The Anthropometrics was approved by the COPTR Steering Committee on February 23, 2012;
Revisions approved 5/23/13; 2/20/14

CHILDHOOD OBESITY PREVENTION AND TREATMENT RESEARCH

COPTR

MANUAL OF PROCEDURES

1. ANTHROPOMETRICS

MAY 2012
REVISED: MAY 2013
FEBRUARY 2014

SUMMARY OF REVISIONS

- Approved on May 23, 2013 - Revisions to the triceps skinfold measurement - when to collect 3rd measurement and when QC out of range. Changed 10mm to 20mm such that the revised limit is 2mm if less than 20mm (was 10mm) and 10% if greater than 20mm (was 10mm). The changes are reflected in 3 places - Page 18. Section 11.k, Page 19. Section 12.2 and Page 24 under triceps on the anthropometric form.
- Approved on February 20, 2014 – Case will added an additional brand of scale and stadiometer. The changes are reflected in 2 places – Page 5 section 4 and page 9 section 7.1 under Scale calibration.

PROCEDURES MANUAL
1. ANTHROPOMETRICS
Table of Contents

1. INTRODUCTION

The purpose of this procedure manual is to provide explicit and detailed instruction on how to collect anthropometric variables in the COPTR studies. There will be four common measurement time points – baseline, 12 months, 24 months and 36 months. All baseline anthropometric data will be collected prior to randomization. All common data collection will occur between May 2012 and March 2017. This document was written, edited and approved by the members of the Primary Outcome and Body Composition Working Group, as well as the Measurement Subcommittee and Steering Committee. Even small deviations from the procedures as they are described here are highly discouraged. Data collectors at all sites should strictly adhere to the main trial procedures outlined in this manual for all common measures. This standardization is crucial to the ultimate goals of our research.

In the COPTR study a "common" measurement is defined as any measurement collected at more than one site. For these variables common procedures are used to collect measurements with the goal of being able to combine data from multiple sites for future analyses.

Height, body weight, waist circumference, and triceps skinfolds are assessed as common measures in the COPTR index children. Sites also collect several anthropometric measures in parents and/or family members. The height and body mass variables collected will be used to calculate BMI (kg/m^2), which is the measure used in the primary outcomes of the four COPTR trials. Other indices that may be calculated include BMI-Z score, waist to height ratio and percent body fat.

Table 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

Additional measurements may be taken at only 1 site (not-common). These are listed in Appendix 1 of the site-specific instructions.

2. TERMINOLOGY TO DESCRIBE RELEVENT INDIVIDUALS

Index child: A child who meets eligibility criteria and is randomized to a study arm with the intention that his or her BMI data will be included in the site's primary outcome analysis as the main exposure.

Master Trainer: The person (or persons) at each site that trains and supervises certification of other anthropometric data collection staff or research associates.

Measurement Coordinator: The person (or persons) at each site that organizes anthropometric data collection activities. This person may or may not be a Master Trainer.

D*ata collection staff*: Personnel who collect anthropometric measurements.

Trainee: The person receiving training and seeking certification to participate as a Research Associate.

3. CONFIDENTIALITY CONSIDERATIONS

Each participant being measured has the right to confidentiality. No form is identified with a participant's name. Every effort should be made to keep observations and data recording as objective and non-judgmental as possible. It is important to not react to any measure, simply observe and record on the form. The staff should be pleasant and respectful to each person who participates in the study and make the experience a

positive one. The staff introduces themselves to the participants, explain all procedures to them, and obtain the participant's approval before taking measurements.

Communication among staff during measurements is done in a quiet and respectful manner so that participants cannot overhear any discussion related to results. It is likely that many participants will ask to be told their measurements results. Height and weight measurements can be easily shown to the participant in a discreet way. However, the skinfold measurement would require explanations which may not be understood by the participants. If these measurement results are requested, staff should explain to the participant that these results have no meaning individually in the way height and weight does. The measurer may show them the numbers, but tell them that they are used in the analysis of the whole study.

Care should be taken that the physical measures are performed in a private area. Privacy also involves sound, so it is important that data collection staff do not speak values aloud in a way that could be overheard. To insure that modesty is respected during anthropometrics measurements these tasks are performed in the presence of another person. Privacy screens are used for measurements when appropriate.

If a participant's physical injuries or deformities result in having to alter or omit procedures this should be noted on the data collection form in the comments section.

To assure safety of participants, the measurers should remove rings, bracelets, or other jewelry that could pose a hazard and be cautious when using pens or pencils while taking measurements.

4. EQUIPMENT

Scales and calipers are marked with a number for identification on the calibration log. The same brand and model of equipment is used throughout the study. Equipment type may vary as specified across research centers, but does not vary within research centers. All data collectors need to be aware of the maximum capacity of each piece of equipment and should discuss with their PI(s) necessary procedures in case the maximum capacities are exceeded.

Body Mass – Calibrated, research, precision-grade scale with digital read out

Case Western – Medichoice Befour Scale (UH CRU) and Mettler Toledo model PTPN (Metro CRU) for on-site assessments; Scaletronix 5602 for community (home, school) based assessments.
Minnesota -- Seca Model 876
Stanford -- Scaletronix 5602
Vanderbilt -- Seca Model 876

Height – Free standing or wall-mounted stadiometer with movable headboard

Case Western -- Holtain (UH CRU) and Easy-Glide Bearing Stadiometer (Metro CRU) for on-site assessments; Seca Model 217 for community (home, school) based assessments.

Minnesota -- Seca 217 stadiometer
Stanford -- Shorr height board
Vanderbilt -- Seca Model 217
A metal calibration rod 600 to 800 mm in length

Hair interference
Micro-Mart #84174 6-inch Metal Ruler

Waist Circumference
Gulick II Tape Measure, Model 67020

Skinfolds
Lange skinfold calipers
Harpenden calipers[1]
Gulick II Tape Measure, Model 67020

The following equipment and supplies may also be needed:

¾" thick plywood square (at least 1 foot wider than the footprint of the scale) to be used to insure the scales and stadiometer work properly, especially on carpeted floors
Extra AA batteries for scale
Calculator
Water-soluble marker
Wipes (alcohol or other – to wipe marks off of arms)
Unstructured shorts, pants and short sleeve T-shirts in range of participant sizes
Hair tie or rubber band to hold shirt back for waist measurement
10-50 kg calibration weight for scale
1 calibration block for calipers
Low footstool
Basket for emptying pockets and removing hand jewelry
Pens, clipboards
Small trash bag/trash can
Privacy screens
Mirror, if waist circumference is collected by only one data collection staff
Data calibration and data collection forms

5. ANTHROPOMERTRIC DATA COLLECTION FORM

Anthropometric data are to be entered directly into a computer data base at some research centers, whereas other centers record the data on paper and then enter it into a computer. Regardless of the method used, the anthropometric data collection (ANT) forms shown in appendix 2 are used as a template to assist the development of paper

[1] Vanderbilt, Stanford and Case plan to use the Harpenden calipers for individuals out of range. Minnesota won't use Harpenden calipers. The Harpenden caliper will be used for any measurements > 67 mm; the Lange caliper will be used for any measurements ≤ 67 mm.

form or the electronic format used for the collection of data. In this document we refer to this document as a "form" whether it is paper or electronic.

6. TRAINING AND CERTIFICATION FOR ANTHROPOMETRICS

COPTR uses a "train the trainer" model. Each research center 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 candidates for Master Trainers are responsible for training and certifying the data collection staff at their center. To be certified, a Master Trainer candidate should have significant prior experience collecting anthropometric measurements in research studies (at least 50 measurement episodes), attend all training sessions as designated by the RCU and have read the anthropometrics protocol and MOP. After the in-person training session and while still at the centralized training, the Master Trainer candidate will measure ten (10) individuals. A minimum of six (6) of these individuals must be children of the appropriate age that the site will use for their study, the remainder can be adults. The children and adults must include both genders and be of varying size, including thin and overweight individuals. If possible, include one person that has an inflexible hair style that requires the height correction. Each Master Trainer candidate completes separately all measures using the anthropometrics data collection form. The instructors of all training also measures the ten individuals. The data forms from each of the Master Trainer candidate is then compared to the instructors and if there is agreement within the guidelines (see below), the Master Trainer is considered certified. If their results are not within the guidelines then they must have their techniques further evaluated by the instructor and then retested.

If a site wants to add an additional Master Trainer after the central trainings have been conducted by the RCU, the RCU needs to be notified. Any Master Trainer candidate, who does not participate in the centralized training at the RCU must have significant experience in the measures as stated above, read the anthropometric protocols and MOPs, and have another certified Master Trainer available to conduct the certification. The Master Trainer candidate and the certified Master Trainer will measure ten (10) individuals as stated above. The candidate and the certified Master Trainer separately complete all measures using the anthropometrics data collection form. The results are sent to the RCU and comparisons are made between the candidate and certified Master Trainer. If the results from the two agree within the guidelines stated for certification (see below), then certification is complete. If their results are not within the guidelines then they must have their techniques further evaluated by a video conference call (Skype) and then complete an additional ten (10) individuals before they are certified as a Master Trainer.

All data collection staff collecting anthropometric measures must be certified before collecting data. The certification is separate for each measurement. Thus, some staff members could be certified to collect one measurement (e.g., triceps skinfolds), more than one (e.g. weight and height) or all the anthropometric measurements (weight, height, waist circumference, and triceps skinfolds).

As part of certification, the data collection staff is trained by a Master Trainer. In the training sessions the trainer reviews the information in the MOP and demonstrates the technique for measurement to the data collection staff. During the session, the data collection staff practices measurements on each other and on age and body size-appropriate volunteers.

A group of ten (10) individuals comprised of at least six (6) children and at least two (2) adults are measured by both the Master Trainer and the trainee. The participants must include boys and girls within the age and BMI ranges to be studied at the site and must be different from the children participating in practice sessions (and the trial). The age range of the children in the certification session can, but is not required to, span from the youngest child to be measured at the beginning of the main trial to the oldest child to be measured at the end of the main trial. During the certification, the measurer collects measurements without assistance from the Master Trainer or other staff. The Master Trainer compares the data from the trainee to their own measurements.

To meet certification criteria agreement between the Master Trainer and trainee must be within the specified limits for 80% of the participants. The absolute difference between the Master Trainer's calculated measurement and the trainee's calculated measurement should be less than 0.3 kg for weight, 0.5 cm for height, 1 cm for waist and 2 mm if either skinfold is less than 10 mm or 10% (((maximum – minimum) / minimum) * 100) if both skinfolds are 10 mm or larger. Data collection staff who does not meet the certification criteria will be offered additional instruction and testing, however, the testing for certification must be completed on a different group of children.

All data collection staff collecting anthropometric measurements must be certified before collecting a measurement in the study. Data collection staff may be certified to collect some anthropometrics and not others or certified to collect all the anthropometric measurements. Each Research Center will keep a Certification Training Log (Appendix 3) and submit the certification training log to the RCU each time a data collector has been certified.

Special training and re-certification may be held for data collection staff that haven't collected data in approximately one year.

Recorders are recommended, but not required, during data collection. Recorders do not have to be certified to take the measurements, but should be familiar with the data collection forms, edit requirements and the anthropometric MOP.

7. GENERAL MEASUREMENT PROCEDURES

7.1. General Equipment Calibration Procedures

Proper calibration of the measurement equipment is the responsibility of the site Measurement Coordinator. At the beginning of each measurement session, the weight scale, skinfold caliper and stadiometer (if mobile) are checked for calibration before each measurement day/session. The weight scale is also recalibrated when the scale is moved. The instrument (i.e. weight scale and caliper) cannot be used if it is not properly

calibrated. Each Research Center keeps calibration logs (Appendices 4, 5 and 6) containing the calibration history of each piece of equipment that are sent to the Coordinating Center at the end of the measurement period (e.g. pilot study, baseline). An additional scale and caliper are available for each measurement team. Measurement Coordinator makes sure that replacements are available.

Scale Calibration: Calibration of the scale is obtained by using a 10-50 kg weight (depending upon site). A scale that is off by more than 0.2 kg cannot be used. Calibration results are to be recorded in the Scale Calibration Log daily (Appendix 7). In order to reduce equipment weight, Case Western, Minnesota and Stanford data collectors will use the stadiometer base and a laptop to check calibration of the scale each time equipment is set up. In addition, weekly checks will be performed in the office with 10-50 kg weights. If a scale is found to be out of calibration at a weekly check, the participants weighed on that scale since it was last found to be in calibration will be re-measured promptly.

Stadiometer Calibration: The calibration is completed each day before a wall-mounted or portable stadiometer is used and recorded in the Height Calibration Log (Appendix 8). In addition the calibration takes place each time a portable stadiometer is moved or re-erected.

1. Construct the portable stadiometer and be sure it is on a flat, level hard surface. If carpeted floor, place stadiometer on plywood.
2. Place the calibration rod on the base of the stadiometer or floor with the wall-mounted stadiometer. Be sure it is vertical.
3. Place the head board firmly on the calibration rod and make the reading.
4. To be considered in range the stadiometer should read within 3 mm of the length of the rod.
5. If out of range, then have the wall-mounted stadiometer adjusted by a data collection staff. If it is a portable stadiometer, take the unit apart, reconstruct, and check calibration. If still out of range do not use the stadiometer until it can be recalibrated by a qualified individual.

Skinfold Caliper Calibration: Each caliper used must measure at “zero” in the closed-caliper setting. This means that ‘at rest’ the caliper needle must read less than 1mm. Calibration is obtained by an initial measurement of a measuring die at the beginning of each day of data gathering. Calibration is completed at 5 settings: 10, 20, 30, 40, and 50 mm. All measures of the die must be within one half mm, or the caliper cannot be used. Calibration results are to be recorded onto the Skinfold Caliper Calibration Log daily (Appendix 9), at each of the 5 settings (10, 20, 30, 40, and 50 mm).

7.2. General Procedures

When possible, measurements are taken in the following order: weight, height, waist circumference and skinfold 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. Each measurement is recorded immediately after it is taken and before any other measurement is collected. When possible all 4 measurements are

taken once, before any measurement is repeated. If logistical considerations prevent this rotation, it is acceptable to repeat measurements in sets of two, rather than 4. However, the same measurement is never repeated immediately after it has been taken, but is always followed by a different measurement.

7.3. Measurement Stations

The scale and the stadiometer must be placed on a hard, flat and uncarpeted surface. If a hard or flat surface is not available, the scale and stadiometer should be placed on the plywood square provided.

7.4. Participant Preparations

Before measurements commence participants are offered the opportunity to visit a restroom or bathroom. The participants are asked to remove any excess clothing (e.g., sweatshirts, sweaters or jackets over other clothing) and should be barefoot or wearing socks. They are asked to remove any items from their pockets and temporarily place them in baskets provided. Watches, belts, necklaces and other jewelry is removed before taking the weight measurement if in the measurer's judgment they might weigh more than 16 oz. For young children, diapers are not considered excess clothing.

For height measurements, participants are asked to remove their eyeglasses, if the Frankfort plane is not visible. If participants have a hair accessory or hairstyle that interferes with the measurement, they are asked to remove the accessory or change their hairstyle, if possible (e.g., take out ponytail band). If the participant refuses to or cannot comply with regard to hairstyle or accessory, they are still measured using the interference.

An anthropometric example script is shown in Appendix 10 and responses to frequently asked questions are shown in Appendix 11.

8. WEIGHT MEASUREMENT

a. Instructions for setting up scales and other preparation differ depending on the scale model used. Site-specific instructions are shown in Appendix 1.
b. The scale should be set up to measure in kilograms and read '0.0' before the participant steps on the scale.
c. The participant stands still over the center of the scale with the body weight evenly distributed over feet, feet comfortably positioned side by side in the middle of the scale, and the arms hanging freely by the sides of the body. The participant should be barefoot or wearing socks. The participant should hold their head up and face forward. You can put a dot or poster on the wall for them to look at. Make sure the participant is not leaning to one side and that the head is held with minimal movement.
d. If the measurement fluctuates so much that a determination cannot be made the participant may not be standing in the middle of the scale base with their weight evenly distributed and feet comfortably positioned next to each other, or the floor may be uneven. The further the center of weight is from the exact center of the base, the more likely the scale reading will fluctuate. This is more likely to

happen with heavier and/or taller individuals. If the weight bounces between 0.1 kg and won't stabilize (e.g., 45.5-45.6), use the even number in the decimal place (45.6).

e. When the digital readout is stable, record the weight to the nearest 0.1 kg on ANT form.
f. Have the participant step off the scales and then complete the measurement round (e.g., height, waist circumference and triceps skinfolds) before taking the second weight measurement.
g. If participant has on a cast, check the cast box in the comments section under weight on the ANT form.
h. If a participant weighs more than the scale can measure, put two scales side-by-side and have the person stand on both. Be sure their weight is evenly distributed and take the measurements from both scales. Note this on the data form as "unreliable". If two scales are not available note on the form that the measurement exceeded capacity.
i. If the two measurements of weight differ by 0.3 kg or more, then the weight measurements are repeated a third time and the value is recorded.
j. In the rare occurrence that no pair of the three measures meets the criterion (less than 0.3 kg difference), start over with new measurements.
k. If there are two measurements the calculated weight is their mean. If there are three measurements the calculated weight is the mean of the two closest weights. If the third measurement is equidistant to the first two, the calculated weight is the mean of the three measurements.
l. If the calculated weight is outside the predefined range and the weight is valid, check the "out of range – valid" box on the ANT form in the comments section. See section 12.3. for range checks and more detail on override procedures.

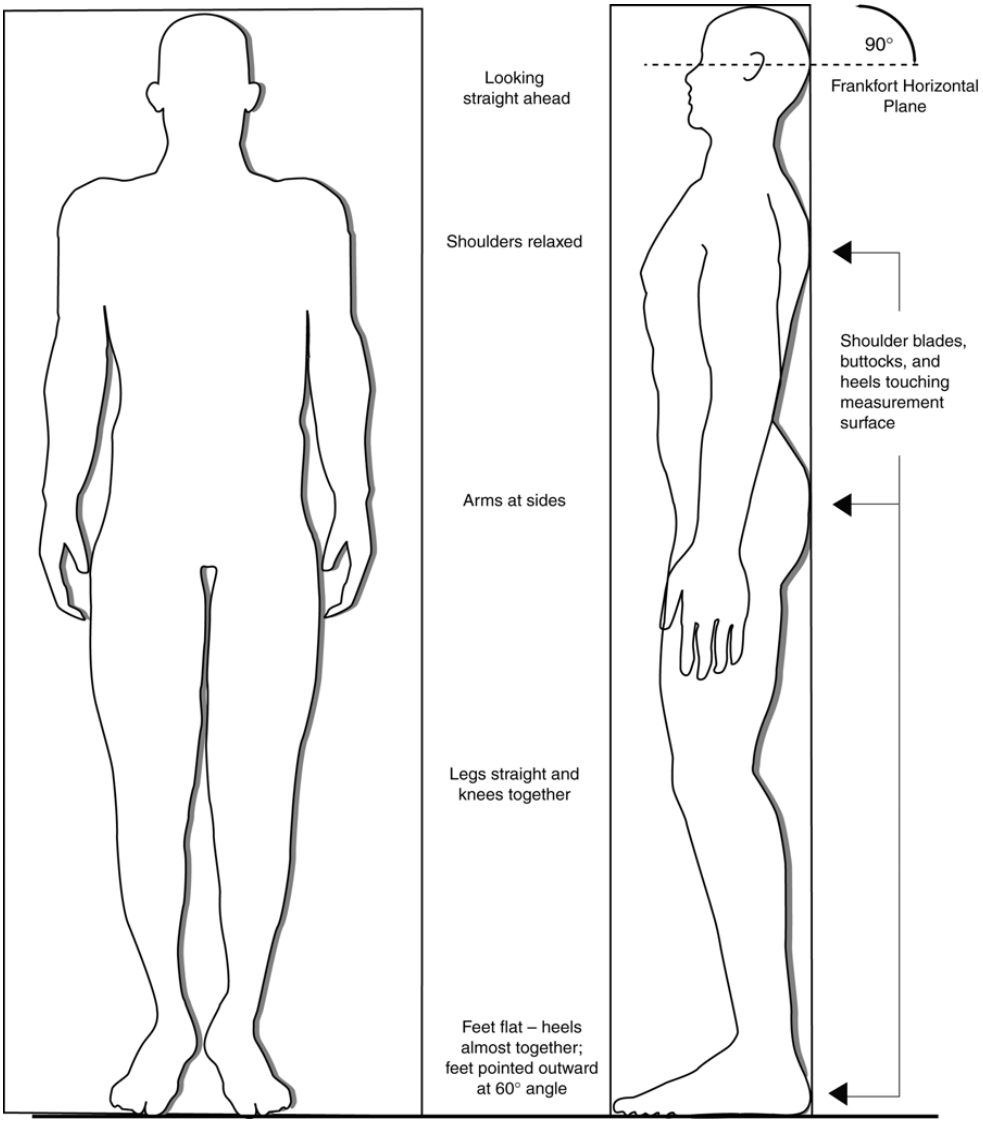
9. HEIGHT MEASUREMENT

9.1. General Height Procedures

a. Instructions for setting up the stadiometer and other preparation differ depending on the model used. Site-specific instructions are shown in Appendix 1.
b. Standing height is measured using a stadiometer with a fixed vertical backboard and an adjustable head piece. Make sure the subject's shoes, and significant accessories are off and that there is nothing tied around the subject's waist (sweatshirt, sweater, etc). Remove eye glasses if the Frankfort plane is not visible. Have the participant back up inside the height board with the head touching the board. Figure 9.1 shows the correct position for the measurement of standing height.
c. If participant cannot stand up (e.g. leg cast), have them stand as "vertical" as possible. Make a note in the comments section of the data form.
d. If participant is sufficiently tall such that the examiner must look up to see the height measurement rather than down or straight ahead, then the examiner must stand on the foot stool. The examiner should read the measure with their eyes at the approximate level of the measure.

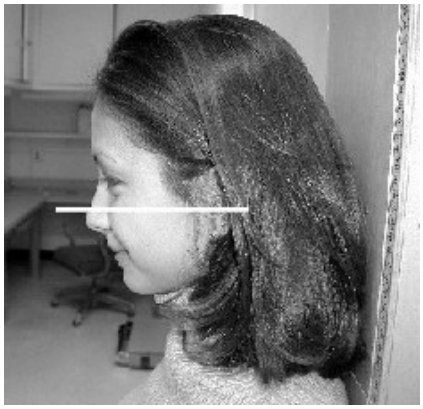
e. Have the participant stand in the center of the base of the main board with the feet together until the ankles or knees touch, whichever touch first, and with heels and bottom as close to the back of the board as possible; back of the head touching the stadiometer if possible. Make sure the palms are facing in towards the thighs. If repositioning is needed, ask for permission before touching the participant.
f. An overweight participant may not be able to position heels against the back of the board. In this case, they stand with their heels slightly away from the back such that their legs are perpendicular to the floor and parallel with the vertical back of the measuring board.
g. Make sure that the participant's head is aligned so that the external auditory canal (ear hole) and the lower rim of the orbit (eye socket) are in a horizontal plane parallel to the floor (Figure 9.2). If the participant cannot keep his/her head against the board and maintain the Frankfurt horizontal plane, begin with the head against the board and position until in the Frankfurt horizontal plane, allowing the head to come away from the board as needed.
h. Some participants may have to undo their hair in order for the wooden carriage to lie flat on their heads.
i. Be sure the head is not tilted and the person is standing as erect as possible.
j. Ask the participant to take a deep breath and hold it (holding a deep breath makes the participant stand up straighter and taller, and allows for a more stable and reliable reading). At the moment you are ready to take the measurement say, "*Now, hold your head still, keep your feet flat, and take a deep breath and hold it; stand up tall."* It might not be appropriate to tell younger children to take a deep breath since they might be too young to understand these instructions, and if they do are likely to rise up on the tip toes, thus, making the measurement incorrect.
k. Engage the sliding headpiece carriage a few inches above the participant's head and slide it gently down so that it rests solidly on the crown of the head (or the top of the ruler). Use a hand to lift the chin, if necessary.
l. The measurement is recorded to the nearest 0.1 cm on ANT form. Tell participants they can release their breath.
m. Complete the measurement round (e.g., waist circumference and triceps skinfolds) before starting the 2nd set of measurements.
n. If the two measurements of height differ by 0.5 cm or more, then the height measurements are repeated a third time and the value is recorded.
o. In the rare occurrence that no pair of the three measures meets the criterion (less than 0.5 cm difference), start over with new measurements.
p. If there are two measurements the calculated height is their mean. If there are three measurements the calculated height is the mean of the two closest. If the third measurement is equidistant to the first two, the calculated height is the mean of the three measurements.
q. If the calculated height is outside the predefined range and the height is valid, check the valid box on the ANT form in the comments section under height. See Section 12.3 for range checks and more details on the override procedures.

Figure 9.1 Position for height measurement



Note: In large subjects it may be difficult for heels to touch each other or the stadiometer. In such cases the participant should stand so that the legs are perpendicular to the ground. It may also be difficult to maintain the Frankfurt horizontal plane and have the head touch the stadiometer. In these cases, the head should start touching the board and the head should be positioned until in the Frankfurt horizontal plane, keeping the head on the board as long as possible.

Figure 9.2 Illustration of the Frankfort Horizontal Plane head position.



9.2. Height Measurement with Inflexible Hairdos

There may be occasions when a hairdo is inflexible, cannot be "taken down," and interferes with the measurement of standing height. If the hairdo appears to be less than ½ cm above the top of the head, measure the height according to the standard protocol by compressing the hairdo down with the sliding part of the height board as far as you can without making the participant uncomfortable. This is regarded as a routine measurement. An example of this would be participants who have small cornrows in their hair. If a hairstyle is higher and is not easy to undo or will not allow you to lay the carriage flat onto the crown of the head, or is higher than ½ cm and inflexible follow the modified procedure below:

~~a.~~ Ask participants if they are willing to take down the hairstyle, and if they are willing, follow the standard protocol for measuring height. If they are unwilling or unable to comply, you should proceed with the height measurement using the 6-inch interference ruler. Check the inflexible hairdo box on the ANT form in the comments section under height.

b. Position the participant on the stadiometer according to the standard protocol.

c. With the head in the Frankfurt plane, and viewing the head from the side, identify the crown (i.e., the highest point of the skull, where height would usually be measured). It may help to palpate the top of the head, around the inflexible hairdo. Ask permission to touch first. If the hairdo covers the crown, palpate around the hairdo and "estimate" the location of the crown. If you are unable to tell where the crown is, ask the participant to locate it. Place the end of the 6-inch ruler on the crown and hold it vertically. Measure the height as described above, but to the top of the ruler.

d. Record the height to the top of the 6-inch pocket ruler. Make sure that you note the use of the 6-inch interference ruler on the ANTH form along with the height measured. The computer will calculate the participant's actual height as the recorded height minus 15.2 cm automatically.

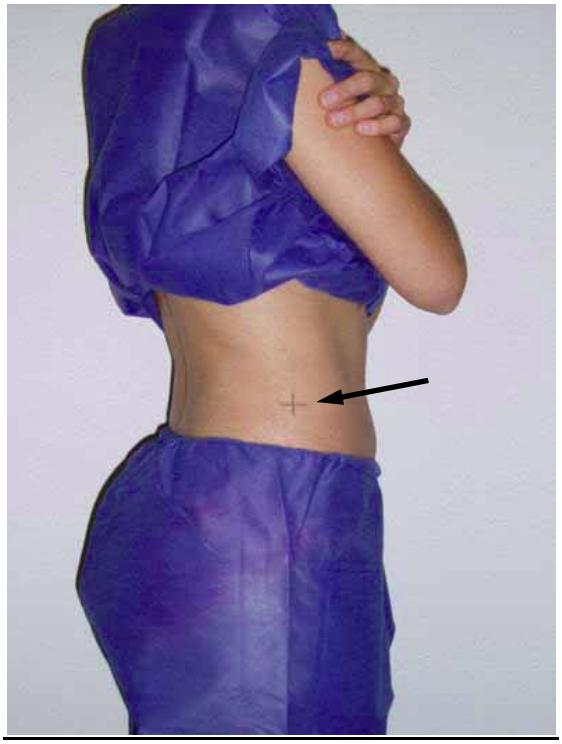
10. WAIST CIRCUMFERENCE MEASUREMENT

Waist is measured just above the uppermost lateral border of the right ilium. The measurement should be made on the skin and not over outer or bulky clothing. It should be done in a way that will not change the natural contour of the waist. Performing the measurement with two measurement staff is preferred. The measurement can also be made by one data collection staff, but is more difficult. If one data collection staff must make the measurement, the data collection staff stands diagonal to the side of the crest of ilium that is marked and then carefully levels the tape, viewing the tape from all sides. It is helpful to use a mirror to view the opposite side of the participant. The mirror helps to assure the horizontal alignment is maintained. Some sites prefer a female data collection staff to collect all of these measurements, but it is not required. If a participant is wearing a dress or other one piece outfit, they are asked to change into two piece clothing. This can be their own clothing if it is available, but otherwise it should be provided.

a. Ask participant to stand straight with feet spaced slightly apart, standing erect and looking straight ahead. The shirt is lifted and pants or skirt lowered in order to expose the waist (crests of the ilium or hip bones). Ask participant to cross arms while marking and taking measurement. Always ask before touching a participant or their clothing.
b. Position yourself so you are eye level with the participant's waist, for example by kneeling or bending over. The measurement is taken while you are on the participant's right side and not standing in front. Tell the participant: "*Now I will measure your waist size. Is that OK?* If "Yes": *Can I touch your hip bones?* If "Yes", continue (see Appendix 10 for details); if "No" stop here and note on data sheet. If necessary, ask if they can adjust their own clothing. If not, remember to ask permission before touching. Ask if they mind if you lift up their shirt slightly and hold it in place.
c. Mark the measurement site. From the participant's right side palpate the hip area to locate the right ilium of the pelvis. With the cosmetic pencil draw a horizontal line just above the uppermost lateral border of the right ilium. Cross this mark at the mid-axillary line, which extends from the armpit down the side of the torso. Figure 10.1 shows the measurement site correctly marked for the waist circumference.
d. Place measuring tape around the participant in a horizontal plane parallel to the floor at the mark. Check that the tape sits parallel to the floor and lies snug but does not compress the skin. Align the tape's "zero line" above the tape graduations (with metric side facing out) allowing the "zero line" to be right next to the mm ticks. Once set, switch zero end of tape to left hand, rest of tape to right hand. Holding the tape in place with the right hand, pull tape with left hand until appropriate tension is achieved (the metal disk between the 2 beads is just visible).
e. Verbally instruct the participant to breath normally. Take the measurement at the end of normal expiration. Record the waist measurement to the nearest 0.1 cm on the ANT form.

f. Complete the measurement sequence (triceps skinfolds) before starting the new measurement series.
g. If the two measurements of waist differ by 1 cm or more, then the waist measurements are repeated a third time and the value is recorded.
h. In the rare occurrence that no pair of the three measures meets the criterion (less than 1 cm difference), start over with two measurements.
i. If there are two measurements the calculated waist circumference is their mean. If there are three measurements the calculated waist circumference is the mean of the two closest. If the third measurement is equidistant to the first two, the calculated waist circumference is the mean of the three measurements.
j. If the calculated waist circumference is outside the predefined range and the waist value is valid, check the valid box on the ANT form in the comments section under waist. See Section 12.3. for range checks and more details on the override procedures.

Figure 10.1 Correct location for waist circumference.



11. TRICEPS SKINFOLD MEASUREMENT

a. Triceps skinfold are measured on the right arm. If a participant's physical injuries or deformities rule out the right arm, the skinfold on left arm should be measured. In the comments section under triceps on the ANT form, check the taken on left side box and record the reason why (i.e. injury or deformity).
b. Skinfolds are measured and recorded to the nearest millimeter. Measurements between two millimeters are rounded to the closest millimeter. Mean values

falling exactly between two whole numbers (e.g., 22.5 mm), are rounded up to the next whole number (e.g.,23).

c. Before measurement, the participants should be told they may feel a slight pinch. The measurer may demonstrate the pinch on their finger or side of the palm if a child appears nervous.
d. The triceps skinfold is measured 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). The measurement site is determined by measuring the distance between the outside edge of the shoulder (lateral projection of the acromial process) and the inferior border of the elbow (olecranon process of the ulna), with the elbow flexed to 90° with the palm facing up.
e. To find the midpoint, stretch the tape measure from the top outside edge of the shoulder to the elbow) along the back of the arm and mark a small cross at the midpoint and mark another small cross two centimeters above the midpoint with a water-soluble marker. The marks should be in the middle of the back of the arm, directly over the triceps muscle. It is important to be eye-level with the marked spots to be sure they create a line that is level (parallel) with the floor.
f. Before measuring the skinfold thickness, ask the participant to relax their arm at their side. The skinfold is measured in the participant standing with the arm hanging loosely (relaxed) and comfortably at the side (Figure 11.1). The measurer stands behind the subject, places the palm of the left hand on the subject's arm proximal to (above) the +2 cm mark, with the thumb and index finger directed inferiorly (down) and picks up the skinfold with the thumb and index finger at the 2 cm mark. If the measurer is unsure if the fold does not include muscle in addition to skin and fat, he/she asks the participant to “make a muscle in their arm”, and then relax the arm again before taking the skinfold measurement. If you feel some of the skinfold pull away, then you need to pinch a smaller fold because the grasp was too big. If the skinfold is too tight and there is difficulty in making a good measurement, ask the participant to let the arm hang and shake it gently. If still unable to make a good measurement, take the skinfold and wiggle it a little to try to loosen the fold from the underlying tissue. Note remaining concerns on the data form.

Figure 11.1

g. The site of measurement must be in the midline. The rectangular faces of the tips of the calipers are applied to the skinfold at the lower 0 cm marked level and held for a 2-3 second count, with the thumb all the way off the lever, while the thumb and index finger of the other hand maintain their pinch.
h. Take the reading, release your hold and the caliper from the skinfold and record the measure on the ANT form. **Caliper jaws need to be opened completely before being removed from the arm**, and the skinfold pinch with your fingers should be held until the calipers have been completely removed to prevent pinching.
i. If the triceps skinfold is greater than the width of the Lange caliper (>67 mm) use a Harpenden caliper and follow the steps above. If the triceps skinfold is larger than the width of the Harpenden caliper fill out the form using the greatest width available on the Harpenden caliper (80 mm) and note the problem on the data form. If the measure of the Harpenden caliper is ≤67 mm (due to different tension than the Lange caliper) enter 68 mm on the data form.
j. After the first triceps measurement is taken, the entire measurement sequence (weight, height, waist circumference) is repeated before the 2nd triceps measurement is taken.
k. A third triceps skinfold measurement is taken and the value is recorded on the ANT form if either of the following occur: 1) If either of the two triceps value is less than 10 mm but the two differ by 2 mm or more; 2) If both skinfold values are 20 mm or larger, with a difference between the two measurements of greater than 10% (((maximum – minimum) / minimum) * 100). Stanford will complete three measurements and the mean value will be calculated using the same procedures as the other sites (e.g. using first 2 measurements only unless 3rd skinfold would have been required).
l. In the rare occurrence that no pair of the three measures meet one of the criteria, start over with new measurements.
m. If there are two measurements the calculated triceps skinfold is their mean. If there are three measurements the calculated triceps skinfold is the mean of the two closest. If the third measurement is equidistant to the first two, the calculated triceps skinfold is the mean of the three measurements.
n. If the calculated triceps values are outside the predefined range and the triceps value is valid, check the valid box on the ANT form in the comments section

under triceps. See Section 12.3. for range checks and more details on the override procedures.

12. QUALITY CONTROL PROCEDURES

12.1. Erroneous Measurements

If paper forms are used, and the data collection staff writes down the wrong number, the data collection staff draws a single line through the error, writes the correct value and dates/initials the change. Computer entered data can be deleted and reentered as needed.

12.2. General QC Procedures

Ten percent (10%) of the anthropometric measures are measured by two different data collectors (duplicate measures for inter-rater reliability). Sites can choose to perform duplicate measures by participant (all anthropometric measures repeated in a single index child and an accompanying adult) or by anthropometric measurement (e.g. height in one child and his/her accompanying adult, waist in a different child and his/her accompanying adult, etc…) as long as each measurement (height, weight, waist circumference and skinfolds) is measured twice at least 10% of the time. When practical this is a 10% random sample, but it can be a systematic sample (every 10th child/adult). If a systematic participant sample is used, the 4th child measured is designated for QC, and thereafter, every 10th child (child #4, 14, 24, 34, etc.). The anthropometric measure or participant to be remeasured is indicated by a message generated by the data management system. If a participant is designated for QC, the duplicate measurements are obtained on the index child and one of the adults measured in association with that child. Duplicate measures are recorded to confirm inter-rater reliability, but the first data collection staff's measurements will be used in the analysis.

If possible, the Master Trainer reviews the 2 sets of measurements while the participant is still present. 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 20 mm or greater than 10% if the skinfold is 10 mm or larger.

If a data collection staff's agreement of 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. This retraining can be completed immediately if circumstances allow the Master Trainer to observe the data collection staff taking measurements and apply corrective instruction. These practice measurements can be taken on the Master Trainer or on other data collection staff. The data collection staff can reinitiate data collection when approved by the Master Trainer, but complete certification exercises are not necessary, unless deemed needed by the Master Trainer.

12.3. Range Checks

Range checks (Appendix 13) are built into the data management system to prevent the collection of erroneous data. Some research centers will enter data directly into a

computer data base, whereas other centers will record the data on paper and then enter it into the computer. Either way, the data entry program will indicate out of range values for validation.

Range checks are set so that participants with extreme and erroneous values are brought to the attention of the data collection staff for scrutiny. An extreme value may be real or erroneous. We decided arbitrarily that these checks would function as intended if they identify for scrutiny more than 1 in 100 participants but less than 1 in 50 for whom the data are valid. Given a normal distribution, plus or minus 2.4 standard deviations includes between 98% and 99% of the observations. When a value is designated as suspect by the data management system, the data collection staff has the option of either verifying that the data are correct, or re-measuring the participant. For anthropometry, often the data collection staff is able to verify that an out of range value is valid by simple visual examination of the subject and confirmation that the protocol was followed and data recorded accurately. When this is the case the verification is indicated on the data form by checking the box "Out of range – valid". However, if there is any uncertainty that the value could be incorrect, the participant is remeasured.

Range checks were determined using age (in yearly increments) and gender-specific anthropometric data from the 2003-2010 NHANES. The bounds for range checks in the baseline data collection vary by center since the anthropometric eligibility criteria for enrollment of index children vary. In the main trial anthropometric measurements in children could change substantially between the time the screening measurements are taken and the time the baseline measurements are taken. Therefore, the range checks have wider limits than the eligibility criteria.

The tentative criteria used to determine range checks for the index child at baseline of the main trial are shown below by research center.

<u>Case Western and Stanford</u>
The eligibility criteria for Case Western and Stanford specify that index children have a BMI ≥85th percentile according to the CDC BMI growth charts. Range checks for weight, BMI, waist and triceps skinfold have a lower bound of the 50th percentile for those variables in the log transformed NHANES 2006-2009. The lower bound for height is at the 25th percentile because heavy children are on average taller than lean children. The upper bound is 2.4 standard deviations above the mean for all measurements and BMI.

<u>Minnesota</u>
The eligibility criteria for Minnesota specify that index children have a BMI > 50th percentile according to the CDC BMI growth charts. Range checks for weight, BMI, waist and height have a lower bound of the 25th percentile from the log transformed 2006-2009 NHANES. The upper bound is 2.4 standard deviations above the mean for all anthropometric measurements (including BMI).

Vanderbilt

Eligibility criteria for the index children at Vanderbilt specify that the BMI must be ≤50th and < 95th percentiles of the CDC BMI growth charts. Range checks are 2 standard deviations below and 2 standard deviations above the mean from the log transformed 2006-2009 NHANES for all measurements (including BMI).

It is expected that body size will change during the study, so the range checks for the index children are wider after the study begins. For all sites the bounds of the range check will be 2.4 standard deviations below and 2.4 standard deviations above the gender and age-specific mean from the 2006-2009 NHANES. This method is also used to determine the range checks for family members measured at both baseline and follow-up examinations at all the research centers.

13. DATA PROCESSING

All collected anthropometric data should be reviewed for completeness by each Measurement Coordinator and then given to the Data Manager at the site. All anthropometric information is entered or downloaded into the site's Data Management System within 2 weeks of data collection. The adopted protocol for transferring anthropometric data to the RCU requires a single data upload from each site on a quarterly basis via the RCU Data Capture website. The RCU may request data at other times for purposes of reporting to the DSMB.

The table below shows the start and end dates of each quarter and when the data transfer to the RCU must be completed.

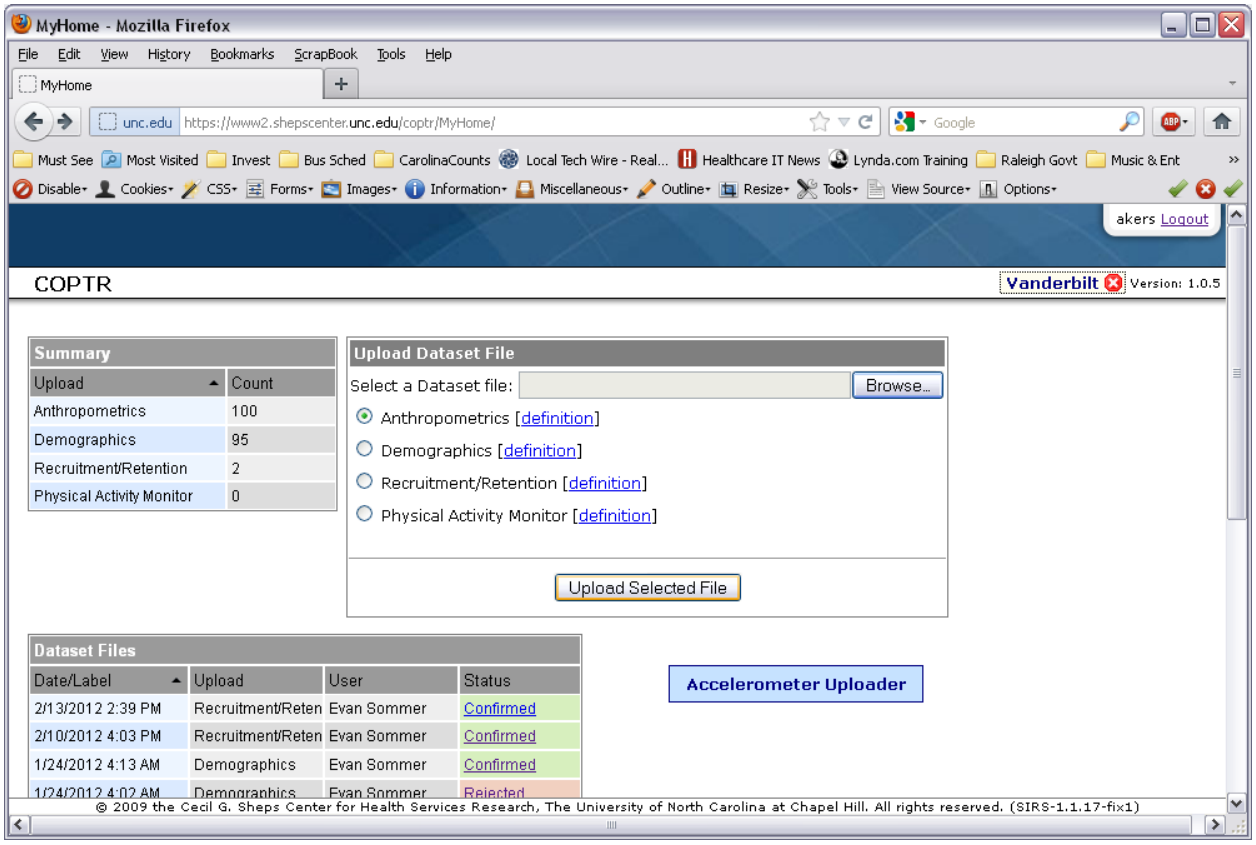
Data upload schedule to RCU

Quarter	Measurement Start Date	Measurement End Date	Due to RCU
1	January 1	March 31	April 15
2	April 1	June 30	July 15
3	July 1	September 30	October 15
4	October 1	December 31	January 15

The Measurement Coordinator stores all the logs detailed in the appendices in either paper or electronic form. The logs must be available for inspection by the site Principal Investigator, the RCU and other officials related to the COPTR study if requested.

Process for Uploading to the RCU (see screen example below)

visit the RCU Data Center at: www.shepscenter.unc.edu/coptr
login with your user id and password
Browse and select the appropriate quarterly output file
Select "Anthropometrics" as the dataset type
Select "Upload Selected File"



If there are errors, you will receive an error response. If the upload was successful and accepted, you will receive a confirmation response and the new file will be added to the list of uploaded files for your site.

APPENDIX 1. SITE-SPECIFIC INFORMATION FOR ANTHROPOMERTICS

Information on pertinent site specific procedures may be placed behind this page. These pages are generated by the investigators at the site rather than by the RCU.

APPENDIX 2. ANTHROPOMETRICS DATA COLLECTION FORM

To be completed by COPTR staff:

Index Child ID: _____ Form Code: **ANT** Version:

Scale #: _____ Caliper #: _____ Stadiometer#: _____

Is 10% Quality Control (QC) record: 0 □ No 1 □ Yes

Anthropometrics Form

1. DOB: ___ / ___ / ____ (mm dd yyyy)
2. Sex: 1 ☐ Male 2 ☐ Female
3. *If adult woman only:* Pregnant 1 ☐ Yes 0 ☐ No
4. Code for index child (C1), other children (C2-C8) or other adults (A1-A8): __ __
5. Visit: __ __ (e.g. 0 for baseline, 12 for 12 months, 24 for 24 months, 36 for 36 months) __ __

	6. Weight (kg) To nearest 0.1 kg Date: ___ / ___ / ___ (mm dd yyyy) Measured by:_ _ _ Recorded by: _ _ _	**7. Height (cm)** To nearest 0.1 cm Date: ___ / ___ / ___ (mm dd yyyy) Measured by:_ _ _ Recorded by: _ _ _	**8. Waist (cm)** To nearest 0.1 cm Date: ___ / ___ / ___ (mm dd yyyy) Measured by:_ _ _ Recorded by: _ _ _	**9. Triceps (mm)** To nearest mm Date: ___ / ___ / ___ (mm dd yyyy) Measured by:_ _ _ Recorded by: _ _ _
Scale 1*	__ __ __.__			
Scale 2*	__ __ __.__			
Measure 1	__ __ __.__	__ __ __.__	__ __ __.__	__ __
Scale 1*	__ __ __.__			
Scale 2*	__ __ __.__			
Measure 2	__ __ __.__	__ __ __.__	__ __ __.__	__ __
	Measure if weight 1 & 2 differ by ≥ 0.3 kg	*Measure if height 1 & 2 differ by ≥ 0.5 cm*	*Measure if waist 1 & 2 differ by ≥ 1 cm*	*Measure if triceps 1 & 2 differ by ≥ 2 mm if either <20mm or ≥10% if both ≥20mm*
Scale 1*	__ __ __.__			
Scale 2*	__ __ __.__			
Measure 3	__ __ __.__	__ __ __.__	__ __ __.__	__ __
Average	*Use the closest 2 values or all 3 values if appropriate* __ __ __.__	*Use the closest 2 values or all 3 values if appropriate* __ __ __.__	*Use the closest 2 values or all 3 values if appropriate* __ __ __.__	*Use the closest 2 values or all 3 values if appropriate* __ __.__
Comments:	☐ Out of range- valid ☐ Refusal ☐ Cast ☐ Measurement exceeds capacity ☐ Unreliable Why: _____	☐ Out of range- valid ☐ Refusal ☐ Cast ☐ Measurement exceeds capacity ☐ Unreliable Why: _____ ☐ Inflexible hairdo (+ 15.2 cm)	☐ Out of range- valid ☐ Refusal ☐ Cast ☐ Measurement exceeds capacity ☐ Unreliable Why: _____	☐ Out of range-valid ☐ Refusal ☐ Cast ☐ Measurement exceeds capacity ☐ Unreliable Why: _____ ☐ Triceps taken on left side Why: _____

* Only filled in when weight exceeds the capacity of one scale and two scales are used. Measure 1, measure 2 and measure 3 are then the sum of the respective scale 1 and scale 2 measurements.

APPENDIX 3. COPTR ANTHROPOMETRICTRAINING CERTIFICATION LOG FOR WEIGHT

Site: _____

Name	Training Date(s)	Certification Date	Certified by

APPENDIX 4. COPTR ANTHROPOMETRICTRAINING CERTIFICATION LOG FOR HEIGHT

Site: _____

Name	Training Date(s)	Certification Date	Certified by

APPENDIX 5. COPTR ANTHROPOMETRICTRAINING CERTIFICATION LOG FOR WAIST CIRCUMFERENCE

Site: _____

Name	Training Date(s)	Certification Date	Certified by

APPENDIX 6. COPTR ANTHROPOMETRICTRAINING CERTIFICATION LOG FOR TRICEPS SKINFOLDS

Site: _____

Name	Training Date(s)	Certification Date	Certified by

APPENDIX 7. COPTR WEIGHT SCALE CALIBRATION LOG

Site: ____

Date	Scale #	Standardized weight (xx.x kg)	Calibration value (xx.x kg)	Initials	Comments

APPENDIX 8. COPTR HEIGHT CALIBRATION LOG

Site: ____

Date	Instrument #	Standardized height (xx.x cm)	Calibration value (xx.x cm)	Comments

APPENDIX 9. COPTR LANGE CALIPER CALIBRATION LOG

Site: ______________________________________

Date	Caliper #	Width (mm)	Value	Initials	Comments
		10			
		20			
		30			
		40			
		50			
		10			
		20			
		30			
		40			
		50			
		10			
		20			
		30			
		40			
		50			
		10			
		20			
		30			
		40			
		50			
		10			
		20			
		30			
		40			
		50			
		10			
		20			
		30			
		40			
		50			
		10			
		20			
		30			
		40			
		50			
		10			
		20			
		30			
		40			
		50			

APPENDIX 10. ANTHROPOMETRIC EXAMPLE SCRIPT

Now I am going to take your height, weight, and body composition measurements. We are going to do height and weight measurements twice and the triceps measurement three times. Please remove everything from your pockets and any large or heavy jewelry and put everything in this basket. Also, please remove your shoes. *[If participants are wearing a sweater, sweatshirt, or jacket over their shirt, ask them to remove it to reduce excess weight.]*

WEIGHT MEASUREMENT:

Now I will take your weight.
[Weight: start by tapping the scale to turn it on. When it shows zero (0.0), say:]
Please stand with your feet evenly spaced over the center of the scale. Make sure your weight is balanced between your two feet. Keep your hands at your sides and look straight ahead [at the sticker or poster on the wall].
[Record weight after it stabilizes.]

Okay, you may step off the scale.

HEIGHT MEASUREMENT

Now we are going to measure your height.

[If the child has a hair accessory or their hair is up, please ask them to remove it. If it would be too difficult to remove or if they refuse, Follow the instructions in Section 12 – "Measuring height with inflexible hairdos" and write in the comments on the form "inflexible hairdo."]

Please step back onto the height board until some part of your body (heels, upper back, buttocks) touches the board and bring your feet together until your ankles or knees touch, whichever touch first. Stand straight up against the board. Your arms should be straight down at your sides, palms facing in. *[check that they are properly aligned, both from front and from left side.]*

Now, I am going to position your head.
[Position head so an imaginary horizontal line can be drawn between the bottom of eye socket and the opening of the ear.]

Please don't move your head until we finish. Now, hold your head still, keep your feet flat, and take a deep breath and hold it; stand up tall.
[Verify body is properly aligned and head position did not shift with deep breath. Move the headboard onto the head with sufficient pressure to compress hair. Record the height on the form.]
WAIST MEASUREMENT:

Take the measuring tape in hand and say: **Now we will measure you waist size. Is that OK?** If "Yes", **Can I touch your hip bones?** If "Yes", continue; if "No" stop here and note on data sheet.

I need to use your belly button as a guide to help me measure exactly around your waist. Please place your finger on your belly button. Please lift your shirt up so that I can see your belly-button. Please lower the waist of your pants so I can see your hip bones. Now stand straight, cross your arms with your hands on opposite shoulders, and relax you stomach, while I find your hip bones.

Now I am going to put a small mark on the top of your hip bones. Now I am placing the measuring tape around your waist. *Check that the tape sits parallel to the floor and lies snug but does not compress the skin.* **Please breathe normally while I get the measurement.** *Take the measurement at the end of normal expiration*

***TRICEP MEASUREMENT**:*

Now we are going to take a triceps measurement on your right arm. Face away from me with your right arm next to your body. Bend your elbow with your palm facing up. I am going to make two marks on your arm, but the markers we are using will wipe off with this handy wipe. Is it all right if I touch your arm so I can find my placement for the measurement? I am going to lightly pinch the skin on the back of your arm three times.

[You may want to ask participants if they want to see how the caliper pinch will feel on their finger before you pinch the back of their arm.

