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1. EXECUTIVE SUMMARY

The Minnesota Center for Pediatric Obesity Prevention was created to evaluate a multi-setting intervention for low-income preschool children and their parents. The intervention, called NET-Works, integrates intervention components that are implemented in four settings in which parents and children already are engaged and spend their time. Thus, such an approach has the potential for long-term sustainability, community reach and maximum impact on behavior and obesity outcomes. The Center provides the opportunity to focus intervention activities on parents, who are the decision-makers and effectors of change for children in this young age range. Data will be collected to not only evaluate the impact of the intervention on primary outcomes and secondary mediating behaviors [physical activity and energy intake], but also on parent behavior and home environmental changes that mediate effects on behavior and body weight change. Thus, the field of pediatric obesity prevention will be moved forward by furthering scientific knowledge about models of parenting behavior, the home environment and community influences on child energy balance behaviors and healthy body mass index development.

NET-Works is poised to begin recruitment in May/June 2012 through its partnerships with 15 primary care clinics in the Minneapolis-St Paul metropolitan area that serve low-income racial/ethnic minority families with preschool children. Through the pilot study experience [June 2011-February 2012], the NET-Works investigators and staff have gained experience and developed partnerships with a broad range of health care systems and specific primary care clinics within these systems. This infrastructure will enable the target 500 families to be recruited and enrolled over an estimated 18-month period. An identification and screening process tailored to each clinic's unique setting has been developed. Interested and eligible families will be screened by telephone and scheduled for a baseline data collection visit.

Baseline data collection takes place in the family home with culturally matched, trained data collection staff. Baseline data collection occurs over two home visits which allows informed consent to be obtained and a comprehensive set of measures to be completed without causing undue burden and fatigue that might result if the measures were completed in a single home visit. Moreover, this "run-in" period will facilitate enrollment of participants who are most likely to remain engaged across the three year study period. Final eligibility determination, consent processes, anthropometric, dietary and other demographic and behavioral survey measures are collected at the first data collection home visit. During the second baseline data collection home visit, the remainder of the dietary and behavioral surveys are completed. Parent-child dyads are randomized following completion of the baseline measurements.

All enrolled parents receive messages from their primary care provider during the well-child visit for their preschool child. Messages target healthy eating and physical activity behaviors and limiting screen time. The importance of creating a healthful home environment around eating, physical activity and limited screen time for overall child health and development is emphasized.

Parents randomized to the intervention group are engaged regularly during the three year intervention through two main channels: a family connector home visitation program and parenting classes held in a nearby community setting and staffed by NET-Works parent educators. The parenting classes and the family connector visits enable parents and their children to be connected with community food, physical activity and school readiness resources in their local neighborhood, as these connections are weaved directly into the parenting classes and family connector visiting programs.

The home visiting component enables a culturally matched, trained family connector to build a relationship with the parent, enhance motivation for target behavior and home environment changes, and facilitate goal setting and skills development in a way that fits within each individual family's home environment and circumstances. The parenting classes provide a group support setting where the same target parenting behaviors and home environment changes are supported, facilitated and reinforced. The home visiting family connector and parenting class components are designed to be synergistic; their combined effect on parent and child behavior change is stronger than the individual additive components. The family connector attends the parenting classes with the parents, and the parent group setting builds social support, creates and enhances social networks within and outside the classroom setting.

The primary outcome of the NET-Works intervention is change in child body mass index at 24 and 36 months. Secondary outcomes are change in energy intake and expenditure. Mediators that will be evaluated are related to the conceptual framework of the intervention, and include changes in the home food, physical activity and sedentary behavior environment, changes in general parenting behaviors and parent feeding behaviors, and interactions with the local neighborhood environment food and physical activity resources. Extensive and detailed process evaluation measures will enable the process of intervention delivery and dose received to be evaluated to describe how intervention components and dose are related to target behavior changes in parents and children.

The results of this research will move the field of pediatric obesity prevention forward in several respects. The evaluation of the efficacy of a multi-setting obesity prevention intervention targeting parents of preschoolers will provide critical information about the scope, scale, type, breadth and intensity of intervention needed to prevent obesity among low-income preschool children. It will provide information about long-term engagement of parents around this issue, and connect it with broader whole child health and development goals that are of high concern among parents of preschool children. The intervention settings and approaches provide potentially sustainable models for broad-scale, long-term, community-based obesity prevention efforts that target parents and young children.

2. SPECIFIC AIMS AND OBJECTIVES FOR MAIN TRIAL

The goal of the Minnesota center is to integrate primary care, home, and community-based intervention strategies to promote sustained patterns of change in food intake, physical activity, and body weight among low income, ethnically diverse children. A

culturally matched family connector will create linkages among the settings to support parents in making home environment and parenting behavior changes conducive to healthy growth and development in their children.

Specific Aim 1
To evaluate the effects of a three-year multi-setting parent-targeted randomized controlled intervention on the primary outcome, child BMI, compared to a standard primary care-only intervention among low income ethnic minority two to four year old children who are at or above the 50th percentile of BMI for age and gender.

Hypothesis 1: Children in the multi-setting parent-targeted intervention will have a lower BMI at 24 and 36 months, compared with children in the standard primary care only control group.

Specific Aim 2
To evaluate the effects of a three-year multi-setting parent-targeted intervention on secondary outcomes, including change in child energy intake and physical activity energy expenditure, compared to a standard primary care-only intervention.

Hypothesis 2: Children in the multi-setting parent-targeted intervention will have lower energy intake and higher energy expenditure over the three-year period, compared with children in the standard primary care-only control group.

Specific Aim 3
To evaluate the effects of the multi-setting parent-targeted intervention on hypothesized mediators of change in dietary intake, physical activity, and BMI.

Hypothesis 3: It is hypothesized that changes in parenting behaviors and the home food and physical activity environment will mediate changes in child energy intake and expenditure, and body mass index.

3. BACKGROUND AND RATIONALE
School-Based Eating and Physical Activity Interventions
The largest and most comprehensive child obesity prevention interventions have been implemented in school settings and have directly targeted children themselves, as opposed to directly targeting parents (Luepker et al, 1996; Caballero et al 2003). Hip-Hop to Health specifically targeted preschool-aged children, (funded by NHLBI, 1999-2002), and randomized 12 Head Start programs that served three-five year old African American children (Fitzgibbon, 2005). Compared to control children, the intervention children's BMI-z-scores were significantly lower at the one-year and two-year follow-up measurements. A second intervention study conducted by the same investigators that targeted Latino three-five year-old children at 12 Head Start centers found no significant BMI z-score differences at post-intervention, one-, and two-year follow-up (Fitzgibbon, 2006). School-based interventions, including those in conducted in Head Start settings, have included limited parent involvement (e.g., newsletters, family nights). Although school-based child-focused obesity prevention interventions have contributed a great

deal to the scientific knowledge about pediatric obesity prevention, the limitations of single-setting approaches have become clear. BMI is a difficult biological outcome to influence with a sustained, single setting intervention that has limited parent involvement.

Family-Based Obesity Treatment Interventions
Results from the family-based child obesity treatment literature also inform the development of effective prevention programs (Epstein, 1994; Golan, 2004). Family-based obesity treatments are founded on the premise that the home environment and parenting practices are critical to the eating and activity behavior changes needed to successfully promote and sustain healthful body weight for children. Epstein's parent-family-based obesity treatment produced impressive results and clearly suggests that targeting parents is of critical importance. Other work also suggests that targeting parents is of critical importance, and can be more effective than targeting the child (Golan, 2004; Golan, 2006). Parent-targeted interventions are even more critical when preschool-aged children's behaviors are the focus. Children at this age are only beginning to establish eating and activity preferences and habits. Parents also are learning how their social interactions with their child influence the child's behavior. This broader set of parenting behaviors has recently become a focus on research interest and is described below.

Reaching Parents Through Community Settings
Reaching and engaging parents in obesity prevention efforts has long been recognized as important, yet is perhaps the biggest challenge facing researchers. Four settings are available for parent-targeted obesity prevention interventions with preschool children. These settings are locations where parents are already engaged in their daily lives, and thereby are promising settings for reaching and sustaining parent involvement. The four settings that are the focus of the NET-Works intervention are: Community parenting classes; home visiting programs, primary care provider clinics and community food and physical activity resources.

Community Parenting Classes
Community parenting classes are widely available in most states, and have broad appeal to parents from diverse racial, cultural and economic backgrounds. Minnesota offers the longest publicly funded parenting education program named Early Childhood and Family Education (ECFE). ECFE classes are offered through the public school system to help parents develop school readiness in their child. ECFE classes provide parents with the opportunity to build parenting skills and social support networks with other parents. A key ECFE program goal is to provide universal access to parents and children of all income levels, racial, ethnic and religious backgrounds. ECFE provides culturally tailored parenting classes, translated materials and active in-class translation as needed.

Parents of preschool children are typically very engaged around the issue of school readiness and are motivated to learn behaviors they can do to promote school readiness for their child. School readiness is a broad behavioral target and includes

child social and behavioral development. Healthy food choices, active play and limited television viewing and screen time are topics that fit well within the ECFE parenting curriculum. Thus, ECFE classes offer an existing parent-focused program in the community that dovetails with the obesity prevention messages of the proposed intervention.

Home Visiting Programs
Home visiting programs are available in most states and have a long history of providing health-related services to low-income at-risk pregnant women or mothers of infants and young children (Kitzmann, Olds et al 1997; Olds et al 1988; Eckenrode et al 2010). In addition to health-related home visiting programs, national early childhood parent education programs offer home-visiting models (such as the Parents as Teachers program). The ECFE program also offers a home visiting component for parents unable to attend group classes. Parents are familiar with many of these model home visiting programs and are very accepting of the one-to-one role that parent educators/home visitors play as part of a home visiting program. Although parenting classes and home visiting programs have been used separately and in various combined approaches, no evaluated programs exist that are designed specifically to work synergistically on similar parenting behavior and home environment change goals, and none have focused on child obesity prevention outcomes. The synergistic intervention combining parenting classes with home visiting represents a natural evolution of what has been to date only partially realized and never rigorously evaluated. For obesity prevention interventions focused on preschool age children, working with parents in the home environment and in a group-based parenting class has obvious advantages because the issues addressed are intimately tied to the home environment, family living circumstances, and parenting skills and challenges.

Reaching Parents Through Primary Care
Primary care is a second potentially important setting through which parents of preschool-aged children may be reached (Taveras, et al 2011). The primary care provider is an influential connection to shape parent behaviors around reinforcing and sustaining healthy child eating and physical activity behaviors related to healthy body weight. Thus, the primary care setting represents a unique intervention opportunity for parent-focused child obesity prevention. Pediatric care providers have frequent interactions with parents of young children and could play an important role in counseling and lending legitimacy to obesity prevention efforts. The primary care intervention will link with the community parenting component to deliver consistent intervention messages of high intensity and lengthy duration.

Community Food and Physical Activity Environments
Community parenting classes, home visiting and primary care intervention components can work synergistically to enhance the intensity, consistency and effectiveness of the child obesity prevention intervention. However, lower income families may reside in communities characterized by or perceived as having few resources for affordable healthful foods and affordable and safe physical activity opportunities (Chung, 1999; Rankin, 1998; Morland, 2002). Without perceived access to these resources, parents

may face significant economic, physical and social barriers to adopting the behavioral intervention messages. Thus, the intervention will enhance access to existing community food and physical activity resources, such as grocery stores, community gardens, community center education and activity resources and park and recreation programs. Enhancing access to existing affordable healthy foods and recreational venues may promote and sustain more healthful food purchases and physical activity behaviors among families.

NET-Works: Linking Parents with Primary Care, Parent Community Education and Community Food and Physical Activity Resources
The proposed intervention integrates primary care, community parenting classes, home visiting and community resources to develop an effective and sustainable community-based child obesity prevention intervention. Engaging parents across multiple settings in an integrated manner requires ongoing communication and coordination across settings and over time. A family connector is one potential approach to create synergy, coordinate resources and sustain consistent behavior change messages with parents. Family connectors can develop supportive relationships with families to provide ongoing motivation and reinforcement for changes in parenting behaviors and the home environment related to healthy eating and physical activity. The family connector concept is currently integrated into the existing format of the ECFE parenting program and there is an existing extensive research literature that supports the efficacy of home visiting on health outcomes. Home visits and regular telephone contact help maintain a consistent connection with a trusted advocate. The family connector has the ability to address the whole child health by assisting parents with connecting with other health, social and economic community resources. This type of integrated intervention can be sustained and adopted widely within the existing community parenting education program that includes a national reach.

INTERVENTION
Conceptual Framework
The NET-Works intervention integrates strategies that address the multiple levels of influence on child eating and physical activity behaviors, and body weight. Implementation of these strategies occurs in the home, family environment, and in the community. The family environment, the most proximal level of influence, includes variables such as parental attitudes and behaviors related to food and beverage offerings, family television viewing guidelines, home opportunities for active play, family meals and parental attitudes and behaviors related to eating and physical activity. Multiple community-level settings will be included in the intervention: primary care, parent-based community education, home visiting, and community food and physical activity resource access.

These components will be linked with each other to synergize within the family home environment, allowing families to receive consistent and multi-sourced messages and support for the targeted parent behavior and home environment changes. The intervention is expected to be feasible and effective partly through taking advantage of the settings that families already inhabit, and through incorporating coordination across

settings to reinforce and link the messages, resources and feedback families receive about healthful food choices, physical activity and healthy body weight for their child.

4. FORMATIVE RESEARCH – PHASE 1
The overall objective of the pilot study was to develop the intervention components into a cohesive, integrated package; implement the intervention among diverse ethnic groups with language translation and cultural tailoring; obtain feedback and experience from the pilot to further refine and adapt the intervention and measures for the full-scale study.

4.1. Specific Aims
The specific aims of the pilot study were to:
1) recruit 40 parent-preschool child dyads (ages two to four years) from three primary care clinics in the Minneapolis and St Paul metro area. Parents of each of three ethnic/cultural groups were recruited (Hmong; Somali; Hispanic);
2) randomize the 40 parent-preschool dyads to intervention or control group for a four-month period;
3) evaluate the intervention's integrated components that link primary care, home visiting, parenting classes, and community resources through a culturally-matched family connector;
4) examine feasibility of working with different cultural groups, including their receptiveness to the intervention and measurements;
5) examine the feasibility of collecting certain types of measures with parents and children ages 2-4 years (DXA, waist circumference);
6) evaluate the feasibility of data collection protocols (in-home; with translation); and
7) evaluate the acceptability of the intervention among participating families, including participation in each intervention component, satisfaction with the program, and behavior changes.

4.2. Results from Phase 1
4.2.1. Recruitment Logistics
For the pilot study, we adapted recruitment processes and procedures used during our previous pediatric primary care-based obesity prevention studies for use with new clinic partners for NET-Works. Our previous studies were conducted within the HealthPartners clinic systems. The HealthPartners system has infrastructure and support that is integral to the conduct of large research studies. Dr. Sherwood is a Senior Research Investigator at the HealthPartners Research Foundation. Both of these exigencies facilitated a smooth recruitment process in her previous studies in HealthPartners primary care settings.

For the NET-Works pilot study, we deliberately chose to create partnerships with three non-HealthPartners clinics to pilot the process of building relationships and creating infrastructure and support for recruitment and intervention activities. Through these partnerships, we identified study needs and requirements that will be used to make

decisions about clinic partnerships. These guidelines are outlined below and arose from our working experiences with the three pilot clinics.

From our work with non-HealthPartners clinics, we learned that it is possible to establish relationships and regular communications with clinic staff, including database staff, clinic managers and primary care providers. We identified a site liaison to help identify eligible families, gain family contact information, conduct training sessions for primary care providers, and set up a clear process to enable primary care providers to screen and approve families for study participation. We also learned that the time and effort involved in organizing study processes with clinic staff involve tradeoffs with the potential numbers of families eligible to enroll in the study, and with the cost of reimbursing clinic database staff for their professional time to work with us to identify families. The quality of the family contact information is an important criterion to consider in decisions about partnership with clinics. Agreement to include all primary care providers at the clinic in the intervention activities is essential, as is an efficient and timely process for primary care providers to review and approve families for study enrollment.

4.2.2. Home Data Collection Visits
For the pilot study, two baseline home data collection visits were conducted. During the first visit (approximately 1 hour and 20 minutes), informed consent was obtained, and height and weight of the index child, parent and other household members were measured, the parent completed the first part of the parent baseline survey and the first parent-reported child dietary recall, staff fitted the child and parent with an accelerometer, and explained to the parent the process for food purchase receipt collection. During the second home visit (approximately 1 hour and 20 minutes), the parent completed the baseline survey, a second parent-reported child dietary recall, and research staff completed a household food inventory and neighborhood block audit. The third parent-reported child dietary recall (30 minutes) was conducted by phone either between the two home visits or soon after the second home visit.

The home data collection visits provide the initial in-person opportunity to establish rapport with the family. We learned that families are receptive to home data collection visits and are able to complete the measures in a reasonable amount of time without undue fatigue. During the pilot follow-up data collection home visits, strategies were evaluated to order different measures within and between the two home visits so that participants remained attentive, interested and focused on the measurement activities.

4.2.3. Accelerometry Data Collection and Quality
Examination of compliance data for accelerometry at baseline for the pilot study showed that approximately 28% of children wear the accelerometers for 6 days/6hrs. If the threshold for compliance is dropped to 4 days, the compliance rate increased to 41%.. Data for 2 year olds indicate 40% compliance with 6d/6h wear time [n=10 2 yr-olds]. There were equipment failures (25% of the GT3X+ models failed). However, the reason for these failures has been identified and resolved. Less than 10% of devices were lost, which was better than anticipated. There has been no clear reason for non-compliance,

although participants were specifically queried about this at the time of the accelerometry wear instructions for the pilot follow-up data collection.

For the follow-up data collection, the following changes in the accelerometer data collection protocol were made:
1) Incentive distribution was changed to make the final part of the incentive payment occur following the accelerometry wear;
2) Changes were implemented to make wearing the accelerometer more fun for kids (stickers, naming the accelerometer);
3) Simplified the tracking tool that participants used to track the day and hours of wearing;
4) Underscored the importance of wearing the accelerometer for the full day and all days [including sleep hours]

Table 4.1.: Accelerometry Completion Rates (1-2 wears)

	Baseline		Follow-up	
	n	%	n	%
6-8 days of 6 hrs	11	28	14	35
4-5 days of 6 hrs	5	13	4	10
0-3 days of 6 hrs	17	43	10	25
Lost device	2	5	1	3
Lost to follow-up	5	13	5	13
Not due yet; in progress	0	0	6	15

4.2.4. Parenting Classes: Location, transportation and staffing
The Early Childhood Family Education (ECFE) Parenting Class format was piloted as initially envisioned, with ECFE Parent Educators and Child Educators conducting the 12 weekly sessions at ECFE community locations (schools). However, the cost of using ECFE staff and of providing transportation to the participating families was higher than the original budget estimate provided to us by ECFE. Further, it has become clear that training and supervising staff whose primary employer is ECFE and who have other significant teaching responsibilities creates many inflexibilities around class scheduling.

Based on the experience from the pilot, the parenting class and home visiting component staffing structure has been modified. To maintain the ECFE relationship, some staff and community space will be shared as part of the partnership. However, to form a more flexible, economical and efficient staffing model, parent educators and home visiting family connector staff will be hired, trained and supervised by our research project and our project director. Synergistic and structural components of the parenting classes, family connector home visits and community resource links are strengthened and amplified through this staffing model.

4.2.5. Pilot Intervention Participation
Moderately high participation was observed in the pilot intervention. Lessons learned from the pilot, including improved enrollment and retention processes, will be applied to

further improve intervention participation in the full-scale trial. There were a total of 20 intervention "doses," or activities that a family was encouraged to participate in, including 13 parenting classes, six home visits and one community grocery store tour. Of the 33 intervention families, 76% participated in one or more intervention activities: 31% participated in 16 - 20 activities; 18% participated in 6-15 activities; 27% participated in 1-5 activities and 24% did not participate in any activities.

4.3. Key Recommendations for Phase 2
4.3.1. Clinic Partnerships and Recruitment Timeline
Guidelines for establishing clinic partnerships to ensure efficient and timely recruitment for the full-scale trial include: 1) the establishment of an onsite clinic liaison; 2) requirements regarding the minimum number of 2-4 year old children seen at a clinic and the clinic's ability to provide accurate and timely information regarding child BMI and family contact information; 3) an efficient process for training all primary care providers in the study protocol and for obtaining primary care provider approval to invite families into the study; and 4) guidelines for establishing fiscal arrangements with clinics.

Based on our experience in the pilot study, the recruitment timeline will be expanded from 12 to 18 months. We are also expanding recruitment efforts and will be working with 15 clinics instead of the 10 clinics initially proposed.

4.3.2. Baseline Data Collection
The home visit data collection measurement visits worked well in the pilot and will be used in the main trial. Some adjustments in the order of the measurements within each of the two home visits will be made to maintain the interest of the parent participant and ensure quality data are collected for the survey measures.

4.3.3. Intervention Changes
The community parenting class component will remain twelve sessions per year. However, sessions will take place monthly instead of weekly. The monthly format delivers the same dose of the intervention component, but meeting monthly instead of weekly enables parents to continue meeting throughout the year, instead of only for a three-month period per year. It also allows time for the family connector to build relationships with the parents, make progress on goal setting and skills building in the home visiting component and provide support and reinforcement for the skills building taking place in the parenting classes.

4.3.4. Language Requirements
Based on recommendations made by the DSMB and our experience in the pilot study, eligibility will be limited to Spanish & English speakers.

5. STUDY POPULATION AND ELIGIBILITY

5.1. Eligibility Criteria

Recruitment will take place from clinics that serve lower income, ethnically diverse families located in targeted neighborhoods including HealthPartners (HP), University of Minnesota (U of MN) Family Medicine, Hennepin County Medical Center-affiliated clinics, and Children's Hospital of Minnesota outpatient clinics. Health care in the Minneapolis-St Paul area is provided mainly within a managed care environment by three large Managed Care Organizations. Because 90% of Minnesota residents are covered by managed care health plans, the age and sex distribution of insured people is comparable to recent U.S. Census figures for the Minneapolis/St. Paul metropolitan area.

Recruitment will include seven HP clinics, one U of MN clinic, two Children's Hospital clinics, and five Hennepin County Medical Center Clinics that serve predominantly minority populations. At each clinic, a clinic liaison connected with the local community will assist with recruitment. Race/ethnicity status and zip code information available in the electronic medical record will be used to focus efforts to recruit a diverse sample. Administrative databases and centralized electronic scheduling systems at our partner clinics provide data needed to target two to four year old children. The clinics have recent data from preventive care visits available for calculation of child BMI. Patient databases are available at each clinic for generating mailing labels and phone numbers. Table 5.1 shows data from each clinic on numbers of 2-4 yr old children served by the clinic.

Table 5.1 Age, Language, and BMI-eligible children seen for a well-child visit during an 18-month period across clinics

	HP-1	HP-2	HP-3	HP-4	HP-5	HP-6	HP-7	CH-1	CH-2	HCMC 1	HCMC 2	HCMC 3	HCMC 4	HCMC 5	U of M-1
Race/Ethnicity (n, %) African American	206, 48%	265, 30%	303, 55%	88, 15%	108,30%	300, 50%	69, 20%	1605, 33%	702, 21.79%	1671, 42%	165, 10%	131, 9%	83, 11%	x	153, 30.5%
Asian	19, 4%	72, 8%	66, 12%	61, 10%	26, 7%	85, 14%	81, 23%	82, 1.69%	141, 4.38%	119, 3%	16, 1%	21, 1%	3, <1%	x	36, 7.2%
Native American	7, 2%	5, 1%	6, 1%	2, <1%	4, 1%	4, 1%	0, 0%	52,1.07%	23, 0.71%		7, <1%	18, 1%	1, <1%		0, 0%
Caucasian	107, 25%	225, 26%	52, 9%	329, 56%	136,38%	120, 20%	130, 37%	1029,21.15%	945, 29.33%	477, 12%	182, 11%	219, 15%	120, 16%		4, 0.8%
Multiple	39, 9%	77, 9%	57, 10%	39, 7%	42, 12%	50, 8%	40, 11%	332,6.82%	325, 10.09%	159, 4%	33, 2%	45, 3%	22, 3%		6, 1.2%
Unknown	50, 12%	236, 27%	68, 12%	64, 11%	40, 11%	44, 7%	33, 9%	513, 10.54%	514, 15.95%	79, 2%	16, 1%	37, 3%	7, 1%		297, 59.3%
Hispanic (n, %)	47, 11%	164, 19%	62, 11%	31, 5%	48, 13%	40, 7%	39, 11%	1253,25.75%	572, 17.75%	1392, 35%	1241, 75%	996, 68%	520, 69%		5, 0.9%
Total Number	428	880	552	583	356	603	353	4866	3222	3979	1655	1465	755		501

HP Total Number=3755
HP-1   = Riverside
HP-2   =St. Paul
HP-3   =Midway
HP-4   =Como
HP-5   =Bloomington
HP-6   =Brooklyn Center
HP-7   = Maplewood
CH-1   =Children's Hospital and Clinics; Minneapolis
CH-2   =Children's Hospital and Clinics, St. Paul
HCMC-1 = Downtown Pediatrics
HCMC-2=Whittier
HCMC-3=Richfield
HCMC-4=East Lake Street
HCMC-5=St. Anthony Village (information not available yet)
U of M-1=Broadway

A child and his or her parent(s) will be eligible for the study if:

- the two to four year old child is scheduled to receive or eligible for (based on an upcoming birthday) a recommended well child visit conducted by a pediatric or family practice care provider;

- the child has no medical problems that would preclude study participation as determined by the physician conducting the well child visit (e.g. serious disease that would make following guidelines for parent encouragement of healthy diet and physical activity infeasible);

- the child's BMI is greater than or equal to the 50th percentile according to CDC age and sex reference standards http://www.cdc.gov/nchs/data/nhanes/growthcharts/bmiage.txt;

- the child's parent/guardian agrees to participation in the study and is not planning to move out of the state in the next three years

- the primary caregiver is willing and able to complete the evaluation measures and participate in intervention activities if assigned to the active intervention group.

- the parent speaks either English or Spanish.

5.2. Exclusions
A child will be excluded if she or he does not meet the above eligibility criteria.

5.3. Inclusion Statement
A parent/child dyad will be eligible for the study, randomized, and considered part of the permanent study denominator if they complete the following measures:

- child and parent completed weight and height measurements;
- two completed parent-reported child dietary recalls (either 2 weekdays or 1 weekend day and 1 weekday);
- valid child accelerometry data (4 days of 6 hours of valid data) either from the initial accelerometry wear, a successful accelerometry re-wear, or a combination of the two accelerometry wears; and
- parent completed all components of the parent survey.

6. RECRUITMENT AND RETENTION
6.1. Recruitment Tracking
The study database and reporting systems will enable the tracking of recruitment progress on a weekly basis. Information will be received weekly from clinics about potentially eligible children who are scheduled for a well-child visit. Parent will be mailed letters from the study investigators and primary care providers, followed by recruitment phone calls on a rolling basis. The number of children identified, the number of children

approved by the provider for recruitment, the number of letters sent, the number of families screened on the telephone, the reasons for ineligibility, the number of parents who schedule a baseline home visit, and the number of child/parent dyads who are eligible and interested in enrolling will be closely tracked on a weekly basis. Examination of weekly recruitment reports will allow the identification of recruitment process components that may need to be improved.

6.2. Recruitment of Minorities

Table 5.1 provides data on the racial/ethnic diversity of the clinics from which we will be recruiting for the NET-Works trial. Recruitment and data collection staff will reflect the ethnic diversity of the sample and every effort will be made to match the race/ethnicity of the data collection staff and family. We anticipate that approximately 30% of the study sample will be comprised of children and families of Hispanic origin, with a significant majority of those families preferring to communicate with the study team in Spanish. Several recruitment/data collection staff members who are fluent in Spanish have been hired.

