to be completed in its entirety. **In order for eligibility to be assessed, the telephone screening status field must be set back to blank.** The e-mail contact field can also be used to track the number of attempts made to contact the participant *via* e-mail. The status identified on the Telephone Screening Form helps to develop reports listing potential participants and participants who should not be contacted. The comment field under the telephone screening status field can be used to record information regarding what time the individual was called, or when the individual's roommate said to call back. This information can be useful to other clinic staff members when making future calls.

1. **Contact Information (NOTE: *Can fill in from internet pre-screen, but all information should be confirmed by participant)***

   The individual's name, phone and e-mail address can be filled in based on the information entered on the Pre-Screening Questionnaire. Any information filled in based upon the Pre-Screening Questionnaire must be verified with the individual during the telephone screening. Other contact information (street address, city, state, and zip code) and preferred contact number should be recorded.

2. **Method of recruitment (*"How did you hear about this program?"*)**

   The staff should ask the individual how he/she heard about the program. Participants can identify more than one response. If the individual has further information about the specific newspaper ad, e-mail, other study

participant, website, radio or TV station or zip code he/she received a mailing, this information should be recorded.

3. **Gender**

   Gender can be filled in based on the response from the Pre-Screening Questionnaire, but must be verified with the individual. Do not assume gender based on the name or voice. This information must be collected and verified for randomization stratification.

4. a. **Are you of Hispanic or Latino origin?**

   The individual responds 'yes' if he/she considers himself/herself to be of Hispanic or Latino origin. If an individual chooses not to answer this question, select 'Refused to answer.' An individual does not have to answer this question.

   b. **Which of the following best describes you? (You can select more than one.)**

   The individual responds by selecting the race that he/she feels best describes them. More than one race may be selected. If the participant selects 'Other,' further clarification is requested. If an individual chooses not to answer this question, select 'Refused to answer.' An individual does not have to answer this question.

5. a. **Age**

   The individual responds by giving his/her current age at the time the form is completed. Individuals must be between the ages of 18 and 35 to participate. If the individuals is 17, but will turn 18 before recruitment in SNAP is closed, he/she may be re-screened when he/she turns 18.

   b. **Date of birth**

   Date of birth is recorded, as month first, day second and year third. Month, day and year of birth are recorded numerically, with two digits included (*e.g.,* 01/21/85).

6. a. **Current weight**

   The individual provides their current weight, in pounds.

   b. **Weight 6 months ago**

   The individual provides their weight six months ago, in pounds. Individuals cannot have lost more than ten pounds in the last six months. If their weight is maintained (<10 lb weight difference) for another six month period, they can be re-screened at a later date.

c. **Height**

The individual provides their height, in feet and inches.

d. **BMI (*must be 20-31),* Use NHLBI BMI calculator**

The SNAP staff calculates the individual's BMI, using the current weight and height, based on http://www.nhlbisupport.com/bmi. BMI must be between 20 - 31 kg/m^2 in order to be eligible to come in for the orientation. If the BMI is borderline SNAP eligibility criteria, it can be confirmed at the orientation visit. If the BMI is not within the SNAP criteria, the individual may be re-screened at a later time.

7. **Have you ever had or are you currently receiving medical treatment for any of the following?**

This question deals with medical history. Read all the conditions. If the individual has ever had or is currently receiving treatment for any of the following, they are excluded from participating in SNAP: type 1 diabetes (7a); heart attack or stroke (7e); HIV (7g); active tuberculosis (7h); schizophrenia, manic depression, bipolar disease (7k); anorexia (7l); bulimia (7m); chronic hepatitis B or C (7n); thyroid disease (7o); liver disease (7p); renal disease (7q); alcohol or substance abuse (7t); surgery for obesity (7u); and/or chronic steroid use (7v).

Individuals who have type 2 diabetes can participate if they are not currently taking insulin or other medications that could lead to hypoglycemia, such as insulins or sulfonylureas. If the individual is taking these medications, they are ineligible. If they are not on these medications, they can participate, but must receive consent from their primary care physician (7b). Individuals who have hypertension – high blood pressure (7c); hyperlipidemia - high cholesterol (7d); heart disease or heart problems (7f) must receive consent from their primary care physician before they may participate in SNAP.

Participants whose treatment for cancer (except non-melanoma skin cancer or early stage cervical cancer) ended ≥ 5 year ago are eligible (7i). If the cancer is non-melanoma skin cancer or early stage cervical cancer, the individual is eligible. If a person has been hospitalized for depression or other psychiatric disorder (7j); hospitalized for asthma (7s); and/or received treatment for inflammatory bowel diseases (Crohn's or colitis) (7r) but ≥ 1 year ago, they are eligible. If the treatment or hospitalization will be more than 5 years ago (for cancer) or more than a year ago (for

depression, asthma, or inflammatory bowel disease) while the SNAP study is still recruiting, the individual can be re-screened at a later time.

If an individual indicates they have another disease, the clinic should record the disease in the comment field below Question 7w and determine whether this will affect the individual's ability to participate in SNAP. If the interviewer is not sure, "Pending Review" should be selected.

Questions 8 through 13 are taken from the Physical Activity Readiness Questionnaire (PAR-Q) and assess the person's ability to perform physical activity.

8. **Do you feel pain in your chest when you do physical activity?**

   If the individual reports having chest pain when performing any type of physical activity, they are ineligible.

9. **In the past month, have you had chest pain when you were not doing physical activity?**

   If the individual reports having chest pain when not performing any physical activity, they are ineligible.

10. **Do you lose your balance because of dizziness or do you ever lose consciousness?**

    If the individual reports losing balance because of dizziness, or previously losing consciousness, they are ineligible.

11. **Do you have a bone or join problem (back, neck, knee or hip) that could be made worse by a change in your physical activity?**

    If the individual reports a bone or join problem that could be made worse by changing their physical activity level, they must receive consent from their primary care physician before participating in SNAP.

12. **Is a doctor currently prescribing drugs for your blood pressure or heart condition?**

    If the individual reports that their doctor is currently prescribing drugs for their blood pressure or a heart condition, they must receive consent from their primary care physician before participating in SNAP.

13. **Do you know of any other reason why you should not do physical activity?**

    If the individual reports another reason they believe they should not do physical activity, they must receive consent from their primary care physician before participating in SNAP.

14. **Do you have any health problems that may influence the ability to walk for physical activity?**

    If the individual reports that they have health problems that could influence the ability to walk for physical activity, they must receive consent from their primary care physician prior to participating in SNAP.

15. **Women only (Men, skip to Question 16)**

    Only women should be asked Question 15. If the individual is male, the interviewer should skip to Question 16.

    a. **Are you currently pregnant?**

       If the individual is currently pregnant, they are ineligible for participation. Six months after giving birth, the individual may be re-screened.

    b. **Have you been pregnant in the last ___ months?**

       SNAP staff to determine number of months between Telephone Screening and Screening Visit 2. Participants cannot have been pregnant ≤ 6 months ago at the time of Screening Visit 2.

       Participants cannot have been pregnant ≤ 6 months prior to the Screening Visit 2. It is at the discretion of the clinic staff to determine if they participant should move forward to orientation, or be held for re-screening, based on the number of months post-partum.

    c. **Are you planning to become pregnant in the next 6 months?**

       Individuals planning to become pregnant in the next 6 months are ineligible. If the individual's plans change, they can be re-screened at a later date.

16. **Are you currently:**

    a. **In another weight loss program?**

       Note: If yes to question 16a, "Are you willing to discontinue participation in the weight loss program?"

       Individuals currently participating in another weight loss program are not eligible for participation. If they are willing to discontinue their participation in this weight loss program, they are eligible.

    b. **Using steroid pills/gels/shots for muscle mass or weight gain?**

       Note: If yes to question 16b, "Are you willing to discontinue use of steroids? "

Individuals currently using steroid pills/gels/shots for muscle mass or weight gain are not eligible for participation. If they are using these steroids for reasons other than muscle mass or weight gain, they are eligible. If they are using steroids for muscle mass or weight gain, but are willing to discontinue use of these medications, they are eligible.

c. **Taking weight loss medication?**

Note: If yes to question 16c, "Are you willing to discontinue use of these medications?"

Individuals currently using weight loss medication are not eligible for participation. If they are willing to stop taking these medications, they are eligible.

17. **Have you ever participated in another weight loss or physical activity study?**

Individuals cannot currently be participating in another weight loss or physical activity study that would interfere with SNAP. If the individual reports that they have never participated in another weight loss or physical activity study, the interviewer should skip to Question 18. If the individual reports that they have participated in another weight loss or physical activity study, the interviewer should obtain more information about the study.

a. **What study?**

The interviewer should record the name of the study (ies) the individual is currently or previously has participated.

b. **Researcher's Name?**

The interviewer should record the name of the researcher(s) responsible for the study the individual previously participated.

c. **Have you completed the study?**

The interviewer should record whether the individual is still currently participating in the study. If the individual has completed the study, the month and date the study ended should be recorded.

Note: If no to question 17c, "Does the clinic staff believe the participant can also participate in this study?

If the individual is still participating in the other study and the interviewer is able to make a decision about whether the current study will conflict with SNAP, they should record the appropriate response. If

further information about the study is needed, the interviewer should check “Pending Review.”

18. **Do you read, write and speak English?**

    The interviewer should confirm that the person can read, write, and speak English. It should not be assumed that because the person speaks English that they can read and write English.

19. **Are you planning to move from the area within the next:**

    The interviewer should record whether the individual has plans to move from the area within the duration of the study.

    a. **6 months?**

       If the individual is planning to move from the area within the next 6 months, they are ineligible.

    b. **12 months?**

    c. **2 years?**

    d. **3 years?**

       Note: If yes to 19b-d, “Does the clinic staff believe that the participant would be able to attend their intervention visits as outlined in the protocol?

       If the individual reports they plan to move from the area with the next year to 3 years, it is at the clinic’s discretion whether they believe the individual would be able to attend their intervention visit as outlined in the protocol (*i.e.,* if they regularly visit the area because of another commitment). If the interviewer is unable to make the decision about whether they believe the individual would be able to attend their visits, “Pending Review” should be selected. If the individual’s plans to move change, they can be re-screened at a later date.

20. **Do you currently live or work within 30 miles of [INSERT CLINIC LOCATION]?**

    The interviewer should record whether the individual currently lives or works within 30 miles of the clinic location.

    Note: If no to 20, “Does the clinic staff believe that the participant would be able to attend their intervention visits as outlined in the protocol?

If the individual does not live or work within 30 miles of the clinic, it is at the clinic's discretion whether they believe the individual would be able to attend their intervention visit as outlined in the protocol (*i.e.,* if they regularly visit the area because of another commitment). If the interviewer is unable to make the decision about whether they believe the individual would be able to attend their visits, "Pending Review" should be selected. If the individual's ability to easily access the SNAP clinic changes, they can be re-screened at a later date.

21. **Are there times during the next 6 months that you might be away for weeks of months at a time?**

    The interviewer should record whether the individual currently has plans to be away from the area for weeks or months at a time during the next 6 months (*i.e.,* during the screening visits and intervention).

    Note: If yes to 21, ask potential participant to specify how long they will be away and when. If it is before the intervention begins and they are able to attend their orientation and screening visits, this is permissible. If the dates they anticipate being away coincide with the initial 4-month intervention, please document how many weeks they would miss. If they know they would miss more than 2 of the 8 initial intervention sessions, they are not eligible for participation.

    If the individual has plans to be away and will not be able to attend the orientation and screening visits, they are ineligible at this time. If they anticipate being away during the initial 4-month intervention, but would only miss a maximum of 2 intervention sessions, they are eligible. If they anticipate missing more than 2 of the intervention sessions, the participant is ineligible. If the interviewer is unable to make the decision about whether they believe the individual would be able to attend their visits, "Pending Review" should be selected. If the individual's plans change, they can be re-screened at a later date.

22. **Are any other members of your household or a roommate (not a house mate) currently participating in or working on this study?**

    If another member of the person's household, or their roommate, is a participant or staff member with the SNAP study, the person is ineligible. It is acceptable if the person lives in a dorm or sorority/fraternity house, and another house member is participating, as long as the house member is not their roommate. If the individual's living situation changes at a later time, they can be re-screened at a later date.

23. **Do you have Internet access on a regular basis?**

    The SNAP study will require participants to have access to the internet on a regular basis. If a participant does not have regular access, they are ineligible. If their ability to have access to the internet changes, they can be re-screened at a later date.

24. **All group meetings will be held on [insert day] evenings at either [insert time] and to be eligible for this study you must be able to make these meeting times. Does [insert day] evening work for you?**

    The interviewer should let the individual know the day and time of group meetings. If these times will not work for the individual, the individual is ineligible. The comment field should be used to record days and times that would work for the individual. If the day and/or time of the group meetings changes, or the individual's schedule changes, the individual can be re-screened at a later date.

Based upon the answers entered into the SNAP website, the website will display a message letting the interviewer know whether the individual is eligible; ineligible or if eligibility is pending. If the participant is eligible, the interviewer will be directed to the Telephone Screening Form, Part II: Eligible Participants (see section 6.13.3). If the participant is ineligible, the interviewer will be directed to the Telephone Screening Form, Part II: Ineligible Participants (see section 6.13.4). The lead project coordinator should review all telephone screening forms where eligibility is pending. Any questions marked as eligibility pending should be verified and the project coordinator should contact the participant to notify them of eligibility status.

6.13.3. Telephone Screening Form, Part II: Eligible Participants

If the participant is eligible, the interviewer will be directed to the Telephone Screening Form, Part II: Eligible Participants. The interviewer should read the appropriate script and notify the individual that they are eligible. If possible, the orientation visit should be scheduled. This form is used for clinic monitoring purposes and information entered on this form will be used for reporting and tracking purposes.

Question-by-Question Instructions

The interviewer must complete the "date form completed" field or the form will not be saved. Administration type for the telephone screening form, part II, will always be "staff-administered."

1. **Has participant been notified of eligibility?**

   The staff records whether the participant has been notified of their eligibility.

2. **Has orientation been scheduled?**

   The staff records whether the orientation has been scheduled.

3. **Orientation date**

   The staff records the orientation date in numerical month/day/year format. The date entered is important for creation of reports that help to guide the staff in preparing materials for upcoming orientations.

6.13.4. Telephone Screening Form, Part II: Ineligible Participants

If the participant is ineligible, the interviewer will be directed to the Telephone Screening Form, Part II: Ineligible Participants. The interviewer should read the appropriate script and notify the individual that they are current ineligible for participation in the SNAP study. The interviewer should offer to supply information about other weight control programs. This form is used for clinic monitoring purposes and information entered on this form will be used for reporting and tracking purposes.

Question-by-Question Instructions

The interviewer must complete the “date form completed” field or the form will not be saved. Administration type for the telephone screening form, part II, will always be “staff-administered.”

1. **Has participant been notified of ineligibility?**

   The staff records whether the participant has been notified of their ineligibility.

2. **Would you like information about other weight control programs mailed to you?**

   The staff should offer participants the option to receive information about other weight control programs and record whether the mailing was requested. If a mailing is requested, the staff should select whether the mailing was sent.

6.13.5. Orientation Form

The Orientation Form is completed by the clinic staff at the orientation visit. This form serves as a record that informed consent has been obtained and provides information that is necessary for programming the SenseWear armbands.

Additionally, this form is used for clinic monitoring purposes and information entered on this form will be used for reporting and tracking purposes. If the individual consents and is eligible based on BMI, screening visit 1 should be scheduled and recorded on the form.

Question-by-Question Instructions

The interviewer must complete the "date form completed" field or the form will not be saved. Administration type for the orientation form will always be "staff-administered."

1. **Orientation Status**

   The orientation status field should be used if the individual does not attend, if the individual refuses, or if it is determined that the participant is temporarily ineligible at the time of orientation. If the individual attends Orientation, this field should be left blank. **In order for eligibility to be assessed, the orientation status field must be set back to blank.** The status identified on the Orientation Form helps to develop reports listing potential participants and participants who should not be contacted. The comment field under the orientation status field can be used to record information regarding the reason for temporary ineligibility or comments about why the participant refused. This information can be useful to other clinic staff members when reviewing potential re-screens.

2. **Consent**

   The staff should record whether the participant consented to participation in consent and record the date of consent in a month/day/year format. If applicable, the staff should record whether the participant consented for DNA and for storage of samples. If consent for these additional things is incorporated into the main consent, these questions should be left blank.

3. **Handedness**

   The staff should record whether the participant is left or right handed. This is necessary information for programming the armband (distributed at screening visit 1). Obtaining this information at the orientation visit, allows clinic staff to have the armband programmed and ready when the participant comes in for their next visit.

4. **Smoking status**

   The staff should record whether the participant identifies themselves as a smoker or non-smoker. This is necessary information for programming the armband (distributed at screening visit 1). Obtaining this information

at the orientation visit, allows clinic staff to have the armband programmed and ready when the participant comes in for their next visit.

5. **Orientation weight**

   Screening Visit 1 (SV1) weight

   The individual should be weighed using the procedures outline in Chapter 11, Physical Measurements. The weight in kg, to the nearest tenth, should be recorded. The participant does need to be in gowns for this measurement. If the participant's BMI is borderline eligible, a screening visit 1 can be scheduled and the participant can be re-weighed. If the participant is re-weighed at screening visit, their updated weight should be data entered into the Orientation Form under 'orientation weight' but recorded on the form as 'sv1 weight.'

6. **Height**

   The individual should be measured using the procedures outline in Chapter 11, Physical Measurements. The height in cm, to the nearest tenth, should be recorded. The participant does need to be in gowns for this measurement.

7. **BMI ineligible, reweigh at SV1**

   The SNAP staff calculates the individual's BMI, using the current weight and height, based on http://www.nhlbisupport.com/bmi. BMI must be between 21 - 30 kg/m^2. If the individual's BMI result is borderline eligible, the screening visit 1 should be scheduled and the participant should be re-weighed. In this circumstance, the box for 'BMI ineligible, reweigh at SV1' should be selected. At the time the BMI is confirmed, either at orientation or Screening Visit 1, this box should be unselected. If this box is selected, the participant will show as eligible at orientation.

8. **Screening Visit 1 scheduled**

   If the individual is deemed to be eligible or pending, based upon their BMI and they consent to participate, screening visit 1 should be scheduled, if possible. The staff records whether the screening visit 1 has been scheduled.

9. **Schedule Screening Visit 1**

   The staff records the screening visit 1 date in a month/day/year format. The date entered is important for creation of reports that help to guide the staff in preparing materials for upcoming visits.

6.13.6. Screening Blood Pressure Form

The Screening Blood Pressure Form is completed by the clinic staff at Screening Visit 1. This provides the participant's baseline blood pressure. Blood pressure and pulse should be measured following the study blood pressure protocol as outlined in Chapter 11, Physical Measurements. The average blood pressure must be less than 140/90 mmHg. If blood pressure equals or exceeds this level, the participant must receive consent from their primary care physician to participate in SNAP. The pulse must be less than 110 beats per minute. If pulse equals or exceeds this level, the participant must receive consent from the primary care physician to participate.

Additionally, this form is used for clinic monitoring purposes and information entered on this form will be used for reporting and tracking purposes. At the conclusion of Screening Visit 1, screening visit 2 should be scheduled and recorded on the form.

Question-by-Question Instructions

The interviewer must complete the "date form completed" field or the form will not be saved. Administration type for the screening blood pressure form will always be "staff-administered." The screening visit 1 status field should be used if the individual does not attend, if the individual refuses, or if it is determined that the participant is temporarily ineligible at the time of screening visit 1. If the individual attends Screening Visit 1, this field should be left blank. **In order for eligibility to be assessed, the screening visit 1 status field must be set back to blank.** The status identified on the Screening Blood Pressure Form helps to develop reports listing potential participants and participants who should not be contacted. The comment field under the screening visit 1 status field can be used to record information regarding the reason for temporary ineligibility or comments about why the participant refused. This information can be useful to other clinic staff members when reviewing potential re-screens.

1. **Time of day**

   The staff records the time of day the blood pressure was measured, using a 12-hour clock. A.M. or P.M should be indicated.

2. **Arm circumference**

   The arm circumference in cm, to the nearest tenth, should be recorded. The staff records whether the measurement was taken on the participant right or left arm.

3. **Cuff size**

   The staff records the type of cuff used for measuring blood pressure. If a type not listed on the form was used, other should be checked and the type of cuff recorded in the box provided.

4. **Pulse**

   Using procedures outline in Chapter 11, the staff records the beats per minute.

5. **Blood Pressure: Record 3 measures**

   Using procedures outline in Chapter 11, the staff takes three blood pressure readings, recording SBP, DBP and the method used to obtain the measure. The technician ID for the staff member performing the test is recorded.

6. **Able to schedule Screening Visit 2**

   Screening visit 2 should be scheduled, if possible. The staff records whether the screening visit 2 has been scheduled.

   Schedule Screening Visit 2

   The staff records the screening visit 2 date in a month/day/year format. The date entered is important for creation of reports that help to guide the staff in preparing materials for upcoming visits.

6.13.7. Blood Specimen Collection Form

The Blood Specimen Collection Form is completed by the clinic staff at Screening Visit 1. This provides the participant's baseline blood samples and provides storage samples for the duration of the study. Blood collection should occur as outlined in Chapter 10, Specimen Collection. The following criteria must be met: fasting glucose ≤ 126 mg/dl, LDL-C ≤ 160 mg/dl, and triglycerides ≤ 500 mg/dl. If the glucose levels, LDL-C or triglycerides are found to be elevated, the participant must receive consent from their primary care physician to participate in SNAP. In general, clinics will be notified of lab values within 48 hours of receipt of sample at the laboratory.

6.13.8. Screening Physical Measurements Form

The Screening Physical Measurement Form is completed by the clinic staff at Screening Visit 2. This provides the participant's baseline weight, height and waist circumference. Participants must have their height, weight and waist circumference measured following the protocols outlined in Chapter 11, Physical Measurements. Their BMI must be between 21 - 30 kg/m^2.

Additionally, this form is used for clinic monitoring purposes and information entered on this form will be used for reporting and tracking purposes.

The screening visit 2 status field should be used if the individual does not attend, if the individual refuses, or if it is determined that the participant is temporarily ineligible at the time of screening visit 2. If the individual attends Screening Visit 2, this field should be left blank. **In order for eligibility to be assessed, the screening visit 2 status field must be set back to blank.** The status identified on the Screening Physical Measurement Form helps to develop reports listing potential participants and participants who should not be contacted. The comment field under the screening visit 2 status field can be used to record information regarding the reason for temporary ineligibility or comments about why the participant refused. This information can be useful to other clinic staff members when reviewing potential re-screens.

6.13.9. AUDIT

The AUDIT assesses whether a potential participant has current symptoms of alcohol dependence. These questions will be completed by the participant online. With the exception of the skip on Question 1, each question must be answered. The score will not be displayed to the participant; but will be displayed to clinic staff prior to Screening Visit 2.

6.13.10. EDA

The EDA assesses whether a potential participant has current symptoms of bulimia nervosa. These questions will be completed by the participant online. With the exception of the skip on Question 1, each question must be answered. The score will not be displayed to the participant; but eligibility status will be displayed to clinic staff prior to Screening Visit 2.

Appendix A - Orientation Outline

Welcome

- We are excited that you are here tonight and are interested in getting your weight under control and preventing weight gain.
- Congratulations on taking this step to improve your health. My goal tonight is to tell you about this program and see if you would be interested in joining us in SNAP.
- First let me just tell you a little about **US**--Weight Control and Diabetes Center Background

The WCDRC opened in 1998. Dr. Rena Wing is the director of the center and is a Professor of Psychiatry and Human Behavior at Brown Medical School. Dr. Wing is an international expert in weight control. We conduct state-of-the-art behavioral interventions related to weight management. A lot of what is known about weight loss, how best to do it, how to maintain it, and its effects on health comes from the work of Dr. Wing and others at the WCDRC. With me tonight are------ Shows the multi-disciplinary nature of our program leaders.

Dr. LaRose is a clinical psychologist and faculty member here in the center who is working with Dr. Wing on the current program.

Erica Robichaud - Project Coordinator and interventionist – is a Registered Dietitian with a Master's in Social Work.

Dr. Jessica Unick – Interventionist on the study – PhD in Exercise Physiology

Caitlin Egan – Interventionist on the study – Masters in Exercise Physiology

Marie Kearns – Interventionist on the study – background in nutrition and masters in counseling

Brittany James and Carrie Wunsch – Research Assistants – Brittany has a background in psychology and Carrie has a background in neuroscience

Angelica Adams – Background in psychology and currently obtaining her masters in health education

So why are we here?

As I am sure you know we have an epidemic of obesity in the US. Nearly two-thirds of adults in the United States are overweight and one-third is obese. And these rates continue to rise. The problem of obesity often begins in between the ages of 18-35. Most 18 year olds are normal weight and by the time they reach age 35, many are overweight or obese. In fact, individuals typically gain almost 30 pounds between the

time they are 18 and 35. Think about that for a minute – take the weight you are today and add 30 pounds!

How do you think you would feel 30 pounds heavier - health would be affected…. .

Why does this weight gain occur - changes in lifestyle - no longer playing sports each day; desk jobs; pregnancies; etc. This weight gain typically sneaks up on people because it is a pound or two here and there, but over time, these are really substantial gains with important health consequences. So even if you think this will NOT happen to you---you may well be wrong…..

We want to help YOU prevent this weight gain and that is the goal of SNAP. We have a great deal of experience in prevention of weight gain and we are convinced that the programs we are offering you can help you prevent weight gain.

We know that ….If you wait until you gain a lot of weight and then try to lose weight, it can be very difficult. So one of the key aspects of SNAP is to PREVENT these weight gains - we want to help you get your weight under control NOW before these larger weight gains occur during young adulthood.

We have studied strategies to prevent weight REGAIN and much of what we learned there can help you prevent weight gain.

> Research has found that behavioral interventions, such as those offered here in the Center, are very successful in helping people make lifestyle changes and achieve weight loss. However, unfortunately, many people slowly regain the weight they lost. So, we developed a program specifically designed to help people maintain the weight they had lost – it was called Stop Regain. The program worked! It was successful in helping people keep off their weight. In addition, participants who weighed themselves daily were most successful in preventing weight regain.
>
> We learned a lot in developing the STOP REGAIN program and used many of these strategies to develop a weight gain prevention program for young adults. The good news is that we found we could be successful here too. So we know what we are teaching you can WORK for weight gain prevention.
>
> What we don't know yet, and **what we are studying**, is whether people can keep from gaining weight over a longer period of time, and whether some of these strategies might be easier to keep doing over time. This is what we are investigating in this program. The study is called SNAP, or the Study of Novel Approaches to Prevention. SNAP is funded by the NIH - the federal government - because they want to tackle this important problem of weight gain and wants us to figure out what will work best…

We will be comparing three different approaches to weight gain prevention in SNAP. All groups will be taught to weight themselves regularly so you know what is happening with your weight and can catch weight gains quickly to help you get control of your weight. In one group, you will be asked to make small changes in your eating and activity - just eat 100 calories less or walk 1 mile more, but the goal is that you will maintain these small changes over time in order to maintain your weight. In the second group we will ask you to make some pretty large changes in your eating and physical activity and to lose 5-10 pounds to create a "buffer" against possible weight gain. In the third group, we give you information about the techniques used in both of those groups and **allow you** to implement them in a way that works best with your lifestyle without having to stick specifically to either program. We'll talk more specifically about what the groups look like in a few minutes, but one of the goals in this program is to determine which of these programs is most effective at helping you to control your weight over time.

A very positive thing about the SNAP program is that we have evidence that **both** the large and small changes treatments in the current study work, and if followed, should produce some initial weight loss, and help you keep your weight under control in the years ahead.

Program Details

- Let's go into the details of SNAP: It is a large study being conducted in 2 centers in the US – here in Providence and in Chapel Hill, NC. Because this is such a large study, we also have a data coordinating center located at Wake Forest University in Winston-Salem, NC. This study is funded by the National Institutes of Health and is part of a larger network of NIH studies that are focusing on weight control in this young adult age group. In this study, we will recruit 300 men and women ages 18 t0 35 here in the Providence area and 300 more in the Raleigh-Durham-Chapel Hill area. Depending upon when you join the study, we'll follow you for 2 to 4 years.
- Go over Study Overview Flowchart
- It is important for you to understand exactly what each of the 3 groups offer, because if you decide to participate you are agreeing to be assigned to either of the programs. You cannot pick the group you are in.
- Discuss assessment visits - frequency (2 screening visits at BL, other assessments at 4 mos. and then annually, procedures (body measurements, blood work, questionnaires, armband), feedback that will be given. (Show examples of armbands, etc.)

Agreeing to Participate/Commitment

- I'd like to say one more thing about our programs as you are deciding whether this sounds like something you want to participate in or not. The programs we offer at our center are research programs. What that means is that we are studying different types of programs for weight control. Our programs differ from clinical programs or weight watchers programs in several ways:
  - One important difference is that our programs are **free**
  - But most importantly, with clinical programs or weight watchers types of programs that you pay for, you might decide to go to one meeting and never go back to the program again. With research programs, we are giving you a free program with state of the art information, and in return you are ***making a commitment*** to us. Once you decide to participate, we will need to see you again for the measurement visits so that we can determine the outcomes of the study. What this means is that whether you stay the same weight, lose weight, or even gain weight during the study we want to be able to weigh you and ask you questions at the end of the program. This is how we move science forward to determine what is effective and not effective.

Next Steps

- Questions?
- If you would like to participate we invite you to stay for a few more minutes. If you've decided this is not for you, you are free to go. Determine your own interest level - if you're interested in continuing with the screening process to get into the program you should stay here for a few minutes and we'll get started on the next phase of the screening. If you don't think this is the program for you, please don't hesitate to leave right now. The point of this orientation is to make sure this is the right program for you. You won't hurt anyone's feelings if you decide to leave.
- We will be starting this program at the end of **October/beginning of November 2010**. There are a few steps that we need you to complete before we can officially enroll you in the study.
  - Complete the Consent form and DNA substudy consent form. We will ask you to initial the top of each page and sign the back page of both copies. We will then sign them and give you one to keep and we will keep one on file here.
  - Sign up for your first Screening Visit. You'll need to come in on a morning during the next few weeks having fasted for 12 hours. At this visit, we will do your blood work and measure your blood pressure. We'll also give you a

link to the study website so that you can fill out several questionnaires. Finally, we'll outfit you with the SenseWear armband which you will wear for a week.

- You'll also come back again for a Second Screening Visit a few weeks before the group meetings start. At that visit, we'll measure your weight and height, your body fat, go over your questionnaires and confirm that you are still committed and eligible to participate in the study.
- Some of you will be required to have your doctor sign a form to make sure it's ok for you to participate. We will give you those forms on your way out tonight if you will need one.
- If you have any additional questions, please speak with staff before you leave.

Appendix B - MD Consent: General

PHYSICIAN CONSENT TO PARTICIPATE IN A DIET AND EXERCISE PROGRAM AT THE MIRIAM HOSPITAL

TO:	**Physician's Name** **Address** **City** **State** **Zip** **( )** **Telephone Number**	**RETURN TO:** **Rena Wing, Ph.D.** **The Weight Control and Diabetes Research Center** **The Miriam Hospital** **196 Richmond St.** **Providence, RI 02903** **Telephone: (401) 793-8959** **FAX: (401) 793-8944**

Your patient _____, has asked to participate in a research program focused on preventing weight gain at the Miriam Hospital. This program is being conducted by Drs. Rena Wing and Jessica LaRose. Since your patient reported either a history of or current health problems on our initial screening questionnaire, we felt it was important to notify you of his/her interest in the program and to obtain your permission for participation.

This is a 3-year study designed to help patients prevent weight gain by making healthy changes in their diet and exercise. It involves attending some initial face-to-face meetings and then patients will be asked to continue to follow the guidelines for their group over time and will be followed up over the next several years through a series of refresher courses and assessment visits.

Patients will be randomly assigned to one of three groups: 1) a Large Changes treatment group where participants are asked to make periodic large behavior changes in their eating and activity, 2) a Small Changes treatment group that teaches participants to make small changes in eating and activity on a daily basis and maintain them over time, or 3) a Self-Guided program in which participants will be taught about both approaches and asked to follow the one they feel is best suited for them.

If assigned to the Large Changes group, your patient will be asked to do the following:

1. Increase their physical activity to a level equivalent to 45-60 minutes of activity on most days of the week during the initial 8-weeks of this intervention. This exercise will be unsupervised and the patient will be encouraged to select brisk walking or a similar activity for his/her activity. Participants will be encouraged to maintain this level of activity over the next several years.

2. Consume a calorie restricted (1200-1800 calories per day) and fat restricted (30 percent of total calories) diet during the initial 8-weeks of this intervention. The specific calorie prescription will be based on your patient's weight when he/she begins the program. The goal is to produce modest weight loss initially to serve as a buffer against anticipated weight gain over the next several years.

If assigned to the Small Changes group, your patient will be asked to do the following:

1. Increase their physical activity by increasing their number of steps by 2000 over baseline (equivalent to adding approximately 20 minutes of walking throughout the day). They will be asked to maintain this level of activity on a daily basis for the next several years.

2. Make small changes in their diet each day with the goal of reducing their daily calorie intake by approximately 100 calories. They will be taught healthy ways to make changes both to their portion sizes as well as what they eat during the initial intervention, and will be asked to continue to make these small changes daily over the next several years.