Find your midpoint on the child and mark it with your water-based marker following MOP protocol. With thumb and index finger pinch the skin fold approximately 2 cm above your midpoint mark. Make sure to have participants flex their triceps to assure you are not including the muscle in your skin fold measure. Hold the skin fold with the calipers for 3 seconds, and take reading looking from the top of the caliper. Record the reading, or call it out loud to the recorder and make sure the recorder repeats the correct number back to you. Repeat this measure as directed by manual of procedures, releasing the skin fold all three times for each measure.]

Got it! Thanks.

All done. Thanks!

APPENDIX 11. FREQUENTLY ASKED QUESTIONS

This space will be used for questions and answers about issues that arise after the MOP is approved.

1. What do the checkboxes on the Anthropometric Data Collection Form stand for?

Out of range – valid	The measurement is out of range. However, the data collector confirmed that protocol was followed properly and the measurements were recorded accurately. The data collector's visual examination agrees with the range check indicating that the value is particularly high or low.
Refusal	Participant refused one or more of the expected measurements for this measure.
Cast	The participant was wearing a cast, which affected this specific measurement or prevented measurement from being taken.
Measurement exceeds capacity	The measurement exceeds equipment capacity and no other equipment (e.g. second scale) was available to take the measurement.
Unreliable	The data collector has any other concern about the measure being unreliable and will indicate a reason for this concern.

APPENDIX 12. ANTHROPOMETRIC RANGE CHECKS

Based on NHANES data (2003-2010). All anthropometrics were log transformed. Used +/- 2.4 SD

Table 1. Children at Prevention Sites (Minnesota and Vanderbilt)

	Weight			Height			Waist			Triceps	
Age	Lower (-2.4 sd)	Upper (+2.4sd)		Lower (-2.4 sd)	Upper (+2.4sd)		Lower (-2.4 sd)	Upper (+2.4sd)		Lower (-2.4 sd)	Upper (+2.4sd)
Boys											
2	9.8	17.7		81.5	106.1		40.8	56.4		5	14
3	10.7	24.3		87.0	114.0		40.9	62.2		5	17
4	11.6	30.9		92.5	121.9		41.0	68.1		4	21
5	12.5	37.5		98.0	129.9		41.2	73.9		4	25
6	13.5	44.2		103.5	137.8		41.3	79.7		3	29
7	14.4	50.8		109.0	145.7		41.4	85.6		3	32
8	15.3	57.4		114.5	153.7		41.5	91.4		3	36
Girls											
2	9.4	14.7		78.2	107.5		40.4	54.8		5	17
3	10.2	22.9		84.1	115.3		40.3	62.0		5	20
4	11.0	31.0		89.9	123.1		40.1	69.2		5	24
5	11.8	39.2		95.8	131.0		40.0	76.3		4	27
6	12.6	47.3		101.7	138.8		39.9	83.5		4	30
7	13.4	55.5		107.5	146.6		39.7	90.6		4	34
8	14.2	63.6		113.4	154.5		39.6	97.8		4	37

Table 2. Children at Treatment Sites (Case and Stanford)

	Weight			Height			Waist			Triceps	
Age	Lower (-2.4 sd)	Upper (+2.4sd)		Lower (-2.4 sd)	Upper (+2.4sd)		Lower (-2.4 sd)	Upper (+2.4sd)		Lower (-2.4 sd)	Upper (+2.4sd)
Boys											
7	12.2	50.3		108.3	145.2		40.0	89.4		3	37
8	14.5	62.6		113.2	152.8		41.0	95.2		3	39
9	16.8	74.9		118.1	160.4		42.1	100.9		3	42
10	19.1	87.1		123.0	168.0		43.2	106.7		3	44
11	21.4	99.4		127.9	175.6		44.3	112.4		3	46
12	23.6	111.7		132.8	183.2		45.4	118.2		3	49
13	25.9	124.0		137.8	190.8		46.5	124.0		3	51
14	28.2	136.3		142.7	198.4		47.6	129.7		3	53
15	30.5	148.6		147.6	206.0		48.6	135.5		3	56
Girls											
7	11.0	66.2		109.4	150.5		37.5	99.1		4	39
8	13.5	74.0		113.9	155.7		39.2	103.2		4	43
9	16.1	81.7		118.4	160.9		40.8	107.3		4	46
10	18.7	89.5		122.9	166.1		42.5	111.4		4	49
11	21.2	97.2		127.5	171.3		44.2	115.5		4	52
12	23.8	104.9		132.0	176.5		45.9	119.6		5	55
13	26.4	112.7		136.5	181.7		47.6	123.7		5	59
14	28.9	120.4		141.0	186.9		49.2	127.8		5	62
15	31.5	128.2		145.5	192.1		50.9	131.9		5	65

Table 3. Adults at all four sites

	Weight			Height			Waist			Triceps	
Gender	0.25th %tile	99.75th %tile		0.25th %tile	99.75th %tile		0.25th %tile	99.75th %tile		0.25th %tile	99.75th %tile
Males	47.7	175.2		152.9	196.8		66.5	155.7		3	38
Females	39.5	164.5		140.9	180.7		63.2	151.1		6	40

CHILDHOOD OBESITY PREVENTION AND TREATMENT RESEARCH

COPTR

MANUAL OF PROCEDURES

2. PHYSICAL ACTIVITY

JULY 2012

PROCEDURES MANUAL
2. PHYSICAL ACTIVITY
Table of Contents

1. INTRODUCTION

The purpose of this procedure manual is to provide detailed instruction on how to collect accelerometry measurements in the COPTR studies. There will be four common measurement time points – baseline, 12 months, 24 months and 36 months. All accelerometry dietary assessment data will be collected prior to randomization. All common data collection will occur between May 2012 and February 2017. This document was written, edited, and approved by the members of the Diet and Physical Activity Working Group, as well as the Measurement Subcommittee and Steering Committee. Lessons learned from the pilot studies were incorporated in this manual of operations. Even small deviations from the procedures as they are described here are highly discouraged. Data collectors at all sites should strictly adhere to the main trial procedures outlined in this manual for all common measures. This standardization is crucial to the ultimate goals of COPTR Consortium.

The ActiGraph GT3X+ (or GT3X) accelerometer is a three-axis accelerometer designed to be worn on the waist, wrist, or ankle. It is slightly smaller than a pager and is used to monitor free-range physical activity levels. The major differences between the two models are increased water resistance and storage memory. The GT3X has 16 MB versus 256 MB for the GT3X+. The GT3X and GT3X+ models collect raw data for one day and eight days, respectively. The GT3X can collect data at 1second epochs for 8 days or more. Unlike the GT3X, the GT3X+ does not filter or accumulate data into epochs. Raw data are collected at a predefined sampling rate (40 Hz) and are post-processed in the ActiLife software.

In COPTR, each participant wears the monitor (GT3X+) for 7 complete days (including while sleeping and naptime) except any water activity (e.g., bathing, swimming, showering). The parent responding to the questionnaire wears the GT3X and GT3X+ ActiGraphs for 7 complete days at the two prevention sites (Minnesota and Vanderbilt, respectively). During the data collection, a reminder phone call is made to each participant to remind him or her to wear the monitor and to answer any questions. Specific procedures for data collection are described below. In COPTR, the monitor will be worn on the right hip. Site-specific instructions are shown in Appendix 1.

2. TERMINOLOGY TO DESCRIBE RELEVENT INDIVIDUALS

Index child: A child who meets eligibility criteria and is randomized to a study arm with the intention that his or her BMI data will be included in the site's primary outcome analysis as the main exposure.

Master Trainer: The person (or persons) at each site that trains and supervises certification of accelerometer data collection staff or research associates.

Measurement Coordinator: The person (or persons) at each site that organizes accelerometer data collection activities. This person may or may not be a Master Trainer.

D*ata collection staff*: Personnel who collect initializes and downloads accelerometer measurements.

Trainee: The person receiving training and seeking certification to participate as a Research Associate.

3. CONFIDENTIALITY CONSIDERATIONS

There are no confidentiality issues with respect to wearing the accelerometer. Any information from the instrument can be obtained only by using a computer that has the ActiLife software installed.

4. SAFETY CONSIDERATIONS

There are no known risks associated with use of the monitors. The activity monitors are designed to be worn in a wet environment, so moisture does not pose a problem. The ActiGraph is powered by a 3-volt lithium ion battery, which does not present a shock hazard when worn in a wet environment. The lithium ion battery is housed securely inside the device. The monitor does not emit radiation, electrical current, vibration, or heat and can be worn under shirt or coat sleeves without causing discomfort.

For very young children or pets, there is a small risk of accidental choking if the device is removed from the waistband and is left within reach. The device is intended to be worn or stored securely fastened at all times to a waistband, ~0.8" wide. There is no reason to remove the device from the waistband. All other components in the ActiGraph (including the batteries) either are in sealed compartments or require special tools to remove.

5. EQUIPMENT

The accelerometer devices have the following specifications:

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
Communication	USB 2.0	USB 2.0
Parameters	Activity, Steps, Inclinometer, Light	Activity, Steps, Inclinometer
Calibration	Not Required	Not Required
Water Resistant	Resistant (up to 1 meter)	Splash

COPTR laptops for activity monitor data collection with at least one USB port and with a minimum of one (1) gigabyte memory. (1/measurement team)
GT3X+ USB cables for activity monitor
GT3X USB cables for activity monitor
Activity monitors with belts of varying sizes (number of activity monitors will vary by site)
Physical Activity Monitor (PAM) Forms
Pens/Pencils

Activity Monitoring instructions
Sports Team Leader or Coach Memo
Teacher/Daycare Provide Memo
Brown padded envelope
Padded FedEx envelope
FedEx airbill

6. TRAINING AND CERTIFICATION

COPTR uses a "train-the-trainer" model. Each research center 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 candidates for Master Trainers are responsible for training and certifying the data collection staff at their center. All activity monitor data collectors must participate in and successfully complete the training and certification procedures designed for the COPTR Activity monitor data collection. In addition, Field Site specific trainings may also occur at each Field Site in order to train and certify additional research staff that will be initializing and/or downloading the activity monitors. Field Site specific training sessions are administered (taught) by individuals who have attended, successfully completed the central training and certification. All activity monitor data collectors must attend either the central or Field Site specific training sessions and complete the certification procedures.

The training sessions include instruction on all procedures outlined in the procedures manual, required data collection forms, and technical skills needed to operate the activity monitor hardware/software. Practice times and exercises for working with the activity monitors are included. The first part of the training includes instructions on how to initialize the activity monitor and wearing the monitor. Participants attending the in-person training session wear the activity monitor for a minimum of 8 hours. During this time, they need to be active in order to have valid data. The second part of the training focuses on the downloading of the activity monitor and preparing the transfer files. The certification procedures for activity monitor data collection are to be completed after the training sessions and participants have at least 8 hours of wear time. The master trainer is certified after he/she has successfully downloaded accelerometer data and transferred to the RCU.

Additional staff/data collectors at each Field Site are trained by their sites Master Training. For certification, each activity monitor data collector is required to collect Activity monitor data on 3 subjects for a minimum of 8 hours. This amount of time allows for the person being certified to observe a variety of different counts that could include different intensities of movement. This exercise only includes the initialization and download of the activity monitors and the completion of one data transfer.

The data transfer is an important part of the certification process, as it assures that appropriate testing of the laptops and web access at each Field Site has been completed. Test IDs are provided by the RCU for this exercise in order to assure that the activity monitor data file naming convention is followed.

All activity monitor data collection staff must be certified before initializing or downloading activity monitors in the study. Each Field Site will keep a Activity Monitor Certification Training Log (Appendix 2) and submit the certification training log to the RCU each time a new certification was added.

7. ID LABELS AND PARTICIPANT LIST

All Activity Monitors should be labeled with Field Site staff contact information. Each device can then be labeled with its own identification number (i.e. the last five digits of the serial number) or with the ID of the participant receiving that device. It is important to match up the correct ID labels to the participant, activity monitor unit, and forms. The ID label on the activity monitor unit may be used during the data downloading process (see Section 10.1) for file naming.

8. PHYSICAL ACTIVITY MONITOR (PAM) FORM

This form is for activity monitor data collection documentation of each participant (Appendix 3). It is started at the visit when a monitor is distributed to a participant. Space is provided on the header of the form for the Index Child ID. Under the section for activity monitor, record the data collection timeframe, Person Code, and Sequence Number of the wear. The Sequence Number allows for multiple wears by an individual within the same timeframe when the first wear did not result in complete data. Next, record on the form the Wear Start Date and Wear Start Time to indicate when the monitor was physically placed on the individual. It is IMPERATIVE that the Wear Start Date and the Wear Start Time on the PAM accurately reflect when the participant starts wearing the monitor. Record the serial number of the monitor unit that is given to the participant. The serial number is the 3 letter plus 10 digit number on the sticker on outside or inside of case or readable when plugged in in the side of the monitor (GT3X+ starts with NEO and GT3X starts with MAT). Record on the form the Start Date to accurately reflect the date the monitor was configured to start recording data. Completing the Wear End Date and Time are optional. Depending on whether the activity monitors are returned in-person or mailed back determines when the Field Sites fill in the Wear End Date and Time on the PAM form. If the Wear End Date and Time are filled out in advance (monitors mailed back), fill in the date and time to reflect when the participant should take the activity monitor off. If the Wear End Date and Time are completed when monitor is returned (in-person), record the Wear End Date and Time to accurately reflect when the monitor was taken off the participant. Last, record any comments that may be helpful in using and analyzing these data.

9. GENERAL MEASUREMENT PROCEDURES

Before data collection begins verify that the date and time are correct on all computers used for activity monitor initialization and download. Do not change the time on the laptop/computer once the ActiLife software begins. The computer clocks will automatically update for the time change in March and November and this will be handled at the RCU in data analysis. Be sure the computer used to initialize the specific accelerometer is the same one used to download the data.

9.1. Charging Accelerometer

Accelerometers must be sufficiently charged in order to be initialized for data collection.

1. Connect accelerometer to a powered hub or a USB port on the computer.
2. During charging the device will emit a flashing LED.
3. Fully charge the accelerometer (until LED is no longer blinking but emitting a solid LED light, 4.18v). Charging time should take no longer than 4 hours.

9.2. ActiLife Software

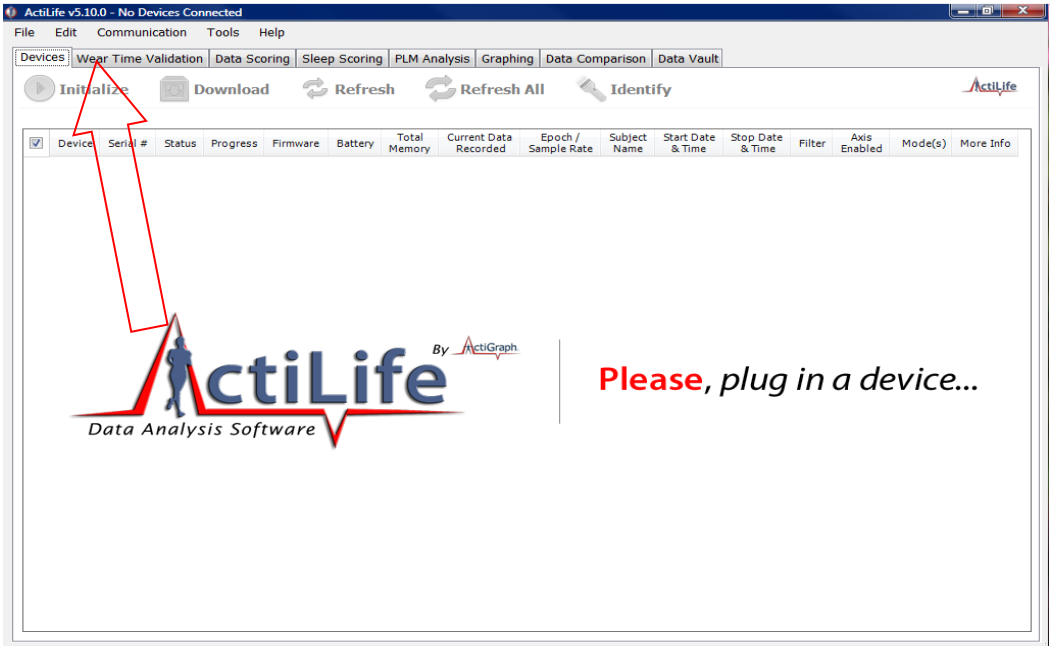
Any major updates in the ActiLife software version used during the trial will be made as a collaborative decision by the Diet and Physical Activity Working Group. If a change does occur, it will be on the same calendar day for all Field Sites. Regular (minor updates within the major version of the ActiLife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

9.3. ActiLife Software Program Setup

The ActiLife software requires some set up to meet that needs of our study.

1. Start up the software
2. When the opening or main screen comes up look at the top for the "**edit**" pull down tab (Figure 9.1)
3. Selection "**options**" from the edit menu

Figure 9.1 ActiLife Openning (Main) Screen



9.3.1. To set up the metric units:

1. Start up the software
2. When the opening or main screen comes up look at the top for the "**Edit**" pull down tab (Figure 9.2)
3. Select "**Options**" from the edit menu
4. The screen should be "**General**" but if not, the left click on "**General"**
5. Under "**Units of Measurement**" select "**Metric (cm and kg)**"
6. Click "**Apply**" then click "**OK**"

Figure 9.2 Setting up Metric options

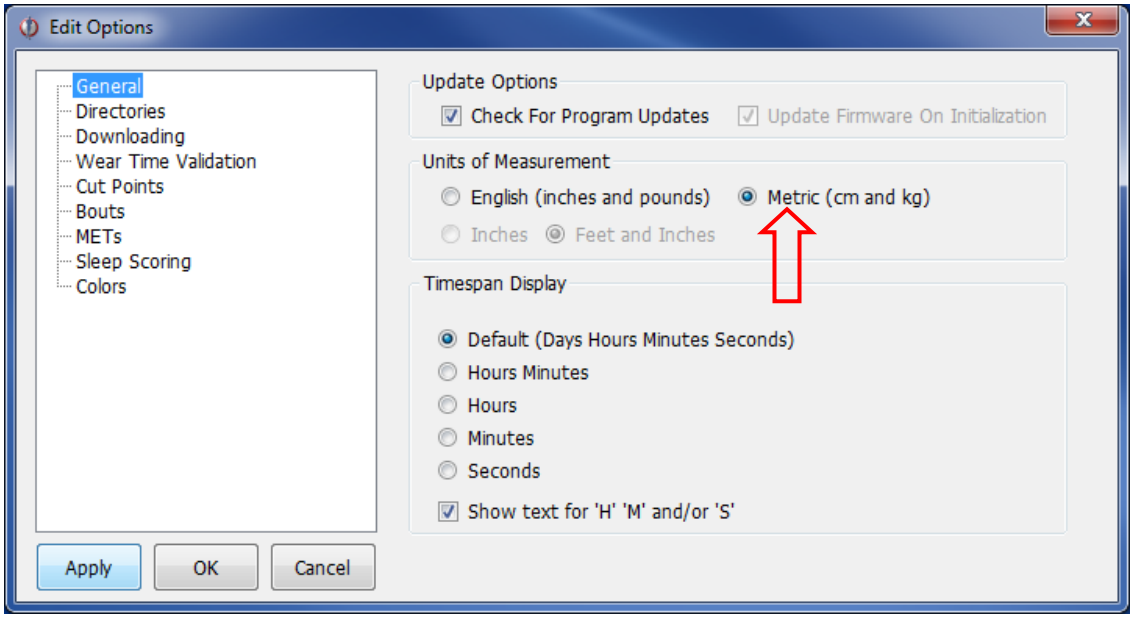
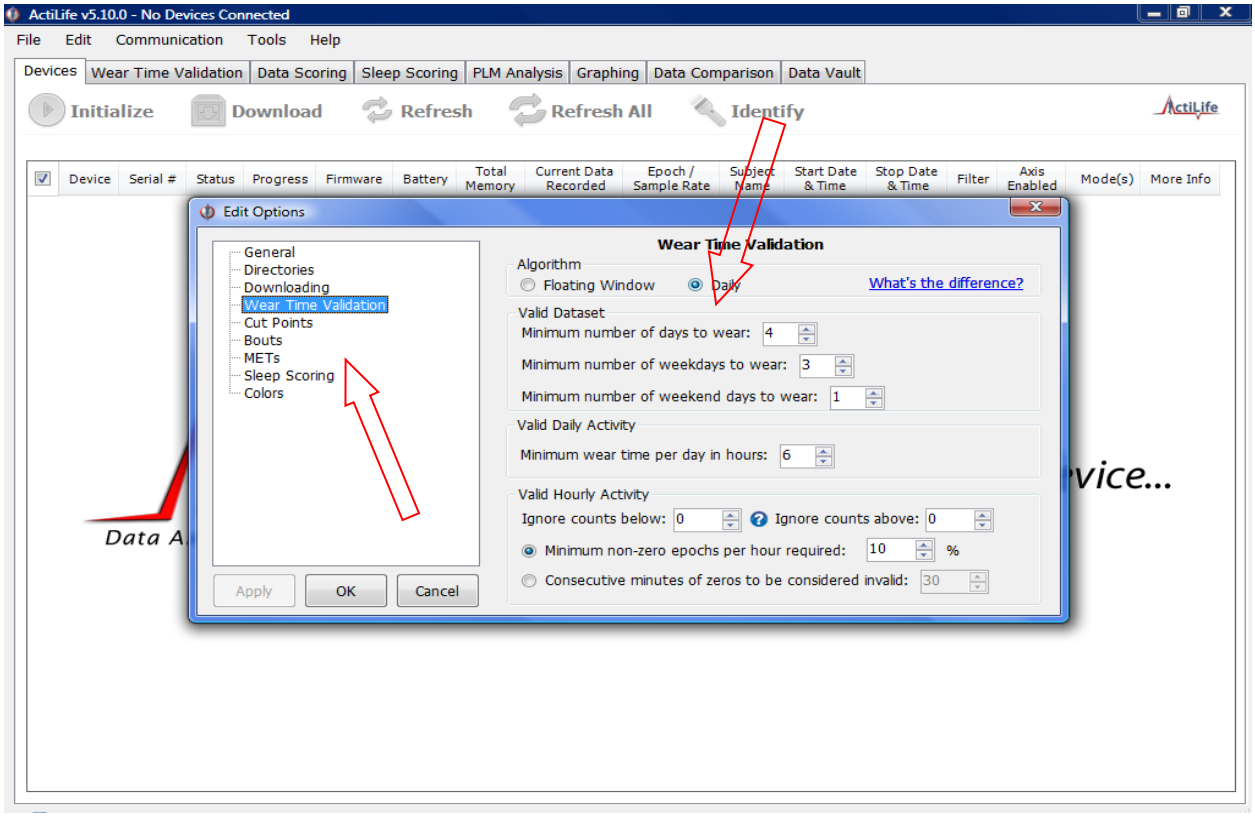


Figure 9.3 Edit Options Wear Time Validation Screen



9.3.2. Setting Wear Time Validation

1. Under options on the left click on "**Wear Time Validation**"
2. Under Wear Time Validation click on "**Daily Algorithm**" (Figure 9.3)
3. Insert the following under "**Valid Dataset**:
   Minimum number of days to wear: 4
   Minimum number of weekdays to wear: 3
   Minimum number of weekend days to wear: 1
   Minimum wear time per day in hours: 6
   Ignore counts below: 0
   Ignore counts above : 0
   Minimum non-zero epochs per hour required: 0%

The click on "OK". This will save these setting for future use.

Now return to the main screen to begin initialization

9.4. Selecting the Start Date and Time for Activity Monitors

The activity monitors must be initialized before collecting data. Initialization may be done on the afternoon or evening before meeting with the participant, or if time permits, at the home, clinic or community center before meeting with the participants. **The start date and time should be programmed for the (expected) day AFTER the participants start wearing the activity monitors at 12:00AM.** This rule is used regardless of whether you are initializing the day before or on the day that the monitors are expected to be given to the participants. Official data for the study begins at 12:00 am on the day after the monitors are given to the participants.

In the event that monitors have been initialized, and a change is made in the schedule such that participants will not be given the monitors on the expected day, the monitors do not have to be re-initialized UNLESS the new schedule is more than 2 days later than the original schedule. Initializing and re-initializing drains the battery more than having the monitors working. In analysis, the RCU will begin using the data based on the date recorded on the Activity Monitor (PAM) form. This is why it is SO important that the date on the PAM form is the date the monitor is put on the participant.

For example, if the participant was originally supposed to receive the monitor on Tuesday, the start day and time would be Wednesday at 12:00:00 am. If he/she misses the visit on Tuesday, but reschedules for Wednesday, and you give him/her the monitor to wear on Wednesday, there is no need to re-initialize. If he/she is absent again on Wednesday, but present on Thursday, and you give him/her the monitor to wear on Thursday, there is STILL no need to re-initialize. However, if he/she is not available until Friday, or you are unable to get back until Friday, you must re-initialize the monitor to start on Saturday at 12:00 am. You must also change the date on the PAM data collection form to reflect Friday's date.

The steps for preparing the monitors for data collection are outlined below. Each data collector must become completely familiar with these instructions in order to properly initialize the monitors prior to data collection and to download the data from the monitors at the end of the data collection.

9.5. Activity Monitor Initialization Instructions

IMPORTANT! INITIALIZING THE ACCELEROMETER WILL DELETE ANY PREVIOUSLY STORED DATA REMAINING ON THE DEVICE. THESE DATA SHOULD BE DOWNLOADED PRIOR TO INITIALIZING.

When the activity monitor is connected to the computer monitor, the application recognizes the device and start its process of internal system checks. ActiLife remembers the initialization parameters from last initialization. This means that many settings are already selected and only need confirmation. However, other settings need to be customized for each use. Make sure the correct settings have been selected.

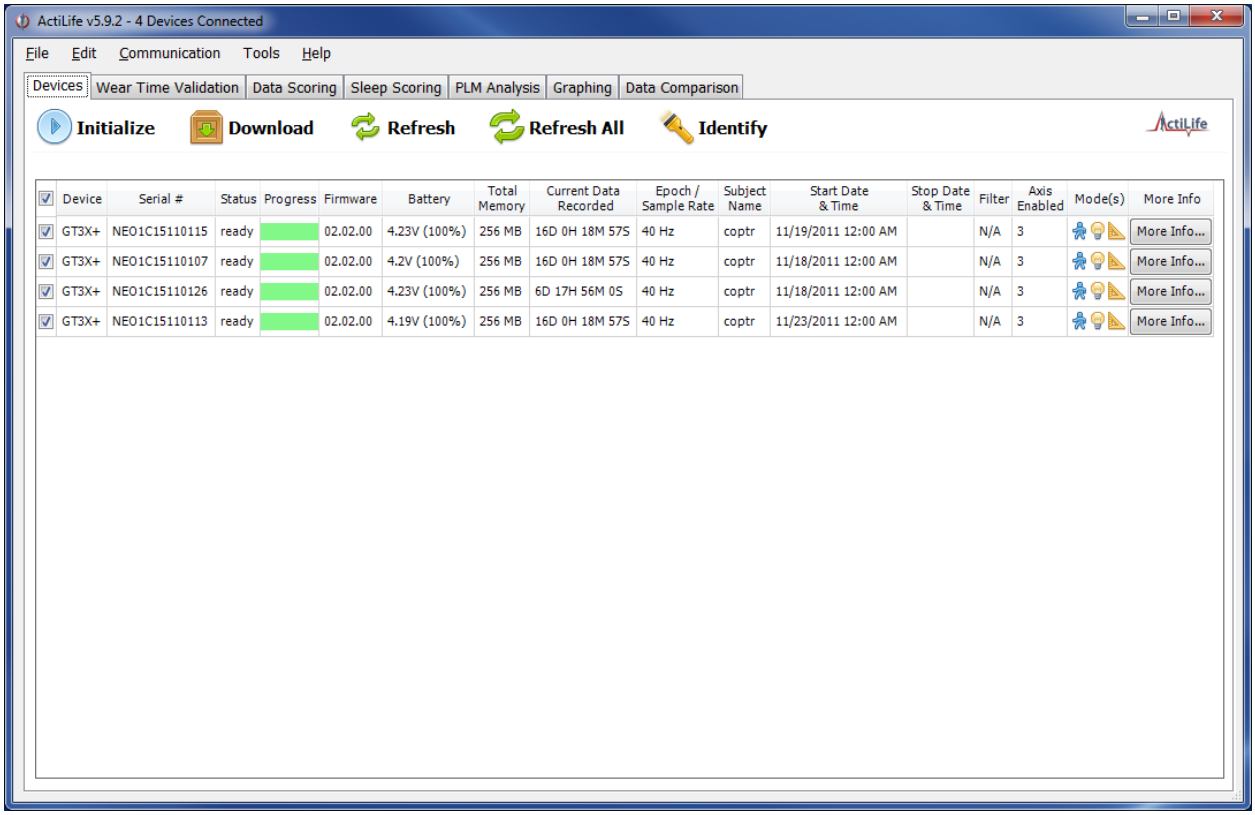
Make sure the device is fully charged. Battery voltage can be determined at any time by connecting the device to the computer and opening the ActiLife software. An error message appears if attempting to initialize a device with less than required.

ActiLife is capable of initializing or downloading multiple devices simultaneously. The software is capable of handling up to 127 devices at one time. Computer limitations and USB ports limit the number of devices a Research Center can do at one time.

1. Connect Monitors (Note: Devices can be connected either before or after ActiLife is launched.)
2. Launch ActiLife software (figure 9.1 above).
3. The software takes time to find the monitors (See figure 9.4 for device screen showing multiple monitors). Once found, the **"Initialize", "download", "Refresh", Refresh all"** portion of the screen shift from a shade of gray to color.

   **** Check the "battery voltage" it should be over 4.17 volts. If not, then recharge the battery. See section 9.1.****

   Figure 9.4 Screen showing multiple monitors



4. Click on "**Initialize**". This brings up a smaller, new screen (Figure 9.4 Initialize Device Screen). The 'Initialize Device(s)' screen contains a separate tab for each type of Actigraph device connected to the PC and appears after clicking the "Initialize" button at the top of the "Devices" screen. Tabs across the top

represent the types of devices to be initialized. If multiple devices of each type are selected, the tab group applies to all devices of that type.

5. Select tab for the device you wish to configure (GT3X+ or GT3X) and set the specific data collection parameters. All monitors of the same type that are initialized simultaneously will be initialized with the same data collection parameters.

   GT3X+ (child monitor and parent monitor @ Vanderbilt)

   a. Sample rate: select **40 Hz** from pull down menu (see figure 9.5 below)
   b. Check the "Maximum record time" it should be around 16D (16 days)
   c. Start date: Enter the start date as the day after the monitor is intended to be given to the participant
   d. Start time: **12:00 am**
   e. The stop data and time are not needed.
   f. Flash LED options (particularly during data collection mode) should not be selected in order to conserve battery life

   GT3X (parent monitor @ Minnesota)

   a. Epoch: select 1sec from pull down menu
   b. # of axis: select 3 from the pull down menu
   c. Start date: Enter the start date as the day after the monitor is intended to be given to the participant
   d. Start time: **12:00 am**
   e. The stop data and time are not needed

6. Look to the bottom of screen and click on the "**Enter Subject Info**" button
   This brings up a new submenu screen (Figure 9.5 Subject name entry form). The Subject Name screen allows users to enter a unique subject name for the attached devices. This data is stored on the device and is available at download

Figure 9.5 Initialize Device Screen

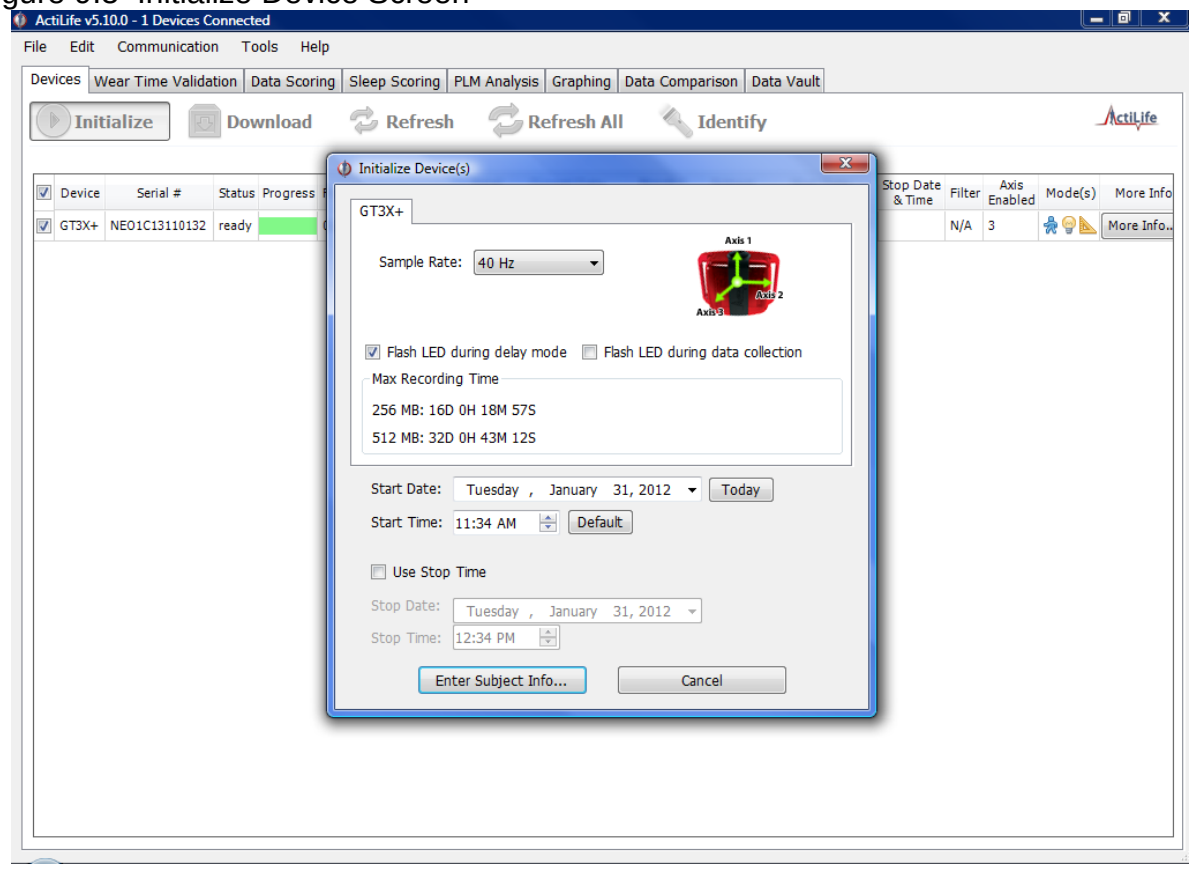
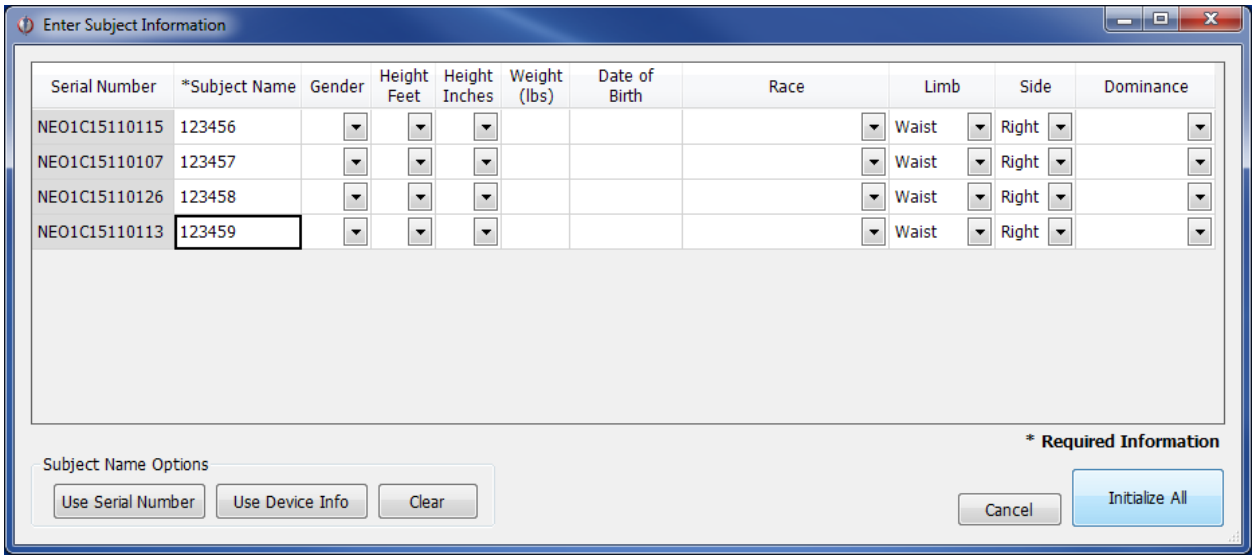


Figure 9.6. Subject name entry form



7. At the bottom of the Screen, select "**Use device Info**" button.
   GT3X+ (child monitor and parent monitor @ Vanderbilt)
   REQUIRED:
   a. Serial number: automatically be pulled from the devices

b. Subject name: enter ID number (see section 9.1)

OPTIONAL:

c. Gender: Use pull down menu to select male or female
d. Height: Use the 2 pull down menus to select height in feet (pulldown) and inches (pulldown)
e. Weight: Enter the weight in pounds
f. Date of birth: Enter date of birth (mm/dd/yyyy)
g. Race: Select race from pulldown menu (Asian/Pacific Islander, Black/African American, White/Caucasian, Latino/Hispanic, Other)
h. Limb: Select "waist" (pulldown menu)
i. Side: Select "right" (pulldown menu)
j. Dominance: Select whether the participant wore the monitor on "dominant" or "non-dominant" side

GT3X (parent monitor @ Minnesota)

a. Serial number: automatically be pulled from the devices
b. Subject name: enter parent ID number

8. Once entered, select "Initialize All" button at the bottom of the screen
9. This brings up a new screen (Figure 9.2 Devices Screen Showing Multiple Monitors). Look about 1/3 way across to the Status and Progress Columns. In the Progress column, you see a green bar. Wait until the green bar fills the space. In the Status column, it will say "finished" when the initialization process is complete.
10. Remove the activity monitors and they are ready to be used.

9.6. Meeting the Participants, Distributing the Activity Monitors

Activity monitor data collection occurs at the same visit that the body composition measures are taken. Explain the procedures regarding wearing the activity monitors to each participant. (This can occur in groups of participants.) The activity monitor is worn on the right hip using an elastic waist belt. To use the elastic waist belt, lace the belt through the side loops of the monitor and secure the belt around the waist. The activity monitor can be worn either above or beneath clothing, and it is not necessary for the device to make contact with the skin. However, the activity monitor **must be held snugly against the body** to prevent erroneous readings. See Appendix 4 for an example script containing the information that the data collection staff should tell the children and parents. Data collectors should practice their site specific script before meeting with the participants (and parents) to be prepared.

9.6.1 Example Script

Follow the example script provided in Appendix 4. For re-measures, follow script in Appendix 5.

Each participant and/or parent should be given a copy of both the child and the parent information and instruction sheet to take home, and for those that need it, a copy of a letter for any sports team coaches or leaders if they are participating in a sport where

they might have to take the monitor off. See Appendices 6, 7, 8, 9 and 10 for example instruction sheets. Each site will tailor the scripts for their specific study population.

9.6.2. Telephone Calls

The decision to make these calls is up to the discretion of each Field Site.
For Field Sites that choose to make these calls: Using the participant telephone listing, each participant and/or parent will be called 2-3 days after they are given the monitor to remind them to keep wearing the activity monitor and to confirm the pick-up date or when they should mail back the activity monitor. Leave a message if the child or parent is not there, either with an adult or on an answering machine.

9.7. Removal and Return of Monitor

For three of the Field Sites (Case, Stanford and Vanderbilt), the monitors are mailed back to the respective site after the data collection is complete. Research staff will arrange to pick up the monitors in person if they had not received the monitor within a designated time. For Minnesota, all monitors are returned in person.

When returning in person, the participant should have worn the monitor for 7 days. At the time the belt is removed from the participant, match the serial number on the activity monitor to the serial number recorded on the participants PAM form. When returning the monitor by mail, the participant (or parent) mails the monitor after the week data collection is completed in the pre-addressed stamped mailing envelope provided by the Field Site. Once the envelope is received, the Field Site staff matches the ID on the activity monitor to the serial number on the envelope and the number recorded on the participant's PAM form.

The label on the monitor remains until the data are downloaded to the laptop. The ID number on the label is used to name the data file when following the download procedures outlined below. Downloading the activity monitors may occur immediately, or within the next 24 hours.

There are no changes in procedure if data are collected during daylight savings time changes, this will be handled during data analysis.

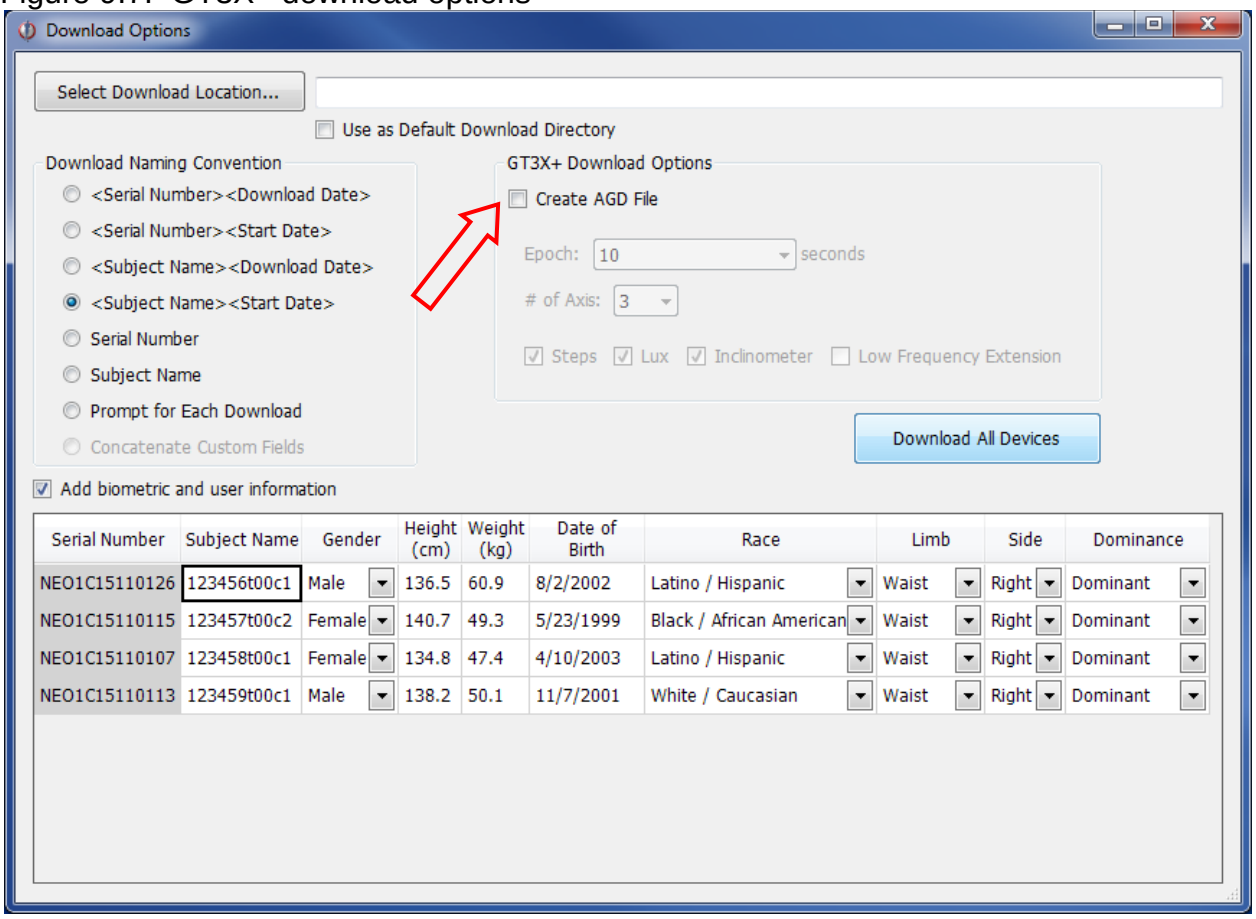
9.7.1. Downloading Data from GT3X+ accelerometer

Data from the GT3X+ monitors are in raw, binary format with file extension *.gt3x. This binary format mirrors the proprietary compressed raw format store on the device itself and is unreadable by standard text editors. These files are in a maximum compression format and are optimal for emailing or FTP file sharing. In order to read the data or process the data with ActiLife, the *.gt3x files needs to be uncompressed (i.e. exported to *.agd) using ActiLife. This can occur during download or later when processing files. ***It is recommended that the process of uncompressing from gt3x files to adg files be done later and not during the download process.***
The downloading steps are:

1. Connect the accelerometer
2. Start software and it will say "**Loading Device**" the "**progress**" bar is totally green when complete.

3. Once the software recognizes the accelerometer to "**initialize / download**" it shifts from shades of gray to color.
4. Select "**download**". This brings up a screen that says "Download Options" (Figure 9.7).
5. At "**Download Naming Convention**" select <Subject Name>. Note: this is site-specific but the COPTR default is subject name.
6. To record the **optional** biometric data (gender, height, weight, race), check box labeled "add biometric and user information". Checking this box expands the box to show a grid of the biometric information for each device. Make sure the gender, height, weight, race etc. are correct. If not, change that information.
7. To select a different download location, select "**Select download location**" and browse to the desired directory. To make this the default location, check "**use a default download directory**"
8. DO NOT click "Create AGD file". Creating an AGD file during download ***increases the download time significantly*** depending on the size of the download. In addition, to create an AGD file, the parameters for the uncompressed file must be set at the time of download if the "Create AGD File" option is checked. These parameters include the uncompressed epoch length, the number of axes, step counting, lux (light data), inclinometer (standing, sitting, lying, or off detection), and/or low frequency extension. ***.gt3x files can be uncompressed at a later time (e.g. after emailing or file sharing).**
9. The click on "**Download All Devices**". This takes you back to the main menu.
10. Check the "**status**" and wait until it states "**finished downloading**" and the "Progress" space is completely green.

Figure 9.7. GT3X+ download options

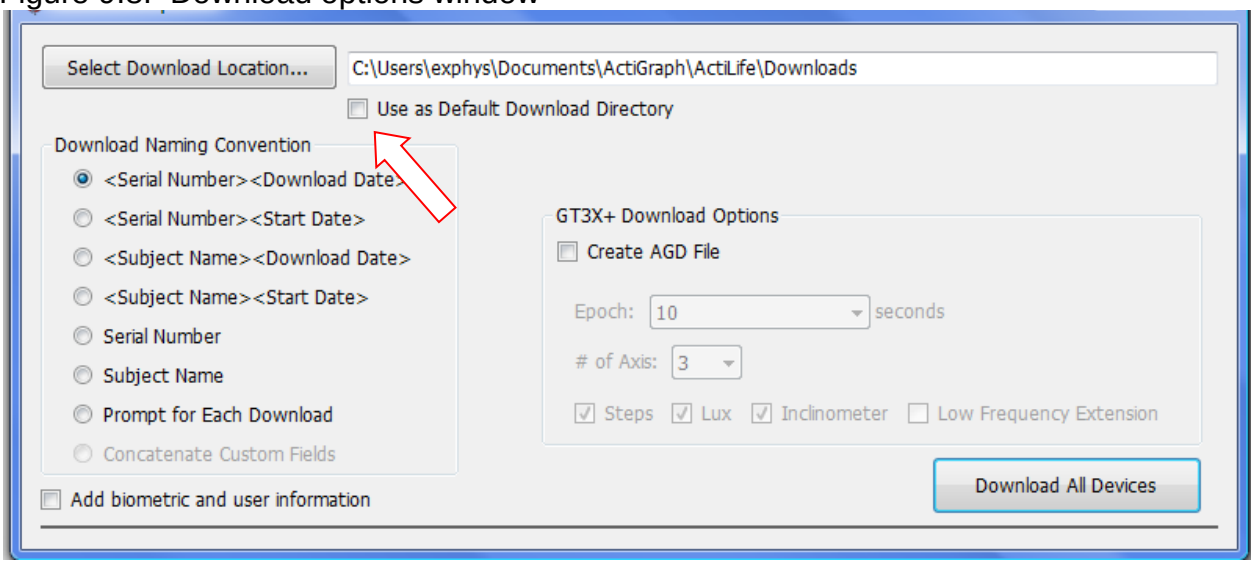


9.7.2. Downloading Data from the GT3X accelerometer

The ActiLife software stores the data from the GT3X accelerometer into the *.agd file format upon downloading. The downloading steps are:

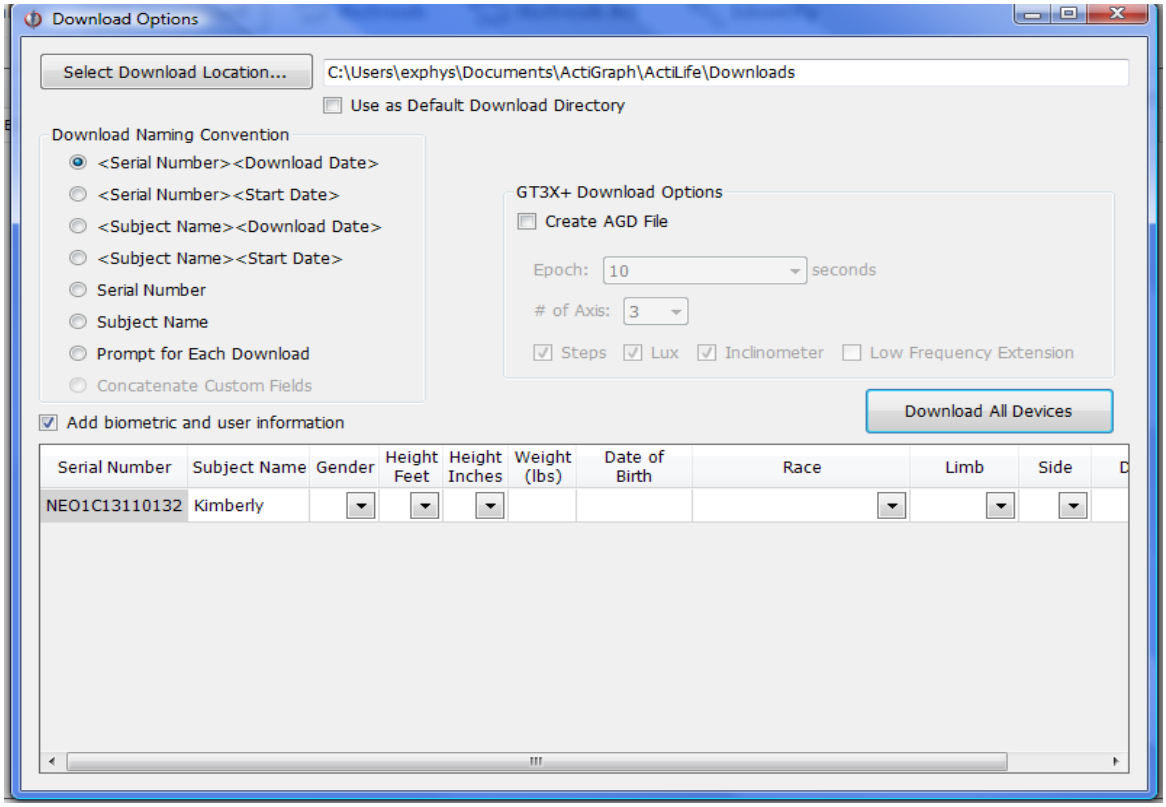
1. Connect your monitor(s) to the computer. ActiLife software detects those devices and they will appear in the Devices grid.
2. Select the devices that need to be downloaded and click "**download**" at the top of the screen.
3. Download option screen (Figure 9.7. Download options window) appears allowing you to select the type of naming convention.
    a. Select <Subject Name>

Figure 9.8. Download options window



4. To select a different download location, select "**Select download location**" and browse to the desired directory. To make this the default location, check "**use a default download directory**" (see arrow Figure 9.8)
5. To record the **optional** biometric data (gender, height, weight, race), check box labeled "add biometric and user information". Checking this box expands the box to show a grid of the biometric information for each device (see Figure 9.9 Biometric and user information during download). Make sure the information is accurate.
6. Click "Download all devices".
7. This creates the *.agd dataset and a *.csv dataset.

Figure 9.9. Biometric and user information during download



9.8. Uncompressing *.gt3x Files Later Time

As mentioned in section 9.7.1, the *.gt3x files can be uncompressed during the download process (takes more time), or at a later time. The Field Sites transfers compressed *.gt3x files to the RCU, however, they will want to uncompress the data files at their site (after downloading) in order to check for participant compliance. The steps to uncompress the files after download are:

1. From main menu, select **File.** Then click on "**Import/Export**". Select create "**AGD/CSV/DAT from Raw GT3X+"**
2. An export window appears (Figure 9.10 GT3X+ Export tool)
3. Individual *.gt3x files can be added by selecting the "Add GT3X+ Files(s)" option. All of the *.gt3x files in a directory can be added by selecting "Add Directory…"
4. Once files are added, the desired file type(s), **an epoch length of 5 seconds or more**, and parameters can be selected within the export tool.
5. Select "**Create File(s)"** to export these files to the default download directory.
6. This file will be used later to determine if the data are valid (section 9.10)

Note: The GT3X+ export tool can also be accessed by clicking "**finished downloading**" hyperlink (Figure 9.11) from the devices grid after downloading.