6.3. Procedures for Obtaining Informed Consent

Informed consent will be obtained during the initial data collection home visit prior to the start of collection of study data. After confirming parent/child eligibility at the data collection home visit, a trained staff member will discuss thoroughly the consent form components with the parent. Staff will prompt parents to ask questions and restate main points of the study expectations and elements. Two pictorial figures are used to visually illustrate the study design, intervention and measurement components. Prior to the home visit, parents will have received a letter that includes a brief description of the study, followed by a phone call from one of the trained study staff. The telephone screening call initiates the process of informed consent, by beginning to describe the study components and answer questions that potential study participants might have. Study staff are trained in the process of informed consent. In the staff training, emphasis is given to fully communicating with potential participants about each study element, to enhance comprehension and commitment to the expectations of the study.

6.4. Randomization Procedures

Parent / child dyads will be individually and equally allocated to the NET-Works intervention or a comparison group. The N=500 randomized children will be boys and girls ages 2-4 whose BMI is greater than or equal to the 50th percentile for age and sex. We anticipate a non-linear trend in BMI over the course of the study that varies by age at enrollment and sex. We want to ensure equal allocation to treatment group within each age*sex stratum, and therefore plan to randomize children within each of these 6 strata.

The study statistician will generate a randomization schedule for each of the 6 age*sex strata. If study participants were enrolled equally across the strata, we would expect 500/6≈83 children per stratum. In anticipation of disproportionate enrollment, each randomization schedule will accommodate 160 randomized children. Each schedule will be divided into blocks of 10 slots, and each slot populated with 5 NET-Works and 5

comparison assignments in random order. Each schedule will be identified by stratum and loaded into the recruitment database. The database security settings will be specified so that only the statistician and database manager will have read privileges. These settings will prevent anticipation (except for the statistician and database manager who do not have direct contact with participants) of the randomization process by any member of the study team.

Each potential participant's contact information, including age and sex, will be loaded into the recruitment database upon identification as a potential participant and assigned a random and unique study identification number (studyid). The recruitment database will follow each potential participant from the point of identification through eligibility assessment and enrollment through disqualification or randomization. The recruitment database will track all eligibility and enrollment criteria, and include a utility that checks still-eligible study candidates for criteria that must be met prior to randomization. Upon identifying candidates who have met all of these criteria, recruitment staff will engage a database utility that performs randomization by identifying the stratum into which each potential participant should be randomized, and populating the next available slot in the appropriate randomization schedule with the participant's studyid. The database user is not able to see, and will be unlikely to anticipate, the treatment group that will be assigned to each participant, particularly when multiple candidates within a stratum are randomized at once. At this point, a permanent link is established between studyid and treatment group assignment. The link is viewable by the study statistician and database manager in the randomization schedules. Individual participants' assignments will be viewable by all study staff on a participant by participant basis so that the daily activities of managing participants may be done without hindrance.

Once randomized, all participants' studyids will be exported into a measurement table along with the fields necessary to conduct timely data collection and on-demand reporting by any study staff. Treatment group assignment will not be viewable by measurement staff

Once randomized, NET-Works participants' studyids will be exported into an intervention table along with the fields necessary to conduct the intervention and on-demand reporting by any study staff. Treatment group assignment will not be exported to the intervention table although its value is implicitly known. As such, intervention staff will know which participants have been assigned to the NET-Works intervention but this is unavoidable

6.5. Techniques for Retention
A wide-ranging menu of retention techniques will be implemented to ensure high cohort retention rates for the evaluation measurements for the three-year study duration. The Co-Principal Investigators are experienced in retaining participants in community-based trials for lengthy durations. However, the present study presents additional challenges because of the lengthy study duration and the inclusion of low-income, racial/ethnic minority participants, who may be more mobile and challenging to track.

Techniques used with success in our previous work include collecting contact persons who live outside the household; regular mailing to update contact information, using address correction requested; provision of financial incentives for data collection visits; provision of transportation and child care for data collection visits; flexible scheduling of visits; reminder phone calls for visits; following up missed visits; use of racially/culturally matched data collectors; establishment of a community liaison who is connected to the community and can build trust in the community with respect to the study; and developing good relationships between study staff and participants. Relationship-building is perhaps the strongest and most effective retention strategy available, and there are a variety of opportunities and methods to build trust and relationships with participants. As a further step to enhance trust, we are seeking a certificate of confidentiality for the study data. This will enable study staff to assure participants who may be in the country illegally that no data will be shared with legal authorities.

7. INTERVENTION
7.1. Conceptual Framework
Social ecological theory provides a theoretical framework for the intervention. The theory recognizes multiple levels of influence on a target set of behaviors (Stokols, 1992). Figure 7.1 illustrates the multiple levels of influence on child eating and physical activity behaviors, and body weight. The family environment, the most proximal level of influence, includes variables such as parental food and beverage offerings, family television viewing guidelines, home opportunities for active play, family meals and parental attitudes and behaviors related to eating and physical activity. Community levels of influence are shown in the outermost circle, and include primary care providers, preschool and daycare providers, parent community education settings, and faith-based organizations. Community physical environment reflects the availability of food retail outlets, recreational spaces and facilities, neighborhood safety, and the socioeconomic status and ethnic/racial composition of the neighborhood. All of these levels can influence the family home environment, which in turn, influences child dietary intake and activity patterns.

Figure 7.1. Social Ecological Model for NET-Works intervention

Figure 7.1 Social Ecological Model for Child Obesity Prevention
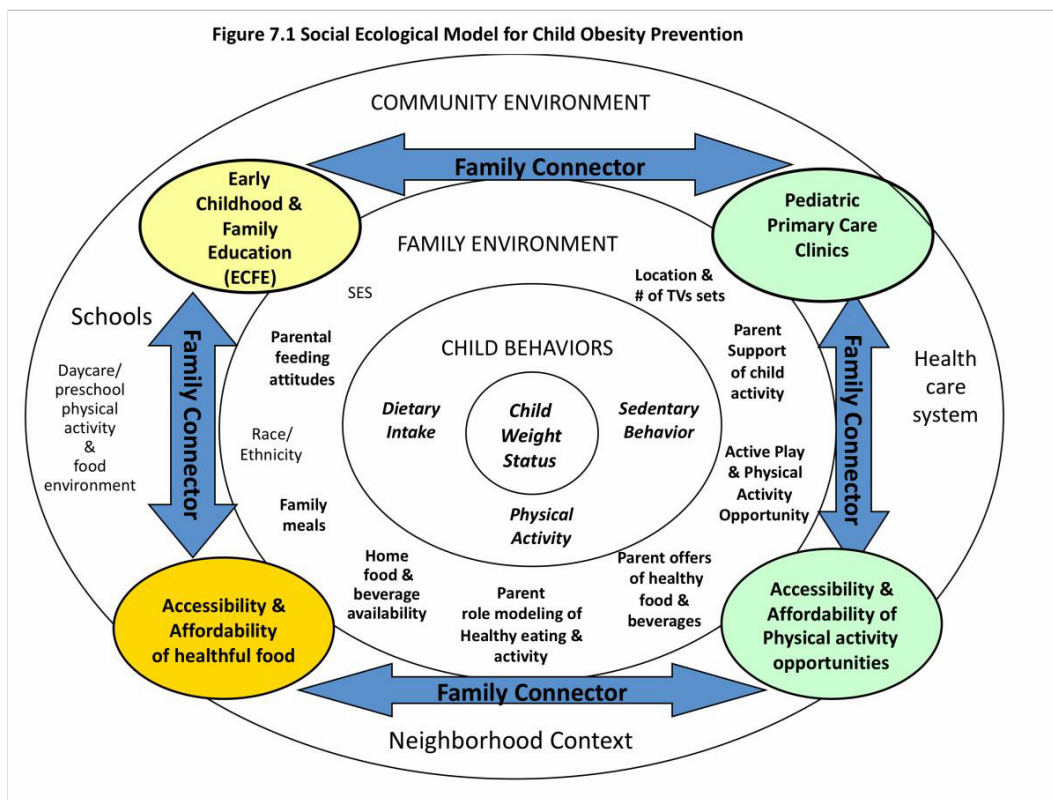
The proposed intervention reaches into the home and family environment to influence home variables including food availability, television viewing, physical activity and active play, parent attitudes and behaviors related to food, physical activity and television viewing. To accomplish this, interventions at the community level will be implemented. Multiple community-level settings will be included in the intervention: a primary care component, a parent-based community education and family connector support component, and a component focused on increasing physical and economic access to food and physical activity opportunities. These components will be linked with each other and with the family home environment, allowing families to receive consistent and multi-sourced messages and support for the targeted behavior and environment changes. The intervention is expected to be feasible and effective partly through taking advantage of the settings that families already inhabit, and through incorporating coordination across settings to reinforce and link the messages, resources and feedback families receive about healthful food choices, physical activity and healthy body weight for their child. The coordination of the three components is facilitated by the family connector.

7.2. Description of the Intervention

Table 7.2 presents a description of the NET-Works main study intervention components and the frequency and dose of each component.

Table 7.2. The NET-Works Main Study Intervention Components

Intervention Component	Year 1 (June 2012- May 2013)	Year 2 (June 2013-May 2014)	Year 3 (June 2014-May 2015)
Primary Care Provider (Well Child Visit)	1 Well Child Visit	1 Well Child Visit	1 Well Child Visit
Family Connector (Home Visiting & Connector calls)	9-12 Home Visits/yr (1 hour; 1 x/mth) Connector Calls between Home Visits and/or Parenting Classes (number; length; content)	9-12 Home Visits/yr (1 hour; 1 x/mth) Connector Calls between Home Visits and/or Parenting Classes (number; length; content)	9-12 Home Visits/yr (1 hour; 1 x/mth) Connector Calls between Home Visits and/or Parenting Classes (number; length; content)
Parenting Classes	12 classes/yr (2 hours; 1x/mth)	12 classes/yr (2 hours; 1x/mth)	12 classes/yr (2 hours; 1x/mth)
Community Initiatives (physical activity, healthy eating, school readiness)	4 initiatives (combination of pa, he and school readiness tailored to neighborhood)	4 initiatives (combination of pa, he and school readiness tailored to neighborhood)	4 initiatives (combination of pa, he and school readiness tailored to neighborhood)
Dose/Contact Per Year	37-42 hours contact time 25-32 doses (points of contact)	37-42 hours contact time 25-32 doses (points of contact)	37-42 hours contact time 25-32 doses (points of contact)

7.2.1. Primary Care

Families enter the study through primary care; the first point of intervention. The primary care provider is a key influential connection for parents and will deliver key messages for parent behaviors around shaping, reinforcing and sustaining healthy child eating and physical activity behaviors and body weight. The NET-Works team will feed back information to the primary care provider on an annual basis to reinforce continuity and integration of intervention messages. The primary care intervention will link with the community parenting classes and home visiting to deliver consistent intervention messages of high intensity and lengthy duration.

7.2.2. Intervention Staffing

The intervention implementation will be facilitated by a trained study team including a Parent Educator who will conduct the parenting classes and assist with coordinating the community initiatives activities, a Family Connector who will conduct the home visiting and connector calls and attend the parenting classes, and child care assistants who implement the child class curriculum and provide child care. Three teams will be hired.

Each team will work with specific neighborhood and cultural groups and work to integrate all of the intervention components in a synergistic manner across the parenting, home, and community environments. A neighborhood-based model will be more likely to enhance class participation, reduce transportation needs/costs, allow the local community resources to be accessed more easily, and foster outside-of-class interpersonal connections among parents for enhanced social support.

7.2.3. Parenting Classes

The parenting classes provide parents with the information, skills and support to parent positively, foster healthy relationships with their children, and promote optimal whole child development. Parents learn skills that can be applied within the context of their daily lives, and are encouraged to learn from and support each other. The curriculum is research-based, facilitated by a Parent Educator, recognizes the cultures of the families and considers the current needs and interests of parents and young children. The year one parenting classes will include the developmental parenting, school readiness and healthy eating and physical activity topics implemented during the pilot. The curriculum in years 2 and 3 will build upon and deepen the topics introduced in year 1, including addressing parenting and developmental issues as children progress from ages 2- 4 yrs. Years 2 and 3 will provide the opportunity for parents and family connectors to address areas in which progress has been more challenging for parents.

Parenting classes will be implemented in partnership with the Minneapolis and St. Paul School Districts Early Childhood Family Education (ECFE). ECFE in both school districts have agreed to partner with us by providing class sites within public schools and community centers, and by subcontracting some parent educator and family connector staff. These staff will be trained and supervised by our research staff. In the pilot, the parenting classes were implemented within the traditional ECFE model of weekly sessions. The pilot study experience showed that greater flexibility with families was needed in the timing of enrollment and class meetings. The main study implementation framework will retain 12 class sessions per year, but classes will be implemented monthly.

The content of the year one parenting education curriculum was implemented during our pilot phase. Table 7.3 shows the parenting topics for each of the twelve sessions. Process evaluation (teacher, parent, and trained observer), and focus group feedback indicate that the course content was well received, congruent with parents' experiences and expectations, and that integration of knowledge and skills were being translated into behavior change evident in the home environment. The curriculum delivery included culturally tailored parenting classes, translated materials and active in-class translation. Key parenting topics (routine and setting limits) and expansion around goal setting framework (specificity and emphasis) will be introduced earlier in the curriculum to facilitate enhanced uptake of behavioral goals in class and at home. Changes planned based on experience from the pilot including earlier introduction of key parenting skills topics and greater specificity and emphasis around behavioral goal setting.

Table 7.3. Parent Classes Topics

#	Topics	NET-Works Construct(s)	Objectives *By the end of the session, participants will be able to:*
1	• **Overview** • **Play**	- Active Play	• Understand the purpose and components of the NET-Works study. • Understand the class role is to support parents in raising healthy and active children. • View parenting skills as tools for establishing healthy eating and play habits in children. • Apply strategies to play with their children each day. • Begin to develop a sense of community through the group experience. • Create an action plan related to encouraging themselves, their child and/or whole family to develop healthy play habits.
2 - 3	• **Physical Activity** • **Attention & Encouragement**	- Active Play - Parent support of child activity	• Describe the experiences with following their action plan from the previous session. • Understand the benefits of active play and regular physical activity for adults and children. • Identify barriers to daily physical activity for themselves and children. • Develop and apply strategies to be active with their children on a daily basis. • Understand the importance of attention and encouragement in child development and managing behaviors. • Demonstrate how to verbalize encouragement and provide attention to their child. • Create an action plan related to encouraging themselves, their child and/or whole family to be active.
4 - 5	• **Feeding Relationships** • **Emotional Coaching**	- Parent support of child activity - Parent offers healthy beverage & food - Role modeling - Home foods - Family meals - Parent feeding attitudes	• Describe their experiences with following their action plans from previous sessions. • Understand the parent-child eating relationship and roles. • Describe challenges they may have when implementing recommendations on the parent's and child's role in the feeding relationship. • Understand the importance of validating children's emotions and behaviors. • Develop skills to listen to and talk with their children. • Create an action plan related to encouraging themselves, their child and/or whole family to develop healthy eating habits.
6 - 7	• **Family Values** • **Reducing TV & Screen Time**	- Parent support of child activity - TV - Role modeling	• Describe their experiences with following their action plans from previous sessions. • Understand the major concepts to help parents teach their children values, and to help parents understand how limits they choose can come from values. • Give examples of how parents are role models to their children. • Identify how, when and why TV is watched by themselves, their children and family. • Understand the importance and benefits of limiting TV time for children, as well as other family members. • Develop strategies for reducing TV/screen time for the parent, child and/or whole family. • Create an action plan related to encouraging themselves, their child and/or whole family to reduce TV/screen time activities.

8 - 9	▪ **Routines** ▪ **Routine Meals & Snacks**	- Parent support of child activity - Parent offers healthy beverage & food - Role modeling - Home foods - Family meals - Parent feeding attitudes	▪ Describe their experiences with following their action plans from previous sessions. ▪ Give examples of routines in their children's and family's daily lives. ▪ Identify the importance and benefits of routines in their family and children's lives. ▪ Apply the process of establishing routines for their child, emphasizing routine meals and snacks. ▪ Create an action plan related to encouraging themselves, their child and/or whole family to develop healthy behaviors (re: healthy eating, physical activity, reducing screen time, parenting).
10-11	▪ **Effective Communication** ▪ **Healthy Food Choices**	- Parent support of child activity - Parent offers healthy beverage & food - Role modeling - Home foods - Family meals - Parent feeding attitudes	▪ Describe their experiences with following their action plans from previous sessions. ▪ Understand the importance of giving effective and positively phrased directions to children (e.g., "can do"). ▪ Describe how effective communication and directives can help set limits for children. ▪ Describe the importance of making healthy snack and meal choices available to family. ▪ Identify potential challenges in making healthy snacks available/accessible to their family. ▪ Identify strategies for adding fruits and vegetables to family snacks and meals. ▪ Generate ideas to make healthier meals and snacks more accessible to their children. ▪ Create an action plan related to encouraging themselves, their child and/or whole family to develop healthy behaviors (re: healthy eating, physical activity, parenting).
12	▪ **Healthy Choices when Eating Out** ▪ **Family Meals**	- Parent support of child activity - Parent offers healthy beverage & food - Role modeling - Home foods - Family meals - Parent feeding attitudes	▪ Describe their experiences with following their action plans from previous sessions. ▪ Assess frequency of and reasons for eating out for the parent, child, and whole family. ▪ Identify and apply strategies to limit fast food eating. ▪ Learn how to make healthy food choices when eating out. ▪ List the benefits of sharing meals as a family. ▪ Develop a plan to continue encouraging themselves, their child and/or whole family to develop healthy behaviors (re: eating, physical activity, parenting).

7.2.4. Home Visiting/Phone Coaching

The goal of the home visiting is to facilitate parent self-efficacy for creating a healthy home environment. The main study will include 9-12 one-hour home visits each year for the three years. Home visiting is parent-focused and centered on the child's whole development including school readiness. We will attempt to culturally match the family and the Family Connector. The Family Connector serves as a coach to build a collaborative, partnership-based goal setting process for healthy parent and child behavior change. Facilitated by the Family Connector, home visits include skills building activities for behavior change, increased parenting skills development to facilitate behavior change, and home environmental changes particularly with TV and unhealthy foods. Facilitation of the visits is strongly influenced by Motivational Interviewing, an approach designed to help individuals explore and resolve ambivalence about behavior change in a non-confrontational manner. Home visiting includes a goal setting process guided by the Family Connector, healthy action activities to create norms and skills integration of the targeted behaviors, and resources for creating linkages in the community to support healthy behaviors. Table 7.4 shows the home visiting topics and behavioral goals.

Table 7.4. Home Visit Topics

Behavioral Area	Outcome Measure	Primary Behavioral Goals	Secondary Behavioral Goals
Physical Activity	Increase Physical Activity	60 mins of PA for kids per day	-Keep active equipment at home -Support activity as a family Increase PA options outside the home
TV/Screen Time	Decrease Screen Time	Limit to one hour per day for 2 year olds, 2 hours or less for older	-Provide alternative activity opportunities (whole child) -Replace TV/screen time with another activity
Fruits/Veggies	Increase Fruits and Veggies	5 servings/day	-Keep options around the house -Aim for each main meal to include a fruit and/or veggie
Breakfast	Increase Breakfast	Eat a healthy breakfast every day	Increase kid friendly bfast options
Sugar Sweet Beverages	Decrease Sugar Sweet Bevs	Limit to 4- 6 oz of juice/ bev per day	Increase water consumption
Family Meals	Increase Family Meals	Eat family meal 5/7 days/week	Aim for as many family meals in the wk as possible
Healthy Meals/Snacks	Increase Healthy Meals/Snack	Increase access to healthy foods; skim milk, etc	Decrease access to unhealthy snacks

Topic Area	Outcome Measure	Primary Behavioral Goals	Secondary Behavioral Goals
Healthy Meals/Snacks	Decrease High fat/sugar meals/snack	100- 200 kcal high fat/sugar snack food/day	
Portion Control	Portion Control	Role model and serve appropriate size portions	Raise awareness of appropriate size portions
Restaurants; Portions/ Unhealthy foods	Limit eating out at restaurants	Limit to one or less times per week	Restaurants; Portions/ Unhealthy foods

The Family Connector is envisioned as a trusted advocate, and can be used strategically to enhance participation, create continuity with goal setting and provide synergy with content, social processes and skill building occurring in the monthly parenting classes. Phone coaching with the Family Connector will integrate and bridge the home visits, parenting classes, and community activities. Motivational interviewing techniques will also be used during the Connector Calls. Calls will be strategically scheduled as needed to serve the above functions 4-6 times during each of the three main study intervention years.

7.2.5. Community Initiatives
During the pilot study, community initiatives were integrated with the parenting classes. We worked with community education in one school district and independent community organizations within another school district to offer three separate physical activity sessions (one per week for three weeks) specifically designed for 2-4 yr olds and their parents in each of the three parenting classes (Zumba dance; yoga; and a music and movement class "Music Monkeys"). The classes were very well received by parents and children. A food-related community resource activity was incorporated into the final parenting class session. This activity was a grocery store tour facilitated by a local nutrition organization that specifically serves low income families. The two-hour in-store tour developed skills around comparative pricing, using coupons, and shopping for healthy, inexpensive foods for family meals. At the end of the tour, families received a $10 gift card and were challenged to create a dinner for a family of four including four key food groups (including both a fruit and vegetable).

Families will have four structured opportunities to access healthy foods and physical activity in the community each year of the three year study. The study team will facilitate these opportunities with family interest, neighborhood location, and scheduling in mind. The activities will include one school readiness community activity (e.g., a library visit) to promote developmental parenting, sustain parent interest, and provide active support for whole child development.

7.3. Process Measures
All of the study intervention process measures were developed by our process evaluation team and piloted during Phase I. Table 7.5 shows the process evaluation measures that will be collected. Methods of collection across each of the domains

include self-report surveys/session evaluations (i.e., parent educators, family connectors, parents), and independent observations (i.e., class observations, audio recordings of home visits and home visit observations) conducted by trained evaluators hired specifically for this data collection task. Treatment integrity will be continuously monitored for all intervention components. Any component that falls outside the predefined minimum implementation requirement will be targeted for further staff training and problem solving to address implementation barriers. Intensified efforts will continue until the fidelity level reaches the targeted goal.

Each intervention component will be assessed across five process evaluation domains:

1) Fidelity will assess the extent to which the intervention is delivered as intended and how well it is being implemented compared to its original design, the content and quality of messages received, adherence to protocol, and intervention staff skills and training.

2) Dose Delivered will assess the amount of intervention that was delivered; including the number and length of sessions (pediatric, class, home visit, and community initiatives) implemented

3) Dose Received will assess the amount of intervention that was received, including but not limited to participant engagement, and intervention messages or materials received.

4) Program Design will assess non-specific treatment effects including but not limited to participant satisfaction, feasibility, and costs of intervention.

5) Reach will include the proportion of intended recipients who actually participate in the intervention and the extent to which the intervention is reaching the target population. It will include constructs attendance, participation, and engagement by group (e.g. race, gender, SES, intervention group).

Table 7.5. Minnesota COPTR Process Evaluation

Fidelity "The extent to which the intervention is delivered as intended; quality of the intervention; how well an intervention is being implemented compared to its original design; could include, but not limited to, content & quality of messages, adherence to protocol, and intervention staff skill/training/certification."				
Fidelity	**Fidelity Construct**	**Data Collection Method**	**Completed By**	**Timing of Data Collection**
Intervention Component #1				
Primary Care Provider Component	Content of Messages Delivered	PCP Adherence Survey	Parent	Baseline, 12-, 24-, and 36-month surveys
Intervention Component #2				
Family Connector Component (home visits & connector calls)	Quality of messages delivered and participant engagement	Home Visit/Connector Call Documentation Forms	Family Connector Process Evaluation Staff	After every home visit/ connector call 20% home visits

		Home Visit Observer Form		
Intervention Component #3				
Early Childhood Family Education/Parent Class Component	Quality of messages delivered and participant engagement	Class Documentation Form Satisfaction Survey Class Observation Form	Parent Educators Parent Process Evaluation Staff	After every class After every class 20% of classes
Intervention Component #4				
Community Component	Quality of Activities Completed	Activity Documentation Form Satisfaction Survey Community Activity Observation Form	Teacher Parent Process Evaluation Staff	After every community activity After every community activity 20% of community activities
Staff Training Component				
Primary Care Provider Component	Attendance, Participation, Satisfaction	Survey	Pediatric Primary Care Providers	After the Primary Care Provider Training
Family Connector Component	Attendance, Participation, Satisfaction	Survey	Family Connectors	After the Family Connector Training Sessions
Early Childhood Family Education/Parent Class Component	Attendance, Participation, Satisfaction	Survey	Parent Educators	After the Early Childhood Family Education/Parent Class Training Sessions
Dose Delivered "The amount of intervention that was delivered; could include, but not limited to, number and length of sessions implemented"				
Dose Delivered	**Dose Delivered Construct**	**Data Collection Method**	**Completed By**	**Timing of Data Collection**
Intervention Component #1				
Primary Care Provider Component	Attendance	Electronic medical records	Clinic Coordinator Staff	Monthly throughout the study
Intervention Component #2				
Family Connector Component (home visits & connector calls)	Activities Completed, Messages/Materials Delivered, Attendance	Home Visit/Connector Call Documentation Forms Home Visit Observation Form	Family Connectors Process Evaluation Staff	After every home visit/ connector call 20% of home visits

Intervention Component #3				
Early Childhood Family Education/Parent Class Component	Activities Completed, Messages/Materials Delivered, Attendance (Teacher Survey, Observer Form)	Class Documentation Form Class Observation Form	Parent Educator Process Evaluation Staff	After every Class 20% of Classes
Intervention Component #4				
Community Component	Activities Completed, Messages/Materials, Attendance	Activity Documentation Form	Parent Educator/Family Connector Process Evaluation Staff	After every community activity 20% of community activities

Dose Received "The amount of intervention that was received; could include, but not limited to, participant engagement, and intervention messages or materials received"

Dose Received	Dose Received Construct	Data Collection Method	Completed By	Timing of Data Collection
Intervention Component #1				
Primary Care Provider Component	Messages/Material Received	PCP Adherence Survey	Parent	Baseline, 12-, 24-, and 36-month surveys
Intervention Component #2				
Family Connector Component (home visits & connector calls)	Engagement	Satisfaction Survey Home Visit/ Connector Call Documentation Forms Home Visit Observation Form	Parent Family Connectors Process Evaluation Staff	Annually After every home visit/ connector call 20% of home visits
Intervention Component #3				
Early Childhood Family Education/Parent Class Component	Engagement	Satisfaction Survey Class Documentation Form Class Observation Form	Parent Parent Educator Process Evaluation Staff	After every class After every Class 20% of Classes
Intervention Component #4				
Community Component	Engagement	Satisfaction Survey Activity Documentation Form	Parent Parent Educator/Family Connector	After every community activity After every community activity 20% of community

		Class Observation Form	Process Evaluation Staff	activities

Program Design "The assessment of non-specific treatment effects, could include, but not limited to participant satisfaction with, feasibility, and costs of intervention"

Program Design	Program Design Construct	Data Collection Method	Completed By	Timing of Data Collection
Intervention Component #1				
Primary Care Provider Component	Participant satisfaction	PCP Adherence Survey	Parent	Baseline, 12-, 24-, and 36-month surveys
Intervention Component #2				
Family Connector Component	Participant satisfaction, interventionists time to prepare and travel for delivery of intervention	Satisfaction Survey Family Connector time logs	Parent Family Connector	Annually After every home visit
Intervention Component #3				
Early Childhood Family Education/Parent Class Component	Participant satisfaction, interventionists time to prepare and travel for delivery of intervention	Satisfaction Survey Family Connector time logs	Parent Parent Educator	After every class After every class
Intervention Component #4				
Community Component	Participant satisfaction	Satisfaction Survey	Parent	After every community activity

Reach "The proportion of intended recipients who actually participate in an intervention; the extent to which the intervention is reaching the target population; could include, but not limited to, attendance, participation, and engagement by group (e.g. race, gender, SES, intervention group)"

Reach	Reach Construct	Data Collection Method	Completed By	Timing of Data Collection
Intervention Component #1				
Primary Care Provider Component	attendance, participation, and engagement by clinic, race, ethnicity	Similar to above measures, but examined by groups noted in previous column		
Intervention Component #2				
Family Connector Component (home visits & connector calls)	attendance, participation, and engagement by race, ethnicity	Similar to above measures, but examined by groups noted in previous column		
Intervention Component #3				
Early Childhood Family Education/Parent Class Component	attendance, participation, and engagement by location, race, ethnicity	Similar to above measures, but examined by groups noted in previous column		

Intervention Component #4				
Community Component	attendance, participation, and engagement by location, race, ethnicity	Similar to above measures, but examined by groups noted in previous column		

7.3.1. Unblinded Process Measures
All process measures are unblinded for the study. These measures have been reviewed by the COPTR Design & Analysis working group.