If assigned to the Self-Guided group, your patient will be asked to do the following:

1. They will be given information about both the Large and Small Changes approaches, as well as resources for following each of the programs. They will be asked to choose the approach that they feel is the best fit for them and to follow that approach for the next several years.

Please indicate below if this program seems appropriate for your patient or if you see any contraindications for his/her participation (*please check the appropriate box below and provide the requested information)*.

☐ The program is appropriate for this patient.

☐ I feel that this program would not be appropriate for this patient for the following reason(s):

_____

_____.

Signature of Physician

Appendix C - MD Consent: Specific

PHYSICIAN CONSENT TO PARTICIPATE IN A DIET AND EXERCISE PROGRAM AT THE MIRIAM HOSPITAL

TO: **Physician's Name**

Address

City **State** **Zip**

( )
Telephone Number

RETURN TO:

Rena Wing, Ph.D.
The Weight Control and Diabetes Research Center
The Miriam Hospital
196 Richmond St.
Providence, RI 02903

Telephone: (401) 793-8959
FAX: (401) 793-8944

Your patient _____, has asked to participate in a research program focused on preventing weight gain at the Miriam Hospital. This program is being conducted by Drs. Rena Wing and Jessica LaRose.

Your patient's initial medical screening with our staff indicated the following:

_____

_____

_____

Based on this value(s) at his/her initial screening visit, we felt it was important to notify you of his/her interest in the program and to obtain your permission for participation.

This is a 3-year study designed to help patients prevent weight gain by making healthy changes in their diet and exercise. It involves attending some initial face-to-face meetings and then patients will be asked to continue to follow the guidelines for their group over time and will be followed up over the next several years through a series of refresher courses and assessment visits.

Patients will be randomly assigned to one of three groups: 1) a Large Changes treatment group where participants are asked to make periodic large behavior changes in their eating and activity, 2) a Small Changes treatment group that teaches participants to small changes in eating and activity on a daily basis and maintain them over time, or 3) a Self-Guided program in which participants will be taught about both approaches and asked to follow the one they feel is best suited for them.

If assigned to the Large Changes group, your patient will be asked to do the following:

1. Increase their physical activity to a level equivalent to 45-60 minutes of activity on most days of the week during the initial 8-weeks of this intervention. This exercise will be unsupervised and the patient will be encouraged to select brisk walking or a similar activity for his/her activity. Participants will be encouraged to maintain this level of activity over the next several years.

2. Consume a calorie restricted (1200-1800 calories per day) and fat restricted (30 percent of total calories) diet during the initial 8-weeks of this intervention. The specific calorie prescription will be based on your patient's weight when he/she begins the program. The goal is to produce modest weight loss initially to serve as a buffer against anticipated weight gain over the next several years.

If assigned to the Small Changes group, your patient will be asked to do the following:

1. Increase their physical activity by increasing their number of steps by 2000 over baseline (equivalent to adding approximately 20 minutes of walking throughout the day). They will be asked to maintain this level of activity on a daily basis for the next several years.

2. Make small changes in their diet each day with the goal of reducing their daily calorie intake by approximately 100 calories. They will be taught healthy ways to make changes both to their portion sizes as well as what they eat during the initial intervention, and will be asked to continue to make these small changes daily over the next several years.

If assigned to the Self-Guided group, your patient will be asked to do the following:

1. They will be given information about both the Large and Small Changes approaches, as well as resources for following each of the programs. They will be asked to choose the approach that they feel is the best fit for them and to follow that approach for the next several years.

Please indicate below if this program seems appropriate for your patient or if you see any contraindications for his/her participation (*please check the appropriate box below and provide the requested information)*.

☐ The program is appropriate for this patient.

☐ I feel that this program would not be appropriate for this patient for the following reason(s):

_____

_____.

Signature of Physician

Appendix D - Instructions for Form Completion on the SNAP Web Site

What Happens Next?

- ☐ Wear the SenseWear armband for one week, following the directions provided to you.

- ☐ **Prior to** your next visit, complete the SNAP study questionnaires. Allow yourself ample time (at least 1 ½ hours) to fill these out on our website. You may fill out a portion and then go back but try not to have too many interruptions.

  Go to: https://snapstudy.phs.wfubmc.edu. Enter the following login information:

  Username: _____
  Your password will be emailed to you at this address.

- ☐ Return for Screening Visit 2

  Date: _____ Time: _____

  - Do not eat or drink anything besides water for 4 hours prior to this visit.
  - Do not take a diuretic for 4 hours prior.
  - Do not engage in vigorous exercise for 8 hours prior.
  - Do not drink alcohol for 12 hours prior.
  - At this visit, you will have your weight, body measurements, and body fat assessed. **Please wear athletic type elastic waist shorts and a T-shirt**. If you have a swimsuit that has no metal on it or a sports bra (women) and compression shorts, please bring them to this visit. You will also have a one-on-one discussion with a study staff member to confirm that SNAP is a good match for you. This visit will last approximately 60 minutes.

- ☐ Physician Consent
  Some SNAP participants need to get their doctor's consent to participate in this research study. If you require consent, we have provided a form for you to have signed. Please bring this to Screening Visit 2.

  _____ I need consent _____ I do not need consent

We look forward to seeing you at your next visit! If you cannot attend your appointment and need to rescheduled, or you have any questions, please call us at (919) 966-5852. Press "2" to be connected directly to our staff.

Appendix E - Participant Activation Instruction

After the subject has completed SV1 and it has been determined that they are currently eligible for the study, the clinic staff should activate their logins for the SNAP website. Activation **should not** occur until after the SV1 visit in order to ensure that the participants have the proper instructions regarding completion of forms and do not receive an e-mail with login instructions if they have been deemed ineligible at SV1.

At the conclusion of SV1, tell the participant their username for the study website (username will be their e-mail address). Let them know they will be receiving an automatic e-mail with their password.

Activate the participant's login and send them their password:

1. From the Eligibility Tracking Report, find the appropriate participant
2. Click on the participant's name
3. Click on the 'Participant Info' Tab
4. Click the button 'EDIT PARTICIPANT PROFILE'
5. On the 'Profile' tab click the 'UPDATE PARTICIPANT PROFILE' button. This will update the username to be the current email address listed on the profile tab.
6. Select the 'Login' Tab
7. Click the button 'SETUP LOGIN ACCOUNT'

An automatic e-mail will be sent to the participant with their password and the link to the study website.

If a participant forgets their password, neither the Coordinating Center nor the clinics can let the participant know their password. The participant should click 'Click here if you have forgotten your password' and after entry of a registered e-mail address, the system will send them an automatic e-mail with their password.

To update their password, participants can click 'Account Settings' from the upper right hand corner and then select 'Change Your Password.' They will need to enter their current password and the new password (twice). Passwords must meant the SNAP criteria and be at least 6 characters, contain at least one number, one upper case letter and one lower case letter.

Please contact Tisha (lperdue@wfubmc.edu) if there are questions or issues.

Appendix F - Study Forms

Completion from Pre-Screening through Screening Visit 2

Form	Visit Completed				
	Pre-Screening	Telephone Screening	Orientation	Screening Visit 1	Screening Visit 2
Pre-Screening	X				
Telephone Screening		X (STAFF)			
Telephone Screening, Part II: Eligibles		X (STAFF)			
Telephone Screening, Part II: Ineligibles		X (STAFF)			
Orientation			X (STAFF)		
Screening Blood Pressure				X (STAFF)	
Screening Physical Measures					X (STAFF)
AUDIT					X
BLOCK (data uploaded)					X
Blood Specimen Collection				X (STAFF)	
CESD				X (STAFF)	
Contact Information					X
Demographics					X
Eating Inventory					X
EDA					X
Exercise Habits					X (STAFF)
Health Behaviors					X
Bio-Electrical Impedance					X (STAFF)
Life Events (Baseline)					X
Medication Use					X
Perception of Program (Baseline)					X
Physical Activity Neighborhood Environment					X
PSS					X
Quality of Life					X
Sedentary Behaviors					X
Self-Weighing					X
Sleep Patterns					X
Smoking and Tobacco Behaviors					X
TSRQ					X
Weight History					X
Weight History of Friends and Family					X
Weight Management Strategies					X
Uploads					
Armband					X
BLOCK					X
BodPod					X
Lab Results				X	

Appendix G - Behavioral Guide

SNAP BEHAVIORAL INTERVIEW – SV2

Date: _____

Participant Name: _____

Interviewer: _____

Recommendation:

_____ Randomize _____ Full Staff Review _____ Do Not Randomize

Understanding of Study and Requirements

1. Can you tell me in your own words what the purpose of the SNAP study is?
2. Tell me your most important reasons for wanting to be in this study.
3. What are your overall goals / expectations for this program?
4. What is your understanding of the commitment required in each of the three arms of the SNAP study?

   Note: *Give the participant a chance to describe each of the groups and requirements first, and review with them if they are unsure*

1. Can you tell me your understanding of what random assignment means?
2. Even though you can't choose which group you will be in since the group assignments are randomly selected, do you have any preference for one group over another?
   a. How would you feel if you weren't assigned to this group?
3. Would you be willing to accept being assigned to any of the three groups?

Review of Behavioral Issues

AUDIT Score _____

***Note**: If ≥9, please review AUDIT responses for any specific items to follow up on (e.g., individuals harmed due to his/her drinking), and also complete general questions below. If score is <9, you can skip these questions.*

1. We're interested in how your current behaviors might influence your adherence in the SNAP study. Can you tell me about your typical drinking habits?

2. How many drinks would you say you have on average in a week?

    a. In a typical sitting / episode?

3. What problems might you anticipate having if you were asked to reduce your drinking in order to meet the dietary goals of the SNAP program?

4. Do you have any history of diagnosis and/or treatment for any psychological problems or conditions (e.g., depression, eating disorder)?

    a. Any medications taken or prior hospitalizations for emotional concerns?

5. Tell me about your emotional health as it relates to your ability to consistently follow a lifestyle change program. Describe any periods in which emotional concerns have interfered with your ability to consistently work, go to school, provide your own health care, or participate with recreational activities.

6. On a scale of 0-10, what is your level of motivation to be in this study: __ / 10

7. Considering your personal schedule for the next year (work, school, family events, vacation/travel, holidays, etc), is this a good time for you to commit to being an active member of the SNAP program? Please keep in mind you are committing to being in any of the three groups, attending meeting(s), and assessment visits.

8. On a scale from 0-10, how ready do you feel you are to begin your involvement with this study at this time? _____ / 10

Attendance and Adherence Issues

1. Are you involved in any other research programs at this time?

   If yes: Tell me about the program. How much of a time commitment does it involve? Is it a medication study? What does the study address?

2. In this study, if you are assigned to the Small Changes or Large Changes groups you will be asked to attend weekly group meetings for 8 weeks followed by 1 meeting/month for the following 2 months). If you are assigned to the Self-Guided group, you will be asked to attend one initial face-to-face session here at the clinic.

   a. Do you anticipate any problems with meeting attendance?

3. Do you have transportation to the center?

4. Are you available on _____ evenings? Groups will be held on _____ at either 5:30 or 6:45.

5. Do you anticipate any upcoming changes to your work or school schedule (and/or instability in hours) that may affect your ability to attend the weekly meetings?

6. If you are assigned to either the Small Changes or Large Changes groups, you will be asked to submit your weight on a periodic basis throughout the study using the study website. What may make it difficult for you to commit to submitting your weight?

7. If assigned to either the Small Changes or Large Changes groups, you would also be asked to attend a refresher group each year, which would entail 4 weekly meetings. What may make it difficult for you to commit to attending these refresher groups?

Assessment Related Issues

1. What was your experience wearing the arm band for 7 days after your first screening visit?

   a. Were you able to wear it for the full 7 days? If not, what made it challenging?

   b. Do you anticipate any problems with wearing the arm band again for your 4 month and 24 month assessments?

2. Describe any problems with the SNAP screening visits thus far. By committing to this study, you will be committing to attending assessments at 4, 12, 24, 36, and 48 months (list months as applicable).

    a. What challenges, if any, do you anticipate occurring that may interfere with completing these assessments?

Other Questions

1. Do you have any questions for me about your participation in this study?

Appendix H - Behavioral Checklist

SNAP BEHAVIORAL INTERVIEW – CHECKLIST

Date: _____

Participant Name: _____

Interviewer: _____

Recommendation:

_____ Randomize _____ Full Staff Review _____ Do Not Randomize

Understanding of Study and Requirements

- — Purpose of study
- — Description of the 3 arms and requirements
- — Reasons for wanting to join study / Goals for program
- — Understanding of random assignment
- — Group preference / Willingness to be assigned to any group

Review of Behavioral Issues

- — Review AUDIT Score / Ask follow-up questions as needed
- — Psych history or medication use
- — General emotional health
- — Assess level of motivation
- — Assess level of readiness
- — Overall assessment of timing for participant

Attendance and Adherence Issues

- — Current involvement in other research programs
- — Attendance at meetings
- — Transportation
- — Available during group times

- Anticipated changes in job or school status / schedule
- Submitting weight regularly as part of the program
- Attendance at refresher groups

Assessment Related Issues

- Any difficulties with assessment process
    - Arm bands
    - Completing future assessments

SNAP MOP - Chapter 7
Randomization
Table of Contents

7. Randomization

7.1. RANDOMIZATION OVERVIEW

Randomization can occur after all eligibility requirements have been met and after all baseline data points have been measured.

Randomization is stratified by clinical center (Miriam Hospital or UNC Chapel Hill), gender (male or female), and ethnicity (non-Hispanic White or others). This ensures nearly equal sample sizes for the three treatment groups within each center. This is necessary because differences between clinical centers are anticipated with respect to target populations and other factors that are difficult to measure or quantify, such as geography, local site personnel, and facilities. Stratification by gender and ethnicity ensures comparability of gender and ethnic representation across the three treatment groups. Randomization assignments are made using a web-based randomization system that is part of the study data management system.

The randomized block method of randomization is used to assign participants to the three intervention groups. This method was chosen because it provides a high probability of balance in group assignment. Block lengths are variable, which makes it difficult to anticipate to which interventions participants will be assigned.

7.2. RANDOMIZATION PROCEDURE

Eight forms and a behavioral interview completed throughout the screening process are used to determine eligibility. The eight forms in sequential order include Pre-Screening Questionnaire, Telephone Screening Form, Orientation Form, Screening Blood Pressure, Blood Specimen Collection Form, Screening Physical Measures, Audit, and EDA. With the exception of the Pre-Screening Questionnaire, these forms must be entered into the database in their entirety. Although not all questions must be answered on the Pre-Screening Questionnaire, key eligibility questions must be entered. As a participant proceeds through the screening process and each form is entered, eligibility checks are performed by the system and/or clinic staff to confirm that all elements of the form have been completed and to confirm eligibility. Once eligibility is confirmed, the participant should complete all baseline data elements. (Note that baseline data can be collected throughout the screening process). Once the baseline data elements are completed, the randomization checklist is reviewed for final eligibility determination.

The randomization checklist includes:

1) Randomization within sixty days of screening visit 2

2) Receipt of blood work data (glucose, LDL-C, triglycerides)
3) EDA score
4) Audit score
5) MD consent received (if required)
6) Behavioral interview results
7) Confirmation that the participant is not pregnant (if female)
8) Confirmation that the meeting time will still work with the participant's schedule
9) Staff review for final decision.

If all elements in the randomization checklist are marked as Passed or Eligible, the clinic staff will see a 'Randomization' button. Clicking this button invokes the randomization computer program and the participant is then randomized (See Chapter 15, Data Management for further details).

Throughout the screening stages, when the eligibility check performed by the system is not successful (i.e., it shows the participant as ineligible) several steps should be taken by the clinic staff in order to resolve the problem. First, review the eligibility tracking system and eligibility reports to determine the screening stage where the participant was deemed ineligible and confirm that the data were entered correctly into the system by comparing the hard copy of the form with the data screens. If an error has been made in data entry, the screens can be corrected and the eligibility check can be run again. Any corrections that are made to the eligibility screens after the eligibility check is run will be documented in the system audit trail and reviewed periodically by the Coordinating Center and Quality Control Committee to assure compliance with the study protocol. Second, confirm that all activities have occurred within the allowable time (see Section 7.4., Allowable Time between Activities). Re-screening may be permissible for participants deemed ineligible at initial screening.

The randomization computer program requires that the Coordinating Center server, the clinic computer, and the phone lines are all operational. In the event of a failure of any of these systems, web-based randomization cannot be performed. The following steps should be followed. First, inform Tisha Perdue (phone 336-716-1336, or lperdue@wfubmc.edu) at the Coordinating Center, particularly if you are having difficulty reaching the Coordinating Center server. Second, if possible, delay randomization. (It may be only a short time before the system is operational again). If randomization must be performed immediately (*e.g.,* an intervention group is due to begin the following day), the Coordinating Center has a back-up plan for randomizing without the computer system: contact Tisha Perdue.

In the event an error in randomization is made (*i.e.*, with data entry or printing a form), contact Tisha Perdue at the Coordinating Center.

7.3. COHORT ASSIGNMENT

Immediately following the randomization, clinic staff will be directed by the system to select the appropriate cohort from a drop down box. The cohort assignment will designate the timeline for future assessment visit windows and the participant will only appear on reports reflecting their assigned cohort letter.

If a cohort is selected in error, clinic staff should e-mail the Coordinating Center to make the appropriate correction. See section 7.6 for circumstances where a participant is randomized to a cohort, but unable to begin or continue intervention with the assigned cohort.

7.4. RANDOMIZATION ERRORS

Occasionally the clinic or the Coordinating Center uncovers information that indicates that a randomized participant was not eligible. One reason for this is that a participant may not have revealed information that made him/her ineligible until after the randomization. Alternatively, a data entry error may have been made in the participant's favor, leading him (her) to be considered eligible and subsequently to be randomized, when he (she) is not eligible.

When a randomization error is known to have occurred: (1) a memorandum signed by the Program Coordinator and Principal Investigator must be sent to the Coordinating Center as soon as the situation is uncovered; and (2) the participant will remain a part of the SNAP study. The Coordinating Center will be monitoring the frequency and type of randomization errors and reporting them regularly to the Data Safety Monitoring Board.

Once a participant is randomized, no changes can be made to the data entered in the screening forms in the database; the database will not allow this. If you discover an error, contact the Coordinating Center and they will make the appropriate changes if needed.

7.5. ALLOWABLE TIME BETWEEN ACTIVITIES

The allowable time from the date of baseline physical measurements (normally completed at Screening Visit 2) to randomization is two months. Baseline weight will have to be repeated if outside of the 2 months window prior to randomization. The randomization checklist will not allow randomization to occur if the date on the Screening Physical Measurement Form is outside the 60-day window.

Occasionally, a participant may be re-screened. Re-screening should occur within 4 months of the Screening Visit 1. If the individual is re-screened and is within the four-month window between SV1 and randomization, the only item that needs to be re-done is the item in question. Consequently, the screening forms do not need to be repeated; only the item in question should be repeated and recorded on the appropriate screening form.

If the re-screening occurs outside of the 4 month window, all assessments and forms, beginning with the Pre-Screening Questionnaire through the Screening Visit 2 forms should be reviewed by staff and participants. Date of form completion must be updated on all forms, and all measurements, including blood collection, must be repeated. The Coordinating Center and Quality Control Committee will review these periodically to assure compliance with the study protocol.

7.6. PARTICIPANTS RANDMIZED BUT UNABLE TO BEGIN INTERVENTION

Randomization assignments will not be shared with participants prior to the first intervention meeting. If a participant attends any intervention groups associated with their cohort, they must remain associated with that cohort.

If a participant has not received their randomization assignment and calls the clinic prior to the start of the intervention meetings for their assigned cohort and is unable to attend the intervention meetings due to circumstances beyond their control (i.e., family change, car accident), they may be assigned a new cohort.

The following steps should be completed:

1. At time of notification by the participant:
    a. Complete Participant Status Form and Interim Medical Event Form (if necessary)
    b. E-mail Coordinating Center (lperdue@wfubmc.edu) the participant ID for removal from their associated cohort.
2. At time of association with new cohort:
    a. Re-complete and re-enter the Baseline Physical Measurement Form
    b. E-mail Coordinating Center (lperdue@wfubmc.edu) the participant ID to be associated with the new cohort.
3. If the participant will be beginning a new cohort, more than 4 months after original randomization date, the following forms and measurements must be repeated:
    a. From SV1, the following should be updated/recollected:

i. Baseline Blood Pressure Form
ii. Blood Collection (excluding DNA)
iii. CESD
iv. If MD consent would be required due to the new lab or blood pressure values, this should be treated as an alert and the physician must be notified.

b. From SV2, the following should be updated/recollected:
i. Exercise Habits
ii. Impedance
iii. Demographics
iv. Contact Information
v. Life Events
vi. Weight History of Friends and Family
vii. Perception of Program
viii. Eating Inventory
ix. TSRQ
x. PSS
xi. Health Behaviors
xii. Medication Use
xiii. Weight History
xiv. Smoking and Tobacco Behaviors
xv. Quality of Life
xvi. Physical Activity Neighborhood Environment
xvii. Weight Management Strategies
xviii. Self-Weighing
xix. Sedentary Behaviors
xx. Sleep Patterns
xxi. BLOCK
xxii. Armband
xxiii. Bod Pod

c. The AUDIT and EDA should be completed on paper versions to ensure that they are still eligible; however, no updates to the system will be made.

    i. If they are not eligible based on either the AUDIT or EDA, the Participant Status Form should be updated to indicate the participant is ineligible (select 'other' and specify reason as ineligibility. No assessment visits will be collected for these participants. These participants will remain a part of the SNAP study.

4. If an individual is not able to be re-contacted or unwilling to join SNAP after initially being randomized, no assessment visits will be collected. These participants will remain a part of the SNAP study.

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Retention and Follow-up Activities
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8. Follow-up and Retention Activities

8.1. RETENTION

Retention will be a challenge in SNAP, as it is in all clinical trials. Essential aspects of maximizing participation and promoting retention are: 1) carefully screening and assessing barriers to adherence and retention prior to randomization; 2) carefully monitoring adherence problems (which often predict retention problems), trying to identify these problems early before participants refuse further study contact; and 3) applying specific strategies to address these problems. The methods most likely to maximize retention will vary by individual and by clinic; therefore each SNAP clinic must design an appropriate retention plan for its participants. General retention strategies and those to be applied in special situations are described in the sections that follow.

Retention will be facilitated by general strategies that include: facilitating access to the clinic, maximizing availability of staff, providing participants tangible support and emotional support, and providing appropriate information to participants and primary care providers.

8.1.1. Promoting Retention

8.1.1.1. Access to the SNAP clinic

Ideally the clinic should be located in a convenient and attractive area containing, as appropriate, a waiting area with receptionist/secretary, rooms that provide privacy for data collection or counseling, and offices for the staff. Participants should be escorted by staff and introduced to personnel in each area used for study activities. Escorting should continue until the participant volunteers to travel from one area to another independently.

Convenience and cost of transportation are two factors that will affect study retention. Information about public transportation stops and parking garages should be included on location maps discussed above. Safety considerations should be addressed. Do not assume that participants know what is risky versus safe behavior related to parking and walking in the area around the study site. Escort services can be provided to parking or transportation areas. Concerns over travel during rush hour should be discussed with volunteers and used to guide the time visits are scheduled. SNAP clinics should develop a reimbursement policy for transportation expenses incurred by participants.

8.1.1.2. Availability of SNAP staff

It is critical that participants keep regularly scheduled appointments. Appointments serve many functions, one being monitoring of participants' progress. Study participants should be considered "customers". As volunteers, they cannot be expected to alter their schedules or to miss work as they would to utilize health care services. The hours that staff is available for SNAP visits should be as flexible as possible to accommodate participants' schedules. Visits may need to be scheduled outside normal clinic hours such as in the evening or on Saturdays.

8.1.1.3. Providing support to participants

Tangible support includes those items that enhance voluntary participation in SNAP and minimize potential barriers to retention, fulfilling endpoint goals. These items include:

- Honoraria, as permitted by individual site's IRB
- Reimbursement for parking
- Motivational/incentive items for achieving goals (items should have progressively greater value and require more effort to achieve)
- Referrals as needed for medical and mental health services.

Clinics may choose to use recruitment funds to reimburse participants for baby-sitting, eldercare, or transportation.

Participants feel supported when they perceive the study staff as caring and when they perceive themselves as full partners in the research process. The local clinic behavioral psychologist should lead efforts to provide participants with appropriate emotional support. In general the following actions increase participant perceptions of support:

- Helping the participant feel the study environment is safe and comfortable
- Creating a relationship in which goals are jointly established
- Expressing interest in important aspects of a participant's personal life
- Asking about the participant's personal reactions to aspects of SNAP
- Acknowledging what the participant has reported
- Creatively conducting study procedures (when possible) in a manner that best meets the specific needs of the participant and family members.

8.1.1.4. Providing feedback to participants

SNAP participants should regularly be sent results of data collected at study visits. In addition, participants are provided with education materials and information via the SNAP intervention website.

1. On entry to SNAP, all participants are provided with an education session on weight gain prevention, facilitated by a trained SNAP staff member.
2. Data related to blood pressure, lipid values, and diet that are obtained during scheduled study visits are provided to participants and their primary care providers, if requested. Standards of care or generally accepted guidelines for interpretation and/or interventions related to these parameters will also be provided.

8.1.2. Identifying and Resolving Retention Problems

Keys to success here include:

- Staff sensitivity to signs of problems, so they can be identified at the earliest possible moment, when intervention is easiest and most effective.
- Careful documentation of problems, allowing timely and complete communication among staff and with the participant to address the problem. Be mindful that all chart documentation should be conducted with the utmost professionalism, and all comments should be entered with the assumption that the individual participant may have access to all entries.
- Interventions designed to effectively resolve problems, especially efforts to maintain positive communication with participants who are having difficulty committing to a regular schedule of clinic visits.
- Active participation of the clinic behavioral psychologist in counseling case managers and meeting with participants.

Efforts to address possible adherence and retention problems should be initiated during screening. Any signs of potential difficulty identified below as “red flags” should be taken seriously and fully discussed with potential participants and among the staff. Special attention should be paid to: problems scheduling screening visits, frequent rescheduling, difficulty establishing or maintaining phone contact, participant reservations about study burden, past problems in modifying behavior, complaints about clinic procedures, or serious reservations about randomization. Two additional points should be emphasized to potential participants prior to randomization.

- First, the critical need for follow-up visits even in the absence of protocol adherence should be made clear at this point and on a continuing basis. We need to make clear our governing paradox:

  "We really, really want you to stick to your active lifestyle program, but even if you decide you don't want to (or can't) right now, we really, really want you to stay in touch. We know there will be times when you may slip from your weight gain prevention program. Therefore, remember how important it is for the success of our study that you come to scheduled clinic visits no matter how you are doing with your program."

- Second, given the critical importance of follow-up, the fact that study staff will make every effort (consistent with good sense and respect for the participant's privacy) to maintain contact during the trial should also be made clear. If the point is made early that we will try to maintain contact no matter what challenges are encountered, it should be easier to do, if required. In addition, making this point might stimulate some useful discussion. Potential participants should be told that their continuing participation is so important, that SNAP staff will do all they can to maintain contact, including calling, writing, and trying to reach an identified contact person. It is often helpful to discuss with potential participants the specific strategies they would most like you to enlist if contact dwindles at any time during the study. Enlisting the participant's involvement in deciding the types and extent of contact strategies to be used should retention become an issue (e.g., contact at work, contact spouse, and enlist PCP in reinforcing importance of study), all may be a powerful factor in the participant's response to and acceptance of these efforts should they be necessitated during the trial.

Strategies to optimize retention during the course of the study include:

- More frequent phone counseling (doesn't apply to control group)
- Face-to-face counseling with the group leader or team problem solving session (not for control group)
- Choose an alternate team member with strong participant rapport to contact the participant
- Consultation with behavioral psychologist or meeting between psychologist and participant
- Plan for intensified efforts for retention for major visits
- Conducting evaluation and motivational interviewing discussions with each participant at various phases of the study (e.g., year-end or other regular

intervals, achieving weight goal, etc.). These serial contacts may allow participants the opportunity to re-affirm the positive aspects of their involvement and to re-dedicate them to participating for an upcoming time interval.

- Absence from an intervention session, or inadequate use of the study intervention website could be recognized by staff with a phone call or e-mail to the participant and by sending a note with intervention materials and stating that they were missed.
- Invite them to attend the “same session” when it is held for another wave or to attend a “make up” session with the group leader.
- Optimize use of retention materials as response to a missed visit by mailing an incentive package (e.g., send a greeting card, calendar, or other material incentive).

8.1.2.1. Protocol adherence issues

Adherence problems (i.e., difficulty maintaining active participation in the intervention) should be noted, discussed among unblinded staff and investigators, and addressed as soon as possible, especially if the problem reflects a dramatic change from participants’ prior behavior. Such changes should be considered a clear indication that the potential for retention problems has markedly increased.

Commonly, early indicators of adherence problems include the emergence of the following red flags:

- Missed visits
- Forms not returned
- Difficulty reaching participants by phone or failure to return calls
- Rescheduling twice or more for a visit
- Weights not entered onto study intervention website.

If any of the above “red flags” are noted, the staff member should try to “validate” the participant’s feelings (e.g., “SNAP demands a lot from people, really more than many people can easily do. What part of the program is hardest for you right now? Perhaps I can help make it a little easier”). Similarly, the group leader is probably the best contact when participants need more attention or a repetition of information. Interventions to be considered in addressing identified red flags include:

- Provide opportunity to meet in any reasonable location or at any reasonable time which is convenient to participants
- Emphasize the positive; praise all successes
- Emphasize general health issues and benefits from participation and follow-up
- Work out a “modified treatment plan” to maintain some degree of adherence and avoid retention problems, such as by simplifying efforts until desired behaviors are re-established, then gradually increase intensity or complexity to protocol goal
- Work to create and maintain best possible group leader/participant match
- Encourage the Principal Investigator and other investigators to hold regular sessions designed to help participants see the “big picture” (i.e.; news about weight gain)
- Encourage Principal Investigator to call participant to offer encouragement
- Involve behavioral psychologist in retention efforts
- Maintain contact through newsletters and scheduled calls, mailed notes when indicated
- Offer extras, if acceptable to local IRBs, including birthday cards, incentives at each major visit, food for extended visits. These incentives should be used to underscore the bonding between staff and participants, not to replace that basic social connection
- Address all concerns about study interventions; involve the Principal Investigator, if appropriate
- Be prepared to explain how some questionnaires help achieve the study goal.

8.1.2.2. Participant behavioral issues

Sometimes participants say or do things that indicate they are dissatisfied or discouraged with certain aspects of their SNAP experience. Staff and investigators should be alert for these signs and address participant concerns as quickly and effectively as possible. Since SNAP relies primarily on a group intervention, comments of opposition or dissatisfaction may produce adverse effect on several participants if not addressed as soon as possible.

Participant behaviors which suggest emerging adherence problems and are considered red flags include:

- Complaints about clinic visits
- Impatience during clinic visits
- “Distance” during clinic visits
- Lack of concern about non-adherence to protocol
- Expressed desire to stop intervention
- Complaints about burden of study (time required and questionnaires)
- Remarks or humor (about study issues) that the staff considers inappropriate.

If any of the above “red flags” are noted, some proposed methods for dealing with retention are outlined below. For participants who feel ignored or taken for granted, the PI *may* be the best person to contact the participant. If the Principal Investigator does initiate contact, he/she should focus on emphasizing the importance of SNAP and of the participant to SNAP. Care should be taken to avoid “guilt tripping” participants or saying things that might be taken as manipulative. If the participant makes progress in adherence or attendance at appointments, the PI should re-contact the participant to express appreciation. Again, care is in order so as not to inadvertently come across as manipulative.

- Communicate caring and respect for participant in all actions.
- Acknowledge and discuss any concerns the participant communicates and address as appropriate. A follow-up phone call to discuss more fully or tell participant about what's being done to address concern can be helpful in facilitating adherence and minimizing risk of retention problems.
- Actively involve behavioral psychologist in efforts to resolve these problems.

Be open to discussing issues participant wants to talk about even when not related to SNAP.

8.1.2.3. Participant medical issues

Medical issues involving participants and their families may make it difficult for some participants to keep scheduled SNAP appointments. Red flags include hospitalization and/or prolonged illness.

All efforts should be made to encourage participants struggling with medical problems to remain active in SNAP. SNAP staff should consult with SNAP medical personnel about these issues, and, if appropriate, participants' medical providers should be contacted to follow up on the medical problems and/or to enlist participants' primary care physicians in emphasizing the importance of staying involved in SNAP.

- Talk to participant about how a health problem may affect participation
- Discuss benefits (if any) of SNAP participation in light of the health problem
- Offer flexible appointments, including home or hospital visits, when appropriate
- Inform intervention staff if participants are involved in the intervention so that the intervention can be adjusted to suit participants' medical needs (this discussion obviously needs to occur only among unblinded staff and investigators).

8.1.2.4. Participant psychosocial issues

Many SNAP participants will experience psychosocial crises (including family problems or transitions, major job changes, and other events) during the course of the study. These events may produce major problems for retention, especially among participants whose coping resources are limited.