Figure 9.10. – GT3X+ Export Tool

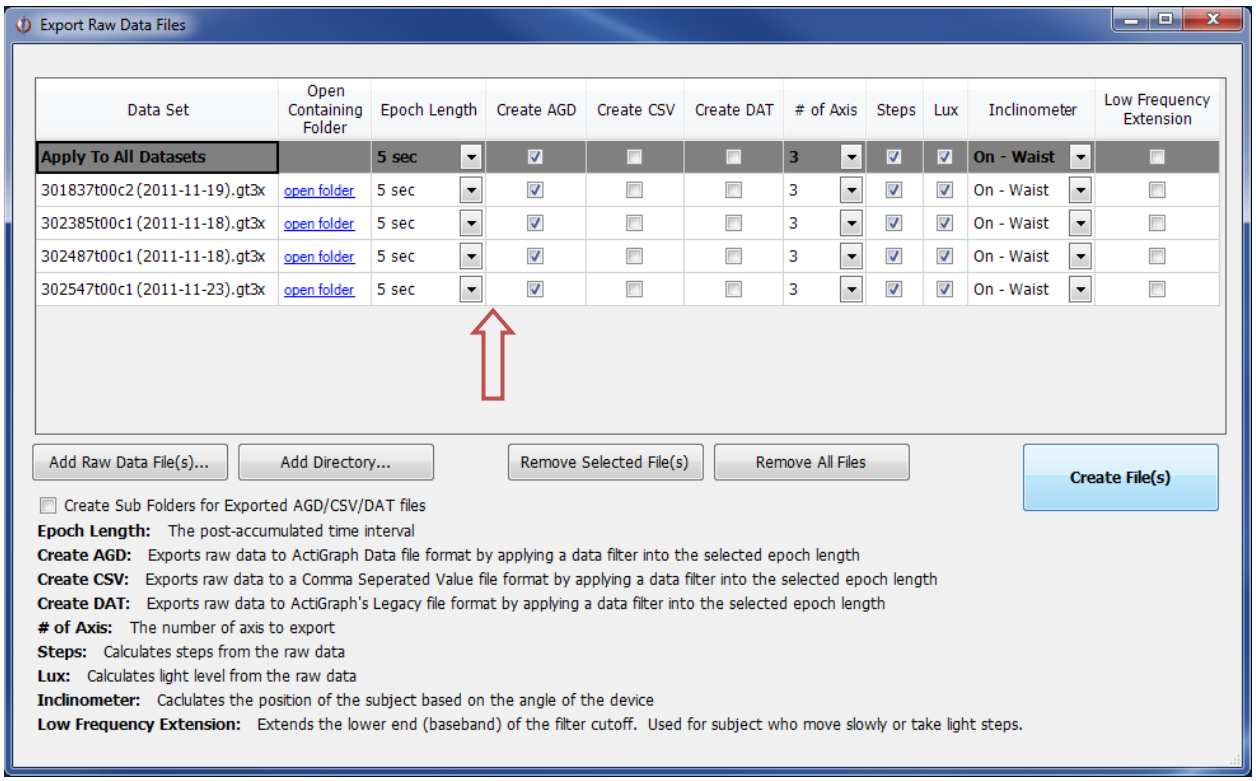


Figure 9.11. Finished Downloading Hyperlink in Devices Grid

9.9. Troubleshooting Download Errors

Data downloaded from GT3X+ devices can be scanned for problems at the time of download. At this time, ActiLife can scan for null data (0s) which may indicate issues with the device accelerometer or non-compliance by the end-user. To enable this scanning:

1. From the main menu, Select **Edit**. Click on the **Options menu** and choose the **Downloading submenu**.
2. In the "**Scan of GT3X+ Download**" section, select the warning threshold. Doing so warns the user during the download process if the number of 0s within the file exceed the threshold. To disable this feature, set the threshold to 100%.

9.10. Checking adherence and re-measuring non-adherent children and parent

The goal of the study is to get a valid activity monitor measure on each participant. The goal is for 7 days of wearing the monitors. 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 (3 weekdays and 1 weekend day) of at least 6 hours each day of awake time, it may be necessary to have the participant wear the monitor again in order to get valid data. A re-wear in the same collection timeframe is indicated by SeqNo (sequence number). The first wear in a timeframe will be SeqNo=1; the second SeqNo=2, etc. The Wear Time Validation tool can identify the number of valid days of data. The steps are:

1. On the main menu, click on "**wear time validation**" tab (Figure 9.12).
2. Check the Valid Wear Time Criteria at the bottom (should be already set)

   Minimum number of days to wear: 4
   Minimum number of weekdays to wear: 3
   Minimum number of weekend days to wear: 1
   Minimum wear time per day in hours: 6
   Ignore counts below: 0
   Ignore counts above : 0
   Minimum non-zero epochs per hour required: 0%

   If the values on screen are different, change to the values above and the click on the "**Save as Default**" key (lower left on screen; see arrow)
3. Click on the "**add dataset**" link on the left side of the screen below the box (green arrow above)
4. This brings up the list of file (Figure 9.12). Choose (double click) on the file(s) to view.
5. Move the cursor to the right side of the screen and click on "**Get results**"
6. Datasets are classified as either valid or invalid (turns it red) based on the minimum wear criteria.

In the event that the wear criteria are not met on the first wear, sites will attempt at least one additional re-wear."

Note: The Wear time validation tool does not distinguish which hours during the day were valid hours, just the total number of valid hours. Since the goal is to have at least 6 hours of valid hours during awake time hours the graphs maybe more informative.

Figure 9.12. Wear Time Validation

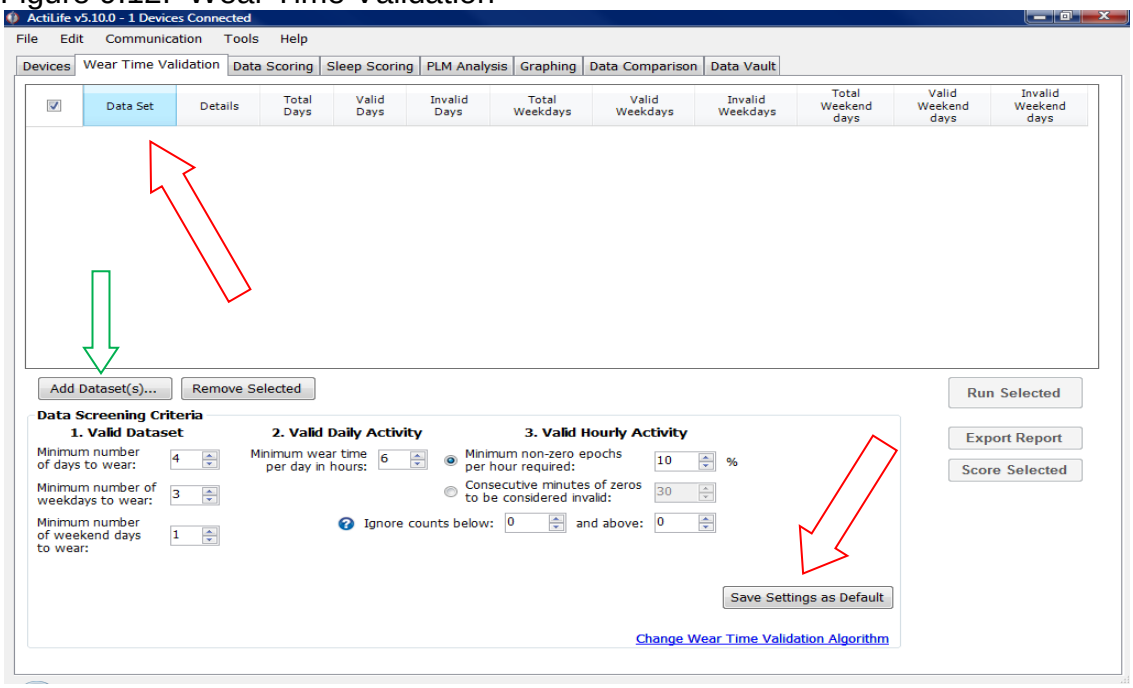
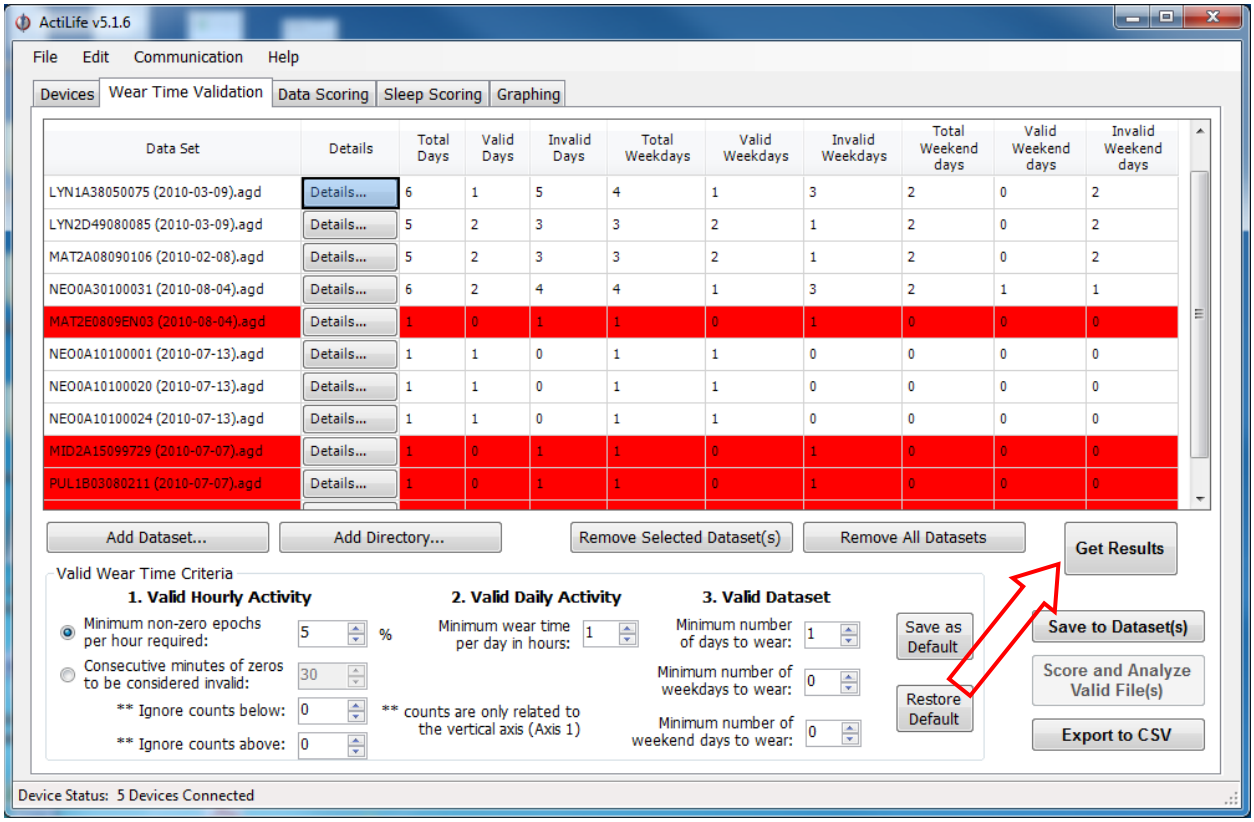


Figure 9.13. Wear time validation screen

Screen showing all files selected



If a re-measure is necessary, a new PAM form should be completed with the Index Child ID, Data Collection Timeframe, Person Code, next Sequence Number, the new serial number, etc. It is not necessary to re-measure body composition or obtain ethnicity.

NOTE: It is very important that the participant receive a *different* monitor than the one he/she wore during the original measure.

9.11. Repeated Wearing

Always aim to obtain full wear from a participant. If a participant does not wear the monitor consistently for a week, check to see if they meet minimum wear before requesting they wear the activity monitor again. If a participant does not meet minimum wear, then they should be asked to wear the monitor again.

Minimum wear:
Minimum number of days to wear: 4
Minimum number of weekdays to wear: 3
Minimum number of weekend days to wear: 1
Minimum wear time per day in hours: 6 hours between 5 am and 12 am of wake time.
Note: younger children (2-5) may take a nap during the day and could have a period of zero counts for up to 3 hours.

Full repeat wear: If a participant has little wear recorded, then a full repeat wear should be requested. For a full repeat wear, the participant should be instructed to wear the monitor for a full week.

Reduced repeat wear: If significant wear has been recorded, but not enough to meet minimum wear, then you can opt for a reduced repeat wear. For example, if the monitor is worn consistently during the week, but there is not enough weekend wear to meet the minimum, you can instruct the participant to only wear the repeat wear monitor during the weekend.

NOTE: When in doubt, err on the conservative side and request the full repeat wear.

Number of repeat wears: For baseline, participants will only be asked to do one repeat wear (wear a monitor for a second time). If after that second monitor, they still don't meet minimum wear, then eligibility for the study needs to be reconsidered. For follow-up visits, a participant should be given a monitor no more than three times. Repeat wears should be decided on a case by case basis. Take into consideration whether the additional wear is needed because of a device malfunction/staff error or because the participant did not wear the device. If it's the former, then you can give the participant an extra repeat wear. If it's the latter, then you should adhere to the guidelines stated above.

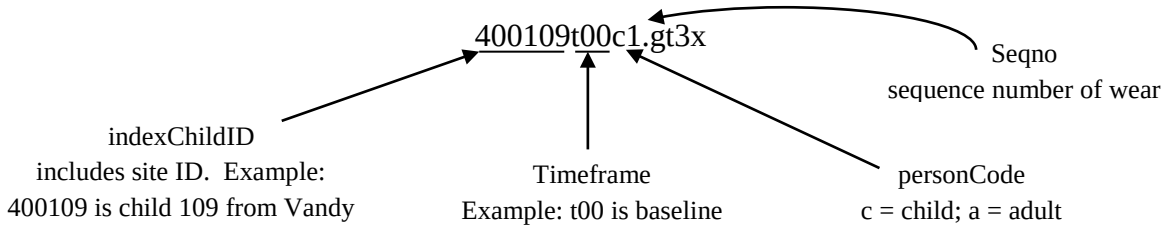
Lost monitors: If a device is lost during original wear, then a second device should be given to the participant. If a repeat wear activity monitor is lost, an additional wear needs to be reconsidered. Always stress the importance of the device.

10. DATA PROCESSING

All physical activity monitor (PAM) data collection forms and activity monitors are given to each Research Center's data management supervisor for data processing at the end of every data collection week. This includes monitors that had only partial data (i.e. participant needed to re-wear.) Field Sites transfer the accelerometer *.gt3x files and the associated PAM data collection records into the COPTR-RCU Data Center. Procedures for processing activity monitor files into the Data Center are detailed below:

10.1. Accelerometer File Naming Convention

The PAM form and the file naming convention will indicate the sequence number of the wears used in attempts to collect complete data. See the PAM Form section below for PAM fields. The accelerometer file naming convention is as follows:



10.2. Activity Monitor Data Submission to RCU

Sites will upload PAM records, GT3X+ data files (compressed RAW data, *.gt3x) and GT3x (parent @ Minnesota) data files (uncompressed data, *.agd) to the RCU on a quarterly basis. The RCU may request data at other times for purposes of reporting to the DSMB.

The table below shows the start and end dates of each quarter and when the data transfer to the RCU must be completed.

Data upload schedule to RCU

	Measurement		
Quarter	Start Date	End Date	Due to RCU
1	January 1	March 31	April 15
2	April 1	June 30	July 15
3	July 1	September 30	October 15
4	October 1	December 31	January 15

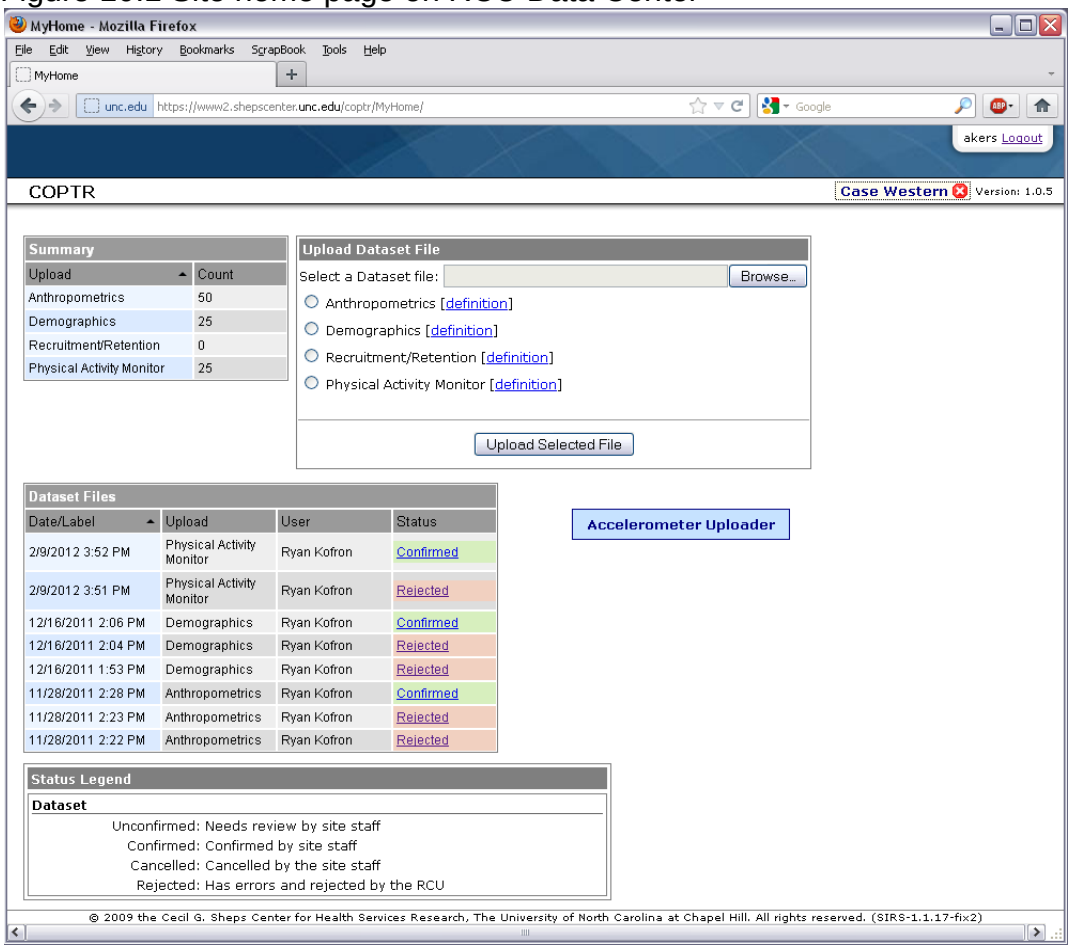
A PAM record for an individual GT3X+ or GT3X file MUST be uploaded and accepted in the RCU Data Center prior to uploading the associated GT3X+ or GT3X file. This sequence of events guarantees the RCU will have metadata critical to understanding

each GT3X+ or GT3X file and prevents orphan GT3X+ or GT3X files from being introduced into the large data repository.

PAM records can be uploaded to the RCU Data Center as CSV records extracted from a site's local data system. After login to the RCU Data Center, you will see a web page for your site similar to Figure 10.1 below. To see the required PAM fields, fields expected and data types, click on the "definition" link beside "Physical Activity Monitor".

To upload a set of PAM records, select "Physical Activity Monitor" as shown in Figure 10.1, click Browse to find and select the appropriate CSV file on your system, then click "Upload Selected File". During the upload process, the RCU data system will check for required fields, expected data types, and valid data ranges (where applicable). If any errors are found, the user will be presented with an error report and all records in that upload process will be rejected. The user can then use the error report to correct errors and submit corrected data following the same process.

Figure 10.1 Site home page on RCU Data Center



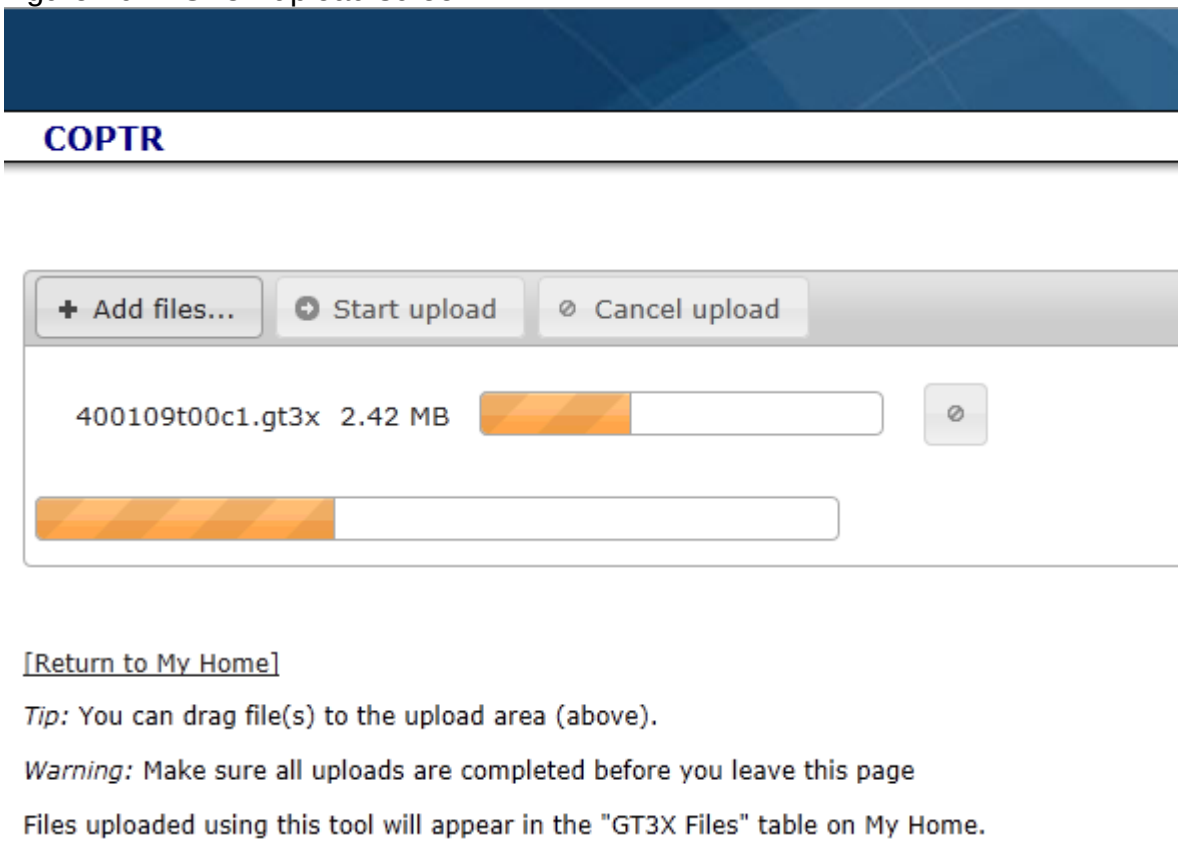
After PAM records have been successfully uploaded, a site can proceed to upload the associated GT3X+ or GT3X files. Click on "Accelerometer Uploader" shown in Figure 10.1 above. The upload screen shown in Figure 10.2 below will open with no files listed

in the upload area. To upload files, simply drag GT3X+ or GT3X files from local file space into that area or use the “Add files” button to browse and select GT3X+ or GT3X files. “Start upload” will initiate a set of data checks to verify there are PAM records for the files listed for upload.

A PAM record for a GT3X+ or GT3X file MUST exist in the RCU data system before the associated GT3X+ or GT3X file will be accepted.

The filename of the GT3X+ or GT3X will be parsed for its individual components and compared to the corresponding fields in the PAM records (indexchildID, visit, personcode, and sequence number). If a corresponding PAM record exists, the GT3X+ or GT3X file will be allowed to upload.

Figure 10.2 GT3X upload screen



10.3. Confirmation by RCU of GT3X+ or GT3X file uploads

Sites must verify accelerometer data when a monitor is removed from the subject to quickly see if the data collection event resulted in good data. That verification must be done at the site to determine if the subject needs to wear the monitor again. After

appropriate procedures from sections 9.7 through 9.10 above are followed, the accelerometer data can be uploaded to the RCU Data Center following the procedures described in sections 10.1 and 10.2 above.

A copy of ALL accelerometer GT3X+ or GT3X files for a site must be kept at the site even AFTER GT3X+ or GT3X files are successfully uploaded to the RCU Data Center.

The RCU does NOT process GT3X files on any routine basis. Adherence checks and data quality checks must be performed at the site prior to uploading to the RCU.

During the upload process, the interface will show progress bars like those in Figure 10.2 and will indicate whether each GT3X+ or GT3X file was successfully received or whether there were problems. The 'My Home" page for each site has a link to a master list of PAM records and uploaded GT3X+ or GT3X files. At any time, a site can use that link to see the current status of the site's PAM records and GT3X+ or GT3X files received by the RCU Data Center.

11. QUALITY CONTROL PROCEDURES

All research staff involved in the initialization, collection and/or downloading of the activity monitor data are trained and certified by the RCU. The training and certification program covers the basic operating features of the activity monitor, initialization, downloading, transferring data to RCU and troubleshooting. Research center performance and rates of valid data are monitored by RCU and Project Manager. Because activity levels change daily and the test retest relationships would be low, no participants will be asked to wear the monitor twice for quality control. In addition, an interview is not a good quality control check, does not provide the necessary data for a comparison, and thus will not be used for quality control. The quality of the data will be examined by the RCU examining the number of useful files in comparison to the number of participants examined. The goal is to obtain >80% useable files. This includes combining data from multiple wears in one timeframe. If the sites do not attain this goal, the RCU will contact the site to determine if correctable problems exist and assist in those issues.

APPENDIX 1. SITE-SPECIFIC INFORMATION FOR ACCELEROMETERS

Information on pertinent site specific procedures may be placed behind this page. These pages are generated by the investigators at the site rather than by the RCU.

APPENDIX 2. COPTR ACTIVITY MONITOR TRAINING CERTIFICATION LOG

Name	Training Date(s)	Certification Date	Certified by

APPENDIX 3. PHYSICAL ACTIVITY MONITOR (PAM) FORM

To be completed by COPTR staff:
Index Child ID: _____
Form Code: **PAM** Version: ____ Series #: ___

Physical Activity Monitor Form

---

1. Visit or Data collection timeframe: _____
   (e.g. t00 for baseline; t12 for 12 months, t24 for 24 months, t36 for 36 months)

2. Person Code: _____ (c=child; a=adult)

3. SeqNo: _____
   (sequence number for wear, if multiple wears for this person at this timeframe)

4. Wear Start Date: ___ / ___ / ____ (date the activity monitor put on the participant)
   mm dd yyyy

5. Wear Start Time: _____ AM / PM (time monitor is put on the participant)

6. ActiGraph Serial Number: NEO ___ ___ ___ ___ ___ ___ ___ ___ ___ ___
   MAT ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

7. Start date: ___ / ___ / ____ at 12:00 am (date configured to start recording)
   mm dd yyyy

8. Wear End Date: ___ / ___ / ____ (date the monitor was taken off the participant)
   mm dd yyyy

9. Wear End Time: _____ AM / PM (time participant takes monitor off)

10. Comments?

_____

_____

APPENDIX 4. GT3X+ AND GT3X ACTIVITY MONITOR DISTRIBUTION EXAMPLE SCRIPT

[If you think the belt on the GT3X+ or GT3X is not the right size for the participant, remove his/her monitor and switch it to a belt of the size needed prior to giving it to him/her.

Script should be presented to 1) the participant, 2) the participant and parent, 3) the parent, or 4) the whole family depending upon the situation.

Prior to starting your presentation on the activity monitor ask if the child is participating in extracurricular sports/activities in which the monitor may get bumped/hit. If yes, then be prepared for the additional instructions toward the end of the script.]

- "Your activity monitor should be worn every day until we collect them on (or you mail them back) _____."
- "Let's go through the instructions for wearing the monitor: Wearing the monitor is a very important part of our study."
- "The monitor is attached to a belt that will be worn around your (your child's) waist. This monitor has been set up for you (your child) so it is important that you (your child) wear this particular monitor during the week.
- "Please wear the monitor all day, even while sleeping."
- "We want you (your child) to wear the monitor as much of the day as possible. It is important for the monitor to be worn as much of the week as possible, so if you take it off for things like showering, bathing, or changing clothes, that means it is really important to always put it back on as soon as you can so you (your child) are wearing it as much time as possible."
- "The only time you should remove the monitor is when you (your child) shower, bathe, swim, or do something that may get the monitor completely wet. Sweating will not hurt the monitor, so you (your child) should wear it when you (he/she) play sports or games."
- "If you need to take the monitor off put it somewhere that it will not be bumped, dropped, or broken."
- "It is VERY important that you (your child) always wear the monitor in the same location on your (his/her) waist, and that the monitor is worn over your (his/her) <u>right</u> hip bone."
- "If you need to take it off, it is very important that you put the belt and the monitor back on your (your child's) waist as soon as you can. Like I said before, we need to have you wear the monitor for as much of the day as you can."

[Show the diagrams of a week of activity and explain that the spikes are show times where the monitor was worn. Where there is nothing on the chart, the monitor was not worn. Give the monitor to participant. Have the participant or parent demonstrate to you that they know where the activity monitor is supposed to be worn and how to hook and unhook the belt. Adjust length of belt as needed so it is snug.]

**** Make sure to write the serial # on the physical activity monitor form. ****

- "You (your child) can wear the monitor over or under your (his/her) clothes, whichever you prefer."
- "Here are three things to remember about wearing the monitor."
    - Keep the belt tight
    - Take it off if you (your child) are going swimming or bathing
    - Put it back on as soon as you can

[Each participant may be given the following sheets to take home: 1)the instruction sheet(s), 2) teacher or daycare provider memo, and 3) Sports/Coach memo. See Appendices 4, 5, 6, 7, and 8 for instruction sheets and memos.]

- "In your packet, we are giving you a sheet that reminds you how and when to wear the activity monitor. Please post this sheet in an area where it will help you remember to wear your monitor, for example, your bathroom mirror or on the fridge."
- "There is a letter for your (your child's) teachers that explains the activity monitor and that you are participating in the research study. You can show it to your (your child's) teachers only if you'd like."
- "Each of these sheets also contains our study's, phone number and email address. Please feel free to call or email if you have any questions."
- *[Ask the participant questions about the information you just provided to him/her to make sure he/she understood.]*
    - "When are you supposed to wear the monitor?"
    - "Where on your body does the monitor go?"
    - "How many days are you going to be wearing the monitor?"
    - "When are we collecting it?"
    - "When are the only times the monitor should be taken off?"
- "Do you have any questions about wearing the monitor?"
- "Do you (your child) participate in any organized sport or physical activity outside of school time where you're not sure if you will be able to wear the activity monitor (or think you won't be able to)?"
- *[If NO, say]:* "Thank you!

[If YES, continue as follows:]

- *[Offer her the letter for her coach/PA leader]* "This letter explains to your coach that the activity monitor is part of a physical activity study. Do you think this will help you be able to wear the monitor during your game?"
  [If NO, offer him/her the Coach letter]
- "Do you have any other questions?"

APPENDIX 5. REMEASURE EXAMPLE SCRIPT

"The reason we are meeting with you today is to talk about the monitor that you were asked to wear. We looked at the output and it appears that you did not wear the monitor long enough (or the monitor failed). In order to get complete data and have you participate in the study (if at baseline), we would need you (your child) to wear the monitor for another 7 days. We really hope that you will wear this again for us. We would like to be able to include your data with the other participants in the study." [*Review monitor instructions in Appendix 4.]*

APPENDIX 6. ACTIVITY MONITOR EXAMPLE INSTRUCTIONS

ACTIVITY MONITOR INSTRUCTIONS

Wear the monitor **ALL DAY – EVERY DAY**

Take the monitor off **only** for:

SWIMMING **SHOWERING** **BATHING**

The monitor should always be worn against your **right hip bone**; colored dot facing up; ID sticker facing your body.

DO NOT take the monitor apart - That will ruin the data and we won't be able to use it.

We may call you during the week to see how you're doing.

We will be back on _____ at _____ to pick up the monitor.

If you have any questions, please call _____ or e-mail us _____.

THANK YOU FOR HELPING US WITH THIS IMPORTANT RESEARCH!!!

APPENDIX 7. EXAMPLE PHYSICAL ACTIVITY MONITOR INFORMATION & INSTRUCTIONS FOR CHILDREN (ACTIGRAPH GT3X+)

What is an activity monitor?

An activity monitor is a small device that records information about body movement during everyday activities such as playing indoor and outdoor or moving around the house. The monitor is safe, and uses a battery similar to a watch battery for power. It is not a GPS tracking device, nor does it record heart rate. Many studies with children and adults have used activity monitors.

What am I supposed to do with the activity monitor?

The monitor will start recording data today after you put it on. We ask that your child wear the monitor for 7 days, all day and night (even while sleeping). It is worn on the waist and should fit your child comfortably. Only remove the monitor for water activities like taking a bath, shower, or swimming. However, if the monitor and waist-strap get wet, you may blot them dry with a towel. I

If your child must take the monitor off for any reason, remember to put it back on the same place as soon as possible with the black disk facing up. If the monitor is removed, please keep it away from your child participating in the study, other children, and pets to avoid accidents.

What do I do after my child have worn the monitor for 7 days?

At the end of the 7-day period, mail back the monitor and the strap. Simply place the monitor in the postage-paid padded envelope you were given and drop it in any United States Postal Service mailbox as soon as possible. Alternatively, you may give it to a staff member at the next meeting if another meeting has already been scheduled.

What if I get questioned about the monitor?

A separate document, the Physical Activity Monitor Description and Photo page, is included in case you need to provide schools, camps, or other places with information about the monitor.

Whom do I contact if I have questions?

If you have any questions about the monitor, please call our office at xxx-xxx-xxxx
The number is also printed on the back of the monitor.

APPENDIX 8. EXAMPLE PARENTAL INSTRUCTION MEMO

MEMORANDUM

TO: Parents/Guardians

FROM:

DATE:

As you know, your child is participating in a health study sponsored by the National Institutes of Health at [your University here]. The purpose of this memo is to inform you of the details of this study, and the importance of wearing the physical activity monitor assigned to your child.

The monitor (attached to a belt) must be worn over the right hip; directly over the hip bone. The monitor will stay in the correct position most easily if it is worn against the skin, underneath clothes. The monitor is very small, is hardly noticeable, and will not interfere with your child's normal, everyday activities.

The monitor must be worn all day. It should be removed for purposes of changing clothes, bathing, or swimming, but should be put back on immediately afterwards.

The monitor should be worn for one week, seven consecutive days - from _____, [date]_____through _____ [date]_____ _. I will return to on _____ to pick-up the monitor assigned to your child, and to administer a short questionnaire.

PLEASE remind your child to wear the monitor. ***It is crucial to the integrity of the study that the monitor is worn as instructed, for the next 7 days.***

We have given your child two signs to remind her wear the monitor. (It will be helpful if these are placed in obvious places, such as the refrigerator and on the bathroom mirror). If you or your child has *any* questions, comments, or concerns regarding the study, please do not hesitate to call me at my office (insert # here). If I am not there, please leave a message and I will promptly return your call.

Thank you for giving your daughter the opportunity to participate in this important physical activity study.

Sincerely,

APPENDIX 9. EXAMPLE TEACHER / DAYCARE PROVIDER MEMO

MEMORANDUM

TO: Teacher/Daycare Provider

FROM:

DATE:

_____ is a participant in a health study sponsored by the National Institutes of Health at [your University here]. For this project, he/she is wearing an activity monitor to measure his/her physical activity. The activity monitor is a small square plastic object that he/she will wear on a black elastic belt around the waist. This is not a pager, nor a toy. Please do not remove it because it is important that we measure the child's activity patterns over a number of complete days. He/she will be wearing this monitor at all times from _____ to _____. Please call us at xxx-xxx-xxxx if you have any questions or concerns.

Sincerely,

APPENDIX 10. EXAMPLE COACHES OR SPORTS TEAM LEADERS MEMO

MEMORANDUM

To: Whom it May Concern

FROM:

DATE:

Greetings! The child carrying this letter is a participant in a National Institute of Health research study designed to stem the obesity problem in children. One of the goals of our project is to increase physical activity.

Each child participating in the study will wear an activity monitor for 7 days so that we can monitor his/her physical activity. The activity monitor is a motion-sensing device, like a pedometer, that is about the size of a small pager and is worn on a belt around the waist, over or under clothing. We are asking each child to wear the activity monitors for a full week, including when playing sports and other physical activities, so that we receive accurate information about his/her activity level. Each child who wears a monitor does have parental consent to do so, and has provided his/her assent as well. There is minimal risk of injury in wearing the activity monitors during sports.

We ask that you allow this student to wear the activity monitor during your organized activity so that we may better measure her activity level. If you have any questions about the study or the activity monitor, please feel free to contact [contact] at [University name] at [xxx-xxx-xxxx]

Thank you for your understanding and cooperation with our research!

Sincerely,

APPENDIX 11. FREQUENTLY ASKED QUESTIONS

What are GT3Xplus Files?
GT3X+ devices produce an interim compressed file with file extension *.gt3x. This is a compressed file and must be extracted to a usable format using ActiLife's import/export tool which is accessible from the File menu in ActiLife. The file can be exported to *.agd format for processing in ActiLife or *.csv/*.dat format for processing using third party tools. The *.gt3x file can also be exported directly to *.agd format during the download process by checking "Create AGD File" from the download prompt.

How can I tell if my device's battery is fully charged?
All of ActiGraph's devices** will indicate that they are fully charged (the battery is at 100%) by displaying a solid LED (light) while attached to either a computer's USB port or powered USB hub. This light could be either white or green, depending of the device.

What does the blinking LED mean?
The LED (the light on the device) blinks for many reasons. Mainly, due to the device charging while attached to your computer. Recharging is automatic and is accomplished by connecting the device to a standard USB port. Charging time will depend on the battery life, *but typically will not exceed four hours* for a fully depleted battery. Once the battery is completely charged (max voltage of approximately 4.18V), the LED light will remain illuminated. If the battery voltage drops below 3.1 volts while in use, the Actigraphs will not have sufficient power to collect data and will warn the user through a series of coded flashes. The battery level, reported in volts, can be viewed at any time by starting ActiLife and plugging in the device.

ActiLife 5 software will not allow initialization if the voltage is below 3.82 volts.

GT3X+ Connected to PC	
Red LED (Fault Indicator)	
2 Flashes	Li-Ion Battery is Faulty
Green LED	
1 Flash	Battery Charging
Multiple Flashes	Communicating with PC via USB
Steady On	Battery Fully Charged
GT3X+ Not Connected to PC	
Red LED (Fault Indicator)	
No Flashing (LED Off)	Normal operating condition or battery dead
2 Flashes	Low Battery (use ActiLife Lifestyle software to check for remaing battery life). The unit needs to be recharged.
3 Flashes	Unexpected Battery Failure (Temporary battery power loss) or Battery Level has fallen below 3.1V and the unit has entered

GT3X+ Connected to PC	
	Halt Mode.
Green LED	
No Flashing (LED Off)	Actively collecting data ("Flash Mode" disabled) or battery dead
1 Flash	Delay before start mode (the LED always flashes prior to starting data collection) or Actively taking data ("Flash Mode" enabled - not recommended)
2 Flashes	N/A
3 Flashes	End of memory reached (Device no longer collecting data) or Battery died while unit was in delay before start mode (no data collected on device)
Note: The LED will ALWAYS flash to indicate LOW BATTERY. If a "Stop Time" has been reached, the Green LED will stop flashing all together.	

The light on my device is solid while unplugged. What does this mean?
When the device's LED (light) is solid while unplugged from your computer, there is a possibility that the device has undergone a serious internal fault. Most likely, your device will not be recognizable or able to be read by the software or your computer. In most cases, the following will fix the problem:
1. Unplug the device and leave it along until the light goes out. This means the battery has completely drained. Once this occurs, you can plug the device back into your computer and try again.**
2. Request an RMA from ActiGraph to get your device repaired.
** This process can take a while depending on the existing charge of the battery. Having the LED on will reduce the amount of time for the battery to deplete, however, this may take one or more days to occur.

What is meant by the "GT3X+ and USB Hub Warning!"
GT3X+ devices have been fully tested and are guaranteed to work with Connectland USB hubs (model CL-HUB20005). Other hubs (like the Belkin F5U237P1) may cause the device to malfunction. Externally powered hubs are required.

What is Low Power Mode?
ActiGraph activity monitors support a low-power mode (LPM) in which the device automatically reduces power during periods of sedentary activity. LPM is activated when the unit records no activity for 10 seconds for the GT3X+ product. The device's power consumption in LPM is reduced significantly and can extend the battery charge life of the unit by approximately 15% if the unit is left untouched**. Upon entering LPM, the device will "wake up" every second (1000 milliseconds) and check for movement in the X and Y direction. If any movement is detected, LPM is switched off and the unit resumes normal operation. At this time, there is no way to disable this feature.

Are there any routine Preventative Inspection, Maintenance and Cleaning issues?
All of ActiGraph's devices are manufactured in such a way that preventative maintenance is typically not required. This includes device calibration. However, in order to ensure proper operation and to minimize loss of data all devices should be visually inspected prior to each deployment. This is especially true for water resistant devices, in which any o-ring/gasket should be inspected to ensure no cracks are present.

Devices may be cleaned using an isopropyl alcohol wipe.

Important: The end user should not, under any circumstance, disassemble a device for maintenance or inspection. Doing so will void any warranty currently in place.

Why can't I graph the data?
The software will only allow the data to be graphed if it is in epochs. To do this you need to convert the raw data file into *.agd file. Consult the ActiLife manual on how to do this.

I initialized the GT3X+ using one version of the firmware but now it will not download because there has been an up-date?
Be sure not to up-date any software between the two processes. Once this has occurred, contact the RCU.

What if you initialize more monitors than you use on a given day, and don't use them within the next 36-48 hours?
Simply re-initialize. DO NOT download as JUNK.DAT. It's not necessary. Whatever data are collected during that window of time will be written over by re-initializing.

How do I document a new serial number and on date for a child/parent who is being remeasured on ActiGraph?
Enter a new PAM form with seqno=2 indicating the new on date and serial number.

What do I do if the screws are stripped and I cannot remove them when trying to change the battery?
Try using wire cutters to help remove the stripped screw. Once removed, replace with new screw.

What if I see a small crack in the case?
Brush some super glue over the crack, being careful not to touch the removable part of the case.

How do I remove the sticky residue from the tape on the back of the monitor?
Try Goo-Gone or Goof-Off.

The Diet MOP was approved by the Steering Committee on April 10, 2012
Revisions approved July 26, 2012; February 5, 2014

CHILDHOOD OBESITY PREVENTION AND TREATMENT RESEARCH

COPTR

MANUAL OF PROCEDURES

3. DIET

JULY 2012
REVISED: FEBRUARY 2014

PROCEDURES MANUAL
3. DIET
Table of Contents

1. INTRODUCTION

The purpose of this procedure manual is to provide explicit and detailed instruction on how to collect diet measurements in the COPTR studies. There will be four common measurement time points – baseline, 12 months, 24 months and 36 months. All baseline dietary recalls are collected prior to randomization. All common data collection will occur between May 2012 and March 2017. This document was written, edited, and approved by the members of the Diet and Physical Activity Working Group, as well as the Measurement Subcommittee and Steering committee. Even small deviations from the procedures as they are described here are highly discouraged. Data collectors at all sites should strictly adhere to the main trial procedures outlined in this manual. This standardization is crucial to the ultimate goals of COPTR Consortium.

In the COPTR study a "common" measurement is defined as any measurement collected at more than one site. For these variables common procedures are used to collect measurements with the goal of being able to combine data from multiple sites for future analyses.

Dietary data for this study are collected by three face-to-face and/or telephone 24-hour diet recall interviews. While the goal is to collect three 24-hour 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. Table 1 summarizes the dietary collection plans for each site.

Table 1. 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	Child & parent	Parent
How collected (1^{st}, 2^{nd}, 3^{rd})	In-person Telephone Telephone	In-person Telephone/In-person Telephone/In-person	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

*Vanderbilt collects dietary intakes of both parent and child.

The recalls are used to obtain a record of the type and amount of foods and beverages consumed by children during a complete 24-hour period (from midnight-to-midnight) for the day preceding the interview. In addition to capturing specific information about the foods and beverages reported, information about the child's "activity while eating" and "eating companions" will be obtained for each meal. Dietary intake variables that are measured include:

- Total energy intake

- Energy density calculated with and without beverages
- Macronutrient intake
- Micronutrient intakes
- Dietary fiber
- Sugar sweetened beverages
- Food Group intake
- Fast Food intake
- Water

In addition, it will be possible to obtain data needed for analysis of pre-defined dietary scores or patterns such as the Healthy Eating Index or to use the data to obtain empirically derived dietary patterns. Note that the COPTR investigative team decided not to utilize a food propensity questionnaire or food frequency. The 24-hour recall approach was considered to be the best suited for consistency in data collection across the COPTR trials.

2. TERMINOLOGY TO DESCRIBE RELEVENT INDIVIDUALS

Index child: A child who meets eligibility criteria and is randomized to a study arm with the intention that his or her BMI data will be included in the site's primary outcome analysis as the main exposure.

Master Trainer: The person (or persons) at each site that trains and supervises certification of other data collectors or research associates.

Measurement Coordinator: The person (or persons) at each site that organizes data collection activities. This person may or may not be a master trainer.

Research Associate/data collection staff: Personnel who collects the measurement data.

Trainee: The person receiving training and seeking certification to participate as a Research Associate.

3. CONFIDENTIALITY CONSIDERATIONS

The dietary interviewer will gain trust by assuring confidentiality of everything the participant says. Dietary intakes will not be discussed with other participants. Any necessary discussion between site lead nutritionists and dietary interviewers about a specific 24-hour dietary recall should be conducted in private, away from other participants.

4. SAFETY CONSIDERATIONS

There are no known risks associated with the collection of dietary data.

5. EQUIPMENT AND MATERIALS

5.1. Forms and Devices

1. Eating Activity Card and Companion Card (Appendix 2.1)

The Eating Activity Card and Companion Card are used as a prompt in the recall to determine if the child was eating while watching television and with whom they were eating.

2. Food Amounts Booklet (2 copies per interviewer, Appendix 2.2)
A COPTR Food Amounts Booklet will be provided to each of the participants for use in the in person recall and it will be sent home with instructions to keep the booklet near the telephone for subsequent 24-hour dietary recalls. There are two copies of the COPTR Food Amounts Booklet. One includes the sizes next to the pictures and copies of this should be given to each interviewer. The second does not include serving sizes next to pictures and is given to each participant. A recall should not be collected without a Food Amounts booklet. If a booklet is lost, a replacement booklet should be mailed to the participant prior to collecting the 24-hour dietary recall.

3. Food Checklist (Appendix 2.3)
The Food Checklist is used to determine the family's usual dietary patterns, specifically the use of modified foods (e.g., low-fat, or reduced calorie), whether or not the child regularly consumes school breakfast and lunch, and typical types of beverages, including the type of milk that the family consumes.

4. Meals consumed at school or day care (Appendix 2.4)
School lunch menus are included to guide recalls of children who report that they consume school lunch or breakfast. Each Field Site will maintain a specific list of contacts.

At Vanderbilt and Minnesota, children who will be eating a meal away from the primary parent the day before the interview, a daycare form will be given. Parents will be asked to give the form to the person providing the child's meal (e.g. day care staff). This person will be asked to fill out this form which also asks for contact information to ask any questions about incomplete forms.

5. In-person interview introduction and telephone interview introduction scripts (Appendices 2.5, 2.6 and 2.7)

5.2. Computer Items

Lap-top computer(s) with NDS-R Version 2012 dietary data collection software program installed.
Extension cord(s)
Surge protector(s)
Battery pack(s) as needed.
Flash drive

5.3. NDS-R Version

For the main trial, all Field Sites will use NDS-R 2011 until version 2012 is available. Any change in the version during the trial will be made as a collaborative decision by the Diet and Physical Activity working group. This will be determined based on the level and magnitude of the changes in the two versions of NDS-R. If an update does occur during the main trial, the change will occur on the same calendar day for all 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 that same older version such that all 3 recalls are collected using the same NDS-R version.

6. TRAINING AND CERTIFICATION

COPTR uses a "train the trainer" model. 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 candidates for Master Trainers are responsible for training and certifying the data collection staff at their Field Site. A potential diet interviewer (includes both master trainer and those trained to conduct interviews) complete the following activities prior to the certification recalls. All diet interviewers are familiar and trained to use NDS-R before attending the COPTR diet training session.

Goal 1. The diet interviewer are familiar with the interview style used to conduct 24-hour recalls.
1. Review the NDS-R COPTR protocols.
2. Listen to at least 1.5 hours of audiotapes of interviews and enter the recalls into NDS-R while listening to the tapes.

Goal 2. The diet interviewer are able to enter foods into NDS-R at the same pace and with the same accuracy as a previously trained interviewer.
1. Listen to additional 1.5 hours of audiotapes of interviews and enter the recalls into NDS-R while listening to the tapes.
2. Check recalls against the standard recall.

Goal 3. The diet interviewer conducts diet recalls with children as the primary respondent (Case and Stanford) and parents as the primary respondent (Minnesota and Vanderbilt) using appropriate interview prompts.
1. Conduct five practice diet recalls (at least 3 must be with children or with parents of preschoolers.)
2. Both diet interviewer and site lead nutritionist conducts quality assurance on all recalls using the quality assurance checklist.

After the Central in-person training sessions in April 2012 for the Master Trainers, the master diet interviewers will conduct 2 recalls for certification and will score an average of 85% using the following scoring scheme for certification and complete the Subjective Assessment. In addition, total calories between the standard recall and the diet interviewers' certification recalls must be at or above 85% agreement. RCU staff experienced in NDS-R training will certify the Master Trainers at each Field Site. Additional diet interviewers (i.e. research staff) at each Field Site are trained and certified by the Master Trainer. If a Field Site wants to add an additional Master Trainer after the central trainings have been conducted by the RCU, the RCU needs to be notified. The Master Trainer candidate is also trained and certified by the Master Trainer. The research staff or Master Trainer candidate will conduct 2 recalls for certification and score an average of 85% using the scoring scheme for certification below and pass the Subjective Assessment.

No diet recalls are conducted until after the interviewer has been trained and certified. The RCU will keep track of who is trained and certified at each Field Site. Each Field Site will keep a Certification Training Log (Appendix 3) and submit the certification training log to the RCU each time a diet interviewer has been certified.

Scoring Scheme for Certification Recalls

Total number of foods and food additions in the standard recalls are counted and used as the denominator (See Appendix 5.1 for diet recall with example score and Appendix 5.2 for diet recall with failing score)

- 2 points are subtracted for inaccurate food selections or missed foods
- 1 point is subtracted for inaccurate food details
- 1 point is subtracted for inaccurate food additions or subtractions
- 1 point is subtracted for inaccurate portion sizes.

Subjective Assessment for Certification Recalls

The subjective assessment will focus on the following interview components:

1. All four passes must be completed according to the protocol.
    a. Pass 1
        i. Listens and prompts for all eating occasions. Food and meal details are not prompted in this pass.
    b. Pass 2
        i. Review of foods and prompts for additional eating occasions
        ii. Speak slowly and clearly
    c. Pass 3
        i. Probe for additions to all foods and beverages until participant says no
        ii. Probe for additional eating occasions
        iii. Assume nothing
    d. Pass 4
        i. Review entire diet with reported portion size and probe for additional foods and beverages at each eating occasion
        ii. Speak slowly and clearly
2. Closure
    a. Complete trailer tab
    b. Assure all notes are complete and accurate
3. Other characteristics
    a. Is prepared
    b. Able to build a rapport
    c. Listens intently
    d. Is clear and able to clarify
    e. Direct and to the point

f. Follows the script and uses appropriate prompts
g. Neutral

7. PREPARATION FOR ADMINISTRATION

7.1. Naming Convention for Quarterly Files

The adopted protocol for transferring Diet Recall data to the RCU requires a single data upload from each site on a quarterly basis. The quarterly files contain ALL recalls that are conducted during that three month period (e.g. quarter 1 (q1) includes all recalls conducted between January 1st and March 31st). Therefore, every participant may not have 3 diet recalls in the quarterly file (e.g. only 1 or 2 recalls were completed before the end of the quarter). The RCU may request data at other times for purposes of reporting to the DSMB. The DSMB files will include only data since the last quarterly report. If a site uses multiple computers to collect the data, they are responsible for "closing out" the completed data for each quarter and merging the records from various site computers into a single Diet Recall set prior to uploading to the RCU. (See section 9.3 "Merging Data" for instructions.)

Diet Recall files must follow this naming convention:

XCPT13q1.zip

Where:

X = site ID; CPT is the COPTR project; 13 = year; q1 = 1st quarter

Site ID Codes

Site	Main
Case Western	5
Minnesota	6
Stanford	7
Vanderbilt	8

Submission Time Codes

Quarter	Start Date	End Date
q1	January 1	March 31
q2	April 1	June 30
q3	July 1	September 30
q4	October 1	December 31
d1	TBD-7 weeks prior to 1st DSMB meeting	
d2	TBD-7 weeks prior to 2nd DSMB meeting	

Example: 8CPT12q3.zip - would contain Vanderbilt's Diet Recall records for the third quarter of 2012.