7.3.2. Treatment integrity

Family Connectors: Our Project Director, Ms. Sara Veblen-Mortenson, and Dr. Jerica Berge, our co-investigator, will meet regularly with the Family Connectors for clinical training to assure consistency of intervention across subjects. All Family Connectors will be provided with a standardized protocol for each home visit and phone call. Family connectors will complete a checklist for each home visit and phone call to indicate the elements of the protocol that were covered. These checklists will be turned in to the Project Director, who will review them for consistency. All home visit sessions will be audiotaped. Randomly selected tapes (20%) will be reviewed by the Project Director to assure that all components of the intervention protocol for each sessions are included in the home visit. Ratings of the integrity of randomly selected tapes across the entire course of intervention delivery will be made by the Project Director. Satisfactory adherence will be defined as 90% or more of the protocol elements covered in a given session.

Primary Care: Physicians will be notified of a patient's participation through their electronic medical record. They will be asked to discuss BMI percentile, as well as healthy eating and physical activity using a study pamphlet. Retraining sessions will be held throughout the study with all participating physicians as part of standing department meetings. Well-child visit completion for all participants will be tracked monthly through clinic-specific methods. Dose received will be measured through parent survey questions at the annual study measurement visits. Implementation adherence will be defined as 90% of participants who attended their annual well-child visit reporting receiving the intervention messages.

Community Parenting Classes: Parenting classes will be regularly monitored for adherence to the intervention curriculum. Parent educators will complete checklists of material covered in each session. Monthly class observations will be conducted by research evaluation staff using structured content checklists to monitor intervention curriculum coverage and fidelity. Implementation fidelity will be defined as 90% coverage of each session's material.

Community Resources: Community food and recreation resource implementation will be monitored by research evaluation staff on a monthly basis. The family "care team" that consists of a parent educator and family connector will consult with NET-Works intervention staff to identify neighborhood-specific food and physical activity opportunities that can be incorporated into the parenting classes and the home visits. It is expected that 100% of the planned community initiatives will be implemented (4 per

family per year; via parenting classes and family connector home visits). Monitoring of implementation will be overseen by the NET-Works intervention staff.

8. CONTROL CONDITION
The participants enrolled in the comparison condition will attend their normal primary care provider well-child visits and any other medical and health-related visits with the primary care provider. They will receive four newsletters each year that address topics related to child cognitive development and school readiness. It is hoped that the quarterly newsletters will contribute to the retention of the families in the comparison condition in addition to the other retention strategies described previously.

9. MEASUREMENTS

9.1. Methods
9.1.1. Primary Outcome and Other Anthropometric Variables*
9.1.1.1. Primary Outcome
Background and Rationale: The measure used as the primary outcome variable of all four COPTR trials is body mass index (BMI). BMI assesses body weight adjusted for height and is correlated with percent body fat as assessed by dual energy x-ray absorptiometry.(Daniels, Khoury et al. 1997; Pietrobelli, Faith et al. 1998; Dezenberg, Nagy et al. 1999; Bray, DeLany et al. 2001) (When calculated using measured anthropometrics BMI is highly reliable. BMI has demonstrated clinical validity in its associations with type 2 diabetes mellitus,(Pinhas-Hamiel, Dolan et al. 1996; Scott, Smith et al. 1997) hyperinsulinemia,(Freedman, Dietz et al. 1999) blood pressure and hypertension,(Daniels, Khoury et al. 1997; Dwyer, Stone et al. 1998; Freedman, Dietz et al. 1999) adverse lipoprotein profiles(Dwyer, Stone et al. 1998; Freedman, Dietz et al. 1999; Teixeira, Sardinha et al. 2001) and early atherosclerotic lesions.(Mcgill, Mcmahan et al. 1995; Berenson, Srinivasan et al. 1998) among children and adolescents Importantly, BMI can be assessed easily in clinical and public health settings and is generally accepted and well understood.

Objective: The objective of the BMI measures is to provide a precise and accurate measure of the impact of the intervention on relevant aspects of body size in the children studied in COPTR.

Methods: All consented index children in the COPTR study have weight and height measured at the beginning and end of the intervention (36 months) and at two common interim time points (12 and 24 months). All baseline anthropometric data will be collected prior to randomization. Weight and height are measured with the participant in light clothing without shoes. Weight is measured to the nearest 0.1 kg using research precision grade, calibrated, digital scales and height is measured to the nearest 0.1 cm using a free-standing or wall mounted stadiometer. BMI is calculated as weight in kilograms divided by the square of height in meters.

All height and weight measurements are collected by trained and certified staff. COPTR will use a "train the trainer" model. Each field center will designate one or more "Master

Trainers" who participate in a central training organized by the RCU at the University of North Carolina at Chapel Hill on April 16-18, 2012. These Master Trainers are responsible for training and certifying the data collection staff at their center.

9.1.1.2. Other Anthropometric Secondary Outcomes

Anthropometric secondary outcomes differ by site as detailed in Table 9.1. Variables measured in the index child at all sites include waist circumference and triceps skinfold. All sites are measuring height and weight in at least one adult family member of the index child and some sites are measuring siblings. Secondary outcomes that will be calculated from anthropometry in at least one site include BMI z-score, waist-to-height ratio (WtHR), and percent body fat.

Table 9.1. Anthropometric Common Measures by Research Center

Anthropometric Measure	Case	Minnesota	Stanford	Vanderbilt
Index Child				
Weight	x	x	x	X
Height	x	x	x	X
Waist circumference	x	x	x	X
Triceps skinfolds	x	x	x	X
Other Children				
Weight	--	x*	x[†]	--
Height	--	x*	x[†]	--
Waist circumference	--	--	x[†]	--
Triceps skinfolds	--	--	x[†]	--
Other Adults				
Weight	x	x*	x	X
Height	x	x*	x	X
Waist circumference	--	--	x	X
Triceps skinfolds	--	--	--	X

* Minnesota: All children and adults in household.
[†] Stanford: Only study eligible children

Background and Rationale: BMI z-scores provide a method for evaluating the weight status of children adjusted for age and gender. The measure is commonly used in clinical practice to track body size trajectory. However, several authors have cautioned against the use of BMI z-scores for research using longitudinal designs citing concerns that their use could result in spurious differences between groups.(Cole, Faith et al. 2005; Berkey and Colditz 2007) One reason for this problem is that children at the extreme ends of the BMI distribution require substantially greater changes in weight than their thinner counterparts for the same change in z-score. Also because the BMI z-score curves were constructed using only data between the 3rd and 97th percentiles, the CDC recommends extreme caution when using the growth curves outside this range.(Kuczmarski, Ogden et al. 2000) Finally, Berkey et al. noted that the difference between z-scores reflect larger differences in BMI in older compared to younger

children.(Berkey and Colditz 2007) For these reasons the COPTR investigators have chosen to study BMI z-score as a secondary rather than a primary outcome.

Abdominal adiposity is associated with metabolic risk factors in children,(Freedman, Srinivasan et al. 1987; Freedman, Srinivasan et al. 1989; Caprio, Hyman et al. 1995; Caprio, Hyman et al. 1996) although evidence to date suggests that anthropometric measures tend to only moderately predict visceral fat.(Goran 1998; Goran, Gower et al. 1998) Waist circumference is a feasible non-invasive measure of abdominal fatness for community-based assessments of children. It has also been shown to be sensitive to change in response to prevention interventions.(Robinson 1999)

Waist-to-height ratio (WtHR) is a simple index that has recently received increased interest from investigators.(Browning, Hsieh et al. 2010) After the age of four years, waist and height appear to simultaneously increase during childhood and adolescence.(Kahn, Imperatore et al. 2005) Thus, WtHR could provide a practical estimate of adiposity that could be consistently applied to a wide range of age groups. Recently Browning et al. published a systematic review of waist to height ratio as a screening tool for cardiovascular and diabetes-related outcomes.(Browning, Hsieh et al. 2010) In their examination of 13 cross-sectional studies in children they found that waist-to-height ratio compared favorably with waist circumference and BMI. In a cross-sectional study of 1,511 youth 8 to 17 years of age McMurray et al. found that waist circumference performed well as a predictor of insulin resistance in boys but not girls.(McMurray 2010) Better performance was observed when waist circumference was divided by height, producing an index that was highly associated with insulin resistance in both genders and over a range of ages. Kahn et al. and Savva et al. have suggested a WtHR cut point of 0.49 to distinguish high and low levels of risk, however, McMurray et al. suggest that a WtHR of 0.54 may result in fewer misclassifications.(Savva, Tornaritis et al. 2000; Kahn, Imperatore et al. 2005; McMurray 2010) WtHR can also be analyzed in the continuous form. COPTR can provide an opportunity to further evaluate this index using both cross-sectional and longitudinal designs.

Triceps skinfold thickness is a measure of subcutaneous fat and is a component of equations used to predict percent body fat. COPTR investigators are using data from the NHANES study to develop a prediction equation for percent body fat that uses triceps skinfold along with other anthropometric variables collected in COPTR (height, weight and waist circumference) together with demographic variables to predict percent body fat (see section 4.8. in RCU protocol). Equations were developed in children in the age ranges being studied by Case Western and Stanford. Preliminary work indicates that this equation has an R^2 of over 0.8. Unfortunately estimates of percent body fat from DEXA are not available in children less than 8 years of age in NHANES. Therefore Vanderbilt and Minnesota will estimate percent body fat in younger children in their study using the prediction equation created by Dezenberg (R^2=0.95 as compared to DEXA, Model SEE=0.46) using data from White and African American 4 to 11 year old children.(Dezenberg, Nagy et al. 1999) This method has been shown to have higher validity across subgroups than other equations(Slaughter, Lohman et al. 1988; Goran,

Driscoll et al. 1996) and has been validated in 3 to 8 year old White and Hispanic children.

Obesity has been shown to cluster in families such that having obese parents increases the risk of obesity in children.(Barness, Opitz et al. 2007; Macfarlane, Cleland et al. 2009; Silventoinen, Rokholm et al. 2010) This clustering is due to both shared environment and genetic factors. The collection of anthropometric variables in the families of the index children in COPTR provides an opportunity to examine longitudinal changes within families in the family members and to assess any impact of the intervention on family members.

Objective: The anthropometric secondary outcomes are assessed to provide a richer understanding of the changes in body size characteristics associated with the COPTR interventions.

Methods: Waist circumference and triceps skinfolds will be measured at the beginning and end of the intervention (36 months) and at two common interim time points (12 & 24 months). Measurement details have been determined with guidance from the 2007 NHANES anthropometry procedures manual.(Center for Disease Control and Prevention 2007) Waist is measured to the nearest 0.1 cm just above the uppermost lateral border of the right ilium using a Gulick II tape measure, model 67020.

The triceps skinfold is measured using a Lange skinfold caliper (or a Harpenden caliper if the measurement exceeds capacity of the Lange skinfold caliper) in the midline of the posterior aspect (back) of the arm, over the triceps muscle, at a point midway between the lateral projection of the acromion process of the scapula (shoulder blade) and the inferior margin (bottom) of the olecranon process of the ulna (elbow). Skinfolds are measured to the nearest 0.1 mm.

9.1.2. Common Demographics, Moderators, Mediators and Secondary Outcomes*
9.1.2.1. Demographics, Moderators and Mediators
Background and Rationale: Self-reported information will be collected from COPTR index children and other household members by obtaining responses to written or verbalized questions. Although we refer to "questionnaires", as discussed in the methods section below, several methods are used to collect these data, and only a minority of the data is collected through the use of paper questionnaires. The information obtained is used to describe the study population or as a confounder, mediator, moderator or secondary outcome of intervention effects.

In general, the mediators chosen for measurement are targeted by the intervention, are expected to change as a result of the intervention and to result (directly or indirectly) in change in BMI. In COPTR, each Field Site's intervention is unique and many of the mediator variables are site-specific because they serve as explanatory constructs for the site-specific theoretical model. A moderating variable is defined as a variable that could influence the primary or secondary outcomes because the variable interacts with the intervention to change study outcomes. In other words, the intervention affects

people differently, depending on their status on the moderator variable. These variables are evaluated at the beginning and the end of the intervention, and in some cases as interim measurements.

Objective: The purpose is to describe the characteristics of participants, to determine possible mediators and moderators of intervention effects and to study secondary outcomes that are impacted by the intervention.

Methods: The demographic, household, mediators and moderators survey is administered to parents/primary caregivers of the participating child and/or to the participating child. Table 9.2. summarizes the location where the questionnaire will be administered and administration format in each site. To accommodate the sample being studied some sites administer questionnaires in Spanish.

Table 9.3. lists the questions used to collect common questionnaire data and shows which sites are collecting each item. All of the common survey questions are not administered at all Field Sites. The source of the 55 common questions and the responses are listed in Table 9.4. There will be four common measurement time points – baseline, 12 months, 24 months and 36 months. All common data collection will occur between May 2012 and March 2017. All baseline data collection will occur prior to randomization. Measurement data collectors are not intervention staff unless data are collected prior to randomization.

A "train the trainer" model is used to prepare staff to collect questionnaire data. Each Field Site designates two or more "Master Trainers" who participate in central trainings conducted by the RCU at the University of North Carolina at Chapel Hill on April 16-18, 2012. These Master Trainers are responsible for training and certifying the data collection staff at their Field Site. To be certified, Master Trainers attends the central training, reads the protocol and manual of procedures, complete the questionnaire and administer the questionnaire. The data collectors are certified by a Master Trainer who will describe the data collection process, insure that the protocol and manual of procedures are read and observe the questionnaire being administered to a volunteer.

Table 9.2. Characteristics of questionnaire administration by Field Sites

| | Field Sites | | | |
	Case Western	Minnesota	Stanford	Vanderbilt
Administration Location	Clinic	Home	Community center, Home, or Clinic	Community center
Administration Format	Interviewer administered	Interviewer administered	Interviewer administered (child) and mix of interviewer and self-administered (parent)	Interviewer administered
Data collection format	Computer	Computer	Paper Computer	Computer
Languages	English	English Spanish	English and Spanish (parents) and English (child)	English only in pilot; English and Spanish in main trial
Respondent	Parent or primary adult caregiver and participating child	Parent or primary adult caregiver	Parent(s) or primary adult caregivers and participating child	Parent or primary adult caregiver

Table 9.3. Questionnaire Common Measures by Field Site

Construct	Item	Case	Minnesota	Stanford	Vanderbilt
Household Configuration	For all children and adults living in your household, please tell me:				
	Gender,	X	X	X	
	Birth date, or age	X	X	X	
	Relationship to the participating child.	X	X	X	
Child's date of birth	Child's date of birth	X	X	X	X
Child Sex	What is this child sex?	X	X	X	X
Child Ethnicity	Is this child Hispanic, Latino/a or of Spanish origin?	X	X	X	X
Child Race	Which of the following best describes your child?	X	X	X	X
Parent Ethnicity	Are you Hispanic, Latino/a or of Spanish origin?	X	X	X	X
Parent Race	Which of the following best describes you?	X	X	X	X
Parent Country of Birth	In what country were you born?		X	X	X
Child Country of Birth	In what country was this child born?		X		X
Years Parent Lived in USA	How many years total have you lived in the United States?		X	X	X
Employment Status	What is your employment status?	X	X	X	X
Marital Status	What is your current marital status?	X	X	X	X
Access to Car	Is there a car that you can use whenever you need to?	X	X		X
Frequency of Speaking English	How often do you speak English at home with your family?		X	X	

Construct	Item	Case	Minnesota	Stanford	Vanderbilt
at Home with Family	(Choose one.)				
	If you do not always speak in English at home with your family, what languages do you speak the rest of the time?	X	*X*		
WIC	Do you participate in WIC? WIC stands for Women, Infants, and Children, a Federal assistance program.	X	X		X
Food Stamps/ SNAP	Does anyone in your household receive food stamps or SNAP? SNAP stands for Supplemental Nutrition Assistance Program.	X	X	X	X
Unemployment/ Social Security/ Disability	Does anyone in your household receive Unemployment, Social Security, or Disability Benefits?	X	X	X	
Education Completed	What is the highest degree or level of school that you have completed?	X	X	X	X
	What is the highest degree or level of school that your child's other parent living in the household or adult caregiver living in the household has completed?	X	X	X	X
Child Care	In a usual week, how much time does this child spend being cared for by someone other than parent/guardian?				
	in your own home		X	X	X
	in someone else's home		X	X	X
	in childcare center/after school program		X	X	X
Household Income	What was your total household income from all sources before taxes last year? By "household", we mean that you should report the combined income of everyone in your home.	X	X	X	X
Child Health Insurance	Is your child covered by a health insurance plan?	X	X	X	
	Which type of plan are they covered by?	X	X	X	
Free or Reduced Price Breakfast or Lunch	Does any child in your household receive free or reduced price breakfast or lunch at school?		X	X	
Maturation Status	Has your daughter started having her menstrual period?	X		X	
	When did she have her first menstrual period?	X		X	
Breastfeeding/ Pregnancy Risk	Did <this child> breastfeed for more than a month?	X	X		X
	How old was <this child> in	X	X		X

Construct	Item	Case	Minnesota	Stanford	Vanderbilt
	months when he/she first received a bottle of formula, cow's milk, water, juice, tea, or cereal at least once a day?				
	How much did this child weigh at birth?	X	X		X
	Did a doctor say that <you/birth mother> had diabetes when pregnant with <this child>?	X	X		X
	Did a doctor say that <you/birth mother> had hypertension (high blood pressure) when pregnant with <this child>?	X	X		X
Food Security	"The food that (I/we) bought just didn't last, and (I/we) didn't have money to get more." Was that often, sometimes, or never true for (you/your household) in the last 12 months?	X[3]	X	X	X
	"I/we couldn't afford to eat balanced meals." Was that often, sometimes, or never true for (you/your household) in the last 12 months?	X[3]	X	X	X
	In the last 12 months, since (date 12 months ago) did (you/you or other adults in your household) ever cut the size of your meals or skip meals because there wasn't enough money for food?	X[3]	X	X	X
	How often did this happen -- almost every month, some months but not every month, or in only 1 or 2 months?	X[3]	X	X	X
	In the last 12 months, did you ever eat less than you felt you should because there wasn't enough money to buy food?	X[3]	X	X	X
	In the last 12 months, were you ever hungry but didn't eat because you couldn't afford enough food?.	X[3]	X	X	X
TV & Media	How many working TVs do you have in your home?	X[1]	X	X	
	Is there a working TV in the room where <this child> sleeps?	X[1]	X	X	X
	Is there a computer in your home?	X[1]	X	X	X
	Is there a computer in the room where <this child> sleeps?	X[1,2]	X	X[2]	X
	Is there a video game player in your home?	X[1]	X	X	
	Is there a video game player in	X[1]	X	X	X

Construct	Item	Case	Minnesota	Stanford	Vanderbilt
	the room where <this child> sleeps?				
	Do you have Internet access in your home?	X[1]	X		
	On an average WEEK day, how many hours does <this child> watch TV?		X		X
	On an average WEEKEND day, how many hours does <this child> watch TV?		X		X
	On an average day, how many hours does <this child> play video or computer games, or use a computer for something that is not school work? (Include activities such as Play Station, Xbox, hand held video games, computer games, and the Internet.)		X		X
Food Norms	During the past seven days, how often did your family eat breakfast together?		X		X
	During the past seven days, how often did your family eat lunch together?		X		X
	During the past seven days, how often did your family eat dinner together?		X		X
Weight Status	How would you classify your own weight?	X	X	X	X
	How would you classify <this child's> current weight?	X	X	X	X

1 – The TV/Media questions for Case are derived from a group of embedded scale questions

2 – Case and Stanford uses the term "desktop" computer in their question.

3—Case questions are embedded into a survey and are not administered as an interview.

Table 9.4. Source and Response Sets of Questionnaire Common Measures

Construct	Item	Response Options	Source
Household Configuration	For all children and adults living in your household, please tell me:		Developed
	Gender,	Male; Female	
	Birth date or age	MMDDYYYY; __ __ yrs	
	Relationship to the participating child.	Mother; Father; Stepmother; Stepfather; Other male CG, (list); Other female CG, (list)	
Child's date of birth	Child's date of birth	MMDDYYY	Developed
Child's sex	What is this child's sex?	Male; Female	HHS data standards (Dorsey & Graham, 2011)
Child Ethnicity	Is this child Hispanic, Latino/a, or of Spanish origin? (Choose all that apply.)	No, not of Hispanic, Latino/a or Spanish origin; Yes, Mexican American, Chicano/a; Yes, Puerto Rican; Yes, Cuban; Yes, Another Hispanic, Latino/a or Spanish origin	HHS data standards (Dorsey & Graham, 2011)
Child Race	Which of the following best describes your child? (Choose all that apply.)	American Indian or Alaskan Native Asian; Black or African American; Native Hawaiian or Pacific Islander; White; Other (please describe)	U.S. Census, 2010
Parent Ethnicity	Are you Hispanic, Latino/a, or of Spanish origin? (Choose all that apply.)	No, not of Hispanic, Latino/a or Spanish origin; Yes, Mexican American, Chicano/a; Yes, Puerto Rican; Yes, Cuban; Yes, Another Hispanic, Latino/a or Spanish origin	HHS data standards (Dorsey & Graham, 2011)
Parent Race	Which of the following best describes you? (Choose all that apply.)	American Indian or Alaskan Native Asian; Black or African American; Native Hawaiian or Pacific Islander; White; Other (please describe)	U.S. Census, 2010
Parent Country of Birth	In what country were you born?	USA; Mexico; Somalia; Laos/Thailand/Vietnam; Other (please describe)	Adapted from (Marin and Gamba 1996; Norris, Ford et al. 1996)
Child Country of Birth	In what country was this child born?	USA; Mexico; Somalia; Laos/Thailand/Vietnam; Other (please describe)	Adapted from (Marin and Gamba 1996; Norris, Ford et al. 1996)
Years Parent Lived in USA	How many years total have you lived in the United States?	__ __ yrs	Adapted from (Marin and Gamba 1996; Norris, Ford et al. 1996)

Construct	Item	Response Options	Source
Employment Status	What is your employment status?	Working full time; Working part time; Not working for pay	Developed
Marital Status	What is your current marital status?	Married or living as married; Single	Developed
Access to Car	Is there a car that you can use whenever you need to?	Yes and I drive; Yes but I don't drive; No	Developed
Frequency of Speaking English at Home with Family	How often do you speak English at home with your family? (Choose one.)	Never; Sometimes; About ½ the time; Most of the time; Always	Adapted from (Marin and Gamba 1996; Norris, Ford et al. 1996)
	If you do not always speak in English at home with your family, what languages do you speak the rest of the time?	*Free text*	
WIC	Do you participate in WIC? WIC stands for Women, Infants, and Children, a Federal assistance program.	Yes; No; Don't know	Developed
Food Stamps/ SNAP	Does anyone in your household receive food stamps or SNAP? SNAP stands for Supplemental Nutrition Assistance Program.	Yes; No; Don't know	Developed
Unemployment/ Social Security/ Disability	Does anyone in your household receive Unemployment, Social Security, or Disability Benefits?	Yes; No; Don't know	Developed
Education Completed	What is the highest degree or level of school that you have completed? (Choose one answer.)	6th grade (elementary school) or less; 7th - 8th grade (attended some middle school/junior high); 9th - 12th grade (attended some high school); High school graduate (received diploma or the equivalent, GED for example); Completed some college credit, (or technical school) but no degree; Technical degree; Associate's degree; College degree; Master's, Professional, or Doctoral degree	Modified U.S. Census, 2010
	What is the highest degree or level of school that your child's other parent living in the household or adult caregiver living in the household has completed? (Choose one answer.)	6th grade (elementary school) or less; 7th - 8th grade (attended some middle school/junior high); 9th - 12th grade (attended some high school); High school graduate (received diploma or the equivalent, GED for example); Completed some college credit, (or technical school) but no degree; Technical degree; Associate's degree;	Modified U.S. Census, 2010

Construct	Item	Response Options	Source
		College degree; Master's, Professional, or Doctoral degree	
Child Care	In a usual week, how much time does this child spend being cared for by someone other than parent/guardian…		Developed
	in your own home?	0 Hours; 1-10 Hours; 11-20 Hours; 21-30 Hours 31-40 Hours; 41+ Hours	
	in someone else's home?	0 Hours; 1-10 Hours; 11-20 Hours; 21-30 Hours 31-40 Hours; 41+ Hours	
	in childcare center/after school program?	0 Hours; 1-10 Hours; 11-20 Hours; 21-30 Hours 31-40 Hours; 41+ Hours	
Household Income	What was your total household income from all sources before taxes last year? By "household", we mean that you should report the combined income of everyone in your home.	$14,999 or less; $15,000 - $24,999; $25,000 - $34,999; $35,000 - $49,999; $50,000 - $74,999; $75,000 - $149,999; $150,000 - $199,999; $200,000 or more; Don't know; I prefer not to answer	Developed
Child Health Insurance	Is your child covered by a health insurance plan?	Yes; No; Don't know	
	Which type of plan are they covered by?	Medicaid, Medicare, CHIP, state funded, or other federally funded; Private - through work or purchased individually; Military; Other, type unknown; Don't know	
Free or Reduced Price Breakfast or Lunch	Does any child in your household receive free or reduced price breakfast or lunch at school?	Yes; No; Don't know	Modified from TAAG2
Maturation Status	Has your daughter started having her menstrual period?	Yes; No; Don't know	Developed
	When did she have her first menstrual period?	MMYYYY	Developed
Breastfeeding/ Pregnancy Risk	Did <this child> breastfeed for more than a month?	Yes; No; Don't know	Schwarz et al. 2010
	How old was <this child> in months when he/she first received a bottle of formula, cow's milk, water, juice, tea, or cereal at least once a day?	_ _ mos.	Schwarz et al. 2010
	How much did this child weigh at birth?	_ _ lbs _ _oz	Schwarz et al. 2010
	Did a doctor say that <you/birth mother> had diabetes when pregnant with <this child>?	Yes; No; Don't know	Schwarz et al. 2010

Construct	Item	Response Options	Source
	Did a doctor say that <you/birth mother> had hypertension (high blood pressure) when pregnant with <this child>?	Yes; No; Don't know	Schwarz et al. 2010
Food Security	"The food that (I/we) bought just didn't last, and (I/we) didn't have money to get more." Was that often, sometimes, or never true for (you/your household) in the last 12 months?	Often true; Sometimes true; Never true; Don't know; Refused	USDA (Bickel, 2000)
	"I/we couldn't afford to eat balanced meals." Was that often, sometimes, or never true for (you/your household) in the last 12 months?	Often true; Sometimes true; Never true; Don't know; Refused	USDA (Bickel, 2000)
	In the last 12 months, since (date 12 months ago) did (you/you or other adults in your household) ever cut the size of your meals or skip meals because there wasn't enough money for food?	Yes; No; Don't know; Refused	USDA (Bickel, 2000)
	How often did this happen -- almost every month, some months but not every month, or in only 1 or 2 months?	Almost every month; Some months but not every month; Only 1 or 2 months; Don't know; Refused; Not asked	USDA (Bickel, 2000)
	In the last 12 months, did you ever eat less than you felt you should because there wasn't enough money to food?	Yes; No; Don't know; Refused	USDA (Bickel, 2000)
	In the last 12 months, were you ever hungry but didn't eat because you couldn't afford enough food?.	Yes; No; Don't know; Refused	USDA (Bickel, 2000)
TV & Media	How many working TVs do you have in your home?	*text*	Derived from Borzekowski, 1999; Robinson, 1999; Robinson et al., 2010
	Is there a working TV in the room where <this child> sleeps?	Yes No	
	Is there a computer in your home?	Yes No	
	Is there a computer in the room where <this child> sleeps?	Yes No	
	Is there a video game player in your home?	Yes No	
	Is there a video game player in the room where <this child> sleeps?	Yes No	
	Do you have Internet access in your home?	Yes, No, Don't Know	
	On an average WEEK day, how many hours does <this child> watch TV?	None Less than 1 hour per day 1 hour per day 2 hours per day 3 hours per day	Schmitz et al., 2004

Construct	Item	Response Options	Source
		4 hours per day 5 or more hours per day	
	On an average WEEKEND day, how many hours does <this child> watch TV?	None Less than 1 hour per day 1 hour per day 2 hours per day 3 hours per day 4 hours per day 5 or more hours per day	Schmitz et al., 2004
	On an average day, how many hours does <this child> play video or computer games, or use a computer for something that is not school work? (Include activities such as Play Station, Xbox, hand held video games, computer games, and the Internet.)	None Less than 1 hour per day 1 hour per day 2 hours per day 3 hours per day 4 hours per day 5 or more hours per day	Modified Schmitz et al., 2004
Food Norms	During the past seven days, how often did your family eat breakfast together?	0 times 1-2 times 3-4 times 5-6 times 7 or more times	Developed
	During the past seven days, how often did your family eat lunch together?	0 times 1-2 times 3-4 times 5-6 times 7 or more times	Developed
	During the past seven days, how often did your family eat dinner together?	0 times 1-2 times 3-4 times 5-6 times 7 or more times	Developed
Weight Status	How would you classify your own weight?	Very Underweight Underweight Normal Overweight Very Overweight	Modified Birch et al., 2001
	How would you classify <this child's> current weight?	Very Underweight Underweight Normal Overweight Very Overweight	Modified Birch et al., 2001

9.1.2.2. Accelerometry

Background and Rationale: Physical activity (PA) will be measured objectively using a commercially available ActiGraph GT3X+ (all youth). For parents and other adults GT3X+ accelerometers (Vanderbilt) or GT3X accelerometers (Minnesota) will be used. (ActiGraph, Pensacola, FL). The rationale for using ActiGraph is that among currently available devices it provides consistent and high quality data supported by feasibility, reliability, and validity testing in children and adults.