Potential "red flags" include: major family crisis, illness, or transition; major job transition; or major psychosocial problems.

Interventions to address participant psychosocial problems may include:

- Take an open, inquiring attitude to find out what is going on for the participant
- Help participant find resources to cope with problems
- Encourage family support for participation in SNAP
- Help participant make contact with other participants for support and facilitation of adherence
- Offer encouragement and support as well as more frequent contact if participant wants that and time is available
- The Program Coordinator, Principal Investigator, Group Leader, and Behavioral Psychologist should collaborate with the participant to generate a plan for appropriate action.

Some participants might have psychosocial problems severe enough to interfere with active participation in the study. In this case SNAP staff should help the participant find help or treatment for the problems outside of the study. Staff should also help such participants modify their goals for study activity to maximize that activity consistent with limits imposed by the psychosocial problems. This modified involvement plan may promote a smooth return to full participation once the psychosocial or emotional issue is suitably resolved.

Participants who have psychological disorders (e.g., major depressive disorder, anxiety disorders, and substance abuse disorders) need treatment for these problems. The center psychologist should refer participants who may be suffering from such disorders for appropriate treatment. If the center does not have a psychologist on staff, other qualified staff should make the referral. All referrals should be documented.

8.1.2.5. Clinic transition issues

Over the course of the study, many things will change at SNAP centers, including staff, and even location. For some participants these changes may threaten continued involvement in the study. SNAP staff should pay close attention to how individual participants respond to clinic changes and offer the support each participant needs to make a comfortable transition.

“Red flags” may include:

- Reassignment to new group leader
- Reassignment to new clinic personnel for any procedure or test
- Less frequent interaction with staff
- Delays in timely progression of clinic visits.

Interventions to address clinic transition problems may include any of the following. For participants who seem to be bothered by some aspect of the clinic organization or procedures, the study coordinator might be the best person to contact the participant. The study coordinator is probably known to all participants, and should be able to communicate the “big picture” of the clinic.

- Let participant know in advance about changes at the clinic
- Introduce participant to new personnel
- Listen to and address any participant concerns

- Ensure privacy for all discussions, so participant feels secure comments are confidential.

8.2. OVERVIEW OF DATA COLLECTION SCHEDULE

Follow-up visits refer to the regular clinic visits scheduled for 4-months after randomization and annually thereafter.

8.3. MASKING OF DATA COLLECTION

Guidelines for masking the collection of data are needed in order to minimize the possibility that staff knowledge about a participant's group assignment will differentially affect measurements in the three groups. The study goal is to observe the basic masking principles in the collection of all study data including all measurements, procedures, forms, questionnaires, and interviews that are designed to help assess the impact of the intervention on weight, blood pressure, blood analyses, other physical measures analyses, diet, physical activity, fitness, and other health and psycho-social factors.

Clinics are encouraged to provide clinic settings and staffing patterns that will support the masking of data collection. However, this ideal is difficult to manage in practice, because participants are not masked to their intervention assignment and thus may reveal this information themselves, and also because resource limitations require that staff members perform multiple functions. Thus, the following principles are recommended for masking in SNAP:

1. The highest priority is given to the masking of staff who collect study outcomes data (i.e., physical measurements, etc.). Outcome assessment should be conducted by staff who are masked to treatment assignment.
2. Intervention tasks and measurements/interviews on a specific participant should be conducted by separate staff members wherever possible, e.g., Intervention staff should not collect post-randomization data from participants on whom they intervene.

To the extent that complete separation of intervention and data collection functions is not possible, staff must be carefully instructed about the need to use identical data collection protocols for both intervention groups as well as the control group.

In situations where a masked person is not available, the clinic coordinator will designate a qualified staff member with the least interaction with the participant to collect the data or perform the measurements.

8.4. SPECIAL REQUIREMENTS FOR CLINC VISITS

Depending on the visit, participants should be asked to report to the clinic for their follow-up visit with the following instructions:

1. Wear (or bring) loose-fitting exercise clothing and sneakers (for body size measures and blood drawing which will require removing clothes to the waist). Clinics should have a supply of hospital-type scrubs to use if a participant is not dressed appropriately.
2. Abstain from alcohol consumption within 12 hours of assessment.
3. Abstain from diuretic ingestion, including caffeine, within 4 hours of assessment.
4. No eating or drinking with 4 hours (4 month visit, 1 year visit, 3 year visit, 4 year visit) or 8 hours (2 year visit). Water is acceptable, except in the case of participants included in the BOD POD assessment, in which case, participants should abstain from drinking water for at least 2 hours prior to assessment.

Avoid moderate or vigorous physical activity or sauna within 8 hours of assessment.

8.4.1. Required Elements of the Follow-up Visits

The components of the follow-up visit are detailed in the Measurement Schedule, Table 1. The Forms Schedule is detailed in Table 2. These components are conducted in all SNAP clinics, unless indicated otherwise.

Table 1. Measurement Schedule

		Month				
Measure	Chapter location of description	4	12	24	36	48
Weight		X	X	X	X	X
Height		X	X	X	X	X
Waist circumference		X	X	X	X	X
Body composition with impedance		X	X	X	X	X
Body composition with BOD POD (UNC clinic only)		X	X	X	X	X
Armband		X	X	X	X	

		Month				
Measure	Chapter location of description	4	12	24	36	48
Blood Pressure		X	X	X	X	X
Fasting lipids, glucose, insulin				X		
DNA, serum, plasma				X		

Table 2. Forms Schedule

	Month				
Form	**4**	**12**	**24**	**36**	**48**
CES-D	S	S	S	S	S
Exercise Habits	S	S	S	S	S
Medical Event	S	S	S	S	S
Missed or Incomplete Visit	S	S	S	S	S
Demographics	P	P	P	P	P
Contact Information	P	P	P	P	P
Life Events	P	P	P	P	P
Weight History of Friends and Family	P	P	P	P	P
Perception of Program	P	P	P	P	P
Eating Inventory	P	P	P	P	P
TSRQ	P	P	P	P	P
PSS (Perceived Stress Scale)	P	P	P	P	P
Health Behaviors	P	P	P	P	P
Medication Use	P	P	P	P	P
Smoking and Tobacco Behaviors	P	P	P	P	P
Quality of Life	P	P	P	P	P

	Month				
Form	**4**	**12**	**24**	**36**	**48**
Intervention Follow-Up Questionnaire	P	P	P	P	P
EDA (Eating Disorder Assessment)	P	P	P	P	P
Weight Management Strategies	P	P	P	P	P
Self-Weighing	P	P	P	P	P
Sedentary Behaviors	P	P	P	P	P
Sleep Patterns	P	P	P	P	P
Physical Activity Neighborhood Environment	P	P	P	P	P
BLOCK (Food Frequency Questionnaire)	P		P		
As needed forms (can be completed at any visit or outside of a visit)					
Serious Adverse Event Form					
Intervention Modification					
Participant Status Form					
Interim Event					
Blood Specimen/Storage					
Individual Contact Form					

S = staff-administered; P = participant-administered; as needed

8.4.2. Participant Data Entry of Follow-up Visit Forms

Data entry for participant-entered forms is available for completion at the time of the window opening. Participants should login to the SNAP study website (www.snapstudy.phs.wfubmc.edu). Staff members are able to view the date the form was entered and the number of warnings associated with each participant data entered form. The number of warnings corresponds to the number of missing fields on the form. Staff should review participant data entered forms for completion prior to the participant coming into the clinic. Staff should direct participants to complete the forms either prior to coming into the clinic, or at the

clinic. If there are questions about completing the form, staff are available to address questions or concerns.

8.4.3. Suggested Order of Tasks

Depending on the visit, participants will come into the clinic at varied lengths of fasting. A snack should be provided for all participants after they have completed blood draw, impedance measurement, and BOD POD assessment. The suggested snack is juice and a muffin.

Blood pressure should be obtained prior to blood drawing for two reasons. First, phlebotomy can be stressful to some participants and stress can raise blood pressure, and second, the arm cuff could re-open the venipuncture site.

Physical measurements, including blood pressure, weight, height and waist measurement, and BOD POD assessment should be done after the participant has changed into clothing appropriate for these tests.

A suggested order of tasks for the follow-up visit is provided below. Depending on staff availability, this order can be modified as needed. Questionnaires can be administered at any time.

1. Completion of participant-entered questionnaires (prior to coming into the clinic)
2. Physical measurements (blood pressure, height, waist and weight measurements)
3. Body composition assessment (impedance and/or BOD POD)
4. Blood collection
5. Staff completed forms
6. Provide instructions for armband (see Chapter 9: Physical Activity and Sedentary Behaviors) and next visit.

8.4.4. Time Windows

A time window is the period of time surrounding the anniversary date during which time the follow-up visit *should be scheduled.* Windows around visit dates are needed for the scheduling system and to minimize within person variability due to seasonality. All follow-up visits (and windows) are based on the anniversary date of randomization.

The window for "*scheduling"* each visit is *two months* total (two weeks prior to the anniversary date and six weeks following). Multiple contacts may be necessary in order to complete all of the procedures and measurements required for a

specific clinic visit. Refer to the SNAP website > Reports > Operational > Randomized for the Visit Window Report.

8.4.4.1. Missed Data Collection Windows

Considerable attempts should be made to schedule a participant for a follow-up visit within the time window described above. It is suggested that at least five telephone calls should be made at different dates and times.

In general, missed data should be avoided and data collected out-of-window are better than no data. If a data collection window is missed, pursue collecting the data “out-of-window” up to the midpoint between the current visit and the next visit.

Once you pass the midpoint to the next annual visit, focus on scheduling the next visit. Data or procedures (or partials elements) that are not collected for a given visit should be recorded on the Missed or Incomplete Visit Form. If no data are collected, complete the Missed or Incomplete Visit Form.

8.4.4.2. Missed Visits

Visits and contacts should be defined by the closest target date. For example, a Month 12 visit should not be conducted after 18 months, since after 18 months the closest target date is the Month 24 visit. Instead, the clinic should focus on scheduling the Month 24 visit in the specified window.

When all attempts to schedule a participant for a visit within the timeframes designated above have failed, the Missed or Incomplete Visit Form should be completed. Note, all attempts at phone contact should be logged in the participant's chart. Normally, five phone calls should be attempted before a Missed Visit report is completed.

8.4.4.3. Out of Window Visits

Occasionally a participant may need to schedule his/her follow-up visit weeks or days outside of the specified window. This is acceptable. All data should be collected at these visits even though the visit falls outside the specified window. However, the completion of the visit will not contribute to within-window follow-up rates. No special form needs to be completed to designate this visit as an “out-of-window visit”. The database can determine this based on the actual visit date and the anniversary date.

For out-of-window visits, participant data entered forms will not be able to be entered by the participant via the SNAP website. Hard copies of the forms should be given to the participant and data entered by the staff.

8.4.5. Data Collection Priorities

The priorities for data collection should be kept in mind when establishing a pattern of visits for a "Follow-up Visit". However, scheduling of contacts for a Follow-up Visit will vary for each clinic based on the staffing, equipment availability, space, and “fasting” requirements. Scheduling patterns will also vary if the participant is unwilling to complete all of the visit requirements.

The following measures take precedence if the participant is resistant or unable to complete the entire follow-up visit:

1. Weight
2. Exercise Habits
3. Blood Pressure
4. Questionnaires (excluding BLOCK).

As the participant is willing, or able, the following should be completed:

1. Impedance
2. Waist Circumference
3. BLOCK
4. Armband
5. BOD POD.

8.4.5.1. Home Visits and “Off Protocol” Assessments

Ideally, the best option is for the participant to complete the assessment in the clinic. However, if the participant is not able to make it into the clinic within the specified window, the “next best” alternatives for obtaining a participant’s weight (primary study outcome) are listed below.

1. IDEAL SCENARIO: In-clinic visit within window
2. In-clinic visit within ±2 months of window
3. Weight verified from SmartScale (staff can send this scale to participant if he/she indicates willingness to use the scale)
4. Weight verified and sent from a clinic or doctor’s office
5. Self-report weight
6. No weight information

If an off-protocol weight measurement is used, participants should be instructed to take three measurements on one day. All three weights should be entered into the Physical Measurement Form.

8.4.5.2. Incomplete Data at the Follow-up Visit

Occasionally a participant will be unable to complete the entire set of components in a clinic visit. Possible reasons for this include participant refusal, equipment malfunction, and inadequate staffing. If a particular component is missed or incomplete and the participant is willing, every effort should be made to obtain these data/measurements even if they are collected outside the visit window. Remember, full data are best, and partial data are better than none at all. Incomplete visits should be reported on the Missed or Incomplete Visit Form.

8.4.5.3. Participants Who Have Relocated

There are occasions when randomized participants relocate to a geographic area that does not have a SNAP clinic. There are several approaches to arranging a follow-up visit or collecting data from these participants.

1. Collection of data by telephone. The highest priority should be given to the collection of the weight measurement (see Section 8.4.5.1) and study questionnaires (see Section 8.4.5). If entry via the study website for participant data entered forms is not possible, a packet of self administered forms can be mailed to the participant and followed by a telephone call to complete staff-administered questionnaires and to review any questions or discrepancies.
2. Explore the possibility of scheduling the visit when the participant will be returning to the area for a visit with relatives or friends.

Clinics may provide travel funds to the participant to facilitate the collection of the follow-up visit measurements and data. The visit may take place at the randomizing clinic or at a SNAP clinic that is closer to the new residence of the participant. Funding for these visits should be provided from the clinic budget.

8.5. REIMBURSEMENTS/INCENTIVES

Participants should be reimbursed for their time and travel at the completion of each follow-up visit. Reimbursements are not to be used as an incentive to attend intervention sessions. Instead, it should be stressed that the most critical element for attendance is the follow-up visit.

Throughout the course of the study, incentives can be used by the clinics to use with their own discretion to motivate participation and retention.

8.6. TERMINATION

Causes of termination may include: participant refusal, moved from area, or death. The Participant Status form is completed when one of these conditions has been met. Once this form is completed, the database will no longer query the clinic to schedule this participant.

Participants are not terminated by the study because they have experienced a serious or interim event (e.g., pregnancy). A participant may have their intervention modified by this event, and depending on the event, may attend clinic follow-up visits. The Intervention Modification Form should be completed for any participant who experiences a major medical event that affects his/her ability to continue receiving intervention. See discussion on intervention modification in Section 8.7 and Chapter 9, Intervention. Participants are not terminated because they are “lost”. See discussion on “lost-to-follow-up” (see Section 8.8).

8.7. INTERVENTION MODIFICATION

The biggest source of dropouts in prior studies with this age group is pregnancy. However, there may be other reasons for intervention to be modified. Depending on the reason for modification, attendance at clinic follow-up visits may not be required. SNAP staff should stay in touch with women during pregnancy and allow them to return to the intervention (and attend follow-up visits) at 6 months post-partum. Individuals in their first trimester can be seen for assessment visits, but they will not participate in the intervention. The Intervention Modification Form should be completed for any participant who has his/her intervention suspended.

8.8. KEEPING TRACK OF AND FINDING LOST PARTICIPANTS

For a long-term study such as SNAP, it is absolutely critical to maintain contact with every participant randomized. One of the most important overall indicators of the quality of our study will be our follow-up rates. Achieving outstanding follow-up rates starts with randomization. All randomized participants will be followed and contribute data to analyses, even if they do not attend or adhere to interventions. Be sure to obtain good contact information on all participants at baseline and update it at every visit.

A participant should not be declared as “lost-to-follow-up.” Occasionally, a participant who may be considered “lost” by a clinic, re-appears. For this reason, no participants will be terminated from SNAP for reasons of “lost-to-follow-up” during

the course of the study. At the end of the study, we will compute the numbers of persons for whom contact was lost during the study.

8.8.1. Strategies for Locating Participants

Below are suggestions and resources to aid your search for participants who are "lost-to-follow-up."

1. Identify one or more clinic staff who will be responsible to conduct search (program coordinator, retention, outcomes staff, other). This may vary across clinics.
2. Set up a process at your clinic to identify which participants are "lost to follow-up."
3. Suggestions for locating participants who are lost to follow-up.
    a. Gather information from all clinic staff that may have information on the participant (clinic notes, phone calls, etc). Be careful with this step when blinded staffs are involved.
    b. Tips for locating participants
        i. Each case is different and may require different actions
        ii. Look for clues in recent hospital records (online resources for locating medical facilities include The American Hospital Directory (www.ahd.com/) and Medical Facilities in the US and abroad (http://www.hospitalsoup.com/hospitalsearch.asp)
        iii. Contact the individuals listed on the Contact Information Form
        iv. Send mail requesting forwarding address
        v. Contact physician's office
        vi. Check real estate (i.e., has ownership changed?). Some states will list current address if ownership has not changed.
        vii. Check public records
        viii. Has there been a name change (e.g., was participant planning to marry or divorce)?
        ix. Keep track of all steps taken to locate the participant and record what happened (including names of people with whom you have spoken).

c. Resources on the World Wide Web:

i. www.ancestry.com/

This is a search by name and provides general information for a fee. See website for details.

ii. www.ancestry.com/search/rectype/vital/ssdi/main.htm

This is a Social Security Death Index (SSDI) search tool and is part of ancestry.com listed above. It is purportedly the most up to date and powerful SSDI available on the internet.

iii. http://ssdi.genealogy.rootsweb.com/cgi-bin/ssdi.cgi?o_xid=0031936443&o_lid=0031936443&o_xt=31936443

This is another SSDI search option and will provide DOB, date of death, last residence, and social security number for decedent free of charge.

iv. http://www.ancestorhunt.com/prison_search.htm

This is a prison inmate search. Scroll down to select state and begin search. Search will provide DOB, picture, location, sentence, etc. free of charge for some states. Other states may provide instructions for verifying that a person is incarcerated.

v. http://www.ancestorhunt.com/county-jail-inmates-search.htm#County%20Jail%20Inmates%20Search%20by%20State

(1) This is a county jail inmate search and is not provided by all counties.

(2) You may also call the county jail of interest and inquire by telephone.

vi. http://www.clearhq.org/boards.htm

This is a licensure, enforcement, and regulation search. If the participant's profession requires a professional license or certification regulated by the state, you can check the status for most states. This information is free of charge.

vii. http://www.whitepages.com/

E-White pages is a good tool for locating contact information for participants, proxies, and other contacts

viii. http://www.yellow.com/

E-Yellow pages are a good tool for locating physicians or other professionals/business owners.

ix. http://www.zabasearch.com/

Name search provides name, address, and date of birth free of charge

x. http://www.google.com/

A tool to locate people and medical facilities.

xi. Websites specifically for your city, county, or state.

(a) Check local medical center websites for physician directories.

(b) Check local newspaper websites for obituary information. Information, search options, and length of time available will vary by website.

(c) Check county website for real estate or geographic information system. This will allow you to search the database by property address.

4. Log actions taken to locate participants on a central SNAP tracking system.

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Physical Activity and Sedentary Behavior Assessment
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9. Physical Activity and Sedentary Behavior Assessment

9.1. INTRODUCTION

In the SNAP study physical activity will be assessed using the SenseWear Pro Armband™ (BodyMedia, Inc., Pittsburgh, PA) and the Paffenbarger (Exercise Habits) questionnaire. In addition, sedentary behavior will be assessed using the PACE Sedentary Behavior questionnaire.

9.2. SCHEDULE

The armband and Paffenbarger (Exercise Habits) questionnaire, and PACE Sedentary Behavior questionnaire will first be administered at the baseline testing period prior to randomization. The PACE Sedentary Behavior questionnaire will be administered online with other study questionnaires while the Paffenbarger (Exercise Habits) questionnaire will be administered at screening visit #1 (SV1). Both questionnaires will be again completed at 4, 12, 24, 36, and 48 months while participants will be asked to wear the armband at baseline, 4, 12 and 24 months.

The armband and the “Guidelines and Instructions for Wearing Armband” (Appendix A) will be given to the participant at SV1. Participants will wear the armband for a period of 7 days. All participants’ height, weight, age, handedness, smoking status and subject ID must be obtained prior to armband configuration. These measures will be obtained either at the orientation visit or at SV1. Height will be measured, without shoes, using a calibrated stadiometer. Weight will be measured, with the participant in street clothes and without shoes, using a calibrated digital scale. These measures will be recorded on an internal form which will provide the necessary information to configure the armband (See example in Appendix B). This form will not be used for data entry purposes. Official height and weight will be assessed at screening visit #2 (SV2).

Please note that data collected from the Paffenbarger (Exercise Habits) and PACE Sedentary Behavior questionnaires will not coincide with the same time period that the armband was worn. This administration order is preferred as application of the armband may influence participant actual and reported physical activity. During subsequent assessments (4, 12 and 24 months) administration of these questionnaires will occur at the scheduled assessment visit, which will also proceed the 7-day armband wear period.

Time windows for data collection are the same as for all other physical measures. Missed data should be avoided. At baseline, data from the armband and activity questionnaires must be collected prior to randomization and the first group meeting. If a data collection window is missed during the remainder of the study, the clinics

should pursue collecting the “out-of-window” data up to the mid-point between assessment periods.

9.3. EQUIPMENT AND SUPPLIES

- SenseWear Pro Armbands (each center will have approximately 40 units).
- AAA size batteries for the armband (replace each time a participant wears the unit).
- USB cable to allow for connection of the armband to the PC.
- Elastic straps for securing armband (small, medium, large sizes). Extra elastic straps should be on hand at all times to ensure proper fitting for all participants.
- At least one PC loaded with latest version of the SenseWear professional software designed to manage the configuration of the armband and downloading of the data.
- Self-addressed, postage-paid padded envelopes to allow participants to return the armband via mail.
- Paper internal tracking document to log armband distribution (tracking participant ID, armband ID, date armband was provided and returned) (See Appendix B).
- Study forms to track height, weight, age, handedness, and smoking status
- Paper armband tracking diary for participants to record times wearing armband unit (See Appendix B).
- Guidelines and Instructions for Wearing Armband Informational handout (See Appendix A) for the participants that includes instructions for use of the armband over the week of data collection (See Section 9.5.2. Instructions for Administration).
- Paffenbarger (Exercise Habits) questionnaire.
- Paper copies of the PACE Sedentary Behavior questionnaire if needed.

It is the responsibility of the 2 participating sites to ensure that the armbands are in good working order. Procedures for the quality checks and cleaning of the SenseWear Armband are provided in Section 9.5.4.

9.4. PERSONNEL

- One staff member who is fully trained in the use of the SenseWear armband device and software. This individual will serve as the center’s armband certification manager, thus being responsible for certifying and re-certifying

center research associates to perform armband distribution and data retrieval. Certification information can be found in section 9.5.5. Certification Procedures for Administration.

- One staff member who is fully trained in the administration of the Paffenbarger (Exercise Habits) questionnaire. This individual will serve as the center's certification manager for this questionnaire, thus being responsible for certifying and re-certifying center research associates to administer the Paffenbarger (Exercise Habits) questionnaire. Certification information can be found in section 9.6.3. Certification Procedures for Administration.
- The PACE Sedentary Behavior questionnaire is a self-administered questionnaire, therefore, certification for administering this questionnaire is not necessary. However, the research associate providing this questionnaire will be responsible for ensuring that the questionnaire is completed in full and that the questionnaire is administered in the order specified at each assessment period.

9.5. SENSEWEAR ARMBAND PROCEDURE

9.5.1. Introduction

The armband unit is the SenseWear Pro Armband™ (BodyMedia, Inc., Pittsburgh, PA). The armband unit is approximately the size of a standard iPod and is worn on right arm, between the shoulder and elbow. The armband evaluates daily energy expenditure based on an established algorithm (BodyMedia, Inc., Pittsburgh, PA). Specifically, it uses a collection of sensors to obtain information such as movement, heat flow, skin temperature, near-body temperature, and galvanic skin response in conjunction with body measurements including sex, age, height, and weight to calculate energy expenditure. Data gathered from the armband is processed with the SenseWear software to obtain a participant's daily calorie expenditure, physical activity duration, activity energy expenditure, daily steps, daily average MET level, and duration of daily use. In addition, the SenseWear professional software will allow for minute-by-minute analysis of physical activity data. In order to provide these data points in the output, the following basic procedures for the use of the armband must be followed.

As noted in section 9.2. (Schedule), the armband will be distributed at baseline during SV1 and repeated at 4, 12 and 24 months.

9.5.2. Instructions for Administration

At the assessment periods indicated above, the participant will be instructed to wear the armband unit for a period of 7 days. Prior to scheduling the participant for this monitoring session, the participant should be aware that the week in which they will wear the monitor should be a "typical" week with respect to their activity level. They should not be going on vacation or engaging in atypical levels of activity – either more sedentary than usual or more vigorous than usual. In addition, the participant's height, weight, age, handedness, smoking status and subject ID are required to configure the armband. NOTE: The height and weight used to program the armband should be determined on the same day the armband is administered. Age, handedness and smoking status data is determined at the orientation visit or SV1.

9.5.2.1. Pre-configuration procedures

a. Prior to configuration, verify that the AAA size battery inserted in the armband is new. A new battery should be placed in the unit for each participant. In addition, verify that time of day on the computer being used to configure the armband is correct, as the configuration procedure will use this to time-stamp the armband.

b. Document the armband intended for use on the internal electronic armband tracking and distribution form (See Appendix B). Record the armband serial number and internal tracking number on the log with the participant's ID, acrostic, and current date.

c. Prepare the paper armband diary and Guidelines for Wearing the Armband forms (See Appendices A & B).

- On the armband tracking diary, record the participant's ID (or acrostic) and the study assessment period. Fill in the dates for wearing the armband. Note the time when the armband is initially placed on the participant's arm.
- On the Guidelines and Instructions for Home Use form note date to start wearing armband, last day to wear armband (7^{th} day following current day), and date to return armband.

9.5.2.2. Configuration procedures

The armband should be configured using the SenseWear software and procedures provided with the unit by BodyMedia, Inc. The user manual for the armband is provided with the armband and software and can be downloaded from the website (www.bodymedia.com). Once the

SenseWear software has been installed onto the PC, the armband can be configured. (Note: The configuration procedure should be performed as close to the time that the armband will be given to the participant as possible – i.e., within two hours.) The configurations steps are outlined below.

a. Attach the USB cable to an available USB port on the PC. Plug the opposite end of the USB cable into the armband. There should be a audible “beep” when the armband connects to the USB cable.

b. Launch the SenseWear software (icon on desktop). If the software is unable to establish communication with the armband, remove the armband from the cable and attempt connection again.

c. Click “Configure Armband” at the top of the screen.

d. Click “Retrieve Configuration.”

e. Click “Subject Info” and enter appropriate information for the study participant using the internal armband initialization form (See Appendix B).

- Subject: use the following naming convention: SWA SNAP PID #_Assessment visit. Therefore, for subject #15 at the 4 month assessment the following should be used: SWA SNAP PID 15_4. (Note: The baseline assessment will be denoted by 0)
- Date of Birth
- Height (enter height in centimeters)
- Weight (enter weight in pounds)
- Sex
- Handedness
- Smoking status

f. Select Armband Parameters tab.

g. Confirm that battery life reads 100%.

h. If the date and time are not in sync with the computer clock, click “Apply” at the bottom of the window.

i. Click OK.

j. Detach armband from cable once the configuration is complete.

9.5.2.3 Outfitting participant with armband

a. Put the appropriately sized elastic strap on the armband unit (The small straps accommodate an arm diameter of 6-12.5”, the medium fits 8-16", and the large fits 13-23.5”.)

b. Place armband on participant’s right arm with the unit upright (with the time stamp button located at the top of the armband) and positioned midway between the shoulder and elbow against the triceps with the sensors on the back of the unit touching the participant’s skin.

c. The elastic band should be secured so that the armband does not move but it is not so tight that it is uncomfortable. Ensure that the sensors maintain contact with the skin at all times.

d. Document time that the armband was applied on the participant’s armband tracking diary (See Appendix B).

e. When the monitor makes secure contact with the participant’s body, it will automatically perform a “turning on” sequence. **This may take up to five minutes.** At this point, they will hear a beep and feel a slight vibration.

f. Provide participant with the Guidelines and Instructions for Wearing Armband form (see Appendix A) and review instructions with the participant. Research associates that will be outfitting participants with armbands should be aware of the following points regarding wearing procedures.

- The participant will wear the armband during all waking hours for a period of seven complete and consecutive days.
- When the armband is returned, a data overview will be performed immediately for compliance. If the data overview shows that participant did not have at least 4 valid wear days (≥8 hours/day), they will be asked to wear the armband again or be deemed ineligible for the study. During subsequent assessments (4, 12 and 24 months) if the data overview shows that participant did not have at least 4 valid wear days (≥8 hours/day), they will be asked to wear the armband again.
- The participant cannot turn off the armband. Data will be continuously collected, and can only be stopped by removing the battery, loss of battery power, or by downloading the data to the study PC.

- Removing the battery or if the battery power runs out will result in the loss of all the data collected since configuration of the unit. The armband will need to be reconfigured before data collection can resume. As noted above, the battery in the armband should be replaced prior to each time the armband is configured and distributed to a new participant.
- The participant will be instructed to immediately return the armband and tracking diary to the investigators after the one week period. For example, if the participant begins wearing the unit at 1:00 p.m. on Tuesday, the monitor should be returned after wearing the unit for a full day on the following Tuesday. That would provide 7 complete days of data collection. Since a new battery lasts approximately 2 weeks, the unit should be returned to the clinic in an expedited manner to prevent the battery power from running out and the resultant loss of data.
- Participants will be given three options for returning the armband. These options in the order of preference include: 1) return the armband in person at the end of the 7 day period; 2) return the armband at SV2 (occurs 8-14 days following SV1); 3) return the armband in a postage paid, padded envelope. **It is critical that the armband be returned within a 2-week window to ensure battery life is maintained.**

g. Provide the participant with the armband tracking diary (See Appendix B) and review logging instructions. Research associates outfitting participants with armbands should be aware of the following points regarding use of the armband tracking diary.

- The participant will be provided with an armband tracking diary to record their wearing of the SenseWear armband. The primary purpose of this diary is for the recording of any unusual conditions that may have occurred during the week resulting in not wearing the armband. Examples would include forgetting to wear the unit after changing clothes or not putting it on in the morning. It may be suggested that the armband be placed in a prominent location when they take it off so they will see it when they first wake-up in the morning. This may be a night stand next to their bed, in the bathroom, or next to their wallet or pocketbook.

- The diary can serve as a reminder to wear the armband by having the participant record the time they started wearing it and when they took the armband off.
- Prior to the participant leaving the building with the armband, be sure to record the exact time and date that the armband was provided to the participant on their armband tracking diary.

9.5.2.4 Data retrieval and file saving

a. Immediately upon return, the certified research associate should log the return of the armband on the paper internal armband tracking file and distribution form.

   Data will be retrieved according to the following procedures:

   - Attach USB cable to available port on a PC that has been loaded with the SenseWear professional software.
   - Attach the opposite end of the USB cable to the armband
   - Double click the armband icon on the desktop to open the SenseWear professional software
   - Click Via USB cable
   - Click Retrieve

b. Data will be saved to the designated SNAP folder for “raw” armband data (local server not personal desktop). For example: J:\Tate_group\SNAP\Assessments\Cohort ____Assessment\Armband data

   - When saving data, be sure that the naming convention match the initial naming convention used to initialize the armband (e.g. – SWA SNAP PID 15_4)
   - Once armband data has been saved, verify that the participant met the wear time criteria using the following procedures.
   - Under settings → applications preferences → reports, uncheck the box next to the line stating “when generating a report for multiple days, ignore partial days”. Then click “apply” then “OK”.
   - On the data summary display page, click the Generate Report button at the bottom of the window.

- Verify the armband has been worn for at least 4 days for at least 8-10 hours per day. If this is not the case, the participant must wear the armband for an additional week.

c. Detach armband from USB cable and discard battery.

d. Collect the armband tracking diary from the participant. File diary in designated site location.

9.5.3. Exporting the Armband Data and Printing Participant Reports

1. In order for the armband data to be analyzed, it must be exported, using the SenseWear Professional software. The following are instructions for exporting the data and printing the appropriate participant report (Note: data should be exported weekly):
   a. Plug the Professional software toggle into the USB port of the computer.
   b. Open the participant data file. Click on “My Data Properties” at the bottom of the main page. Click the “Activity Levels” tab.
   c. Note: It is <u>extremely</u> important that the information on this tab be entered correctly.
      a. Choose the number 4 from the drop down menu which asks about the # of activity levels desired.
      b. The following labels and upper MET values should be used:
         i. 1) Sedentary – 1.5
         ii. 2) Light – 3.0
         iii. 3) Moderate – 6.0
         iv. 4) Vigorous - ∞
      c. Click Save.
2. Generate and print a participant report using the following instructions:
   a. Once activity levels have been saved, on the data summary display page, click “Generate Report” at the bottom of the window.
   b. A new pdf window will appear. On the right hand side of the report, ensure that MET levels are displayed correctly (ie – sedentary: up to 1.5 METS).
   c. Print report and close pdf window.

d. File paper report in designated site location.