NDS-R uses the term "Project" to represent a set of related Diet Recall data. Sites can name the Diet Recall projects on individual site computers whatever names are helpful in their site organization. (See the suggestion in the next section.) However, the quarterly project ZIP to be uploaded to the RCU must follow the naming convention above.

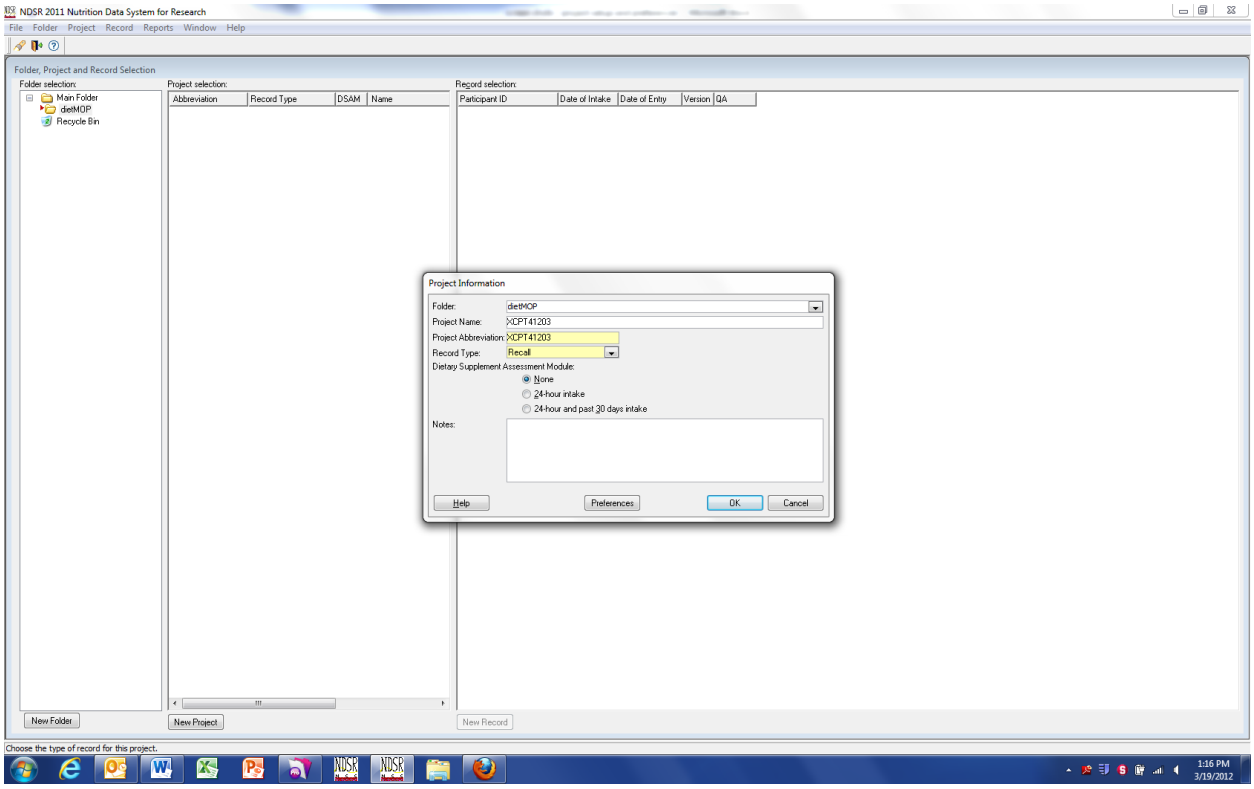
7.2. Start-up

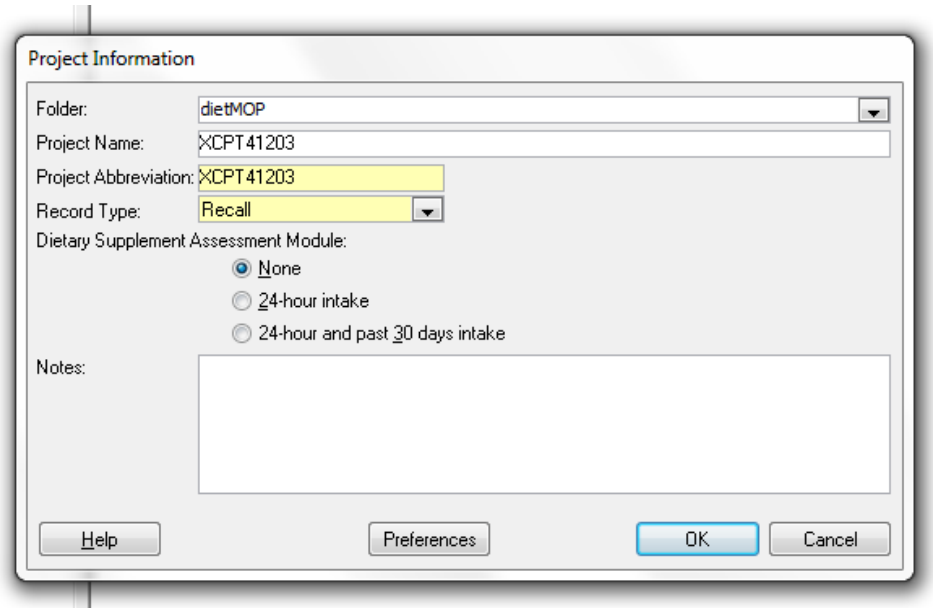
1. NDS-R version 2012 must be loaded on each computer

2. Log on to computer using the Username and password

3. Go to Start Menu (lower left corner) and select **Programs → NDS-R 2012→ NDS-R Interview**
   - **Don't** use other older versions of NDS-R that may be on the computer
   - Recommend a unique folder be made where the actual record projects and QA projects reside

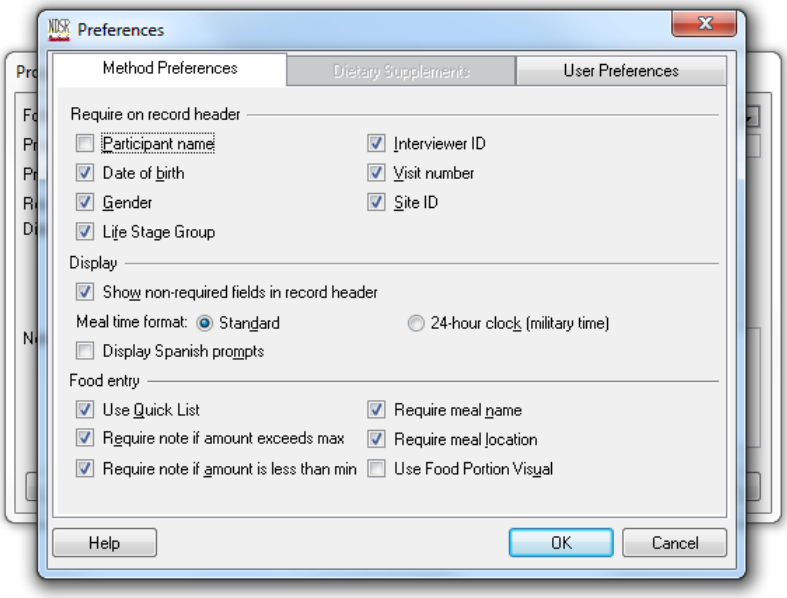
4. Set up your project
   a. All COPTR recalls for a given month will be stored in a project using a standard naming convention that may include: Site ID (number), CPT, computer # (if many computers are used at one site), the year, and the month (March). E.g., 7CPT41203
   - Click on **New Project** (bottom left corner)
   - Enter **Project Name** as suggested above (4a)
   - Enter **Project Abbreviation** – could be the same as Project Name
   - Go to the drop down menu under **Record Type** and select "Recall"
   - Double check that "none" is clicked under **Dietary Supplement Assessment Module** – this should automatically populate correctly





Project Name stands for: X (site ID) CPT (COPTR) 4 (laptop #) 12 (year) 03 (month)

5. Select Preferences
   - Once you set up your project (step 4), you should now be able to click the **Preferences** box.
   - Uncheck **Participant name**. Preferences that should be checked in the project include: Date of birth, Gender, Life stage group, Interviewer ID (which may or may not be related to computer #), Visit number and Site ID. Note that Site ID in preferences is NOT Stanford University, Case Western, University of Minnesota, or Vanderbilt University. Site ID refers to if the recall was done in person (1) or over the phone (2).



7.3. Preparing for Interview

These steps should be completed before the start of the interview.

1. Highlight the appropriate COPTR project (corresponding to the current month diet recall is completed) on the left hand side of the screen. Do NOT hit return.

2. Select **New Record** (bottom of the screen in the middle). Now you should be in the Header Tab of a new record (interview). You can also create a new record by selecting **Record** from the menu bar and pull down to **New**.

3. Fill out the first half of the **Header.**

   Enter **Participant ID**
   Enter **Date of Intake** as **yesterday's** date
   Enter **Gender**
   (**Date of Birt**h and **Life stage group** will be filled in once the child is on the phone and you ask the birthday)

   Complete the second half of the **Header** according to the appropriate study protocol:

   Subject ID
   Interview ID's - Use Interviewer initials.
   Visit Number - *1.1--Baseline recall #1*
   1.2--Baseline recall #2
   1.3--Baseline recall #3
   2.1--12 month follow-up recall #1
   2.2--12 month follow-up recall #2

2.3--12 month follow-up recall #3
3.1--24 month follow-up recall #1
3.2--24 month follow-up recall #2
3.3--24 month follow-up recall #3
4.1--36 month follow-up recall #1
4.2--36 month follow-up recall #2
4.3--36 month follow-up recall #3

Site ID 1 (in person)
2 (phone)
3 (other – add note to explain)

You are now ready to telephone or begin the interview with the participant. These set-up procedures should not be done while the participant is waiting to begin the interview. They should be done before you begin the interview, or before you dial the phone.

4. Now that the participant is on the phone with you (or in person), you may finish filling out the header tab.

Ask participant their **Date of Birth** and enter in appropriate field
Click on **Life Stage Group** and the field should automatically populate

5. Click on **Continue Recall** on the bottom right corner of screen.

6. Telephone Recalls Only

If the respondent is not home, do NOT attempt to save the HEADER. Instead type over the HEADER for the next respondent that you are going to call. Delete this record if it is the last person who you will call.

8. ADMINISTRATION OF THE DIETARY RECALL

Children's dietary intake data are collected by 24 hour recalls using the multipass method on Nutrient Data System for Research (NDS-R). Data must be entered directly into the computer at the time of the interview. For Case and Stanford, the child is the primary respondent and parents or caregivers may assist as needed for the baseline and follow-up (12, 24 and 36 months) dietary recalls. This also applies to 7 year old children (at baseline) from Stanford so the same methodology is used for all of study participants at a Field Site. For Minnesota and Vanderbilt, the parent or caregiver is the primary respondent for the baseline and follow-up (12, 24 and 36 months) dietary recalls. This also applies to the children who will be 8 years old at the 36 month dietary recall so the same methodology is used for all study participants at a Field Site.

Participant training on portion size estimation using the Food Amounts Booklet is conducted in person during the first recall or in a separate training session (Vanderbilt only). During the in person recalls, participants are guided to use appropriate images. (See Appendix 2.5 for sample script). The Food Amounts Booklet should be used for collecting dietary recalls.

Dietary recalls at each time point (baseline,12-, 24-, and 36-month follow-up) are collected either over the telephone or in person. A new Food Amounts Booklet (FAB) should be given in person or mailed to the participant at each time point. If a participant loses his/her Food Amounts booklet, a new booklet should be mailed or given in person. Every attempt should be made to ensure that all diet recalls are completed with the Food Amounts Booklet and diet recalls conducted without the Food Amounts Booklet should be minimal. If the window for data collection will close within a week and the respondent does not have the Food Amounts Booklet then the diet recall may be conducted without the Food Amounts Booklet. All diet recalls conducted without the FAB will be tagged as "No FAB" in the trailer. After the diet recall is completed, the lead nutritionist will review the data to determine if the recall data are reliable. Reliability will be determined based on preset cutoff points for total energy, percent kilocalories, fruit servings, vegetable servings and grams of fluid (See section 9.3). Diet recalls that are determined as reliable will be used. Diet recalls that are deemed unreliable by the lead site nutritionist should not be used and marked "unreliable" in the trailer. In addition, the lead nutritionist may ask the diet interviewer their impression of whether or not the respondent was confident when reporting sizes.

To avoid collection 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 need to be collected within 30 days. All baseline recalls must be completed prior to randomization and should be completed using the Food Amounts Booklet.

For Case-Western and Stanford, a Food Checklist (Appendix 2.3) is collected from adult caregivers prior to the initial interview and is used to determine patterns of consumption of modified (e.g., reduced fat and low sodium) foods, type of milk and other beverages consumed.

Interviewers should ask for school/day care/headstart menus (e.g. breakfast, lunch, snack, dinner) to assist with coding meals consumed at school/daycare. For Case and Stanford, if the school menu does not match the children's report, always assume the children's report is correct and do not question the accuracy of their report. Minnesota and Vanderbilt, will ask the parent for usual amounts of foods reported on menus.

For Minnesota and Vanderbilt, the parents with children in daycare/school will be given the Food Record Form (Appendix 2.4) to give to their daycare provider. The daycare staff/teacher will be asked to fill out the food recode for the day of the recall. Parents will use the record to report child's food consumption while at daycare/school. If record is not completed, parents will be asked to report meals that they provide to child and diet recall staff may ask for contact information for the child's daycare/school to obtain a report of foods served at daycare/school on the recall day.

Note: The Food Checklist will be collected over the phone with a parent if the person who accompanies the child at the first visit is unfamiliar with the family's food habits.

Begin the interview using a standard script examples are provided in Appendices 2.5, 2.6 and 2.7. The script provides continuity between interviews.

8.1. Guidelines for Working with Participants

A. Interaction with the participant

The dietary interviewer must be able to motivate the respondent to provide complete and accurate information. The dietary interviewer must always remain neutral and not let anything in words or manner express criticism, surprise, approval or disapproval related to the participant or his/her responses during the dietary interview. Interviewers should not suggest that amounts may be unreliable or suggest additional foods (e.g, did you have jelly with your peanut butter.)

The two primary prompts used throughout the interview are:

Did you (your child) have anything else to eat or drink with your (his/her) <last food reported>?
Did you (your child) have anything else to eat or drink between <primary foods from two eating occasions>?

The dietary interviewer will need to document information for any participants who missed a meal or had very little food during the day. A NDS-R Note should be entered to confirm missed meals or a very limited food intake. Prompts that may be used to illicit additional meals or foods for limited diet reports are:

Did you (your child) have anything to eat or drink after school? Anything before your (his/her) (insert time e.g., evening meal) and (before bed)?

Additional foods are inserted at any time. If the participant hesitates and can't remember eating anything for a long period of time, the interviewer may say:

Can you think what you (and your child) were doing (after school, at dinner/supper time, etc)? Sometimes if you think about where you (your child) were or who you (your child) were with it helps to remember what you (your child) ate.

B. Objectivity

Every effort should be made to keep 24-hour dietary recall collection as objective and non-judgmental as possible. The interviewer should avoid congratulating participants for eating certain foods or reacting with dismay to reports of other foods. The interviewer can stress that he/she wants to know that the participant really ate and that honesty is appreciated.

C. Possible conflicts between the information provided by the child and the parent

For Case and Stanford, the dietary interviewer should accept the child's information about the foods and beverages he/she recalls. Parents may be asked to elaborate on

the type of food that a child reports. However, if there is a conflict with what the child reports as having eaten and the parent's recollection of the previous day, the child's information will be used in entering NDS-R food selections.

For Minnesota and Vanderbilt, the parent's report should be recorded if there are any conflicts.

D. Incomplete data from daycare/child care providers.
Prior to starting the recall, diet interviewers will ask if parent/caregiver has the Food Record Form (Appendix 2.4) or school/daycare menu. Parents will use the record to report child's food consumption while at daycare/school. If record is missing or incomplete, parents will be asked to report meals that they provide to child and diet recall staff may ask for contact information for the child's daycare/school to obtain a report of foods served at daycare/school on the recall day.

8.2. Four Pass Method

1. **PASS 1 and 2: Using the NDS-R Quick List**
   The Quick List will be used to collect an outline of the previous day's intake. It is designed to get participants to begin thinking about what and when he/she (his/her child) ate. Foods and beverages as reported by the participant are entered on the Quick List screen along with time eaten and meal name if provided by the participant at this time. The Quick List is the first pass in the NDS-R multiple-pass approach. The second pass is the review of the quick list when participants are asked if he/she can think of any additional foods consumed during the day.

   If the participant does not volunteer the time of the meal or give a specific meal name during the Quick List, the dietary interviewer need not interrupt to ask for this information. NDS-R will prompt for this information during the third pass.

2. **PASS 3: Collecting complete meal, food and amount detail**
   (a) To help the participants remember what they had to eat, information about the time, name, and location of the meal are provided in the Meal Information Window. At this time, the dietary interviewer will use the Activity, Eating Companions and Home Codes (only for child) to identify which activities the participant was involved in during most of the meal and others present at the meal and the home in where the child consumed the food. Codes assigned to each activity, eating companions and home are entered in the NDS-R Note on the Meal Information Window. Each of these codes is separated by a comma and space. If appropriate, this is followed *immediately* by a comma and space and the word "restaurant" followed by the name of the restaurant if unavailable in the data base. This is especially pertinent to take-out meals and enables us to track the consumption of all restaurant food. In addition, notes regarding missing foods or beverages are written in this field (e.g., no beverage with a meal, no bun with hamburger)

(b) Complete descriptive detail for foods and beverages is obtained during the third pass of the NDS-R multiple-pass approach. The participant is asked about additions to foods and beverages entered on the Quick List. The dietary interviewer asks probing questions based on the information displayed in the NDS-R window and utilizes the NDS-R food search feature to obtain complete detail for food descriptions, preparation methods and variable ingredients.

(c) After specifying the food, the participant will be asked to use the COPTR Food Amounts Booklet to describe the amount consumed. The dietary interviewer may guide participants to choose graphics in the COPTR Food Amount Booklet that will help them estimate portions. For example, if beverages are reported the interviewer should tell the respondent "to turn to pages (with glasses)". The dietary interviewer should always use the grid when the participant gives dimensions in inches. The interviewer continues to define the food, selecting food variables as required on each screen. An online prompt for the amount will remind you to say: **How much did you eat (drink)? How much did you eat (drink)?** Some foods require additional quantity details, with required fields indicated in yellow. After entering the amount provided by the participant, the NDSR displays a conversion to a common unit. At this time, the interviewer must be able to visualize the amount reported and confirm as needed any questionable amounts, making reference to other familiar items or recognizable standards.

(d) After entering the amount specified by the participant, NDS-R displays a conversion to a common unit. The dietary interviewer needs to be able to visualize the amount reported and subsequently confirm with the participant any questionable amounts by using the COPTR Food Amounts Booklet. The NDS-R note field in the Food Detail window is used to enter information to confirm how the portion size was determined, if the participant ate all of the serving, or if ingredients from a food need to be removed. If a participant does not report eating all of the serving, the interviewer may ask participant to estimate the amount not consumed using the same estimation tools from the Food Amounts Booklet or interviewer may ask if he/she ate more or less than half the serving. The interviewer should ask if the complete amount described was eaten: **Were you able to finish that?** or **the** *(insert name of food)***?** When interviewing children, the diet interviewer may estimate the about eaten based on the child's response (e.g. if he/she reports eating more than half, then ¾ of the reported serving is coded and less than half ¼ of the reported serving is coded). Notes requiring additional coding or checking may be flagged with a Priority Note.

3. PASS 4: Reviewing the recall

(a) The fourth and final pass of the NDS-R multiple-pass approach occurs after entering all of the food detail. During this review, the interviewer probes for missed meals, beverages and snacks and any other information that was inadvertently omitted. For recalls with missing meals or long periods between

eating episodes, the interviewer should ask, “Did you eat anything between <food reported> and <food reported>? Edits are made as needed and notes are provided.

(b) Foods not found in the database are flagged as M for missing or PN (priority note) and complete detail is collected from the participant in a corresponding note field including name or brand of the food, descriptions of what the food or food packaging looks like as well as ingredients and the amount eaten. If it is a food that the respondent cannot name in English, ask them to describe it or have them spell it in their native language. These foods should be reviewed by the site lead nutritionist and an appropriate substitution should be made User recipes are discouraged. Criteria for matching missing foods is that the substitute food must be within +/- 85 kcal/100 gm of the missing food and the substitute food must be in the same food subgroup as the missing food. If an adequate substitute cannot be determine the site lead nutritionists will contact NCC for resolutions. Upon receipt of the resolution, sites will edit the 24-hour dietary recall accordingly. Priority Notes (“**PN**”) can be used at each site’s discretion.

The RCU will maintain a shared User-recipe list (see Appendix 1.6 for protocol). This will provide a standard approach to entering commonly reported foods that are not in the NDS-R database. This list will be updated regularly and available on the COPTR website. Field Sites with a food requiring resolution (these would be foods marked as **M**issing in NDS-R) will first check the COPTR new food list (on the website) to make sure that food has not already been resolved. If one has not been created, they will verify by sending this request to the RCU. Once cleared (meaning no site has requested the food or the list has not been updated), then that site can proceed with requesting the new food. Once in, the User-recipe file will be shared with all Field Sites and the new food list will be updated with that food. This method will prevent any one Field Site from using up their allotted food resolutions. The RCU will manage this list.

(c) For Case and Stanford, after the final review, the parent will be asked to provide additional information about the foods and beverages that the child was unable to provide during the recall. This applies mainly to the ingredients and the preparation of home-prepared foods. Targeted foods will include mixed dish ingredients, beverages, type of milk and other dairy products. Also targeted will be confirmation of amounts identified as very small or very large, large gaps in eating occasions, and missed meals.

(d) All priority notes and missing foods must be resolved prior to sending data to the RCU.

4. Trailer question(s)

Notes are made in the trailer if the parent or child reports significantly more or less food was eaten on the day of the recall. Notes are also documented for any missed meals or if child/parent reports no snacks throughout the entire day. If child/parent

reports that the amount of food eaten yesterday was either a lot more or a lot less than usual to explain due to sickness or dental work some Field Sites may elect not use the recall and obtain a replacement recall. It is recommended not to collect recalls on the day after Halloween (Nov. 1), Christmas, Easter, Thanksgiving or any local holidays that would significantly increase food consumption. If a child/parent reports excessive consumption because they attended a party the Field Sites most likely will include the recall.

Documentation using NDS-R Note Field

Notes should be collected on every food. Notes can also be used to clarify contradictory, questionable or unusual food items or amounts, or document cases where typical companion foods are not consumed. Notes are entered in the Meal Information Box, the Food Detail Box and in the Trailer Tab. Notes serve as communication between the dietary interviewer, and the site lead nutritionist.

Notes in the Meal Information Box include the codes for Eating Activity, Eating Companions and the home where the meal was consumed. Home code is only included when the meal was consumed at home as noted in the location box. In addition, meals where only beverages or only foods were consumed may be noted in this field.

Notes in the Food Detail box are used to document portion sizes, and changes to the ingredients of a specific food. NDS-R forces a note when the amount reported exceeds what has been established in the database as more than the usual amount reported at one time. Notes which include a reference to the graphics in the Food Portion Amounts booklet (e.g., bowl 3, line d) should be added to explain how the amount was determined. Graphics may be abbreviated as follows:

Bowls- Bowl 2, line a—b2a
Glass - Glass 3, line d - g3d
Mounds - Mound 1- m1

Additional information to include in Food Detail notes include:

- modifications to foods (e.g., not eating the crust of a piece of pizza or removing or adding an ingredient to a mixed dish or soup),
- eating foods without anticipated companion foods (e.g., hamburger without a bun or ketchup)

Trailer Tab Notes

Notes that address missed meals or extremely small or large intakes should be included in the trailor tab regardless of participants' assessment of usual intake to assure that the diet recaller was aware of missed meals and probed appropriately.

Notes allow the site lead nutritionist to make appropriate changes to the recall to reflect what was actually eaten as well as confirming that the interviewer entered what the participant reported.

8.3. Special Instructions for Collecting the COPTR 24-hour Meal Information Box

8.3.1 Entering meal time

In general, the approach to collecting the 24-hour dietary recall is to find out when people eat and what they eat versus asking what they ate for specific meals. The NDS-R program does requires a time, however, if exact eating times cannot be determined, a general time frame may be associated with approximate times. When participants are not able to provide the time of meals and snacks, dietary interviewers may use the following times for a general framework, using additional times as needed for other meals or snacks reported:

- Morning meal 7a
- Noon meal 12p
- Dinner meal 5p
- Evening snack 8p

8.3.2 Entering the meal name

NDS-R meal names include Breakfast, Lunch, Dinner/Supper, Snack, School Lunch and Other. If the meal name is not stated by the participant, the dietary interviewer may ask the participant the meal name saying: "Was this your (insert most obvious meal name)? A meal name may be repeated several times in the context of a recall. For example, the participant may report snacks several times throughout the day.

8.3.3 Entering the meal location

NDS-R meal locations include Home, Work, Friend's Home, School, Day Care, Restaurant/Cafeteria/Fast Food, Deli/Take-out/Store, Community Meal Program, Party/Reception/Sporting Event and Other. Where the food was consumed, not where it originated from should be recorded. The meal location helps to determine which food variables to enter during the 24-hour dietary recall. For example, many foods in NDS-R differentiate between home prepared and restaurant prepared foods. Collecting information on the source of the meal can aid in the food description process.

In addition, we will determine if children **live** in more than one household at the start of the first recall. If he/she lives in more than one household and reports eating a meal "at home", we will code in the notes whose home he/she ate the meal at as:

Mother's & father's home (i.e., intact family)-both
Mother's home – mom
Father's home – dad

These codes apply only to homes where the child lives. For example, if they live with both their grandmother and grandfather the code from the pull down menu is "home" and the code in the notes would be "both." Conversely, if they are eating Sunday dinner at his/her grandparents' home, but do not live with them, the meal will be coded as "friend's home" in the pull down menu and no home code is required.

8.3.4 Entering the eating activity code (Appendix 2.1)

Diet interviewers will record a code number in the NDS-R Note Field to identify the activity the child was involved in during eating.
Prompt is: What were you (your child) doing while you (he/she) ate?

COPTR Activity Codes include:

1 Just eating (no TV or video games, etc.)
2 Watching television
3 Watching a videotape or movie on a VCR or DVD
4 Playing video games or playing on a computer
[NOTE – 9 is coded during QA when this code is missing; Watching TV shows or movies on the computer will be coded as 2 or 3 NOT as 04]

8.3.5 Entering the eating companion code

Diet interviewers will record a letter in the NDS-R Note Field to identify with whom the child was eating. The person must not just be present, but must also be eating with the child.
Prompt is: Who was eating with you (your child)?

COPTR Eating Companion Codes include:

A Eating alone
B Eating with family only
C Eating with others and family
D Eating with others (not family)

[NOTE - Z is coded during QA when this code is missing; Grandparents, cousins, etc. are considered family.]

8.4. Selecting Food Descriptions

Follow the guidelines below when making decisions about how to code foods in the Food Classification box.

8.4.1. Brand Names

Always select brand names as the desired option for children's or parent's description of foods. This is especially important for juice or other beverages, cereals and fast foods. Ask the participant to find the box/carton in the cupboard/refrigerator so the interviewer can verify the brand. If the respondent does not know the brand (or has no access to the brand or label), but can describe the label, code as a "missing food" and note their description of the label. Include color of label and drawings or words that he/she knows are on the label, as well as the size, type of package and portion size. If the child/parent reports the food is a generic brand, then the generic option may be selected. Unless completely unique food, it is recommended the diet interviewer find a best match. If not, then diet interviewer will employ rules for entering a missing food.

8.4.2. Recipes and Mixed Dishes

Avoid coding recipes by using mixed dishes already in the database. Ingredients may be added or subtracted from mixed dishes. Children and some parents usually cannot

reliably report ingredients in mixed dishes and asking increases the respondent burden. Use stews for most homemade soups and add vegetables, meat or other ingredients.

For Case and Stanford, do not code ingredients that a child reports are in a food. If possible, ask mother/caregiver at the end of the interview to describe the food. If mother can only provide ingredients code as a "missing food" and list ingredients and amounts child ate in the Food Detail Box.

If the food is a casserole, stir fry or other type of mixed dish, type the major ingredient (e.g., beef) and select mixed dish or stir fry according to the respondent's description of the food.

Exception is building sandwiches using ingredients, unless the sandwich was identical to the default sandwich.

8.4.3. Fat and Salt

For Case and Stanford, check with caregiver to determine fat and/or salt were added. If the caregiver is not available, check the Food Checklist for low fat /low sodium food patterns (i.e., consumes low fat, fat free milk or indicate they use other low fat, low sodium or reduced fat products)

8.5. Serving Sizes and Food Specific Units

8.5.1. Serving Sizes

Always ask the children or parents if he/she finished a food. Children and parents often report the entire serving, not the portion they (the child) actually ate. If the amount left cannot be determined using the Food Amounts Booklet, used the following defaults: if less than half of a serving consumed code as ¼ serving, if more than ½ serving consumed but not all of it code as ¾ serving. Include notes to explain all serving sizes.

8.5.2. Food Specific Units

The type of serving size, the amount and number of servings of each food must be selected. Food Specific Units (FSU) are typical portion sizes for many foods and should be used whenever available. Food Specific Units are available for foods that come in standard portion sizes including all fruit, some vegetables, cookies, eggs, prepackaged food (e.g., fish sticks, cookies, candy, ice cream bars, canned beverages.) To determine the appropriate FSU, ask the respondent to use the graphics in the Food Amount Booklet to estimate the size of the serving and using his/her size estimate, select the most appropriate FSU.

8.5.3. Food portions larger or smaller than Food Specific Units

If the respondent reports that a food differs by more than ¼ inch from standard FSU, use geometric shapes and the size guides (circles, squares, thickness and wedges) in the Food Amounts Booklet to estimate the portion sizes. For baked goods use the respondents' actual report as the NDS-R FSU tend to be *small (e.g, most bread slices are large).* For fruit or vegetables, use the size closest to the respondent's estimate and always round down. If the fruit or vegetable is ***significantly*** *(defined as more than 1/4"*

difference) larger or smaller than the FSU ask respondent to estimate the diameter of the sphere using the circles page(2), and code unit as a sphere. Enter the exact diameter as reported by the respondent. Fruits with a core or pit are coded as 0.9 of the serving. This is consisted with coding using FSU. [ie: an apple reported to be "circle e" would be entered as a 4" sphere. If child ate all, the quantity would be entered as 0.9. However, an orange reported to be "circle e" would be entered as a 4" sphere and if child ate all, quantity would be entered as 1] (See Appendix 1.7 for additional details).

8.5.4. School Lunch Serving Sizes

If interviewing the child or parent, for foods from school lunch programs use the standardized school lunch serving sizes unless the Field Site knows that the schools are using different serving size. Ask children what portion of their serving they consumed. Most school lunch foods are in standard serving sizes. The standard school lunch serving sizes are as follows:

- Bread: 1 oz. - the average serving 4 x 4.5 X .5" slice of bread.
- Cereal: 1 oz.- usually in a prepackaged single serving container. The Food Specific Unit for breakfast cereal is a single serving container.
- Milk: 1 cup (8 oz)
- Juice: ½ cup (4 oz)
- Fruit: 1 piece fresh or ½ cup canned
- Vegetables: ½ cup
- Meat: 2 oz.

Additionally the RCU will maintain a shared food rules list (Appendix 1.8). This will provide a standard approach to entering commonly reported foods that are not in the NDS-R database. This list will be updated regularly and available on the COPTR website.

If the food cannot be estimated by a FSU or the respondent does not report a FSU, the Food Amounts Booklet should be used to describe the amount consumed. After entering the amount specified by the participant, NDS-R displays a conversion to a common unit. The dietary interviewer needs to be able to visualize the amount reported and subsequently confirm with the participant any questionable amounts by using the Food Amounts Booklet or by making reference to other familiar items or recognizable standards. The size and shape (e.g., m3 for mound 3) should be entered in the NDS-R note field along with other information that may be used to confirm atypical amounts.

The dietary interviewer should guide participants to choose graphics in the COPTR Food Amount Booklet that will help them estimate portions when appropriate. For example, if beverages are reported, the interviewer should tell the respondent to turn to pages XX (Specify the page in the food amount booklet to the respondent). The dietary interviewer should always use the grid when the participant gives dimensions in inches.

8.5.5. Common Comparisons

Tennis ball diameter = 2 inches
Softball diameter = 3 inches

New pencil = 7.5 inches
Chalk Brush = 4 inches X 2 inches X 1 inch = 6.5 oz meat or cheese
CD = 4.75 inches

8.6. Troubleshooting

If you are not getting a Meal Information Box, use EDIT on the menu bar and insert a meal.

To insert foods, highlight the meal you want to add the food to and use the insert food button on the bottom of the screen (or in the Edit menu.) If you make a mistake and want to change the food you are entering click on cancel, and either insert a new food or a new meal.

8.7. Tracking Telephone Recalls

After the initial face to face recall or training session, dietary recalls may be collected over the telephone. Telephone recalls are conducted in the same way as in-person recalls.

1. A separate data management system for tracking participant's recalls is developed at each Field Site.
2. Dietary recalls may NOT be made on consecutive days until the last 5 days of the 30 day recall window. The COPTR goal is to collect three dietary recalls per participant (one weekend and two weekdays). All efforts will be made to obtain a minimum of two recalls (1 weekday and 1 weekend) for each participant.
3. 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.
4. The Field Site checks and updates daily the diet recalls that are in progress. When all of the follow-up interviews are completed for a child, the dates of his/her interviews are recorded, and his/her contact form is filed. This participant is complete.

8.8. Leaving messages for Phone Interviews

If you reach an answering machine - leave a scripted message as described in the example below. Record that you left an answering machine message in the NOTES section of your contact form layout. The number of messages left and the calling frequency is site-specific.

a) **Example Scripts for Answering Machine Messages:**

<u>First message:</u>

Hi. My name is (*your name*) and I am calling from the (*site study name*). C*hild's name* is taking part in interviews about the food that he/she eats. We were calling to do the follow-up interviews. If there is a convenient time for *(child's name and/or caregiver's name)* to talk on the telephone, she should call me, (*your name*), (*your phone number*) and let me know this time. If I don't hear back, I will try to reach them again tomorrow. Thank you very much.

Second message:
Hi. This is (*your name*) and I tried telephoning you on (*insert last time you left a message*). We are working with the (*site study name)* to learn more about child and family health. It is important that I complete the interviews with *(child's name and/or caregiver's name)*. If there is a convenient time for *(child's name and/or caregiver's name*) to talk on the telephone, she should call me, (*your name*), at (*your phone number)* and let me know this time. Thank you very much.

b) **No Answer**
If no one answers record your contact attempt.

c) **You Reach Someone on the Phone**
Verify that you have reached the residence of the child
Use the script below to explain your call.

Calling for child
"Hello, I'm calling from the (*site study name)*. (*Child's name)* participated in a project about their eating habits and physical activity. I am calling to do the (*first/second*) follow-up interview. May I please speak to (*name of child)* to do a food recall, or would you like me to get permission from his/her mother or father. He/she should be expecting my call.

If this is an incorrect phone number, fill out contact attempt in your contact form, and give contact form to your supervisor.

If neither the caregiver or child are at home, leave a message (e.g. baby-sitter there, older kid there)

If adult is home, but the caregiver or child are unavailable, ask for convenient time to call back and talk with him/her and note the time on the contact form.

d) **Messages with Another Adult in the Household**
Hi. My name is *(your name)* and I am calling about the (*site study name)*. I'm hoping to talk to *(child's/caregiver's name)* to do a follow-up interview. He/She should be expecting my call. When would be convenient for me to call back and talk with him/her? Will you please let her know to expect a call from me tomorrow about this project.

9. QUALITY ASSURANCE

Upon completing each Diet Recall, interviewer must check over the header and food tab for completeness and then backup the project according to site protocol (See section 10.1). Full quality assurance must be conducted on at least 10% of recalls. The quality assurance flag is check in the record if full quality assurance is conducted on the recall by the site lead nutritionist. Full quality assurance includes review using the AQ checklist and record review based on nutrient cutpoints.

9.1. Editing the recall

The dietary interviewer should review and edit 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. The dietary interview checks the following items:

1. Foods not found in the database will be indicated by NDS-R as missing with capital M instead of the green check. Complete detail about the missing food should be included to ensure that adequate information has been provided to make a resolution. Remember another person should be able to picture the reported food so information about the color, size, shape, ingredients, and preparations should be included in the note. Diet interviews should inform the lead nutritionist of missing foods as soon as possible so a resolution can be developed.

2. The NDS-R note field provides documentation to clarify or confirm contradictory, questionable or unusual food items. Notes serve as communication between the dietary interviewer, and the site lead nutritionist. Notes should be made on every food item to clarify unusual portion sizes, modifications to foods (e.g., not eating the crust of a piece of pizza), and eating foods without anticipated companion foods (e.g., hamburger without a bun or ketchup).

3. Check header and trailer for accurate and complete information.

9.2. Quality Assurance Checklist

Below is the quality assurance checklist that is done for at least 10% of recalls conducted by each diet interviewer. Stanford and Case are conducting basic quality assurance on 100% of the diet recalls. Stanford is printing all diets flagged by SAS for detailed review. Minnesota is selecting a 10% random sample and the diet recalls flagged from SAS (see section 9.3). Vanderbilt is selecting a 10% random sample. 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.

Quality Assurance checks include:

Header Tab:

- ID entered correctly
- Date is the day before
- Visit number is correct
- Site ID is correct
- Gender is correct
- Life-stage group is correct

Meal Information Window:

- Meals are in order by Time
  - Am/pm is correct
  - Meal location is correct, including second household codes
- Eating and activity codes are entered correctly
  - Ex: 1, B, mom (no others notes before the code; 9 entered if activity code is missing and cannot be resolved or Z if companion code is missing and cannot be resolved)

Food Tab:

- Foods are entered correctly
- Amounts match their note
- Missing Foods resolved
- Priority Notes resolved
- Notes to look for:
  - Ate crust
  - Type of bread
  - Nothing to drink
  - Plain, no condiments – French fries, bread, waffles, carrot sticks…
  - Drank milk (with cereal)
  - No snacks, nothing between meals
  - Verify unusual portions – 1 chip, 1 M&M, ate 6 pieces of pizza
    Check both serving size reported, amount listed in parenthesizes following it, and the note field to make sense of unusually small or large servings
  - Missed meals or beverages
    A note should be provided if there is a missed meal or if a meal does not contain a beverage.
  - Food entry or size incorrect per location
    Check to be sure the preparation is reasonable based on location (e.g., they should enter unknown for type of fat used to fry foods if purchased in a restaurant). Check for a reasonable size based on the reported location (e.g., school milk comes in ½ pt cartons)
  - Selecting inappropriate/incorrect forms of food
    Check to see that liquids are entered as FO instead of OZ
    Check the form of food (e.g., applesauce is ½ cup solid while ½ cup of turkey should be entered as cut pieces)
  - Modifications of fast foods or mixed dishes

Use the output file to determine the exact food and amount to subtract or add to fast foods or mixed dishes (e.g., subtract off the pickle on a McDonalds cheeseburger if the note indicated the participant did not eat it)

- Inappropriate picture in Food Amounts Booklet
  Check to see that the Food Model used to estimate the size makes sense (e.g., you can't have a heaping TS of hot sauce because it is liquid but a heaping TS of peanut butter makes sense)
- All non-liquid measuring spoon amounts have a heaping or level note
- All thicknesses are entered a x/16 and all rectangles are entered as x/4.

Trailer Tab:

- Both questions are answered
- Note entered if needed

Other:

- Note if the recall was done without the Food Amounts Booklet
- Note if the recall was done with a child only but without the Food Checklist

9.3 SAS Quality Assurance (Optional – can be done in Excel or other apps)

SAS reports that list: Total energy, % kcal from fat, Fruit servings, Vegetable servings and grams of fluid are listed for each record. Records with values beyond the following cutoff points are printed out, checked and put in the QA binder.

	School Aged Samples	Preschool Samples
Total Energy	<500; >2500	<250; >1800
% kcal from fat	<25%; >45%	<25%; >45%
Fruit Servings	>3	>2
Vegetable Servings	>3	>2
Grams of Fluid	<300; >2000	<200; >1500

Instructions are in the SAS file (See Appendix 4)

There will be quarterly reviews of data entry issues and shared user recipes to standardize the data entry process across all sites.

10. DATA MANAGEMENT

The adopted protocol for transferring Diet Recall data to the RCU requires a single data upload from each site on a quarterly basis. The RCU may request data at other times for purposes of reporting to the DSMB. Each site will submit all records (1, 2, or 3 recalls per participant) each quarter to the RCU. If a participant has only completed 1 or 2 recalls by the end of the quarter, those files are sent to the RCU. The other recalls are included in the following quarterly report. Sites are responsible for "closing out" the completed data for each quarter and merging the records from various site computers into a single Diet Recall set. See section 10.2 "Merging Data" for instructions. These procedures describe how to transfer all the data from multiple site computers to a Main

Diet Recall computer. From the Main Diet Recall Computer, an output file that converts foods into nutrients is created as a zip file.

10.1 Backing up Data

These procedures are done on every computer after a Diet Recall is completed for each project that is currently underway.

Saving NDS-R diet data on disks and the [site specific] drive

1. Back up data in NDS-R:
   Highlight project you want to save.
   Go to Project – backup – selected
   It is now saved on the C drive in the NDS-R backup folder.
2. Save data onto a password-protected Flash Drive.
   Start – Explore – Program files – NCC – NDS-R 2012 – backup
   Copy the file you just saved.
   Paste onto Flash drive
3. Save data onto the [site specific] drive:
   Paste in [site specific] drive – COPTR2diet – COPTRdiet

10.2 Quarterly "close out" and Merging Data

At the end of a quarter sites must stop using the current Project files, thereby closing them out, and prepare that quarter's data for upload to the RCU. Sites will need to create new Project files for the next quarter and shift to recording Diet Recalls into the new Project files. As an example, at the end of March 2013, the XCPT13q1 files are processed for upload and new Project files are created – XCPT13q2 – for recording Diet Recalls from April 1, 2012 to June 30, 2013.

If a site uses multiple computers to record Recalls, the Project files from all site computers must be moved to a site's Main Diet Recall computer for merging into a Master Project for the quarter. After the Master Project has been built to include recall records from all computers for the quarter, a Master OUTPUT file must be generated following the approved naming convention (XCPT13q1.zip) and uploaded to the RCU. See section 7.1 for more details on the naming convention.

Steps:

Create next quarter's Project on site computer(s)
Restore current quarter's Project file(s) to Main Recall computer
Create Master Project for quarter following naming convention – XCPT13q1
Move records from individual files into Master Project
Backup Master Project
Output Master Project to ZIP file
Upload to RCU via website file upload

The "close out" dates for the DSMB reports cannot be determined in advance but will be approximately 7 weeks prior to the respective DSMB meeting. For these submission,

the naming convention will remain the same except the last codes will be either d1 (1st DSMB report of the year) or d2 (2nd DSMB report of the year).

10.3. Making Output File to Send to the RCU

This is done on the quarterly compiled data in the Master Project file (from Main Recall Computer). All data from other computers must be included in the current quarter's Master Project on the Main Recall Computer to compile the data into the current quarter's project.

At the beginning of each quarter, make an output file:

1. In NDS-R - Highlight the current quarter's project
2. Go to Reports – output file – selected project - save

Open/extract file with winzip

3. Double click on the output file you just created.
4. Open the evaluation version of winzip
5. Extract to [site specific] drive -
6. Click extract (and "yes to all" if you're copying over a previous version)
7. Open the error file - "file00" – and look for any reported errors in the data. If there are no errors, the quarterly output file is ready to be uploaded to the RCU.

10.4. Uploading Data to the RCU

Diet Recall data will be uploaded to the RCU via the Data Center website on a quarterly basis following the end of each quarter. The RCU may request data at other times for purposes of reporting to the DSMB. It is the responsibility of each site to clean the NDS-R data and verify its completeness prior to upload to the RCU. "Closing a Project each quarter will allow data cleaning without introducing new records. Procedurally, records collected after the Quarter 1 Project is closed will need to be entered into the Quarter 2 Project. The RCU Data Center website will provide a running record of all quarterly Recall files submitted, accepted, and stored.

The table below shows the start and end dates of each quarter and when the data transfer to the RCU must be completed.

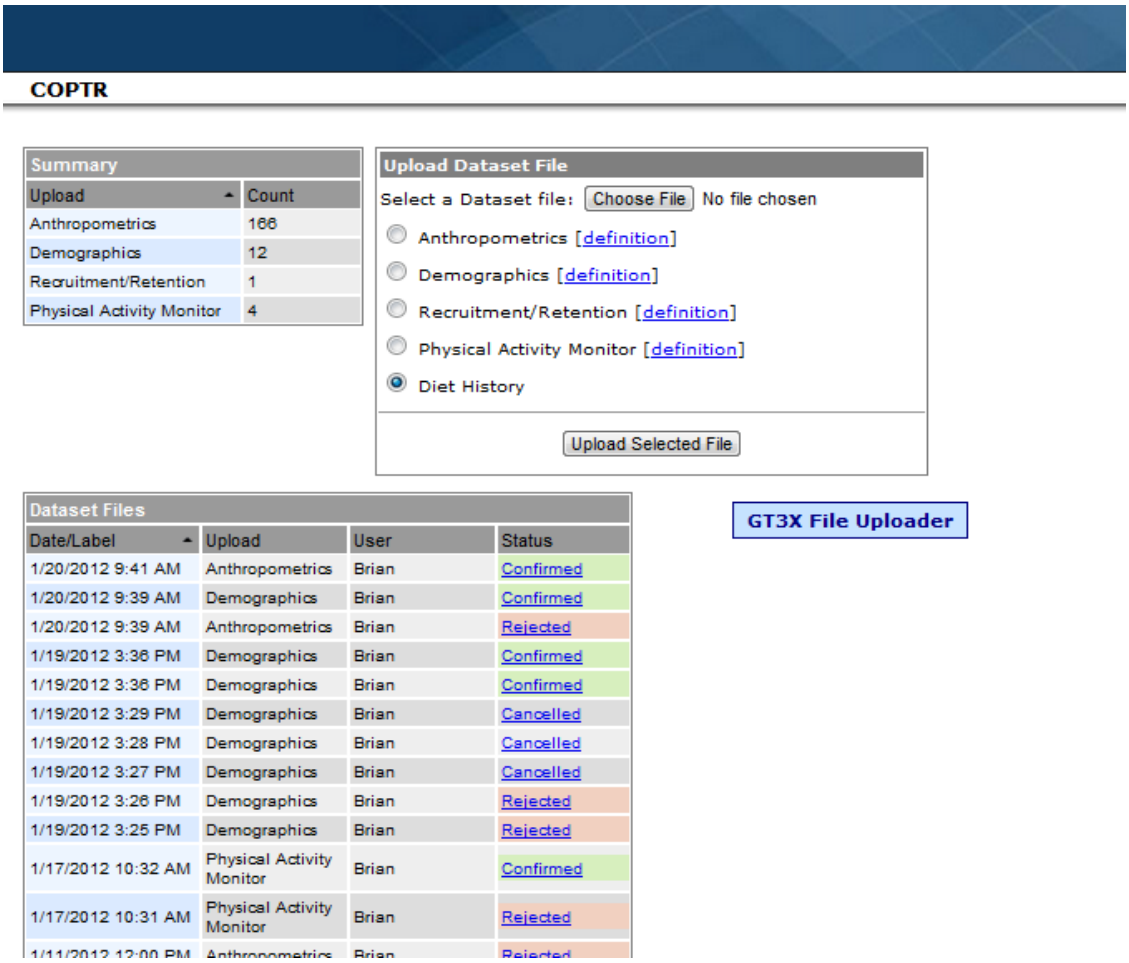
Data upload schedule to RCU

	Data collection		Data due to
Quarter	Start Date	End Date	RCU
1	January 1	March 31	April 15
2	April 1	June 30	July 15
3	July 1	September 30	October 15
4	October 1	December 31	January 15

Process for Uploading to the RCU (see screen example below)

visit the RCU Data Center at: www.shepscenter.unc.edu/coptr
login with your user id and password
Browse and select the appropriate quarterly output ZIP file

Select “Diet History” as the dataset type
Select “Upload Selected File”



If there are errors, you will receive an error response. If the upload was successful and accepted, you will receive a confirmation response and the new file will be added to the list of uploaded files for your site.

APPENDIX 1. FREQUENTLY ASKED QUESTIONS ABOUT FOOD CODES

Listed below is a table of common foods eaten by children and some basic examples on how to enter them into NDS. These are to be used as a reference so that entry is consistent especially within Field Site. If it is reported (by child or parent) that a child ate one of the following foods use the directions to help you determine the correct method of entry.

Appendix 1.1. Examples of Specific Food Coding

Burritos and Tacos	• If the burrito or taco is from a fast food restaurant, type in "fast food" and choose the restaurant. • If the burrito or taco is homemade do not list separate components. Use meat, cheese and bean options and add or subtract any foods not listed.
Cereals	• Use brand name listing for all cereals, if possible. • Use the generic cereal type if the respondent says it is generic • Do not use flakes, puffs, etc. In particular, determine if children ate regular or sugar coated cereals. They may refer to frosted flakes as cornflakes. (eg., ask if they were Tony the Tiger cornflakes)
Milk on Cereal	• Use 1:2 ratio for milk to cereal (i.e., use ½ the amount of milk relative to the amount of cereal).
Cheeseburgers	• Don't type "cheeseburger" into the Meal Description Box • Type in "sandwich", choose "hamburger on a bun", and then choose "with cheese"/ "without cheese."
Chicken Legs	• Use small, med, and large in Food Specific Unit.

Fast Food	• If any food **or** beverage is purchased at a fast food restaurant this should be recorded for the meal *and* the food items. For example, "fast food" would be entered three times if a child consumed a hamburger, French fries, and soda. It is important that each food consumed in a fast food restaurant be "tagged" with restaurant label so that we can accurately assess the amount of fast food consumed. This is particularly easy to overlook with beverages.
	• MEAL: Enter "restaurant and the name of the restaurant in the Meal Information Box as described in 8.2.2.
	• FOOD:
	  • You can type the first few letters of the restaurant name instead of "fast food" to go directly to the restaurant window.
	  • Use fast food serving sizes for foods consumed at fast food restaurants
	  • In the Notes box on the Food Detail window the first words entered must be "fast food", followed by the name of

	the restaurant if unavailable in the database.
Frijoles	• If a respondent reports consuming frijoles ask if they were just boiled or refried (or mashed) • If boiled, ask if the broth was consumed. If broth was consumed assume that ½ the reported amount was broth and enter as low sodium chicken broth. Tap water is not counted in energy density calculation and vegetable broth may increase vegetable counts.
Milk	• If the type of milk the child consumes is not available from the Food Checklist or cannot be resolved with confidence, code as missing. • If the child consumed unknown type of milk at school, code as missing and make a note of what school district he/she attends.
Pizza	• NDS has the following Fast Food pizza places: Domino's, Little Caesars, Pizza Hut, Papa John's. Use Domino pizza for Round Table or Chucky Cheese pizza. If pizza is eaten from one of these restaurants, enter "fast food" and select the restaurant name. For all other pizzas use restaurant or homemade . • Do not add toppings to pizza; use the list of pizzas that are in the program. If a topping needs to be added, include a note and site nutritionist will add later. To enter PORTION SIZE: (If child/parent knows the size of pizza ordered) • The FSU for pizza is an entire pizza, **not a slice**. Ask child/parent if it was a personal, small, med, lg, extra lg pizza, and choose appropriate size from the pull down menu under UNIT • Ask child/parent how many slices he/she ate and make sure to put that number over the total number of slices • The number of slices in different sizes of Pizza Hut pizzas are as follows: 8 inch -4 slices – personal 10 inch –6 slices – SM 12 inch –8 slices – MED 14 inch – 8 slices-LG 16 inch – 8 slices-XL (ie: 2/8 slices would represent that the child ate two slices of a med. pizza from Pizza Hut) • Ask about crust for each slice of pizza and note whether or not they ate the crust on ALL or just some of the slices (If child/parent DOES NOT know size of pizza ordered) • IF child/parent did not order the pizza and there is no one

	available to verify what size was ordered, guide child/parent to the wedges pg(3) and ask them for the length of the pizza slice (what number the slice(s) was/were closest to). This will give you the radius you need to determine the original size of the pizza and then follow standard protocol above to portion size.
Salad	• Do not add dressing to salad, code as salad with salad dressing
Sandwiches	• Whenever possible code the components of the sandwich by entering bread, meat, cheese, other fillings and vegetables separately. This may be coded as an assembled food.
Smoothies	• Use fluid oz.
Pancake Syrup	• Use 1.5 TB per 4 inch pancake for average amount of syrup. Use 2 TB if the syrup is described as spilling over on to the plate.
Lunchables	If a child reports consuming a lunchable, ask what was in it. If it was a pizza lunchable code as one slice of pepperoni pizza. If it is a lunchable with crackers code as 1.5 oz crackers 1oz cheese or meat or peanut butter 4 cookies • If it is another kind of Lunchable is reported, code it as missing and describe the type of foods that are in it. We will check in the store for portion sizes. Also check the Missing Foods Book if it had been previously coded.
Lettuce	Ask if light or dark green lettuce. Code as iceburg or romaine, respectively.
Sips	Code a sip as 1/2 FO = 1 TBSP
Frozen French Fries	If the respondent didn't know if the Frozen French fries were baked or fried, then if consumed at home, code as fried If consumed at school, code as baked.