ActiGraph monitors have been used in numerous studies to assess PA in children (Freedson, Pober et al. 2005; Cliff, Reilly et al. 2009; De Vries, Van Hirtum et al. 2009; Reilly 2010). The validity of the ActiGraph has been examined in several studies involving children aged 2 to18 years. ActiGraph has been validated using direct observation (Kelly, Reilly et al. 2004; Sirard 2005; Hands 2006), doubly labeled water (DLW) (Montgomery, Reilly et al. 2004; Reilly, Kelly et al. 2006), indirect calorimetry (Garcia 2004; Schmitz, Treuth et al. 2005; Pate, Almeida et al. 2006; Trost, Way et al. 2006; Choi, Chen et al. 2010) and other accelerometers (Garcia 2004; Kelly, Reilly et al. 2004) as reference methods. Correlations between ActiGraph counts and observed activity was moderate to high (r = 0.52-0.77) in older ActiGraph models (Kelly, Reilly et al. 2004; Sirard 2005; Hands 2006) and higher in a newer ActiGraph (GT1M) model and when using more advanced algorithms (Choi, Chen et al. 2010). Although the validity of ActiGraph GT3X and GT3X+ models in populations including children has not be reported, it is expected to be at least as high or higher than the GT1M and older ActiGraph models.

The GT3X+ and GT3X contain electronic motion sensors consisting of piezo-electric sensors that generate an electric charge in response to a mechanical force, thus, acceleration. They do not respond to constant acceleration. Their major advantage is that no power supply is required, except for data storage, resulting in a considerable reduction in the size and weight of the device. Both monitors provide activity counts, vector magnitude, and inclinometry data. Other data calculated by the ActiGraph manufacturer-provided software includes activity intensity levels, energy expenditure (METs) and number of steps.

The GT3X+ collects data in the raw format at a pre-defined sample rate from 30 to 100 Hertz (Hz). When collecting data at 40 Hz, the battery life is stated to be 13 days and the data memory lasts for 16 days. The GT3X has the ability to collect 1-second epoch data for at least 7 days. The GT3X does not have adequate data storage capacity to collect raw data for multiple days.

Accelerometry technology is still improving and mathematical models to predict PA and PA-related energy expenditure are being developed. We expect these advances to continue. Thus, COPTR investigators will collect raw acceleration data in the index child that could be used to measure physical activity and sedentary behavior using both currently existing algorithms and new algorithms/approaches that emerge during the study (next 6 years). Table 9.5 summarizes the specifications of the GT3X devices.

Table 9.5. Specifications of the GT3X devices

Specifications	GT3X+	GT3X
Transducer	Tri-axis, solid state accelerometer	Tri-axis, solid state accelerometer
Dynamic Range	+/- 3G	+/- 3G
Dimensions	4.6cm x 3.3cm x 1.5cm	3.8cm x 3.7cm x 1.8cm
Capacity	16 Days (Raw data at 40 Hz)	16MB or 400 Days (60 sec epoch)
Battery Life	13 Days (Fully Charged at 40 Hz)	20 Days (Fully Charged)
Weight	19 g	27 g
Resolution	12-bit A/D conversion; 1.46 mG (Raw Data)	12-bit A/D conversion; 1.46 mG (Raw Data)
Sample Rate	30Hz-100 Hz	30 Hz

Limitations of accelerometry.
Accelerometers are the best currently available relatively simple and precise device for objectively assessing physical activity and sedentariness. However, they do not provide information on types of activities, nor can they be used to assess lifestyle activities such as raking and shoveling, static activities such as bicycling and weight lifting, and aquatic activities such as showering and swimming. These limitations may be addressed as new algorithms emerge during the course of the study. Other limitations are related to use and application of collected data in device-specific arbitrary counts (PA counts) or more comparable approach of using acceleration (m/sec^2) to summarize accelerometry data.

Objective: Accelerometry monitoring will provide an objective measurement of the amount and patterns of physical activity and sedentary behavior.

Methods: Accelerometry data on children and parent (Minnesota and Vanderbilt) will be collected at four common data collection time points – baseline, 12 months, 24 months and 36 months. All baseline accelerometer data will be collected prior to randomization. The GT3X+ will be set to 40-Hertz frequency and the GT3X will be set to 1-second epoch.

The index children in the study will wear the GT3X+ monitor on the right hip for seven complete days (including while sleeping and naptime) except during water activity (e.g., bathing, swimming, showering). The responding parent in Minnesota and Vanderbilt will also wear the GT3X and GT3X+ monitor, respectively for seven days on their right hip. A consensus has been reached that the monitoring period should include two weekend days and five weekdays. In some cases, participants may be able to provide only 6 days of data, which is acceptable. If the participant does not wear the activity monitor for four days, it may be necessary to have the participant wear the monitor again in order to get valid data. The valid wear time criteria (minimums) are 4 days (3 weekdays and 1 weekend day) of at least 6 hours of awake time with 33% non-zero epochs per

hour.   For some participants, accelerometer data for the 2 wears will be combined in order to meet the minimum wear time criteria.

Any major updates in the ActiLife software version used during the trial will be made as a collaborative decision by the Diet and Physical Activity Working Group. If a change does occur, it will be on the same calendar day for all Field Sites. Regular (minor) updates in the ActiLife software will be done by each Field Site as they are released by ActiGraph. The Accelerometer Manual of Procedures will be updated only after major updates in the ActiLife software (e.g. Version 6.0 to Version 7.0).

COPTR will use a "train the trainer" model. Each field center will have at least two activity monitor master trainers who will participate in a central in-person training organized by the RCU at the University of North Carolina at Chapel Hill on April 16-18, 2012. Following part 1 of the training session, the master trainers will wear the accelerometer for at least 8 hours. The certification process requires the master trainer to successfully initialize, download and transfer accelerometer data. The master trainers will train and certify additional research staff at their site. Data collectors/staff do not initialize or download accelerometer data until after they have been trained and certified.

9.1.2.3. Dietary Assessment
Background and Rationale: The 24-hour recall is the most widely used method to assess diet in studies of populations, and is used in national food consumption surveys such as the NHANES. This method allows assessment of all foods, beverages and dietary supplements consumed during the 24-hour period obtained – typically beginning with the first item consumed the previous day. The 24-hour method, which can be performed face-to-face or by telephone, has been validated in lean and obese individuals.(Conway, Ingwersen et al. 2004) In face-to-face interviews, the use of visual aids such as food models, food portion booklets and measuring utensils improves the accuracy of estimation of quantities consumed.(Moshfegh 1999) For telephone interviews, visual aids and instructions are often mailed to subjects.(Posner, Smigelski et al. 1992) In addition, with a trained interviewer, they are relatively quick and easy to administer. An important strength of the 24-hour recall method is that it allows comparison of groups of individuals by demographic variables such as age, gender, race/ethnicity or geographic region. Another strength is that the 24-hour recall (Nutrition Data Systems for Research or NDSR) has been used to generate Healthy Eating Index scores, and thus to assess dietary quality.(Miller, Mitchell et al. 2011)   The main limitations of capturing quantitative dietary intake information by use of 24-hour recalls are: 1) the variability in day-to-day dietary intakes; 2) reliance on subject memory; and 3) the potential of over or underreporting of intakes. To compensate for these possible limitations, interviewers typically capture data on more than one day of the week which includes both weekdays and weekend days, and use the USDA 5-step multi-pass method.(Moshfegh 1999)

Objective: The purpose of performing dietary intake assessment is to capture quantitative nutrient information on all the foods, beverages and dietary supplements that study subjects consume. The dietary intakes are analyzed for: volume of food, total energy, macronutrients, micronutrients, water, dietary fiber, added sugars and specific food groups. We will also examine glycemic load, dietary energy density, nutrient adequacy ratios, and dietary pattern and quality. Examples of diet quality indices used in children are shown in Table 9.6.

Table 9.6. Examples of dietary quality indices used in children

Citation	Subjects N	Sex	Age	Diet Assessment	Group/Index	Methods
Daniels, EJCN, 2009	1,810	m/f	2y	24 hr recall	Diet Diversity score(DDS-10g) - FAO (score 1-9)	Cross-sectional: 1 pt per 10g of a each food group or 1 pt for 1g oil.
Feskanich, JAmDietAssoc, 2004	16,452	m/f	9-14y	132 item FFQ	Youth HEI- 13 components (score 0-100)	Modified HEI and compared to YHEI (Note: YHEI not strongly related to energy intake).
Freedman, JNutr, 2010	17,311	m/f	≥2y	24hr recall	HEI-2005: 12 dietary components	NHANES ('01-'04) data- 3 part model (they create) based on Tooze 2- part model(Tooze, Midthune et al. 2006) in >1000 subjects.
Guenther, JAmDietAssoc, 2008	8,650	m/f	≥2y	24 hr recall	HEI-2005	NHANES ('01-'02) compared HEI-2005 assessed validity through 4 methods (concluded valid).
Kennedy, JNutr, 2007	3,164	m/f	24-71 mo	24 hr recall	Diet Diversity Score (DDS) – 10 food group & DDS-10g	Filipino Nutrition Database. DDS summed unique food groups for score. DDS-10g required minimum amounts (see: Daniels, 2009).
Manios, JAmDietAssoc, 2009	2,287	m/f	2-5y	24 hr recall + weighed records + food diaries	HEI- 10 component	Weighed records were used in nurseries and recalls or diaries were used outside nurseries. Summed individual scores- used quartiles of the scores for analysis.
Steyn, Public Health Nutr, 2006	2,200	m/f	1-8y	24 hr recall	DDS- following FAO guidelines Food Variety Score (FVS) (Score 0-45)	Secondary analysis of NFCS in South Africa. 1 24 hr recall by caregivers. Also used nutritional adequacy ratio and mean adequacy ratio.
Serra-Majem, EJCN, 2003	3,166	m/f	6-24y	24 recall +16 item FFQ	KIDMED- Mediterranean diet measure (Score: -3 to 12)	Assessed diet from Spanish children has high, med, low KIDMED.
Kranz, JAmDietAssoc, 2006	5,437	m/f	2-5y	24 recall	Created new- RC-DQI	Continuing Survey of Food intakes by individuals (1994-1996, 1998) components chosen based on My Food Pyramid, ADA, and APA recommendations (Nutrient-based)
Hurley, JNutr, 2009	317	m/f	11-19	131 item- youth/ adolescent FFQ	Compared HEI and YHEI	Compared the indices to body composition and found HEI better correlated with body composition and disease risk.
LaRowe, JAmDietAssoc, 2010	135	m/f	2-5	24 hr recall	My Food Pyramid	Great Lakes Inter-Tribal Council Head Start programs- baseline data from HCSF intervention.
Cheng, JNutr, 2010	376	m/f	6-8y	3-day weighed record	Nutritional Quality Index (NQI)- Density measure RC-DQI- nutrient based	German Cohort

Methods: Dietary Intakes will be measured using 24-hour recalls that are conducted on two weekdays and one weekend day per study time-point using NDS-R version 2012. Any update in the NDS-R version during the trial will be made as a collaborative decision by the Diet and Physical Activity Working Group. If a change does occur, it will be on the same calendar day for all Field Sites with one caveat. Participants who have already completed 1 or 2 recalls in the old version of NDS-R will have their remaining recalls conducted using the same older version of NDS-R such that all 3 recalls are collected using the same version of NDS-R.

Dietary assessment data will be collected at baseline, and 12, 24 and 36 months during the study. All baseline dietary assessment data will be collected prior to randomization. Table 9.7 summarizes the specific data collection plans for each Field Site. To avoid collecting days with similar foods, recalls should not be conducted on consecutive days. In addition, in order to capture variability of food supplies in the home, all three recalls should not occur within a seven day period. The third recall needs to be collected more than one week after the first recall. All three recalls must be collected within 30 days. This is a hard deadline. While the goal is to collect three dietary recalls per participant, it is possible that a limited number of participants at each Field Site may only have two dietary recalls completed within the 30 day window. All efforts will be made to obtain a minimum of two recalls (1 weekday and 1 weekend) for each participant. All dietary intakes (i.e., food, and beverages including water) will be collected. For Diet Recall of young children, those responsible for child feeding (e.g. parents, daycare providers) will be the reporter. Details of the procedures to be used in dietary assessment are in the COPTR Manual of Procedures for Dietary Assessment.

COPTR will use the "train- the- trainer" model. Each field center will have two diet master trainers who will participate in a central in-person training organized by the RCU at the University of North Carolina at Chapel Hill on April 16-18, 2012. Following the training session, the master trainers will complete two dietary recalls for certification by the RCU. The master trainers will train and certify additional research staff at their site. No diet recalls will be conducted until after the trainer has been trained and certified.

Table 9.7: Site specific 24 hour dietary recall data collection plans

	Case	Minnesota	Stanford	Vanderbilt
Number of recalls	3	3	3	3
# weekdays	2	2	2	2
# weekends	1	1	1	1
Recaller	Child & parent	Parent & day care provider	Child & parent	Parent & day care provider
How collected (1st, 2nd, 3rd)	In-person Telephone Telephone	In-person In-person/Telephone In-person/Telephone	In-person Telephone Telephone	Telephone Telephone Telephone
Announced/ Unannounced	Announced	Announced	Unannounced	Announced
Language administered	English	English, Spanish	English, Spanish	English, Spanish
Use of Portion Size Devices	Food Booklet	Food Booklet	Food Booklet	Food Booklet

9.1.3. Site-Specific Mediators, Moderators and Secondary Outcomes
Table 9.8. Minnesota site-specific mediators and moderators

Construct	Respondent	# Questions
Child Ethnicity	Parent	1
Parent Ethnicity	Parent	1
Living Situation	Parent	1
Smoking	Parent	2
Breastfeeding duration (age stopped)	Parent	1
Perceived Home Physical Activity Environment	Parent	6
Parental enjoyment of physical activity	Parent	1
Types of Child Physical Activity	Parent	3-13
Participation in Parenting classes	Parent	1
Perceived neighborhood environment	Parent	6
Parental support for child physical activity	Parent	4
Child eating behavior	Parent	20
Fast food	Parent	2
Parent feeding	Parent	7
Food and Physical Activity neighborhood resource use	Parent	4
Parenting styles	Parent	10
Social networks	Parent	TBD
Verbal test	Child	Series of questions

9.2. Quality Control
9.2.1. Primary Outcome and Other Anthropometric Variables*

Ten percent (10%) of the measurements (height and weight) that compose the primary outcome (BMI) and the other anthropometric measurements (waist circumference and triceps skinfold) are measured by two different data collectors. Ideally one of the data collectors is a Master Trainer. The method used to select the 10% sample is site specific and is incorporated into the site's data management system to track who requires the second measurer. Duplicate measures are recorded to confirm inter-rater reliability, but the first data collection staff's measurements will be used in the analysis. To be acceptable, the absolute difference between the calculated values by the two data collectors must be less than 0.5 cm for height, 0.3 kg for body mass, 1 cm for waist, and no larger than 2 mm if the skinfold is less than 10 mm or greater than 10% if the skinfold is 10 mm or larger. If a data collection staff's agreement on a measurement (height, weight, waist circumference or skinfold) is outside this range in more than two out of ten individuals, then he/she must complete retraining.

Range checks are built into the data management system to prevent the collection of erroneous data. The 2003-2010 NHANES was used to determine age and gender-specific range checks for the anthropometric variables. Range checks are set so that participants with extreme and erroneous values are brought to the attention of the data collection staff for scrutiny.

The bounds for range checks in the baseline data collection vary by center since the anthropometric eligibility criteria for enrollment of index children vary.

9.2.2. Common Demographics, Mediators, Moderators, and Secondary Outcomes*

The demographic variables are collected via questionnaires along with additional mediator variables (e.g. food security, tv and media). The survey collection, review and editing procedures are site specific. The RCU monitors for missing and out of range values on the common questions across the Field Sites.

Physical activity is measured by accelerometry. Because activity levels change daily and the test retest relationships would be low, participants are not asked to wear the activity monitor twice for quality control. In addition, an interview is not a good quality control check since it does not provide the necessary data for a comparison, and thus are not used for quality control. The RCU monitors and reports the amount of data (e.g. the number of valid days, number of re-wears). The valid wear time criteria (minimums) are 4 days (3 weekdays and 1 weekend day) of at least 6 hours of awake time with 33% non-zero epochs per hour. For some participants, accelerometer data for the 2 wears will be combined in order to meet the minimum wear time criteria.

The dietary interviewer reviews and edits the 24-hour dietary recall as soon as possible after its administration. During editing, special attention is paid to NDS-R Missing Foods, Priority Notes and all other Notes. Full quality assurance must be conducted on at least 10% of recalls. The quality assurance checks include ensuring information is entered correctly in header tab, meal information window, food tab and trailer tab. In the header tab the goal is to make sure information is filled in correctly (e.g. ID, Date of intake, Site ID). The meal information window should have meals in order by time and the eating and activity codes entered correctly. The quality assurance checks in the food tab include checking that foods entered correctly, amounts match code, missing foods and priority notes are resolved. Recalls that have issues that need to be resolved are put into the FIX project. All data must be cleaned and missing foods, or priority notes must be resolved before the output file is run and sent to the RCU on a quarterly basis. All missing foods are discussed at diet interviewer staff meetings. There will be quarterly reviews of data entry issues and shared user recipes to standardize the data entry process across all sites.

In SAS or other statistical package a quality assurance report is run to generate for each record total energy, percent kilocalories from fat, fruit servings, vegetable servings and grams of fluid. Ranges are set for school aged children and preschool aged children. Records with values beyond the cutoff points below are printed and checked.

	School Aged Samples	Preschool Samples
Total Energy	<500; >2500	<250; >1200
% kcal from fat	<25%; >45%	<25%; >45%
Fruit Servings	>3	>2
Vegetable Servings	>3	>2
Grams of Fluid	<300; >2000	<200; >1500

9.2.3. Site-Specific Mediators, Moderators and Secondary Outcomes
The contact management database will use scripts to identify cases where study events have been missed or are overdue. For example, if a measurement visit is scheduled but the eligibility screening is not complete then the record will be flagged for the Evaluation Coordinator. Anthropometric range checks (described in the MOP) will be

performed during data entry at the home visit. Ten percent of households will be flagged for repeat anthropometry to evaluate inter-rater reliability. During data collection the REDCap database will prompt for verification of out of range or missing values. Accelerometers will be downloaded during the home visit and new accelerometers distributed if wear time is insufficient (as described in the MOP). Ten percent of diet recalls will be flagged quality control review and be edited as needed.

Once SAS data sets have been created ranges for all variables will be hand checked for plausibility. Improbably high or low values will be reviewed in the original data and corrected as needed. The RCU upload process will re-verify plausibility of data.

9.3. Measurement Schedule
The measurement schedule is shown below in Table 13.1. Measurements will take place at baseline, prior to randomization, 12, 24 and 36 months. All measures are collected at each of these time points.

10. PARTICIPANT SAFETY AND ADVERSE EVENTS MONITORING
10.1. Potential Risks and Protection against Risks
Expected risks to participants include mild injury associated with participation in physical activity, and slowed growth if a parent misinterprets the intervention messages and restricts a child's dietary intake. These risks are considered to be minimal and are addressed in the protocol and consent form. The intervention focuses on making modest changes in the diet and activity-related home environment with a focus on prevention of unhealthy weight gain, it is highly unlikely that the intervention will have an adverse impact on growth velocity. However, growth will be monitored and the study statistician, PI, and Independent Monitor will review this data bi-annually. All decreases > 1 percentile line on the stature-for-age and gender chart in a 6 month period will be reviewed and the child's pediatrician will be consulted to determine whether any action should be taken.

10.2. Potential Benefits
The possible benefits of the study include that parents will learn ways to help their child develop healthy eating and physical activity habits. They may also learn parenting skills that will facilitate their child's cognitive, behavioral and social development.

10.3. Safety Monitoring Plan
Participant safety and reporting procedures will be adopted according to the procedures developed for the COPTR consortium. Serious adverse events will be immediately reviewed by the site PIs. If the PI classifies the event as serious, unexpected and possibly/probably/definitely related to study participation, it is deemed to be a Serious Adverse Event and will be reported to the Research Coordinating Center RCU. COPTR asks that reports of serious adverse events be made within four working days of becoming aware of the event, and the RCU, NIH and the U of MN IRB will be notified. Such events include death during study activities, serious or life-threatening physical injury, injury resulting in persistent or significant disability/incapacity, or other health-related events that require immediate hospitalization for emergency care. Once the

event is initially reported, if more information is gathered concerning the SAE, these details must be reported to the RCU and IRB no later than 15 calendar days following the event.

Adverse events that are not serious will be reported in monthly reports to the COPTR DSMB. Adverse events will be brought to the attention of study staff through several channels, including reports from parents, intervention staff, and measurement staff. COPTR has developed clear and concise documentation forms that will be used electronically by the Minnesota site.

10.4. Informed Consent Documents

The consenting process will be an ongoing commitment between study staff and participants. Consent documents have been carefully prepared, along with two pictorial teaching tools to accompany the consent form. All aspects of the study have been covered in the consent form including background and procedures, risks and benefits, random group assignment, confidentiality, and voluntary nature of the study. The pictorials will aid in staff discussions surrounding the study procedures, timeline, and individual measures. The primary participating parent will sign the consent document thus enrolling themselves, along with their child, into the study. Any additional family members who wish to participate in anthropometric measures must also be consented. The staff is committed to having a continuing discussion with participants about informed consent, throughout the duration of the study.

11. STUDY DESIGN, STATISTICAL CONSIDERATION AND ANALYSIS PLAN

11.1. Study Design

The study is an individually randomized group trial. Families will be randomized equally to the NET-Works intervention or a control group. The NET-Works intervention duration is thirty-six months. Outcome measures will be assessed at baseline and at 12, 24 and 36 months post-randomization.

11.2. Primary Research Question and Hypothesis

Specific Aim 1
To evaluate the effects of a three-year multi-setting parent-targeted randomized controlled intervention on the primary outcome, child BMI, compared to a standard primary care-only intervention among low income ethnic minority two to four year old children who are at or above the 50th percentile of BMI for age and gender.
Hypothesis 1: Children in the multi-setting parent-targeted intervention will have a lower BMI at 24 and 36 months, compared with children in the standard primary care only control group.

Specific Aim 2
To evaluate the effects of a three-year multi-setting parent-targeted intervention on secondary outcomes, including change in child energy intake and physical activity energy expenditure, compared to a standard primary care-only intervention.
Hypothesis 2: Children in the multi-setting parent-targeted intervention will have lower energy intake and higher energy expenditure over the three-year period, compared with children in the standard primary care-only control group.

Specific Aim 3
To evaluate the effects of the multi-setting parent-targeted intervention on hypothesized mediators of change in dietary intake, physical activity, and BMI.
Hypothesis 3: It is hypothesized that changes in parenting behaviors and the home food and physical activity environment will mediate changes in child energy intake and expenditure, and body mass index.

11.3. Primary Outcome

The primary outcome variable is child Body Mass Index (BMI) measured at baseline,12, 24, and 36 months. BMI is not a perfect measure of body fatness. However, it is widely recognized as a suitable measure for children, with age and gender specific standards for healthy BMI. Child weight will be measured directly to the nearest 0.1 kg on a calibrated electronic scale in light clothing and without shoes. Height will be measured to the nearest centimeter using a wall-mounted ruler, at baseline, 12, 24, and 36 months. BMI will be computed (weight in kilograms/height in meters[2]). All measurements will be conducted by trained and certified research staff using the COPTR standard measurement protocol.

Measurements are taken in the following order: weight, height, waist circumference one time and then repeated in the same order. A third measurement is taken when a set of two measurements differ by more than the specified amount. If the two measurements of weight differ by 0.3 kg or more, then the weight measurements are repeated a third time and data entered. If the two height measurements differ by 0.5 cm or more, then the measure must be repeated. The mean of the two closest measures will be used as the final measurement.

11.4. Primary Analysis

11.4.1. Statistical model and approach
The primary analysis will test whether NET-Works participants have lower BMI at 24 and 36 months relative to comparison participants. We will use data from all randomized participants (intent to treat approach) to estimate two mixed models in which 24 or 36 month BMI values are predicted from randomized treatment group with age group at baseline, sex and BMI at baseline as covariates, and a random intercept for ECFE cohort membership (u_{0j}):

$$BMI_{ij} = \gamma_{00} + \gamma_{01}NET\text{-}Works_j +$$
$$\gamma_{20}3yo_i + \gamma_{30}4yo_i + \gamma_{40}female_i + \gamma_{50}BMI\ baseline_i + [u_{0j} + e_{ij}].$$

We will conclude that NET-Works was efficacious if the γ_{01} parameter in both mixed models is statistically significant and negative, meaning that BMI is significantly lower among NET-Works children than comparison children.

BMI assigned to 50th and 75th BMI %tile (boys)


11.4.2. Assumptions with justification
We have used evidence from

3 yr old   4 yr old   5 yr old
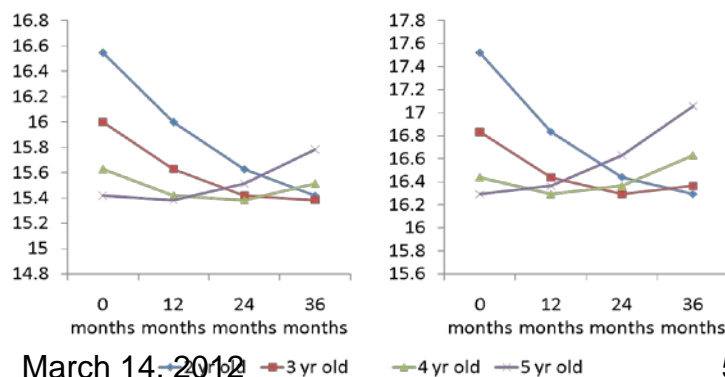
multiple sources, including CDC growth charts, recent NHANES data, and data shared by the Stanford site from the Growth Study (Agras et al, unpublished data), to approximate changes in BMI among 2-4 year old study enrollees over a 3-year period. These data suggest a non-linear BMI trajectory over this time period, with the nadir for BMI occurring at about 5-6 years of age, so that the nature of BMI changes will depend on the child's age at enrollment. Figure 11.1 shows how BMI changes over time for an average boy at the 50th or 75th%ile who is 2-4 years old at the beginning of a 3-year period.