3. Export the data

   a. At the bottom of the data summary display screen click “Export”

   b. A window will appear. Specify the location (designated SNAP folder for “exported” armband data) on the local server to where you wish to save the data. (DO NOT CLICK SAVE YET)

   c. Check to make sure the file name is correct. (DO NOT CLICK SAVE YET)

   d. Copy the file name as it will disappear after the following step.

   e. Under file type, choose CSV data files from the drop down menu.

   f. Paste the file name back into the “file name” box and click “Save”. A window will appear indicating that export was completed successfully. Click OK.

   g. This will save the data as a csv file in the correct location. Now go to that location in which the file was saved, open the file, and check to be sure that there is data in all columns. As a quality check, specifically make sure that columns A-L do not contain all zeros. (NOTE: Step counts in column K may have some zeros if no steps were taken during this time, but it should not be all zeros). If there are all zeros in any column, contact the armband certification manager at your site immediately since it is likely that there is a problem with the armband.

   h. Once this has been completed, add your initials next to the participant ID on the armband tracking and distribution form to indicate that the export has been completed and there were no problems within the csv file. Note any problems in the “Comments” column.

   i. Following the completion of all assessments for a particular cohort these csv files will be sent to Providence for further analysis.

9.5.4. Quality Checks and Equipment Maintenance

1. Quality checks should include the following:

   a. Development of an orderly and systematic method of storing data in the SNAP data folder/website with immediate back-up of data to a floppy disk, CD, or ZIP drive for security.

   b. Development and maintenance of a regular schedule for sending data to Providence for processing.

c. Development of a procedure to verify that the armband is collecting reasonable data (See Section 9.5.3.3.g). In the event of faulty data, the procedure will have to be repeated within the next week or two.

d. Development of a system to download and examine the data in a timely fashion (See Section 9.5.3.1).

2. Equipment maintenance

a. Upon return of the armbands, certified research associates should remove the elastic strap and clean on gentle cycle in washing machine or with mild soap and water.

b. The armband sensors and back of the armband should be wiped with an alcohol pad.

c. When not in use, the armbands should be stored properly in a secure location.

9.5.5. Certification Procedures for Administration

1. At each SNAP study center, one staff member will be designated as the center's armband certification manager, thus being responsible for certifying and re-certifying center staff members to perform armband initialization, distribution, and data retrieval. See Appendix C for the certification checklist.
2. The certification manager will administer initial certification prior to the launch of the SNAP (or upon hire of new staff) study for select research associates.
3. Re-certification will be scheduled on an as needed basis.
4. Certification will be performed in a mock/role play setting. Research associates must be able to demonstrate proficiency with armband initialization, distribution and data retrieval.
5. The certification and recertification checklist will be completed and signed by the certification manager.

9.6. PAFFENBARGER (EXERCISE HABITS) QUESTIONNAIRE

9.6.1. Introduction

The Paffenbarger (Exercise Habits) questionnaire (See Appendix D) is a valid and reliable tool that will be used to assess leisure-time physical activity for the participants enrolled in the SNAP study. In addition, this questionnaire allows for data to be analyzed by total energy expenditure, or by subcategories of light,

moderate, and vigorous forms of leisure-time physical activity. In the SNAP study the Paffenbarger (Exercise Habits) questionnaire will be interviewer-administered.

As noted in section 9.2. (Schedule)), the Paffenbarger (Exercise Habits) questionnaire will be administered at baseline during SV1 and repeated at 4, 12, 24, 36, and 48 months.

9.6.2. Instructions for Administration

1. Introduce this questionnaire by telling the participant that you are now going to ask some questions about the exercise they have done in the past week. (It is recommended that participants be provided a calendar to aid with activity recall)
2. There are 6 separate questions. Read the questions to the participant as written.
    - **Question #1:** Was there anything about the past week that made exercising especially different for you in terms of extended illness, injury, or vacation?
        - Use the “past week” unless the subject reports an unusual activity pattern during this period due to extended illness, injury that prohibited activity or vacation. If these situations did not occur, the subject is to respond “NO” and use the previous 7 day period when reporting their physical activity.
        - If the subject responds as “YES”, the most recent “typical” week that occurred within the past 30 days should be used to report activity.
    - **Question #2 (Average number of flights of stairs climbed)**
        - Emphasize walking UP when asking about use of stairs, as walking DOWN stairs is not counted (may include at home and at work).
        - If the answer seems questionable (e.g. > 10 flights/day), verify that the participant is only counting stairs climbed up and (averaged) per day over the past seven days.
    - **Question #3 (Average time spent brisk walking)**
        - Emphasize average number of minutes walked indoors or outdoors each day over the past seven days for both exercise and transportation. To be included, bouts must be greater than 10 continuous minutes in duration.

- Emphasize that walking for exercise and transportation are both included here.
- 3a: “days in the past week” is permitted to range from 0-7. If no walking met the criteria described here, enter “0”
- 3b: The “total minutes per week” can be computed by multiplying “days in the past week” by “minutes per day.” Please query the subject if the computed “total minutes per week” is > 300 minutes.

- **Question #4 (Sports Fitness and Recreational Activities)**
  - Activities will be entered on the data form and in the data entry system as the specified activity. Activity intensity codes will be derived from database of activities stored in the data entry system. Therefore, the interview will not need to determine intensity codes.
  - Some activities such as bowling, tennis, golf, swimming, etc. will need more probing to allow for accurate data entry. The documentation of these activities needs to follow standardized procedures as described in the Appendix C.
  - Emphasize time physically active**. Do not record walking reported in question #3 again.**
  - Emphasize that occupational activities and household activities are not to be included here as they are not considered sport, fitness, or recreational activity.
  - Emphasize that you are interested in the number of minutes each time, not total minutes for this activity.
  - Write each activity in the blanks under Sports, Fitness, Recreation, and then go back and ask “how many times last week” (response can range from 1-7), and “average time per day”. Query the subject if “average time per day” was > 120 minutes (2 hours). Emphasize that the time should only include the time actually active in the specified activity.
  - If there are more than four activities, record them on the back of the form.
  - If an activity is recorded and the activity does not exist in the database, SNAP staff exercise physiologists will communicate and determine appropriate activity documentation for data entry.
- **Question #5 (Typical week?)**

- The subject is to compare the week used to answer questions #2, 3, and 4 with what they consider to be a typical week.

- **Question #6 (General activity level)**
  - This question does not specifically refer to the "past week." It refers to whether in general, someone regularly engages in physical activity long enough to work up a sweat, get the heart thumping or get out of breath. NOTE: the activities that produce these physiological symptoms do not have to be reported in questions 2-4. .
  - Document the average number of times per week that the person engages in an activity that works up a sweat and gets the heart thumping.
  - If the person exercises two times in one day (e.g. – elliptical for 30 minutes and walking for 20 minutes), this only counts as 1 day/wk. "Days per week" can range from 1-7.

9.6.3. Certification Procedures for Administration

1. At each SNAP study center, one staff member will be designated as the center's Paffenbarger (Exercise Habits) certification manager, thus being responsible for certifying and re-certifying center staff members to perform the Paffenbarger (Exercise Habits) questionnaire interview. See Appendix E for the certification checklist.
2. The certification manager will administer initial certification prior to the launch of the SNAP (or upon hire of new staff) study for select research associates.
3. Re-certification will be scheduled on an as needed basis.
4. Certification will be performed in a mock/role play setting. Research associates must be able to demonstrate proficiency with completing the interview and the required data conversions.
5. The certification and recertification checklist will be completed and signed by the certification manager.

9.7. PACE SENDENTARY BEHAVIOR QUESTIONNAIRE

9.7.1. Introduction

The PACE Sedentary behavior questionnaire (See Appendix F for example) is a valid and reliable tool that will be used to assess time spent in sedentary behaviors among participants enrolled in the SNAP study.

9.7.2. Instructions for Administration

The PACE Sedentary behavior questionnaire is a self-report measure. It will be administered online at all major assessment visits, described above. This questionnaire will measure time spent watching TV, playing computer or video games, listening to music, talking on the phone, doing paperwork/computer work, reading, playing music, doing arts and crafts, and sitting time during driving or transportation. The questionnaire uses an eight point scale with responses ranging from “none” to “6 hours or more”. Participants in the SNAP study will be asked to report time spent in these activities on a typical weekday and weekend day.

Appendix 9.A - Guidelines and Instructions for Wearing Armband

Introduction

You have volunteered to participate in a study in which you will be asked to wear a small device that will be attached to your arm. You will wear this device during all your waking hours for 7 full days, starting today. This device will allow the researchers associated with this study to learn more about individual physical activity patterns and the relationship to other measures of interest in this study.

When should you wear the armband?

- You will wear the BODYMEDIA Armband for seven consecutive days.

Start Wearing the armband:	Date:	_____
Stop Wearing the armband	Date:	_____
Return the armband to investigators	Date:	_____

- Place the armband on your body when you get out of bed in the morning and take it off before going to sleep at night.
- The armband must be removed before showering, bathing, or swimming.
- Wear the device while you exercise.
- The following explains special instructions for the device. Please read over the instructions before you begin your 7-day collection period.
- Please call our office at **XXX-XXX-XXXX** if you have any questions during this time period.

Proper placement of the armband

- Place the armband upright (smaller button on top) on your ***right arm*** between your shoulder and elbow with the sensors against your triceps (back of your arm).
- Secure the strap tight enough so the sensors remain in contact with your arm, however avoid pinching your skin.

- Place the unit in the same location for each day. The researcher will demonstrate the correct positioning of the device at the time you are instructed.
- Refrain from using any body lotion or other products on the spot where the sensors make contact with your arm.
- Put the armband on when you get up in the morning and remove it before you go to bed at night.
- The armband is not waterproof; thus, remove before showering, bathing or swimming. Sweating and wearing the armband in the rain should not cause any problems.
- There is no on/off button on the armband. When the monitor makes secure contact with your body, it will automatically perform a "turning on" sequence. **This may take up to five minutes.** At this point, you will hear a beep and feel a slight vibration.
- YOU DO NOT NEED TO PRESS ANY BUTTONS TO INITIATE DATA COLLECTION. When you remove the armband it will turn off and also beep indicating that it has lost contact with your arm.

Precautions for use and care of the device

- The device is a sensitive piece of equipment and should not be dropped or submerged in water. It cannot be worn in a shower or in a pool. If you wear it in the rain, a jacket or other clothing should protect it.
- The device is expensive and care should be taken not to misplace the device at times when you are changing clothes away from home. At bedtime, the device should be stored in a safe location where it will not be damaged by water or falling to the floor.
- If you hear beeping and feel frequent vibrations during the day, try tightening the elastic strap slightly to ensure the armband remains in contact with your arm.
- Do not open the battery compartment at any time. You will not need to replace the battery during the monitoring period (The battery lifetime should be approximately 2 weeks). However, it is critical that you return the armband to the research center immediately following your 7-day period to ensure all data will be saved.
- If you are not sure that the armband is collecting data, with the armband on your arm-press the button on the front of the armband, if you hear a beep followed by a slight vibration, the armband is collecting data. If this does not occur, consult the instructions listed below.

- On the front of the armband you will notice 2 lights- these are battery status and system/data memory indicators. To retrieve status indication, depress the button located on the front of the armband. Consult the following guide to understand what the 3 indicator lights represent:

  GREEN: battery status and memory are **okay**

  AMBER: **caution**, either the battery is low or the memory is approaching capacity (depending on which light is amber). You must immediately replace the battery (call XXX-XXX-XXXX immediately for directions).

  RED: **Data is NOT being collected**. Please call our office **(XXX-XXX-XXXX).**

Return of the device

- The device and diary should be returned to the investigators at the end of your 7 day wear period.
- Your instructions will be to either return it in person to the investigator or place it in the pre-postage paid and padded envelope that the investigators provided to you on the day that you were instructed on wearing the device.
- You will not be able to turn the device off.
- Since the life of the battery is short, please return the device promptly following the seventh day.

Questions about the device

If you have any questions about the device after you have returned home, you may call the investigator at **XXX-XXX-XXXX.**

APPENDIX 9.B - ARMBAND CONFIGURATION AND TRACKING FORMS

- Armband Initialization Form (B1)
- Internal Armband and Tracking Distribution Form (B2)
- Armband Tracking Diary (B3)

Appendix 9.B1 - Armband Initialization Form

Subject Number: _____ Date: ___/___/___

Acrostic: _____

Assessment Period: ___ Baseline ___ 4 Months

___ 12 Months ___ 24 Months

Height: _____ cm (measure to the nearest 0.1 cm)

Weight: _____ lbs (read from digital scale to the nearest 0.1 pounds)

Date of Birth: _____/_____/_____

Age: _____ years

Gender: _____ Male

_____ Female

Handedness: _____ Right Handed

_____ Left Handed

Smoking Status: _____ Non-smoker

_____ Smoker

Appendix 9.B2 - Internal Armband and Tracking Distribution Form

Cohort # ___________

Study ID	Acrostic	Assessment Period	Internal Armband #	Armband Serial #	Date Provided	Date Returned	Export Completed	Comments
		Baseline						
		Baseline						
		Baseline						
		Baseline						
		Baseline						
		Baseline						
		Baseline						
		Baseline						
		Baseline						
		Baseline						
		Baseline						
		Baseline						
		Baseline						
		Baseline						
		Baseline						
		Baseline						
		Baseline						
		Baseline						
		Baseline						

Appendix 9.B3 - Armband Tracking Diary

ID/Acrostic: _____

Test Period: ___ 0 Months ___ 4 Months ___ 12 Months ___ 24 Months

How to use the armband diary

- The diary will be used to keep track of when the armband is worn.
- On this form, please record the date and the time of day that you put the monitor on and when it is removed. Please do this for each of the seven days you wear the armband.
- Typically, once you put it on in the morning, you will not need to take it off except for bathing, swimming, or other water exercises. Removing it for only a few minutes while you bath or change clothes does not need to be recorded in the diary.
- If you forget to put it on for a day or part of a day, please note this on the armband diary. Examples of these recordings would be not putting it on until afternoon, or not transferring it to a new set of clothes when you change clothes.

Please call XXX-XXX-XXXX if you have any questions regarding the wearing of the armband or the completion of this form.

Date	Time Put "ON"	Time Taken "OFF"	Did you take the armband off at any other time of the day? (Please circle your response)		Comments
	____:____ AM / PM	____:____ AM / PM	No	Yes	
	____:____ AM / PM	____:____ AM / PM	No	Yes	
	____:____ AM / PM	____:____ AM / PM	No	Yes	
	____:____ AM / PM	____:____ AM / PM	No	Yes	
	____:____ AM / PM	____:____ AM / PM	No	Yes	
	____:____ AM / PM	____:____ AM / PM	No	Yes	
	____:____ AM / PM	____:____ AM / PM	No	Yes	

Appendix 9.C – SenseWear Armband Certification/Recertification Checklist

Technician Name: _____ Staff ID: _____

Prior to administration of armband:

1. ☐ Demonstrates sufficient knowledge of Armband rationale.
2. ☐ Confirms with participant that the week in which they will wear the monitor should be a "typical" week with respect to their activity level. (i.e. They should not be going on vacation or engaging in atypical levels of activity – either more sedentary than usual or more vigorous than usual).
3. ☐ Obtains the participant's height, weight, age, handedness, smoking status from the participants file. (NOTE: the height and weight used to program the armband should be determined on the same day the armband is administered).
4. ☐ Assembles proper materials.
5. ☐ Documents the armband intended for use on the internal electronic armband tracking and distribution form.
6. ☐ Prepare the paper armband diary and Guidelines for Wearing the Armband forms.
7. ☐ Configures armband correctly following the procedures outlined in the physical activity section of the MOP.

Observes the following procedural steps during armband administration:

1. ☐ Selects appropriate sized elastic strap for attaching armband.
2. ☐ Describes and assists in proper positioning of armband.
3. ☐ Describes activation/deactivation sequence and potential trouble-shooting tips for wearing armband.
4. ☐ Instructs correct procedures for wearing armband.
5. ☐ Asks participant to document use of armband.
6. ☐ Schedules date and mode of armband return.

Comments: _____

_____

_____

_____

Observer: _____ Date: _____

Observed: _____

APPENDIX 9.D - PAFFENBARGER (EXERCISE HABITS) QUESTIONNAIRE & ACTIVITY CLASSIFICATION GUIDELINES

- Paffenbarger (Exercise Habits) Questionnaire (D1)
- Activity Classification Guidelines (D2)

APPENDIX 9.D1 - Paffenbarger (Exercise Habits) Questionnaire

Office Use Only			
Subject ID #:		**Assessment #:**	

EXERCISE HABITS

1. Was there anything about the past week that made exercising especially different for you in terms of extended illness, injury, or vacation?

☐ Yes If "YES", please complete this questionnaire about the previous week.
☐ No If "NO", please complete this questionnaire about this past week.

2. First, we are interested in the number of flights of stairs you climbed on average **EACH DAY** in this past week. We only want to know the number of flights you climb going *UP* - not down.
When answering this question, One Flight of Stairs = 10 steps if you know the number of steps.

☐☐ Flights per day

3. Next, we want to know how many city blocks or their equivalent you walked on average **EACH DAY** in this past week. We are only interested in walking done out of doors and walking done indoors for the sole purpose of exercise. We do not want walking done around the house or at work.
When answering this question, consider that 12 city blocks = 1 mile. If you do not know the blocks or distance, 20 minutes of walking = 12 city blocks.

☐☐ Blocks per day

4. Were there any sports, fitness, or recreational activities in which you participated during the past week? We are interested only in time that you were physically active. For example, if you lift weights only include the time that you actually are lifting the weights, not the time you spend moving from machine to machine.
***Note: All walking should only be included in Question 3**
***Note: Household activities such as cleaning and laundry are not to be included here as they are not considered to be a sport, fitness, or recreational activity.**

Sport, Fitness, or Recreation	**Times per Week**	**Average Time per Episode**	***Office Use Only (Code)***
a.	☐☐	☐☐☐ Minutes	☐
b.	☐☐	☐☐☐ Minutes	☐
c.	☐☐	☐☐☐ Minutes	☐
d.	☐☐	☐☐☐ Minutes	☐

5. At least once per week, do you engage in regular activity akin to brisk walking, jogging, bicycling, etc. long enough to work up a sweat, get your heart thumping, or get out of breath?

☐	Yes	If yes:	Activity:		☐☐	times per week
☐	No		Activity:		☐☐	times per week
			Activity:		☐☐	times per week

APPENDIX 9.D2 - Activity Classification Guidelines for Documenting Sports/Recreation Activity

The following guidelines are to be used for classifying sport and recreational activities on the Paffenbarger (Exercise Habits) questionnaire (question #4)

1. Aerobics- Ask the participant to specify the type of aerobic class/video performed. Document the response from the choices below
   a. Aerobic general- includes aerobic or walking videos, Wii aerobic activity, etc.
   b. High Impact aerobics
   c. Kickboxing
   d. Circuit training (including aerobics)
   e. Low impact aerobics
   f. Step aerobics
   g. Water aerobics
2. Bicycling- Ask the participant to distinguish the specific type of bicycling selecting from the choices below and document accordingly.
   a. Stationary (includes Spinning)
   b. General outdoor cycling
   c. Mountain biking or BMX
3. For game activities, such as Basketball, Football, Hockey, and Soccer, determine whether it was a game or non-game situation and how many minutes physically active and document accordingly.
4. Bowling – 1. Ask number of games. Score 1 game = 10 minutes active. 2. If number of games is not known, amount of time spent playing (1 hour of time spent playing = 10 minutes active).
5. Canoeing – Ask specifically how much time active (using arms to paddle).
6. Fishing – Ask specifically how much time was spent walking. Document the number of minutes spent walking, otherwise do not document at all.
7. Golf – Ask specifically whether walked or used cart, and number of holes played.

   Use the following coding system to score minutes active:
   a. 18 holes cart = 30 minutes
   b. 9 holes cart = 15 minutes

c. 18 holes walking = 150 minutes

d. 9 holes walking = 75 minutes

e. some cart and some walking = document separately as performed

f. If par 3 golf, code 18 holes par 3 as 9 holes above and code 9 holes par 3 as 4.5 (half the # minutes for 9) holes above.

8. Hiking

   a. Be careful not to code "hiking" twice. Document under sports (question #4) – not under walking (question #3).

   b. Document number of miles if known. Then convert to minutes (1 mile = 25 minutes)

9. Hunting – Ask specifically how much time was spent walking. Document the number of minutes spent walking, otherwise do not document at all.

10. Running or Jogging – Specify approximate pace. If running or jogging is given in miles only, document 1 mile = 10 minutes active.

11. Miniature Golf – Document 1 hour reported = 10 minutes active.

12. Weight Training - Ask specifically how much time was spent weightlifting versus waiting and resting in between machines. Specify if the weight training was light-moderate or vigorous effort; document accordingly

13. Rafting or Rowing – Ask specifically how much time active (using arms).

14. Skiing – Specify if skiing was downhill or cross country. If downhill, ask specifically how much time was spent actually down the slopes (do not count chair lift time).

15. Swimming – Document swimming activity using the following guidelines and document accordingly.

    a. Ask if lap swimming or fun type at pool/ocean.

    b. If lap swimming specify intensity light-moderate or vigorous effort.

    c. Document treading water specifically.

    d. To derive time spent active in lap swimming, ask subject about minutes spent swimming vs. resting.

    e. For fun type/unspecified swimming, convert hours to minutes and divide by 3 to get number minutes to score, e.g. 1 hour = 20 minutes active.

16. Tennis - Specify singles or doubles. Document actual time spent moving.

17. Treadmill – Document treadmill walking and running using the following guidelines and document accordingly.
    a. Treadmill walking should be included under question #3, not as part of walking in question #2
    b. For treadmill walking specify intensity light-moderate or vigorous effort and document accordingly.
18. Yoga, Pilates or Stretching - Document as stretching, hatha yoga.

Appendix 9.E – Paffenbarger (Exericse Habits) Certification/Recertification Checklist

Technician Name: _____ Staff ID: _____

During assessment:

1. ☐ Questions are presented individually.
2. ☐ Item specific prompts are provided with questions as needed.

Item specific evaluation:

Question 1: Past week's exercise

1. ☐ Technician marks appropriate response.
2. ☐ If participant responds "yes", technician emphasizes that response is based on illness, injury or vacation ONLY.
3. ☐ If participant responds "yes", technician cues participant to think about most representative week in terms of activity, within the past month and emphasizes that following responses should reflect this "typical" week.
4. ☐ If participant responds "yes", technician notes if activity in past month was entirely disrupted due to illness, injury or vacation and then cues the participant to consider this past week a typical week.
5. ☐ If participant responds "no", technician proceeds to item 2, emphasizing that following responses should reflect the past 7 days.

Question 2: Flights of stairs climbed

1. ☐ Emphasizes daily flights climbed up and only up.
2. ☐ Prompts participant to consider all environments: home, work, school, malls, etc.
3. ☐ Accurately determines average flights climbed per day.
    a. Considers varying daily flights appropriately
4. ☐ Asks for verification if reported **flights/day ≥10**. If the participant responds no to either question, prompt them to recalculate their answer.
    a. Is this an accurate daily average?
    b. Does this include fights climbed up and only up?

Question 3: Walking for transportation or exercise

1. ☐ Emphasizes responses should only include bouts of walking that were at least 10 continuous minutes
2. ☐ Assists participant in recall of days walked- encouraging day-day event recall
    a. Think about what you did during each day this week.

   b. Did you take any walks during the day, at work, at home, to/from classes, for the purpose of exercise?
3. □ Accurately determines average minutes walked per day.
   a. Considers varying daily durations appropriately

Question 4: Sports, Fitness and Recreational Activity

1. □ Emphasizes responses should only include time spent in activity.
   a. e.g.: if you went bowling, playing basketball, soccer, etc. for 2 hours, indicate only the time when you were actually moving.
2. □ Probes for activity detail when necessary and documents detail of all activities, if necessary.
   a. e.g.: swimming (what type- laps, recreation)
   b. e.g.: "muscle pump, P90X"- 'Please describe that activity to me'
   c. NOTE: The activity coding will be determined by the primary investigator, study coordinator or primary certifying staff member.
3. □ Determines appropriate average time per episode, per activity. Does not include periods of inactivity.
4. □ Does not include household activities (e.g. cleaning, yard work)
5. □ After each response, provide the question: did you participate in any other sports, fitness or recreation activities this week?

Question 5: Typical Week

1. □ For all screening visits: asks the participant if during the week used for responses in items 2-4 the participant was less, more, or about as active as usual.

Question 6: General activity

1. □ Asks the participant "in general" if the participant engages in physical activity long enough to work up a sweat, get the heart thumping, or get out of breath. NOTE: the activities that produce these physiological symptoms do not have to be reported in questions 2-4.

Comments: _____

_____

_____

_____

Observer: _____ Date: _____

Observed: _____

APPENDIX 9.F - PACE Sedentary Behavior Questionnaire

SEDENTARY BEHAVIOR: Weekday

On a typical WEEKDAY, how much time do you spend (from when you wake up until you go to bed) doing the following?

	None	15 min. or less	30 min.	1 hr	2 hrs	3 hrs	4 hrs	5 hrs	6 hrs or more
1. Watching television (including videos on VCR/DVD).	O	O	O	O	O	O	O	O	O
2. Playing computer or video games.	O	O	O	O	O	O	O	O	O
3. Sitting listening to music on the radio, tapes, or CDs.	O	O	O	O	O	O	O	O	O
4. Sitting and talking on the phone.	O	O	O	O	O	O	O	O	O
5. Doing paperwork or computer work (office work, emails, paying bills, etc.)	O	O	O	O	O	O	O	O	O
6. Sitting reading a book or magazine.	O	O	O	O	O	O	O	O	O
7. Playing a musical instrument.	O	O	O	O	O	O	O	O	O
8. Doing artwork or crafts.	O	O	O	O	O	O	O	O	O
9. Sitting and driving in a car, bus, or train.	O	O	O	O	O	O	O	O	O

SEDENTARY BEHAVIOR: Weekend Day

On a typical WEEKEND DAY, how much time do you spend (from when you wake up until you go to bed) doing the following?

	None	15 min. or less	30 min	1 hr	2 hrs	3 hrs	4 hrs	5 hrs	6 hrs or more
1. Watching television (including videos on VCR/DVD).	O	O	O	O	O	O	O	O	O
2. Playing computer or video games.	O	O	O	O	O	O	O	O	O
3. Sitting listening to music on the radio, tapes, or CDs.	O	O	O	O	O	O	O	O	O
4. Sitting and talking on the phone.	O	O	O	O	O	O	O	O	O
5. Doing paperwork or computer work (office work, emails, paying bills, etc.)	O	O	O	O	O	O	O	O	O
6. Sitting reading a book or magazine.	O	O	O	O	O	O	O	O	O
7. Playing a musical instrument.	O	O	O	O	O	O	O	O	O
8. Doing artwork or crafts.	O	O	O	O	O	O	O	O	O
9. Sitting and driving in a car, bus, or train.	O	O	O	O	O	O	O	O	O

Study of Novel Approaches for Prevention

SNAP

Central Biochemistry Laboratory

CBL Manual of Procedures

Specimen Collection
Processing
Shipment

NORTHWEST LIPID METABOLISM AND DIABETES RESEARCH LABORATORIES

August 2010

Contents

ABOUT THE LABORATORY

Brief History

The Northwest Lipid Metabolism and Diabetes Research Laboratories (NWRL) was established in 1971 as one of twelve laboratories involved in the Lipid Research Clinics Program and subsequent Coronary Primary Prevention Study, funded by the National Heart, Lung, and Blood Institute. During the program, this laboratory participated in the development and standardization of methods for the separation of lipoproteins and for the chemical quantification of their components, and performance was monitored continually through the Lipoprotein Standardization Program of the Centers for Disease Control. The laboratory is directed by Santica Marcovina, PhD, ScD, Research Professor of Medicine, Division of Metabolism, Endocrinology, & Nutrition, Department of Medicine, University of Washington.

The laboratory is an Abell Kendall reference network laboratory of the National Reference System for Cholesterol, and participates in the lipid standardization programs offered by the National Heart, Lung, and Blood Institute, Centers for Disease Control, and the College of American Pathologists. In addition, the laboratory serves as the reference laboratory for the International Standardization of Apolipoproteins AI, B, and Lp(a) and is one of the five World Health Organization laboratories.

For more than 30 years, the laboratory has participated in studies to identify the prevalence of hyperlipidemia in the population and to evaluate the efficacy of intervention. Results of the Coronary Primary Prevention Study, reported in 1983, demonstrated that lowering cholesterol was effective in reducing the risk of premature heart disease; this information was key in the development of treatment recommendations issued by the National Cholesterol Education Program. To maintain a high level of accuracy and consistency in results, we continue to perform the Beta Quantification procedure as outlined in the Manual of Laboratory Operations for the Lipid Research Clinics Program without introducing any technical change. The NWRL has been involved in numerous and varied multi-center investigations throughout the United States and internationally. We currently serve as the Central Laboratory for the following NIH-sponsored studies:

Current (NIH funded)

Action to Control Cardiovascular Risk in Diabetes (ACCORD) Trial (Coordinating Center: Wake Forest University School of Medicine, Winston-Salem, NC), Dr. Marcovina – PI, Central Laboratory
Adolescent Bariatric: Assessing Health Benefits and Risks (Teen LABS) (Coordinating Center: Cincinnati Children's Hospital Medical Center, Cincinnati, OH) Dr. Marcovina – PI, Central Laboratory
Atherothrombosis Intervention in Metabolic Syndrome with Low HDL/High Triglyceride and Impact on Global Health Outcomes (AIM HIGH) (Coordinating Center: University of Washington Seattle, WA), Dr. Marcovina – Co-Investigator, Central Laboratory
Clinical Islet Transplantation Consortium (Coordinating Center: University of Iowa, IA) Dr. Marcovina – PI, Central Biochemistry Laboratory

Diabetes Prevention Program Outcome Study (DPPOS) (Coordinating Center: George Washington University, Rockville, MD), Dr. Marcovina – PI, Central Laboratory
HEALTHY (Coordinating Center: George Washington University, Rockville, MD), Dr. Marcovina – PI, Central Laboratory
Longitudinal Assessment of Bariatric Surgery (LABS) (Coordinating Center: University of Pittsburg, PA), Dr. Marcovina – PI, Central Laboratory
Longitudinal Studies of Coronary Artery Disease Risk Factors in Young Adults – CARDIA (CARDIA Coordinating Center: University of Alabama at Birmingham, AL), Dr. Marcovina – PI, Central Laboratory
Look AHEAD (Coordinating Center: Wake Forest University School of Medicine, Winston-Salem, NC), Dr. Marcovina – PI, Central Laboratory
SEARCH for Diabetes in Youth (Coordinating Center: Wake Forest University School of Medicine, Winston-Salem, NC), Dr. Marcovina – PI, Central Laboratory
STOPP-T2D Today Treatment Study – (Coordinating Center: George Washington University, Rockville, MD), Dr. Marcovina – PI, Central Laboratory
Translational Diabetes Prevention in GDM (PI Ferrara, Kaiser Foundation Resource Institute) Dr. Marcovina – PI, Central Laboratory
TrialNet (Coordinating Center: George Washington University, Rockville, MD), Dr. Marcovina – PI, Central Biochemistry Laboratory, Co-Investigator, Beta Cell Function Laboratory

Vision Statement

To be a model organization, thriving in a dynamic environment and respected as a leader in quality laboratory services with a strong commitment to continuous quality improvement.

Mission Statement

The mission of the Northwest Lipid Research Laboratories is to continuously provide the highest standards of professional and technical expertise and organizational support.

Our commitment is to not only provide the utmost in quality analytical, interpretative, advisory and consultation services, but also to offer comprehensive support as a central biochemistry laboratory for research and clinical trial studies. Our pledge is to take the steps necessary, whatever they may be, to ensure the greatest success of the studies in which we are involved.

WE ARE HAPPY TO ASSIST!

Should you have any questions, we are happy to answer them or to assist you at any time. Please feel free to contact any of the following people. We are committed to you and to the study, and we will do what it takes to ensure our combined success!

DIRECTOR

Santica Marcovina, PhD, ScD
Research Professor of Medicine
Phone: (206) 685-3331
FAX: (206) 897-1815
Cell: (206) 372-8625
smm@u.washington.edu

Operations Personnel:

SITE LIAISON

Jessica Chmielewski
Phone: (206) 543-3694
FAX: (206) 616-4889
Cell : (206) 369-9148
jjc8@u.washington.edu

If you are unsure to whom to addess a question, contact me and I will direct you to the appropriate person.

SUPPLY COORDINATON and SHIPPING

Marlon Ramirez
Phone: (206) 685-3328
FAX: (206) 616-4889
marlonrj@u.washington.edu

Supplies Provided by the Laboratory for Collection and Shipment

For Blood Collection and Processing

- Vacutainers: only those used as outlined in this manual

For Specimen Identification:

- Specimen shipment forms (originals provided, clinics to make copies)
- Labels for specimens and shipment forms

For Specimen Shipping:

- Ziploc bags
- Cold packs
- Polyfoam tube holders with absorbent pad and cardboard outer shell
- Polyfoam shipping containers with cardboard outer shell
- Biohazard plastic bags
- Shipping declaration labels
- **EXEMPT HUMAN SPECIMEN LABELS -** Affix to shipping box when no known pathogens exist.

Equipment & Supplies Required at Collection Sites

These are suggested supplies only; sites may use equivalent substitutions, if desired.