How to Code Juice and Drinks

- When prompted "juice or drink" choose "juice" for the following fruits:

Apple	Pineapple-Orange	Minute Maid Juice Boxes
Orange	Pineapple-Orange-Banana	Juicy Juice Boxes
Grape	Pineapple	

- "Drink" is applicable to the following drinks

Strawberry	Lemonade
Cherry	Limeade
Cranberry	Tropicana Twister
Cran-Grape	V-8 Splash

Cran-Apple	Kool-aid
Sunny Delight	Tampico
Capri Sun	Gatorade

- If the child can only describe the color, code as missing and use the Food Checklist

Appendix 1.2. Mexican Diet Recall Rules

The following foods are in NDS and we will use them.

- Bolillo
- Horchata
- Mexican Cheese like Cotija and Queso Fresco
- Sopes

Beverages

AGUA FRESCAS
In database
Substitute fruit exchanges from list below if fruit used in agua fresca is not an option

LICUADO
Substitute fruit from fruit exchanges list below if fruit reported is not an option
If more than one fruit is used add it to the licuado
If Nesquik is used make an addition in the add box as Quik

CAL-C-TOSE
Use Ovaltine chocolate milk. Do Not use Quik

Caldos, Soups, Stews

CANNED OR PACKAGED SOUPS
Search for soups, not stews.
Add extra meat or vegetables only if respondent reports additions

CALDOS/HOMEMADE SOUPS
Search for stew for all homemade caldos

CALDO DE POLLO, CALDO DE RES, AND SOPA CON POLLO CON O SIN VERDURA
Use Tomato-based Beef or Chicken Stew

If respondent describes many vegetables in stew add more using vegetable combinations. (25 gm of vegetables = approx 1/6 cup)
If Fideo is added then add Fideo. Fideo is in NDS.
Add Pasta if the noodles have not been fried.

CALDO DE CAMARON AND CALDO DE PESCDO

Use vegetable soup plain
Add shrimp or fish if needed

FIDEO

Always use seasoned with fat
Ask if oil was drained—if no add 1 tsp oil per cup
Ask if any veggies or meat were added to fideo

ALBONDIGAS

Hispanic soup Albondigas is has tomato, rice, carrots squash, potato, cabbage, celery, corn and ground beef. May use this soup as a starting point to code a stew by noting additions and subtractions
Search as – Soup- Hispanic. If made with ground beef use default of 25% fat.

BEANS AND BROTH

When respondents report boiled beans (not mashed or refried) they are often consumed with broth. Enter the bean amount as half of the given bowl size. Enter **low sodium canned chicken broth** for other half. Do NOT enter vegetable broth because it may inflate our vegetable counts. Do NOT enter tap water because it would be omitted in our energy density calculation. In the notes field, type the bowl size, and broth or no broth.
Do NOT use *Hispanic Soup-Sopa de habichuelas blancas* for beans broth. It includes rice, vegetables, oil.

CLEAR BROTH SOUP WITH MEAT OR VEGETABLES

If a clear broth is used with chicken and vegetables use “vegetable soup plain” and add vegetables and meat if needed. If whole pieces of chicken are in the soup (e.g, a chicken thigh or wing) add only what the respondent ate.

PUPUSA (SALVADOREAN GORDITA)

Already fried in NDS and you do not need to use additional oil.

GORDITA

Ask if it was fried and make a note in the note section either way.

CHILE RELLENO

Use Stuffed Pepper. Add egg in the Additions Box.

TACOS

Use fried tortilla and make additions for the filling.

TOSTADAS

Choose fried tortilla and make additions for toppings. Never use taco shell for tostadas.

TAMALES

Sweet Tamale - the sweet tamales in NDS are about 1/2 the gram weight of a meat tamale. We may need to adjust the serving accordingly if you don't think the sweet tamales are this small. Flag all sweet tamales for portion size check.

Regular tamales enter them *from recipe*, ask about lard, and for beef use shredded.

Miscellaneous

CREAMA

Use extra heavy cream for creama
Do NOT substitute sour cream unless this is what was actually reported if creama was used in chicken or pasta salads and add 1 tbsp per cup of salad

CORN OIL

Use as the default oil unless participant specifies another kind.

TACOS DORADOS

Select Tortillas- Fried. Do NOT use Taco shells.

THIN CUT MEATS LIKE DIEZMILLO, PULPA NEGRA, AGUAYON

Use Beef- Flank Steak

PORTIONS SIZE

Use the circle portion size tool for pancakes and homemade tortillas.

CARNITAS

Enter pork->shredded->fried

PAM SPRAY

Ask mother/caregiver for the skillet size (small/medium/large) and demonstrate how long a 1 second spray sounds like. Ask mother/caregiver to demonstrate how she sprays that skillet. Write as most information as reasonable in notes field.
Unit: Spray-1/3 second

For 1/3 second spray enter 1 (Small skillet)
For 1 second spray enter 3 (Medium skillet)
For 2 second spray enter 6 (Large skillet)

TORTILLA CHIPS

From Mi Pueblo- Use fried tortilla. 6 chips=1 standard corn tortilla
Example: If she tells you she ate 10 chips, for unit pick 6" size corn tortilla (fried), enter 10/6 for amount.

Appendix 1.3. Fruits and Vegetables Exchanges

VEGETABLE SUBSTITUTIONS

To save time, if a soup or salad has multiple vegetables in relatively small amounts you can combine and enter portions as one food.
The combinations are:

1. Cabbage and Celery
2. Lettuce and Cucumber
3. Carrots, Tomatoes and Sweet Potatoes
4. Onion and garlic
5. Corn and Peas—use Mixed Vegetables
6. Cauliflower, Broccoli and Asparagus

FRUIT SUBSTITUTIONS

To save time, extra fruits added to smoothies, or fruit salads may also be combined.
The combinations are:

1. Banana
2. Apple and Pear
3. Citrus - Orange, Grapefruit, Lemon, Mandarin
4. Peach and Nectarines
5. Melons- Watermelon, Pineapple, Cantaloupe and Honeydew
6. Mango and Papaya
7. All Berries and Kiwi

Appendix 1.4. Food Preparation

Ask if the food was cooked in the oven or on top of the oven. Code as baked or fried, respectively.

Appendix 1.5. Food Checklists and School Menus

For Case and Stanford, the Food Checklist Form is completed at the baseline visit with the child's caregiver.
Refer to this form to enter details on type of milk, juice, soda, or fat-free food products consumed.

This form also tells us if the child regularly eats school breakfast or school lunch.

Each laptop bag has a copy of the breakfast and lunch menus for the surrounding school districts. There will also be a copy for phone interviewers to use during evening calls. If the child eats school-prepared meals, ask the child what they had to eat and then confirm using the menus. If child's report and the school menu do not match, always use the child's report.

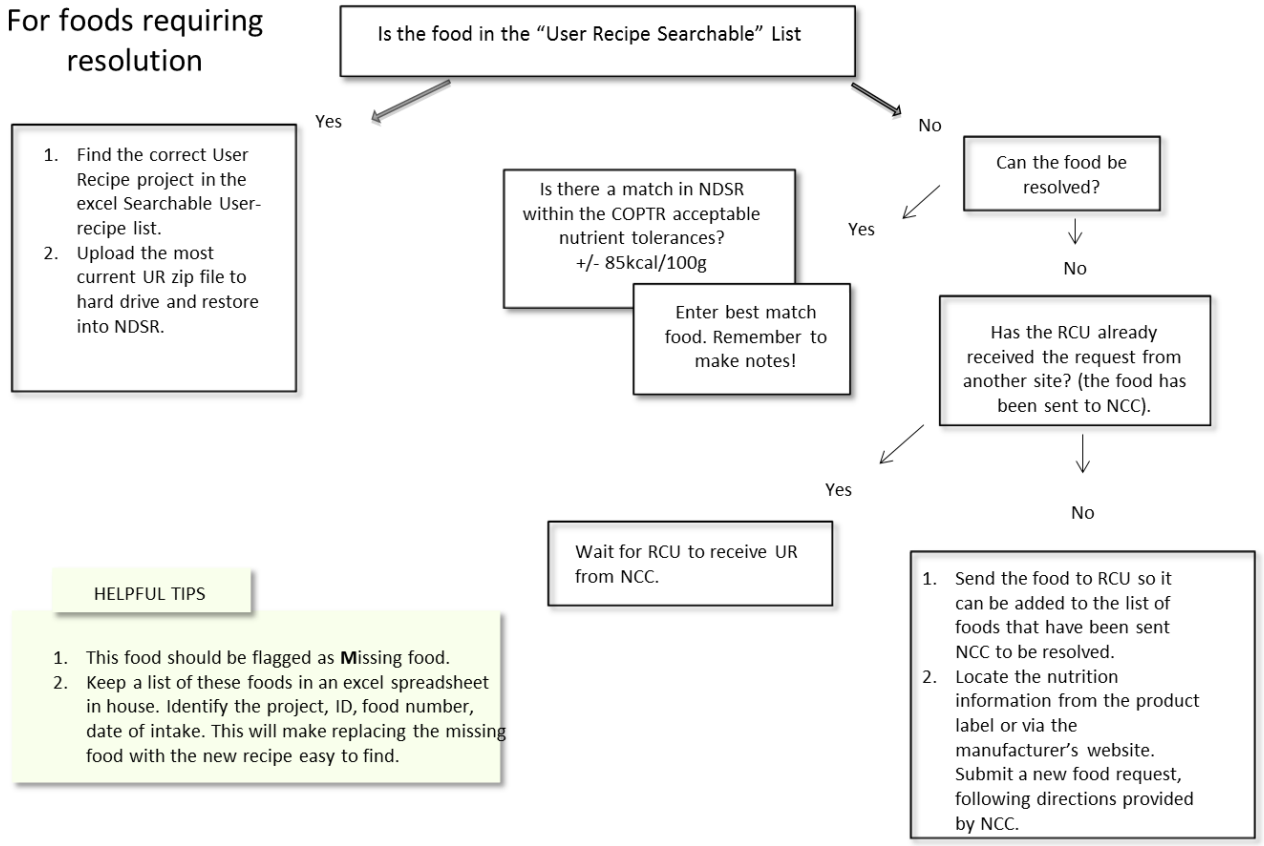
Appendix 1.6. COPTR New Food Resolutions and User Recipes Protocol

Introduction

This section is designed to facilitate standardization and to prevent any one site from using up their allotted new food requests. If you find a frequently reported food that is not available in the most recent version of NDSR and is not in the user recipe searchable list, then it may be necessary to request a new user recipe. This protocol (below) describes this process.
All user recipe files can be found at the COPTR website.

Important files

1. User Recipe Protocol.doc: (This document) Basic information regarding user recipes and how to create a user recipe.
2. User Recipe Searchable List [NDSR YEAR, i.e. 2011].xls: These are the searchable list for all foods in the respective NSDR version.
3. Request & Resolutions List.xls: Use this to track all new food requests to NCC and the NCC resolutions.
4. Zip Files (.zip): These are the original files that contain all the user recipes to be uploaded into the NDSR 2009 or 2010 versions


For foods requiring resolution
Is the food in the "User Recipe Searchable" List
Yes
No
1. Find the correct User Recipe project in the excel Searchable User-recipe list.
2. Upload the most current UR zip file to hard drive and restore into NDSR.
Is there a match in NDSR within the COPTR acceptable nutrient tolerances? +/- 85kcal/100g
Yes
Enter best match food. Remember to make notes!
Can the food be resolved?
No
Has the RCU already received the request from another site? (the food has been sent to NCC).
Yes
No
Wait for RCU to receive UR from NCC.
1. Send the food to RCU so it can be added to the list of foods that have been sent NCC to be resolved.
2. Locate the nutrition information from the product label or via the manufacturer's website. Submit a new food request, following directions provided by NCC.
HELPFUL TIPS
1. This food should be flagged as **M**issing food.
2. Keep a list of these foods in an excel spreadsheet in house. Identify the project, ID, food number, date of intake. This will make replacing the missing food with the new recipe easy to find.

Foods Not in NDSR

Checklist

Follow the above flow chart to determine if the food can be matched or a request should be sent to NCC to create a new recipe.
Check to see if an existing resolution or User Recipeis available (see the User Recipe Searchable List for the NDSR version in which you are working).
Check to see if the food has already been sent in by another site. Contact RCU.
If so, make a note in the header tab of the recall for which you are trying to the resolve the food so you can go back and fix the food at a later time.
Check the NDSR manual for the list of "Data Entry Rules" (Appendix 15) to see if any apply and a match can be found.
If no match is found through the Data Entry Rules, see if you can match the food within the acceptable NCC tolerances: (+/-) per 100 grams of foods: 85 kcal
If no match can be made at this time, then forward the food to RCU.
Send the food to NCC to be resolved.

http://www.ncc.umn.edu/services/newfoodrequests.html**), to initiate a New Foods Resolution Request (see Initiating a New Food Resolution) to NCC.**

Guidelines
A food that is not in the database and cannot be described using a generic database entry.
An existing product whose form has changed.
A homemade recipe, regional, or ethnic food that cannot be described using database entries.
A food from a national fast food restaurant that cannot be described using database entries.
A new national brand product. The category of the product in NDSR must include a brand listing.

If the food does not meet these guidelines, then:

Create a new UR (see "Creating a new UR" below)

and/or

Enter as an error/issue or concern/wishlist item as appropriate (there should be a wishlist document in the User Recipe folder)
Errors/issues are mistakes or problems in NDSR that we think they should know about (e.g. no vegetables on their vegetable pizza)
Concern/wishlist items are foods we would like to see in the database or would like to see handled more efficiently (e.g., it would be nice if standard sandwiches, such as PB&J, had an option of choosing whole wheat bread while still using standard amounts of the contents).

Organizing and saving New Food Resolutions from NCC

When New Food Resolutions come in from NCC:

Save the NCC recipe.zip project sent by NCC.
Restore it in the appropriate version of NDSR.

Send notice to RCU that the new UR has been received. Include the zip file so the RCU can upload this file to the COPTR website.

Technical issues or error messages

For technical issues with NDSR (error messages, etc.), hit Alt + PrtSc to copy the error messages, paste them into a word document and email the document with explanation to:

Huong Duong (verify that she's still the contact person at:
http://www.ncc.umn.edu/about/staffcontacts.html)
duong001@umn.edu
612.626.9429

For more info, see the latest NDSR manual troubleshooting tab, and:
http://www.ncc.umn.edu/products/ndsrsupport.html

For errors regarding foods (i.e., non-technical, such as the "vegetarian" soup that was made with beef broth), see "errors/issues" below.

Appendix 1.7. How to Code Fruits and Vegetable Smaller or Larger than Food Specific Units

For fruits WITH pits (ie: apple, pear, nectarine, peach, etc.)

1) Guide respondent to circles pg. (2) and ask what circle size the piece of fruit was.
    a. If respondent reports circle size to be within ¼" of the predefined (VSM, SM, MD, LG), select the closest option
        i. If in question for, fruits with THICK peels round down
    b. If respondent reports circle size to be greater or smaller than the ¼" RULE, enter manually
        i. Select unit as "SPH – sphere"
        ii. Enter diameter of sphere according to what child/parent reported
        iii. Ask respondent if he/she finished the piece the fruit
            1. If Yes: **code quantity as 0.9** (this takes the pit into account)
            2. If No: ask if they had ½, more than ½, or less than ½ and code QUANTITY as follows –

                Less than ½ = 0.23 [=0.9*0.25]
                Equals ½ = 0.45 [=0.9*0.5]
                More than ½ = 0.68 [=0.9*0.75]

For fruit WITHOUT pits

** exact same coding as fruits with pits except for when the respondent reports the circle size to be out of the ¼" RULE, when you ask the child if they finished it, had half, more than half, less than half, etc. the totally quantity is out of 1 (because there is no pit to account for)

- ie: an orange reported to be cir e would be coded as:

    "SPH – sphere", diameter 4" → if child ate all: quantity = 1
    If child ate more than half: quantity = ¾
    If child ate half = ½
    If child ate less than half: quantity = ¼

Appendix 1.8. Specific Data-Entry Food Rules

Food	Situation	Data-Entry Rule
Chocolate covered strawberry	Not an option	Choose fresh strawberry, with solid chocolate as an addition
Cinnamon roll with unique frosting	Different frosting types not an option	Choose the cinnamon roll with frosting/glaze (type of frosting does not matter)
Spaghetti-Os	Not an option	Choose canned spaghetti
Airhead Extremes	Not an option	Choose licorice candy
Kool-Aid Fun Fizz	Not an option	Choose Crystal Light
Natural peanut butter	Not an option	Choose regular peanut butter, ask if salted or unsalted
Kids Clif Z Bar	Not an option	Choose Clif Z Bar, indicate 1.2oz for entire bar
Apple cinnamon Clif Z Bar	Flavor not an option	Choose honey graham flavor
100% cranberry juice	Not an option	Select juice option (cranberry and white grape)
Chicken sausage	Not an option	Choose turkey sausage
Corndog without breading eaten	Corndog is an option, but can't choose without breading.	Choose regular hot dog
Chocolate Cheerios	Not an option	Choose Frosted Cheerios
Mayonnaise with olive oil	Not an option	Choose low fat mayonnaise

Freezie	Not an option	Choose popsicle, 50 ml
V-8 Fusion, All Flavors	Not an option	Choose V-8 Splash
Little Critters Calcium Gummy Bears or other one-a-day gummy vitamins	Not all listed	Chose One-A-Day Kids Scooby Doo! Gummies
Kefir & Yogurt drinks	Unit selection	Enter as FO, not OZ
Kashi cereal bar	Not an option	Choose Nutri-Grain bar
Gluten-free pancake	Not an option	Choose regular pancake
Ring pop	Not an option	Choose hard candy, indicate 14g for entire pop
Toaster Strudel	Not an option	Choose Pop Tart
Milk box	Not an option	Choose milk, indicate 6.75ox for entire box
Coconut milk for drinking	Not an option	Choose 1/8 coconut milk & 7/8 tap water
Lunchables – all meat/cheese/cracker/ cookie combination	Not an option	Enter 4 of each: Ritz crackers, select type of meat in Lunchables (2” diam), type of cheese (cube 8/4 x 8/4 x 2/16), & 2 small cookies
Idahoan Instant Mashed potatoes (any flavor)	Not an option	Choose mashed potatoes, dehydrated
Pear Sauce	Not an option	Choose applesauce
Kraft swirl cheese stick	Not an option	Choose string cheese
Capri-Sun 25% less sugar, all flavors	Not an option	Choose original Capri-Sun
Italian Wedding Cookies, Mexican Wedding Cookies, or butterballs	Not an option	Choose rumballs

Fruit2O (Flavored Water)	Not an option	Choose soda water
Sparkling Mango Lemonade	Not an option	Choose lemonade
Kraft ½ Skim Milk String Cheese	Not an option	Choose regular string cheese
Blueberry frozen pancake	Not an option	Choose regular frozen pancake
Risotto	Not an option	Choose pilaf
Oatmeal made with Half and Half	Not an option	Choose “made with milk” and add half and half
100% CranGrape juice	Not an option	Choose cran-grape drink
Spinach and cheese ravioli	Not an option	Choose just spinach ravioli
“Vruit” juice	Not an option	Choose vegetable juice or cocktail
Mott’s Mango and Peach Applesauce	Not an option	Choose applesauce, unsweetened
Chobani Greek Yogurt	Not an option	Use food recipe provided by NCC
McDonalds Double Cheeseburger—plain	Plain not an option	Choose cheeseburger→double cheeseburger, amount: 146g
Gluten free bread	Not an option	Choose “low gluten”
No crusts on bread	Amount not an option	Choose 7/8 of slice
Earth Balance Natural Buttery Spread	Not an option	Choose margarine→spread→100% fat→salted→soybean, canola, palm, olive oil
Skipps All Natural with Honey	Not an option	Choose peanut butter→regular→salted

100% Peach Mango Juice	Not an option	Choose juice→orange, peach, mango juice
Fiesta Sides (Spanish Rice, e.g.)	Brand not included	Choose rice→commercial seasoned mix
Lay's Tangy Carolina BBQ flavor chips	Flavor not an option	Choose K.C. Masterpiece B.B.Q.
Individual size box of Cap'n Crunch	Size not an option	26 g
Individual bowl of Raisin Bran	Size not an option	1.25 OZ
Dixie cup	Size not an option	3 FO
Kettle corn	Only brands are an option	Act II and Pop Secret are the same nutritionally, choose either
"Reduced Fat" Kemps ice cream	Unable to find online or in NDSR	Choose regular
Ring Pop	Not an option	Choose either "sucker" or "lollipop," 14g
"Propel" water	Not an option	
Chex Mix small bag	Amount not listed	½ cup
Strawberry lemonaid	Not an option	Choose regular lemonaid
Hershey's Kiss with Coconut Cream	Not an option	Choose regular Kiss
Cinnamon Burst Cheerios	Not an option	Choose regular Cheerios
"Bomb Pop" popsicle	Not an option	Choose popsicle, regular, 52g
Pop Rocks candy	Not an option	Choose 7g hard candy

Lunchables-Extra Cheesy Pizza (no drink)	Not an option	Choose 3 3”-diameter pizza crusts, 30g pizza sauce, ½ tbsp part skim processed mozzarella cheese, ½ tbsp unknown processed cheese
Bolthouse Farms Orange Passion Guava juice	Not an option	Choose smoothie→non dairy
Glass1 to the top	Amount not specified	Enter 7.5 FO (same as glass3betweenBandC)
Dole fruit cup—mandarin oranges	Not an option	Choose mandarin oranges, 4 OZ
Carnitas	Not an option	Choose pork→shredded→fried
Pam cooking spray	Not an option	Choose vegetable oil
Ice Breakers Sours	Not an option	0.8g per piece
Mixed fruit in gelatin, Dole brand	Not an option	Choose jello→fruit→123g
Culver’s Grilled Cheese	Not an option	117g
Strawberry milk carton	Hard to find	Milk→mixtures and milk drinks→strawberry and other flavors→purchased ready-to-drink
“Little Hugs” drinks in barrels	Not an option	1.3 FO kool-aid + 6.7 FO water
Crunchy Nut cereal	Not an option	Choose cornflakes→presweetened
Gluten free rotini pasta	Not an option	Choose regular rotini
Ocean Spray White Cran Peach drink	Not an option	Choose Ocean Spray Summer Cooler
Kraft Easy Mac cup	Not an option	Choose mac and cheese→dried cheese→no fat used→whole milk→7/8 cup
M & M’s fun size pkg	Not an option	21g

Fruit leather, organic	Size not specified	14g
V8 Fusion Smoothie	Not an option	Choose fruit smoothie→made without dairy products
Individual cup of Cinnamon Toast Crunch	Not an option	2 OZ
Golden Oreos	Not an Option	Choose regular oreo's
Half chocolate half vanilla cookies	Hard to Find	Cookies→sandwich→chcolate and vanilla cookies with filling
Juicy Juice Kiwi Strawberry flavor	Not an option	Choose apple
Ocean Spray 100% Cranberry Juice	Confusing	Choose cranberry juice with white grape juice
Cinnamon Life cereal	Not an Option	Choose regular Life cereal
Basmati rice in low sodium vegetable broth	Not an Option	Choose white rice in chicken broth low sodium
Ocean Spray Cranberry Light	Not an Option	Choose cranberry drink→light→saccharine
Raw Cookie dough	Not an Option	Choose regular cookie
Golden Grahams Treat Bar	Not an Option	Choose granola bar→cereal bar→regular→40g
McDonald's Hamburger Ketchup only	Not an Option	Choose McDonalds hamburger
Papa Murphy's cheesy bread	Not an Option	Choose Domino's cheesy bread, for two pieces choose 70g
Doritos Munchies Mix	Not an Option	Choose equal parts Doritos, Sun Chips, Run Gold Pretzels and Cheetos
Apple juice with tin foil lid	Size not specified	Choose 1 cup/8 FO

Subway Sandwich, without one or all of included condiments	Not an Option	Choose sandwich, then add condiments with negative amounts for those not included on sandwich (amounts here http://www.subway.com/nutrition/NutritionList.aspx?id=breadtop&Countrycode=USA)
Trader Joe's Whey Protein Powder	Not an Option	Choose Slimfast High Protein Creamy Chocolate prepared with milk, 1 less FO than drank
Annie's Organic Snack Mix	Not an Option	Combine 1/3 hard pretzels, 1/3 cheese crackers and 1/3 whole wheat crackers
Laffy Taffy	Not an option	Choose taffy→ 43g
Happy Meal size fries from Mcdonald's	Not an option	1.1 OZ
Blackberry, 1 single berry	Not an option	Choose 1 level tbsp of blackberries
Orange chicken	Not an option	Choose General Tso chicken
Dunkaroos	Not an option	Choose appropriate graham cracker (cinnamon, plain, etc.), choose bite-sized pieces. Add 1 level tbsp of frosting
Ice	Not an option	Enter as water
Krave Cereal	Not an Option	Enter as Special K Chocolatey Delight
Got Milk? Magic Milk Straw, Chocolate	Not an option	Enter 3.5g of chocolate
Uncrustable	Not an Option	3.3/5 of a peanut butter and jelly sandwich is 207 calories and uncrustables are 210
Lunchable (Nachos)	Not an Option	Package amount is 4.4oz (unknown if that includes the packaging). "Nachos with cheese-processed cheddar" and 3.2oz for amount.
Blueberry Chiobani Greek Yogurt	Not an option	Use user recipe for plan chiobani yogurt, then add 0.75 tbsp of blueberry jam or preserves

APPENDIX 2. FORMS AND SCRIPTS

Appendix 2.1 Activity Card and Eating Companion Card

Activity and Eating Companion Codes Guide

Eating Activity Codes

	"What was your child doing while he/she ate?" "What were you doing while you ate?"
1	Just eating (no TV or video games, etc.)
2	Watching television
3	Watching a videotape or movie on a VCR or DVD
4	Playing video games or playing on a computer
5	[NOTE – 09 is coded during QA when other codes are missing]

Eating Companion Codes

	"Who was eating with your child?" "Who were you eating with?"
A	Eating alone
B	Eating with family only
C	Eating with others and family
D	Eating with others (not family)
E	[NOTE – 09 is coded during QA when other codes are missing]

Food Amounts Booklet

Interviewer Copy

Amount Estimation Tools
Conversion Guide for Dietary Interviewers

When the participant shows a picture in the Food Amounts Booklet, convert to NDS-R amounts per the following information.

Squares and Rectangles ¼ inch grid (p.1)	Circles (p.2)		
Each square is ¼″ x ¼″. Select shape, cube (3 dimensions) or rectangle (2 dimensions) per NDS-R. Enter as fractions, e.g. 2/4 wide x 13/4 long	Select shape, circle or sphere. Enter diameter in inches per the following:		
	A = 1 inch B = 2 inches C = 2 ½ inches	D = 3 inches E = 4 inches F = 5 inches	G = 6 inches H = 7 inches

Wedges (p.3)							
Radius	**Length of Arc (width of rounded edge)**						**Fraction of Circle**
Select shape, wedge, enter radius: 1 = 4″ radius (8″D) 2 = 4 ½″ radius (9″D) 3 = 6″ radius (12″D) 4 = 8″ radius (16″D) 5 = 9″ radius (18″D)		**A**	**B**	**C**	**D**	**E**	Select circle, enter width: A = 1/40th B = 1/20th C = 1/12th D = 1/9th E = 1/6th
	1	0.6″	1.1″	2.1″	2.6″	3.9″	
	2	0.7″	1.3″	2.4″	2.9″	4.4″	
	3	0.9″	1.6″	3.1″	3.9″	5.9″	
	4	1.1″	2.1″	4.1″	5.1″	7.8″	
	5	1.3″	2.4″	4.7″	5.8″	8.9″	
For 3D wedge, also use **Thickness** (p.4, height = x/16) or **Squares and Rectangles** (p.1, height = x/4)							

Thickness (p.4)	Measuring Spoons (p.5)	Eating and Serving Spoons (p.6)	Measuring Cups (p.7)
Each unit is 1/16″ thick. Enter thickness as fraction. E.g.: 1 = 1/16″ 2 = 2/16″ 3 = 3/16″ 18 = 18/16″ 40 = 40/16″	Standard Measures ½ teaspoon (TS) 1 teaspoon ½ tablespoon (TB) 1 tablespoon	Teaspoons: Level = 1 TS Heaping = 2 TS Tablespoon: Level = 1 TB Heaping = 2 TB	Standard Measures 1 = ¼ CP 2 = ⅓ CP 3 = ½ CP 4 = 1 CP

Glasses (pp.8-9)			
1 A = 1 ¼ FO	2 A = 2 ½ FO	3 A = 4 FO	4 A = 6 FO
1 B = 2 ½ FO	2 B = 5 FO	3 B = 8 FO	4 B = 12 FO
1 C = 3 ¾ FO	2 C = 7 ½ FO	3 C = 12 FO	4 C = 18 FO
1 D = 5 FO	2 D = 10 FO	3 D = 16 FO	4 D = 24 FO

Bowls (pp.10-11)				Wine gl (p.12)	Mug (p.13)
1 A = 1/8 CP	2 A = 3/8 CP	3 A = ¾ CP	4 A = 2 CP	A = 2 FO	A = 2 1/2 FO
1 B = 1/4 CP	2 B = ¾ CP	3 B = 1 ½ CP	4 B = 4 CP	B = 4 FO	B = 5 FO
1 C = 3/8 CP	2 C = 1 ¼ CP	3 C = 2 ¼ CP	4 C = 6 CP	C = 6 FO	C = 7 1/2 FO
1 D = 1/2 CP	2 D = 1 ½ CP	3 D = 3 CP	4 D = 8 CP	D = 8 FO	D = 11 FO

Mounds (pp.14-15)	Meats (p.16)	Chicken (p.17)	Fish (p.18)
1 = 1 CP 2 = ¾ CP 3 = ½ CP 4 = ⅓ CP 5 = ¼ CP	All are edible portion 1 = 3 OZ 2 = 3 OZ 3 = 1 ½ OZ	*** NDS 2013 changed the size of chickens so please see second page of this doc for correct chicken ounces ***	Edible portion 1 = 2 OZ 2 = 3 OZ 3 = ½ OZ 4 = 1 OZ

1 = just eating
2 = watching television
3 = watching a videotape
4 = playing video games/computer

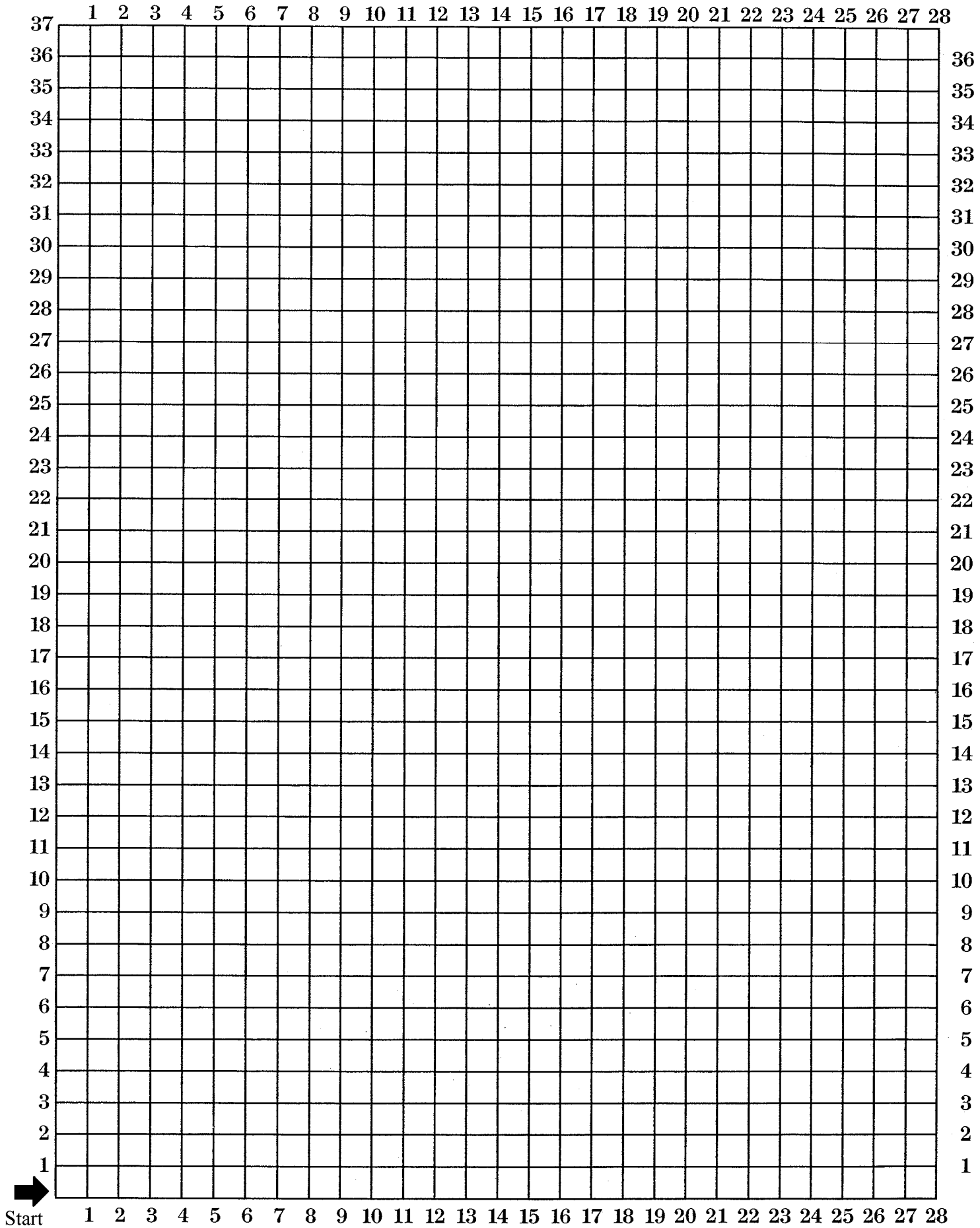
A = eating alone
B = eating with fam. only
C = eating w/fam. & others
D = eating w/others (not fam.)

Morning meal = 7am
Noon meal = 12pm
Afternoon meal = 5pm
Evening snack = 8pm

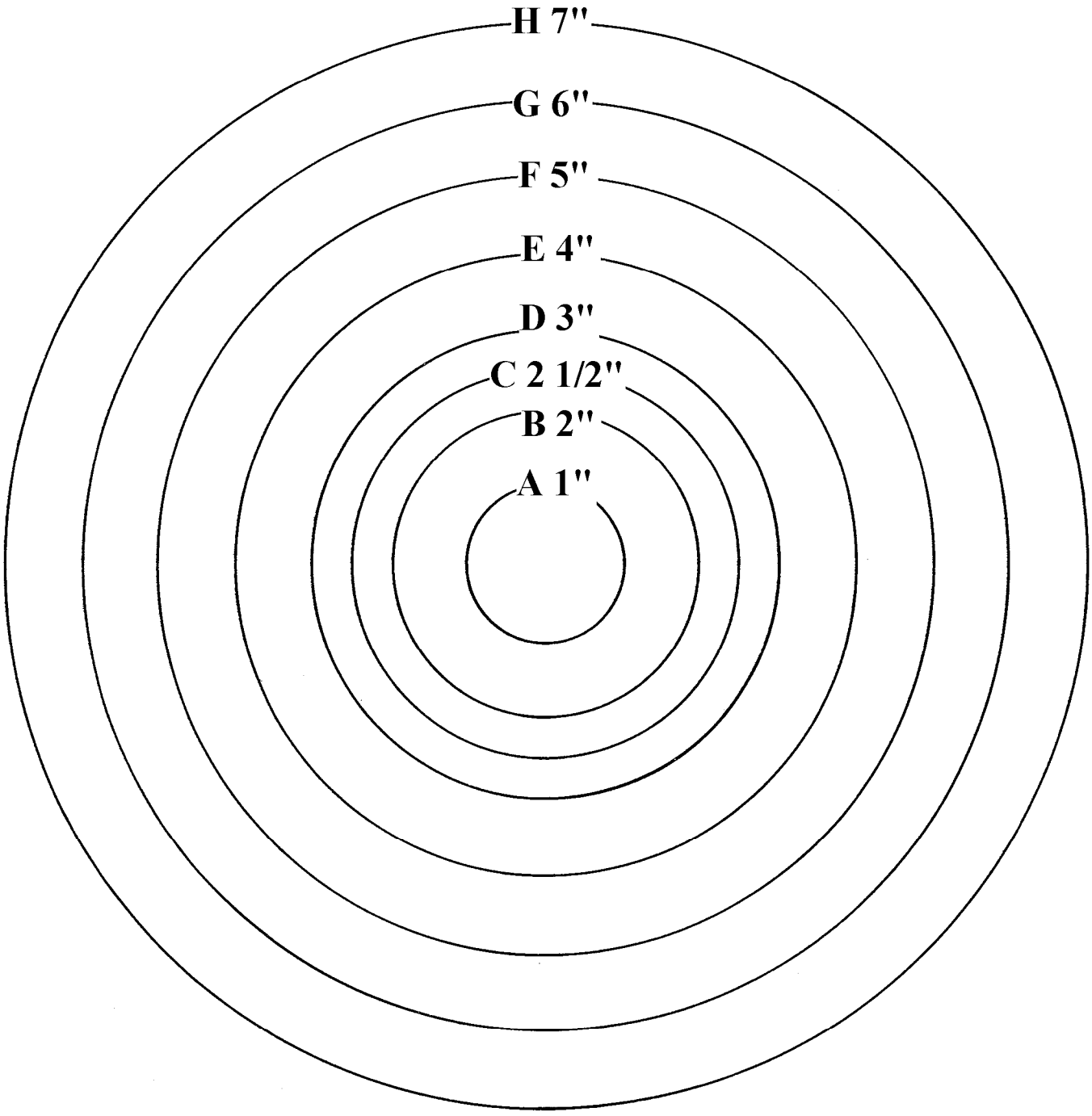
These are the chicken ounces taken from NDS 2012 which we will use in NDS 2013 versions and moving forward to be consistent over the course of the study. Instead of using the FSU Sm/Med/Lg you must manually enter the number of ounces according to the table below

Chicken (p.17)
Breast:
Sm = 2.7 OZ no skin 3.0 OZ with skin
Med = 3.0 OZ no skin 3.5 OZ with skin
Lg = 3.5 OZ no skin 3.9 OZ with skin
Wing:
Sm = 0.7 OZ no skin 1.1 OZ with skin
Med = 0.7 OZ no skin 1.2 OZ with skin
Lg = 1.0 OZ no skin 1.6 OZ with skin
Drumstick:
Sm = 1.2 OZ no skin 1.4 OZ with skin
Med = 1.6 OZ no skin 1.8 OZ with skin
Lg = 2.1 OZ no skin 2.4 OZ with skin
Thigh:
Sm = 1.6 OZ no skin 1.9 OZ with skin
Med = 1.8 OZ no skin 2.2 OZ with skin
Lg = 2.5 OZ no skin 3.0 OZ with skin

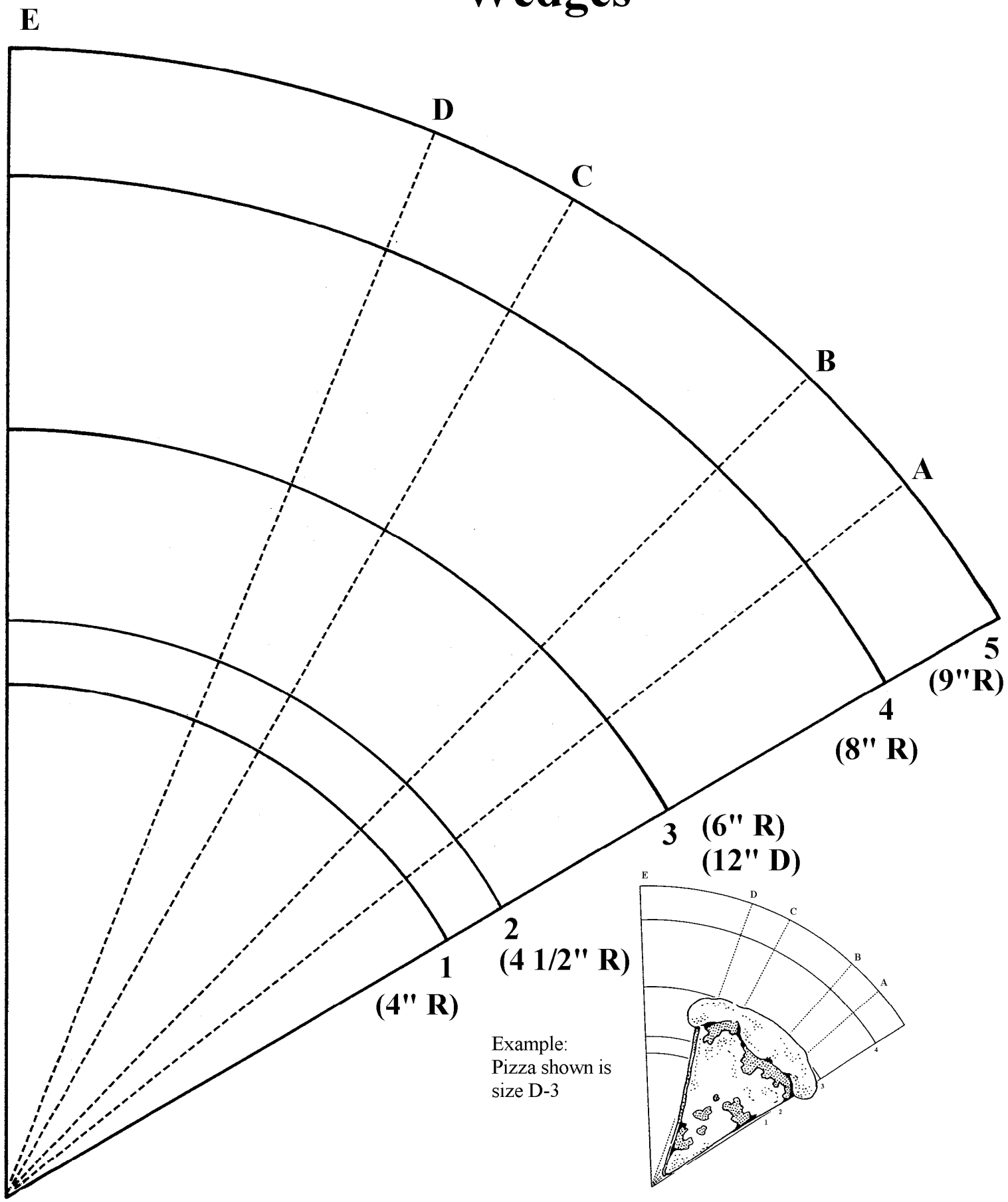
Squares and Rectangles



Circles

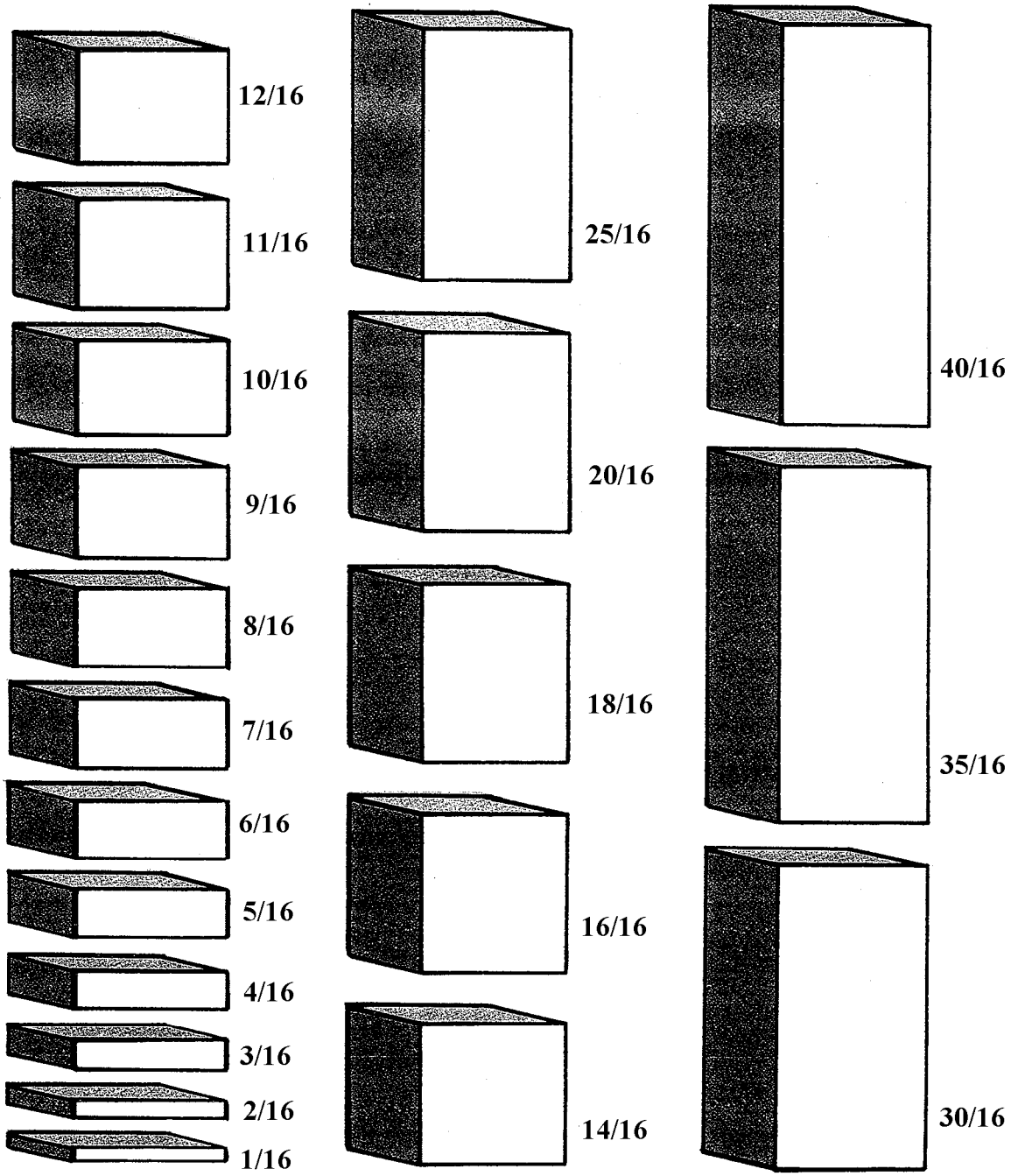


Wedges

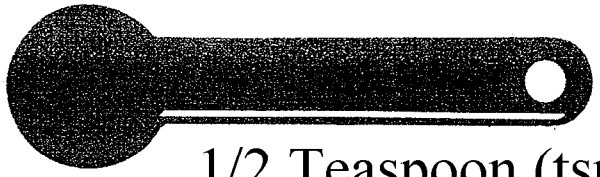


Example:
Pizza shown is
size D-3

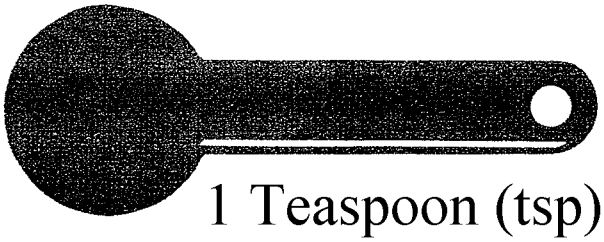
Thickness


12/16
11/16
10/16
9/16
8/16
7/16
6/16
5/16
4/16
3/16
2/16
1/16
25/16
20/16
18/16
16/16
14/16
40/16
35/16
30/16

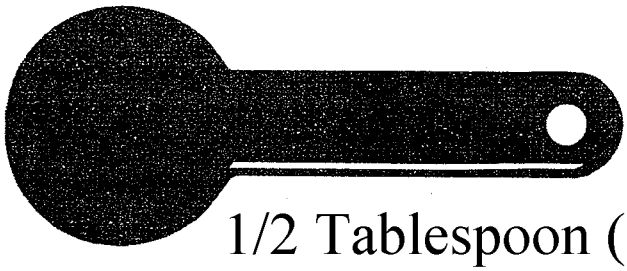
Measuring Spoons



1/2 Teaspoon (tsp)



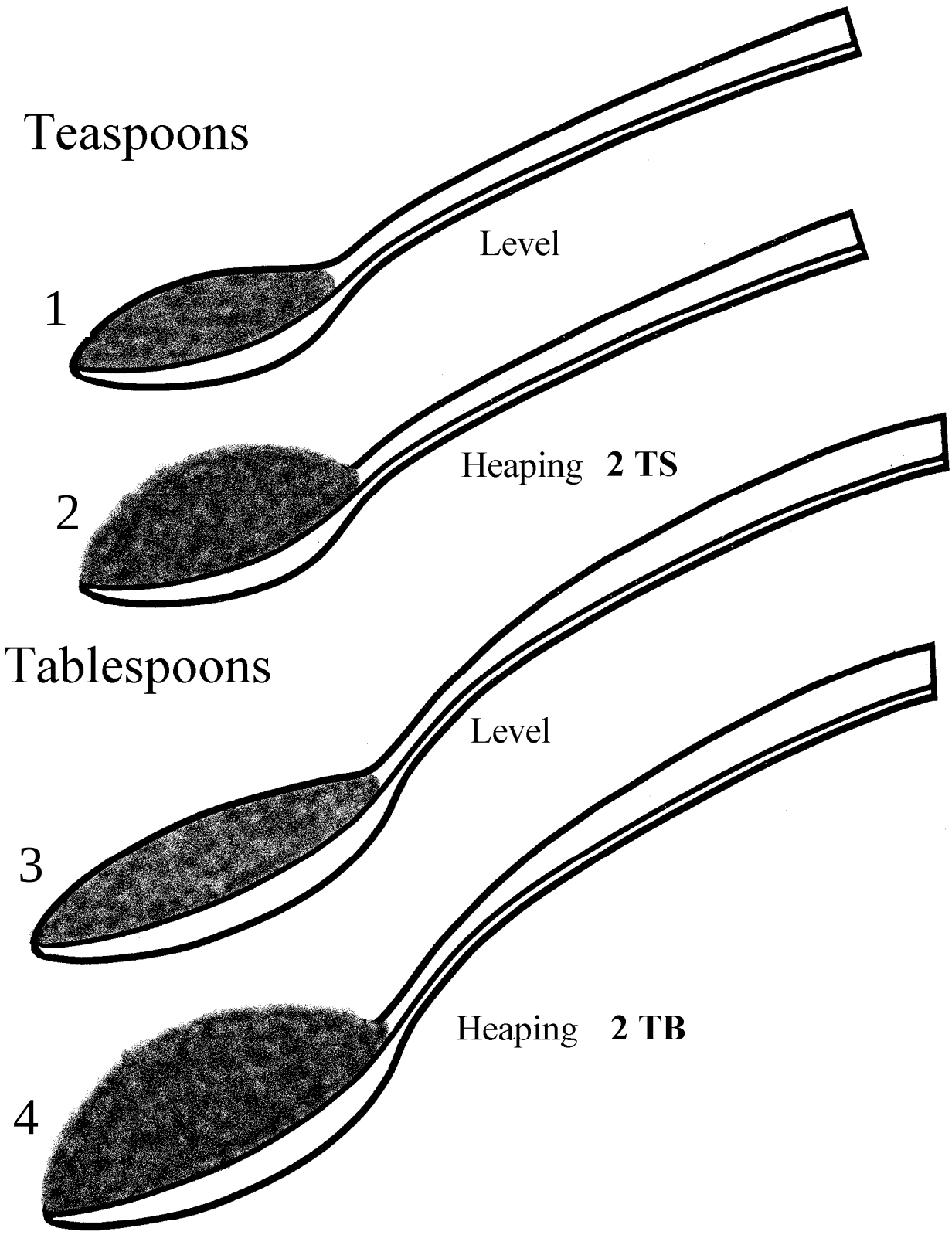
1 Teaspoon (tsp)



1/2 Tablespoon (Tbsp)