We anticipate that BMI in the NET-Works and comparison groups will be M=17.1 kg/m2 (SD = 1.7) at baseline. The comparison group BMI is expected to increase slightly over the study period, with the expected BMI to be M=17.2 (2.7) at 24 months and M=17.6 (2.7) at 36 months. Examination of the CDC growth curve data and recent NHANES data, in combination with our expectations based on the literature and our proposed

Figure 11.2. Anticipated Minnesota BMI patterns
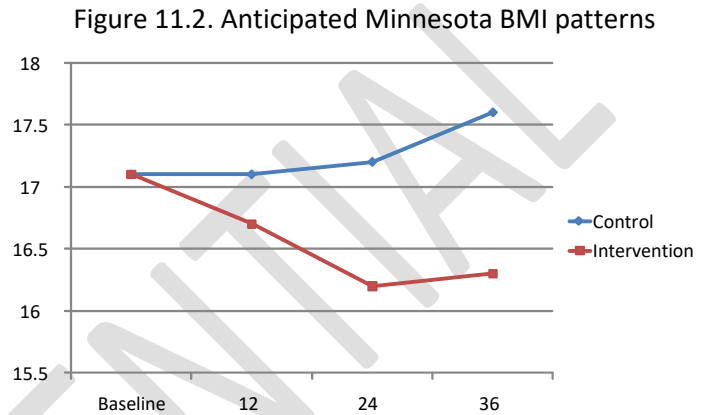
intervention, leads to the expectation that BMI will decline among NET-Works participants to M=16.2 (2.0) at 24 months and M=16.3 (2.0) at 36 months. These estimates are based on examination of BMI values for CDC growth curves, recent NHANES data and a review of the literature on preschool obesity prevention interventions, and our expectations about the timing and magnitude of the intervention effect. They also assume equal numbers of 2, 3 and 4 year old enrollees that are evenly split between study groups. The largest differences in BMI between NET-Works and comparison groups will therefore be observed at 24 and 36 months. (Figure 11.2). We will consider a standardized between groups difference of Cohen's d=.30 to be practically meaningful. A recent meta-analyses of lifestyle interventions targeting weight in youth populations found that among studies with both post-treatment and follow-up measures of weight, an average between-groups difference of d=.31 was estimated post-treatment, which dropped to d=.22 at follow-up (Kitzmann et al., 2010). Another meta-analysis that specifically quantified effects of 3 interventions with family and environmental components found an average between-groups effect of only d=.16, although one intervention (d=.08) accounted for nearly 80% of the sample amid heterogeneous effects across studies (Katz et al., 2008). The NET-Works intervention will last a full 3 years, decreasing in intensity over time. The 24 and 36 month between-groups differences may not be as large as if they immediately followed an intensive treatment period (e.g., d=.31) but should be larger than the follow-up effects following a shorter-lived intervention (e.g., d=.22). More to the point, however, NET-Works will need to generate effects of d≥.30 to justify its intensity and expense. Hence, we assert that d=.30 is clinically feasible and practically meaningful.

We have proposed to recruit N=500 parent/child dyads equally to the NET-Works and comparison groups. Several considerations bear on estimates of sample size available

for the 24 and 36 month comparisons of BMI. The first of these is the proportion of randomized participants who provide BMI data at each time point. For the purposes of the power analysis, we assume that 80% of the randomized children will have a BMI measurement at the 24 and 36 month follow-ups, and allow this estimate to range from 75% to 85%. In a recently completed weight maintenance intervention at HPRF we were able to obtain valid weight data from 87% of randomized participants at both 12 and 24 months post-randomization, a level of retention that is consistent with other behavioral interventions conducted at HPRF. We will employ numerous methods to ensure 24 and 36 month sample sizes greater than 80% of the randomized sample but believe that this range is conservative for the purposes of the power analysis.

A second consideration involves the possible dependence in BMI observations among NET-Works participants. The most likely source of dependence will derive from the ECFE component of NET-Works. The ECFE component will be delivered to NET-Works parents in 16 groups, each consisting of 15-16 families. The ECFE cohorts will be formed based primarily on ethnicity, which is likely to covary with residential neighborhood and other sociodemographic factors. While BMI may vary systematically across ethnic groups and other sociodemographic factors, the BMI inclusion criterion (≥ 50th percentile) should reduce this covariance. Parents will be expected to maintain involvement with their assigned group over the course of the 3 year intervention, such that continued interaction among parents in class sessions may promote dependence.

A third source of dependence lies in the family connector (FC) assignment. Because FC assignment will be culture-specific, it will covary with ECFE cohort and other sources of dependence associated with cohort membership. All three potential sources dependence will be indexed by ECFE cohort, so it will be important to account for dependence introduced into BMI by ECFE cohort.

We used screening data from a related, ongoing study at HPRF to estimate an ICC for BMI. These screening data come from N=841 2-5 year olds with a BMI at or above the 50th percentile and an upcoming visit at one of 19 primary care clinics in the Twin Cities metropolitan area. Because choice of primary care clinic is influenced by convenience and residential neighborhood, it is likely to be determined by factors that will also be related to ECFE cohort assignment, such as country of origin, primary language, and socioeconomic status. BMI in these children was M_{BMI} = 17.4 (SD_{BMI} = 1.4; $M_{BMI\%}$ = 77.0, $SD_{BMI\%}$ = 15.0) and ICC_{clin} = .007. This is consistent with NET-Works pilot data in which baseline BMI among 39 2-4 year olds with a BMI at or above the 50th percentile was M_{BMI} = 17.4 kg/m^2 (SD_{BMI} =1.5). Given the common sources of dependence, and the likelihood that the ICC is relatively low for a biological measure such as BMI, we assert that an ICC of .007 is a reasonable starting place for estimating the ICC_{ECFE} that will be observed in this study. We assume in the sample size estimations that the ICC_{ECFE} will range from .01 to .03 among NET-Works children, four times higher than our starting point of .007, with ICC=.00 among comparison group children.

A final consideration are the dependencies in BMI measurements within participants and ECFE cohorts at baseline and 24 or 36 months later (Teerenstra, Eldridge, Graff, de Hoop, & Borm, 2012). Among 30 participants enrolled in a related study involving 2-5 year olds with a BMI at or above the 50th percentile , the correlation within participants

between BMI measurements at baseline and 6 months was r=.69. Because more time will elapse between baseline and 24 or 36 months in NET-Works, likely resulting in a lower correlation, power was estimated assuming r_{child}= .40-.60 for all randomized children and r_{ECFE} = .30-.50 for NET-Works children.

11.4.3. Missing data including level of attrition, loss to follow-up, and missing data treatment

Our recent experience with weight-related studies at HPRF is that participants who lose interest in the study do so early in their participation and thereby have missing data at all post-baseline observations (i.e., monotone missing data). We have not observed that early study loss is differential across treatment groups or other baseline characteristics, although an inferential test of this would be poorly powered given the low rate at which early study dropout has occurred. We suspect that this missing data mechanism most likely produces MAR data.

A second mechanism contributing to missing post-baseline observations are sporadically missing observations within participants, possibly due to perceptions that they are not doing well in the study (non-random) but also due to a hectic schedule (random). This missing data process may produce a similar number of missing observations as early dropout but has greater potential for biasing the parameter estimates if intervention participants perceive more pressure to be "successful" and therefore more likely to have MNAR data. In spite of this possibility, we found no evidence that the missingness of a follow-up weight observation was predicted by treatment group, baseline weight, last observed weight, or interactions among these variables in a recently completed weight maintenance intervention. Again, the power to detect such differences was low given the proportion of missing data we observed. The primary analysis will be conducted using multiply imputed datasets so that participants lacking follow-up BMI measurements will be included in estimating the efficacy of NET-Works. We will take a fully conditional specification approach to the imputation process, and will include in the imputation model all variables included in the primary analytic (scientific) model as well as interactions among them to improve the precision of the imputations. All covariates in the primary analysis will have been measured at baseline prior to randomization and are therefore available for observed and unobserved BMI values. The random effects estimated in the primary analytic model will also be estimated in the imputation model (Andridge, 2011).

The mechanisms that are likely to produce missing observations in the analytic dataset should result in missing observations that are MAR (early dropouts, busy schedule) or possibly MNAR (sporadic missing). The primary analytic model will be estimated from imputed datasets that assume all missing observations to be MAR. Sensitivity analyses will assess the severity of non-random missingness that would be necessary to reconsider the conclusions drawn from the primary analysis. The primary analytic models will be re-estimated under the assumption that all missing values are non-random, using a range of values to modify MAR-imputed data to capture the hypothesized non-random mechanism. Three sets of sensitivity parameters will represent mild (e.g., imputed BMI + 0.5), moderate (e.g., imputed BMI + 1.0) and extreme (e.g., imputed BMI + 1.5) departures from expected BMI values. In order to differentiate between sporadic and monotone missingness, we may also consider a set

of sensitivity parameters that assume an upward trend in consecutively missing BMI values.

11.5. Detectable Difference, Sample Size, and Power

A power analysis was performed for the primary hypothesis test that BMI at 24 months and at 36 months will differ between children randomly assigned to the NET-Works versus comparison group. This hypothesis test will be carried out by assessing the significance of the treatment parameter (γ_{01}) in each of two mixed models predicting BMI at 24 or 36 months controlling for baseline BMI, age at baseline and sex. The effective number of BMI observations at 24 and 36 months from NET-Works and comparison children was estimated by imposing assumptions about the design effect resulting from NET-Works dyads clustered within ECFE cohorts (ICC$_{ECFE}$ =.01-.03 NET-Works, .00 comparison), the design effect resulting from cluster (r$_{ECFE}$=.30-.50 NET-Works, r$_{ECFE}$=.00 comparison) and subject (r$_{child}$=.40-.60) autocorrelation between baseline and follow-up BMI values, and the proportion of randomized participants from whom a BMI measurement will be available (75-85%).

We anticipate randomizing 250 parent/child dyads each to the NET-Works and comparison groups. NET-Works dyads will be clustered within about 16 ECFE cohorts for an average of n=250/16=15.6 dyads per cohort, and ICC$_{ECFE}$ = .01-.03. The clustered sample size was divided by the design effect introduced by clustering within ECFE cohorts, DEFF$_{ECFE}$ = [1+(n-1)ρ], to estimate the effective number of independent dyads in each treatment group. Next, the effective number of independent dyads was divided by the design effect introduced by cluster and subject autocorrelation in BMI, DEFF$_{corr}$ = (1-r^2), to adjust for the efficiency gain resulting from controlling for baseline BMI values. In this case,

$$r = [n\rho / (1+(n-1)\rho)]\rho_c + [(1-\rho) / (1+(n-1)\rho)]\rho_s ,$$

where n is the average number of dyads per cluster; ρ is the correlation in BMI values of different children in the same cluster at a single point in time, ICC$_{ECFE}$; ρ_c is the cluster auto-correlation in BMI values, r$_{ECFE}$; and ρ_s is the subject auto-correlation in BMI values, r$_{child}$. (Teerenstra et al., 2012; Borm, Fransen & Lemmens, 2007) Finally, the NET-Works and comparison sample sizes were reduced to 75-85% of their estimated values to account for the anticipated number of children with a BMI measurement at 24 or 36 months.

The minimum detectable standardized effect (MDSE), Cohen's d, was estimated for an independent samples t-test comparing BMI in NET-Works versus comparison participants at 24 or 36 months. We will use a generalized Holm procedure to ensure a family-wise Type I error rate of .05, so that the $\square_{01}$ with the smaller p-value will be tested at α_2 = .025, while the $\square_{01}$ with the larger p-value will be tested at α_2 = .05 (Holm, 1979; Lehmann & Romano, 2005; Keselman, 2011). The assumptions for the power calculation were that power = 1 - $\Phi(z_p)$ = .80, α_2 =.025, equal and standardized variance estimates in both groups (i.e., σ^2_{Net} = σ^2_{Comp} = 1), z_α = 2.24 and z_p = -0.84. The common standard deviation was calculated as

$$\sigma_{xbar} = ((\sigma^2_{Net}/N_{eff\ Net\ 36m}) + (\sigma^2_{Comp}/N_{Comp\ 36m}))^{1/2},$$

and the minimum detectable d was calculated as

$$d = z_\alpha\sigma_{xbar} - z_p\sigma_{xbar}.$$

The estimated MDSE sizes, d, for the comparison of 24 or 36 month BMI values among NET-Works versus comparison children are displayed in Table 11.5. Given median values for our ICC and retention assumptions (ICCECFE=.02, 80% follow-up) and conservative alpha and autocorrelation assumptions (α_2 = .025, r_{ECFE}=.30, r_{child}=.40), the MDSE is d = .305.When α_2 = .05, the comparable MDSE is d=.277. These effect sizes are in keeping with our stated goal of detecting a between groups difference of d=.30 at 24 and 36 months. The primary analysis will therefore be powered to detect a NET-Works versus comparison group difference of about .28-.30*2.35=0.65-0.72 kg/m^2 at follow-up, lower than our expected differences of 17.2-16.2=1.0 kg/m^2 and 17.6-16.3=1.3 kg/m^2 at 24 and 36 months.

Table 11.5. Minimum detectable effect size, d, when α_2 = .025 ICC$_{ECFE}$ = .01-.03, r_{child} = .40, r_{ECFE}=.30, and 75-85% of randomized participants provide follow-up BMI data.

ICC$_{ECFE}$	follow-up BMI data		
	85%	80%	75%
.01	.286	.294	.304
.02	.296	*.305*	.315
.03	.307	.316	.326

11.6. Analysis for Possible Effect Modifiers
As stated above, it is possible, likely even, that age and sex will be predictive of BMI. Regression homogeneity is an assumption of the ANCOVA model, so the extent to which age and sex modify the treatment effect will be assessed to ensure its accurate estimation. In addition, secondary mixed models that incorporate all observed BMI values per participant will be estimated so that, as examples, non-linear change in BMI that differs by age (age*time interaction), and the impact of the intervention on the non-linear, age-specific trajectories in BMI (age*time*NET-Works intervention) may be assessed. It is also possible that the intervention will be more effective for children with a relatively high BMI at baseline (i.e., BMI stratum >85th vs. 50-85th percentile). Secondary analyses will also estimate NET-Works*BMI_stratum and NET-Works*BMI_stratum*time interactions.

11.7. Analysis for Possible Effect Mediators
To date, we have not explicitly discussed potential effect mediators, although there are numerous constructs measured in each survey for which treatment effect mediation could be assessed. If we were to carry out mediational analyses, we would use a product of coefficients approach, likely based on coefficients derived from a mixed model, to calculate the strength of indirect relationships between treatment group assignment and BMI by way of the hypothesized mediator(s). The magnitude of indirect effects would be calculated as abX-M*M-Y and their significance assessed by constructing asymmetric 95% confidence limits around ab to determine whether these limits include zero.

11.8. Secondary Hypotheses and analysis
The primary analysis will be carried out as two time-specific mixed models to ensure that heterogeneity with respect to ECFE cohort-specific changes in BMI over time does not inflate the Type I error beyond the nominal value (Murray, Hannan, Wolfinger, Baker & Dwyer, 1998). Should the primary models demonstrate that NET-Works was efficacious without an inflated risk of a Type I error, the secondary analyses will be carried out by means of a mixed model that predicts all observed BMI values from randomized treatment group, the time at which BMI was measured and the treatment group by time interaction. Due to the likelihood that BMI will depend on age at baseline and sex, these

will be included as covariates as well as other variables (e.g., BMI stratum) as appropriate to the secondary research question. The anticipated mixed model includes random intercepts for child (u_{0ij}) and ECFE cohort membership (v_{00j}):

$$BMI_{tij} = \gamma_{000} + \gamma_{001}NET\text{-}Works_j + \gamma_{100}12m_t + \gamma_{200}24m_t + \gamma_{300}36m_t +$$
$$\gamma_{110}NET\text{-}Works_i{*}12m_t + \gamma_{210}NET\text{-}Works_i{*}24m_t + \gamma_{310}NET\text{-}Works_i{*}36m_t +$$
$$\gamma_{020}3yo_i + \gamma_{030}4yo_i + \gamma_{040}female_i + [v_{00j} + u_{0ij} + e_{ti}].$$

Secondary analyses may be also performed on the BMI z-score or other transformations (e.g., slope) of the primary outcome.

The primary analyses will be performed using a multiply imputed dataset assuming that missing data are MAR. Secondary analyses will be carried out that model non-random missing processes that increasingly depart from MAR assumptions. This will help determine the severity of a non-random missing process that would be required to arrive at different conclusions from the primary analysis.

12. DATA MANAGEMENT & QUALITY CONTROL

12.1. Common Database*
The COPTR Data Center was designed after extensive discussions with representatives from all of the sites to provide a secure, easy, and effective set of tools for submitting Common Measures to a central repository for the consortium. Each of the four Field Sites has a site-specific data system for conducting the daily tracking and data collection.. The COPTR Data Center does not dictate how those disparate site systems are designed or used. Instead, the Data Center provides a set of web-based tools for sites to upload completed Common Measures to the central repository at the RCU.

Field Sites collect a subset of the Common Measures following the protocols and manual of procedures (MOPs) for those common measures. The common measure subsets for each Field Site differ slightly but the MOPs and protocols defining the measurement/collection procedures are identical. The recruitment data elements identified for submission to the RCU are identical at each Field Site. Each Field Site submits the current collection of common measures quarterly and the recruitment and retention data monthly to the RCU to be included in the central data store of the Consortium. Variables collected at only one Field Site are not transferred to the RCU.

One or more representatives from each Field Site have been designated as members of the Data Capture Working Group. These representatives contributed to the design of the Data Center tools and continue to contribute to improved functionality of the Data Center site. These representatives also serve as the primary contacts at a Field Site when the RCU notices irregularities with the submitted data.

The RCU data transfer system utilizes a restricted access website to provide encrypted transfer of data files containing common measures (measurements collected at more than one Field Site) to a central data repository at the RCU. Each Field Site will have one or more project staff authorized to have access to the Data Center website. An individual at a site must receive authorization from the site's PI prior to getting an assigned Data Center userid and password. Field Site staff login to the Data Center via

the following URL: http://www.shepscenter.unc.edu/coptr

After successful authentication, the user will land on the "MyHome" page of the affiliated Field Site. Access is restricted according to Field Site affiliation and defined roles. An authorized staff for a Field Site only has permission to work within that site's defined workspace. Some RCU staff are authorized to work across all Field Sites' workspace. Figure 12.1 is a screenshot of the Case Western MyHome space.

On this MyHome page, a Field Site user (e.g. Case Western user) will see two sections that give real-time information on successful uploads and attempts. The top left box provides a Summary of the data records by type that have been uploaded to the Data Center and Confirmed by any of the site's authorized users. The Dataset Files box just below the Summary box provides more detailed information on each upload attempt. Authorized site users always have access to these status displays. Furthermore,

authorized RCU users can see the status displays of all four Field Sites, providing an opportunity for RCU staff to monitor upload processes and provide assistance when errors are displayed. In addition to the MyHome displays, the Data Center system has extensive error logging available to RCU staff to troubleshoot any problems encountered. Last, to the right of the Summary box are the tools for uploading data sets.

Figure 12.1: Screenshot of the MyHome space
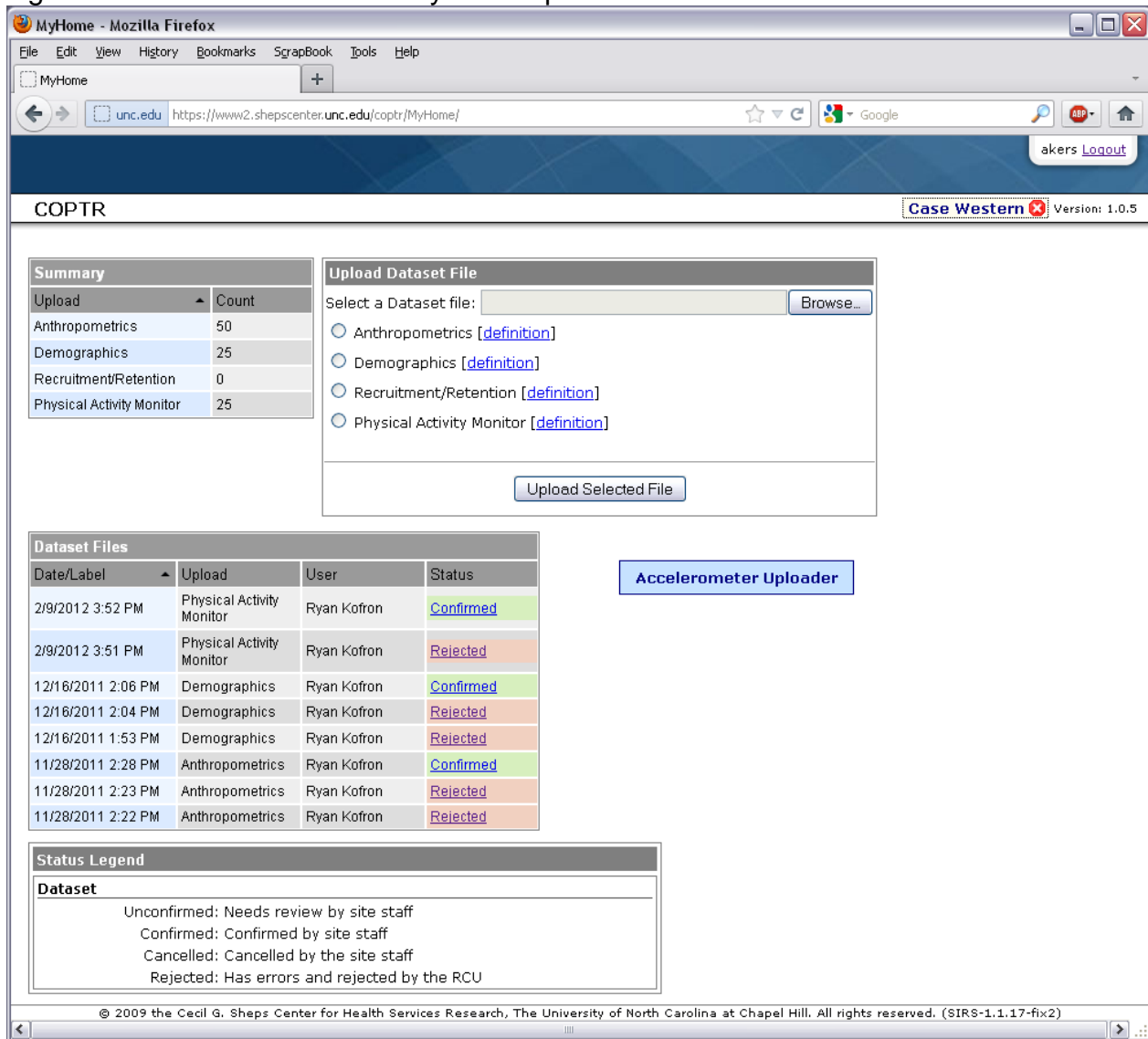
Data Capture and Data Audits
Uploading Data to the RCU: The COPTR Data Capture Working Group decided to use file upload facilities versus web data entry forms for submitting site data to the Data Center. To upload a data set, the user will Browse his/her local file space for the desired CSV file, select the corresponding type by clicking on the appropriate radio button (e.g. Anthropometrics, Demographics, etc.), then click "Upload Selected File". The upload process evaluates the incoming data file, looking for the required unique identifiers, the

correct site ID, and comparing the field names, data types, and data values according to the predefined "definition". (The "definition" files are available to read via the "definition" links.) If any required data check fails, the RCU rejects the incoming file and reports the reasons to the user. The user can then correct those issues and upload the file again. If all required data checks pass, the incoming file is held with "Unconfirmed" status and the user is presented a report on the number of new records and number of modified records found in this incoming file. This report provides the user an opportunity to confirm that those numbers are as s/he expects. If the numbers are as expected, the user can "Confirm" the upload and the process is complete. Otherwise, the user can "Cancel" the upload then investigate the issues offline and attempt the upload again at another time.

The next section on the screenshot in Figure 12.1 shows a running log of the dataset upload activities for the site. The log shows the date and time of each upload attempt, the type of upload, the user performing the upload, and the status of that upload attempt. Clicking on a "Confirmed" link in the Status column loads more detailed information about the confirmed upload. Figure 12.2 shows the details of a confirmed Demographics upload from Case Western. The more detailed information includes the local File Name of the uploaded file, the Upload Summary, and the unique identifiers of the New Records that were included in that file. In addition, if there were records uploaded that were intended to update or correct data that had previously been uploaded to the RCU Data Center, details of those changes would be listed in the right hand table labeled "Changed Records in this upload". Changes to data fields in existing records are made by matching the unique record key of an existing record with that of an incoming record then accepting the new incoming record as the most up-to-date. (The older record is kept for reference. It is not overwritten.)

The Data Center is designed with three objectives in mind:
1) Promote the submission of the highest quality data to the RCU for future use of the Common Measures;
2) Provide an upload facility that is efficient and easy to use from the individual site's perspective;
3) Give the users enough information and flexibility to track progress and correct problems with Common Measures submissions.

To that end, all data uploads with the exception of the accelerometer GT3X or AGD uploads, follow the same general model: organize your data to fit the approved definition, upload a CSV file via the website, confirm the upload or correct the errors and try again. Figures 1-3 illustrate the information provided and assistance with identifying and correcting problems prior to the RCU accepting data.

Figure 12.2: Screenshot of a confirmed demographics upload
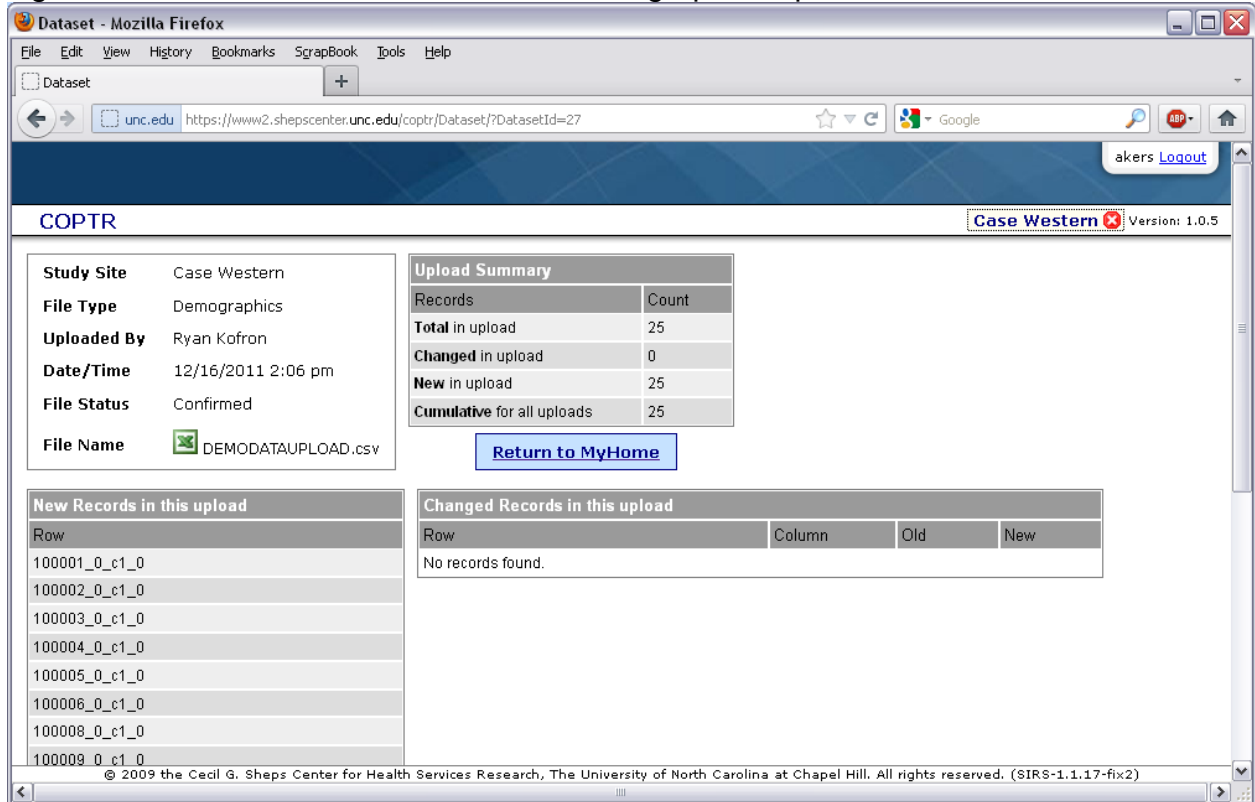
Clicking on a "Rejected" link in the Status column will load more detailed information about a file with data that did not match the required criteria for acceptance in the Data Center. Figure 12.3 below shows the details of a rejected Demographics upload. Again, the local File Name is displayed along with Date/Time and Uploaded By user. The File Errors box in this example indicates that an upload was attempted that contained extra fields that the RCU was not expecting (first message). Also, the second message indicates there are fields or columns missing in the upload that are required as Demographics Common Measures. If there had been any data type mismatches or data values out of range, error messages would be presented in the "Row Errors" box.