For Blood Collection:

- ✓ Alcohol wipes
- ✓ Band-Aids
- ✓ Cold compresses
- ✓ Disposable gloves (powder-free, to avoid possible cross-contamination from powder)
- ✓ Numbing cream
- ✓ Needle holders for vacutainers
- ✓ Paper and/or other dermatological tape
- ✓ Sterile and non-sterile gauze pads
- ✓ Sterile, 21 gauge, 1" needles (multiple-sampling)
- ✓ Sterile, 21 gauge butterfly needles (multiple-sampling)
- ✓ Tourniquets

For Blood Processing/Shipping/Storage:

- ✓ Ice bucket
- ✓ Tube racks
- ✓ Plastic-backed table covers
- ✓ Waterproof pens (such as laundry markers, fine-point, for scribing on labels)
- ✓ Centrifuge: refrigerated (preferably), swinging-bucket type (ideally, 2 centrifuges)
- ✓ Freezer: -20°C, non-cycling, or -70°C freezer
- ✓ Thermometers to measure storage temperatures
- ✓ Dry Ice with storage container
- ✓ Thick gloves suitable for handling dry ice
- ✓ Wide (2") packing tape for sealing shipping containers
- ✓ Cooler for transporting HbA1c samples from the school to the site
- ✓ Large polyfoam container with dry ice transport serum samples from the school to the site.

For Specimen Handling:

- ✓ Lab coat
- ✓ Goggles or face shield
- ✓ Paper towels
- ✓ Bleach decontaminant -1 part Clorox to 9 parts water, stored in a labeled bottle. Clorox wipes can be used to clean surface between blood draws.
- ✓ Biohazard waste containers with orange or red-plastic liners
- ✓ Sharps/biohazard containers - rigid red or orange plastic containers for sharps waste
- ✓ Hand sanitizer for decontaminating hands if sink is not available

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The ***Phlebotomy Area*** should include a chair for the subject, a table for blood collection supplies, a bed, exam table, or treatment chair that flattens out, and phone/ intercom/physical access to emergency equipment. Accommodations should ensure that the subject can sit quietly in a chair for 5 minutes prior to the venous blood draw, as recommended by NCEP guidelines.

Universal Precautions

Universal Precautions were mandated into standards on December 6, 1991, by the Occupational Safety and Health Administration (OSHA) in response to increasing public concern over possible transmission of the Acquired Immune Deficiency Syndrome (AIDS) virus and the Hepatitis B virus. This standard states that any health care worker who might potentially come into contact with body fluids should be educated in infection control and treat all body fluids as though they are potentially infected.

It is assumed that you have already had training in universal precautions. The following is a summary of the basic knowledge required by health care workers, and is not intended to be a complete picture of universal precautions but only the basics. For a more complete overview of universal precautions, you can visit the following web sites:

- http://www.osha.gov
- http://www.niehs.nih.gov

According to OSHA, the following is the recommended protective barrier: gloves, gown, mask and goggles, or face-shield, and they should be used when handling any body fluids.

A. Gloves

1. Wear gloves for all patient contact when body fluids are involved.
2. Change gloves between patients and when gloves are soiled or torn.
3. Wash hands or apply hand sanitizer thoroughly after removing gloves.
4. Remove gloves before touching telephones, charts, computers, monitors, doorknobs, refrigerator handles, food, pens/pencils, and elevator buttons. The only exception to this is telephones designated as contaminated.
5. Carry spare non-sterile vinyl exam gloves in uniform/lab coat pocket for use with unexpected contact with blood and body fluids.

B. Gowns

Wear water-repellent gowns, plastic disposable aprons, etc. when soiling with blood or body fluids is anticipated.

C. Face-Shields

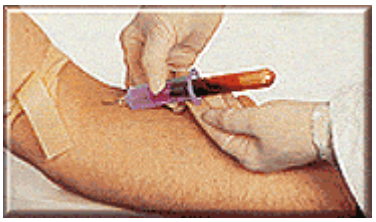
Protect mucous membranes (eyes, nose, mouth) by wearing a mask and/or glasses/goggles, or use a counter-top splashguard, etc. when performing procedures where splashing of the face is likely to occur (de-capping, decanting, etc).

Phlebotomy Procedures

As with universal precautions, it is assumed that you have already had training in blood collection and completed a phlebotomy course. This section provides a brief review of the basics and also includes information specific to this study. For a more complete overview of blood collection procedures, you can visit a number of web sites. These sites are suggested only, and their usefulness must be determined individually. To choose from a list of sites, go to the following URL:

http://phlebotomy.com/

It is understood that universal precautions will be employed during any specimen collection. The following is a suggested method of performing blood specimen collection by venipuncture.



1. Make positive patient identification.
2. Gather necessary equipment.
3. Wash your hands.
4. Don non-sterile exam gloves.
5. Explain planned procedure to patient.
6. Position patient's arm in comfortable position.
7. Select appropriate collection site.
8. Place the tourniquet above the selected collection site. Do not leave tourniquet on for longer than one minute.
9. Clean site with alcohol using circular motion from center outward; allow to air dry (using a gauze pad may re-contaminate the area).
10. Grasp arm 1-2 inches below the site to decrease vein rolling.
11. Enter the vein with the vacutainer needle bevel up at a 15 degree angle.
12. Fill necessary blood tubes.
13. Place sharps in puncture resistant sharps container.
14. Apply gauze and tape, holding pressure for 2-3 minutes to minimize the formation of a hematoma.
15. Remove gloves and wash hands.

Specimen Collection Chart

VISITS: Baseline & Month 24

Analyses	Blood Collection Tube	Visual Reference	Clinic Instructions
Glucose Lipid Profile Insulin Serum Storage	1 x SST tube 7.5 mL tiger-top		• Room temp 20-30 min. • Centrifuge • Ship Fresh **Label: Glu/Lipid/Ins/Store (2 x 0.5mL)**
Plasma Storage	1 x PPT tubes 5.0 mL pearl-top		• Ice for 30 min. • Centrifuge • Ship fresh **Label: Plasma Storage (4 x 0.5mL)**
DNA • Only collect at M24 if DNA wasn't able to be obtained at Baseline.	1 x ACD 8.5mL yellow-top		• Ship fresh the day of blood collection. • **DO NOT COLLECT ON FRIDAYS.** **Label: DNA**

Specimen Labeling

Draw date information and specimen ID must be handwritten on the labels at Baseline with a permanent marker. Month 24 follow-up labels will be pre-printed and shipped to the site three months prior to the anticipated M24 visit.

Fine-point Sharpies are recommended.

Blood Collection

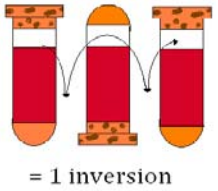
Briefly, the sequence is:

1. Verify that the participant has been fasting a minimum of **8-10 hours.**
2. Label blood collection tubes with subject ID information and draw date.
3. Collect blood specimen.
4. Centrifuge and process tiger-top and pearl-top vacutainers.
5. Keep specimens refrigerated until shipment.
6. Ship on cold packs within 24 hours.

As you draw blood, remember to:

1. Mix each pearl-top blood tube **8-10 times immediately after collection** by inverting the tube gently and evenly.

2. The same needs to be performed with the tiger-top vacutainers to assure adequate mixing of silica particles with the blood, which is required to activate clot formation. Gently invert these tubes **5 times**.



3. **Avoid under-filling** the vacutainer tubes.

4. **DNA must be received by the NWRL within 24 hours of blood draw.**

DO NOT COLLECT DNA SPECIMENS ON FRIDAYS OR DAYS PRECEDING A HOLIDAY.

Once blood has been collected and mixed:

1. Transfer yellow-top (for *DNA* collection) tubes to a refrigerator set at 4°C. **Do not centrifuge these tubes**.

2. To allow clot formation prior to their transfer to the centrifuge, tiger-top SST tubes must stand upright at **room temperature for at least 20 minutes, but no longer than 30 minutes**. Prolonged standing can have a compromising effect on analyte levels.

3. Place the pearl-tops (plasma storage) in an ice bucket or in the refrigerator for 30 minutes prior to their transfer to the centrifuge.

    - Samples kept on crushed ice for longer than 30 minutes will result in hemolysis.
    - The use of ice cubes instead of crushed ice will result in hemolysis.

Processing Specimens

Centrifuge blood tubes

Transfer the tiger-top tubes and pearl-top tubes to the centrifuge, loading it according to the manufacturer's instructions.

Centrifuge at 1200 - 1500 RCF(g) [~3500 RPM] for 10 minutes.

Refrigerated Centrifuge
If using a refrigerated centrifuge, set the temperature to 4°C. Following centrifugation, transfer the SST tiger-top and pearl-top tubes to a refrigerator set at 4°C or prepare the tubes for immediate shipment (as described in the next section).

Non-refrigerated Centrifuge
If using a non-refrigerated centrifuge, it is *imperative* that blood tubes not be allowed to sit unattended after rotation has ceased. Because the process generates heat, tubes must be immediately transferred to the refrigerator once spinning has stopped. It is recommended that a timer pinned to the lab coat be used to alert you when tubes will need to be transferred. *Leaving tubes in a non-refrigerated centrifuge or at room temperature will compromise the accuracy of the analyses*.

Preparing Fresh Shipments

Fresh Specimens

Shipments of fresh blood vacutainers will be made inside polyfoam tube holders (with cardboard outer shells) to protect the tubes from breakage, to keep blood from freezing during shipment, and to keep participant sets together. ***Please freeze cold-packs in a -20°C freezer, as opposed to a -70°C freezer, as excessive freezing of the cold-packs may cause partial freezing of the specimens during transport.***

To ship FRESH specimen sets, follow these steps:

- Obtain the *Specimen Shipment Form (Attachment A).* Master copies of the Specimen Shipment Forms are provided in the *Attachments* section of this manual. Make multiple copies for your use. The form is used to indicate the number and types of vials included in the shipment, the identity of the samples, and pertinent clinic information. The form is designed so that one form must be filled out per subject per shipment.

- Obtain a polyfoam tube holder (with cardboard outer shell) and place it open on the work surface.

- Obtain the blood tubes from the refrigerator and place them on the work surface.

- Check the specimen tubes and verify the draw date and other pertinent information. Complete the shipment form, checking-off the space corresponding to each vial present. Should there be any missing vials, indicate the reason for this in the 'comments' section of the form.

- As the vials are being tallied and verified, place them on their sides in the open polyfoam tube holder (in the slots provided), until all vials for a single participant set have been accounted for.

- Obtain a polyfoam shipping container and place up to 3 tube holders (with cardboard outer shells and containing the participant tubes sets) upright in the container, fill with 3 cold-packs frozen at least overnight, preferably longer, and fit the polyfoam lid on tightly.

- Make a copy of each of the shipment forms and retain at the clinic. Place the originals in a ziploc bag, positioning it on top of the shipping container. Close the cardboard exterior shell around the polyfoam container and tape shut. Affix completed air bill and appropriate packing labels to the container, choose **Priority Overnight**, and call FedEx for pickup.

Shipping Schedule

Shipments should be made Monday through Thursday of the week.

Holiday Schedule

The CBL is officially closed on all US federal holidays and, more importantly, **FedEx will NOT deliver on these days.** Therefore, avoid shipping on any day *preceding* a US federal holiday (see calendar below).

When a holiday falls on a Monday or Tuesday, the last day to ship samples is the Thursday of the preceding week. The samples are expected to be delivered on Friday, but if there is a FedEx delay we will have personnel in the laboratory to receive the samples on Saturday.

When a holiday falls on a Friday, the last day to ship samples is the Wednesday of that week. The samples are expected to be delivered on Thursday, but this allows for receipt on Saturday if there are FedEx delays.

Due to the length of the **Thanksgiving holiday**, and possible FedEx delays, we strongly recommend **NOT** shipping after Monday of Thanksgiving week.

Federal Holiday	2010	2011
New Year's Day	Friday, January 1	Friday, December 31
MLK Jr's Birthday	Monday, January 18	Monday, January 17
President's Day	Monday, February 15	Monday, February 21
Memorial Day	Monday, May 31	Monday, May 30
Independence Day	Monday, July 5	Monday, July 4
Labor Day	Monday, September 6	Monday, September 5
Veterans Day	Thursday, Nov. 11	Friday, Nov. 11
Thanksgiving	Thursday, November 25 Friday, November 26	Thursday, November 24 Friday, November 25
Christmas Day	Friday, December 24	Monday, December 26

ATTACHMENTS

A:	**Shipment Form**
B:	**Fax Notification Form**
C:	**Supply Request Form**
D:	**Storage Destruction Request**

The SNAP CBL
Northwest Lipid Metabolism and Diabetes Research Laboratories – University of Washington
401 Queen Anne Avenue North, Seattle, WA 98109-4517
Phone: (206) 616-6474 FAX: (206) 685-6880

FRESH SPECIMEN SHIPMENT: This form is used to accompany samples drawn from a single subject and shipped to the CBL for analysis. Refer to the Laboratory Manual of Procedures for detailed instructions – **This form is not an instruction sheet**. Photocopy the completed form- and retain the copy at the center.

Participant Information:

ID Number:

Shipment Form Label Here

Date of Blood Draw:

Visit (Circle): **BASE** **M24**

Check ✓ Tube Included in Shipment		Tube Type	
☐	**Lipid Profile/ Glu/Ins/Store**	**7.5mL tiger-top**	☐ **Missed blood draw**
☐	**DNA**	**8.5mL yellow-top**	☐ **Missed blood draw**
☐	**Plasma Storage**	**5ml pearl-tops**	☐ **Missed blood draw**

It is important that the laboratory be able to contact the person who performed this visit and completed this form, if needed

Contact: _____

Phone:_____

Comments: _____

_____

FAX

*The **SNAP** Central Laboratory*

Northwest Lipid Metabolism and Diabetes Research Laboratories – University of Washington

TO: Specimen Processing
FAX: (206) 685-6880
Phone: (206) 616-6474

From: _____

Phone: _____

Email Address: _____

PLEASE BE ADVISED OF THE FOLLOWING SHIPMENT ARRIVAL:

Clinical Site: _____ Number of boxes shipped: _____

Date specimens shipped: _____

Fed Ex Tracking Numbers: _____

_____

Remarks:

SNAP STUDY
Supply Request Form

ALL REQUESTS FOR SUPPLIES SHOULD BE MADE AT LEAST TWO WEEEKS PRIOR TO YOUR ANTICIPATED NEED.

Clinic: _____ Order Completed By: _____ Phone: _____

Date Ordered: ____/____/____ **Date Needed: ____/____/____**

Laboratory Use Only

Date Request Received by the Lab: ____/____/____ Date Supplies Shipped from Lab: ____/____/____

Item	Quantity Desired	Quantity Shipped	Quantity Pending
7.5mL SST Tiger-top Vac.			
5.0mL PPT Pearl-top Vac.			
8.5mL ACD Yellow-top Vac			
Polyfoam Tube Holders			
Polyfoam Shipping Container			
Absorbant Pads			
Cold Packs			
Biohazard Plastic Bags			
FedEx Air bills/Shipping Labels			

Comments

Questions? Please call: Marlon Ramirez at 206-685-3328

Fill in the amount of each item desired on the table to the left.

Fax the completed form to the lab: 206-616-4889

Your order will be processed and shipped to you with a copy of this form enclosed.

In Insure that contents exactly match the supplies specified on this form.

If there are no discrepancies, sigh the form and fax back to the lab.

I have reviewed the contents of my shipment and confirm that all supplies listed have been received.

Signed: _____ Date: _____

Request for Sample Destruction

At any time, participants who have given written consent for the collection and storage of white cells, serum, plasma and/or urine may decide to withdraw their consent. Participants have the right to request that their stored specimens be retrieved and destroyed. Participants are entitled to written confirmation that their stored specimens have been destroyed.

The Request for Sample Destruction is used to communicate the participant's request for their specimens to be destroyed. The clinical site is responsible for conveying this request to the Central Chemistry Laboratory (CCL) where the specimens are being stored.

The Request for Sample Destruction form is divided into three sections. Section 1 is the request for stored specimen destruction and is completed by the clinical site. Sections 2 and 3 are completed at the CCL verifying that stored specimens have been retrieved and destroyed.

Upon receipt of a Request for Sample Destruction form from the clinical site, the CCL will destroy all stored specimens specified by the request. Destruction of stored specimens will be done in accordance with standard procedures for decontamination and removal of human specimens.

Section1 must be completed by the clinical site identifying the study participant and type of stored specimens to be destroyed. It is required that this section be signed by the Principal Investigator or Study Coordinator. After completion, the Request for Sample Destruction form is transmitted via FAX (206-616-4889 or 206-685-6880) or sent by regular mail to the CCL.

Section 2 and 3 are completed at the CCL. After receipt of the signed Request for Sample Destruction, the Database Administrator will identify the sample ids for the stored specimens involved. The sample id's along with the Request for Sample Destruction form will be forwarded to Specimen Management. Specimen Management will pull and deliver the identified samples to the Autoclave Technician. Specimen Management will sign their part of Section 2 after samples are retrieved from storage and delivered to autoclaving. Section 2 is also signed by the Autoclave Technician, who personally autoclaves and disposes of the samples, attesting that samples provided to him have been properly destroyed. Notation regarding storage status of the samples is then updated by the appropriate staff person at the CCL.

Section 3 is signed by the Laboratory Director as final confirmation that removal and destruction of the samples has been properly performed and documented.

The completed Request for Sample Destruction is then faxed to the clinical site to confirm that the destruction of stored specimens has been completed. The Request for Sample Destruction is then filed at the CCL as confirmation that the destruction has been completed.

SNAP

Request for Sample Destruction

Section 1

Clinical Site: _____ Participant ID: _____ Collection Date: _____

I formally request that the vial(s) obtained from the above study participant containing the stored specimens checked below be disposed of and not retained for use in any research activities.

❑ DNA **Check which is applicable**
❑ Reserve Serum
❑ Reserve Plasma

Signature: _____ Date: _____
Principal Investigator or Study Coordinator

Section 2

I attest that the samples requested for disposal have been identified, retrieved, and provided to the autoclave technician for destruction, and status of these samples updated in the database.

Signature: _____ Date: _____
Specimen Management

I attest that the samples delivered to me by Specimen Management have been destroyed in accordance with standard procedures for decontamination and destruction of human specimens.

Signature: _____ Date: _____
Autoclave Technician

Section 3

As requested by the Clinical Site on behalf of the study participant listed above, I confirm that all samples requested for disposal have been completely and properly destroyed.

Signature: _____ Date: _____
Santica M. Marcovina, PhD, ScD
Laboratory Director and PI

Section 1: to be completed by the Clinical Site, then fax or mail to the CCL.

Sections 2 & 3: to be completed by the CCL, then faxed or mailed back to the Clinical Site.

SNAP MOP - Chapter 11

Physical Measurements

Table of Contents

11. Physical Measurements

11.1. MEASUREMENT OF WEIGHT, HEIGHT AND WAIST

11.1.1. Overview of Body Size Measurements

Change in body weight is the primary measure of effectiveness of the intervention in this trial. Although weight can be measured with accuracy and precision using relatively simple equipment, the preparation of the subject, standardization of procedure, and maintenance of equipment are critical in order to obtain reliable data. Body weight relative to height, expressed as Quetlet's index, or body mass index (BMI, kg/m^2), is an index of fatness and is highly correlated with more direct measures of body fat. Waist circumference and changes in waist circumference are indicators of subcutaneous and visceral fat deposits in the abdominal region and have been shown to be independently associated with cardiovascular disease.

All measurements are to be made with the participants wearing light clothing, e.g., a short sleeve shirt or blouse (or surgical gown), shorts, socks and without shoes (for weight and height). A supply of shirts and shorts (or gowns) should be maintained at the clinic for participants who forget to wear or bring the appropriate clothes for body size measurements. Participants should be sure pockets are empty.

Body size measurements should be taken by staff masked to the intervention assignment of the participant. If possible, measurements, especially waist circumferences, should be taken by a team of two persons, one acting as observer and the other as recorder. The observer takes the measurements, reporting the results to the recorder, who repeats them. The observer keeps the measuring instrument in place until the recorder repeats the number. The recorder generally checks the participant's position during the procedure. If a second observer is not available, a mirror can be used to check for the correct position (e.g., whether the tape is horizontal for waist circumferences). Body weight, height and waist circumference will be measured at screening/baseline and at 4, 12, 24, 36 and 48 month visits.

11.1.2. Body Weight

Tanita BWB 800 digital scales (Tanita Corp., Arlington Heights, IL) are provided for each clinical site. The scales should be set to be read in kilograms. Ideally, body weight is measured in the morning after voiding and before breakfast. If this is not possible, efforts should be made to weigh each subject under conditions as similar as possible on all visits (e.g., same time of day, fasting, limited consumption of fluids).

The subject should be instructed to stand still in the middle of the scale platform with head erect and eyes looking straight ahead. Record the weight in kilograms to the nearest 0.1 kg as indicated on the digital display. Ask the subject to step off the scale and check that the digital display returns to zero. Repeat the measurement and record the weight. If t**he 2 measurements are not within 0.2 kg, a third measurement is to be taken.** ***All 3 measures are to be entered into the database, and the average of the 3 measures is to be used for study-wide analyses.***

If a participant's balance is unstable making it difficult to obtain the two weight measures, staff may instruct them to **lightly** touch a mounted bar, wall, chair, or walker to provide balance. It is strongly recommended to locate your scale next to a wall or bar. If this is not possible at your site, a chair or walker can be placed in front of the scale. Only the lightest touch should be used (use the finger tips, do not allow the participant to grip or use entire hand). Usually the weight will lock once the participant's balance is stabilized for a short moment using the method described above.

11.1.2.1. Quality Control

Instructions on the use of the scale and warranty information were shipped with the scales. These documents should be stored in a convenient location for future reference. Follow the manufacturer's instructions in putting the scales into service and using them. The scale must be positioned on a level floor. Never drop a weight on, or subject the scale platform to shock loading and do not store equipment or weights on the platform. Moving of scales should be avoided, and calibration should be rechecked after moving a scale to a new location.

The weight used for calibrating the scale should be stored on the floor adjacent to the scale and used according to the manufacturer's instructions. Recalibration of this weight is not necessary unless some damage has been incurred.

11.1.2.2. Weekly Calibration Checks

Calibration checks will be carried out prior to the weighing of the first subject at the start of the study, at least weekly thereafter so long as subjects are scheduled for measurement visits, and before weighing a subject after a period of time greater than one week during which no weight measurements were made. At each calibration, values will be recorded in a log maintained for this purpose (Appendix 11A.). The log will be reviewed during site visits.

The tolerance on a scale capable of weighing up to 200 kg will be considered as ± 0.1 kg (one scale division). Deviations of more than one scale division will require corrective action, specifically; the scale must be shipped to the manufacturer for calibration. Contact Tanita Technical Assistance at 1-877-682-6482. Tanita will provide you with an authorization number and instructions on shipping the scale.

The calibration procedure described below is a compromise between frequent time-consuming checking in order to rule out a rare and improbable event (i.e., scale failure), and the highly undesirable event of having erroneous or missing weight data in a study largely focused on weight maintenance.

11.1.2.3. Calibration Procedure

Calibration checks should be carried out on equipment in its normal location. A class F certified 20 kg calibration weight will be used for checking scale calibration. The calibration weight should be stored and used according to manufacturer's instructions (which should be saved and filed along with accompanying certificates).

The calibration weight should be stored on the floor against the wall near the scale, NOT on an elevated surface. This will keep carrying the weight to a minimum. Staff should review the recommended procedures for lifting heavy objects (bend at the knees, keep back straight, etc.) Sites might assign a staff member who is more physically capable to do the calibration on a regular basis. Finally, the 20 kg weight could be replaced with two calibrated 10 kg weights. A good procedure for placing the calibration weight is to put the weight in the center of the scale platform leaving some room at the edges for the feet.

The following procedure checks the repeatability of readings and the linearity of the scale in a portion of the working range.

1. Place the 20 kg weight (gently) on the scale platform. Record the weight indicated on the scale.
2. Remove the weight from the scale platform and allow the display to return to zero.
3. Step (or have an assistant step) on the scale. Record the weight indicated on the scale.
4. Step off the scale. Allow the display to return to zero.
5. Have the assistant step on the scale platform while holding the 20 kg weight. Record the scale reading.

6. Step off the scale. Allow the display to return to zero.
7. Repeat the six steps above at least once, and then compare the values obtained.

If the repeated weighing of the calibration weight, or the assistant's weight, or the weight of the assistant plus the calibration weight do not yield the same values each time, or, if the weight of the assistant plus the calibration weight is more than 0.1 kg different from the sum of the two weighed individually then the scale is probably faulty. Contact Tanita (as described above) for instructions on how to ship the scale to them for calibration.

Results of the above tests should be recorded in the calibration log, signed and dated by the person performing the calibration, and the form will be retained as part of the study documentation. If the tests indicate that the equipment is out of tolerance or faulty, the nature of the deviation and the action taken should be noted as a comment on the calibration form.

11.1.2.4. Annual Commercial Calibration

Annually, beginning one year from the date a new scale is placed into service, or if the scale is not new, before the date the scale is placed into service and annually until all Year 4 visits have been completed, the scale should be calibrated. The calibration of the scale must be certified by either by the site's institution or state inspector or by the manufacturer of the scale (Tanita). Weekly calibration of the scales as outlined in the MOP will continue. Service and repairs should be performed as needed. If service is required, instructions found in this chapter should be followed.

Contact information:

Tanita Corporation of America, Inc.

2625 South Clearbrook Drive

Arlington Heights, Illinois 60005, USA

Phone: (847) 640-9241

Fax: (847) 640-9261

Customer Service: (847) 640-9241

Calibration must be carried out with a sufficient number of test weights to load the machine at four or more points across its working range. A calibration certificate should be issued by the commercial contractor recording:

- the date of calibration
- serial number of the scale

- test weights used and scale readings at those test weights
- deviations observed at each load
- the nature of any adjustments or corrections made to the scale (i.e., before/after readings)
- name and signature of the technician who carried out the calibration.

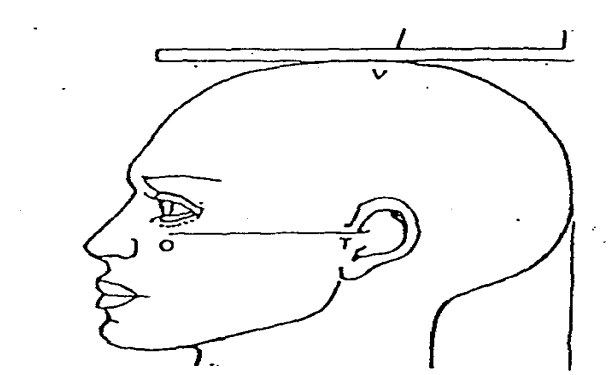
This certificate will be kept in the log along with the record of weekly site staff calibrations.

11.1.3. Body Height

A wall-mounted stadiometer graduated in centimeters with a horizontal measuring block (or fixed angle) is to be used. If the stadiometer is not wall-mounted, you will need a level to ensure that the horizontal measuring block is level.

The subject stands erect on the platform with his/her back parallel to the vertical mounted measure scale (but not touching the wall), looking straight ahead with his/her head in the Frankfort horizontal plane (the horizontal plane is defined by the lower margin of the bony orbit - the bony socket containing the eye - and the most forward point in the supratragal notch - the notch just above the anterior cartilaginous projections of the external ear). See Figure 1 for an example of how the participant should be positioned. The horizontal measuring block is brought down snugly, but not tightly, on the top of the head. The subject should be instructed to stand as straight as possible with feet flat on the floor. The subject's height is recorded to the nearest 0.5 cm. Ask the subject to step away, raise measuring block and ask subject to return and repeat measure. **If the 2 measurements are not within 0.5 cm, a third measurement is to be taken.** ***All 3 measures are to be entered into the database, and the average of the 3 measures is to be used for study-wide analyses.***

The following alternate protocol may be used to obtain the height measure on participants with extreme kyphotic posture or a large posterior. In these instances it may not be possible to obtain contact between the head board and scalp when the participant's back is against the wall-plate. In this case, measure height with the participant standing sideways (side of arm and shoulder in contact with the wall-plate) and positioned so that the headboard contacts the scalp. The head should be in the Frankfurt Horizontal Plane. There is no modification to the Physical Measurement Form; however, staff should record that the participant was measured in the sideways position in the source document so that follow-up measurements can be made in the same position.



ORBITALE:	Lower margin of eye socket
TRAGION:	Notch above tragus of ear or at upper margin of zygomatic bone at that point
FRANKFORT PLANE:	Orbitale tragion line horizontal

Figure 1. Participant position for measuring height

11.1.4. Waist Girth

The Gulick II Tape Measure (model 67020) will be used for accuracy in obtaining duplicate waist girth measurements. The design of the tape measure eliminates the guesswork by applying a known amount of tension (four ounces) to the measuring tape. When used properly, tape tension is always four ounces. Therefore, accurate measurements are possible no matter who is doing the measuring.

The Gulick II is standardized equipment for SNAP. An ordinary tape measure (without the special four ounce tension indicator device) will vary in measurement and is dependent on how tightly the tape is pulled; if you pull harder and harder, tissue compression will be greater and greater, and the measured circumference will become smaller and smaller. Two consecutive measurements are usually quite different. If two or more people take the same measurement, the results rarely agree. It is clear that only by applying a constant tension (as the Gulick II does), can accurate and repeatable measurements be taken.

The Gulick II Tape Measure uses a no-stretch, retractable tape with both Metric and English gradations (centimeters and inches). The tape is non- metallic, thereby eliminating the discomfort of a cold object touching the skin and any possibility of scratches or cuts. The self-retracting tape is kept at the desired length until the retract button is pushed.

The most important part of the Gulick II Tape Measure is the tensioning device attached to the measuring tape. Its function is to provide a known amount of tension while a measurement is being taken. Each individual tensioning device is calibrated to indicate precisely a four ounce tension. Note that a stainless-steel *compression* spring is used. This guarantees that the calibration will last a lifetime, since it is impossible to "over-compress" a spring of this type.

To take measurements: Pull an appropriate amount of tape out of the housing. Wrap the tape once around the waist (see instructions below). Align the tape's "zero line" along side of the tape graduations. Use the Metric units (cm). Now simply pull on the end of the tensioning mechanism until the **calibration point** is just seen. Read the measurement next to the tape's "zero line".

What is meant by "calibration point": When you pull slightly harder and harder on the tensioning device, two colored beads will be seen separated by a silver disk. When you are pulling with exactly four ounces of force, you will see a silver disk separating the two beads. When you see one of the two beads, you are at the "calibration point". Remember, four ounces is not a great deal of force, in fact, it is approximately equal to the force required to lift a stack of 20 U.S. quarters. So don't pull so hard that the beads start to disappear into the end cap of the tensioning device. That is too much force.

Ideally, waist circumference would be measured in the morning after voiding and before breakfast. If this is not possible, efforts should be made to measure each subject under conditions as similar as possible on all visits (e.g., same time of day, fasting, limited consumption of fluids).

Participants should stand with feet together. The measure should be taken around the abdomen horizontally at midpoint between highest point of the iliac crest and lowest part of the costal margin in the mid-axillary line. To define the level at which waist circumference is measured, a bony landmark is first located and marked. The participant stands and the examiner, positioned at the right of the subject, palpates the upper hip bone to locate the right iliac crest. Just above the uppermost lateral border of the right iliac crest, a horizontal mark is drawn, and then it is crossed with a vertical mark on the mid-axillary line. Mark the midpoint on both sides using a washable marker. (Participant may be asked to assist in passing the tape around the abdomen by holding the end of the tape in position). See Figure 2 for an example of locating bony landmarks. The tape should be aligned with the markings and positioned in the horizontal plane at the correct height. At this point, it may be helpful to mark the position of the tape on the participant's back in order to insure proper placement for the second reading. The participant should be asked to keep relaxed arms at the sides and to breathe naturally. Ask the participant to breathe in, out, and hold at the end of a normal

exhalation. Record the waist circumference to the nearest 0.1 centimeter. Remove the tape and repeat the procedure. If t**he 2 measurements are not within 1.0 cm, a third measurement is to be taken.** ***All 3 measures are to be entered into the database, and the average of the 3 measures is to be used for study-wide analyses.***

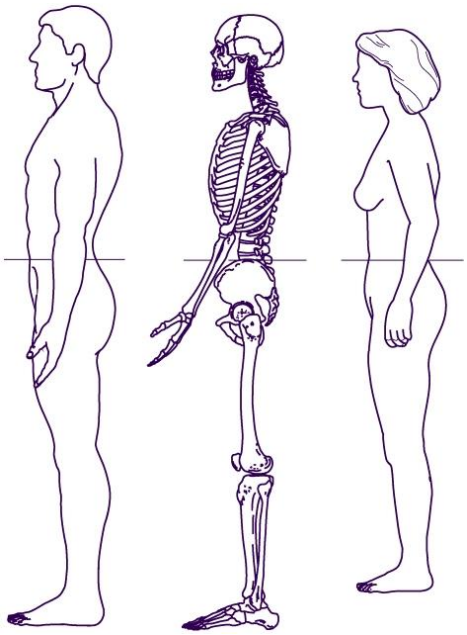


Figure 2. Participant position for measuring waist circumference.

11.2. SEATED BLOOD PRESSURE

11.2.1. Introduction and Rationale

Blood Pressure (BP) level is a major risk factor for coronary heart disease, congestive heart failure and stroke. Heart rate reflects autonomic nervous system function and cardiovascular fitness. Risk for serious cardiovascular events is especially high for persons who are overweight.