1 Tablespoon (Tbsp)

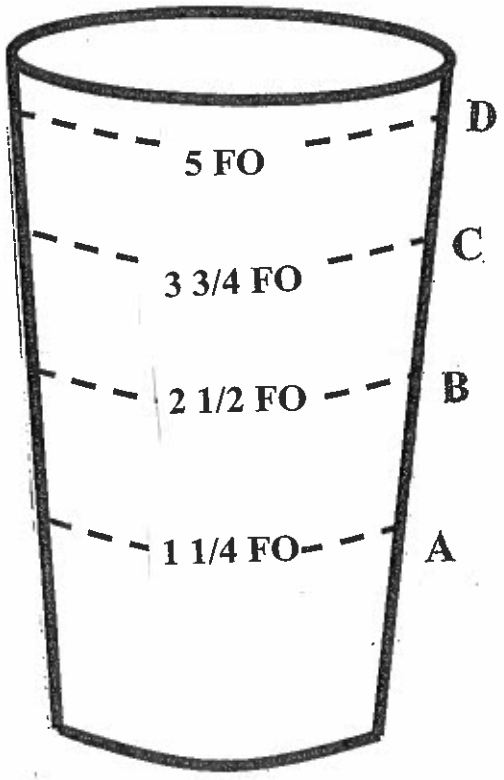
Eating and Serving Spoons



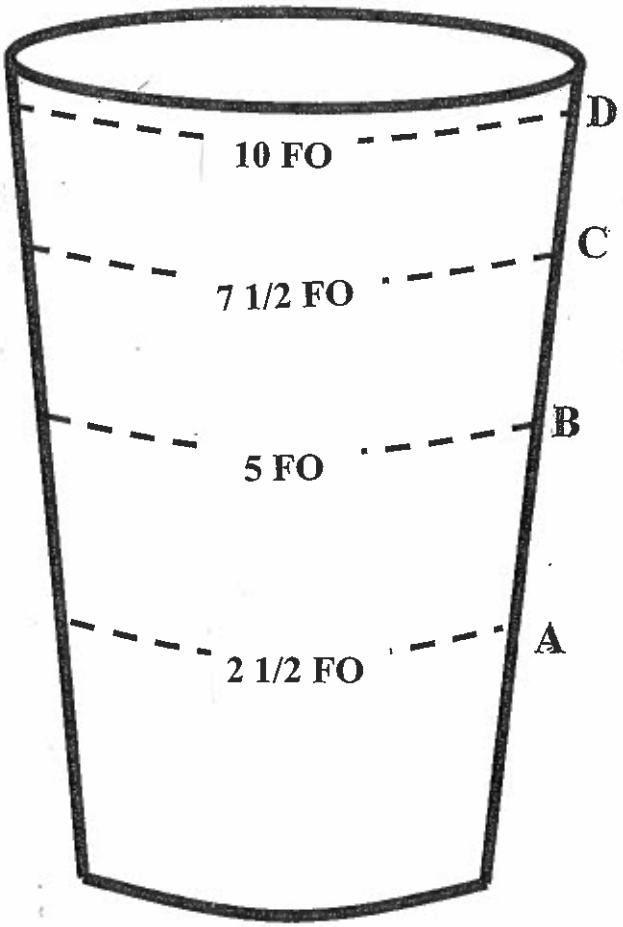
Measuring Cups

Glasses

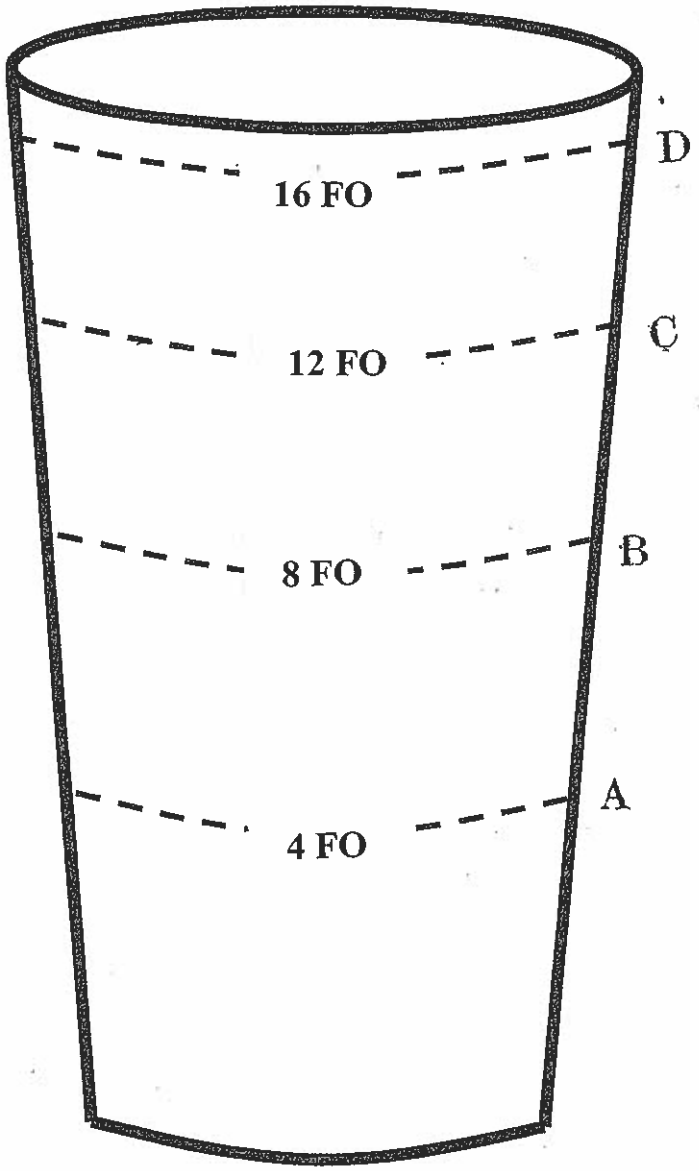
1


D
5 FO
C
3 3/4 FO
B
2 1/2 FO
A
1 1/4 FO

2

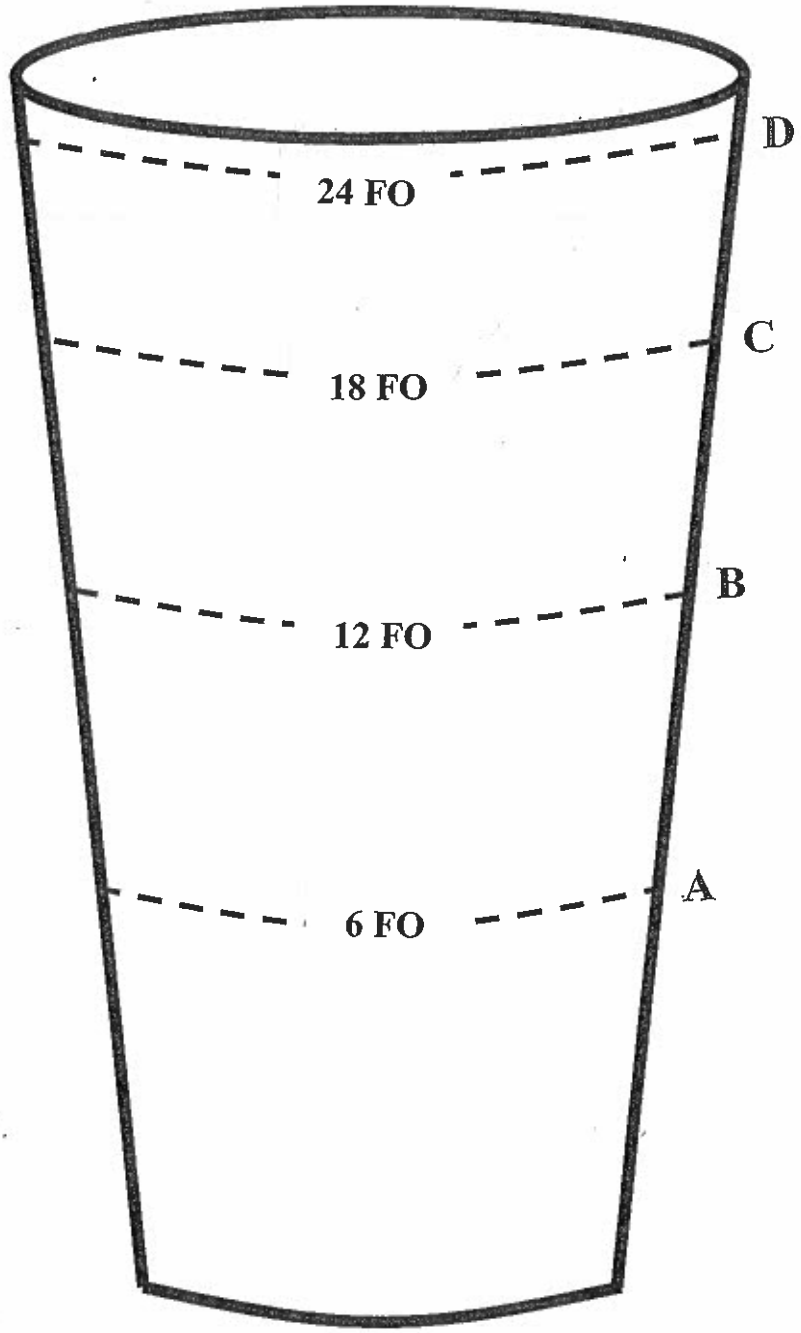

D
10 FO
C
7 1/2 FO
B
5 FO
A
2 1/2 FO

3


D
16 FO
C
12 FO
B
8 FO
A
4 FO

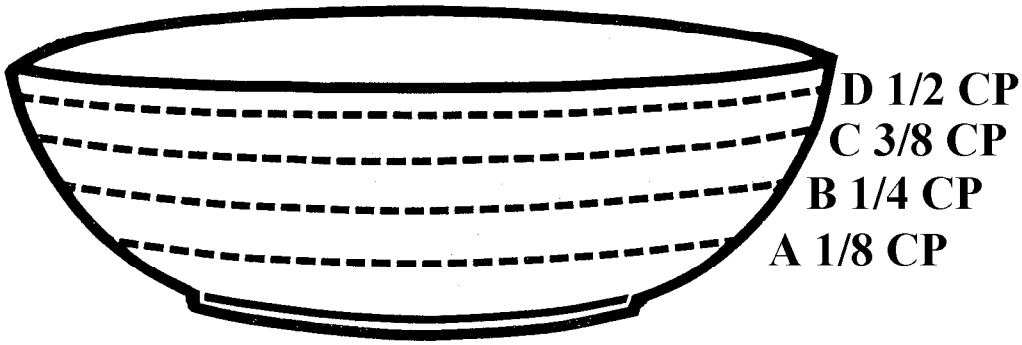
Glasses

4

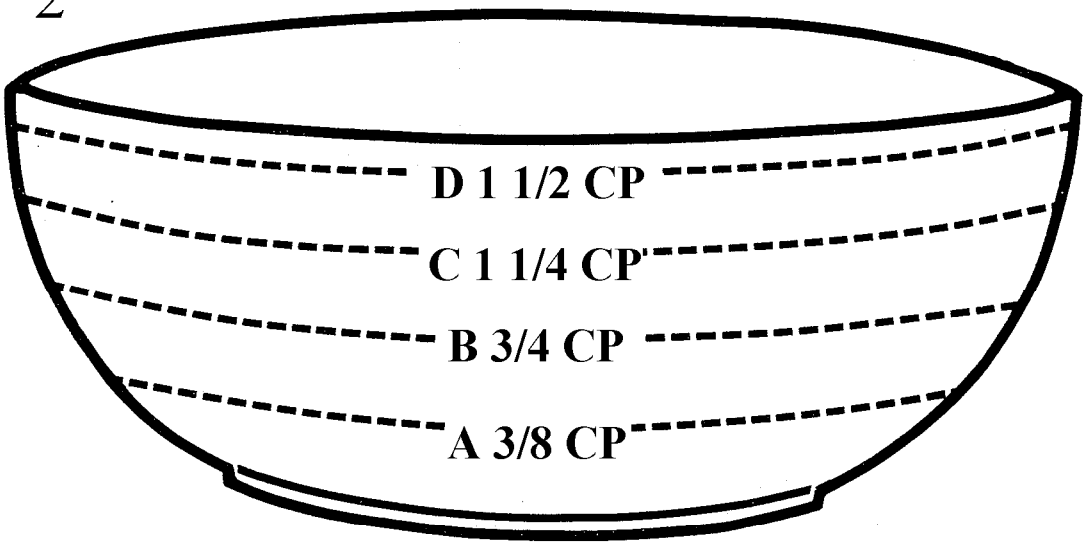


Bowls

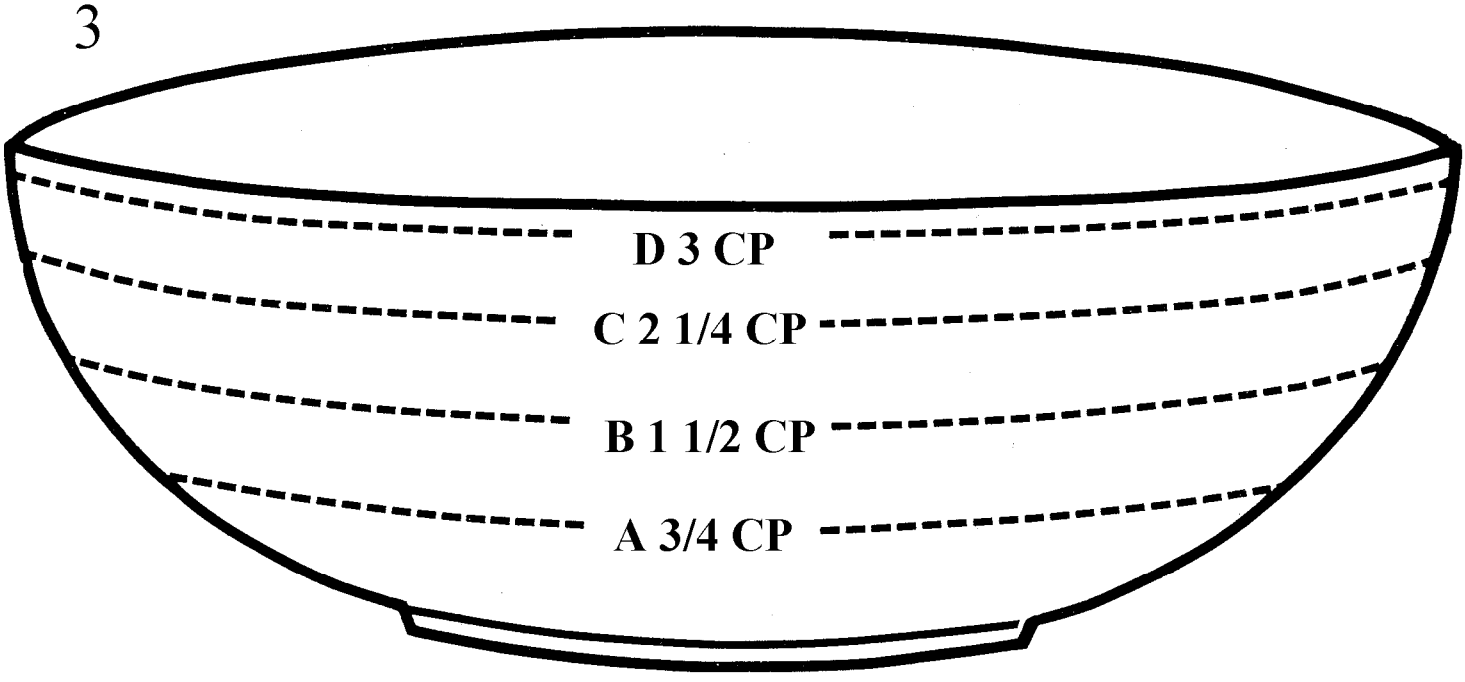
1

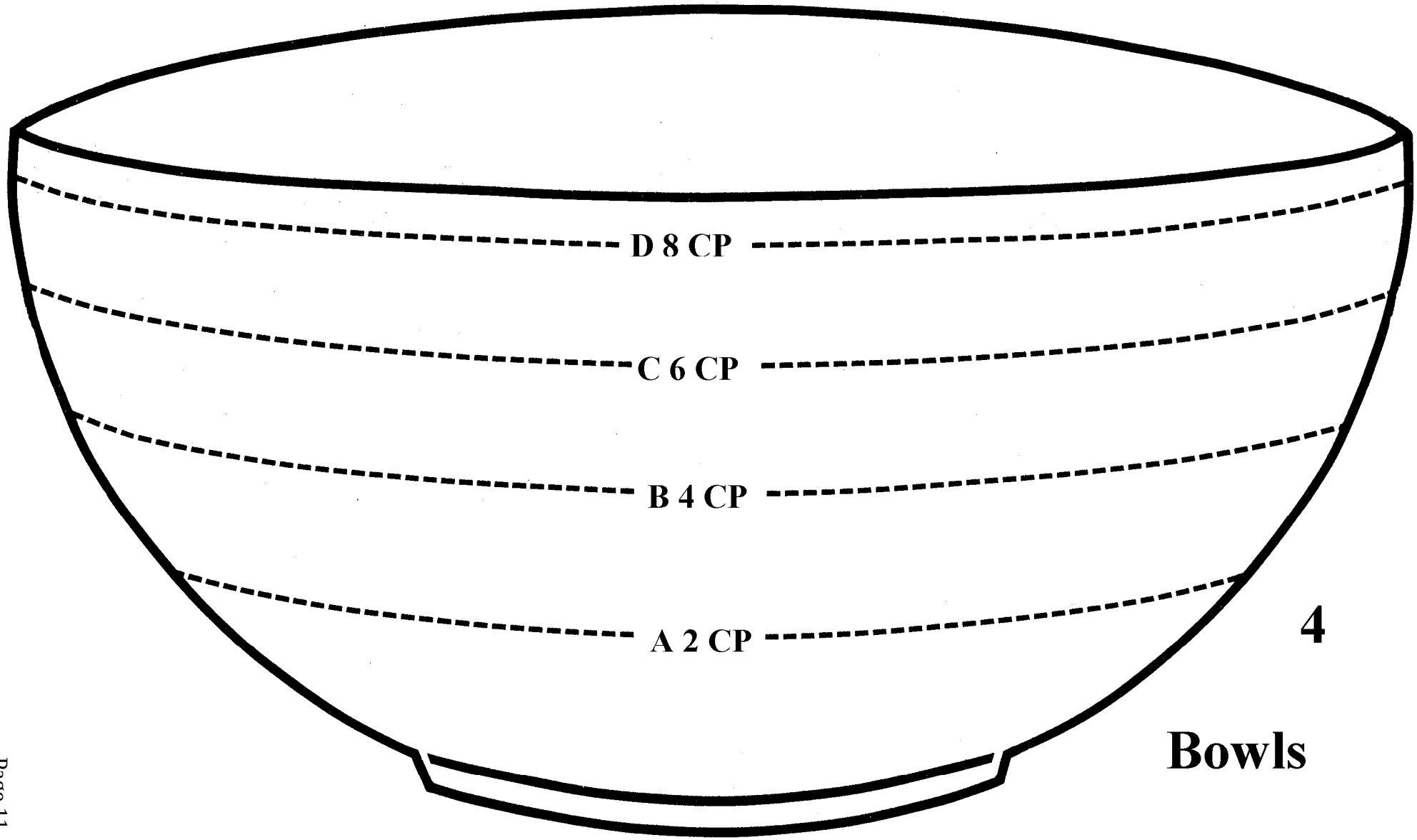

D 1/2 CP
C 3/8 CP
B 1/4 CP
A 1/8 CP

2


D 1 1/2 CP
C 1 1/4 CP
B 3/4 CP
A 3/8 CP

3

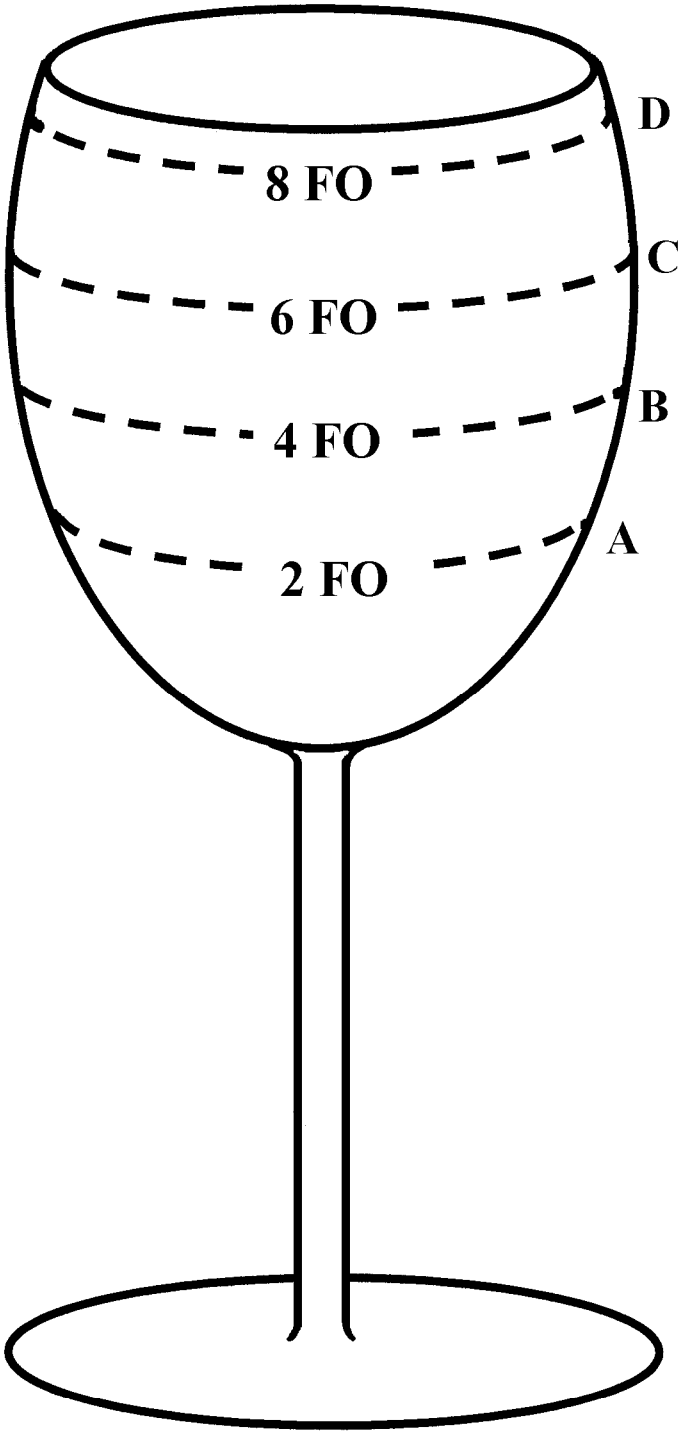

D 3 CP
C 2 1/4 CP
B 1 1/2 CP
A 3/4 CP



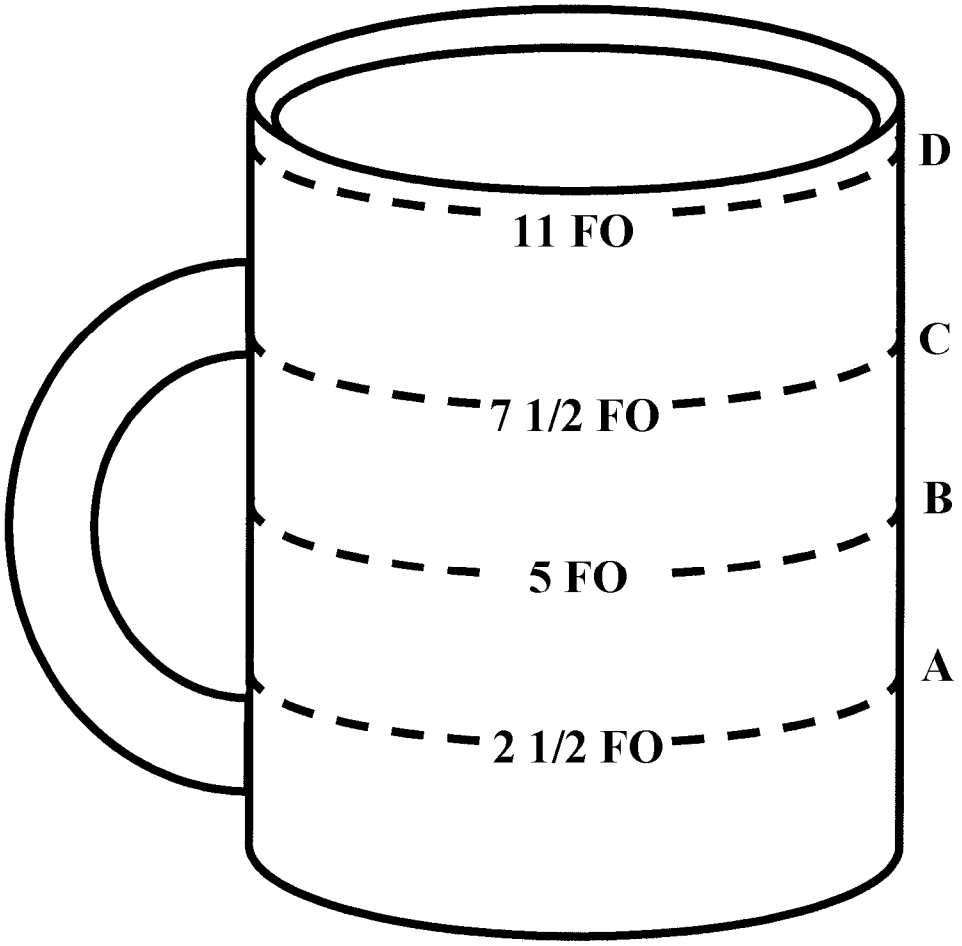
4

Bowls

Wine Glass



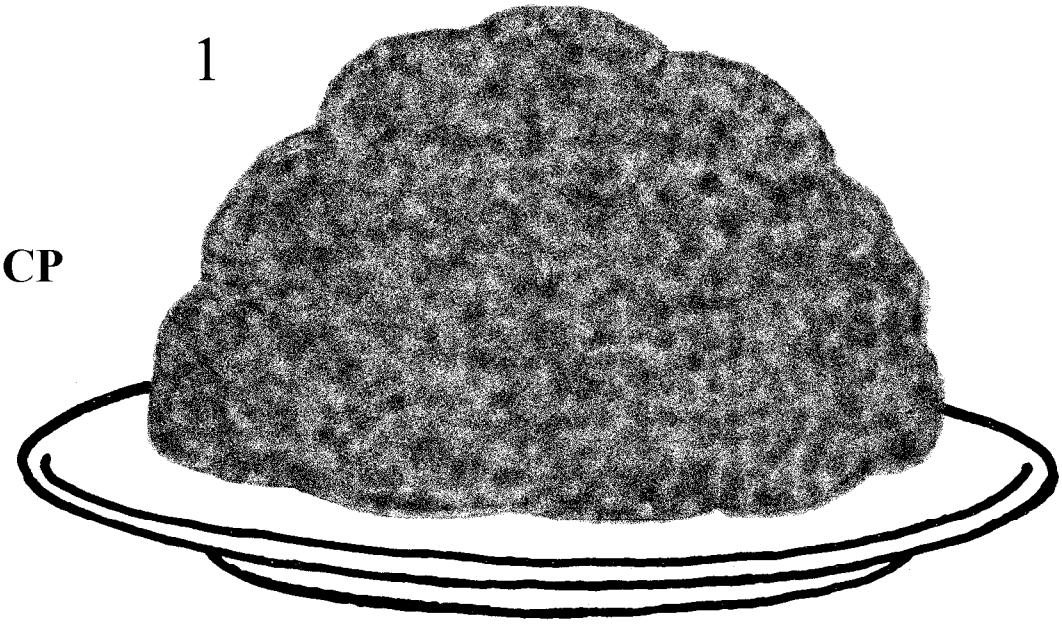
Mug



Mounds

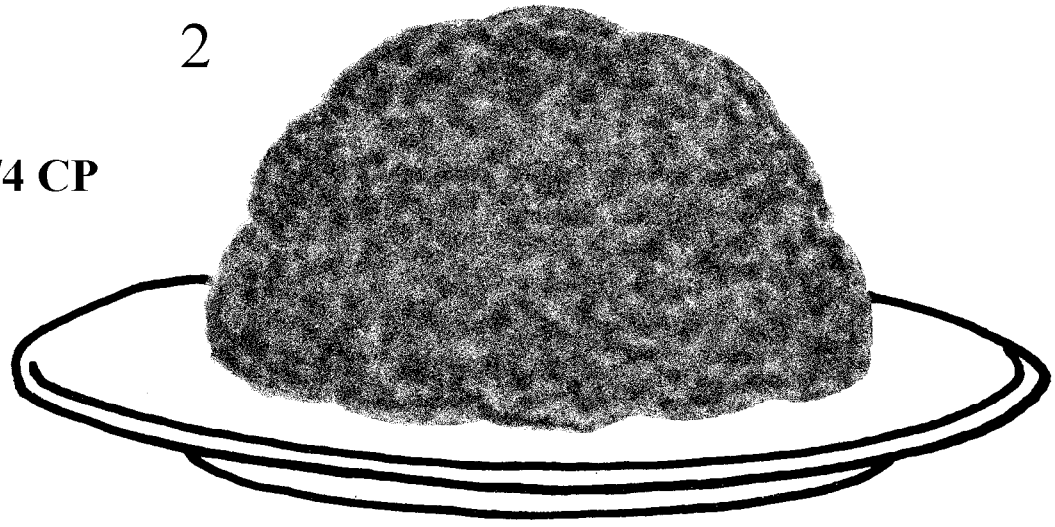
1

1 CP



2

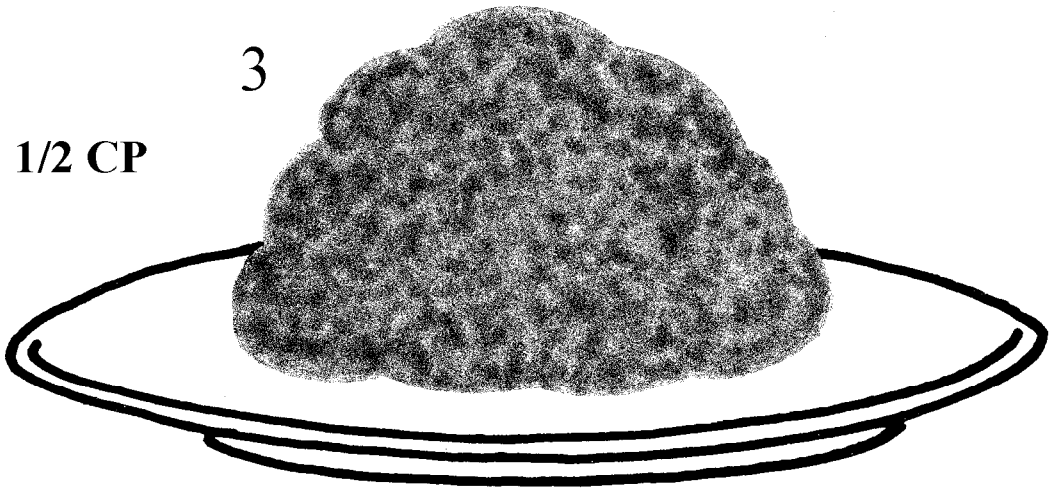
3/4 CP



Mounds

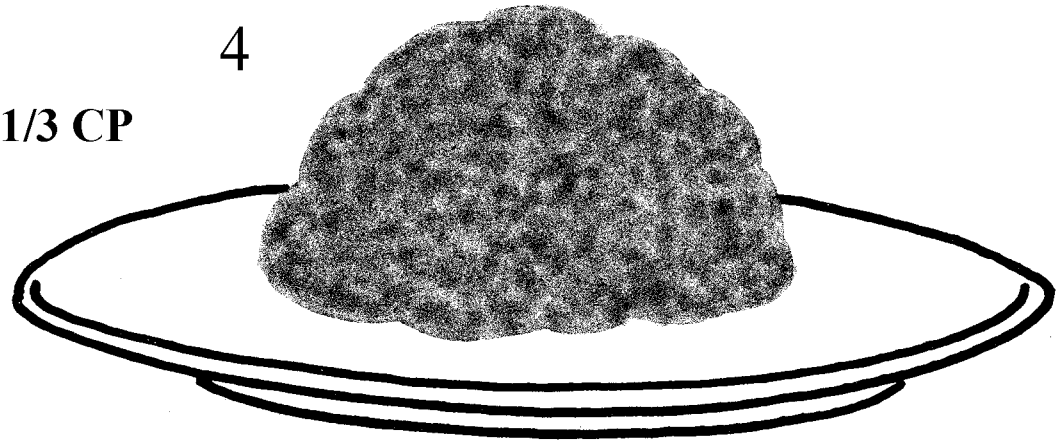
3

1/2 CP



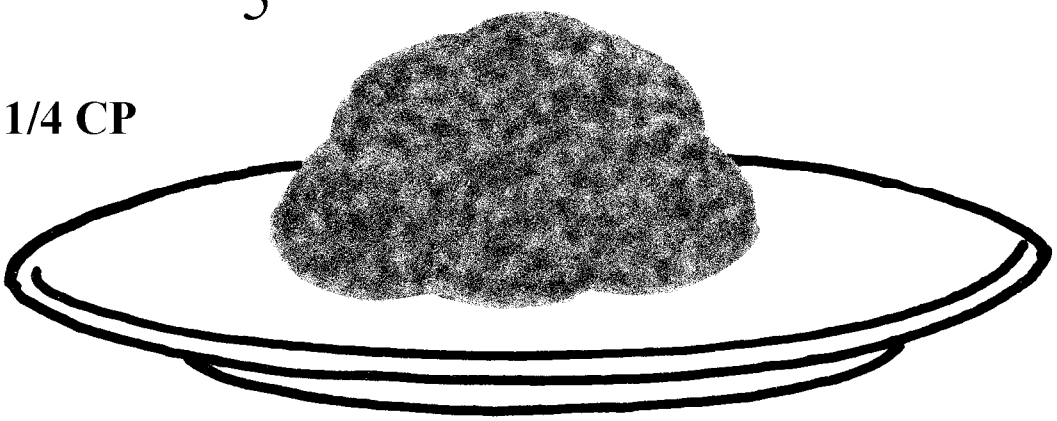
4

1/3 CP



5

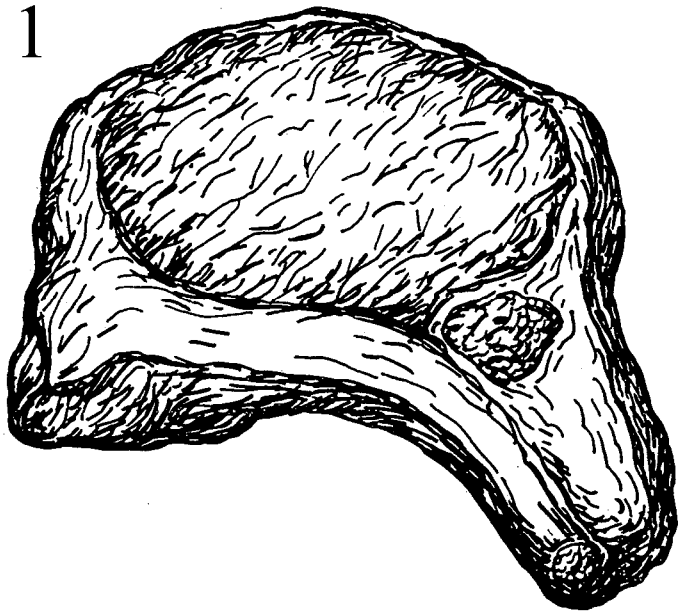
1/4 CP



Meats

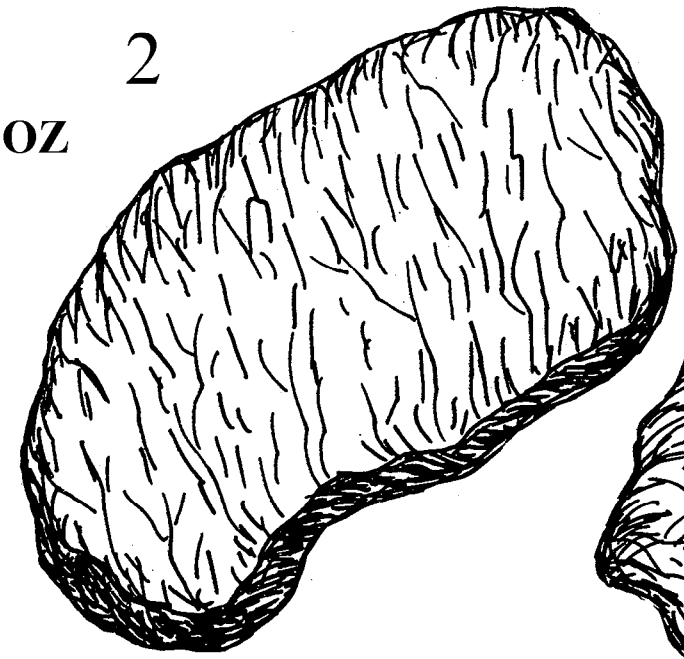
1

3 OZ



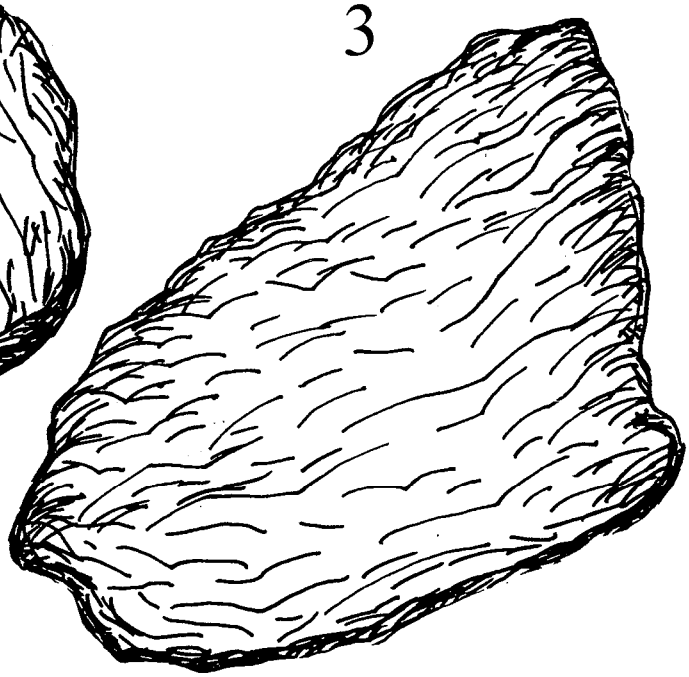
2

3 OZ

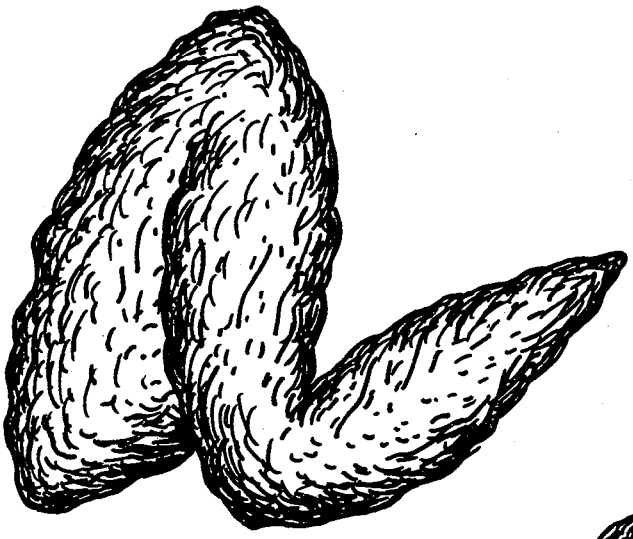


1 1/2 OZ

3

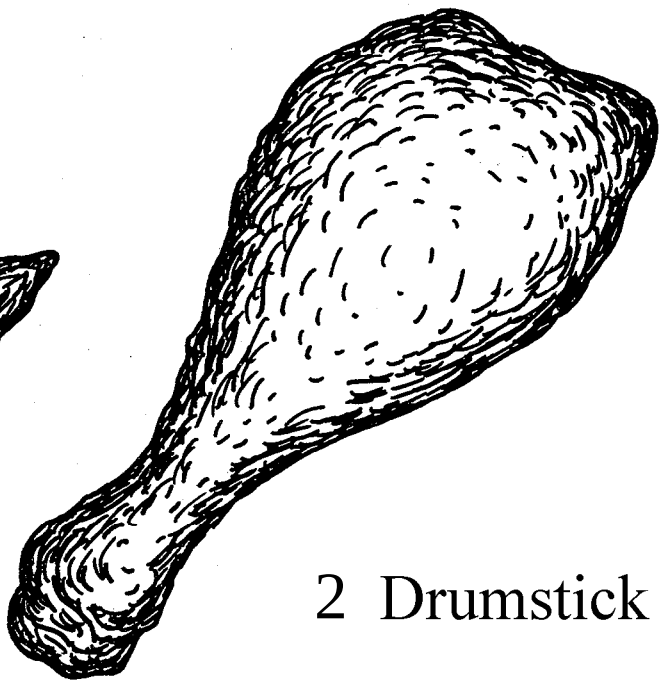


Chicken



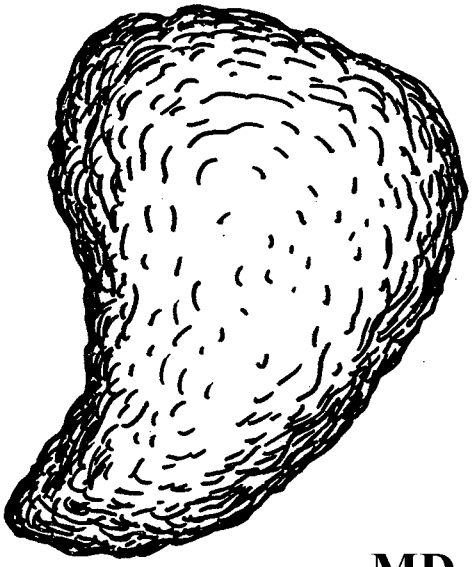
1 Wing

MD



2 Drumstick

MD



3 Thigh

MD

4 Breast

MD

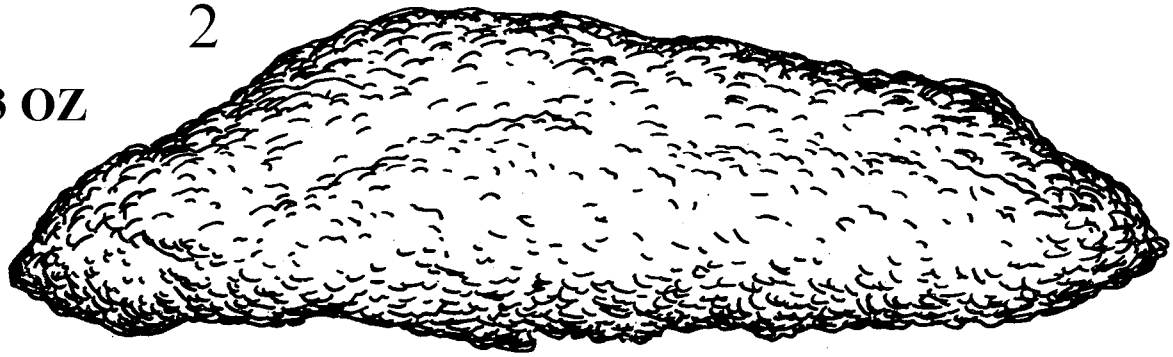
Fish

1

2 OZ

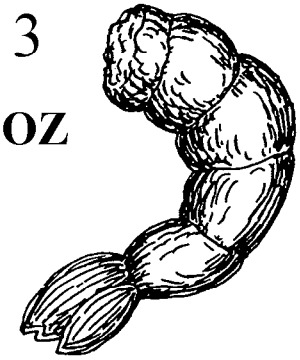
2

3 OZ



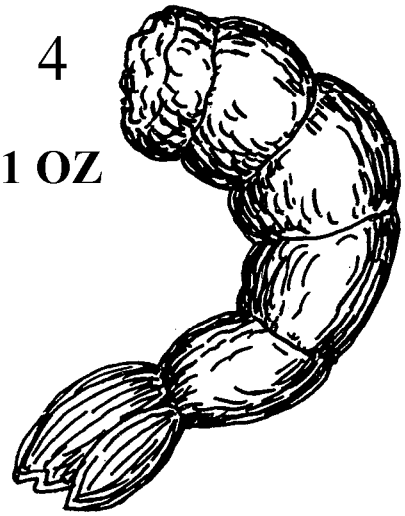
3

1/2 OZ



4

1 OZ



Adapted from: Van Horn LV, Stumbo P, Moag-Stahlberg A, Obarzanek E, Hartmuller VW, Farris RP, Kimm SY, Frederick M, Snetselaar L, Liu K. The Dietary Intervention Study in Children (DISC): dietary assessment methods for 8- to 10-year-olds. J Am Diet Assoc. 1993 Dec;93(12):1396-403.
Modified by Alejandra Valencia, Mary Stevens, Nutrition Coordinating Center, University of Minnesota for the Hispanic Community Health Study, Study of Latinos, 2007.

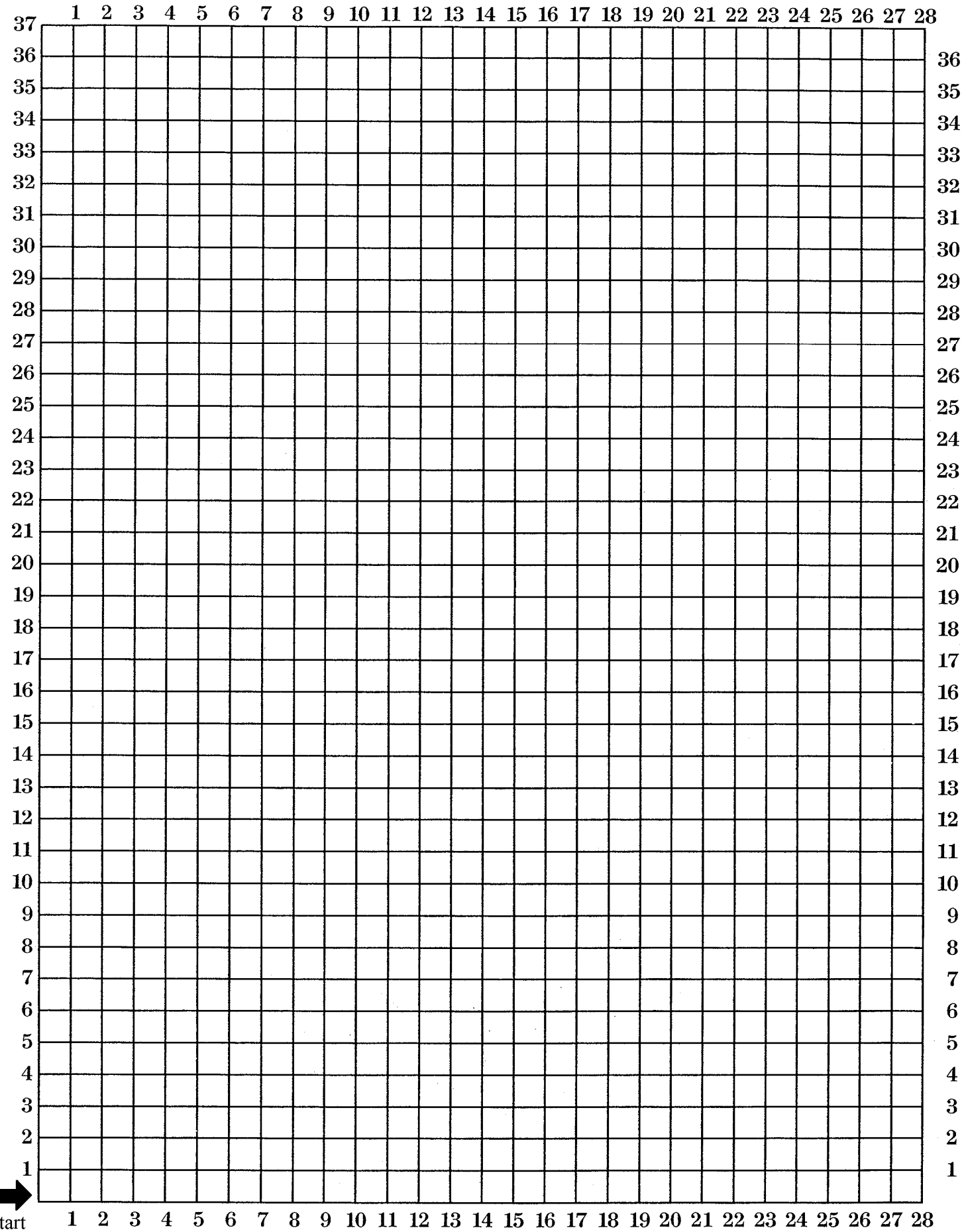
Food

Amounts

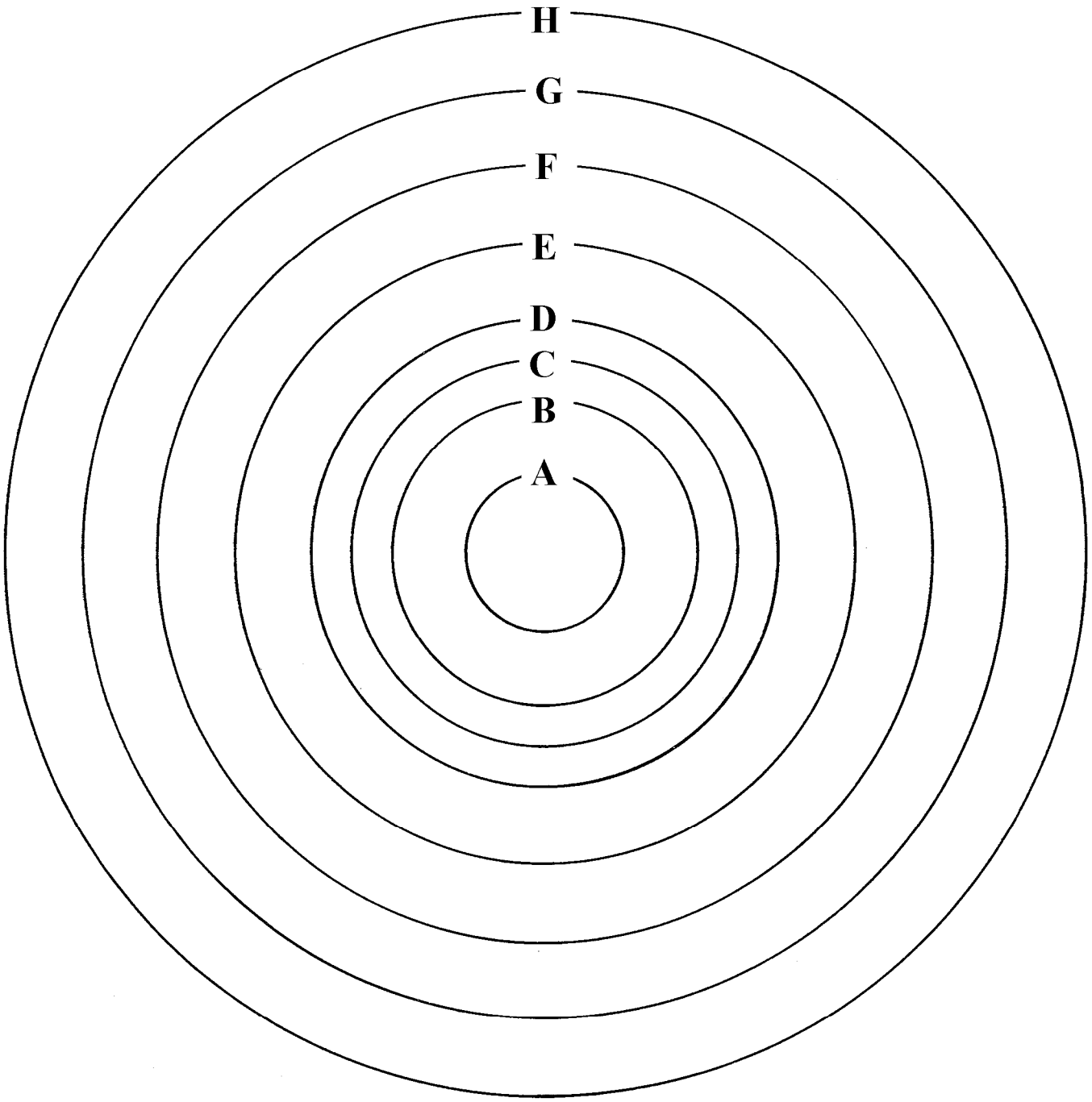
Booklet

Please, keep this near your phone.