Figure 12.3: Screenshot of a rejected demographics upload
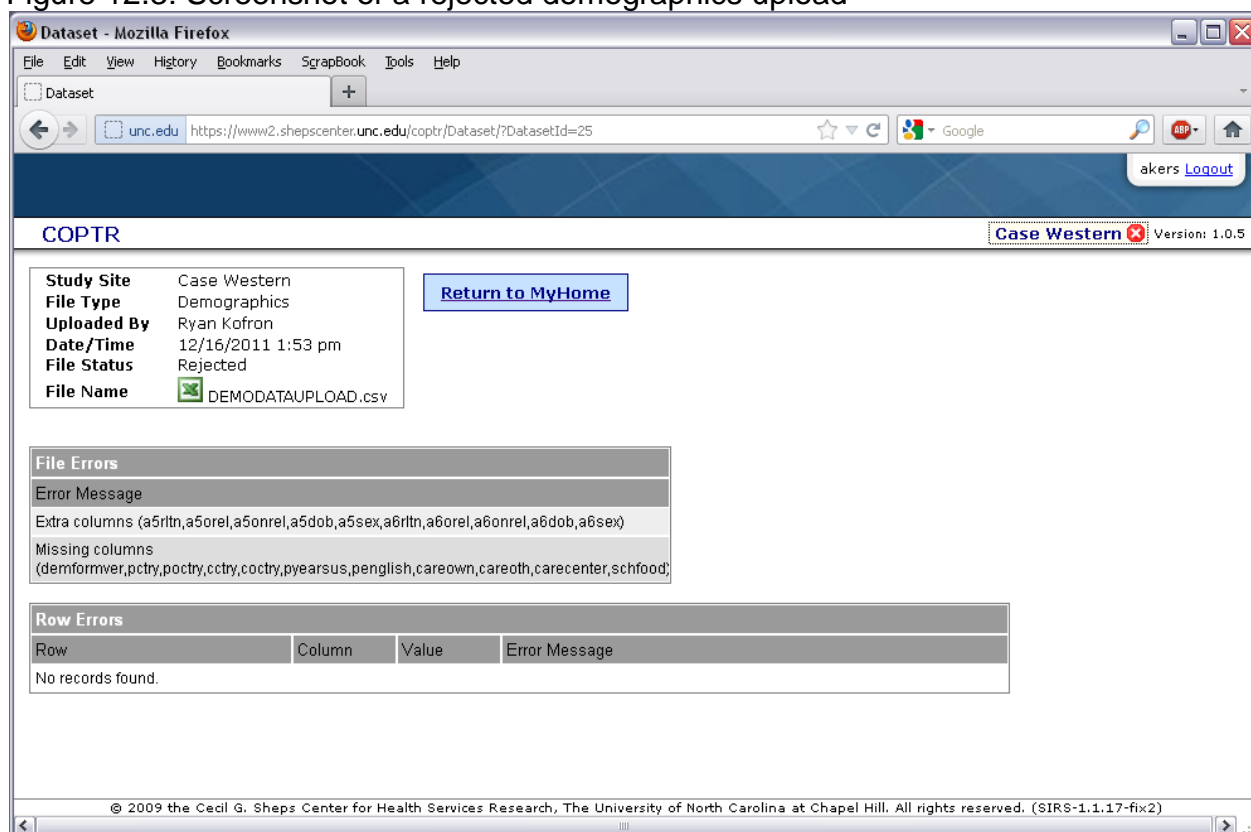
Authoritative ID File – Study Arm: The RCU Data Center requires one of the data uploads to be the authoritative source for Index Child IDs. Having an authoritative "master" list of Index Child IDs allows the RCU to prevent orphan records from being introduced in any of the other data uploads. The consortium has designated the Study Arm upload to be this source. As such, a Study Arm record for an Index Child must be uploaded to the RCU before any other Common Measure records are accepted into the Data Center. The Index Child IDs in other data uploads (e.g. Anthropometric, Demographic, etc.) are verified against the RCU's Study Arm records prior to accepting the data records. Data records that do not have a matching Index Child ID in the RCU's Study Arm data are rejected to prevent orphan records from being introduced into the Data Center.

Accelerometer Data: Accelerometer data on an individual consists of two distinct parts: a Physical Activity Monitor (PAM) record, and recorded data from the ActiGraph device (GT3X or AGD format). The RCU requires sites to upload the PAM record of the pair prior to uploading the matching GT3X or AGD file. The steps for uploading PAM records follows the same steps described above for other data uploads. However, the steps for uploading GT3X or AGD files are different because of the difficulties introduced in handling these large files. (We are anticipating the average size of these files to be around 200MB.) After successfully uploading and confirming PAM records, the user clicks the "Accelerometer Uploader" button shown in Figure 12.1. The user is then presented with a screen similar to Figure 12.4 below. The user can then queue up

one or more GT3X/AGD files for upload either by clicking "Add files…" or by dragging files from local file space into the upload area. Clicking "Start upload" will begin uploading the queued files in the order they are shown. Each GT3X/AGD file is verified against the uploaded PAM records to ensure a PAM record exists for a GT3X/AGD file before allowing the upload to proceed. This verification allows the RCU to accurately link a PAM record to an incoming GT3X/AGD file. The user must make sure all queued uploads are completed before leaving this web page.

Figure 12.4: Screenshot of the accelerometry file upload screen
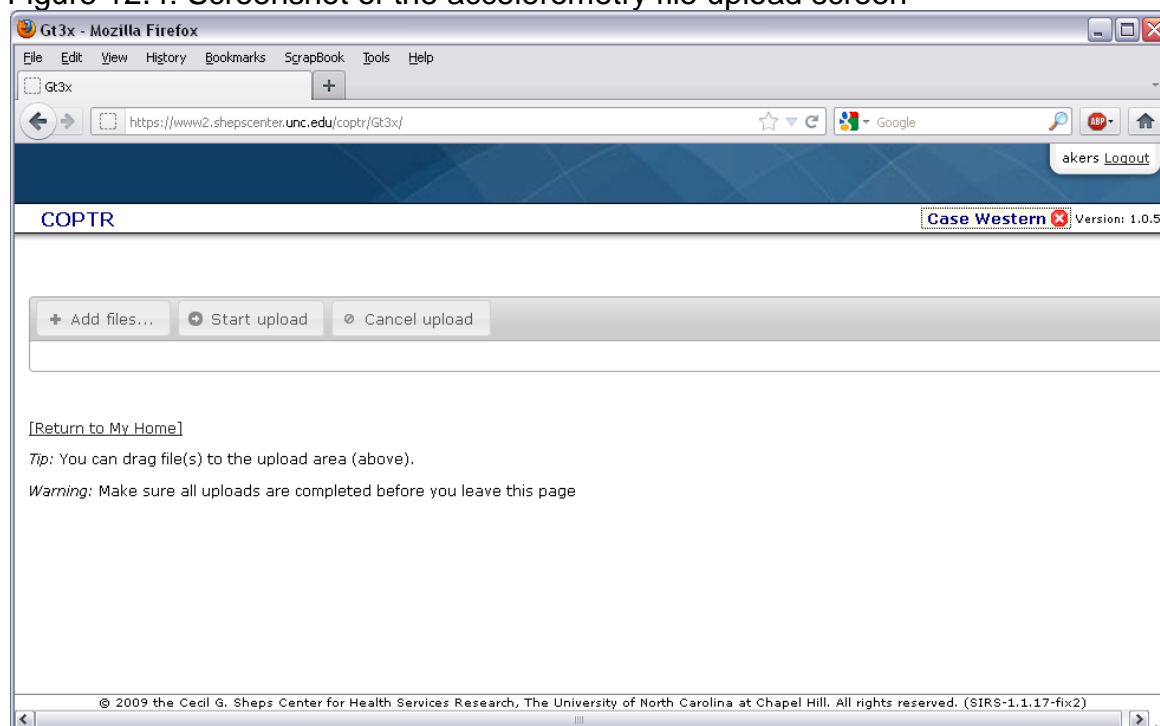
Uploaded GT3X and AGD files are not automatically analyzed at the RCU. The files are simply stored in a file system for later use. Each site is responsible for analyzing GT3X and AGD files for completeness prior to uploading to the RCU Data Center.

12.2. Site-specific Data Capture

Infrastructure

- The contact management and intervention databases will be located on a FileMaker server housed in the Division of Epidemiology & Community Health at the University of Minnesota. The server and files are password protected and must be reached via the Division's local area network or VPN.
- The survey and anthropometric measurements will be entered into a REDCap database housed in the Academic Health Center at the University of Minnesota. The web interface requires a password protected login.
- Division of Epidemiology laptops will be used for dietary recalls, accelerometry and transfer of data to University servers. The laptops require password protected login and are encrypted. Data will be uploaded onto a Division shared server with file access limited to the study staff.

- Paper records will be housed in locked filing cabinets in the Division of Epidemiology. Anthropometry and certain administrative forms will be captured on paper, and paper surveys may be used if internet connectivity is lost during a visit.

Flow of data

Basic information from clinics (name, DOB, contact information) will be provided by partner clinics and imported into a FileMaker database by the data manager. This database will handle screening, tracking participant progress, process evaluation and reporting functions for the study. Reports to the RCU and DSMB may come directly from the database or pass through SAS, depending upon format requirements.

Accelerometry files will be uploaded directly to the RCU. Participant data from anthropometry, surveys, NDSR and accelerometry will be saved as text files and converted to SAS data sets on Division of Epidemiology servers. The SAS data sets will be used for data cleaning, to prepare data for shipment to the RCU, and for analysis.

Access to data

The FileMaker databases will require login using a University of Minnesota ID and password. Each user will be assigned to one of several privilege sets:
- Full access
    What: Allows deletion of records, database design, view of randomization table;
    Who: Site Statistician, Database Manager, IT director
- Evaluation
    What: limited viewing and modification of recruitment and measurement tables but not deletion, no access to intervention or randomization tables
    Who: Data collectors
- Evaluation Coordinator
    What: Evaluation access plus additional reporting
    Who: Evaluation Coordinator
- Intervention
    What: Limited viewing and modification of recruitment and intervention tables but not deletion, no access to measurement or randomization tables
    Who: Intervention implementation staff
- Intervention Coordinator
    What: Evaluation access plus additional reporting;
    Who: Intervention Coordinator

Blinding

The Site Statistician will provide the randomization table to the RCU and database manager prior to enrolling participants. As participants complete baseline the index child ID will be added to the randomization table by a staff member with Full Access privileges. A date/timestamp will record when this occurs and the user that performed the action. If the ID is assigned to the NET-Works intervention then a record will be created in the intervention database. Evaluation staff will not have access to the

intervention table. Intervention staff will not have access to the evaluation table nor the REDCap survey database.

Quality Control
The contact management database will use scripts to identify cases where study events have been missed or are overdue. For example, if a measurement visit is scheduled but the eligibility screening is not complete then the record will be flagged for the Evaluation Coordinator. Anthropometric range checks (described in the MOP) will be performed during data entry at the home visit. Ten percent of households will be flagged for repeat anthropometry to evaluate inter-rater reliability. During data collection the REDCap database will prompt for out of range or missing values. Accelerometers will be downloaded during the home visit and new accelerometers distributed if wear time is insufficient (as described in the MOP). Ten percent of diet recalls will be flagged quality control review and be edited as needed.

Once SAS data sets have been created ranges for all variables will be hand checked for plausibility. Improbably high or low values will be reviewed in the original data and corrected as needed. The RCU upload process will reverify plausibility of data.

13. SITE-SPECIFIC TIMELINE
Data collection for 36 month follow up will continue through year 7 (Table 13.1). This is due to the increase in length of the recruitment, enrollment and baseline data collection period during the first 18 months of the trial. While an 18 month recruitment and enrollment period is planned, every effort will be made to enroll all 500 participants between 12 and 15 months. This will enable data collection to be completed prior to the end of year 7.

Table 13.1 NetWorks Seven-Year Timeline

Phase 1 (1-2 years): Protocol development, Planning, Formative Research, & Pilot Testing												
Year 1 (2010)	Month											
Project Activities	J	F	M	A	M	J	J	A	S	O	N	D
Partnership/Dev mtgs									x	x	x	x
Year 2 (2011) Pilot Study	Month											
Project Activities	J	F	M	A	M	J	J	A	S	O	N	D
Develop Provider, ECFE, Community Food/PA, and Family Advocate /HVisit	x	x	x	x	x	x	x	x				
Develop Recruitment, Evaluation, Intervention Protocols and Manuals	x	x	x	x	x	x	x	x	x	x	x	x
Pilot Study Recruitment & Baseline						x	x	x				
Pilot Study Intervention									x	x	x	x
Phase 2 (4 years): 36 Month Full-scale trial												
Year 3 (2012)	Month											
Project Activities	J	F	M	A	M	J	J	A	S	O	N	D

	J	F	M	A	M	J	J	A	S	O	N	D
Pilot Study Intervention	x	x										
Pilot Study Follow-up meas			x									
Refine full-scale trial protocol	x	x	x	x	x	x	x					
Recruitment/Baseline meas					x	x	x	x	x	x	x	x
Intervention							x	x	x	x	x	x

Year 4 (2013)	Month											
Project Activities	J	F	M	A	M	J	J	A	S	O	N	D
Recruitment /Baseline Measures	x	x	x	x	x	x	x	x	x	x	x	x
Intervention	x	x	x	x	x	x	x	x	x	x	x	x
12 month measures						x	x	x	x	x	x	x

Year 5 (2014)	Month											
Project Activities	J	F	M	A	M	J	J	A	S	O	N	D
Intervention	x	x	x	x	x	x	x	x	x	x	x	x
12 month measures	x	x	x	x	x	x	x	x	x	x	x	x
24 month measures						x	x	x	x	x	x	x

Year 6 (2015)	Month											
Project Activities	J	F	M	A	M	J	J	A	S	O	N	D
Intervention	x	x	x	x	x	x	x	x	x	x	x	X
24 month measures	x	x	x	x	x							
36 month measures						x	x	x	x	x	x	X

Year 7 (2016) Phase 3 Data analysis, sustainability measures, and dissemination												
Intervention		x	x	x	x	x	x	x	x	x	x	X
36 month measures		x	x	x	x	x	x	x	x	x	x	X

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APPENDIX 1

- Home Visit 1
- Positive Parenting Supports
- Family and Community Connections
- Taking Steps for Healthy Family Actions
- Family Meals Assessment
- Healthy Topics (parents)
- Smart Steps 1-2
- Smart Step 3
- Healthy Action Activities
- PA Follow the Leader
- No Calendar Goal Sheet
- Pamphlet for Clinic

Key Objectives

The Family Connector serves as a health coach and will:

- Establish relationship with parent and child
- Establish structure for Home Visits (goal setting)
- Provide an overview of NET-Works
- Learn about the family's neighborhood and community support system
- Initiate behavioral goal setting (assessment, contemplating, establishing)

Contemplating a Goal → Establishing a Goal → Building on a Goal → Completing a Goal → Sustaining a Goal

- Infuse parenting skills and developmental parenting

Session Summary

Activity	Materials Needed
Parent/Child Greeting Activity (Physical Activity focus)	NET-Works activity card
Child engagement Activity (FC choice)	NET-Works activity supplies
Positive Parenting/Healthy Family Actions Overview (translated)	Overview Sheet (flower)
Taking Steps for Healthy Actions (assessment) (translated)	Healthy Actions Worksheet/ Tracking Calendar
Family and Community Connections Worksheet (translated)	Connections Worksheet
Closure	Materials Needed
Healthy Actions Activity Cards	Healthy Actions Envelope & Cards
Busy Bag	Busy Bag and one item

1. **Parent/Child Greeting Interactive Activity**

   Greet the Family

   Prepare mat and EXPLAIN

   > *Each time I come to visit we will do a fun 'Healthy Action"*
   > *activity at the beginning of our time together to get everyone*
   > *moving, to help you learn some new activities and ways to*
   > *be healthy. I will use this activity card to show you how to do*
   > *the activity and then I will leave it with you to keep and use*
   > *when you choose. I will give you many activity cards over*
   > *time and you can keep them in this envelope.*

   Do the activity 3-5 times so the family feels comfortable with how to complete it on their own.

2. **Child Engagement activity/ies (Family Connector's choice)**

   Choose an activity for the child to engage in while you take time to introduce the parent to NET-Works. The activity will be one that you choose based on their age, interest, and initial phone call you had with the parent.

3. **Positive Parenting/Healthy Family Actions Overview**

   Give parent the overview sheet

POSITIVE PARENTING
SUPPORTS
HEALTHY FAMILY ACTIONS

MODEL
Be a good example
Set rules and routines

NETWORK
Use your community
Ask he

GUIDE
Set limits
Offer choices

SHAPE
Develop healthy habits
Use rewards and consequences
Find solutions together

NURTURE
Give attention, praise and encouragement
Reinforce positive actions
Communicate and respect each other

Do more active play
Exercise regularly
Reduce TV and screen time
Have healthy snacks and meals
Eat more fruits & vegetables
Drink less sugary beverages
Have family meals together
Eat out less
Get school ready

NET-WORKS
NOW EVERYBODY TOGETHER
FOR AMAZING AND HEALTHY KIDS

EXPLAIN

I am excited that you decided to participate in the NET-Works study. I want to spend some time telling you what the project is about and how we will work together during our home visits.

This flower shows what the project is about. The project is about making healthy changes in your home and with your family to help your child grow healthy and strong and get ready for school.

We will work together to decide on goals you would like to have for your family that will help you and your child do the healthy actions in the middle of the flower.

You and I will be partners in this because you are the one that knows your child best and what changes make sense and are the most important to you. I will offer support in this process.

Go through each of the Healthy Action areas with the parent.

So, we know the things that help a child be their healthiest are these; Do more active play, exercise regularly (you and your child!), watch less TV, have healthy snacks and meals, eat more fruits and vegetables, drink less sugary beverages, have family meals together, eat out less, and get school ready by doing things that help with early reading skills, coordination, self-control, and creative and imaginative play.

Get an idea of how the parent feels about these.

ASK

How do you feel about these healthy actions?

Have you heard about all of these areas for keeping children healthy?

Do all of these make sense to you as you think about your own child's healthy development?

We are going to explore these areas more in a few minutes, but I also wanted to talk to you about some of the parenting behaviors that are included on our flower. They make up the outer petals of the flower, because everything you do as a parent supports your child's healthy growth and development. Through the ECFE parenting classes and during our home visits, you will learn more about all of these areas and I will support you to work on the areas that are important to you and your family.

Role Model
Being a good role model is important. Your kids are watching you, paying attention to what you are doing and copying what you do, even when you aren't aware of it! Your kids want to do what you do, so the more positive things you can show them, the healthier they will be. Part of that is setting rules and routines. That helps kids feel safe.

Shape
Your parenting helps shape healthy development for your child. We will have a chance to look at healthy discipline with rewards and consequences and ways you can work with your child to find good solutions to challenges together.

Nurture
Of course you know that giving attention, praise, and encouragement is so important to help a child's self-confidence grow. Reinforcing positive actions will get the results you want, and communicating with respect and love will show your child you care.

Guide
You have a right as a parent to guide your child by setting limits, showing them how to behave. I can help you learn how to offer choices so your child and you feel in control.

> *Network*
> *This might be an area you haven't thought a lot about. But your community and neighborhood can offer support when you need it. You just need to know where to look, and who to ask for help. We can work on that together. I have some ways to help you think about that.*

These are things we will work on together. You can keep this to look at more later if you like. I will refer back to it during our visits.

4. **Family and Community Connections Worksheet**

   EXPLAIN

> *This sheet is a way for me to get to know you and your family better. It will also help me understand ways I can support you better in making healthy changes in your home and with your family. We can also learn about ways the community can support your family's healthy changes. Let's fill it out together and we can talk about it as we go. Does that sound OK to you?*

Complete the Worksheet with the Parent.

> **Family Connector Note**
>
> If you feel that your time is getting short in this Home Visit Session, you can introduce this worksheet at the end of the session and either decide to give it to the parent to complete between this visit and your first call or complete it in Home Visit 2.

5. **Taking Steps for Healthy Actions Assessment**

   EXPLAIN

> *We just looked at the Healthy Actions on the flower that can help your child be their healthiest and get ready for school. You may not feel like you know all the things you need to know about each of those areas and how that effects your child's health and if you are doing the right things.*

*One of the things we know that can help people work towards making healthy changes is working on small steps to get there. That will be what we do together as part of our home visits and when you go to the parenting classes. I have learned how to help parents figure out what steps **they want** to take in those different areas.*

One way I can learn more about how to help you make changes is to understand what you do in your family right now in these different areas and get your ideas about things you might like to change or other ways you want to handle things in your family.

So, let me ask you some of these questions and I can fill this out with you. It will serve as a nice guide as we work together over the next few months.

Complete the Worksheet with the Parent

Family Connector Note

Once you have completed some or all of the assessment (depending on how much time things have taken so far), you will work with the parent to establish one goal during this Home Visit.

The goal is…

To support the parent in completing one (or more) step/s towards setting a goal in one of the behavior topic areas. The goal could include any component of the SMART model or be any where on the Stages of Change continuum. It will depend on where the parent is with their knowledge, interest, and motivation.

Tracking Calendar

Record the goal on one of the tracking calendars and ask the parent to post it in a visible place to remind them of their goal.

Session Closure

The session will end with:

- Giving the family their "Healthy Actions" envelope for their activity cards.

- Giving the family the Busy Bag with one item and explaining that each visit you will bring something else to add to the bag that supports active play for you and your child.

- Scheduling Home Visit #2 (in approximately one month).

- Scheduling Connector Call #1 (between Home Visit #1 and Home Visit #2).

POSITIVE PARENTING BEHAVIORS

SU??OR.T

HEALTHY FAMILY ACTIONS

NETWORK

Use your community

Ask for help

MODEL

Be a good example

Set rules and routines

GUIDE

Set limits

Offer choices

Do more active play
Exercise regularly Reduce TV and screen time Have healthy snacks and meals Eat more fruits & vegetables Drink less sugary beverages Have family meals together
Eat out less
Get school ready

SHAPE

Develop healthy habits

Use rewards and consequences

Find solutions together

NURTURE

Give attention, praise and encouragement

Reinforce positive actions

Communicate and respect each other

NET-WORJ(S

NOW EVERYBODY TOGETHER
FOR AMAZING AND HEALTHY KIDS

FamilY- and CommunitY- Connections

Other Family _____   Fri nds _____
_____
_____

— Faeth
ommunity _

Important People in My Life

Other
Family   My Family   Other
Family

Family members living in the
home w/ages of children
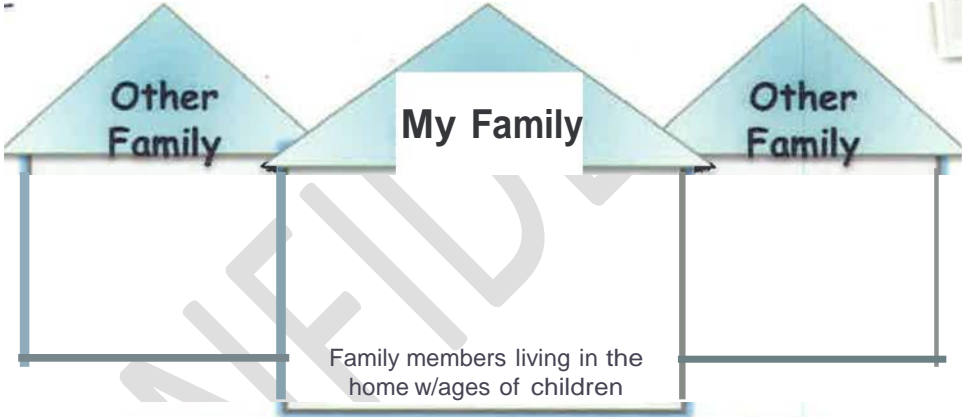
Important Places in My Life

Education

Food Shopping
_____
_____
_____

Childcare

Community
Resources _____
_____

Physical Activity and
Recreation

Work

_____
_____

Taking Steps *tor* Healthy Family Actions

Here's an activity to help you look at your family's eating and physical activity. On each line, write down what you and your family do now. In the second box, write what your family could do to eat better or be more active.

NET-Works Topics	Describe what you do now	Describe what you would like to do
Example: Eating family meals together	*We eat breakfast together on weekends and dinner twice a week*	*We could eat lunch together on weekends too*
Sweetened beverages available (e.g. soda, fruit drinks Kool-Aid®)		
Salty/high fat snack foods available		
Sweets available		
Fruit and vegetable availability at snack		
Eating family meals together		
TV/Screen time (e.g. TV, DVD, video games, internet)		
Your child's physical activity level		
Your physical activity level		
Active play equipment available for indoor and outdoor use		
Being active together as a family		

Where would you like to start? _____

POSITIVE PARENTING BEHAVIORS

SUPPORT

HEALTHY FAMILY ACTIONS

NETWORK
Use your community
Ask

MODEL
Be a good example
Set rules and routines

GUIDE
Set limits
Offer choices

SHAPE
Develop healthy habits
Use rewards and consequences
Find solutions together

NURTURE
Give praise and encouragement
Reinforce positive actions
Communicate and respect each other

Do more active play
Exercise regularly
Reduce TV and screen time
Have healthy snacks and meals
Eat more fruits & vegetables
Drink less sugary beverages
Have family meals together
Eat out less
Get school ready

NET-WORKS
NOW EVERYBODY TOGETHER
FOR AMAZING AND HEALTHY KIDS

Taking Steps for Healthy Actions in Your Family

Here's an activity to help you look at your family's eating and physical activity. On each line, write down what you and your family do now. In the second box, write

what your family could do to eat better or be more active.

NET-Works Topics	Describe what you do now	Describe what you would like to do
Example: Eating family meals together	We eat breakfast together on weekends and dinner twice a week	We could eat lunch together on weekends too
Sweetened beverages available (e.g. soda, fruit drinks, Kool-Aid®)		
Salty/high fat snack foods available		
Sweets available		
Fruit and vegetable availability at snack		
Eating family meals together		
TV/Screen time (e.g. TV, DVD, video games, internet)		
Your child's physical activity level		
Your physical activity level		
Active play equipment available for indoor and outdoor use		
Being active together as a family		

Where would you like to start?_____

Family Connector

Here are some questions you can ask that might help a family visualize what goal they would like to set when it comes to having more consistent Family Meals in their home.

1. How many *breakfast* meals does your family eat together:

    during a typical work/school week (M - F) _____   during a typical weekend _____

2. How many *lunch* meals does your family eat together:
    during a typical work/school week (M - F) _____   during a typical weekend _____

3. How many *dinner* meals does your family eat together:
    during a typical work/school week (M - F) _____   during a typical weekend _____

4. What types of routines do you have for having family meals in your home?

It may also be helpful to think about what kinds of foods are being served at family meals and what is going on during the meal.