11.2.2. Background

Individuals with who are overweight are at particularly high risk of cardiovascular and all-cause mortality, as are individuals with low levels of physical activity or poor fitness levels. Documented changes in heart rate and blood pressure measurements over time, when these measurements have been taken by trained personnel under controlled conditions, can be indicators of improvement or diminishment in fitness, and therefore of increased or decreased risk for cardiovascular event.

11.2.3. Schedule of Administration

Seated blood pressure and heart rate measurement is performed at screening/baseline and at 4, 12, 24, 36 and 48 month visits. Blood pressure measurements should be done prior to drawing blood for laboratory analysis in order to prevent the risk of additional bleeding.

It is suggested that seated blood pressure and heart rate measurements be done at the beginning of a visit, but only after the participant has been sitting quietly for at least five minutes. The five-minute rest preceding the first measurement will allow blood pressure and heart rate to stabilize after movement or activity, such as walking.

During this five minute resting period, participants should NOT be engaging in any of the following: reading, filling out forms, talking or crossing their legs or ankles.

Clinic staff should explain the blood pressure procedures to the participant prior to the five minute rest period. Participants should be educated about how blood pressure can be affected by any of the above, and told that the five minute resting period helps the SNAP study obtain more accurate measurements. Making these the first procedures done in a participant's visit will help to avoid any physiological response which might occur due to stress related to anthropometric measurements, phlebotomy or questionnaires.

11.2.4. Required Equipment, Materials & Personnel

Dinamap Monitor Pro 100: This automated device offers the advantages of greater accuracy when compared with manual mercury sphygmomanometer along with reduced potential for observer biases and decreased demand on staff in terms of training and effort in data collection. All SNAP locations will use only this instrument for the seated blood pressure measurement.

Cuffs: Cuff size will be determined by arm circumference. Each of the following cuff sizes should be available: Adult, Large Adult, Thigh and Long Large Adult.

Gulick Measuring tape: To be used for measurement of the participant's arm circumference.

Other materials: A dark-colored cosmetic pencil is also helpful for marking the skin when finding the location of the arm circumference measurement.

Personnel: Only technicians who are masked to treatment assignment and have been certified by the CoC, Program Coordinator or another certified SNAP staff member should perform the seated blood pressure and heart rate measurements on study participants.

Printer Set-up:

Printer paper is loaded by pressing the notched (thumb print) indentation on the printer door to open. With the monitor turned on, place the roll of paper in front of the silver roller and the paper will automatically feed. As the paper touches the plates, it will begin to auto-feed into the printer. Once the paper begins feeding, slip the loose end through the slot in the door, close it and press the notched indentation to lock it.

The gray knob at the upper right of the monitor functions in a manner similar to a computer mouse. Rotate the knob to highlight options on the display. Push the knob to select a highlighted option (like “clicking” with the mouse).

It will be most advantageous to preset the printer with automatic printing as the default setting. This eliminates having to change the printer setting with each subject. To set the printer to this default, use the following steps:

1. With the monitor turned on, turn the gray knob to highlight MORE… and press. Next turn the gray knob to highlight SERVICE and press.
2. To enter Clinician Service Mode, a series of four code numbers must be entered. Highlight and press, in order, the numbers 1, 2, 3 and 4. Turn the gray knob to again highlight MORE... and press. Next turn to highlight PRINT and press. When the question appears RESTORE PRINT MODE ON POWER UP? Highlight YES and press.
3. Turn the monitor off, and then back on. Turn the gray knob to highlight PRINT and press. When AUTO/MAN is highlighted in the PRINT menu, press the gray knob to toggle between options until the option PRNT: AUTO appears on the lower right side of the screen. Return to the main menu by highlighting MAIN and pressing. The printer is now set for automatic printing.

The printed tape that comes out of the Dinamap should be kept in the participant’s source document or clinic chart. The telephone number to order paper for the Dinamap is 1-800-558-5102.

11.2.5. Setting Initial Target Inflation

It has been recommended that we set the initial target inflation pressure as a permanent default at 180 mm Hg. The instructions are in the Dinamap manual but have been summarized as follows:

1. Select MORE… from the main menu
2. Select SERVICE… from the next menu

3. Select the numbers 1, 2, 3, 4 sequentially to access the clinician service menu (page 57 in operations manual)
4. Select PRESS and adjust the target pressure to 180 mm Hg by turning the gray knob, then press the knob to set (page 58)
5. Select OK and press, then select MAIN.

Remember that the target inflation pressure can be adjusted at any time from the main menu by selecting SET BP and changing as desired. However, once the monitor is powered off the clinician service default of 180 mm Hg returns on power-up.

11.2.6. Procedures

Preparation: First it is necessary to determine the participant's right arm circumference, in order to select the appropriate cuff size for the blood pressure measurement. This is done by the following steps:

1. Ask the participant to bare the right arm and hold it at the side of the body with the elbow flexed to 90 degrees in a handshake position with the palm up.
2. Measure the length of the arm from the acromion process (bony extremity that forms the highest point of the shoulder) to the olecranon process (tip of the elbow) and determine the halfway point in this length. Mark this midpoint on the posterior surface of the arm.
3. Have the participant relax the arm along the side of the body and place the measuring tape around the arm at the midpoint mark.
4. Holding the tape parallel to the floor, draw it around the arm with a degree of tension that keeps it snug against the skin, but without indentation of the flesh.
5. Measure the right arm circumference to the nearest tenth of a centimeter and record on the data form. Note that this measurement is not meant to be a precise anthropometric measurement; it is meant to determine appropriate cuff size only.
6. Using the arm circumference measurement, determine the correct cuff size according to the chart that follows:

Arm Circumference	Cuff Size
17-26 cm	Small Adult
22-33 cm	Adult
33-47 cm	Large Adult
46-66 cm	Extra Large Arm or Thigh (Or Large Adult Long, see text)

The sizes for cuffs are overlapping in order to have some flexibility in choice. The first choice for cuff should always be for the larger size. However, if the participant is small in stature, the smaller cuff size might be used to avoid having the cuff slide up over the shoulder or down the antecubital fossa.

If a participant's upper arm circumference would indicate use of the thigh cuff, but the arm is too short for the cuff, or the cuff does not remain secured when inflated, the Large Adult Long arm cuff should be used. Difficulty with placement is often a problem with obese participants, resulting in readings that are too high or too low when compared with manual measurements.

Taking the seated blood pressure and heart rate readings:

The subject should be seated with both feet flat on the floor and the right forearm resting on the table. Palpate the antecubital fossa and position the cuff around the arm so that the midpoint of the bladder length is at heart level, and the cuff arrow marked "artery" is aligned with the brachial artery. Cuffs are labeled with range and index lines. The correct cuff has been selected if the index line is within the range as the cuff is wrapped around the arm. The cuff should be wrapped snugly enough that no more than one finger-width distance exists between cuff and skin.

Have the participant rest for five minutes prior to taking the first measurement. To begin the procedure, push the green and orange START/STOP button at the lower right corner. This will inflate the cuff and initiate the first reading. Once the reading is obtained, the data will appear on the screen, and the cuff will automatically deflate. The print out will begin to emerge from the printer.

After a minimum 30-second wait, push the START/STOP button to obtain the second reading. When this reading is completed, tear the print out from the printer and record the first and second blood pressure readings. Record the heart rate data from the first reading as the pulse on the data forms. A third

measurement should be taken if the systolic of the first two measurements are not within 10 and/or if the diastolic of the first two measurements is not within 6.

If the cuff accidentally becomes inflated and it is not on a limb, it can be manually deflated by unscrewing the cuff from the cord and manually pressing the air out.

> Note: Monitor battery and screen life are optimized if the monitor is left plugged in, but is turned off at the ON/OFF button when the device will not be used for several hours, or until another day.

11.2.7. Quality Control

All technicians performing the seated blood pressure and heart rate measurements on SNAP participants must be certified. Certification must be renewed annually.

Annual calibration of the Dinamap Pro 100 instrument should be done by the manufacturer, GE Medical Systems. To set up a return of the machine, call 1-800-558-7044. There is an option on voice mail for "service dispatch". Press that option and set up a return for calibration. Each clinic will be given an authorization number for return. If you desire a loaner, you must ask for customer service, and will need to provide a purchase order number to insure that the loaner is returned. You will be charged if it is not returned. Fees for calibration of the instrument have ranged from $300-600 over the course of the study. Confirm the charges before proceeding with the process.

11.3. BIOELECTRICAL IMPEDANCE ANALYSIS

11.3.1. Introduction and Rationale

Bioelectrical impedance analysis (BIA) measures the impedance or opposition to the flow of an electric current through the body fluids contained mainly in the lean and fat tissue. Impedance is low in lean tissue, where intracellular fluid and electrolytes are primarily contained, but high in fat tissue. Impedance is thus proportional to body water volume (TBW).

In practice, a small constant current, typically 800 uA at a fixed frequency, usually 50 kHz, is passed between electrodes spanning the body and the voltage drop between electrodes provides a measure of impedance. Prediction equations, previously generated by correlating impedance measures against an independent estimate of TBW, may be used subsequently to convert the measured impedance to a corresponding estimate of TBW. Lean body mass is then calculated from this estimate using an assumed hydration fraction for lean

tissue. Fat mass is calculated as the difference between body weight and lean body mass.

11.3.2. Schedule of Administration

Biological impedance analysis is performed at screening/baseline (SV2) and at 4, 12, 24, 36 and 48 month visits.

11.3.3. Preparation

Prior to performing BIA, determine if the subject followed the suggested preparation guidelines:

- Abstain from alcohol consumption within 12 hours of assessment
- Abstain from diuretic ingestion, including caffeine, within 4 hours of assessment
- No eating or drinking within 4 hours of the assessment (water is acceptable and participants will be asked to maintain normal hydration prior to measurement)
- Avoid moderate or vigorous physical activity or sauna within 8 hours of assessment
- Review and note any deviations on the documentation form
- If the participant has not complied with preparation guidelines, the screening visit must be rescheduled.

11.3.4. Required Equipment and Materials

- RJL Systems Quantum II Bioelectrical Impedance Analyzer
- 9-volt Battery
- RJL Systems BIA adhesive electrodes (4 per/participant)
- Alcohol prep pads or gauze and rubbing alcohol

11.3.5. Procedures

The following steps should be followed when measuring BIA:

1. Have subject void.
2. Remove all jewelry from right side of the body. If jewelry cannot be removed, make note of this on data sheet and proceed with measurement.
3. Remove all shoes and socks.

4. Instruct participant to assume a supine position on the exam table positioning arms 30 degrees from the body (not touching), palms down and legs not touching.
5. Skin must be cleaned with alcohol and dried prior to electrode placement.
6. Apply electrodes as shown in Figure 2 to right side of the body. If the subject has right lower extremity edema, use the left leg. If both legs are edematous, use the right leg and make a notation on the documentation form.
7.

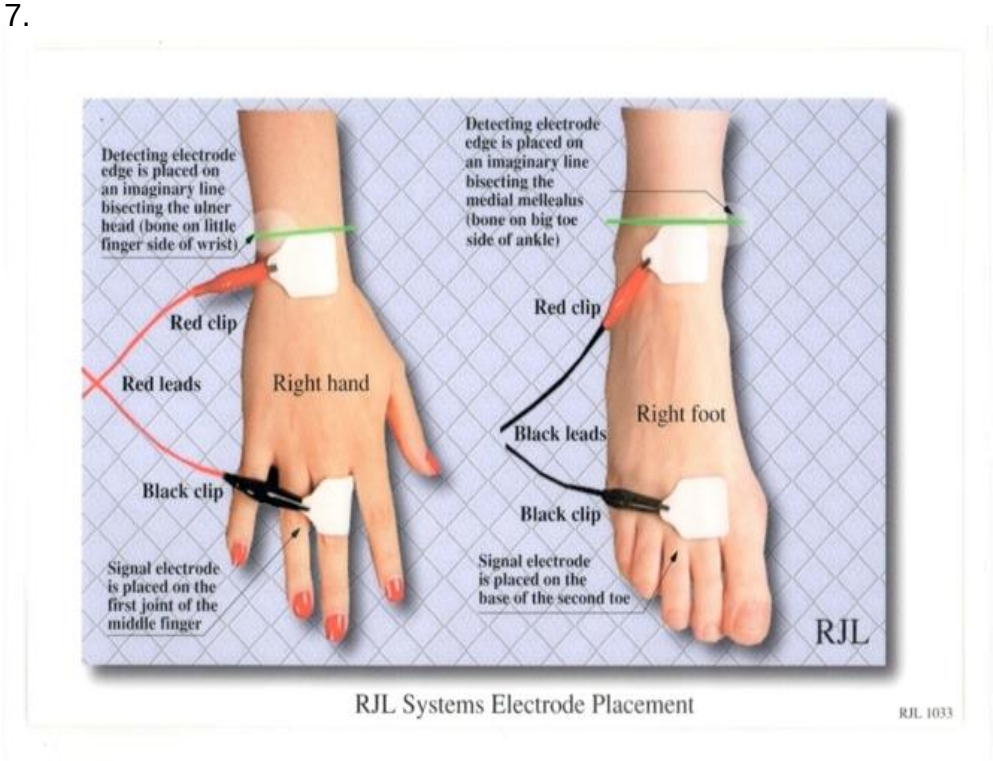


Figure 2. Placement of electrodes for BIA.

8. Measure the distance between electrodes on both hand and foot. Distance must be $\geq$ 8 cm. When measuring, make sure to measure from the top of one electrode to the top of the other. If the distance is less than 8 cm, replace electrodes and re-measure, moving them more distal if possible and re-measure. Record distances on data collection sheet.
9. Attach cables to the electrodes. Be sure the red cable and clips are proximal (“red to head”) and black cable and clips are distal. The red cable goes to the hand electrodes and the black cable goes to the foot electrodes.

10. Be sure subject refrains from moving while obtaining the readings. The values must be stable for at least 2 seconds. Therefore, once you get a reading for both resistance and reactance; use the buttons on the device to go back to each measure to ensure that these values have not changed. Resistance should be between 250 and 900 ohms. Reactance should be between 10 and 120 ohms.
11. Take two measurements. If the two measurements do not match exactly, repeat the test.
12. Record values on the measurement data collection sheet.
13. Remove and dispose of electrodes.

11.3.6. Quality Control

The BIA instrument should be calibrated quarterly using a 500 ohm test resistor according to the procedures recommended by the manufacturer. The following are instructions for calibration:

- Connect clips to the 500 ohm resistor as shown in Figure 3 and place resistor on a non-metal table (Technician should not touch or hold this device during calibration)
- Turn on BIA device and read resistance and reactance values and record on calibration log sheet. If values are outside the ranges indicated in Figure 3, make sure clips are positioned correctly and try again. If still outside range, contact the manufacturer.

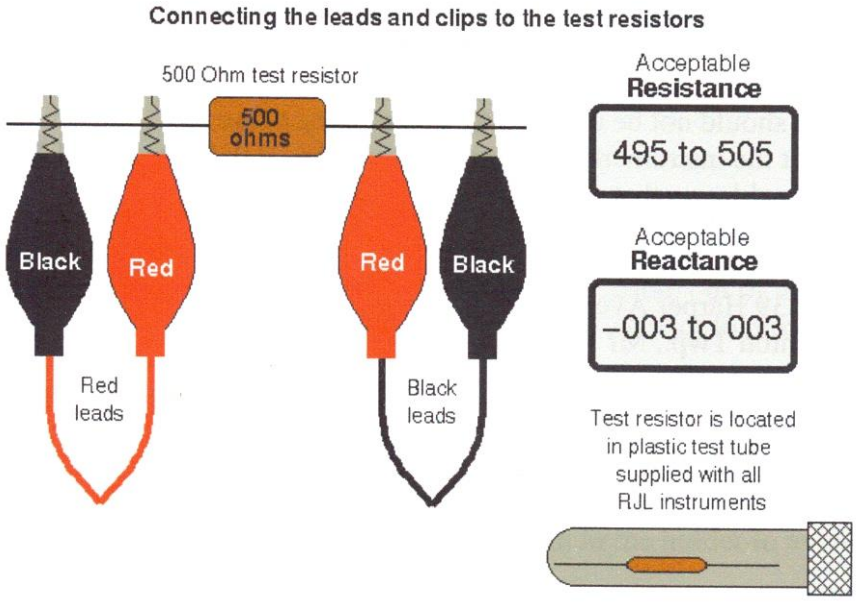


Figure 3: Proper placement of clips for calibration

If calibration fails the study center coordinator will contact the manufacturer for repair/replacement. Calibration will be documented in the study center calibration/cleaning log.

11.3.7. Certification Procedures for Administration

At each SNAP study center, one staff member will be designated as the center's BIA certification manager, thus being responsible for certifying and re-certifying center staff members to perform the BIA assessment. The certification manager will administer initial certification prior to the launch of the SNAP study (or upon hire of new staff) for select research associates. Re-certification will be scheduled on an as needed basis.

Certification will be performed in a mock/role play setting. Research associates must be able to demonstrate proficiency with completing the interview and the required data conversions. The certification and recertification checklist will be completed and signed by the certification manager (Appendix B).

11.4. BOD POD ASSESSMENT

11.4.1. Introduction and Rationale

The BOD POD uses the principles of whole body densitometry to estimate the amount of fat and lean tissue in the body. Whole body densitometry is based on the determination of body density by measuring body mass and volume. Body mass is measured using the BOD POD electronic scale and body volume is measured in the BOD POD. Once body density is determined, the subject's percentage and absolute amounts of fat and fat free mass are calculated using the principles of whole body densitometry. The measurement procedure takes approximately 5 minutes.

The BOD POD consists of two chambers. The front, or Test Chamber, is where the subject sits and is comprised of a seat that forms a common wall separating it from the rear, or Reference Chamber. During the brief data collection period of the volume measurement, the chamber door is secured by a series of electromagnets and a gasket. A Diaphragm is mounted on the common wall, which oscillates during testing. This causes small changes in volume inside the chamber, of which the pressure response to these small volume changes is measured. This is done by measuring the interior volume of the empty BOD

POD chamber, then measuring it again when the subject is seated inside. By subtraction, the subject's body volume is obtained. For example, if the interior air volume of the empty chamber is 400 liters, and the volume of the chamber is reduced to 350 liters with the subject inside, the body volume of the subject would be 50 liters.

11.4.2. Schedule of Administration

The BOD POD Assessment is performed at screening/baseline (SV2) and at 4, 12, 24, 36 and 48 month visits.

11.4.3. Preparation

Prior to performing the BOD POD Assessment, the subject should abstain from food, water and exercise for at least 2 hours prior to the test.

11.4.4. Required Equipment and Materials

- BOD POD and system components (details can be found in the BOD POD Operators manual stored at the study center)
- Tube and filter kits for thoracic gas volume measurement.
- Swim caps
- Washable compressive shorts and sports bras (assorted sizes)
- Window cleaner and cloths for weekly cleaning.

11.4.5. Procedures

The following steps should be followed when performing the BOD POD assessment:

1. Show participant to assessment room.
2. Have participant change into appropriate clothing (unpadded compression shorts and spandex swim cap for men; swimsuit with no metal or underwire for women or unpadded compression short and sports bra without wire or metal plus spandex swim cap for women) and put on the robe over the top (note that is opens in the front and ties on the side).
3. Ask them to remove all jewelry, watches, etc
4. The technician should use the following script to describe the Bod Pod assessment:

   We will be using the Bod Pod to measure your body composition. We will be doing three sessions that will last 50 seconds each. You will need to sit completely still-no shifting, coughing, talking, laughing, etc. Please try to breathe normally. The third time you will use the breathing tube to

measure the amount of air in your lungs, but I will give you more details before we begin that session.

You will hear some pops and clicks while you are in the Bod Pod and you may feel a slight change in pressure. If you feel uncomfortable at any time during the test, please let me know and I will instruct you to press the emergency button (point it out) to release the magnets and allow you to exit the Bod Pod.

Do you have any questions about anything?

5. Follow prompts on Bod Pod screen to take volume measurements. After first session, open door and check in to make sure participant is fine.
6. After volume measurements are complete, describe and perform thoracic gas volume measurement.

Standardized Instructions for V_{TG} Measurement (3rd round in Bod Pod)

The technician should use the following script to describe 3rd round in the Bod Pod:

We have one more procedure to complete. During this portion of the test you will use the tube and filter that we installed earlier. This test will measure the amount of air in your lungs. You will be in the Bod Pod for about 50 seconds. During the entire procedure you will be wearing a plugging your nose to limit air flow to your mouth.

The procedure will include 3 main steps.

Step 1:

After I close the door, please hold the breathing tube in one hand and watch the monitor for the purple and green progress bar telling you when to breathe IN and OUT. We want you to breathe at the SAME RATE as the progress bar.

Step 2:

After about 4 breaths a message will appear on the screen that says “Prepare to put tube in mouth”. At this point, bring the tube close to your mouth. Immediately after, you will see the message, “Put tube in mouth.” Please put the tube in your mouth. Seal your lips tightly around the tube and continue breathing according to the progress bar. You will hear some pops and clicks inside the BOD POD, similar to the first procedure.

Step 3:

After a few more breaths you will see a message on the screen that says "Prepare to huff." This will alert you that during the next exhalation the airway connected to the tube will close for 2 seconds. Immediately after, you will see the final message that says "HUFF, HUFF, HUFF." At this point please keep your lips sealed tightly around the tube and huff very gently 3 times in a row as if you were fogging up your glasses.

We will go through a practice trial first with the BOD POD door opened.

Technician Notes:

1. During the practice trial:
    - Have the participant plug their nose.
    - Take the tube out of the BOD POD and hold the filter side.
    - Have the participant hold the other end of the tube.
    - Have the participant take a few breaths in and out of their mouth with their nose plugged.
    - Verbally instruct participant to put the tube in their mouth, and take two breaths with the tube in their mouth.
    - Watch the rise and fall of their chest. In the middle of the second exhalation (chest falling) completely cover up your end of the tube with your hand while simultaneously instructing the subject to huff 3 times in a row.
    - After the test put the tube back into the BOD POD and proceed with the actual V_{TG} measurement procedure.
2. During the practice and actual trials:
    - Ensure that the cheeks do not puff out
    - Ensure that the participant maintains a tight seal around the tube
    - Make sure the participant does not puff too hard
    - Encourage the participant to avoid holding their breath, coughing, clearing their throat, avoid contracting their abdominals to hard. NOTE: these instructions should also be provide for the initial body volume measurement.
3. Following the actual test you will evaluate the participant's compliance.
    - Examine the merit value (M).

- M=0 indicates perfect agreement (between airway pressure and chamber pressure curves)
- M~100 indicates little relationship between the two pressure curves
- $M \leq 1.0$ is established as a criterion for acceptance of V_{TG}
- If M >1, try it again with the participant. Try up to 3 times total. If participants do not get the desired merit value, choose the option for predicted equation and note that on the form.

4. After Bod Pod is complete, ask participants about their activity level. Read the criteria on the Bod Pod form to find out how they characterize their activity level (sedentary, low activity, etc.). Input reported value in the computer.

11.4.6. Quality Control

1. On an annual basis, a manufacturer representative will visit to inspect and perform necessary calibration procedures. If determined necessary the study center coordinator will contact the manufacturer for repair/replacement.
2. Calibration will be documented in the study center calibration/cleaning log.

11.4.7. Certification procedures for administration

At each SNAP study center, one staff member will be designated as the center's Bod Pod certification manager, thus being responsible for certifying and re-certifying center staff members to perform the Bod Pod assessment. The certification manager will administer initial certification prior to the launch of the SNAP (or upon hire of new staff) study for select research associates. Re-certification will be scheduled on an as needed basis.

Certification will be performed in a mock/role play setting. Research associates must be able to demonstrate proficiency with completing the interview and the required data conversions. The certification and recertification checklist (Appendix C) will be completed and signed by the certification manager.

Appendix 11.A - Scale Calibration Log

Scale Model & S/N:							
Date	20 kg	Tech. Wt.	Tech + 20 kg	20 kg	Tech. Wt.	Tech + 20 kg	Initials/Comments

Appendix 11.B – BIA Certification/Recertification Checklist

Technician Name: _____ Staff ID: _____

Prior to assessment:

1. ☐ Demonstrates sufficient knowledge of BIA rationale.
2. ☐ Assembles proper materials.
3. Determine if the subject followed the suggested preparation guidelines:
   - ☐ Abstain from alcohol consumption within 12 hours of assessment
   - ☐ Abstain from diuretic ingestion, including caffeine, within 12 hours of assessment
   - ☐ No eating or drinking within 4 hours of the assessment (small amounts or water are acceptable)
   - ☐ Avoid moderate or vigorous physical activity or sauna within 8 hours of assessment
   - ☐ Reviews and notes any deviations on the documentation form.
     NOTE: If the participant has not complied with preparation guidelines, the research assistant must reschedule the visit.
4. ☐ Asks subject to void, if necessary.
5. ☐ Has participant remove all jewelry, shoes and right sock.

During assessment:

1. ☐ Keeps participant comfortable.
2. ☐ Discourages participant from moving.

Observes the following procedural steps:

1. ☐ Instructs participant to assume supine position on the exam table with arms separated 30 degrees from the torso (not touching), palms down, and legs not touching.
2. ☐ Cleanses right wrist and food areas with rubbing alcohol and gauze or alcohol prep pads. If a subject has right lower extremity edema, use the left leg. If both legs are edematous, use the right leg and make a notation on the documentation form.
3. ☐ Places electrodes on wrist (between medial and lateral malleoli) and hand (index and middle fingers).
4. ☐ Places electrodes on ankle area (between medial and lateral styloid processes) and foot (between second and third toes).
5. ☐ Measures distance between electrodes on both hand and foot. Distance must be $\geq$ 8 cm. If distance is less, replace electrodes and re-measure.
6. ☐ Records distances on data collection sheet.

7. □ Ensures the subject refrains from moving while obtaining the readings. The values must be stable. Resistance should be between 250 and 900 ohms. Reactance should be between 10 and 120 ohms.
8. □ Records values on the measurement data collection sheet.
9. □ Asks participant to remove and dispose of electrodes.

Comments: _____
_____
_____
_____

Observer: _____ Date: _____
Observed: _____

Appendix 11.C – Bod Pod Certification/Recertification Checklist

Technician Name: _____ Staff ID: _____

Prior to assessment:

6. ☐ Demonstrates sufficient knowledge of BOD POD rationale.
7. ☐ Performs complete calibration on BOD POD prior to the day's assessments.
8. ☐ Assembles proper materials.
9. ☐ Determine if the subject has abstain from food, water and exercise for at least 2 hours prior to the test.
10. ☐ Reviews and notes any deviations on the documentation form.
    NOTE: If the participant has not complied with preparation guidelines, the research assistant must reschedule the visit.
11. ☐ Asks subject to void, if necessary.
12. ☐ Has participant remove all jewelry and eyeglasses.

Observes the following procedural steps:

7. ☐ Instructs participant change into appropriate clothing (unpadded compression shorts and spandex swim cap for men; swimsuit with no metal or underwire for women or unpadded compression short and sports bra without wire or metal plus spandex swim cap for women).
8. ☐ Allows participant to put on hospital gown during calibration procedures if participant expresses discomfort.
9. ☐ Correctly enters participant's information into the BOD POD computer.
10. ☐ Performs 2 volume calibration procedures prior to measuring each participant.
11. ☐ Follows the script to describe the BOD POD assessment (available in physical measurement section of the MOP)
12. ☐ Offers participant practice trial and opportunity to ask questions.
13. ☐ Follow prompts on Bod Pod screen to take volume measurements.
14. ☐ Opens door and checks in to make sure participant is comfortable between 2 volume measurements.
15. ☐ Describes thoracic gas volume measurement utilizing the script provided in the physical measurements section of the MOP.
16. ☐ Follows prompts on Bod Pod screen to take thoracic gas volume measurements.
17. During the practice and actual trials:

- Ensures that the cheeks do not puff out.
- Ensures that the participant maintains a tight seal around the tube.
- Makes sure the participant does not puff too hard
- Encourage the participant to avoid holding their breath, coughing, clearing their throat, avoid contracting their abdominals to hard. NOTE: these instructions should also be provide for the initial body volume measurement.

12. Following the actual test evaluates the participant's compliance.
    - Examines and records the merit value (M).
    - If M >1, try it again with the participant. Try up to 3 times total.
    - If participants do not get the desired merit value, choose the option for predicted equation and note that on the form.
13. After Bod Pod is complete, asks participants about their activity level.
14. Read the criteria on the Bod Pod form to find out how they characterize their activity level (sedentary, low activity, etc). Input reported value in computer.
15. Saves and prints participants data.

Comments: _____

_____

_____

_____

Observer: _____ Date: _____

Observed: _____

SNAP MOP - Chapter 12
Dietary and Nutrient Intake Assessment
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12. Dietary and Nutrient Intake Assessment

12.1. BACKGROUND AND RATIONALE

SNAP is uniquely positioned to address many of the pressing questions related to nutritional approaches to preventing weight gain in young adults. Weight gain has been associated with a worsening in cardiovascular disease risk factors and an increase in the prevalence of metabolic syndrome. Preventing weight gain at an early age is key to curbing the obesity epidemic. This is the primary motivation for dietary and nutrient intake assessment in the study. Many dietary factors including intake specific nutrients and whole foods may be important in the development of cardiovascular disease in young adults, either as a function of energy balance or through metabolic pathways that are independent of obesity. Also, because comparison of the weight-gain prevention approaches presented in the SNAP study is novel, assessment of these dietary factors may be helpful in understanding how implementation of the approaches differ and how the resulting changes affect clinical outcomes.

The SNAP dietary assessment is designed to facilitate analysis of specific nutrients and whole foods, as well as overall dietary patterns. It is designed to be sensitive to dietary change that is likely under the planned interventions. The opportunity to analyze and contrast dietary intake across and within intervention and control groups, in a diverse study population, is a unique and important aspect of the study, which is likely to increase our understanding of how differences in dietary intake, with or without weight loss, are related to the study outcomes.

12.2. PROTOCOL OVERVIEW

Participant’s usual diet will be characterized at baseline, 4 months and two years. The Block 2005 food frequency questionnaire (FFQ) will be used. This full-length (approximately 110 food item) questionnaire was designed to estimate usual and customary intake of a wide array of nutrients and food groups. Both the food list for this questionnaire and nutrient database for its analysis were developed from more recent data than used for the Block 1998 FFQ. The food list was developed from NHANES 1999-2002 dietary recall data; the nutrient database was developed from the USDA Food and Nutrient Database for Dietary Studies (FNDDS), version 1.0. A series of "adjustment" questions provide greater accuracy in assessing fat and carbohydrate intake. Individual portion size is asked for each food, and pictures are provided to enhance accuracy of quantification.

12.2.1. Mode of Administration

The BLOCK FFQ will be primarily self-administered using an online (web-based) questionnaire. The online system was chosen to complement online administration of other study questionnaires, for quality control, and for ease of data access across the sites. Project staff will provide the participant with both verbal and written instruction on accessing and completing the online form from the participant's personal computer. If a participant does not have access to a computer, they will be instructed to self-administer the questionnaire using the online system from a computer in the clinic. In the event that online administration is not possible, the participant will be given a paper copy of the Block 2005 FFQ and will be instructed to complete the questionnaire using the paper form and a #2 pencil.

12.2.2. Period of Recall

The Block 2005 FFQ is designed to capture a one month period of intake. Instructions for completing the BLOCK direct the respondent to consider diet over the past month. SNAP will use this reference period.

12.3. METHODS

Most participants will self-administer the questionnaire online, with support from certified clinic staff to introduce and explain the online system to the participant. If paper administration is to be used, participants will be given a form and they will self-administer the questionnaire. Upon return of the forms, clinic staff will review and edit the form and obtain clarifications if needed. Guidelines are provided below.

The goal of the diet interview is to obtain information about **usual** dietary practices of the participants, and to do so consistently at all clinical centers. Consistently applying the mode of administration (self-administration) with standard introduction, instruction and review is critical to the quality of the data obtained from the assessment.

The Coordinating Center will manage online form usernames and passwords. Tracking of form completion will be on the SNAP website. Online form tracking will be managed by the Coordinating Center. Clinic staff will be responsible for the provision of instructions for completing the diet assessment and for following up with study participants during the assessment period to ensure completion of the diet assessment.

12.3.1. General Guidelines

A clear, positive introduction and explanation of the questionnaire is extremely important to obtaining valid information from the questionnaire. Importantly, this

information will allow the participant to complete the questionnaire with minimal frustration.

To help participants feel oriented to the form, tell them that the items are grouped by type of food (e.g., fruits, vegetables, meats). Note that some of the foods may be unfamiliar to the participant, due to inclusion of an ethnically diverse study population. Remind participants to think of foods eaten at home and away from home. Remind them to include both meals and snacks.

12.3.2. Guidelines for Online Administration

Based upon the participant's login, when a participant selects the "BLOCK FFQ" from the list of participant-entered forms, the participant will be automatically directed to the BLOCK website to complete the BLOCK FFQ.