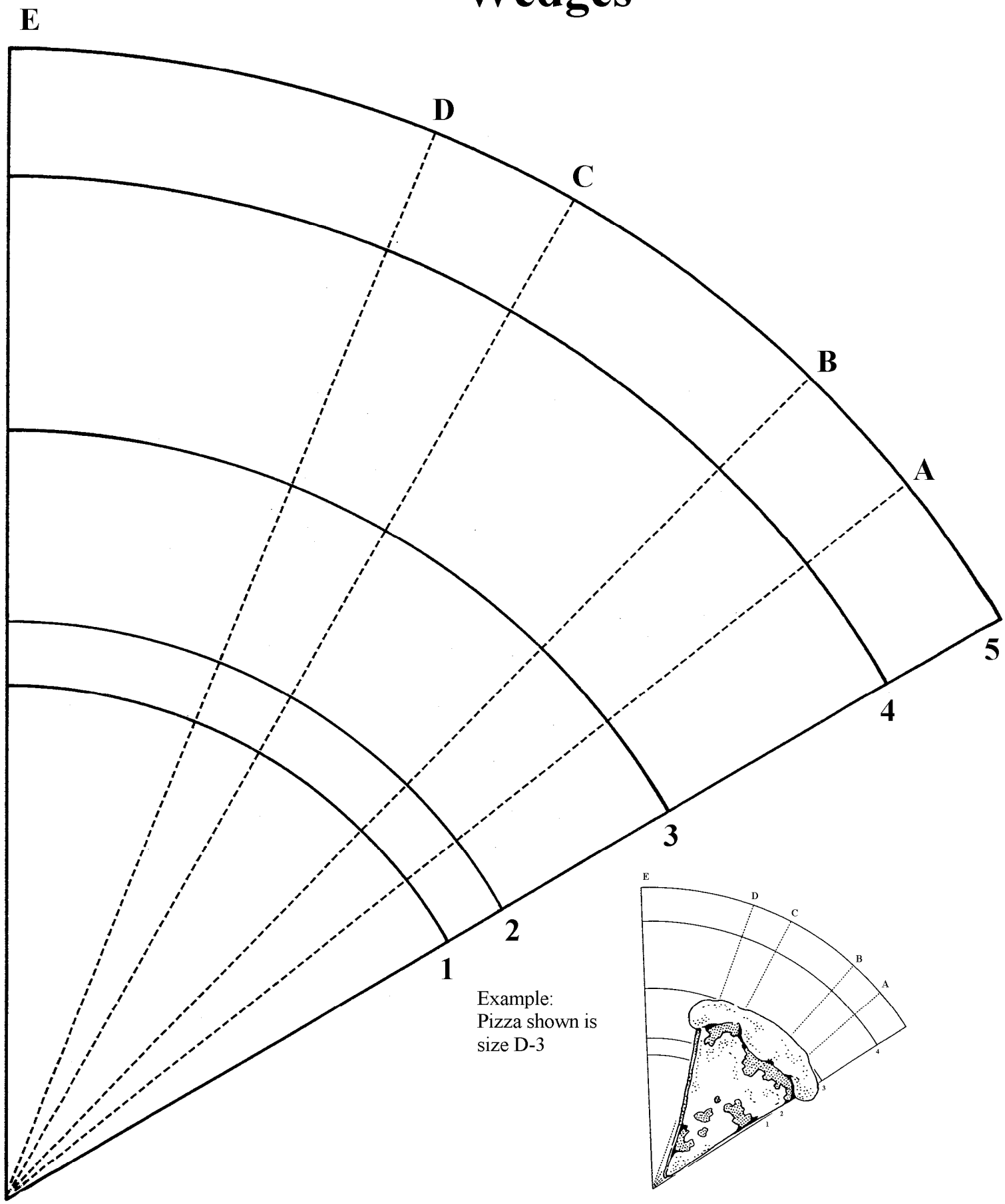
Squares and Rectangles



Circles

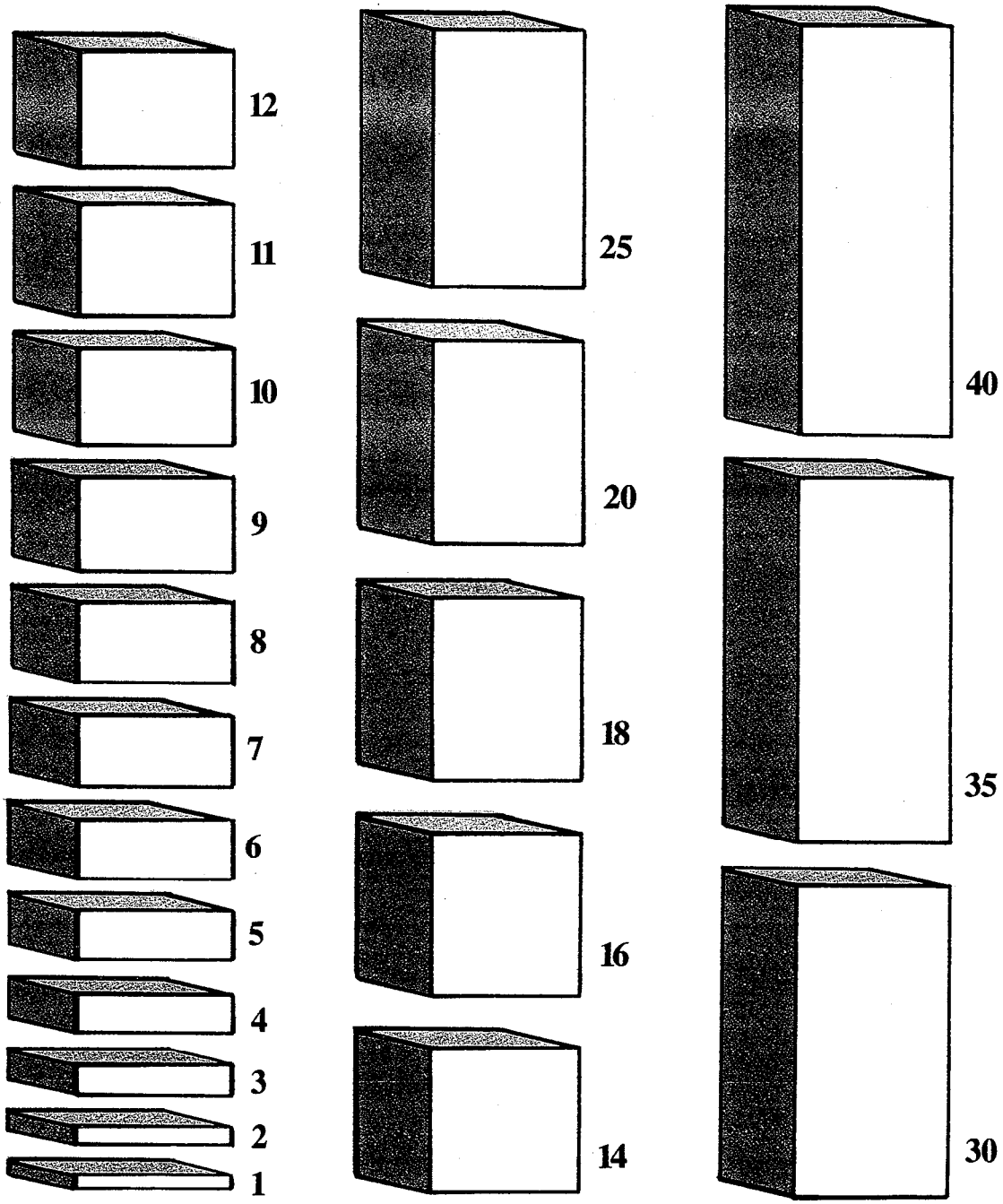


Wedges

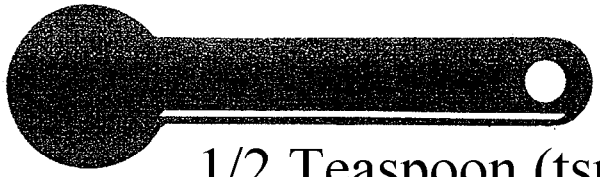


Example:
Pizza shown is
size D-3

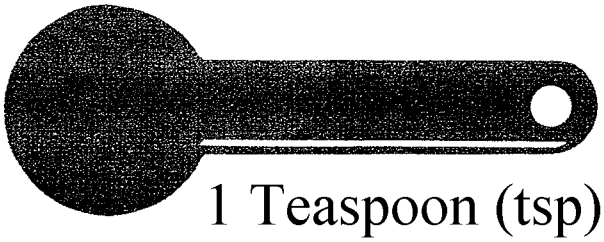
Thickness



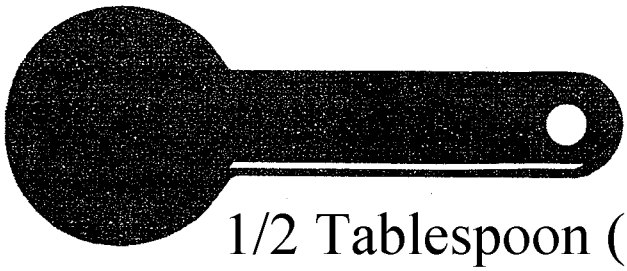
Measuring Spoons



1/2 Teaspoon (tsp)



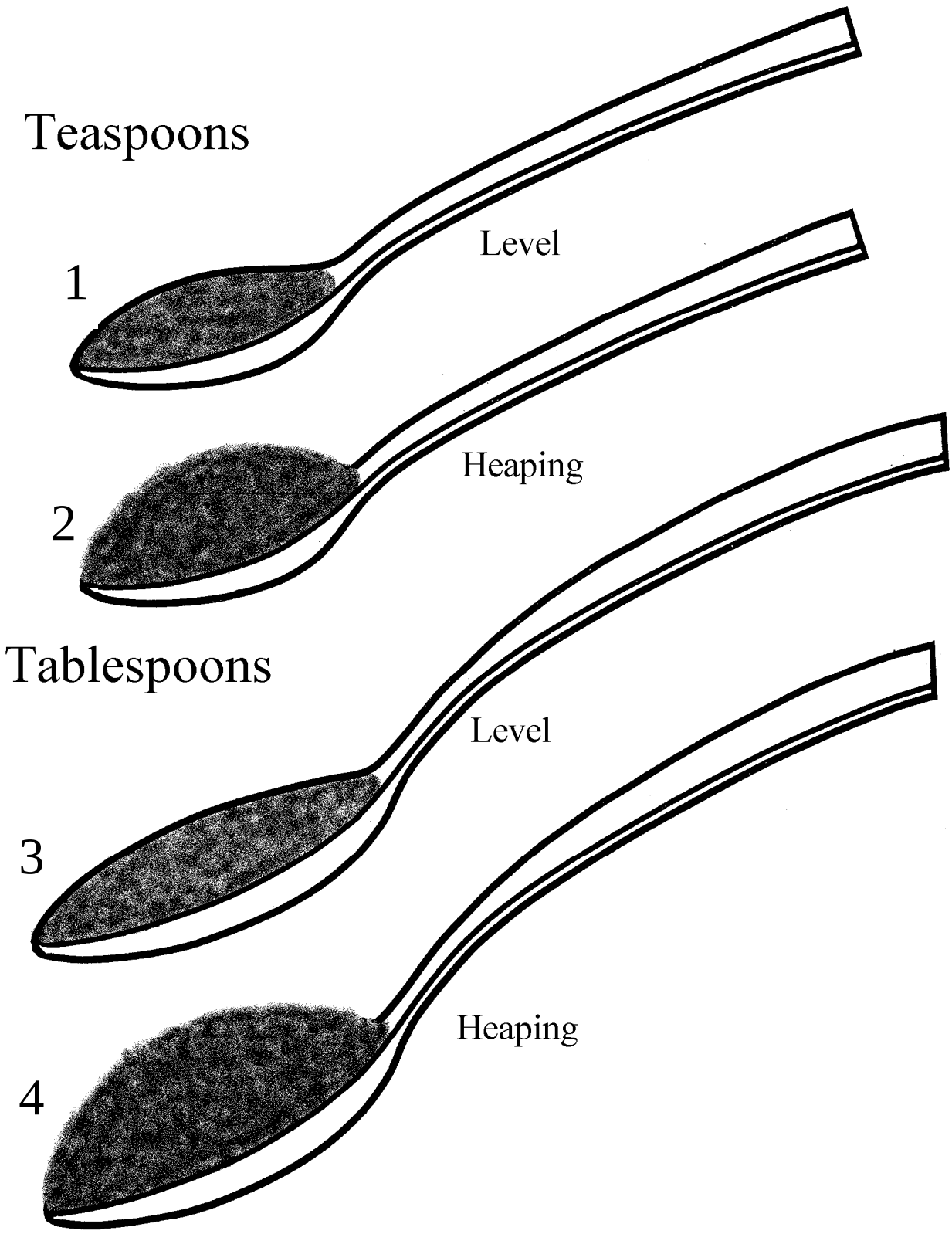
1 Teaspoon (tsp)



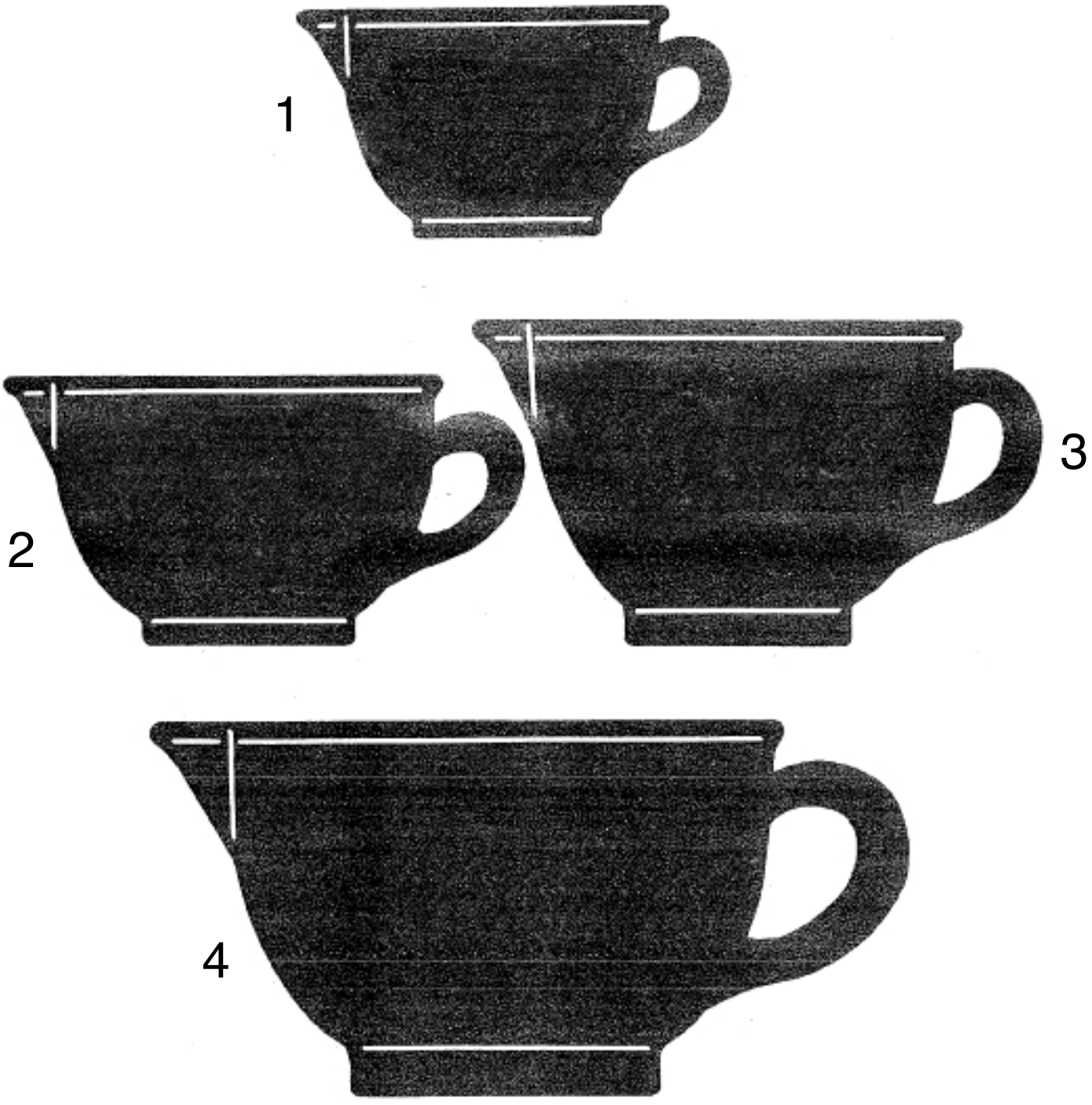
1/2 Tablespoon (Tbsp)

1 Tablespoon (Tbsp)

Eating and Serving Spoons

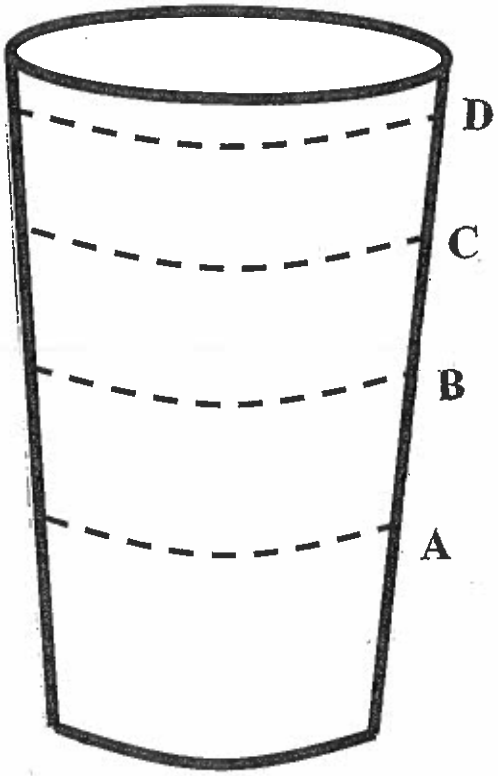


Measuring Cups

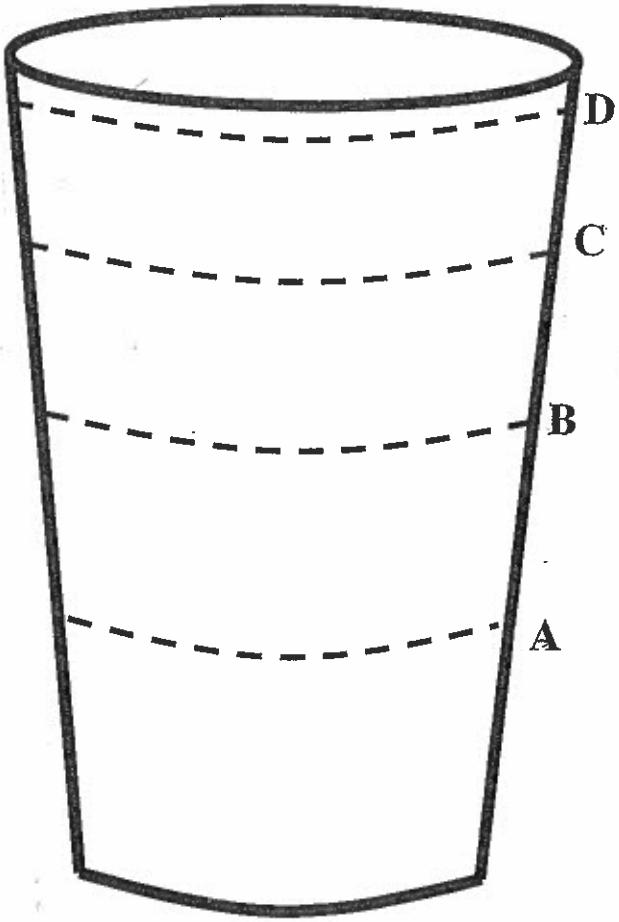


Glasses

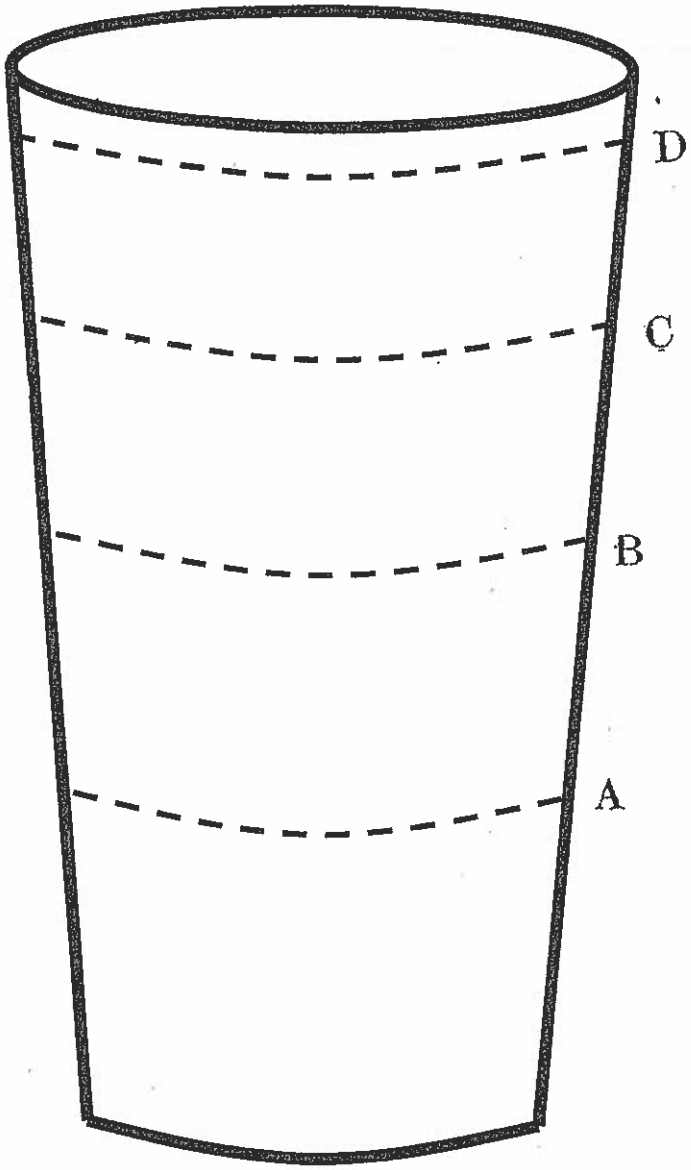
1



2

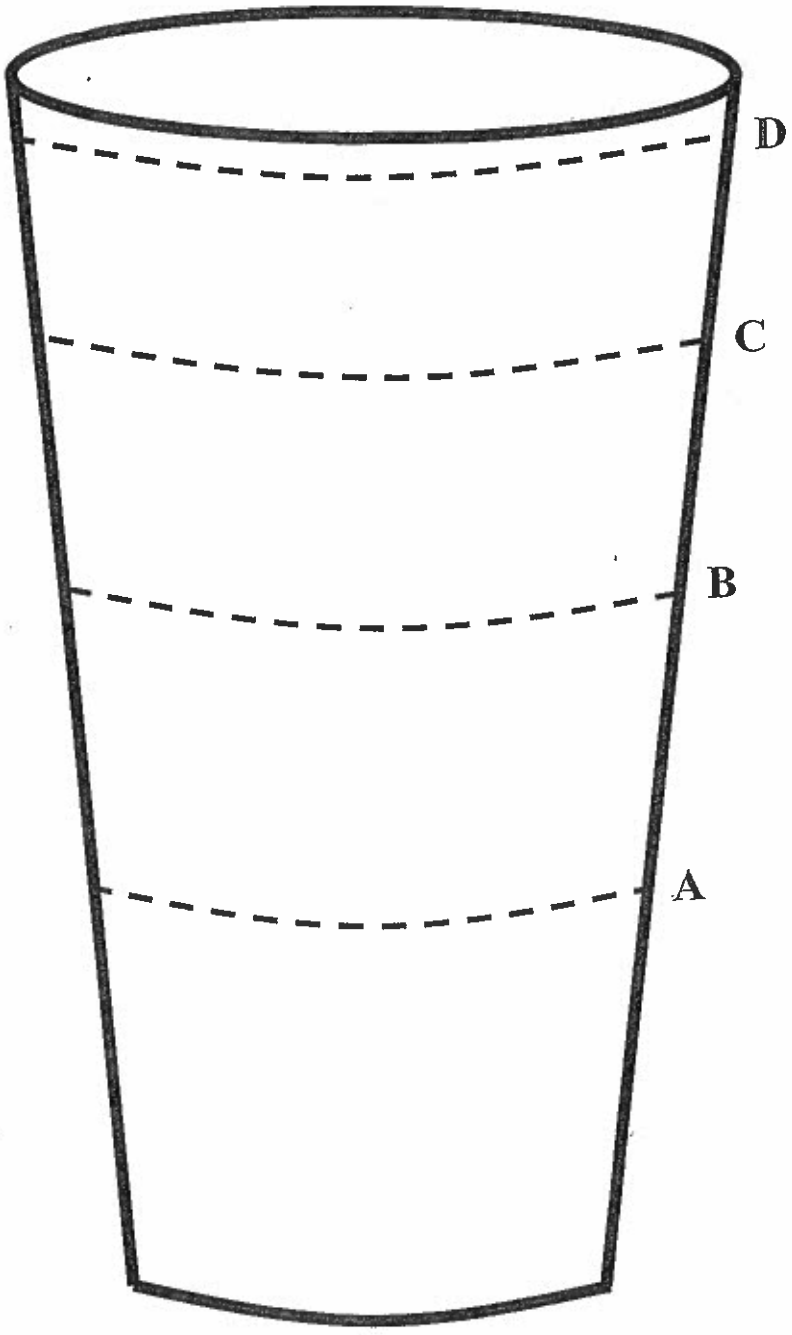


3



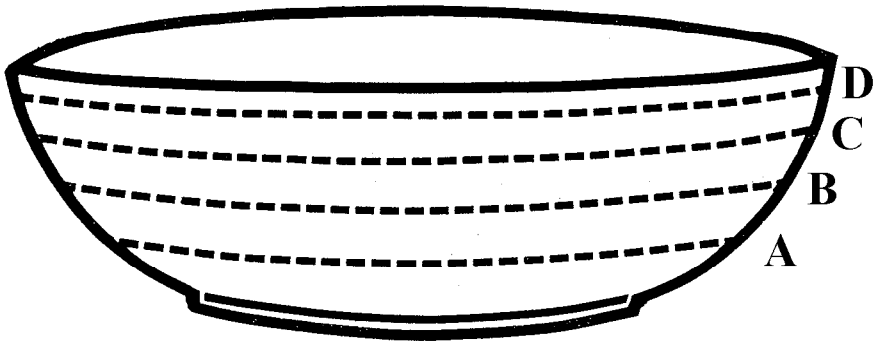
Glasses

4

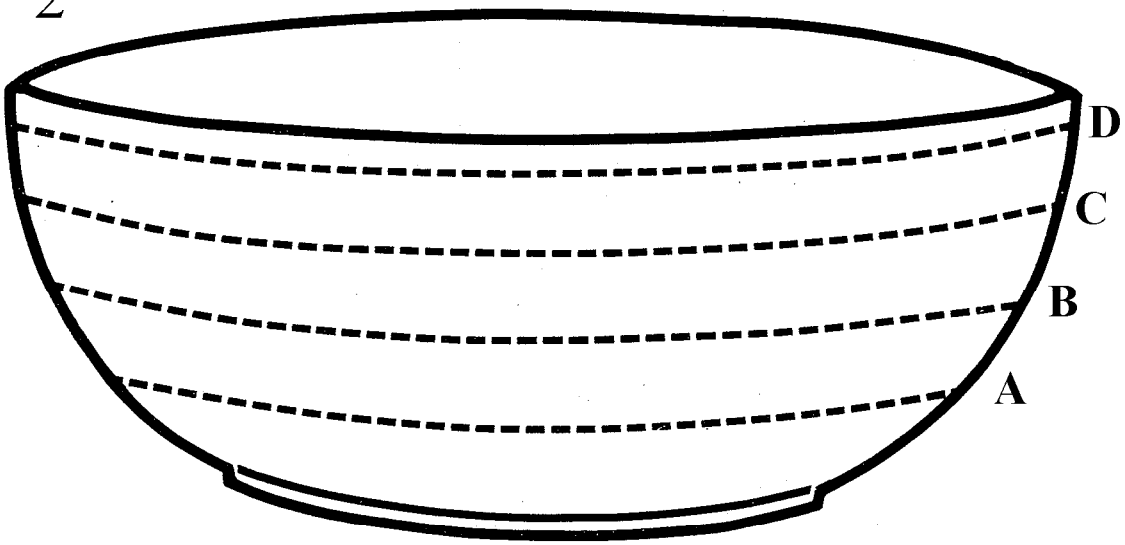


Bowls

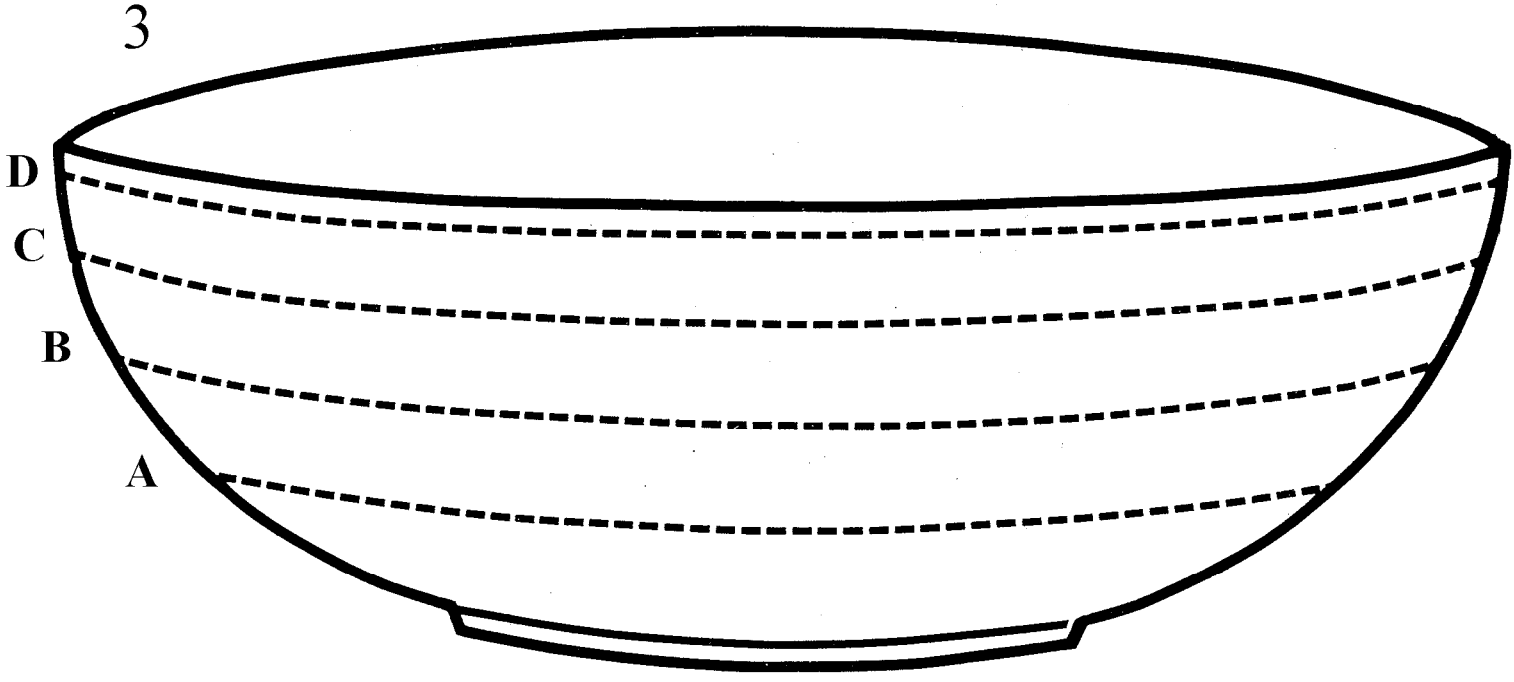
1

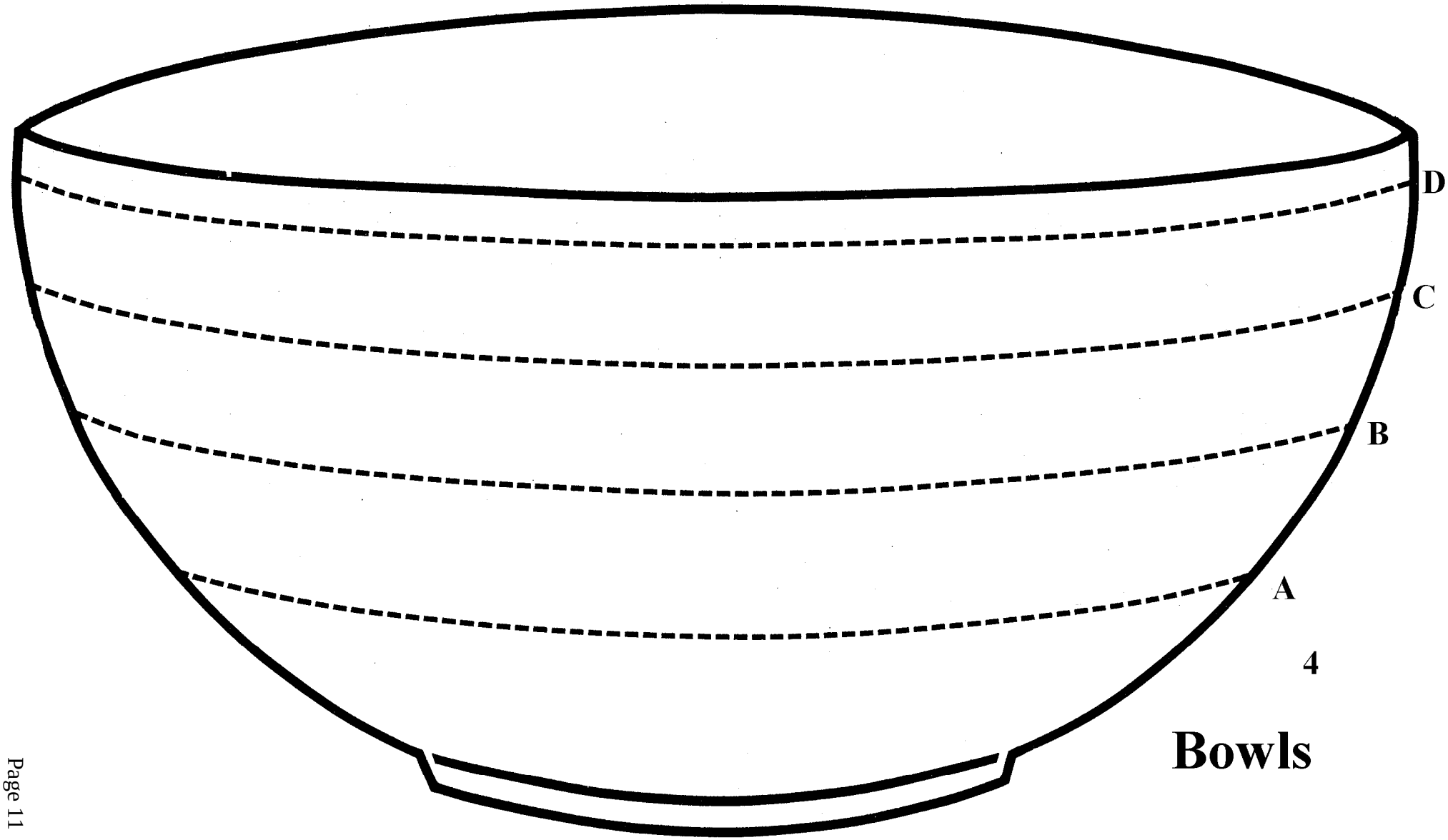


2



3

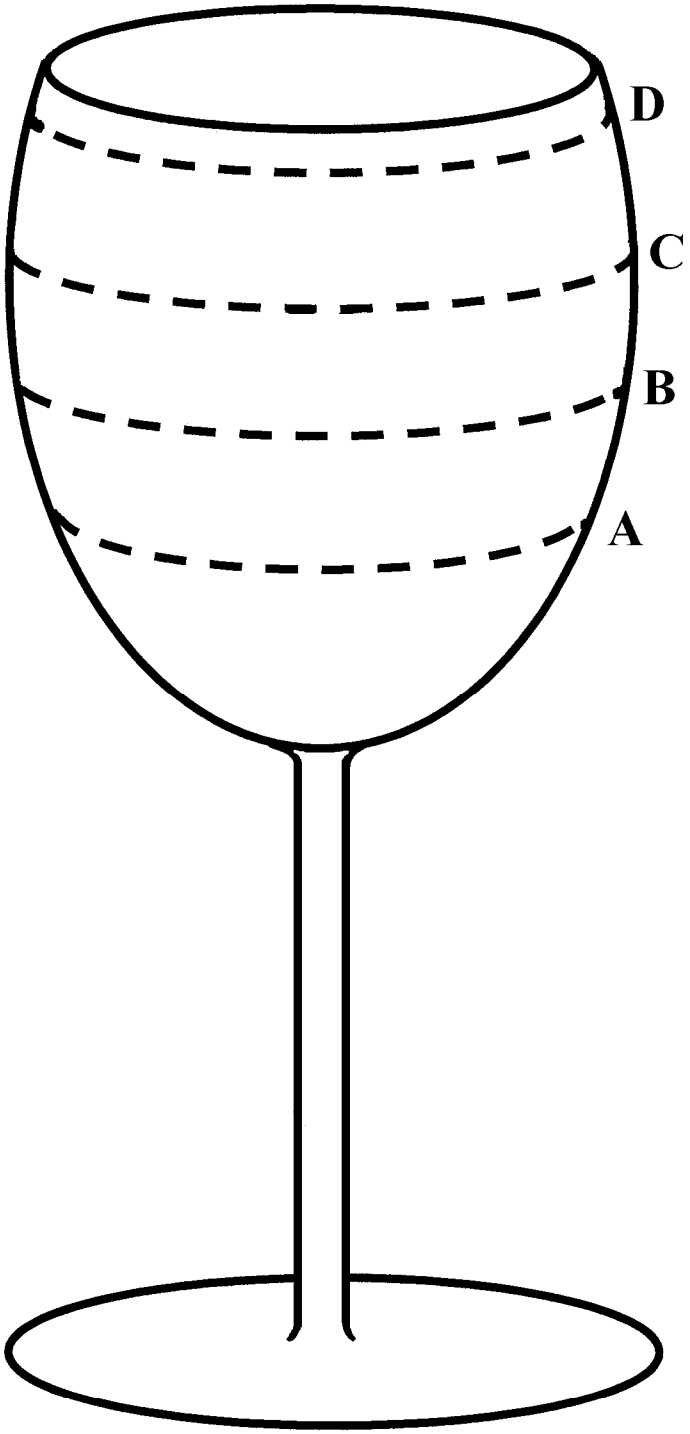




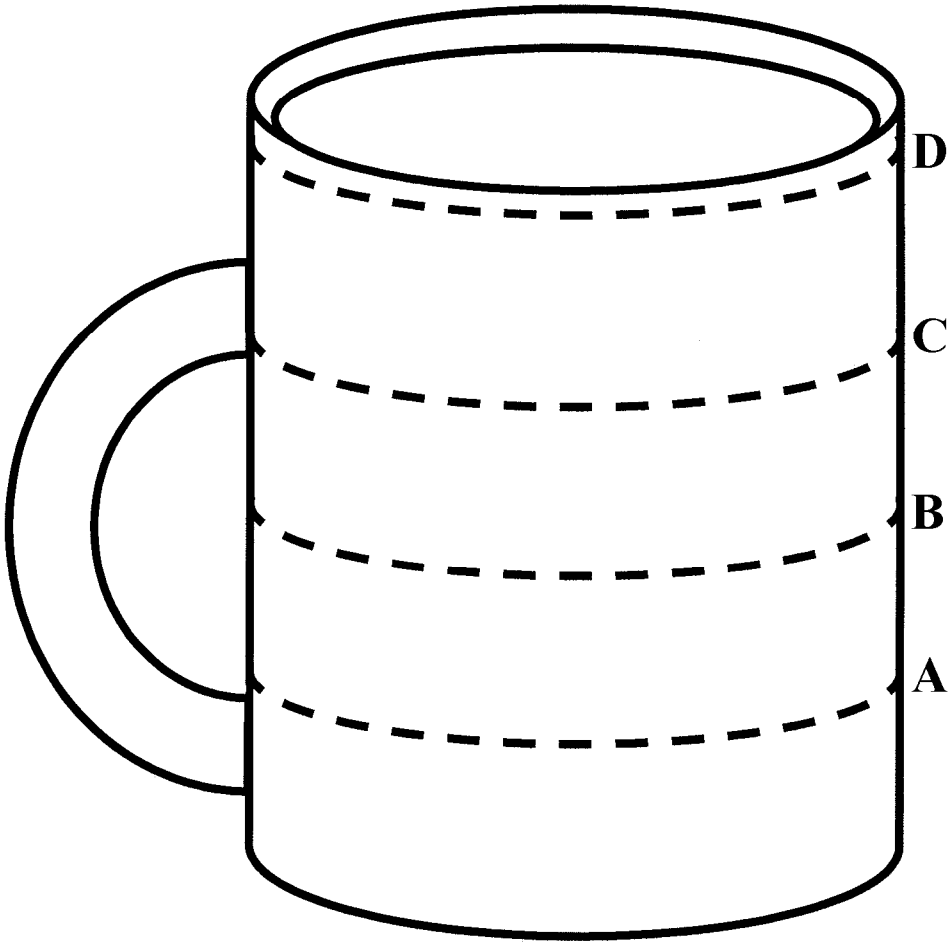
4

Bowls

Wine Glass

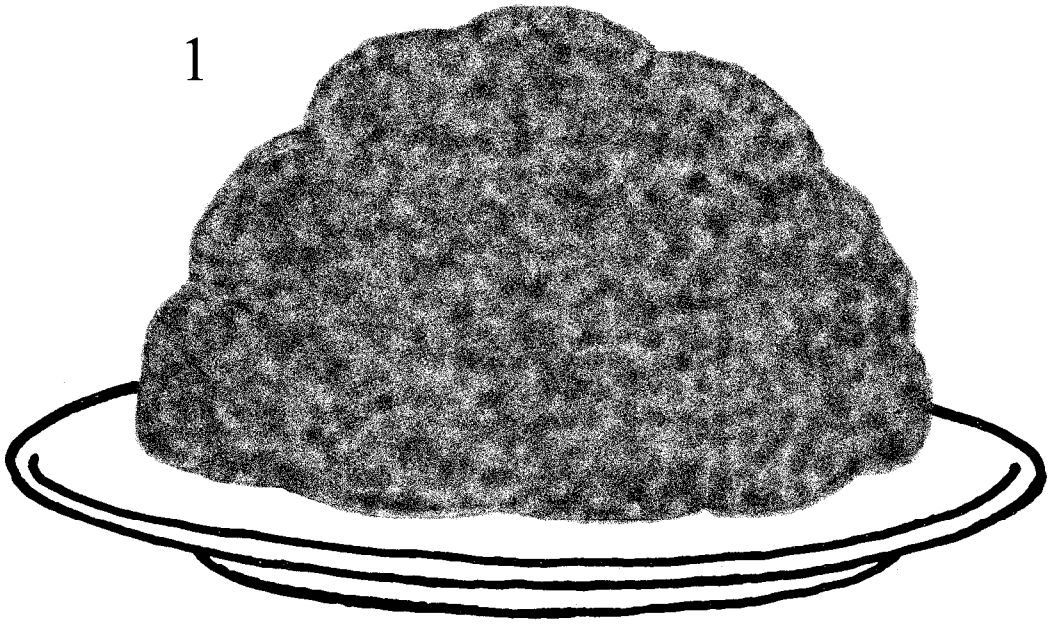


Mug

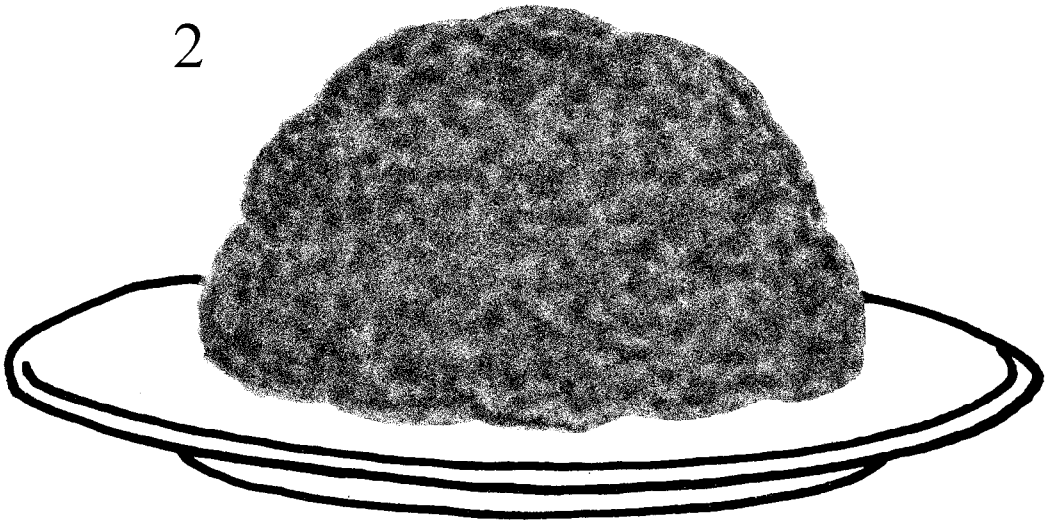


Mounds

1

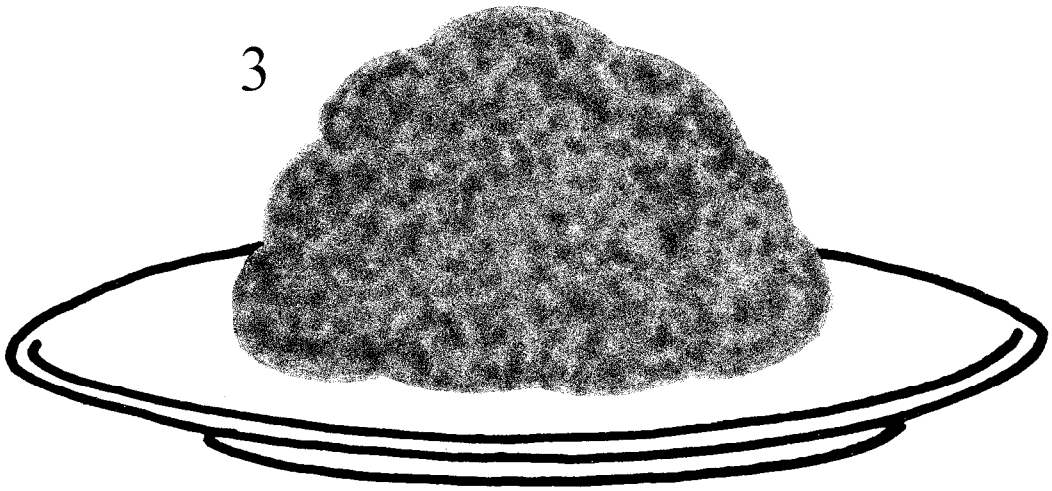


2

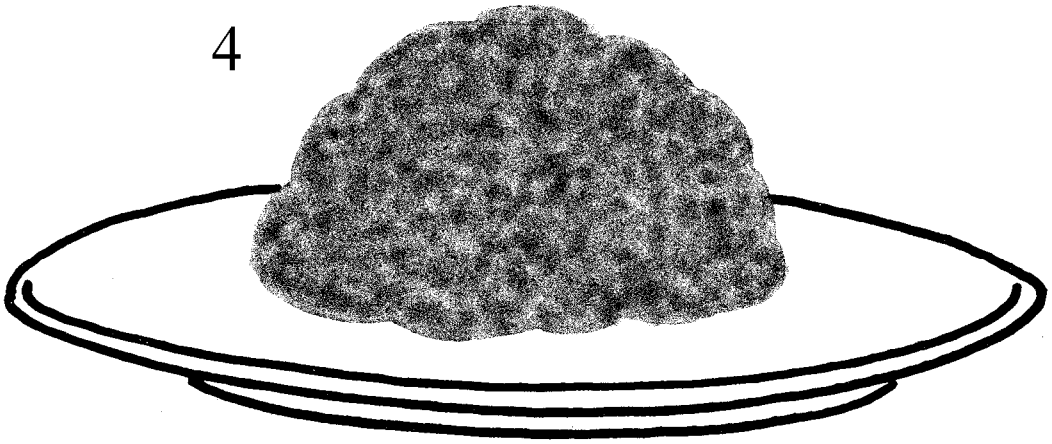


Mounds

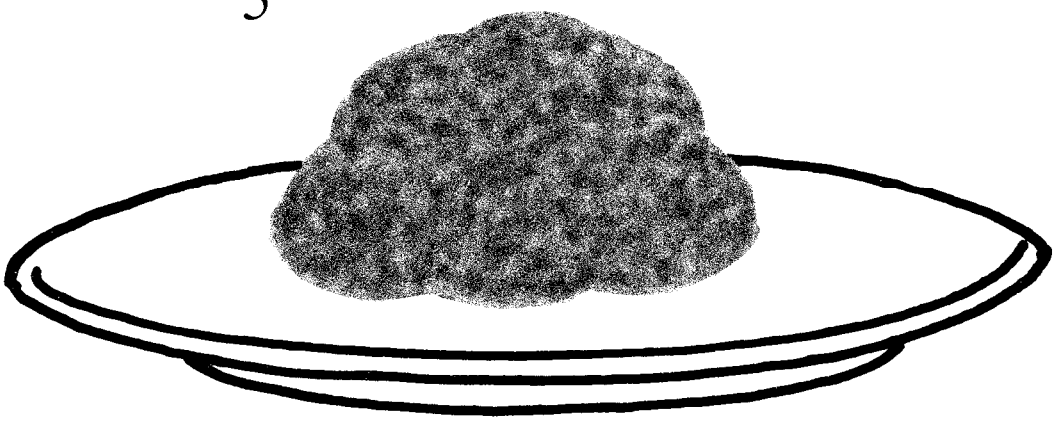
3



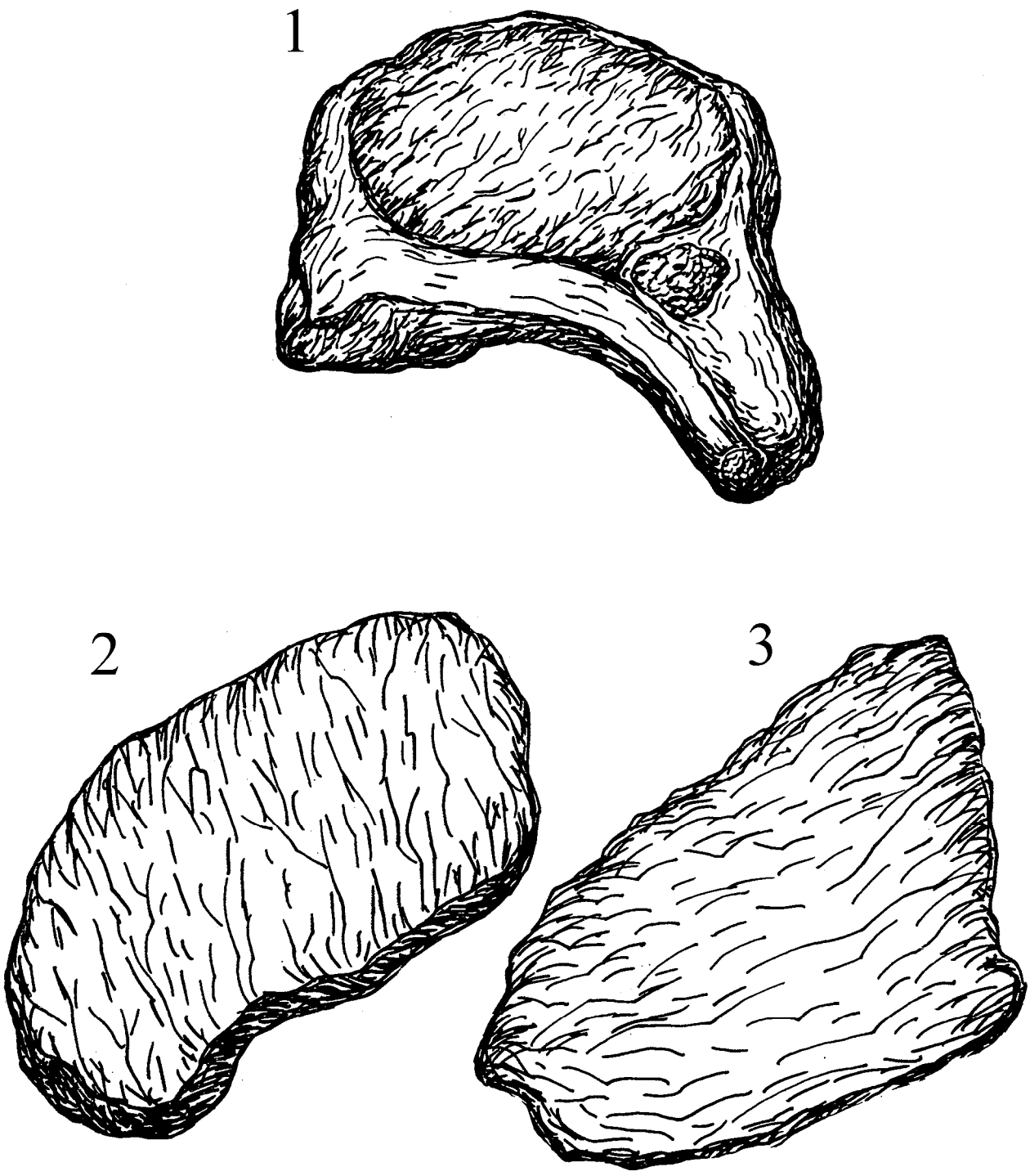
4



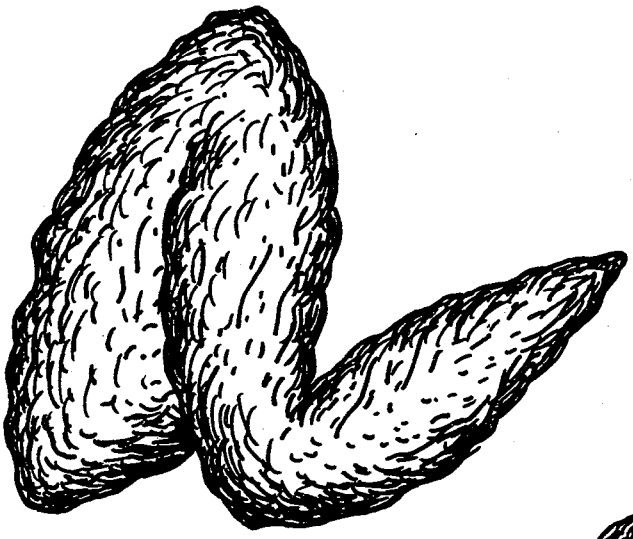
5



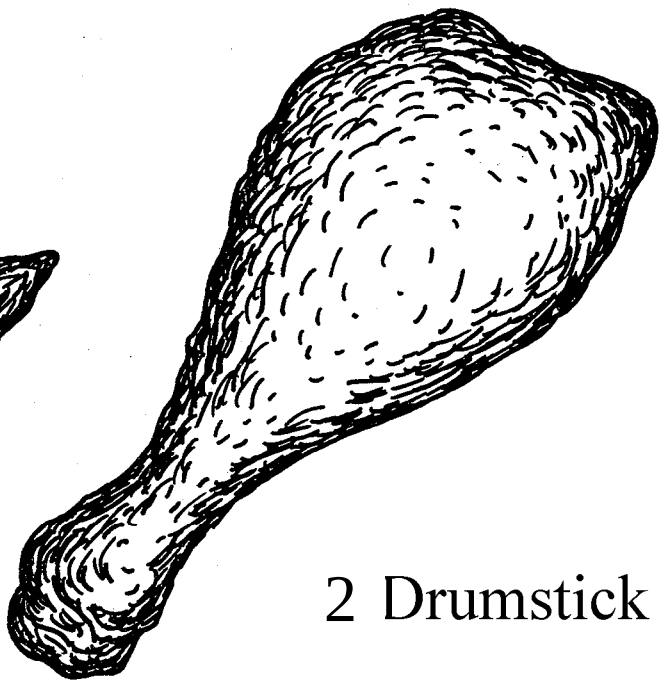
Meats



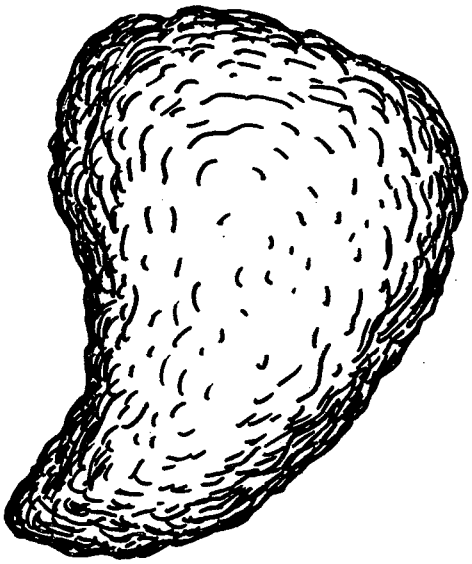
Chicken



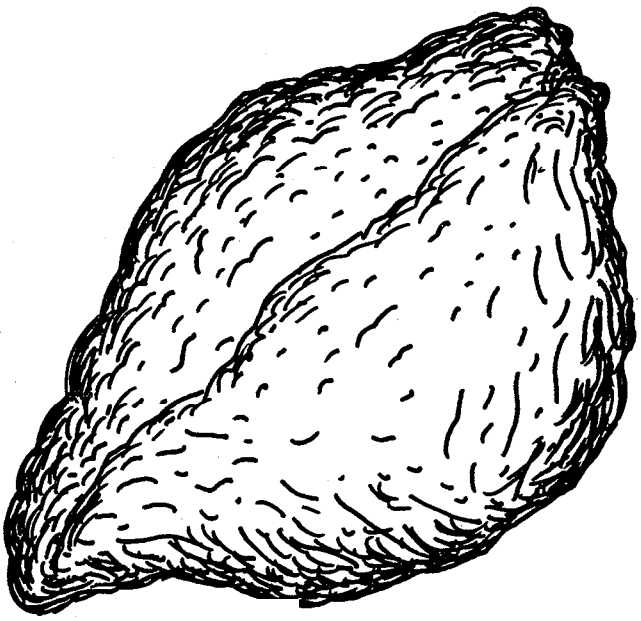
1 Wing



2 Drumstick



3 Thigh

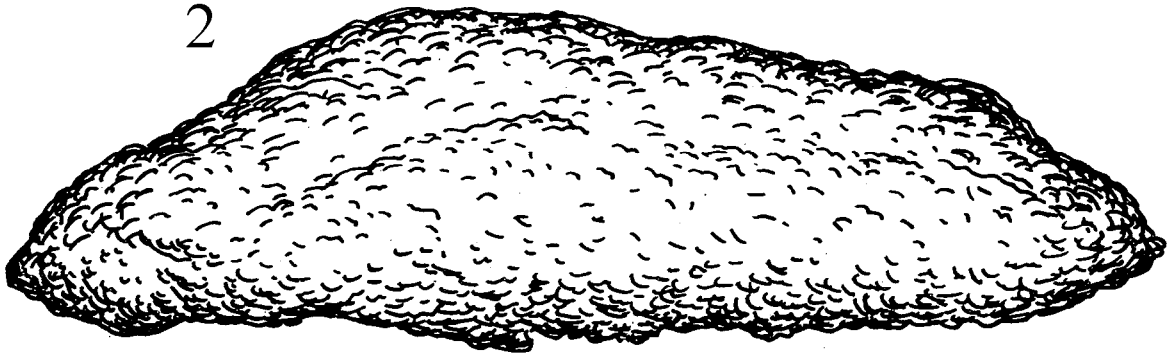


4 Breast

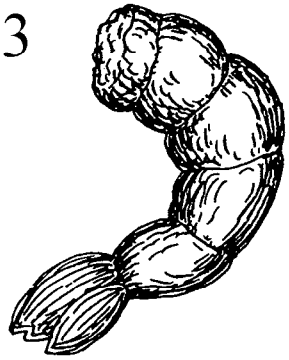
Fish

1

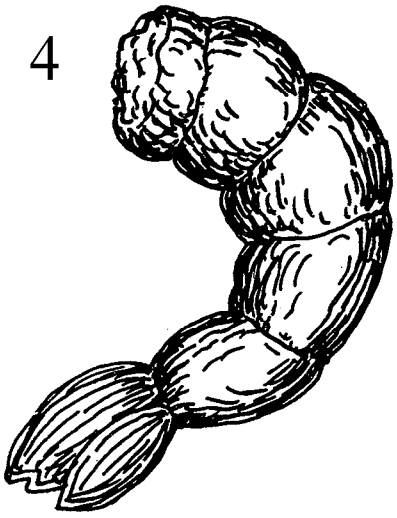
2



3



4



Adapted from: Van Horn LV, Stumbo P, Moag-Stahlberg A, Obarzanek E, Hartmuller VW, Farris RP, Kimm SY, Frederick M, Snetselaar L, Liu K. The Dietary Intervention Study in Children (DISC): dietary assessment methods for 8- to 10-year-olds. J Am Diet Assoc. 1993 Dec;93(12):1396-403.
Modified by Alejandra Valencia, Mary Stevens, Nutrition Coordinating Center, University of Minnesota for the Hispanic Community Health Study, Study of Latinos, 2007.