1. How many fruits and vegetables do you serve at a typical family meal? _____ fruits _____ vegetables

2. Do you always serve a dessert after a family meal? _____ Yes _____ No

3. How often is media used during your family meals …

	Always	Sometimes	Never
… TV is on		_____	_____
… Someone is using a cell phone (texting or talking)		_____	_____
… Someone is listening to their ipod	____	_____	_____
… Someone is using their laptop, ipad, DSI, handheld computer game	____	_____	_____

4. How do family members talk and get along during family meals?

5. How do family meals fit into your family's daily routine?

6. What is the value around eating together as a family?

7. What is the cultural value for eating together?

Notes for Family Connector: Find one way to reinforce something positive the parent is doing with regard to having family meals.

Family Meals

Why having family meals together is important!

Research is showing and families are recognizing that eating family meals together has many benefits and parents are putting them back on their "menu" of family routines.

+ Shared family meals are more likely to be nutritious

+ Kids who eat regularly with their families are more likely to eat fruits, vegetables, and whole grains and less likely to snack on unhealthy foods.

+ Everyone eats healthier meals.

+ Kids are less likely to become overweight or obese.

+ Parents and kids will talk more.

+ Kids will feel like you're proud of them.

+**There** will be less stress and tension at home.

And when your children are older ...

+**You'll** be more likely to hear about a serious problem.

+ School grades will be better.

+ Kids more likely to stay away from cigarettes.

+ They're less likely to drink alcohol.

+ They won't likely try marijuana.

+ They're less likely to use illicit drugs.

+ Friends won't likely abuse prescription drugs.

There's no "magic number" of meals you should eat as a family, although research suggests that having about 5 family meals brings the most benefits to kids and parents. Adding a few more family meals each week can have positive effects on your child and family.

It may also be helpful to think about what kind's of foods are being served at family meals and what is going on during the meal.

Studies are also showing that if you can't have dinner meals together that a breakfast or lunch meal may have the same benefits as a dinner meal. Beyond health and nutrition, family meals provide a valuable opportunity to reconnect. This becomes even more important as kids get older.

Healthy Meals and Snacks
Helping Your Kids *Develop*
Healthy Eating Habits

Why it's important!

+ Good nutrition supports lifelong health and begins in infancy. Providing healthy snacks and limiting unhealthy snacks is important for growing bodies.

+ Snacks play a major and growing role in children's diets. Between 1977 and 1996, the number of calories that children consumed from snacks increased by 120 calories per day.

+ Research shows that many children today are eating snack foods that are high in fat, sugar, and salt.

Children who eat healthy foods will be more likely to ...

+ Make better food and nutrition choices are adults.

+ Maintain a healthier weight overtime.

A good general rule is to limit "junk food; salty/high fat snacks, sweets and sugared drinks to one serving (150-200 calories) per day or less. For example, that could be 12 oz of sweetened soda, a small package of potato chips, a carton of chocolate milk, OR a small scoop of ice cream (1/2 cup).

No matter how good your intentions, trying to convince your three year old that an appl.e is as sweet a treat as a cookie is not a recipe for success! However, you can ensure that your children's diet is as nutritious and wholesome as possible, even while allowing for some of their favorite treats.

It is important t9 monitor the serving size of your child's snacks, especially if you give your child prepackaged snack foods. For example, if your child's snack consists of Oreo cookies, keep in mind that it takes just three Oreos to add 160 calories and a lot of extra fat and sugar. And if six or nine Oreo cookies are eaten, that quickly adds up to an extra meal-and not a very health meal, either.

Snacks can be a good part of your child's diet, though, including low-calorie snacks and low-fat snacks like fresh fruit, pretzels, cheese sticks, or veggies.

Physical Activity and Active Play for Young Children
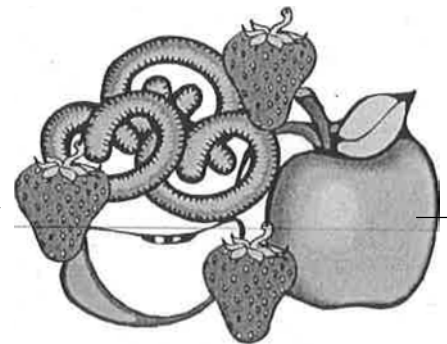
Why it's important!

How much activity do young children need?

Kids between the ages of 2 and 6 are learning to master basic movements like walking, running, kicking, and throwing. Anyone who's seen kids on a playground knows that most are naturally active and love to move around. So be sure to provide lots of opportunities for your child to practice and build on these skills. Helping kids achieve a lifetime of being active is the goal!

How much is enough?

Aim for at least 60 minutes of activity each day.

+ Get at least 30 minutes of structured physical activity (adult-led).

+ Get at least 30 minutes unstructured physical activity (free play).

+ Not be inactive for more than 1 hour at a time (except for sleeping).

Healthy Practices and Routines

Parents can instill a love of activity and help kids fit it into their everyday routines. Establishing habits and routines at a young age will help children be naturally fit all their lives.

Developing a routine of physical activity over time can also help kids with ...

+ Strong bones and muscles.

+ Heart health.

+ Healthy weight.

+ Lowered chance of getting diabetes.

+ Better sleep.

— Betw em-otional hea.lth and -s-el -esteem.

What Motivates Kids?

Active Play is the best way for kids to be physically active!

So there's a lot to gain from regular physical activity, but how do you encourage kids to do it? The three keys are:

+ *Choosing the right activities for a child's age:* If you don't, the child may be bored or frustrated.

+ *Giving kids plenty of opportunity to be active:* Kids need parents to make activity easy by providing equipment and taking them to playgrounds and other active spots.

+ *Keeping the focus on fun:* Kids won't do something they don't enjoy.

Sugar-Sweetened Beverages and Kid's Health

Why it's important f

One of the keys to healthy eating and keeping a healthy weight is to limit easy access to high sugar foods that may taste good, but don't have much nutritional value. This includes sugared drinks like soda, sports drinks, Kool-Aid®, and even fruit juice.

The American Academy of Pediatrics recommends that children ages 1-6 years old drink no more than 6 ounces (one serving) of juice a day.

Fruit juice can be·rich in vitamins, minerals, and cancer-fighting compounds. However, consider this....

+ It is high in calories.

+ Kids are also less likely to feel full from fluid calories and more likely to over eat.

+ It replaces milk, an important calorie source.

Sugar-sweetened beverages also increase ...

+Tooth decay.

+ Child's chances of becoming overweight over time.

Consider making alternatives to juice the rule in your family.

Your best bet is to drink water, seltzer or flavored waters with little or no added sugar. Tap water is always a good choice. It's healthful, has no calories and costs nothing. Water and low-fat or fat-free milk are healthier choices.

Try to buy 100% fruit juice and avoid the added sugars of juice drinks, · punches, fruit cocktail drinks, or lemonade. Drinks that contain at least 50% juice and no additional caloric sweeteners are also healthful options. To find 100% juice, look at beverage nutrition labels for the percentage of the beverage that is juice.

Portion Alert

+ Portion sizes in the United States are getting bigger. Soda that used to come in 8 oz bottles now comes in 12 oz cans.

+ When you choose to have a sweetened beverage, pour it into a six ounce glass, instead of drinking out of the bottle.

Healthy Habits for TV/Screen Time and Young Children

Why it's important!

TV and screen time are sources of education and entertainment for kids. But according to the Kaiser Family Foundation, *today's young children spend nearly as much time in front of some sort of screen, whether it's a computer, video game, or TV, as they spend playing outside.*

The American Academy Of Pediatrics (AAP) recommends that kids older than two watch no more than 1 to 2 hours a day of quality programming.

That's why it's wise to monitor and limit the time your child spends watching TV and playing on the computer, and other electronic devices so they can focus on things like active play and getting school ready with creative and imaginative activities.

> Kids in the United States watch an average of 4 hours of TV a day. That's double the American Academy of Pediatrics' recommended maximum.

Keep this in mind!

+ Sitting still replaces active play.

+ Advertisers market junk food on TV and kids want it:

+ Kids eat more when watching TV especially as they get older.

There are really two key ways to develop healthy TV/screen time habits.

+ Limit the number of TV-watching hours.
  - Turn off TV during meals
  - Set family TV time/time limits
+ Offer fun alternatives to television.
  - Play a game, read, go outside!.

Setting Goals for Healthy Family Actions

Topic: Family Meals

Goal: Aim for five family meals a week

STEP 1: Visioning: *What do you envision for your family and having family meals together?*

Families are recognizing that eating family meals together has many benefits and they are putting them back on their 'menu' of family routines.

A family meal is when the family is together eating a common meal (breakfast, lunch, or dinner) with no distractions such as media, and talking about ideas and their day.

Shared family meals are more likely to be nutritious, and kids who eat regularly with their families are more likely to eat fruits, vegetables, and whole grains and less likely to snack on unhealthy foods.

There is no "magic number" of meals you should eat as a family, although research suggests that having about 5 family meals per week brings the most benefits to kids and parents. Adding a few more family meals each week can have positive effects on your child and family. Beyond health and nutrition, family meals provide a valuable opportunity to reconnect. This becomes even more important as kids get older.

Start with small steps and soon you will achieve the goals you have for you and your family!

On each line, write down what you and your family do now when it comes to family meals. First, describe what you do now, then describe what you would like to do, and then describe what keeps you from doing that. This is a great first step for setting some healthy family meal goals.

NET-Works Topic	Describe what you do now	Describe what you would like to do	Describe what keeps you from doing that?
Family Meals	*We* rarely eat together as a family. It might be one or two of us, but usually I am just making food for my kids.	Eating together more often sounds like a good idea. I didn't know it was so important.	My family is busy and we just don't have a routine about eating together at the same time.
Family Meals			

STEP 2: Visioning: *Thinking about setting a goal*

The key to making successful changes is creating a good "action plan." Once you've decided which change or changes you and your family .would like to make around family meals, you should think about how you're going to make them happen. You can visualize your success by creating a SMART goal. SMART stands for:

Specific Measureable Attainable Realistic Time-based.

When planning what steps to take, it's helpful to think about the following:

+ decide on your SMART goal,

+ rehearse the steps in your mind and anticipate problems,

+ start with small steps that are easy to do,

+ commit to the plan by telling others, and

+ come up with a way to track your progress and create a simple reward system for a job well done.

Here's an example of a good action plan for family meals.

1. Set a routine for having at least one family meal together a day. Maybe breakfast is a good and easy place to start. Think of something the whole family will eat (cereal, milk and a fruit?) and try to do at least 5 times a week. See how that feels!

2. Set limits/rules that there is no media being used during family meals (e.g. TV, laptop, ipad, ipod, cell phones).

3. Check off or put a sticker on your calendar for each time your family has a meal together. When you get up to five in the week, do something special together as a family! That could be playing a game, going on a family walk, or reading a special book together.

Topic: Healthy Meals and Snacks

Goal: Limit to one treat (sweet, fat, salt) per day
         on most days of the week

STEP 1: Visioning: *What do you envision for your family and healthy snacking?*

Here's an activity to help you look at your family's snacking habits.

Good nutrition supports lifelong health and begins in infancy. By encouraging healthy eating habits now, you can make a huge impact on your children's lifelong relationship with food and give them the best opportunity to grow into healthy adults.

Snacks play a major and growing role in children's diets." Between 1977 and 1996, the number of calories that children consumed from snacks increased by 120 calories per day. Providing healthy snacks and limiting unhealthy snacks is important for growing bodies.

A good general rule is to limit "junk food; *salty/ high fat snacks, sweets and sugared drinks to one* serving (150-200 calories) per day or less. For example, that could be 12 oz of sweetened soda, a small package of potato chips, a carton of chocolate milk, OR a small scoop of ice cream (1/2 cup).

Start with small steps and soon you will achieve the goals you have for you and your family!

On each line, write down what you and your family do now when it comes to healthy meals and snacking. First, describe what you do now, then describe what you would like to do, and then describe what keeps you from doing that. This is a great first step for setting some healthy snacking goals for you and your family.

NET-Works Topic	Describe what you do now	Describe what you would like to do	Describe what keeps you from doing that?
Healthy Snacks	I let my child have a few sugary snacks per day.	I want to limit the number of snacks my child has each day.	I just didn't think about it because he is growing and I thought the extra snacks didn't really matter.
Healthy Snacks			

STEP 2: Visioning: *Thinking about setting a goal*

The key to making successful changes is creating a good "action plan." Once you've decided which change or changes you and your family would like to make with healthy meals and snacks, you should think about how you're going to make them happen. You can visualize your success by creating a SMART goal. SMART stands for:

Specific Measureable Attainable Realistic Time-based.

When planning what steps to take, it's helpful to think about the following:

+decide on your SMART goal,

+ rehearse the steps in your mind and anticipate problems,

+ start with small steps that are easy to do,

+commit to the plan by telling others, and

+ come up with a way to track your progress and cr:eate a simple reward system for a job well done.

Here's an example of a good action plan for increasing healthy snacking for your child.

1. Give your child just one kid size sugary snack per day. Keep snacks in a place only an adult can reach so you can monitor how much your child gets each day.

2. Help your child make choices about what his favorite snacks are and let him choose among those during the week. Replace one unhealthy snack with a healthy one if you have another snack in the day.

3. Put a check mark or sticker on the days of the weeks that you are able to limit the sugary snacks to one a day. Give yourself a pat on the back for making healthy choices wityour child!

Topic: Physical Activity/Active Play

Goal: 60 mins of activity per day

(For kids: 30 minutes of structured/30 of unstructured)

STEP 1: Visioning: *What do you envision for your family and physical activity/active play?*

Here's an activity to help you look at your family's physical activity. Kids between the ages of 2 and 6 are learning to master basic movements like walking, running, kicking, and throwing. Anyone who's seen kids on a playground knows that most are naturally active and love to move around. So be sure to provide lots of opportunities for your child to practice and build on these skills. Helping kids achieve a lifetime of being active is the goal!

How much is enough? According to the National Association of Sports and Physical Education, each day young children should:

1. get at least 30 minutes of structured physical activity (adult-led)
2. get at least 60 minutes unstructured physical activity (free play)
3. not be inactive for more than 1 hour at a time (except for sleeping)

Your family also learns about physical activity from watching and being active with you! Adults needs 60 minutes of moderate to vigorous activity each day. Start with small steps and soon you will achieve the goals you have for you and your family!

On each line, write down what you and your family do now when it "comes to physical activity/active play. First, describe what you do now, then describe what you would like to do, and then describe what keeps you from doing that. This is a great first step for setting some active goals for you and your family.

NET-Works Topic	Describe what you do now	Describe what you would like to do	Describe what keeps you from doing that?
Physical Activity/ Active Play	We don't have any routine to our physical activity but we like being active.	I would like us to be an active family together.	Our house is busy and there are many other people that have activities and need my attention. We don't make physical activity something we do together.
Physical Activity/ Active Play			

STEP 2: Visioning: *Thinking about setting a goal*

The key to making successful changes is creating a good·"action plan." Once you've decided which change or changes you and your family would like to make with physical activity/active play; you should think about how you're going to make them happen. You can visualize your success by creating a SMART goal. SMART stands for:

Specific Measureable Attainable Realistic Time-based.

When planning what steps to take, it's helpful to think about the following:

+ decide on your SMART goal,
+ rehearse the steps in your mind and anticipate problems,
+ start with small steps that are easy to do,

- commit to the plan by telling others, and
+ come up with a way to track your progress and create a simple reward system for a job well done.

Here's an example of a good action plan for increasing structured physical activity.

1. Set a time when you and your child (and other children) do one active play game together for 10 minutes (throwing a ball outside or inside, playing Simon Says, dancing together). Try for three days in the week.

2. Ask your family to come up with a list of ideas for things you can do to be active together. Try one new thing each week for 10 minutes.

3. Have your child put a sticker on the calendar or tracking log for each time that you do active play or some physical activity together. Do something special or fun when your family has done something active together for 3 days.

Setting Goals for
Healthy Family Actions

Topic: Sugar-Sweetened B verages
Goal: Limit to no more than 6 oz of sugar-sweetened beverages per day (including juice)

STEP 1: Visioning: *What do you envision for your family and sugar-sweetened beverages?*

Here's an activity to help you look at your family's habits when it comes to drinking sugar-sweetened beverages.

One of the keys to healthy eating and keeping a healthy weight is to limit easy access to high sugar foods that may taste good, but don't have much nutritional value. This includes sugared drinks like soda, sports drinks, Kool-Aid®, and even fruit juice.

The American Academy of Pediatrics recommends that childrn ages 1-6 years old drink no more than 6 ounces (one serving) of juice a day.

Fruit juice can be rich in vitamins, minerals, and cancer-fighting compounds. However, it is high in calories.

Try to buy 100% fruit juice and avoid the added sugars of juice drinks, punches, fruit cocktail drinks, or lemonade. Drinks that contain at least 50% juice and no additional caloric sweeteners are also healthful options. To find 100% juice, look at beverage nutrition labels for the percentage of the beverage that is juice.

Sugar-sweetened beverages also.....
+ promote tooth decay
+ increase a child's risk of becoming overweight over time.

Start with small steps and soon you will achieve the goals you have for you and your family!

On each line, write down what you and your family do now when it comes to drinking sugar-sweetened beverages. First, describe what you do now, then describe what you would like to do, and then describe what keeps you from doing that. This is a great first step for setting some healthy goals to limit sugar-sweetened beverages for you and your family.

NET-Works Topic	Describe what you do now	Describe what you would like to do	Describe what keeps you from doing that?
Sugar-Sweetened Beverages	My child drinks about 3-5 juice boxes a day (I don't know how many oz there are in each).	I would like my child to drink more water, so I guess that means less juice, too.	She really likes juice and it is just a habit now.

Sugar-Sweetened Beverages			

STEP 2: Visioning: *Thinking about setting a goal*

The key to making successful changes is creating a good "action plan." Once you've decided which change or changes you and your family would like to make with sugar-sweetened beverages, you should think about how you're going to make them happen. You can visualize your success by creating a SMART goal. SMART stands for:

Specific Measureable Attainable Healistic Time-based.

When planning what steps to take, it's helpful to think about the following:

+ decide on your SMART goal,
+ rehearse the steps in your mind and anticipate problems,
+ start with small steps that are easy to do,

+ commit to the plan by telling others, and
+ come up with a way to track your progress and create a simple reward system for a job well done.

Here's an example of a good action plan for sugar-sweetened beverages and your child.

1. I will buy less sugar sweetened beverages this week and replace one or two juice drinks with a healthier alternatives like wpter or lowfat milk.

2. I will let my child select when or at which meal he or she wishes to drink their 6 oz of sugar-sweetened beverage each day.

3. Check off or put a sticker on your calendar for each time you give your child an alternative drink OR put a sticker on the days that you give your child just one 6 oz serving of a sugar-sweetened beverage (and what meal) so you can keep track. Your success means a healthier child!

Topic: TV/Screen Time   Goal: Limit TV to no more than 2 hours/day

STEP 1: Visioning: *What do you envision for your family and TV/screen time?*

Here's an activity to help you look at your family's TV and screen time use. Screen time includes any time you spend watching or using electronic devices for entertainment or work. Screen time includes DVD watching, computer use and other hand-held equipment. When you are watching TV or doing something on other screens your time being sedentary increases!

On each line, write down what you and your family do now when it comes to TV/Screen time. First, describe what you do now, then describe what you would like to do, and then describe what keeps you from doing thaL This is a great first step for setting some positive TV/Screen time goals for you and your family.

NET-Works Topic	Describe what you do now	Describe what you would like to do	Describe what keeps you from doing that?
TV/Screen Time	We watch TV while eating meals.	I don't want my child to watch TV at lunch or dinner.	My child is used to watching TV while eating so she might get mad if I take away that activity.
TV/Screen Time			

STEP 2: Visioning: *Thinking about setting a goal*

The key to making successful changes is creating a good "action plan." Once you've decided which change or changes you and your family would like to make, you should think about how you're going to make them happen. You can visualize your success by creating a SMART goal. SMART stands for:

Specific Measureable Attainable Realistic Time-based.

When planning what steps to take, it's helpful to think about the following:

+ decide on your SMART goal,
+ start with small steps that are easy to do,
+ rehearse the steps in your mind and anticipate problems,

+ commit to the plan by telling others, and
+ come up with a way to track your progress and create a simple reward system for a job well done.

Here's an example of a good action plan for watching less TV while eating meals.

1. Set a day and time to communicate to your child (and other family members) that you would like to make mealtimes a time when the family talks rather than watches TV.
2. Create a new routine (like things to talk about, table games) for eating lunch and dinner without the TV on. Get some ideas from your family.
3. Have your child put a sticker on the calendar or tracking log for each meal that the TV is not on. Do something special or fun when your family has had the TV off for lunch and dinner on 3 days.

SMART Goals for Healthy Actions

STEP 3: Goal Statement

My SMART goal (for me arid/or my family) is to:

_____

_____

Meeting this goal is important to me because:

_____

_____

The action steps I need to take to achieve this goal are to:

1. _____

2. _____

3. _____

4. _____

5. _____

I will ask — — — — — — — — — — — — — — to support me in working toward this goal, and this is how s/he (or they) could be helpful:

_____

_____

I will post my goal progress here:

D Tracking Chart on the Refrigerator

D Calendar

D Notebook or journal

D Other (explain) — — — — — — — — — — — — — — — — — —

_____

Participant Sign and Date

Healthy Action Activities

Family Meals Activities:

- Designing Your Plate - *demo only* Making A Family Placemat – *demo only* Family Picnic Play Musical Places We Like To Eat Together
-
-
-

Healthy Meals And Snacks Activities:

- Fruit And Vegetable Hopscotch
- If You Like To Eat An Apple
- Fruit And Vegetable Scavenger Hunt
- Today I Ate A Rainbow
- What Would The Monkey Eat Identify Healthy and Non Healthy Snacks - *demo only*

Physical Activity and Active Play Activities:

- Dance
- Follow The Leader
- Skipping
- Stretch
- Playful walk
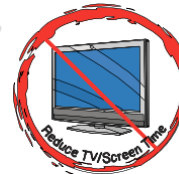
Reduce TV/Screen Time Activities:

- Shadow Game
- Animal Charades
- I Spy
- Simon/Sarita Says
- Instead of TV - *demo only*

Reduce Sugar Sweetened Beverages Activities:

- Bowling with Water Bottles One Juice A Day The Water Song Sugar Content Of Sweetened Beverages - *demo only* Itsy Bitsy Spider
-
-
-

Follow the leader

Turn on the Music. ♪♪♪

Start with everyone marching in place.

Take turns leading.

The leader can carry the rainbow ribbons.

Walk in any pattern you want to. Chose a different type of walk each time:
fast walk, slow walk, tip toes, large steps, backwards etc.

Taking turns develops cooperation.

Take Action!

Be physically active with your young children 60 minutes every day!

- Aim for active play throughout the day
- Be a role model for your children.
- Provide plenty of water and healthy foods.

What you need for this activity:
- Music
- Rainbow ribbons
- You and your imagination!

NET-WORKS
NOW EVERYBODY TOGETHER
FOR AMAZING AND HEALTHY KIDS

Physical Activity and Active Play

Healthy Action!	Each time you do one of these Healthy Activities you get to put a sticker in that section!
Physical Activity and Active Play	
Family Meals	
Reduce Sugar Sweetened Beverages	
Healthy Meals and Snacks	
Reduce TV/Screen Time	

NET-WORKS
NOW EVERYBODY TOGETHER
FOR AMAZING AND HEALTHY KIDS

Healthy Tips for Parents of 2-4 Year Olds

2 is Terrific

3 is Tremendous

4 is Fantastic
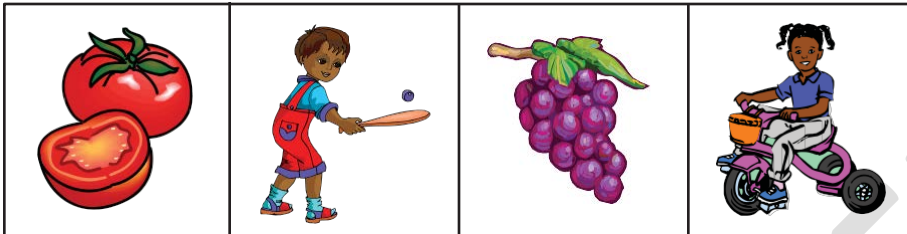
The goal of the clinic and staff is to help
you make changes at
home to develop healthy habits and
get kids ready for school.

UNIVERSITY
OF MINNESOTA
PHYSICIANS

Broadway Family Medicine
1020 West Broadway
Minneapolis, Minnesota 55411
612-302-8200 Phone
612-302-8275 Administrative Fax
612-521-4725 Medical Records Fax

UNIVERSITY
OF MINNESOTA
PHYSICIANS
*Broadway
Family Medicine*
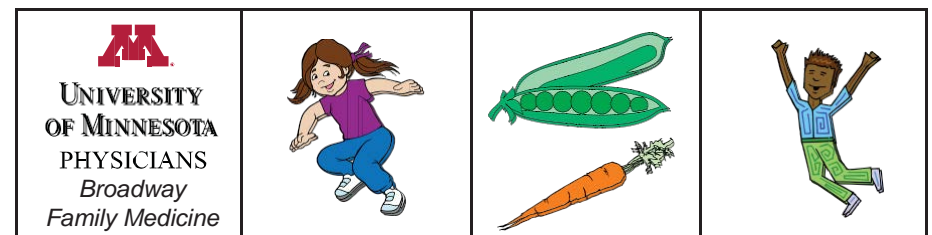
When kids eat a healthy diet and get lots of physical activity there are so many benefits!

Kids will:

- Maintain a healthy weight
- Sleep well through the night
- Develop coordination
- Have good behavior
- Improve motor skills
- Enhance positive brain development
- Develop tastes for a wide variety of foods

When families support healthy lifestyle changes there are even more benefits!

Families will:

- Spend quality time together
- Have more time to focus on school readiness
- Play together
- Have positive family meal time
- Explore their neighborhood
- Learn the art of family conversation
- Respect each other

All of these things can greatly help a child
GET READY FOR SCHOOL!

Your child's height is _____, weight is _____, and Body Mass Index (BMI) percentile is _____.

A child's BMI percentile helps show whether he/she is at a healthy weight for his/her height and age. A single BMI percentile calculation gives a snapshot of your child's growth. Keeping track of your child's growth over time helps you make sure he/she stays at or moves toward a healthy weight. Make sure to talk to your provider if you have any questions about what BMI percentile means for your child.

BMI Percentile

0–5th	6–84th	85–94th	95–100th
↑ Underweight	↑ Healthy weight	↑ Overweight	↑ Obese
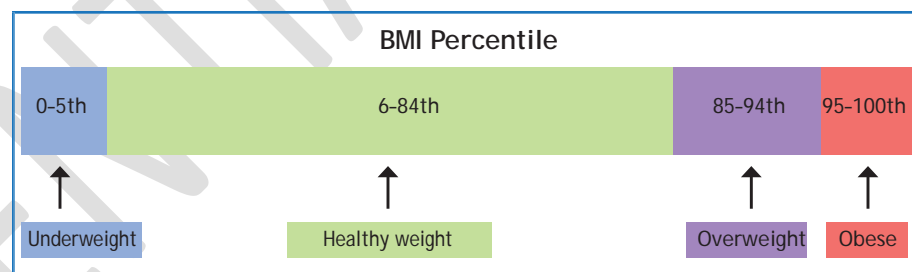
To keep your child on the road to a healthy BMI, here are some tips to keep in mind:

- Limit TV and other "screen time" to no more than 2 hours a day.
- Look for opportunities for your child to be physically active. Involve the whole family for better health!
- Choose healthy snacks like fruits & vegetables. Get creative and involve your child in food choices and preparation.
- Eat regular family meals together. There are countless benefits for kids.
- Reduce the amount of sugary beverages your family drinks. Sugar sweetened drinks like soda have lots of calories, few vitamins & minerals, and are bad for teeth.
- Set a good example for your child by eating healthy foods and being active yourself!

APPENDIX 2

- Main Trial Invite Letter
- Main Trial PS Script
- Main Trial PS Questions
- Main Trial HV Conf Letter
- Consenting Script
- Main Trial Overview
- Measure-Me Visits Overview
- Main Trial Comparison Letter
- Main Trial Intervention Letter

<Clinic Letterhead>

<Date>

Dear Parent or Legal Guardian of _____ :

Our clinic and researchers at the University of Minnesota are working together on a research study called *NET-Works: Now Everybody Together for Amazing and Healthy Kids*. We are inviting your family to participate because your child is between the ages of 2 and 4 and has seen me for a visit in the past or has an upcoming well-child visit with me.