1. Explain the purpose of the questionnaire, which is to understand the individual's usual diet over the past month.
2. Let the participant know that the questionnaire will take approximately 30 to 40 minutes to complete and asks questions about the types and amounts of foods the person eats.
3. The participant can suspend the form and return to it at a later time if they are interrupted or experience fatigue, however, discourage frequent interruptions or discontinuous completion of the form if possible because this may affect the quality of the diet data collected.
4. Tell the participant that the form should be completed prior to returning for the clinic visit. Encourage the participant to block out a period of time to complete it and to avoid waiting until the day before they return to the clinic for their visit.

Specific Instructions for the Online form:

Note: The online FFQ has built-in instructions, prompts, skip patterns, missing value checks and help functions to facilitate accurate and complete collection of the diet data.

1. When the participant first logs in, the website will assess the computer's settings to ensure that it meets the site requirements for the questionnaire. Instructions are provided to either return to the questionnaire or to install the necessary components for completing the questionnaire. The following are requirements for using the online form:
    a. Macromedia Flash player version 7 or newer
    b. Latest versions of Microsoft Internet Explorer, Netscape Navigator, Mozilla and AOL

c. JavaScript 1.2 or later must be enabled.

2. Each food or supplement question comes with a "More Info" button and pull-down menu. Clicking on this button (in the upper right hand of the screen) will assist in understanding the question.
3. The user can only proceed to the next page/screen by answering all of the questions appearing on the current screen. Arrows and check marks will show questions needing to be answered and questions completed.
4. Answers are recorded each time the user clicks the "Next" button**.**
5. Changing a response on a previous page is easy to do. The user should click on the "Back" button. The user should NOT use the Internet browser's "back" arrow at the top of the screen.
6. If necessary, a user can quit the online session and then resume it later to complete the questionnaire. When logging in again, the system will remember where the user left off and will go directly to the page where entry stopped.
7. Let the participant know that once they complete all questions in the questionnaire, they are not able to go back and change their responses.

12.3.3. Guidelines for Paper Form Administration

1. Provide the participant with a Food Questionnaire (version Block 2005.1 which is printed on the bottom of the questionnaire - this form is printed in orange, blue and black), a copy of the Serving Size Choices handout, and a #2 pencil. *It is very important that the participant receives both the Block 2005 Food Questionnaire booklet and the Serving Size Choices handout. The Serving Size Choices handout provides the participant with reference sizes needed to complete the questionnaire.*
2. Explain the purpose of the questionnaire, which is to understand the individual's usual diet over the past month.
3. Let the participant know that the questionnaire will take approximately 30 to 40 minutes to complete and asks questions about the types and amounts of foods the person eats.
4. The participant may want to complete the questionnaire over more than one block of time if they are interrupted or experience fatigue, however, discourage frequent interruptions or discontinuous completion of the form if possible because this may affect the quality of the diet data collected.
5. Tell the participant that the form should be completed prior to returning to the clinic. Encourage the participant to block out a period of time to

complete it and to avoid waiting until the day before they return to the clinic for their visit.

6. Reiterate the general instructions that will be provided in the survey
    a. Answer each question as well as you can. If you aren't sure, give your best guess. (If the participant is concerned about not remembering what she/he ate, acknowledge the concerns and encourage them to recall to the best of his/her ability.)
    b. You will be answering questions about "how often" foods are eaten and "how much" of the food is eaten. Refer to the Serving Size Choices handout for portion size estimations.
    c. Do not skip any foods. Mark "Never" if you didn't eat any of the foods.
    d. Use a #2 pencil to complete the questionnaire. DO NOT USE PEN!
    e. Fill in each bubble completely. (Show the participant the bottom of the first page of the questionnaire for a demonstration.)
    f. If you answer "Never" about how often you at a certain food, you do not have to fill out a bubble under "How Much". However, all other foods for which you consumed at least "A Few Times per Year", you must fill in a portion size under "How Much."
    g. On the back of the questionnaire, be sure to fill in a bubble in the "How Often" section for each of the Multiple Vitamins and the Single Vitamins. If you did not take any of these, fill in the bubble that corresponds to the "Didn't Take" response.

12.3.4. Paper Form Preparation

1. Fill in the participant's Study ID in the "Respondent ID#" space on the upper left hand section of the first page of the questionnaire. Fill in the corresponding bubbles under the written numbers. Use the following numbering convention:
    - 3 leading zeros (2 leading zeros for 2 year assessment) + 5-digit ID + assessment month
    - (Assessment month: Use 0 for baseline, 4 for month, 24 for 2 year, etc.)
    - For example, 000211110 would be participant 21111 at baseline.

2. In the section where the respondent is asked to write their name, write in the Group number. This is specific to the study. The SNAP group number is 434.

12.3.5. Tracking Forms

Encourage the prompt completion of the questionnaire. If the participant is completing the online questionnaire, use the SNAP website to track completion of the form. Follow local clinic procedures for monitoring and reminding participants of completion of online forms. If the participant is completed a paper version of the form, remind them when reminding them of the appointment to bring the completed BLOCK FFQ to the clinic visit.

If the participant has not completed the online questionnaire when they arrive for the clinic visit, ask them to complete the form while they are attending their visit on a clinic computer. If they are unable to complete the form during the visit, provide them with the paper form and instructions for completing the paper form. Provide them with a stamped envelope and ask them to mail the completed from back within a week.

12.3.6. Checking/Editing the Paper Form

When the paper form is returned, spend a few minutes checking over the questionnaire. Ideally, you will do this while the study participant is still there. If the questionnaire is returned by mail, check the form as soon as possible in case clarification is needed. Do <u>not</u> mail the form to Block Dietary Data Systems until editing is complete**. The goal is to identify <u>obvious</u> omissions or errors, NOT to judge the quality of the participant's diet.**

- Check for omissions – skipped foods, missing information. Prevent skipped foods by careful instruction beforehand that the participant should check "Rare or Never", rather than skipping foods she/he rarely or never eats. If there are any omissions, attempt to fill out the blank spaces with the participant's help (either in person or over the phone).
- Check to be sure that the Respondent ID is correctly filled in and the Group Number is written in the Name box on the first page.

12.3.7. Instructions for Mailing Paper Forms to Block Dietary Data Systems

Forms should be sent to Block Dietary Data Systems as completed. Batching forms may be helpful. Prior to sending the questionnaire, make a copy to store in the participant's file.

Send the forms by Federal Express or other reliable courier. It is very important to be able to track the forms with the FedEx or other tracking number. Include a

cover memo with a note requesting that the questionnaires be processed and the data uploaded to the Data On Demand system for Group number 434. Completed questionnaires should be sent to:

Block Dietary Data Systems

15 Shattuck Square, Suite 288

Berkeley, CA 94704-1151

Phone: 510-704-8514

12.4. GLOSSARY OF ETHNIC FOOD ITEMS ON THE BLOCK FOOD QUESTIONNAIRE

Food Item	Description
Ajiaco	Vegetable stew
Caldo de res	Broth-based soup with beef
Chorizo	Sausage, salami
Enchiladas	Corn tortilla filled with meat or beans
Menudo	Mexican soup made with tripe (stomach)
Pozole	Corn on a rich stew-like dish made from corn
Sancocho	Broth-based soup with meat and vegetables
Sopa Seca	Noodle dish with tomatoes, chilies and cheese
Tacos	Mexican-style sandwich of a folded corn tortilla with various fillings
Tamales	Corn-based dough that is steamed and often filled with cheese or meat
Tempeh	Fermented soybean cake

SNAP MOP - Chapter 13
Safety Management and Serious Adverse Event Reporting
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13. Safety Management and Serious Adverse Event Reporting

13.1. SAFETY MANAGEMENT OVERVIEW

Safety management in SNAP is intended to achieve five objectives: 1) to minimize the occurrence of adverse effects, especially those related to interventions; 2) to effectively manage adverse events as they relate to the study; 3) to identify when SNAP interventions should be suspended because of concerns for participant safety; 4) to determine when interventions may be resumed after having been suspended; and 5) to provide information to the participant related to management of hypertension, dyslipidemia and other cardiovascular disease risk factors.

Each SNAP investigator will have primary responsibility for the safety of participants as it relates to the study protocol. The Data Safety Monitoring Board will have responsibility for monitoring study data for evidence of adverse effects attributable to participation in SNAP. This chapter describes safety considerations for the study, SNAP alerts, the reporting of Medical Events, Serious Adverse Events, and Intervention Modification procedures.

13.1.1. Medical Problems occurring at the Study Clinic or Intervention Site

It is anticipated that some medical problems will occur during the course of the study while some participants are in the SNAP study clinic or at the site of the Lifestyle Intervention program. The following is a summary of a plan of action based on level of acuity of the problem.

Emergent problems and problems that are life threatening or require immediate life saving attention should be dealt with using the local Emergency Medical System (EMS). Clinical staff may provide basic life support as an interim measure when appropriate until EMS personnel arrive. CPR training is recommended but is not required. The study staff will be responsible for notifying the participant's family or designated contacts.

Urgent medical problems and problems that require immediate attention but that do not require life saving attention such as fainting in the blood draw chair, should be dealt with by taking measures to ensure the participant's comfort and offering first aid, as appropriate. Disposition plans should be made with the participant, clinic staff, investigators, and family. The clinic staff may arrange transportation of the participant to another medical care site for definitive care if needed. The family or designated contacts should always be notified.

13.2. SAFETY CONSIDERATIONS WITH RESPECT TO STUDY PROTOCOL

The SNAP trial will not directly provide medical care to participants in either the Intervention or Control arms. Instead, participants will receive medical care from a PCP. Medical therapy to achieve contemporary standards of control of hyperglycemia, lipids, blood pressure and glucose will, accordingly, be the responsibility of a participant and his or her PCP. These will not be considered safety issues except when alert levels are reached. These alert levels are defined in this chapter of the MOP.

13.2.1. Plasma Lipids

Fasting plasma lipids will be measured at baseline and year 2. Participants will be given the National Heart, Lung, and Blood Institute's Adult Treatment Panel (ATP) III lipid recommendations and follow-up guidelines at each visit. The goals are as follows:

LDL cholesterol: < 100 mg/dL

Triglycerides: < 200 mg/dL

HDL cholesterol for men: > 45 mg/dL

HDL cholesterol for women: > 55 mg/dL

It will be the responsibility of the participant and his/her PCP to take action to achieve these goals.

An alert value has been set for fasting plasma triglycerides of $\geq$ 500 mg/dL and LDL cholesterol > 160 since High triglycerides above this level increase the risk of acute pancreatitis and high LDL cholesterol levels increase the risk of cardiovascular disease. If triglyceride or LDL values exceed these levels, SNAP staff will inform the participant by letter and encourage follow-up with their PCP.

13.2.2. Blood Pressure

13.2.2.1. Hypertension

Blood pressure will be measured at baseline, Month 4, and annually and reported to each participant along with the recommended NHLBI Join National Committee on the Detection, Evaluation and Treatment of High Blood Pressure (JNC) VII goal of < 120/80 mmHg. It will be the responsibility of the participant and his or her PCP to take action to achieve this goal.

The alert values for hypertension are taken from JNC VII guidelines. The blood pressure result placing the participant in the highest category should be used. For example, if the BP is 158/110, use the BP alert level for DBP = 110. If blood pressure is ≥ 160 mmHg systolic or ≥100 mmHg diastolic at any study visit, the participant will be advised of the problem and asked to see their PCP within one month to evaluate their blood pressure.

If blood pressure at any clinic visit is > 180/110 clinic staff should refer the participant to the PCP to treat immediately or within 1 week depending on the clinical situation or complications. For example, participants with elevated blood pressure in this range with symptoms such as headache, shortness of breath, or chest pain should be evaluated immediately. The study clinician will evaluate the symptoms and review of all previous blood pressures and may require referral to an emergency department based on this review. The participant will be asked to see his or her PCP for evaluation. The participant will be instructed to suspend SNAP interventions involving exercise until blood pressure is controlled.

13.2.2.2. Hypotension

In some young adults, weight loss and exercise interventions can increase the risk of hypotension. On the other hand, relatively low blood pressure is not uncommon in young adult women who may be participating in SNAP. During SNAP, if at any clinic visit the systolic blood pressure is <90 participants should be asked: Are you feeling dizzy or lightheaded?

If yes, participant should be counseled to see a healthcare provider within 1 month. Note that some young adult women may report occasional episodes of dizziness or lightheadedness on standing up from sitting or reclining. The key is to determine if their pattern has changed, whether the problem is new, more severe or more common, or if there is no change in these symptoms. Referral may not be needed for uncommon episodes that have not changed in frequency, severity, or pattern.

13.2.2.3. Tachycardia

Heart rate will automatically be measured with the SNAP blood pressure devise after the prescribed rest period. If a participant heart rate is > 110 beats per minute, the participant should be referred to the PCP or emergency room as appropriate based on their heart rate and symptoms for evaluation. SNAP interventions involving exercise will be suspended until the PCP has provided written approval for the resumption of exercise.

13.2.3. Glucose

Fasting blood glucose 126 mg/dl or higher may indicate that a participant has diabetes. Low blood sugar or hypoglycemia may be present and cause symptoms if glucose is below 60 mg/dl. However, minimally decreased glucose levels, commonly in the range of 55-59 mg/dl may indicate that the blood specimen was not processed rapidly enough, leaving the blood cells in contact with the plasma for too long and allowing them to continue to metabolism the plasma glucose. If a participant has a blood glucose of < 60 or >126 staff will re-check the glucose at the clinic site. If glucose remains abnormal on the re-check the staff will inform the participant and encourage them to follow-up with their PCP.

13.2.4. Excessive Weight Loss

If BMI decreases to $\leq$ 18.5 kg/m^2 OR > 20% weight loss from baseline, as a result of SNAP interventions, staff must meet individually with the participant within two weeks to council participant on excessive weight loss, in addition, staff should schedule a 1 month follow-up visit with the participant. If participant remains below 18.5 or continues to lose more weight, intervention activities will stop.

13.2.5. Eating Disorder

If a participant develops Bulimia Nervosa during the course of the trial (i.e., they meet full diagnostic criteria based on the EDA form at any follow-up assessment), we will temporarily discontinue treatment until the participant is healthy. A qualified staff member will meet with the participant individually and counsel them to seek professional treatment, and a list of referrals and / or a community resource guide will be provided. The participant will need medical clearance from his/her physician before resuming treatment in the current study.

13.2.6. Pregnancy or Nursing

If a participant in one of the intervention arms becomes pregnant, the weight loss intervention should be suspended until after 6 months after delivery or after weaning if the participant is nursing. At that time, we will encourage participants to return to the intervention and assessments visits.

13.2.7. Cancer

If a participant should develop cancer SNAP weight loss interventions may need to be stopped. This will be done if either the participant's PCP or a SNAP Principle Investigator decides that further weight loss is medically undesirable for that participant.

13.2.8. SNAP Alert Summary

The table below summarize the SNAP alerts and describes the appropriate action for each alert.

ALERT	ACTION
Blood Pressure SBP $\geq$ 160mm/Hg DBP $\geq$ 100mm/Hg	Evaluate within 1 month, If BP > 180/110 refer participant to PCP to treat immediately or within1 week depending on clinical situation or complications. Participants will be given the JNC VII blood pressure recommendations and follow-up guidelines at each visit.
LDL > 160 Triglycerides TG $\geq$ 500 mg/dl	Clinic staff will inform the participant by letter within 1 month to encourage follow-up.
Glucose < 60 or >126	Re-check in clinic, if abnormal on re-check, inform participant to encourage follow-up
Excessive weight loss BMI $\leq$ 18.5 or greater than 20% weight loss from baseline weight	Meet in person to council participant, with a 1 month follow-up visit. If participant remains below 18.5 or continues to lose more weight, intervention activities will stop.
Eating Disorder Eating habits	If a participant develops Bulimia Nervosa during the course of the trial (i.e., they meet full diagnostic criteria

	for BN at any follow-up assessment), we will temporarily discontinue treatment until the participant is healthy. A qualified staff member will meet with the participant individually and counsel them to seek professional treatment, and a list of referrals and / or a community resource guide will be provided. The participant will need medical consent / clearance before resuming treatment in the current study.

13.3. INTERVENTION MODIFICATION FORM

The Intervention Modification Form is to be completed when the Lifestyle Intervention needs to be stopped or modified for a participant because of an event. Examples include but are not limited to the following: pregnancy, blood pressure alerts where it would be unsafe for the individual to exercise, physical injury and other events such as developing an eating disorder, cancer etc. The Intervention Modification form **should not** be filled out if the intervention is only being modified for a short time, i.e. because of the flu, a sore muscle etc. If the intervention is being modified for a month or more, then the form would be filled out, for example if a participant had knee surgery, the exercise intervention might be stopped for several months.

13.4. MEDICAL EVENT AND SERIOUS ADVERSE EVENT REPORTING

13.4.1. Overview

The timely and complete reporting of medical events, adverse events (AE) and Serious Adverse Events (SAE) is a critical requirement in the conduct of this clinical trial. It allows the study to track the occurrence of events of a serious nature for review by the Data Safety Monitoring Board, NIH, regulatory agencies, institutional review boards and the investigators, to guard the safety of participants. It also allows us to describe and contrast the major side effects associated with each study arm.

13.4.2. Medical Event Form

Information for medical events, medical events, AE’s and SAE’s will be collected using the study medical event form. This form will be administered by staff

trained and certified in the identification and collection of the Medical Events form, the Adverse Events/Interim Events form and the Serious Adverse Events Form. The medical event form will be staff interview administered at the four month visit and at all annual visits. The information on this form will guide staff and investigators in determining if the event requires the SAE form to be filled out. It asks questions on hospitalizations, medical events, motor vehicle accidents and study terminating events. For each medical event reported, staff will record the date of onset and the date of resolution; should the problem be ongoing then staff will enter NA for date of resolution.

Based on the participant report of the event staff should determine if the event was life threatening, defined as an event that places the participant at immediate risk of death from the event as it occurred, or if the event resulted in a disability that is significant or persistent (lasted a month and changed the participant's life).

Questions 2a though 2j and Question l are single answer questions.

Question k asks about pregnancy and the outcome. Staff should gently probe to determine if the child was born with a congenital abnormality or birth defect which would trigger a SAE form.

Question 2m: asks if the individual is using weight loss medications including herbal remedies and asks you to write in the herbal products in a text field.

Question 2 n: asks about motor vehicle accidents, if yes, please complete additional questions in Question 4.

Question 3: provides a text field for any yes answers. In this space you will fill in all the important details of the medical event including information that can help determine if this is study related. An example might be: participant was hospitalized for June 1 – 5, 2010 for a ruptured appendix. Developed high fever post-op and received several days of IV antibiotics. Fever resolved with no additional complications and participant was released to home with instructions to follow-up with surgeon in one week. Participant is 2 months post op with no further complications.

Question 4: asks for additional information on any motor vehicle accidents.

Question 5: asks you to if a. a SAE occurred yes no

An SAE is an event that:

- Is fatal or life threatening
- Results in a significant or persistent disability
- Requires or prolongs hospitalization

- Results in congenital abnormality or birth defect

and b. if any study terminating event occurred.

A study terminating event is defined as a yes answer to2k pregnancy or the occurrence of any event or condition that would make continuation in the study unsafe for the participant or others.

13.4.3. Serious Adverse Event Definitions and Reporting

For SNAP purposes, a Serious Adverse Event is defined as a health related unfavorable or unintended medical occurrence that happens during the process of screening or after randomization. Specifically meets one or more of the following criteria:

- An event that results in death

  All deaths should be reported on the Serious Adverse Event Form at the time clinic staff learns of a participant's death, and faxed to the coordinating center within 24 hours.

- Is a life threatening event

  A life-threatening event is one that places the participant at immediate risk of death from the event. A urinary tract infection is not considered a life threatening event; however, a urinary tract infection complicated by pyelonephritis and septicemia may be considered life-threatening. Cancer would be considered a serious event; however in most circumstances cancer would not put the participant at immediate risk of death from the event.

- An event that resulted in a disability

  This would be an event that is significant or persistent (lasted at least 1 month and changed your life). Any event or condition that changes or disrupts the participant's ability to carry out normal life functions is considered a serious adverse event if it was permanent or severe. Clinical judgment is required to determine if the event is truly permanent or disabling. For example, a participant might have a ligament tear, which could be surgically repaired; therefore this is not a permanent or severe disability. However, if the participant has decreased range of motion as a result of the tear and was not a surgical candidate due to other health problems, then it may be reported as a permanent disability and should be recorded on the Serious Adverse Event Form.

- A pregnancy resulting in a congenital abnormality or birth defect

Any pregnancy outcome with a congenital abnormality, regardless of lifestyle intervention or medication use during the study, requires completion of the Serious Adverse Event form.

- Any hospitalization (overnight or longer)

Any time the participant is hospitalized overnight in an acute care facility a Serious Adverse Event Form must be filled out. Examples include emergency hospitalizations, planned hospitalizations, such as surgery for an elective Cesarean section and hospitalizations for mental health.

13.4.3.1. SNAP Serious Adverse Event Form

The Serious Adverse Events Form is completed by an unmasked staff member (aware of intervention group assignment) as soon as a serious adverse event is identified based on the Medical Event Form. This is necessary so that the staff member can probe regarding a possible relationship between the intervention and the serious adverse event. The purpose of the form is to collect information on SAE's for reporting to the DSMB, IRB and NIH; it identifies those SAE's which require expedited reporting to NIH. The form will be completed by clinic staff trained and certified in SAE identification and collection and reviewed by the investigator. The form should be completed whenever an SAE is identified.

- Based on SAE's identified on the Medical Events form at regular data collection visits.
- Based on interim reporting, for example an intervention visit or a telephone contact.

Once completed, a copy of the form must be sent to the coordinating center on a weekly basis except in the case of death which must be faxed within 24 hours to the Coordinating Center. This provides for central safety monitoring of all serious adverse events in a timely manner. In addition, local needs for Institutional Review Board reporting are also met as well as data for DSMB reports.

Question 1: This question asks if a Serious Adverse Event occurred, if the event was reported at a regular data collection visit or at an interim visit, and how the event came to our attention. This data may be helpful in determining if there is any ascertainment bias within the SAE reporting.

Question 2: Is used to collect information that will help determine the severity of the event and if the event is related to the study. This question will ask you to describe details of the event; whether or not the event was diagnosed by a health professional; if the event is one that existed prior to the study; what the

individual was doing at the time of the event; if treatment was needed and if so, what type of treatment.

Question 3: Asks you to record the current recovery status of the event.

Question 4: Asks you to define how the event may have impacted the study intervention. For example, if the participant was hospitalized for leukemia and was undergoing chemotherapy, it is likely that the intervention has been stopped. If the individual was hospitalized for knee surgery, it is likely that the intervention has been modified. If the participant was in the control group, it is likely that the event had no impact on study participation.

Question 5: Asks in the opinion of the investigator was the SAE related to the study.

Question 6: Asks in the opinion of the investigator, was the SAE Expected or Unexpected. This is a very important determination; expected events are defined in the study protocol and are known to occur to young adults in the age range included in SNAP. A list of the Expected Events are found in the Appendix to this chapter.

Question 7: Asks you to choose a category for the event. If one or more applies, choose the one most likely to be study-related and/or unexpected.

13.4.4. Expedited Events

Two types of events will require expedited reporting:

First, Events or problems which are unexpected or unanticipated;

AND

Possibly, probably, or definitely related to participation in the study;

AND

Are fatal, life threatening, or serious.

These events will require reporting within 7 calendar days to the NHLBI Program Office.

For example, if a participant came into the clinic, slipped stepping off the scale as they were being weighed, fell on the floor, sustains a head injury and dies, this would be serious, unexpected and related to the study and require reporting within 7 days.

A second example of events that may not be serious but are events or problems which are unexpected or unanticipated;

AND

Possibly, probably, or definitely related to participation in the study;

AND

Not serious, but suggest greater risk or harm to study participants than was previously known or recognized. These events will require expedited reporting within 30 calendar days to the NHLBI Program Officer.

For example, three participants' have come into the clinic all complaining of oozing sores on the upper arm from wearing the arm bands. Further investigation reveals that this is serious contact dermatitis. This would be an example of something unanticipated (we would not have expected an exercise arm band to cause serious dermatitis) it is related to the study because we have asked participants to wear the arm bands, and it suggests a risk of harm to participants. This suggests greater risk of harm to study participants than was previously known or recognized, and will require expedited reporting within 30 calendar days to the NHLBI Program Officer.

13.4.4.1. Expedited Reporting Procedures

For expedited reporting reporting to NHLBI please use the following guidelines for the information supplied:

- Study Name, Grant/contract number, PI name
- Description and date of the event including why it merits expedited reporting
- If available, dates the event was reported to IRB
- Any corrective action planned or taken in response to the event or problem. For example, study suspension, consent or protocol changes, and additional training or security measures.

A form for Expedited Reporting is found in Appendix A.

13.4.5. Study Termination Form

The purpose of the study termination form is to collect information on how many participants terminate the study and why. Termination is defined as stopping the study entirely (both intervention and data collection). This form is completed by

research staff whenever a termination occurs and records the reason for termination. It will also be used when participants re-enter the study.

13.5. DATA SAFETY MONITORING BOARD

An external Data Safety Monitoring Board (DSMB) has been established to periodically review study data for the occurrence of serious adverse events, safety concerns, and outcomes of interest. This board will be asked to address serious adverse effects and the risk to benefit profile for all study participants. Guidelines for early stoppage of the study and for recommendations for changes in the study protocol will be defined for use by the Data Safety Monitoring Board. The board will review these guidelines and make recommendations for early stoppage of any component of the trial based on regular review of all pertinent study data. The coordinating center will have the responsibility for analyzing interim data and preparing data safety monitoring reports that the committee will review. These reports will include data on all serious adverse events and study outcomes for all study participants. An annual report from the DSMB will be sent to the clinical centers to update local Institutional Review Boards.

Appendix 13.A – Expedited Report Form

1. Study Title _____

2. Grant/Contract Number _____

3. IRB Number _____

4. PI Name _____

5. Participant Study ID_____

6. Date of Event and description of problem.

_____

_____

_____

_____

7. Why does this event merit expedited reporting?

_____

_____

_____

_____

_____

8. Date reported to local IRB ___/___/____
   Not yet reported ____

9. Any corrective action planned /taken in response to the event?

_____

_____

_____

The report should be emailed with Expedited SAE in the subject header and a copy sent to the following individual and a copy sent to Judy Bahnson at the CoC:

Joni Poe, RN, BSN, MA
Clinical Trials Specialist
NHLBI, DPPS, CAPB
Suite 10018, Room 10104, MSC 7936
6701 Rockledge Drive
Bethesda, MD 20892
(301) 435-0408
poej@mail.nih.gov
Fax: (301) 480-5158

Appendix 13.B – Serious Adverse Events Categories for Coding

FOR CODING PURPOSES:

Event	Category for coding
a. Heart trouble	Cardiovascular
b. Fainting	Cardiovascular or other
c. Stroke, ministroke (TIA) or other neurological problem	Cardiovascular
d. Muscle or bone injury (for example, broken bone, torn ligament, sprain)	Musculoskeletal
e. New diagnosis or hospitalization for diabetes	Diabetes
f. Gall bladder attack or surgery or gallstone pancreatitis	Gall bladder disease
g. New diagnosis, started treatment or hospitalized for depression	Psychiatric
h. Eating disorder (such as bulimia, anorexia, etc)	Psychiatric
i. New diagnosis, started treatment or hospitalized for any other mental health problem	Psychiatric
j. Asthma attack: leading to hospitalization or visit to emergency department or urgent care	Asthma
k. Pregnancy	Obstetric
l. Weight loss treatment (such as bariatric surgery, stomach banding, liposuction)	Wt loss-related
m. Weight loss medication (including herbal remedies)**	Wt loss-related
n. Motor vehicle accident (See additional questions below)	MVA
o. Other	Other
p. Site specific AE	To be specified by site

Appendix 13.C – Anticipated and Expected SNAP Events

Common causes of serious adverse events and/or hospitalization in this age range include:

- digestive system diseases
- mental disorders
- unintentional injuries,
- genitourinary diseases,
- respiratory diseases,
- musculoskeletal diseases,
- endocrine diseases,
- neoplasm's/cancer,
- diseases of the heart,
- Pregnancy and pregnancy-related complications, and infections. Births with congenital anomalies also occur although rates are rare.
- spontaneous and elective abortion
- the development or worsening of eating disorders (e.g. bulimia nervosa),
- asthma exacerbation
- various injuries,
- Death, including unintentional injuries (accidents, homicide),
- intentional injury (suicide),
- malignant neoplasm's,
- diseases of the heart,
- congenital malformations,
- HIV disease,
- pregnancy/childbirth/puerperium,
- cerebrovascular diseases,
- diabetes mellitus,
- influenza/pneumonia,
- chronic lower respiratory diseases,
- chronic liver disease, and
- Septicemia.

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Data Management
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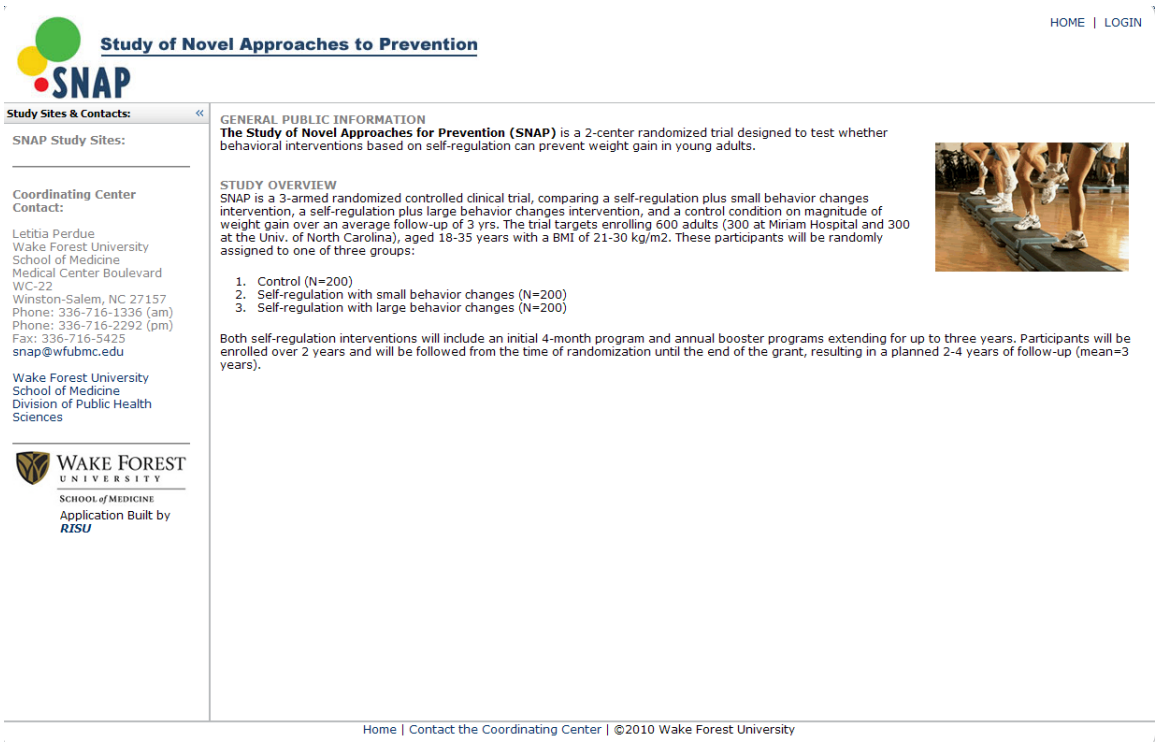
14. Data Management

14.1. OVERVIEW

The SNAP study website is designed to provide data entry, reporting and study management capabilities for study personnel. It also provides data entry, reporting and visit tracking capability for study participants. It is best viewed using Microsoft Internet Explorer 6.X or higher.

14.2. PUBLIC SITE

The first page displayed when going to the site (http://www.snapstudy.org) is the public home page:

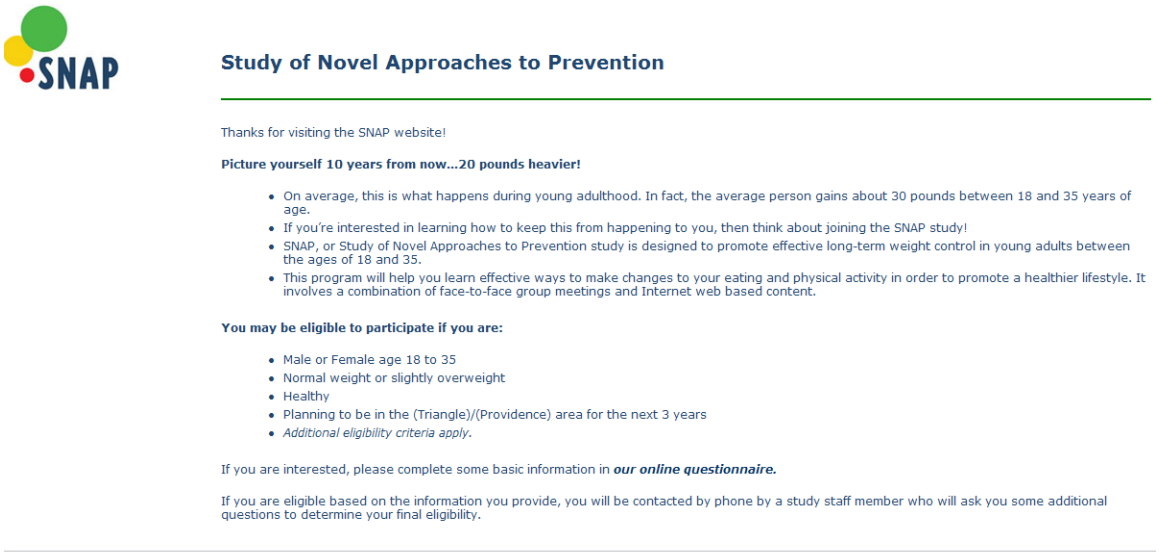


It is designed to provide general information about the study. This area does not require a password. The page is comprised of 5 areas:

- Top header: contains the logo and Home and Login links
- Left side: contains information and links to the Participant Information and Pre-Screening form, Study Sites and Coordinating Center contact information
- Middle: The main body of the page that contains an overview of the SNAP Study. It includes a description of the study and the aims
- Bottom: Includes a link to the study's funding agency (NHLBI)

- Footer: Contains ‘Home’ and ‘Contact the Coordinating Center’ links

Both study staff and participants will access the public home page as their starting point for data entry and tracking. However, as participants are recruited, they will first be directed to the SNAP Study Information page (www.snapstudy.org/info/):



Here they will find information about the study, and, if they agree to the terms of participation, they can complete the online Pre-Screening form to begin the eligibility evaluation process.