The *NET-Works* study is about helping families with young children make healthy choices and get ready for school.

If you join, you will receive:

- Extra advice from your provider about ways to help your child be healthy, and
- Up to a total of $200 in gift cards for helping us learn how the program works for families. You would do this by meeting with *NET-Works* staff to answer some surveys about your child's eating, activity, and health habits. This will be done at the beginning of the study and then once a year for 3 years.

You may also get to participate in:

- *NET-Works* parenting classes with other families in your community, and
- Phone calls and home visits with a personal *NET-Works* Family Connector.

One of the *NET-Works* staff will call you in the next week to tell you more about the study and see if you would like to participate. You may send an e-mail to NET-Works@umn.edu or call the study line, at 612-624-9105 at any time to ask about the study. Please contact us if you choose *not* to participate. Taking part in this study is voluntary. Your decision will not affect the care your family receives at our clinic.

Thank you for your time and consideration.

Sincerely,

<PCP Name>, <Title>   Simone French, PhD   Nancy Sherwood, PhD
<Clinic>   Lead Researcher,   Lead Researcher,
                             University of Minnesota   HealthPartners Research Fnd

My name is _____ and I'm calling from the University of Minnesota about the NET-Works research study. Did you get the letter from Dr._____ inviting your family to participate?

IF NO CONFIRM ADDRESS AND CONTINUE

Do you have a few minutes to hear more about the study?

IF IT SOUNDS LIKE THE FAMILY'S FIRST LANGUAGE IS NOT ENGLISH: **SPANISH: "I don't speak Spanish. I'll have someone else call you back later."**

IF NO: Could I call you back at a more convenient time? (**IF YES:** SET TIME TO CALL BACK and CONFIRM PHONE NUMBER. **IF NO:** For our records, could I ask you why you're not interested? CHANGE STATUS TO "Not Interested Pre-Screening" AND RECORD REASON.)

IF YES: Great! We are working with the doctors at the _____ clinic on the study. Our goal is to help kids develop healthy habits around food and activity and get ready for school. The study includes information from your child's doctor, and also the possibility of parenting classes close to home, and sessions with a family home visitor. We would also do a set of measurements. We are calling these "Measure-Me" visits and we'll come to your home at the beginning of the study, and once each year for three years. To thank you for helping us evaluate the program we will give you up to $200 in gift cards, or in other words up to $50 each year.

Can I tell you a little bit more about the study?

IF NO: Ok, thanks for taking time to talk to me. For our records, could I ask you why you're not interested? (CHANGE STATUS TO "Not Interested Pre-Screening" AND RECORD REASON.)

IF YES:

We want to take some time to describe what it means to be in a research study, and what you do if you decide to participate. The NET-Works study is part of a large national study looking at the best ways to support parents so their kids develop healthy habits. We hope once you learn about this opportunity you will share the excitement we feel about helping young children. Have you ever been in a study before? Is your family currently participating in any other child health related research studies? *(INELIGIBLE: if a sibling is already in NET-Works or the family is involved in any other study involving healthy eating, physical activity and parenting. If another study is mentioned, get details about name of study, sponsor and confer with Nancy or Simone before confirming eligibility.)*

Ok, now, because this is a study, we will divide everyone into 2 groups. This is done by chance, like flipping a coin. We do this so that at the end of the 3 year study we can compare the groups and see how the program worked.

So the 2 groups are: the NET-Works Group, and the Comparison Group.

If you are in the Comparison Group your child's doctor would talk to you about healthy eating and activity at your annual well-child visit and you would complete the annual measurement visits, once a year, for 3 years.

If you are assigned to the NET-Works Group, you would get this same information from your child's doctor *and* you would go to community parenting classes *and* you would receive home visits with a family connector. These classes and visits will be about helping your child get ready for school by eating healthy and being active. You would also complete the annual "Measure-Me" visits, once a year, for 3 years. Everyone who joins the study does the "Measure-Me" visits.

We are asking for a 3 year commitment from families. Do you have any plans to move outside of the metro area within the next 3 years? *(INELIGIBLE: If yes)*

So the first thing we would do is schedule a "Measure-Me" visit at your home where we will measure your child's height and weight and find out if your family is eligible for the study. If you're *not* eligible based on this information, we'll give you a $10 gift card to thank you for your time.

If your family *is* eligible and wants to participate, we'll sign you up for the study and take some other measurements. This first "Measure-Me" visit will last about two hours. A week later we'll do a second "Measure-Me" visit to pick up some equipment and do some other measurements, and again this visit will last about another two hours.

Ok, one other question. We are trying to recruit families of similar backgrounds for the study. So may I ask: was your total household income from all sources before taxes last year $65,000 or less? By "household", we mean the combined income of everyone in your home. *(INELIGIBLE: If no)*

Great. Being in a research study can be really interesting and fun, but there is also a commitment involved.

It is a lot to consider, and I want you to think about whether this will be ok, or if it will be too much for your family. We try really hard to keep all families in the study for the full 3 years.

Do you have any questions?

Does this sound like something you would be interested in?

IF YES: Ok, great! Do you have a few more minutes to answer some questions to see if you are initially eligible? (PROCEED TO SCREENING QUESTIONS.)

IF NO: Thank you for your time. For our records, could I ask you why you're not interested? (CHANGE STATUS TO "Not Interested Pre-Screening" AND RECORD REASON.)

Phone Screen Eligibility Questions

Ok, I'm going to ask you all of the questions to find out if you are eligible:

1. What is your name? *(Select parent in database if available.)*

2. What is your relationship to < name of child>? *(Select mother, father, stepmother, stepfather, other female caregiver, other male caregiver in database.)*

3. Does the child have any other parents you would like me to list? *(Add additional parents to database.)*

4. Can you confirm your child's birth date? *(ELIGIBLE: If upcoming birthday turns the child 2, 3 or 4 years old)*

5. What is your child's gender?

6. Does s/he spend at least half of the time living with you, at this address?

7. As I mentioned before, if you were assigned to the NET-Works Program, you would be asked to attend parenting classes. Would you be willing to attend monthly parenting classes if it worked for your schedule? (INELIGIBLE: If no, ineligible)

8. If you were assigned to the NET-Works Program, you would also have home visits and phone calls with a NET-Works staff. Would you be willing to do monthly home visits? (INELIGIBLE: If no, ineligible)

9. Have you ever been told your child has a chronic condition such as kidney disease, Type 1 diabetes, lupus, a thyroid condition, cancer, Down's syndrome, or Turner's syndrome?

    ("Yes" with a drop-down list including all medical conditions as well as a free text area or "No". ELIGIBLE: if cancer or other disease is not current, INELIGIBLE: If kidney disease, Type 1 diabetes, lupus, a thyroid condition, cancer, Down syndrome, or Turner's syndrome.)

10. In the past six months, has your child taken any steroid medications such as Prednisone, Prednisolone and Decadron on a daily basis *(NOTE: This does not include inhalers with steroids)*:

    IF NO: *Continue to question 10.*

    IF YES: Was he/she taking this medication daily for more than a month? *(INELIGIBLE: If they have been taking any one of these medications on a daily basis for more than one month at a time in the past six months, or if they have recently started taking one of these medications and will be taking it for more than a month.)*

11. What language would you prefer to speak in for this study? *(English, Spanish)*

IF ELIGIBLE:
Great! So far, your family is eligible for the study. Let's try to set up your first "Measure-Me" visit:

- Set the date of the first "Measure-Me" visit
- Confirm addresses, phone numbers- home, work, cell & preferred number; e-mail address of all parents.
- Confirm who will be the primary contact for this & that that person would also be doing the NET-Works classes
- Ask for the name of two other people we could contact in case we can't get a hold of you; enter names, addresses, and phone numbers of these people and their relationship to the family.
- Ask if the parent would prefer to receive reminder texts instead of phone calls.

If your family is eligible at this visit and would like to participate, we will:

- Measure your height and weight and the heights and weights of any other family members in your home,
- Fit you and your child for an activity monitor belt (a small device like a pedometer) that will measure your activity for one week,
- Ask you about the foods your child ate the day before,
- Ask you about your family's activity, nutrition, rules and parenting styles, and
- Collect information about food and drinks in your home.

We'll send you a confirmation letter with the date and time of this visit. We'll also include some more study information.

Will anyone other than you be feeding your child, like a daycare provider or Head Start teacher, on the day before this visit?

IF YES: Because we'll be asking about the foods that your child ate, we will also send you a form for another adult to write down details about what your child ate. On the form we also ask for that person's phone number in case we have any questions. It's very important that we have this form filled out, so look for this form in the mail and make sure to give it to the person who will be feeding your child the day before the visit.

If you have any questions you can always call or e-mail us. Our phone number is 612-624-9105 and our e-mail address is NET-Works@umn.edu.

Generate confirmation letter if at least three days before visit.

IF NOT ELIGIBLE:

Thank you so much for your time, but unfortunately it looks like your family will not be eligible for this study.

Give reason for ineligibility:

Not willing or able to attend parenting classes: Because we want to see how the NET-Works program helps families, we need people to be available to attend the classes.

Child living in other home 50% or more of the time: Because we want to see how our program affects kids in your home, and your child spends most of their time at a different household, your family will not be eligible for the study.

Chronic disease/and or ineligible medications: Because your child has a chronic disease (or condition) or because they are taking _____ medication, if he/she were randomized to the NET-Works Classes & Connector part of the study, he/she would need more individual advice on nutrition, diet and exercise than this study can provide.

Moving outside of the metro area in the next 3 years: For this study, we will be following families for a three year time period, so because you will be moving, your family will not be eligible for the study.

Not in age group: We're sorry, this study is for children between the ages of 2 and 4 and your child is not in this age group.

Annual Household Income Above $65,000: We're sorry, this study is for families with an annual household income of $65,000 or less.

Already participating in NET-Works or another study about weight, physical activity, exercise or parenting:

If NET-Works: We're sorry, we can only have one child in a family participating in this study.

IF ANOTHER CLOSELY RELATED STUDY: We're sorry, because you already are participating in a study very similar to NET-Works, your family would not be eligible for this study.

NET-WORKS
NOW EVERYBODY TOGETHER
FOR AMAZING AND HEALTHY KIDS

Dear _____:

Thanks for your interest in the *NET-Works* research study. Your participation is so important to us in helping us learn what works best to keep families healthy.

To find out if your family is eligible for the study, we have scheduled a "Measure-Me" visit at your home on:

_____ at _____.

At this visit we will measure your child's height and weight. Your family may or may not be eligible for the study based on this measurement. If your family is not eligible, we will give you a $10 gift card to thank you for your time. If your family is eligible we will:

1. Explain the study to you in more detail,
2. Measure the heights and weights of any other family members in your home,
3. Fit you and your child for an activity monitor belt (a small device like a pedometer) that will measure your activity for one week,
4. Ask you about the foods your child ate the day before,
5. Ask you about your family's activity, nutrition, rules and parenting styles,
6. Collect information about food and drinks in your home.

After the visit, we will schedule a second "Measure-Me" visit at your home to pick up your activity monitor belts and ask you again about the foods your child ate the day before.

If you have any questions about the study or need to reschedule your "Measure-Me" visit, please call the *NET-Works* phone line at 612-624-9105 or send an e-mail to NET-Works@umn.edu. We look forward to meeting you.

Again, a big THANK YOU on behalf of the entire NET-Works Staff! You are key to making the study a big success!

Sincerely,

Simone French, PhD   Nancy Sherwood, PhD
Lead Researcher,   Lead Researcher,
NET-Works   NET-Works

HV Conf Letter 2012.03.13

NET-Works Consenting Script

Background

 What we'd like to do next is walk through the consent form to tell you about each part of the study, get your permission to participate, and see if you have any questions.

First, the purpose of this study is to find out if the two NET-Works programs we offer help parents with 2-4 year old children make changes at home to help their kids develop healthy habits and get ready for school. The study will last for 3 years.

What interests you about the study?

Procedures

- Refer to "Measure-Me" card to describe the measurements taking place at each visit.

Today we would like to also take some measurements on any other family members who are home, ask you what your child ate yesterday, give you and your child an activity monitor to wear for the next week, and ask you some questions about your beliefs on physical activity, nutrition, and parenting. We'll also schedule another home visit in about a week. At the end of the visit today we have a $10 gift card to give you.

Then about a week later, we have a few more pieces of information to collect. At this second visit we will give you another $10 gift card. We'll complete another survey, collect information about food you have in your home, and ask you again what your child ate the day before. This visit will last about an hour. If you and your child are able to wear the activity monitor for the whole first week, we can complete the third visit by phone! If not, we will need to ask you to wear the activity monitors again for an additional week and we'll schedule a third home visit to pick up the monitors. Also at that 3rd visit, we'll ask you about what your child ate one last time. If you wear the activity monitors for enough time, either week, we will mail you a $30 gift card once all the information has been verified. If you don't wear the monitor for enough time, unfortunately you will not be enrolled in the study, and we won't be able to give you that $30 gift card.

- Use "500 Families" as a visual to explain how the study works. After you complete these first two or three visits you will be randomly put into one of two groups. This means that it is like a flip of a coin to determine getting into one group or the other. You will need to fully complete the first set of Measure-Me visits to be able to continue to the next phase of the study.

Because this is a research study we have two groups so that we can compare and see how our program is working and see how our families react to the program.

If you are put into the NET-Works Group, again this happens by chance, you will get to attend monthly parenting classes, home visits and phone calls each year of the 3-year program to talk about healthy eating, physical activity, and parenting.

If you are in the Comparison Group you will follow your usual schedule of medical visits. You won't receive additional phone calls or home visits.

We will ask that both groups, all families, do the same set of "Measure-Me" visits, where we will come to your house after 1 year, after 2 years and after 3 years of being in the study.

Risks and Benefits
This is a relatively "low-risk" study. You may feel uncomfortable having your height and weight measured or answering some of the survey questions. But, remember that you can skip any questions you don't want to answer. There is also a small risk that increasing activity can lead to injury.

Your family may or may not benefit from the study, but we hope that you do. We hope you learn ways to keep your family healthy and active. We also hope that what we learn from your family will help other families in the future.

Compensation
To compensate you for your time, you'll receive up to $200 in gift cards over the next three years. You'll receive up to $50 for each set of Measure-Me visits. Remember, that in order to receive the $30 portion of the gift cards, both you and your child need to wear the activity monitors for a week.

Mandated Reporting
The NET-Works staff members are mandated reporters. This means it is required of us to report any abuse or neglect we may see in a home.

Confidentiality
We keep all of your information private and confidential. We label all of your information with a study ID number and take off your name or other identifying information like birth date before sharing this with other researchers.

If you are in the NET-Works Group, we could share information about your progress with your doctor.

Voluntary Nature of the Study
It's important that you know your participation in this study is voluntary and you can stop at any time without it affecting your care at your clinic.

Certificate of Confidentiality The study has special protection with regards to your personal information. Legal authorities will NOT be able to see any personal information about you. In other words, your personal information cannot be looked at by any legal or law enforcement authority.

Additional Information about the Study

A description of the study can be found online at www.clinicaltrials.gov if you're interested in looking up any information. This website will NOT contain any information that can identify you in any way.

Contacts and Questions

Do you have any questions? By signing this form it means that you understand what has been explained to you, and you agree for you and your child to take part in this study.

If you have any questions throughout the study, you can call our Project Director at this number (point to number in the first paragraph on pg. 1). If you would like to talk to someone outside of the study, we also have the number for our "Research Subjects Advocate Line" listed here (point to number in last paragraph on pg 3).

Can you tell me in your own words what you are being asked to do for the study?

NET-WORKS
NOW EVERYBODY TOGETHER
FOR AMAZING AND HEALTHY KIDS

500 Families

250 Families

NET-Works Group
3 Years

Information @ Well-Child Visits

Parenting Classes

Home Visits & Phone Calls

"Measure-Me" Visits

& &

Up to $50 in Gift Cards

Year-1 "Measure-Me" Visit

& s &

Up to $50 in Gift Cards

Year-2 "Measure-Me" Visit

s

& &

Up to $50 in Gift Cards

Year-3 "Measure-Me" Visit

s

& &

250 Families

Comparison Group
3 Years

Information @ Well-Child Visits

School Readiness Mailings

Up to $50 in Gift Cards

Contact Us: (612) 624-9105   or   NET-Works@umn.edu

<Date>

Dear < insert parent or legal guardian name >,

Thank you for completing your first NET-Works "Measure-Me" visits. We appreciate your involvement in the study. As you know, there are two programs offered in the study. Your family has been selected at random to participate in the ***NET-Works Comparison Group***. As part of this program, you will receive information and materials from your child's doctor about eating healthy and being active. The NET-Works study will also send you quarterly information through the mail including tips on school readiness and healthy behaviors.

We will be contacting you again in about a year for another set of "Measure-Me" visits in your home. And then remember that the study is 3 years in length, so we will see you a few more times as the study progresses. The information we collect during these visits will be used to find out how well the NET-Works study works to help families make healthy changes for their kids. You will receive up to $50 in gift cards for completing each set of "Measure-Me" home visits.

If you haven't heard from us already, we will be calling you soon to find out if you have any questions about the study. Thank you again for your continued participation and we look forward to working with you in the NET-Works study!

Your participation in all the "Measure-Me" visits is what will make the NET-Works study a success!

Sincerely,

Simone French, PhD
Lead Researcher,
NET-Works

Nancy Sherwood, PhD
Lead Researcher,
NET-Works

Comparison Group Letter 2012.03.13

<Date>

Dear < insert parent or legal guardian name >,

Thank you for completing your first NET-Works "Measure-Me" visits. We appreciate your involvement in the study. As you know, there are two programs offered in the study. Your family has been selected at random to participate in ***NET-Works Group***. As part of this program you will:

- Get to participate in monthly NET-Works parenting classes,
- Receive monthly home visits from your Family Connector, and
- Receive quarterly check-in phone calls from your Family Connector.

In addition, we will contact you again in about a year for your next set of "Measure-Me" home visits. And then remember that the study is 3 years in length, so we will see you a few more times as the study progresses. The information we collect during these visits will be used to find out how well the NET-Works program works to help families make healthy changes for their kids. You will receive up to $50 in gift cards for completing each set of "Measure-Me" home visits.

If you haven't heard from us already, we will be calling you soon to find out if you have any questions about the study, give you NET-Works class information and set up your first home visit with your Family Connector at a time that's convenient for you.

Thank you again for your continued participation and we look forward to talking with you soon. Your participation is what will make the NET-Works study a success!

Sincerely,

Simone French, PhD
Lead Researcher,
NET-Works

Nancy Sherwood, PhD
Lead Researcher,
NET-Works

Intervention Letter 2012.03.13

APPENDIX 3

Consent Form

CONSENT FORM

"NET-Works": Now Everybody Together for Amazing and Healthy Kids
Main Study Consent Form

Background

You are invited to take part in a research study about helping families with young children make healthy choices that will last a lifetime. The purpose of the study is to find out if parents who receive messages and support from their primary doctor, community parenting classes, and a trained family home visitor can make changes at home to help their child develop healthy habits and get ready for school. The study will last for 3 years. You and your child can decide to end your participation at any time.

You are being asked to take part in this study because your child is between the ages of 2 and 4 years and you attend a University of Minnesota-affiliated Family Medicine Clinic, HealthPartners Clinic, Hennepin County Medical Center Clinic, or Children's Hospital of Minnesota Clinic.

The study is being led by Simone A. French, PhD from the University of Minnesota's Division of Epidemiology & Community Health and Nancy E. Sherwood, PhD from the HealthPartners Research Foundation. The study is funded by the National Institutes of Health (NIH) in Washington, DC and is part of a larger, multi-site study.

Procedures for Participating Child and Adult

If you choose to take part in the study, you will be asked to do the following:

1. Visit by trained research staff in your home to determine study eligibility.

Trained research staff will come to your home to measure your child's height and weight. Your family may or may not be eligible to take part in the study based on this information.

2. Complete a set of measurements.

If your family is eligible and you agree to be in the study, we will ask you and your child to complete a set of home measurement visits at the beginning of the study, after 1 year, after 2 years, and after 3 years of being in the study. These measurements include:

   a) You and your child's height and weight ,

   b) Your child's waist circumference (using a tape measure),

   c) A skinfold measure on the back of your child's upper arm,

   d) A survey to learn more about your beliefs about physical activity, nutrition, and your parenting practices (e.g. family rules and parenting styles),

   e) 3 interviews about your child's eating during the previous day,

   f) You and your child wearing an Actigraph (a small device like a pedometer that measures activity) for 7 days to help us learn more about your activity patterns. You and your child will be asked to wear the Actigraphs for 7 additional days if the devices were not worn for enough days the first time,

g) Collecting information about food and beverages in your home.

3. Random assignment to study groups.

After your first set of home measurement visits, you will be put into one of two study groups. You will have an equal chance of being placed in either the "*NET-Works"* group or the "Comparison**"** group. You will receive a letter in the mail and a follow-up phone call informing you of your group assignment.

- *__NET-Works group__*: Families in this group will take part in monthly community parenting classes, home visits, and phone calls each year of the 3-year program to talk about healthy eating, activity, and parenting.
  Each of the home visits will be audiotaped for evaluation purposes.
- *__Comparison group__*: Families in this group will follow their usual schedule of medical visits. They will not receive the additional phone calls, home visits, or community parenting classes.

Procedures for Other Family Members

All other family members who live in the household and who are at the home during the first home measurement visit will be asked to have their height and weight measured. Those who agree to this at the first home measurement visit will also be asked to do the same measurements at the year-1, year-2, and year-3 home measurement visits.

Risks and Benefits

Your family may or may not benefit from this study. We do not know if the study activities will be helpful. That is why we are doing the study.

The possible benefits of the study include learning ways to help your child develop healthy habits including eating a healthy diet and being physically active.

The information we learn from this study may benefit other children in the future.

With any research study there may be an element of risk. The risk in this study is minimal. The NET-Works program may help parents make small changes at home to help children develop healthy lifestyle habits including physical activity. There is a small risk of injury associated with increases in physical activity. There is also a small risk that these changes could have a negative effect on children's growth (e.g. weight gain or loss). We will work with you and your child's doctor to check for and address any concerns. You may feel uncomfortable answering personal questions about your family or talking about issues with your doctor or family connector. You may skip any questions you do not want to answer or leave the study at any point.

Compensation

To compensate you for your time as a participant in the study, all participants who complete the home measurement visits will receive up to a total of $200 in gift cards:

- Up to $50 for the first set of home measurement visits

- Up to $50 for the year-1 home measurement visits
- Up to $50 for the year-2 home measurement visits
- Up to $50 for the year-3 home measurement visits

For each home measurement visit, payment up to $50 in gift cards will be made as follows:
-$10 gift card given at the home upon completion of Home Visit #1
-$10 gift card given at the home upon completion of Home Visit #2
-$30 gift card mailed after Home Visit #3 if all measures are fully completed and verified.

No partial payments will be made if all measurements are not completed. Payment is not dependent on whether parents and children assigned to the NET-Works Classes & Family Connector group attend and participate in the group activities.

Mandated Reporting
All of the NET-Works staff are "mandated reporters." This means that Minnesota State law mandates the reporting of alleged physical/sexual abuse and/or neglect by individuals. Reports of alleged physical/sexual abuse and/or neglect will be made to the local welfare agency, police department or county sheriff.

Confidentiality
All information gathered as part of this study is confidential. Information will be identified by a code number only. Any reports or publications will present only grouped information, not information on individuals. Data may be shared with other researchers and scientists not directly involved in the study. Other scientists may request data from this study. Data will be released only after ensuring that you or your child's name and other identifying information are not given to any researchers. This means they can look at some of the information we collect, but they will not be able to see any information about who you are (e.g. birthdates, addresses, names). For families participating in the NET-Works group, information on progress of program activities will be shared with your doctor.

Voluntary Nature of the Study
Your participation in this study is voluntary. You may withdraw from the study at any time without affecting your relationship with the University of Minnesota-affiliated Family Medicine Clinics, HealthPartners Clinics, Hennepin County Medical Center Clinics, Children's Hospital of Minnesota Clinics, the researchers, or your doctor. If you decide to stop, please talk with the Project Director at 612-624-9378 or 612-624-9105.

Certificate of Confidentiality
The researchers have obtained a special legal protection from NIH, the funders of this research, called a "Certificate of Confidentiality". The data that is gathered from families in the study are protected from being shared with legal authorities by this Certificate.

Legal authorities cannot see any personal information about anyone enrolled in the study. This means that your personal information cannot be looked at by any legal or law enforcement authority.

Additional Information about the study
A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Contacts and Questions
If you have any questions about the study, you may ask them now. If you have any questions about the study later, please contact Simone A. French, PhD, at the University of Minnesota, Division of Epidemiology & Community Health (612-626-8594). If you have any questions or concerns regarding the study and would like to talk to someone other than the researchers, please contact the Research Subjects' Advocate Line, D528 Mayo, 420 Delaware Street Southeast, Minneapolis, MN 55455 (612-625-1650).

Statement of Consent for Participating Child and Adult

I agree to take part in the research study described above. I have asked any questions I had and have been given answers. A trained study translator was provided as needed. I consent to take part in the study. I have been given a copy of this consent form for my records. I consent to have my child participate in this study.

Adult #1/Child consenting to participate in the full 3-year study

_____

Name of Participant (adult)   Birthdate (m/d/y)

_____

Signature of Participant (adult)   Date of Signature

_____

Relationship to child participating in the full study

_____

Name of child participating in the full study   Birthdate (m/d/y)

_____

Name of person obtaining consent (study team member)

_____

Signature of person obtaining consent (study team member)   Date of signature

Adult #2 consenting to participate in the full 3-year study

_____

Name of Participant (adult)   Birthdate (m/d/y)

_____

Signature of Participant (adult)   Date of Signature

_____

Relationship to child participating in the full study

Translation provided by:

_____

Name   Signature

Copies to: Participants   Researchers′ file

Statement of Consent for Other Family Members

Consent of other adults and brothers or sisters for height and weight measurements during the 3-year study.

I have read the above form and consent to have my height and weight measured during the first set of "Measure-Me" visits and the year-1, year-2, and year-3 "Measure-Me" visits. A trained study translator was provided as needed.

Adults (age 18 and older)

_____
Name (adult)   Signature   Date

_____
Relationship to child participating in the full study   Birthdate

_____
Name (adult)   Signature   Date

_____
Relationship to child participating in the full study   Birthdate

_____
Name (adult)   Signature   Date

_____
Relationship to child participating in the full study   Birthdate

_____
Name (adult)   Signature   Date

_____
Relationship to child participating in the full study   Birthdate

Children (age 7 to 17)

_____ _____ _____
Name (child/sibling)   Name of consenting adult   Child Birthdate

_____ _____ _____
Signature (child/sibling)   Signature of consenting adult Date

_____
Relationship to child participating in the full study

_____ _____ _____
Name (child/sibling)   Name of consenting adult   Child Birthdate

_____ _____ _____
Signature (child/sibling)   Signature of consenting adult Date

_____
Relationship to child participating in the full study

_____ _____ _____
Name (child/sibling)   Name of consenting adult   Child Birthdate

_____ _____ _____
Signature (child/sibling)   Signature of consenting adult Date

_____
Relationship to child participating in the full study

_____ _____ _____
Name (child/sibling)   Name of consenting adult   Child Birthdate

_____ _____ _____
Signature (child/sibling)   Signature of consenting adult Date

_____
Relationship to child participating in the full study

Children (age 2 to 6)

Name (child/sibling)   Name of consenting adult   Child Birthdate

Signature (child/sibling)   Signature of consenting adult   Date

Relationship to child participating in the full study

Name (child/sibling)   Name of consenting adult   Child Birthdate

Signature (child/sibling)   Signature of consenting adult   Date

Relationship to child participating in the full study

Name (child/sibling)   Name of consenting adult   Child Birthdate

Signature (child/sibling)   Signature of consenting adult   Date

Relationship to child participating in the full study

Name (child/sibling)   Name of consenting adult   Child Birthdate

Signature (child/sibling)   Signature of consenting adult   Date

Relationship to child participating in the full study

Translation provided by:

Name   **Signature**

Copies to: Participants   Researchers' file