14.3. NAVIGATION TIPS

Text may sometimes extend beyond the limits of the computer screen. The user will see vertical and/or horizontal scroll bars to the right and at the bottom of the screen when this occurs. Click on these bars with the computer mouse to move the text into view. Links may or may not be underlined. Selecting a link will take the user to the other areas of the website. The main method of navigation should be the use of the menus, tabs and links to ‘Home’ and ‘Logout’ rather than the use of the browser’s ‘Back’ button.

14.4. STAFF WEBSITE ACCESS

All staff members are given access to the website. When new staff members are hired, the Program Coordinator should provide the following information to the Coordinating Center:

- Full name
- Study role
- Valid e-mail address

- Contact information such as mailing address, telephone number, fax number, pager or cell phone information
- Administrative assistant information (where applicable)

A member of the web development team will add the person to the website directory and the system will assign an identification number to the new staff member. A user name and system-generated password will be e-mailed to the new staff member. This password **must** be used to login to the website for the first time, at which time they will be prompted to change the password to one they create. Enter the new password in the 'New Password' field and then enter it a second time in the 'Confirm Password' field. The password the user creates must be at least 6 characters in length and contain at least one number and one upper case letter. Users who have forgotten their password information may contact a member of the web development team at the Coordinating Center and a reset password will be e-mailed to them.

14.5. PARTICPANT WEBSITE ACCESS

Clinic staff will create Participant's Login accounts at the SV1 visit using the 'Add New User' section of the website. Once the login information is saved, a username and temporary password will be generated and displayed on the screen. This can be printed and given to the Participant with instruction on how to access the site and login.

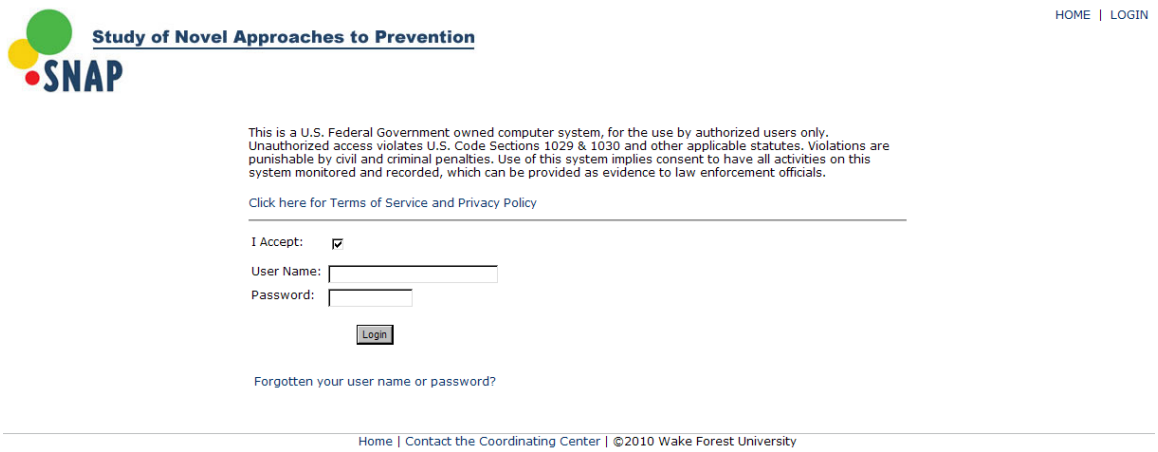
14.6. FEATURES OF THE WEBSITE (STAFF)

14.6.1. Login

Once the browser is invoked on the computer, the following URL (web address) should be entered:

http://www.snapstudy.org

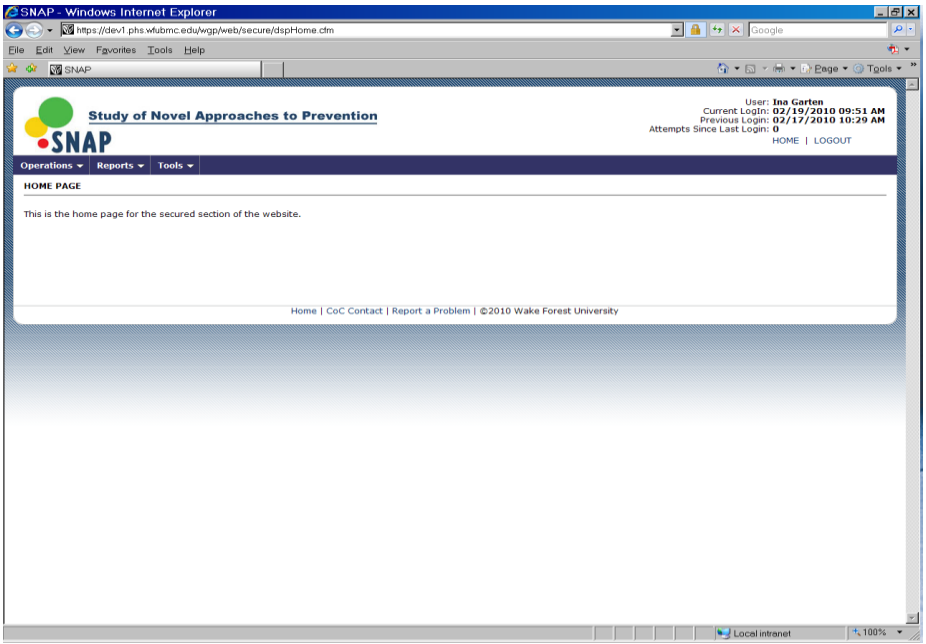
The SNAP study public home page will appear. A link to login is found in the upper right hand corner of the screen. Enter user name and password and click on 'Login.' The Login page will be displayed:



The system then utilizes an authentication system to verify the user information submitted. Once a valid username and password combination has been confirmed, the home page will be displayed. User should always login using their own username and password. Web activity, including access to the data management system, is tracked on an individual basis, using the individual's identification number that is assigned when login accounts are created. Levels of access to various areas of the site are determined by the person's role of the study, such as Data Entry.

14.6.2. Secure Home Page

Once the user has successfully logged into the website, the secure (non-public) home page is displayed. The major areas of the secure home page are described below.



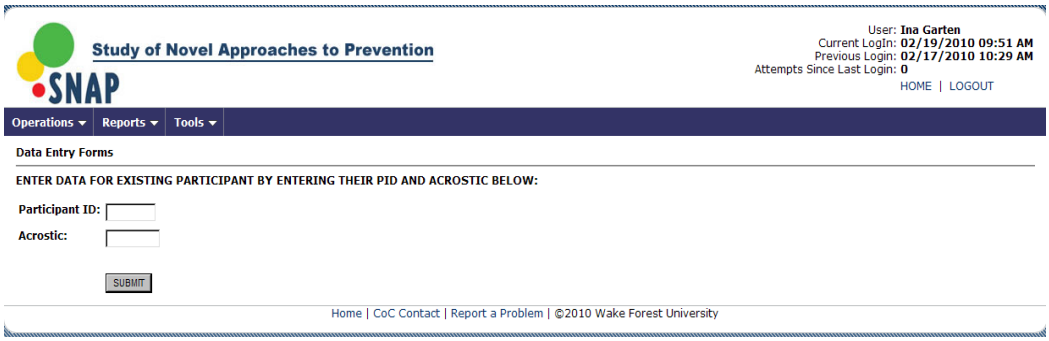
Header Information: In addition to the SNAP study logo, the following appears at the top right corner of every screen: 'Home' will return the user to the secure home page. 'Logout' should be used for exiting the website. The user's name, current login data and time, previous login date and time and number of login attempts since the last successful login are also displayed.

Main Menu Bar: The main menu is displayed on the blue bar and is available on all pages, except when data entering a form. The menu options are described below:

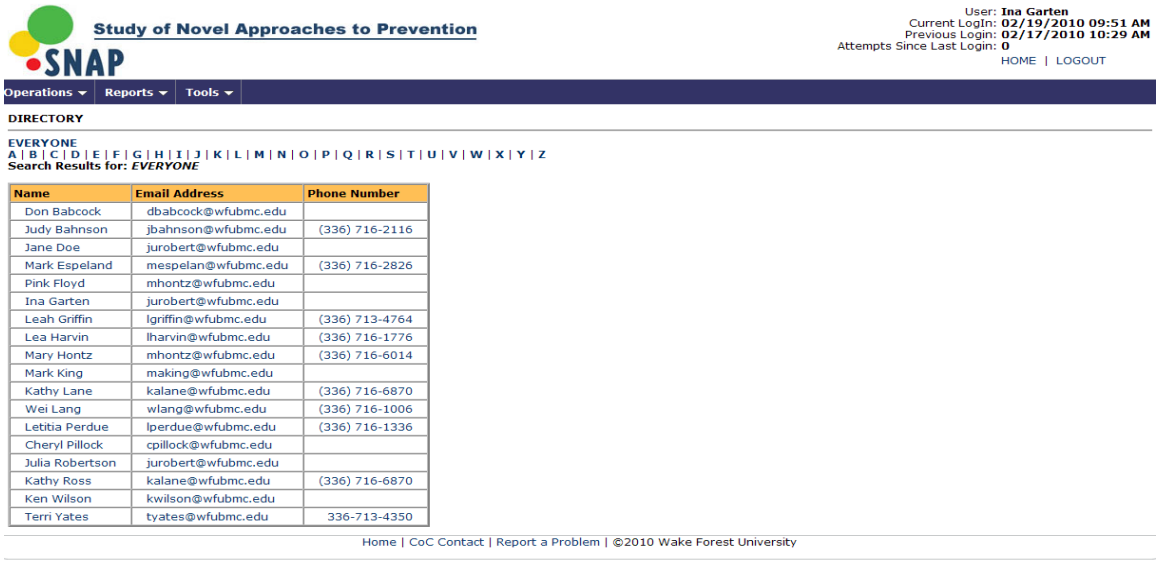
Operations:

The Operations menu item contains 4 sub menus:

1. *Data Entry:* This menu item displays the page that is the starting point for viewing and entering participant information:



2. *Directory:* The study maintains a directory of all staff that contains their contact information. Users may click on the letter associated with the first letter of a staff member's last name and get a targeted list of names. In addition, there is a way to search alphabetically. The link 'Everyone' will display all staff in alphabetical order. It is possible to send an e-mail to all staff members or to select staff to e-mail.



3. *Committees:* The Committees section will contain information on SNAP Study committees and its members.

4. *Documents:* The Documents section is designed to provide a central location for the various documents concerned with the study.

Reports:

The Reports menu item will contain submenus for each report created for study management and tracking.

Tools:

The Tools menu item will contain submenus for tools created for study management. Currently it contains the scheduling sub menu. The scheduling sub menu will provide the ability to maintain a SNAP study calendar for use by clinic staff to indicate their availability for in-clinic appointments and for participants to review and choose available –in-clinic appointment dates and times.

Footer Information: The following text appears at the foot of every screen. 'Home' returns the user to the home page. 'CoC Contact' provides the ability to send the Coordinating Center an email. 'Report a Problem' is a means by which users can notify the web development team of any problems they may encounter on the site.

14.7. FEATURES OF THE WEBSITE (PARTICIPANT)

14.7.1. Login

Once the browser is invoked on the computer, the following URL (web address) should be entered:

http://www.snapstudy.org

The SNAP study public home page will appear. A link to login is found in the upper right hand corner of the screen. The login process for Participants is the same as described above in the Login section for Staff.

14.7.2. Secure Home Page

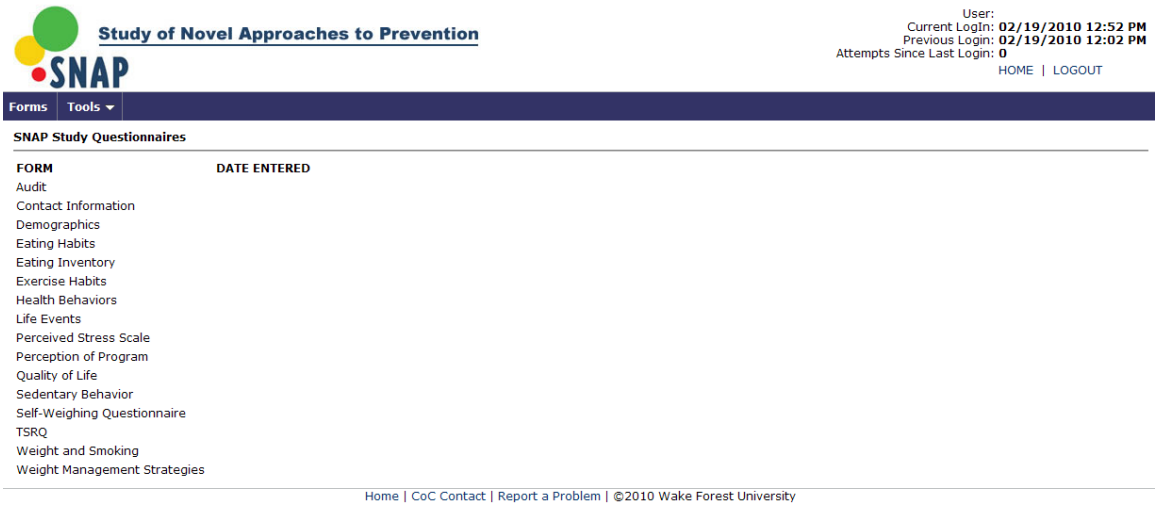
Once the Participant has successfully logged into the website, the secure (non-public) Participant home page is displayed.

The major areas of the home page are described below:

Header Information: In addition to the SNAP study logo, the following appears at the top right corner of every screen: 'Home' will return the user to the secure home page. 'Logout' should be used for exiting the website. The user's name, current login data and time, previous login date and time and number of login attempts since the last successful login are also displayed.

Main Menu Bar: The main menu is displayed on the blue bar and is available on all pages, except when data entering a form. The menu options are described below:

1. *Forms:* This menu item will display links to each of the questionnaires they need to complete for their upcoming clinic visit. Only the forms associated with the upcoming clinic visit will be displayed. If a Participant logs in greater than 2 weeks prior to their clinic visit, a message will be displayed, 'Questionnaires for X visit will be available on mm/dd/yyyy. Below is a view of what the Participant would see if logged in prior to their SV2 visit:

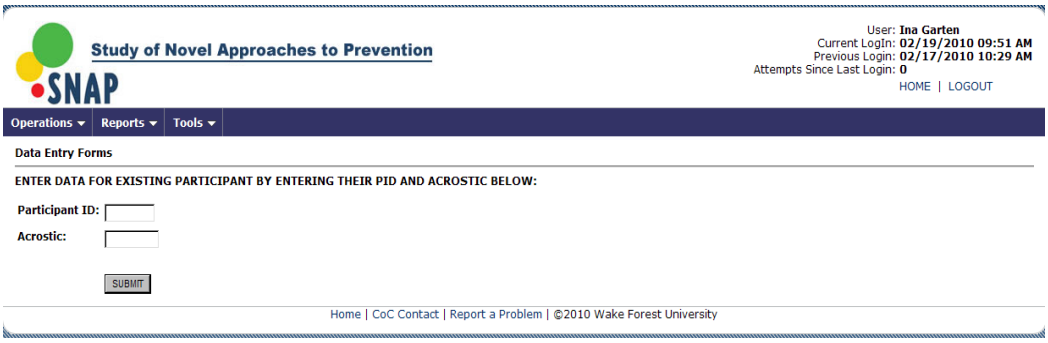


Footer Information: The following text appears at the foot of every screen. 'Home' returns the user to the home page. 'CoC Contact' provides the ability to send the Coordinating Center an email. 'Report a Problem' is a means by which users can notify the web development team of any problems they may encounter on the site.

14.8. SNAP STUDY DATA MANAGEMENT SYSTEM

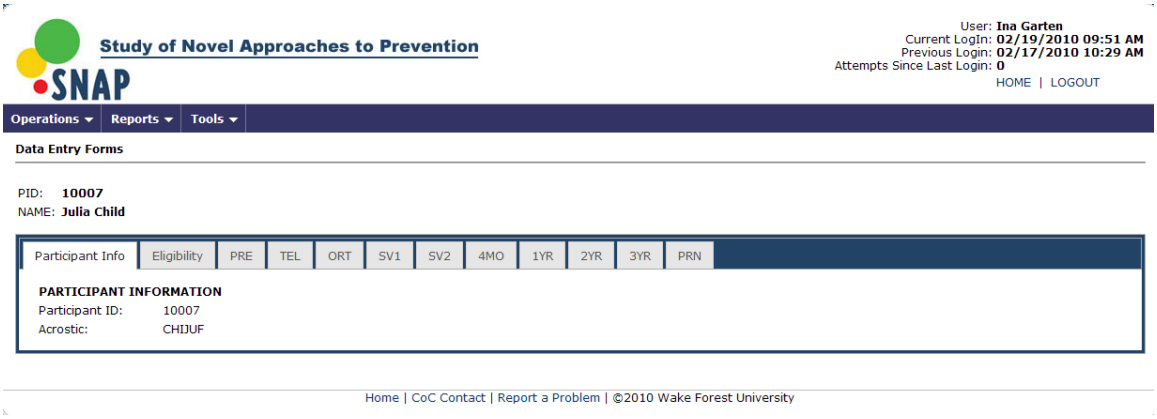
14.8.1. Accessing the SNAP Data Management System

Once staff members are logged into the SNAP Study website, staff members with data entry privileges should see a link on menu bar named ‘Operations.’ The data entry section can be accessed by choosing ‘Data Entry’ under the ‘Operations’ menu item. Clicking this link will display the Data Entry home page:



To begin data entry on a participant or to view participant information, including eligibility status, enter a valid Participant ID (PID) and Acrostic combination and click the ‘Submit’ button. The system checks the validity of the information entered and display the following message if there is an error: *The Participant ID and Acrostic combination you entered was not found.*

Once a valid Participant ID/Acrostic combination has been entered and verified by the system, the Participant ‘dashboard’ is displayed:



Further descriptions of each tab are below:

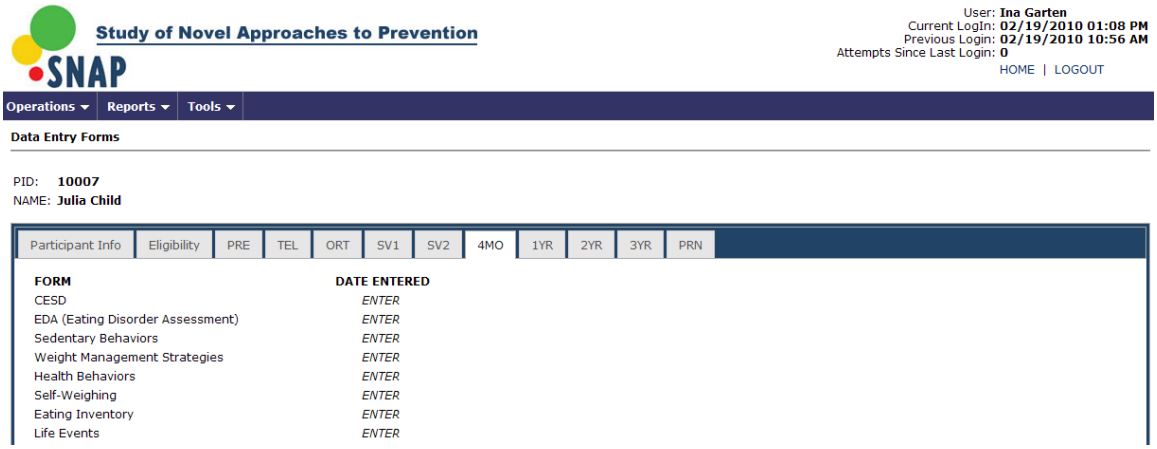
- Participant Info – lists participant name, ID, email address and phone number that can be used when calling the participant for the telephone screen.

- Eligibility – a report of the eligibility status for the participant by study time point. Drill down links are available to get more details on what items make the participant ineligible at each time point.
- Pre – the participant's Pre-Screening form (read only)
- Tel – the Telephone Screening Form
- ORT – the Orientation Form (includes information about informed consent)
- SV1 – Screening Visit 1 forms
- SV2 – Screening Visit 2 forms
- 4MO, 1YR, 2YR, 3YR, 4YR – Follow-up forms
- PRN – Special use forms such as the Medical Events Form, Serious Adverse Event Form, Intervention Modification Form and Participant Status Form.

14.8.2. Data Entry Screen Layout

The SNAP Study data entry area for clinic staff is organized with tabs for each visit, a participant information tab and an eligibility tab. Each visit tab contains a list of the data entry forms for that visit. Displayed on each visit tab will be a link to the questionnaires. The date the form was last entered/updated will be displayed in a column to the right of the form name. If a questionnaire has not been entered, 'enter' will appear in the column.

Below is an example of a screen that is displayed after a visit tab is selected, in this case, 4MO:



To add a new entry, users click on the ‘ENTER’ link under the date entered column.

14.8.3. Data Entry System Features

The system allows for data to be entered in HTML fields that are similar in appearance to the hard-copy form. The data management system performs several validation checks upon submission of the form. Data must match the correct type (numeric data in numeric fields), and required fields must be entered. When a form is submitted, an alert message appears if any required fields have been omitted or are outside of a specific range.

The main types of fields that appear on the data entry screen are:

Select boxes: for questions where only one response is acceptable

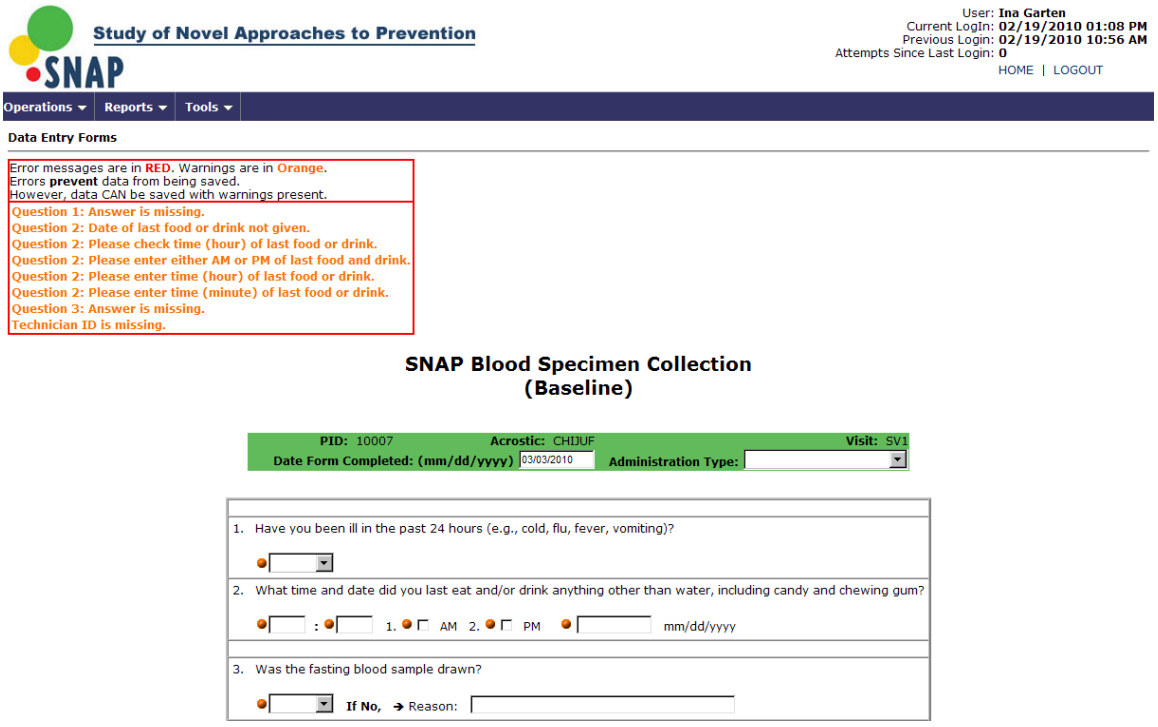
Text boxes: for entering text or numeric data such as age, weight, etc.

Checkboxes: for questions where multiple answers are acceptable

Date fields: for fields such as date of form or date of birth

The data management system automatically formats dates with slashes as they are entered. A date that is entered as 060601 will automatically be displayed as 06/06/01. Enter two digits for month and day. Use leading zeros in date fields when appropriate. The year must be entered as two digits.

After data has been entered and the user clicks the ‘Submit’ button, a list of rule violations may be displayed in the upper left corner of the screen. Error messages will appear in Red and warnings in Orange. There are also eye catchers of the same color to match the message being displayed next to the questions with a violation. A form may be saved with warnings but it cannot be saved with errors.



At this point, the user can either correct the data and 'Save' the form or elect to 'Save with Warnings.' This allows the user to save the form without addressing the edits. Keep in mind that this does not satisfy the need for the edit. It will continue to appear until the appropriate action is taken. The following screen confirms that their information has been successfully saved:

By clicking the 'Next Forms or Visit' link, the user will be sent back to the visit tab page now displaying information including the record previously added or edited. The 'Next Participant' link will return to the page where the user can begin entering data on a new participant.

14.8.4. Randomization

The randomization process starts with the completion of the randomization checklist. This can be found by choosing ‘Data Entry’ under ‘Operations’ from the menu bar and entering the PID and Acrostic. Once submitted, choose the ‘Eligibilty’ tab. This will display all of the participant’s eligibility information and provide a link to the final randomization checklist. Once the checklist is reviewed and information is completed, if the participant is eligible, the ‘randomize’ button will be displayed. If the participant is ineligible, the reasons for ineligibility will be listed.

14.9. WEB DEVELOPMENT TEAM CONTACT INFORMATION

Use the ‘CoC Contact’ from the SNAP website to send the Coordinating Center an e-mail.

SNAP MOP - Chapter 15
Quality Control
Table of Contents

15. Quality Control

15.1. OVERVIEW

Study-wide quality control is the ultimate responsibility of the SNAP clinical centers and the coordinating center. The SNAP Project Coordinator at each clinical site must become familiar with SNAP requirements and schedule clinic activities so that there is adequate time for clinic staff to carry out their responsibilities while meeting quality standards.

15.2. TRAINING

Key clinic staff from each clinical site will be trained at the initial SNAP central training session. We will use a train-the-trainer model, i.e., the key staff that is trained at the central training session will be responsible for training and re-training other staff members. Certification is mandatory in order to assure that clinic staff have a clear understanding of the SNAP Protocol and Manual of Procedures (MOP) and for standardization of procedures at all clinical centers. Training sessions will be designed for those staff obtaining core measures and interviews, the recruiters and the interventionists. In this chapter, both general and specific procedures will be described.

15.2.1. Certification

Certification is required of SNAP staff who perform any of the following activities: biological impedance; Bod Pod; Paffenberger or armband. The Program Coordinator (or designee) is responsible for documenting that each of the certification tasks has been completed using the SNAP Certification Forms found in Chapters 9 and 11 of the SNAP MOP. These forms and supporting documents are to be maintained at the clinical center in a certification file, and will be reviewed at the time of a site visit. The documents should not be sent to the coordinating center.

15.2.2. Certification of New Program Coordinators

Clinics will notify the coordinating center when a new Program Coordinator is hired at a SNAP site. A certified SNAP Program Coordinator will be designated to train the new staff in the SNAP procedures. Trainings may be conducted by several conference calls in addition to onsite training.

15.3. QUALITY CONTROL ACTIVITIES

15.3.1. Clinical Center Activities

Specific quality control activities to be carried out at the SNAP clinical center include:

1. Training of clinic staff in all components
2. Monitoring of regular equipment calibration and maintenance
3. Recording of participant identifier on the top of each questionnaire/data collection form prior to their completion at all clinic visits.
4. Regular observation and monitoring of clinical procedures including specimen collection.
5. Review of all questionnaires and data collection forms prior to data entry (and before the participant leaves the clinical center). Additionally, certain key data elements will be double data entered to ensure accuracy.
6. Compilation and review of data on lost laboratory samples, packaging problems, errors in packing, shipping and labeling of specimens.
7. Reporting of quality control concerns or problems to the SNAP coordinating center and/or the central laboratory for prompt resolution.

The Project Coordinator should regularly monitor clinical center procedures to be sure that they are being carried out properly and with consideration for the SNAP participant. Corrective action should be taken immediately if problems are observed.

The clinical center staff are encouraged to communicate with the coordinating center about quality control or other concerns or problems.

15.3.2. Equipment

The SNAP investigators have standardized much of the equipment for the trial. Such standardization (and the attendant maintenance and calibration of the equipment) assures one level of reliability across the SNAP clinical centers. Each clinical center is responsible for the proper operation and maintenance of equipment used in the SNAP trial. Some of the equipment is subject to standard calibrations and inspections (e.g., scales). It is suggested that responsibility for monitoring these standards be assumed by a specific individual, either the Project Coordinator or a designated Quality Control Officer. Any real or

suspected equipment problems should be reported promptly to the coordinating center. Details regarding equipment maintenance and calibration are contained in the respective MOP chapters.

All standard maintenance should be documented by date in a permanent log at the clinical center. Problems and solutions should also be recorded. Copies of the calibration records must be kept on file.

15.3.3. Data Quality

Clinical center staff are ask to review all of the participants' questionnaires and data collection forms prior to ending each clinic visit. Forms must be completed neatly and accurately, and every question should be answered. Written responses to any items on the questionnaires/forms should be legible.

The data entry screens will be designed to mirror the paper data collection forms to allow smooth flow from item to item and thereby minimize error with data entry. Verification of participant identifiers and visit numbers will be incorporated into the data entry system, in addition to gross range checking of fields.

The coordinating center will regularly perform internal comparisons of the entered data to detect missing records or suspicious or invalid data. These comparison will include logical consistency checks of data within and across forms/questionnaires. When inconsistencies are detected, the clinical center will be notified and will be asked to verify, if possible, some entries. Prompt action with these verification requests is essential for an efficient quality control system.

15.3.4. Quality Control for Central Laboratory

Results of quality control procedures carried out at the Central Laboratory will be regularly reported to the Steering Committee.

15.3.5. Coordinating Center Activities

Quality assurance will be a major activity of the coordinating center throughout the study. Activities will include:

1. Training/retraining of clinical center staff in data collection procedures
2. Data control (filing, manual editing, special coding efforts)
3. Monitoring of data entry activities and error rates
4. Documentation of database changes

Monitoring of the SNAP study data will take place at the coordinating center. These activities include validation, data control and report generation. Some of the monitoring and quality control reports will be transmitted to the clinical centers for immediate action and attention; other quality control and monitoring reports will be generated for the NHLBI Project Officer, the Steering Committee and the Data and Safety Monitoring Board. For examples, these reports will include data on:

- Recruitment yields at each clinical center
- Serious adverse events
- Deviations from the protocol
- Missed visits, refusals, losses to follow-up
- Errors in collection, labeling, storage, shipping of laboratory specimens

It is the responsibility of coordinating center personnel to review these reports on a timely basis, to initiate action to remedy any problems as soon as possible, and if necessary, to participate in site visits at the clinical centers, as well as to perform follow-up evaluations of action taken.

15.3.6. Reports to NHLBI and Steering Committee

During the recruitment period of the trial, real-time reports on recruitment activities by each SNAP clinical center will be available via the study website for use and viewing by the Steering Committee, the Principal Investigators and the NHLBI Project Officer.

During all phases, monitoring reports and analyses will be generated for each clinical center and the whole study. These will be available to the Principal Investigator, the Steering Committee and the NHLBI Project Officer.

15.3.7. Data Safety Monitoring Board Activities

The Data Safety Monitoring Board (DSMB) is an independent panel of experts who review and advise on the scientific and operational progress of SNAP. The DSMB will periodically review and evaluate data on recruitment, quality control, adverse events, and outcomes. This panel will report directly to the NHLBI and may recommend corrective action, changes in the protocol, or early stoppage of the study. The DSMB will also review and advise on proposed changes in the protocol originating from the Steering Committee.

15.3.8. Changes in the Manual of Procedures (MOP)

Changes in the MOP may need to be made from time to time. Clinic staff will be advised via e-mail and study conference calls when changes to the MOP are posted to the study website.