Appendix 2.3. Food Checklist to be Completed During Visit (Case and Stanford only)

Interview ONE completed: _____ Coptr ID: _____

Date of Interview: _____ Randomized ID: _____

Interviewer Name: _____ referring to: _____

Did the mother complete information for the first recall? Yes No Refusal

---

Date: _____ Randomized ID: _____

Food Checklist:

1. What type of milk does your child consume at home?
2. What other drinks does your child consume at home? (probe for diet vs. regular)
3. What types of soda does your child usually consume? (diet vs. regular)
4. Do you regularly buy any low-fat products? Yes No
   If yes, list the low fat products that are currently in the home.
5. What oil(s) are currently in your home?

   Which of these oils do you use for frying?
6. Do you regularly buy reduced sodium products? Yes No
   If yes, list the low sodium products that are currently in your home.
7. Does your child usually eat school lunch or school breakfast? Yes No
   Which meals do they eat at school?

Appendix 2.4. Food Record for Meals Consumed at School or Day Care (Minnesota and Vanderbilt only)

24-Hour Diet Record Form for Caregivers

Dear Caregiver: Please use this form to write down all of the foods and drinks that _____ has today.

Today's Date:_____ Day of Week: Sun Mon Tues Wed Thurs Fri Sat

Meal or Snack Time	What is the Name of the Food or Drink? (Please include all foods and drinks, including water)	How Much Did the Child Have? (Please tell us how many pieces, slices, servings, packets, cups, teaspoons, tablespoons, ounces, etc.)	Can you Describe this Food or Drink Item for us? (Please tell us brand name, how it was prepared, or if you put anything on it like gravy, sauce, dressing, butter or sour cream)

May we contact you if we have any questions about this diet record? If yes, please provide contact information:

Phone: _____ **Email:**_____

Appendix 2.5. Sample NDSR Introduction and Food Amount Booklet Script

During this part of your visit, I will be asking you about what you (your child) ate and drank yesterday, and I'll enter the information in my computer. Remember that there are no right or wrong answers. Whatever you (he/she) ate is okay.

What we'll do first is make a list of the foods and beverages you (your child) had from midnight the day before yesterday (insert the day of the week) until midnight last night. This includes all meals, snacks, beverages, tap water, as well as tastes or samples of foods.

I'll need you to tell me the approximate time you (your child) had each item. For example 'at 6 am I (my child) had this' or 'at 8 AM I (my child) had that'. We'll make a general list at first and then we'll go back and fill it in with more detail. Finally, we'll go through the list once more to make sure we haven't missed anything.

We have many ways to help estimate the amounts of food you (your child) had yesterday and I want to take a minute to show them to you."

Show and explain the Food Amounts Booklet and models.

We'll use the Food Amounts Booklet and the glasses, bowls, and other things I have here to help estimate the amount of foods and beverages you (your child) had yesterday.

You may use page 1, the squares and rectangles, to describe the size of a piece of cake, a brownie, or other food that is the shape of a square or a rectangle. Then you can use page 4, thickness, to tell me how thick the brownie was. If the brownie was frosted, just think about the brownie, not the frosting.

The circles on page 2 are used to estimate the size of foods like doughnuts, tortillas, and hamburger patties.

The wedges on page 3 are used to describe foods like a piece of cake, pizza, or pie. First you'll tell me how far from the tip the pie was and then how far over it was.

Pages 5, 6, and 7 are pictures of measuring utensils..

The glasses on pages 8 and 9 can be used to help you estimate amounts of beverages you (your child) consumed. We also have actual glasses to represent the ones in the Food Amounts Booklet. You can choose a glass that looks like one that you (your child) used yesterday. If it's available, the actual glass you (your child) used yesterday can be helpful. Next think about how much of the beverage was in the glass, for example, 'I had milk in a glass like number 3, filled to line C.'

Next let's look at the pictures of the bowls on pages 10 and 11. The smallest bowl, bowl 1, is very small and might be used in a restaurant to server salsa or a single scoop of ice cream. Bowl 4 is the largest bowl and might be used for foods that are often shared with others like popcorn, chips, or salad. Select the bowl that seems most like the one you (your child) used yesterday and then look at the lines to tell me how much you (your child) ate.

There is a mug on page 13.

The mounds on pages 14 and 15 are used to describe scoops or handfuls of food such as casseroles, ice cream, pretzels, or goldfish crackers.

Pages 16, 17, and 18 are pictures of meats and fish.

I will be helping you with describing amounts when we get to that part of the interview. Do you have any questions?

Take a moment to think about yesterday, what you did, where you went and so forth. Thinking about the day can help you remember what you did yesterday and when you ate or drank.

Now let's begin.

Appendix 2.6. Sample In-person Interview Script

Start the interview with:

I am going to ask you to tell me what you ate and drink in the past 24 hours.

The two primary prompts used throughout the interview are:

Did you have anything else to eat or drink with your <last food reported>?
Did you have anything else to eat or drink between <primary foods from two eating occasions>?

The dietary interviewer will need to document information for any participants who missed a meal or had very little food during the day. A NDS-R Note should be entered to confirm missed meals or a very limited food intake. Prompts that may be used to illicit additional meals or foods for limited diet reports are:

Did you have anything to eat or drink after school? Anything before your (insert time e.g., evening meal) and (before bed)?

Additional foods are inserted at any time. If the participant hesitates and can't remember eating anything for a long period of time, the interviewer may say:

Can you think what you were doing (after school, at dinner/supper time, etc)?
Sometimes if you think about where you were or who you were with it helps to remember what you ate.

Appendix 2.7. Sample Telephone Interview Script

TELEPHONE INTERVIEW SCRIPT

If you reach an answering machine - leave a scripted message as described below. Record that you left an answering machine message in the NOTES section of your contact form layout. (No more than two answering machine messages should be left - if you reach the answering machine a 3rd time hang up. Leave messages at least 1 day apart. Hang up rather than leave a message if a message has been left the day before.)

b) **Answering Machine Messages:**

First message:

Hi. My name is (*your name*) and I am calling from the (*site study name*) . C*hild's name* is taking part in interviews about the food that he/she eats. We were calling to do the follow-up interviews. If there is a convenient time for *(child's name and/or caregiver's name)* to talk on the telephone, she should call me, (*your name*), (*your phone number*) and let me know this time. If I don't hear back, I will try to reach them again tomorrow. Thank you very much.

Second message:
Hi. This is (*your name*) and I tried telephoning you (*insert last time you left a message*) We are working with the (*site study name)* to learn more about child and family health. It is important that I complete the interviews with *(child's name and/or caregiver's name)*. If there is a convenient time for *(child's name and/or caregiver's name*) to talk on the telephone, she should call me, (*your name*), at (*your phone number)* and let me know this time. Thank you very much.

b) **No Answer**
If no one answers record your contact attempt.

c) **You Reach Someone on the Phone**
Verify that you have reached the residence of the child
Use the script below to explain your call.

Calling for child

"Hello, I'm calling from the (*site study name)*. *Child's name* participated in a project about their eating habits and physical activity. I am calling to do the (*first/second*) follow-up interview. May I please speak to *name of child* to do a food recall, or would you like me to get permission from his/her mother or father. He/she should be expecting my call.

If this is an incorrect phone number, fill out contact attempt in your contact form, put #1 in RESULTS box and give contact form to your supervisor.

If neither the caregiver or child are at home, leave a message (e.g. baby-sitter there, older kid there)

If adult is home, but the caregiver or child are unavailable, ask for convenient time to call back and talk with her and note the time on the contact form.

d) **Messages with Another Adult in the Household**

Hi. My name is *(your name)* and I am calling about the (*site study name)*. I'm hoping to talk to *(child's/caregiver's name)* to do a follow-up interview. He/She should be expecting my call. When would be convenient for me to call back and talk with him/her? Will you please let her know to expect a call from me tomorrow about this project.

APPENDIX 3. COPTR DIET RECALL CERTIFICATION LOG

Site: _____

Name	Training Date(s)	Certification Date	Certified by

APPENDIX 4. SAS CODE FOR QUALITY ASSURANCE

School aged cut points

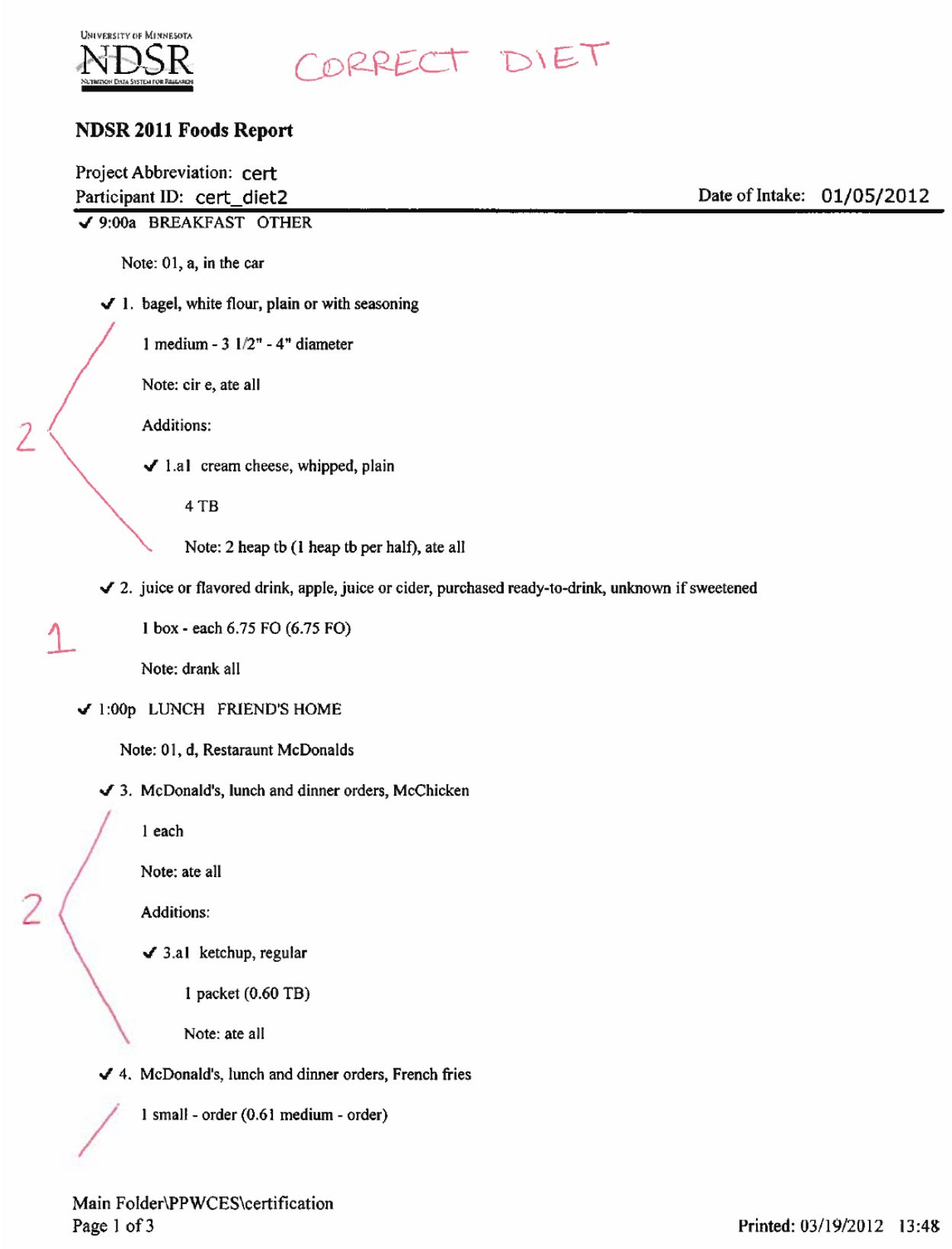
```
proc print data= record label;;
    id id;
    var dintake day cvisit calories rifat ripctfat ritcho ripro fserv vserv fliquid pro_date
cintvw;
     where calories>2500 OR calories<500 OR ripctfat<25 OR ripctfat>45 OR fserv>3
OR vserv>3 or fliquid<300 or fliquid>2000;
run;
```

Preschool cut points

```
proc print data=record label;
    id id;
    var dintake day cvisit calories rifat ripctfat ritcho ripro fserv vserv fliquid pro_date
cintvw;
 where calories>1800 OR calories<250 OR ripctfat<25 OR ripctfat>45 OR fserv>2 OR
vserv>2 or fliquid<300 or fliquid>1500
Run;
```

APPENDIX 5. SCORING FOR DIET RECALLS

Appendix 5.1. Sample Diet Recall Scoring Key



University of Minnesota NDSR Nutrition Data System for Research

CORRECT DIET

NDSR 2011 Foods Report

Project Abbreviation: cert
Participant ID: cert_diet2 Date of Intake: 01/05/2012

✔ 9:00a BREAKFAST OTHER

Note: 01, a, in the car

✔ 1. bagel, white flour, plain or with seasoning

2

1 medium - 3 1/2" - 4" diameter

Note: cir e, ate all

Additions:

✔ 1.a1 cream cheese, whipped, plain

4 TB

Note: 2 heap tb (1 heap tb per half), ate all

✔ 2. juice or flavored drink, apple, juice or cider, purchased ready-to-drink, unknown if sweetened

1

1 box - each 6.75 FO (6.75 FO)

Note: drank all

✔ 1:00p LUNCH FRIEND'S HOME

Note: 01, d, Restaraunt McDonalds

✔ 3. McDonald's, lunch and dinner orders, McChicken

2

1 each

Note: ate all

Additions:

✔ 3.a1 ketchup, regular

1 packet (0.60 TB)

Note: ate all

✔ 4. McDonald's, lunch and dinner orders, French fries

1 small - order (0.61 medium - order)

Main Folder\PPWCES\certification
Page 1 of 3 Printed: 03/19/2012 13:48

UNIVERSITY OF MINNESOTA
NDSR
NUTRITION DATA SYSTEM FOR RESEARCH

NDSR 2011 Foods Report

Project Abbreviation: cert
Participant ID: cert_diet2 Date of Intake: 01/05/2012

Note: ate all

2

Additions:

✔ 4.a1 McDonald's, condiments, sauces, barbecue

2 package

Note: ate all

✔ 5. McDonald's, beverages, soft drink (carbonated)

1 small with ice - 16 FO cup (10.67 FO)

1

Note: drank all

Food Variables:

5.v1 I: soda pop or soft drink - 7UP

✔ 4:00p SNACK FRIEND'S HOME

Note: 03, d

✔ 6. apple, fresh, with skin

.9 sphere 4" diameter (2.27 medium - 3" diameter)

2

Note: cir e, ate all

Additions:

✔ 6.a1 peanut butter, regular, without salt

2 TS (0.67 TB)

Note: 2 lev ts, ate all

✔ 7:30p DINNER/SUPPER HOME

Note: 01, b, both, no drink

✔ 7. rice, brown, cooked in salted water

1

3/4 CP, after cooking

Main Folder\PPWCES\certification
Page 2 of 3 Printed: 03/19/2012 13:48

University of Minnesota
NDSR
Nutrition Data System for Research

NDSR 2011 Foods Report

Project Abbreviation: cert
Participant ID: cert_diet2 Date of Intake: 01/05/2012

Note: m3 all m5 all

Food Variables:

7.v1 P: no fat added

Additions:

✓ 7.a1 chicken, breast, skin removed before cooking

1/2 CP, cut pieces (2.38 OZ)

Note: m3, ate all

Addition Variables:

7.a1v1 P: broiled or grilled, without basting fat or marinade

7.a1v1v1 P: salt - no salt added

2

✓ 8. salad, lettuce, tossed, with dressing, with tomatoes and/or carrots, without avocado, cheese or egg

3/4 CP

Note: m2, ate all

1

Food Variables:

8.v1 I: salad greens - mixed greens

8.v2 I: dressing for salads - ranch style, from bottle, regular

✓ 9. cake, chocolate, purchased ready-to-eat, frosted

1 cube 10/4" length X 12/4" width X 35/16" height (16.41 CI)

Note: sq 10 x 12 x 35(thick), ate all

1

Food Variables:

9.v1 I: frosting - chocolate

[End of Record]

Legend: a = addition; i = component/ingredient; v = variable; ✓ *= complete; ? = incomplete; M = missing food; PN = priority note*

total: /14

Main Folder\PPWCES\certification
Page 3 of 3 Printed: 03/19/2012 13:48

Appendix 5.2. Sample Diet Recall with Failing Score

University of Minnesota NDSR Nutrition Data System for Research

SAMPLE

NDSR 2011 Foods Report

Project Abbreviation: cert
Participant ID: cert_diet2 Date of Intake: 01/05/2012

✓ 9:00a BREAKFAST OTHER

Note: 01, a, in the car

✓ 1. bagel, white flour, plain or with seasoning

1 medium - 3 1/2" - 4" diameter

Note: cir e, ate all

Additions:

✓ 1.a1 cream cheese, regular, soft (tub), plain

4 TB

Note: 2 heap tb (1 heap tb per half), ate all

-1

-1 for inaccurate food detail → should be "whipped"

✓ 2. juice or flavored drink, apple, juice or cider, purchased ready-to-drink, unknown if sweetened

1 box - each 6.75 FO (6.75 FO)

Note: drank all

✓ 1:00p LUNCH FRIEND'S HOME

Note: 01, d, Restaraunt McDonalds

✓ 3. McDonald's, lunch and dinner orders, McChicken

1 each

Note: ate all

Additions:

✓ 3.a1 ketchup, regular

1 packet (0.60 TB)

Note: ate all

✓ 4. McDonald's, lunch and dinner orders, French fries

1 small - order (0.61 medium - order)

Main Folder\PPWCES\certification
Page 1 of 3 Printed: 03/19/2012 13:53

UNIVERSITY OF MINNESOTA
NDSR
NUTRITION DATA SYSTEM FOR RESEARCH

NDSR 2011 Foods Report

Project Abbreviation: cert
Participant ID: cert_diet2 Date of Intake: 01/05/2012

Note: ate all

Additions:

✓ 4.a1 McDonald's, condiments, sauces, barbecue

2 package

Note: ate all

✓ 5 soda pop or soft drink, 7UP

16 FO, with ice (crushed or cubed) (12.00 FO)

Note: g3d, drank all

-2 for inaccurate food selection → should be from McDonald's

-2

✓ 4:00p SNACK FRIEND'S HOME

Note: 03, d

✓ 6. apple, fresh, with skin

1 sphere 4" diameter (2.52 medium - 3" diameter)

Note: cir e, ate all

Additions:

✓ 6.a1 peanut butter, regular, without salt

2 TS (0.67 TB)

Note: 2 lev ts, ate all

-1 for inaccurate portion size [pits w/ fruits should have quantity of 1 if ate all & selected from spheres]

-1

✓ 7:30p DINNER/SUPPER HOME

Note: 01, b, both, no drink

✓ 7. rice, brown, cooked in salted water

3/4 CP, after cooking

Note: m3 all m5 all

Food Variables:

Main Folder\PPWCES\certification
Page 2 of 3 Printed: 03/19/2012 13:53

University of Minnesota
NDSR
Nutrition Data System for Research

NDSR 2011 Foods Report

Project Abbreviation: cert
Participant ID: cert_diet2 Date of Intake: 01/05/2012

7.v1 P: no fat added

Additions:

✓ 7.a1 chicken, breast, skin removed before eating

-1 for inaccurate food detail

-1

1/2 CP, cut pieces (2.38 OZ)

Note: m3, ate all

Addition Variables:

7.a1v1 P: broiled or grilled, without basting fat or marinade

7.a1v1v1 P: salt - no salt added

✓ 8. salad, lettuce, tossed, with dressing, with tomatoes and/or carrots, without avocado, cheese or egg

3/4 CP

Note: m2, ate all

Food Variables:

8.v1 I: salad greens - mixed greens

8.v2 I: dressing for salads - ranch style, from bottle, regular

✓ 9. cake, chocolate, purchased ready-to-eat, frosted

1 cube 10/4" length X 12/4" width X 35/16" height (16.41 CI)

Note: sq 10 x 12 x 35(thick), ate all

Food Variables:

9.v1 I: frosting - chocolate

[End of Record]

Legend: a = addition; i = component/ingredient; v = variable; ✓ *= complete; ? = incomplete; M = missing food;*
PN = priority note

-5 total: 9/14 = 64 % DID NOT PASS

Main Folder\PPWCES\certification
Page 3 of 3 Printed: 03/19/2012 13:53

CHILDHOOD OBESITY PREVENTION AND TREATMENT RESEARCH

COPTR

MANUAL OF PROCEDURES

4. QUESTIONNAIRES – DEMOGRAPHIC, HOUSEHOLD, MEDIATOR AND MODERATOR VARIABLES

MAY 2012

PROCEDURES MANUAL
4. QUESTIONNAIRES – DEMOGRAPHIC, HOUSEHOLD, MEDIATOR AND MODERATOR VARIABLES
Table of Contents

1. INTRODUCTION

The purpose of this procedure manual is to provide explicit and detailed instruction on how to collect demographic, household, mediator and moderator variables in the COPTR studies. 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. This document was written, edited and approved by the members of the Mediators and Moderators Working Group, as well as the measurement subcommittee and Steering Committee. Even small deviations from the procedures as they are described here are highly discouraged. Data collectors at all sites should strictly adhere to the main trial procedures outlined in this manual for all common measures. This standardization is crucial to the ultimate goals of our research.

In the COPTR study a "common" measurement is defined as any measurement collected at more than one site using identical wording for the question stem. For these variables common procedures are used to collect measurements with the goal of being able to combine data from multiple sites for future analyses.

The demographic, household, mediators and moderators survey is administered to parents/primary caregivers of the participating child and or to the participating child. Table 1 summarizes the administration format by site. Site-specific instructions are shown in Appendix 1.

Table 1. 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 interview- 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

This Manual of Procedures (MOP) describes only the common administration protocol information. Site-specific details are included in each site's protocol.

2. TERMINOLOGY TO DESCRIBE RELEVENT INDIVIDUALS

Index child: A child who meets eligibility criteria and is randomized to a study arm with the intention that his or her BMI data will be included in the site's primary outcome analysis.

Master Trainer: The person (or persons) at each site that trains and supervises certification of other data collectors or research associates.

Measurement Coordinator: The person (or persons) at each site that organizes data collection activities. This person may or may not be a master trainer.

Research Associate/data collection staff: Personnel who collects the measurement data.

Trainee: The person receiving training and seeking certification to participate as a Research Associate.

3. DATA COLLECTORS

Data collection staff will be determined by each site. Data collectors must be separate from intervention staff unless data are collected prior to randomization. All data collection procedures need to be performed by personnel who have completed the appropriate training and certification procedures referred to in this manual.

4. CONFIDENTIALITY CONSIDERATIONS

Each index child and/or parent completing the questionnaires has the right to confidentiality. No form is identified with a participant's name. The staff should be pleasant and respectful to each person who participates in the study and make the experience a positive one. The staff introduces themselves to the participants, explain all procedures to them, and obtain the participant's approval giving them the questionnaires. The data collector is available to answer any question that the index child or parent may have.

Survey data will be handled according to the confidentiality procedures described in each site's protocol. These confidentiality procedures have been approved by the local IRB and are adequate to protect privacy and confidentiality of participant data.

5. EQUIPMENT

Equipment needed for survey administration includes:

- Computer for survey administration
- Paper copy of the survey
- Pencils / pens
- Visual aids (e.g. hard copies of question response categories for interviewer-administered surveys)

6. TRAINING AND CERTIFICATION REQUIREMENTS

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 MOP, complete the questionnaire and administer the questionnaire. The data collectors are certified by a Master Trainer who describes the data collection process, insure that the manual of procedures is read and observe the questionnaire being administered to a volunteer.

If a site wants to add an additional Master Trainer after the central trainings have been conducted by the RCU, the RCU needs to be notified. To be certified, the Master Trainer candidate attends the training session conducted by the Master Trainer, reads the protocol and MOP, complete the questionnaire and is observed administering the questionnaire to a volunteer.

All survey data collection staff must be certified administering questionnaires. Each Field Site will keep a Questionnaire Certification Training Log (Appendix 2) and submit the certification training log to the RCU each time a new certification was added.

7. SURVEY QUESTIONS

The demographic, household, mediator and moderator questions are administered to the participating parent or adult caregiver of the participating child. There are 55 common questions that cover demographic, household, mediator and moderator variables. All of the common survey questions are not administered at all Field Sites (Table 2). Each Field Site may have additional questions in its site-specific survey (Appendix 3).

Common demographic, household, mediator and moderator questions are administered at the beginning (baseline) and the end (36 months) of the intervention with interim measurements (12 and 24 months) for some questions. All baseline measurements are collected prior to randomization.

Table 2. 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

Construct	Item	Case	Minnesota	Stanford	Vanderbilt
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 at Home with Family	How often do you speak English at home with your family? (Choose one.)		X	X	
	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",	X	X	X	X

Construct	Item	Case	Minnesota	Stanford	Vanderbilt
	we mean that you should report the combined income of everyone in your home.				
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 months when he/she first received a bottle of formula, cow's milk, water, juice, tea, or cereal at least once a day?	X	X		X
	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

Construct	Item	Case	Minnesota	Stanford	Vanderbilt
	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 the room where <this child> sleeps?	X[1]	X	X	X
	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.

8. PREPARATION FOR ADMINISTRATION

Procedures for preparation administration are described in each Field Site's specific protocol. The number of research staff, their training and languages spoken, specific materials and equipment needed are included in each Field Site's protocol.

9. ADMINISTRATION OF THE SURVEY

Survey administration descriptions are included in each Field Site's specific protocol. Generally, surveys may be conducted on any day of the week. The common questions do not have to be asked in the order they are provided on the questionnaire form (Appendix 4) at all sites. Since all common questions are not asked at each site and some sites will ask additional questions (Appendix 3) the total number of questions will vary across the four Field Sites and site-specific questions may be inserted into the survey at any point that retains the logical flow of the sequence of the common questions. Appendix 5 includes an example of a general introductory survey administration staff script. Appendix 6 includes standard answers to frequently asked general questions and to common mediator and moderator questions.

10. QUALITY CONTROL

Survey collection, review and editing procedures are included in each site's specific protocol. Sites that use a computer-administered survey will not need to complete field editing. The RCU will monitor for missing values on the common questions across the Field Sites.

All data collection staff will be trained and certified prior to administering the questionnaires to participants.

11. DATA MANAGEMENT

All collected questionnaire data should be reviewed for completeness by each Measurement Coordinator and then given to the Data Manager at the site. The adopted protocol for transferring Questionnaire data to the RCU requires a single data upload from each site on a quarterly basis via the RCU Data Capture website. The RCU may request data at other times for purposes of reporting to the DSMB. It is the responsibility of each Field site to clean the questionnaire data and verify its completeness prior to upload to the RCU.

The Table 3 shows the start and end dates of each quarter and when the data transfer to the RCU must be completed.

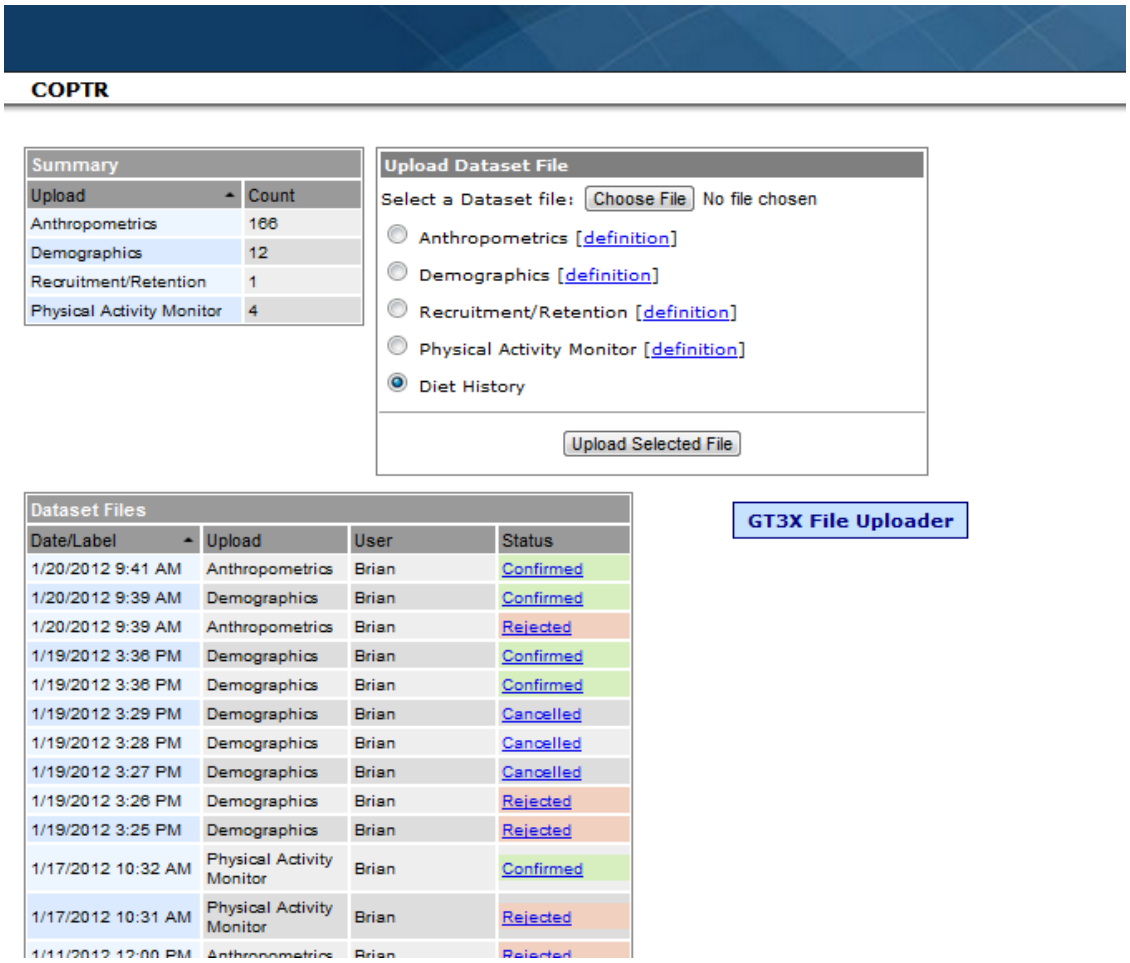
Table 3. Data upload schedule to RCU

Quarter	Measurement Start Date	Measurement End Date	Due to RCU
1	January 1	March 31	April 15
2	April 1	June 30	July 15
3	July 1	September 30	October 15
4	October 1	December 31	January 15

The Measurement Coordinator stores all the logs detailed in the appendices in either paper or electronic form. The logs must be available for inspection by the site Principal Investigator, the RCU and other officials related to the COPTR study if requested.

Process for Uploading to the RCU (see screen example below)

visit the RCU Data Center at: www.shepscenter.unc.edu/coptr
login with your user id and password
Browse and select the appropriate quarterly output ZIP file
Select “Demographics” as the dataset type
Select “Upload Selected File”



APPENDIX 1. SITE-SPECIFIC MEDIATOR AND MODERATOR MEASURES

APPENDIX 1.1. CASE WESTERN RESERVE UNIVERSITY

Construct	Respondent	# Questions
Treatment Self-Regulation Questionnaire	Child	6
Brief scale for sedentary equipment in the home	Child	9
Brief scale for physical activity in the home	Child	14
Active Where? Survey – Rules for TV	Child	8
Parental Monitoring Scale	Child	6
Social Support and Exercise Survey	Child	10
Self-efficacy scale for physical activity barriers	Child	4
Modified Rosenberg Self-Esteem Inventory	Child	6
Center for Epidemiological Studies Depression Scale for Children	Child	20
Neighborhood environment walkability scale – Safety scales	Child	13
Youth Risk Behavior Survey physical activity	Child	3
Modified activity questionnaire	Child	10
Active Where? Survey – Active transportation to school	Child	2
Active Where? Survey – Food scale	Child	18
Active Where? Survey – Rules for eating	Child	12
Child Food Security Survey	Child	9
School wide food practices scale	Child	7
Social support and eating habits survey	Child	20
Children's self-efficacy for eating habits survey	Child	15
Modified -Youth Eating Disorder Examination Questionnaire	Child	3
Family Ritual Questionnaire – dinnertime subscale	Child	7
Sleep evaluation questionnaire (SEQ)	Child	10
Adolescent sleep wake scale (ASWS)	Child	28
Pediactric Daytime Sleepiness Scale	Child	8
Perceived Stress Scale	Child	10
Systems Thinking Scale	Child	16
Index of Self-Regulation	Child	7
Impact of weight on quality of life (IWQOL)	Child	27
Health Utilities Index	Child	40
Physical Exam	Child	7
PACER Test	Child	1
Brief scale for sedentary activity equipment in the home	Parent	9
Brief scale for physical activity equipment in the home	Parent	14
Active Where? Survey – Rules for TV	Parent	8
Child Behavior Checklist – social problems subscale	Parent	7
Center for Epidemiological Studies Depression Scale	Parent	20
Family Assessment Device	Parent	12
Neighborhood environment walkability scale – Safety scales	Parent	13
Active Where? Survey – Active transportation to school	Parent	2
Active Where? Survey – Rules for eating scale	Parent	12
The Child Feeding Questionnaire	Parent	31
Obstructive Sleep Apnea screen	Parent	8
Systems Thinking Scale	Parent	20
The Stress Index for Parents of Adolescents	Parent	34
Family Health History	Parent	20
Maternal History	Parent	5
Medical History	Parent	9

The Questionnaires MOP was approved by the COPTR Steering Committee on March 10, 2012; Revisions approved 5/11/12

APPENDIX 1.2. THE UNIVERSITY OF MINNESOTA

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

The Questionnaires MOP was approved by the COPTR Steering Committee on March 10, 2012; Revisions approved 5/11/12

APPENDIX 1.3. STANFORD UNIVERSITY

Construct	Respondent	# Questions
Short diet questionnaire on product use	Parent	8
Transportation to school	Child	4
Eating with screens/homework	Child	7
Time spent in sedentary behavior	Child	48
Hunger after eating / 2nd / 3rd helpings	Child	3
McKnight over-concern with body size and shape	Child	5
CDI Depressive symptoms	Child	10
Implicit theory questions – body weight, general habits, sports ability and eating habits	Child	15
Do you think of yourself as an athlete	Child	1
Tanner	Child	2
Child's most recent grades	Parent	1
Child's after school physical activity/sports program	Parent	2
Child school lunch eaten in a typical week	Parent	1
Child meals (breakfast, dinner) eaten outside of home in a typical week	Parent	2
Child Home TV/media environment	Parent	22
Children's sleep habits questionnaire	Parent	17
Child's unsupervised time at home on typical week and weekend	Parent	3
Family members' weight status	Parent	1
Acculturation status of other parent	Parent	2
Employment status of other parent	Parent	1
Medrich Household TV	Parent	4
Washburn physical activity	Parent	3
Washburn physical activity of other parent	Parent	3
Implicit theory questions – body weight, general habits, sports ability and eating habits	Parent	15

The Questionnaires MOP was approved by the COPTR Steering Committee on March 10, 2012; Revisions approved 5/11/12

APPENDIX 1.4. VANDERBILT UNIVERSITY

Construct	Respondent	# Questions
Acculturation	Parent	4
Behavior change/goal setting/monitoring	Parent	6
Daily Physical Activity	Parent	2
Parenting around eating	Parent	45
Healthy Snacks and Drinks	Parent	2
Daily Serving of Fruits and Vegetables	Parent	2
Monitoring Sugar and Fiber	Parent	1
Meal Planning	Parent	1
Portion Control and Plating	Parent	2
Sleep	Parent	6
Group Cohesion	Parent	8
Social Network	Parent	8
Parenting Self-efficacy	Parent	16
Eating Location	Parent	2
Community Center Use	Parent	3
Stress	Parent	10
Parent Depression	Parent	21
Built Environment	Parent	85
Time Spent with Child	Parent	2
Exclusive Breastfeeding	Parent	1
Preterm Birth	Parent	1
Fast Food	Parent	1
Cognitive Functioning	Child	Series of tasks

APPENDIX 2. DEMOGRAPHIC DATA COLLECTION FORM

To be completed by COPTR staff:
Index Child ID: _____
Form Code: **DEM** Version: Series #: Seq. #: ___

Demographics Form

1. Today's Date: ___ / ___ / ____
   mm dd yyyy
2. Visit: (visit) (e.g. 0 for baseline, 12 for 12 months, 24 for 24 months, 36 for 36 months)

3. Child's DOB: ___ / ___ / ____
   mm dd yyyy

4. What is <this child> sex? (Choose one answer):
   1 ☐ Male
   2 ☐ Female

5. Is <this child> Hispanic, Latino/a or of Spanish origin? (Choose all that apply):
   1, missing ☐ No, not of Hispanic, Latino/a or Spanish origin
   1, missing ☐ Yes, Mexican, Mexican American, Chicano/a
   1, missing ☐ Yes, Puerto Rican
   1, missing ☐ Yes, Cuban
   1, missing ☐ Yes, Another Hispanic, Latino/a or Spanish origin

6. Which of the following best describes <this child>? (Choose all that apply):
   1, missing ☐ American Indian or Alaskan Native
   1, missing ☐ Asian
   1, missing ☐ Black or African American
   1, missing ☐ Native Hawaiian or Pacific Islander
   1, missing ☐ White
   1, missing ☐ _____ Other (please describe):

7. Are you Hispanic, Latino/a or of Spanish origin? (Choose all that apply):
   - 1, missing ☐ No, not of Hispanic, Latino/a or Spanish origin
   - 1, missing ☐ Yes, Mexican, Mexican American, Chicano/a
   - 1, missing ☐ Yes, Puerto Rican
   - 1, missing ☐ Yes, Cuban
   - 1, missing ☐ Yes, Another Hispanic, Latino/a or Spanish origin

8. Which of the following best describes you? (Choose all that apply):
   - 1, missing ☐ American Indian or Alaskan Native
   - 1, missing ☐ Asian
   - 1, missing ☐ Black or African American
   - 1, missing ☐ Native Hawaiian or Pacific Islander
   - 1, missing ☐ White
   - 1, missing ☐ _____ Other (please describe):

9. In what country were you born?
   - 1 ☐ USA
   - 2 ☐ Mexico
   - 3 ☐ Somalia
   - 4 ☐ Laos/Thailand/Vietnam
   - 5 ☐ Other (please describe): _____

10. In what country was <this child> born?
    - 1 ☐ USA
    - 2 ☐ Mexico
    - 3 ☐ Somalia
    - 4 ☐ Laos/Thailand/Vietnam
    - 5 ☐ Other (please describe): _____

11. How many years total have you lived in the United States? __ __

12. What is your employment status?
    1 ☐ Working full time
    2 ☐ Working part time
    3 ☐ Not working for pay

13. What is your current marital status?
    1 ☐ Married or living as married
    2 ☐ Single

14. Is there a car that you can use whenever you need to?
    1 ☐ Yes and I drive
    2 ☐ Yes but I don't drive
    0 ☐ No

15. How often do you speak English at home with your family?
    1 ☐ Never
    2 ☐ Sometimes
    3 ☐ About ½ the time
    4 ☐ Most of the time
    5 ☐ Always

16. If you do not always speak in English at home with your family, what languages do you speak the rest of the time?

    _____

17. Do you participate in WIC? WIC stands for Women, Infants, and Children, a Federal assistance program.
    1 ☐ Yes
    0 ☐ No
    99 ☐ Don't know

18. Does anyone in your household receive food stamps or SNAP? SNAP stands for Supplemental Nutrition Assistance Program

    1 ☐ Yes

    0 ☐ No

    99 ☐ Don't know

19. Does anyone in your household receive Unemployment, Social Security, or Disability Benefits?

    1 ☐ Yes

    0 ☐ No

    99 ☐ Don't know

20. What is the highest degree or level of school that <u>you</u> have completed? (Choose one answer)

    1 ☐ 6th grade (elementary school) or less

    2 ☐ 7th - 8th grade (attended some middle school/junior high

    3 ☐ 9th - 12th grade (attended some high school)

    4 ☐ High school graduate (received diploma or the equivalent, GED for example)

    5 ☐ Completed some college credit, (or technical school) but no degree

    6 ☐ Technical degree

    7 ☐ Associate's degree

    8 ☐ Bachelor's degree

    9 ☐ Master's, Professional, or Doctoral degree

21. What is the highest degree or level of school that <this child's> other parent living in the household or adult caregiver living in the household has completed? (Choose one answer)
    - 0 ☐ No other parent lives in the household or no other adult caregiver lives in the household
    - 1 ☐ 6th grade (elementary school) or less
    - 2 ☐ 7th - 8th grade (attended some middle school/junior high
    - 3 ☐ 9th - 12th grade (attended some high school)
    - 4 ☐ High school graduate (received diploma or the equivalent, GED for example)
    - 5 ☐ Completed some college credit, (or technical school) but no degree
    - 6 ☐ Technical degree
    - 7 ☐ Associate's degree
    - 8 ☐ Bachelor's degree
    - 9 ☐ Master's, Professional, or Doctoral degree

In a usual week, how much time does <this child> spend being cared for by someone other than the parent/guardian …

22. …in your own home?
    - 0 ☐ 0 Hours
    - 1 ☐ 1-10 Hours
    - 2 ☐ 11-20 Hours
    - 3 ☐ 21-30 Hours
    - 4 ☐ 31-40 Hours
    - 5 ☐ 41+ Hours

23. … in someone else's home?
    - 0 ☐ 0 Hours
    - 1 ☐ 1-10 Hours
    - 2 ☐ 11-20 Hours
    - 3 ☐ 21-30 Hours
    - 4 ☐ 31-40 Hours
    - 5 ☐ 41+ Hours

24. … in child care center/after school program?
    - 0 ☐ 0 Hours
    - 1 ☐ 1-10 Hours
    - 2 ☐ 11-20 Hours
    - 3 ☐ 21-30 Hours
    - 4 ☐ 31-40 Hours
    - 5 ☐ 41+ Hours

25. 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.
    - 1 ☐ $14,999 or less
    - 2 ☐ $15,000 - $24,999
    - 3 ☐ $25,000 - $34,999
    - 4 ☐ $35,000 - $49,999
    - 5 ☐ $50,000 - $74,999
    - 6 ☐ $75,000 - $149,999
    - 7 ☐ $150,000 - $199,999
    - 8 ☐ $200,000 or more
    - 99 ☐ Don't know
    - 88 ☐ I prefer not to answer

26. Is your child covered by a health insurance plan?
    - 1 ☐ Yes, Go to Question 26
    - 0 ☐ No , Go to Question 27
    - 99 ☐ Don't know

27. Which type of plan are they covered by? (Choose all that apply)
    - 1, missing ☐ Medicaid, Medicare, CHIP, state funded or other federally funded
    - 1, missing ☐ Private – through work or purchased individually
    - 1, missing ☐ Military
    - 1, missing ☐ Other _____
    - 1, missing ☐ Don't know

28. Does any child in your household receive free or reduced price breakfast or lunch at school?
    1 ☐ Yes
    0 ☐ No
    99 ☐ Don't know

29. Has your daughter started having her menstrual period?
    1 ☐ Yes, Go to Question 29
    0 ☐ No
    99 ☐ Don't know

30. When did she have her first menstrual period? __ __ / __ __ __ __
    mm yyyy

31. Did <this child> breastfeed for more than a month?
    1 ☐ Yes
    0 ☐ No, Skip to Question 30

32. 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"? __ __ months

33. How much did this child weigh at birth? __ __ lbs __ __ oz or __ .__ kg

34. Did a doctor say that <you/the birth mother> had diabetes when pregnant with <this child>?
    1 ☐ Yes
    0 ☐ No
    99 ☐ Don't know

35. Did a doctor say that <you/the birth mother> had hypertension (high blood pressure) when pregnant with <this child>?
    1 ☐ Yes
    0 ☐ No
    99 ☐ Don't know

I'm going to read you two statements that people have made about their food situation. Please tell me whether the statement was OFTEN, SOMETIMES, or NEVER true for (you/you and the other members of your household) in the last 12 months.

36. The first statement is, "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?
    1 ☐ Often true
    2 ☐ Sometimes true
    3 ☐ Never true
    99 ☐ Don't know
    88 ☐ Refused

37. "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?
    1 ☐ Often true
    2 ☐ Sometimes true
    3 ☐ Never true
    99 ☐ Don't know
    88 ☐ Refused

38. 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?
    1 ☐ Yes
    0 ☐ No (GO TO 39)
    99 ☐ Don't know (GO TO 39)
    88 ☐ Refused (GO TO 39)

39. How often did this happen --almost every month, some months but not every month, or in only 1 or 2 months?
    1 ☐ Almost every month
    2 ☐ Some months but not every month
    3 ☐ Only 1 or 2 months
    99 ☐ Don't know
    88 ☐ Refused
    4 ☐ Not asked

40. In the last 12 months, did you ever eat less than you felt you should because there wasn't enough money to buy food?
    1 ☐ Yes
    0 ☐ No
    99 ☐ Don't know
    88 ☐ Refused

41. In the last 12 months, were you ever hungry but didn't eat because you couldn't afford enough food?.
    1 ☐ Yes
    0 ☐ No
    99 ☐ Don't know
    88 ☐ Refused

42. How many working TVs do you have in your home? __ __

43. Is there a working TV in the room where <this child> sleeps?
    1 ☐ Yes
    0 ☐ No

44. Is there a computer in your home?
    1 ☐ Yes
    0 ☐ No

45. Is there a computer in the room where <this child> sleeps?

1 ☐ Yes

0 ☐ No

46. Is there a video game player in your home?

1 ☐ Yes

0 ☐ No

47. Is there a video game player in the room where <this child> sleeps?

1 ☐ Yes

0 ☐ No

48. Do you have Internet access in your home?

1 ☐ Yes

0 ☐ No

99 ☐ Don't know

49. On an average WEEK day, how many hours does <this child> watch TV?

0 ☐ None

1 ☐ Less than 1 hour per day

2 ☐ 1 hour per day

3 ☐ 2 hours per day

4 ☐ 3 hours per day

5 ☐ 4 hours per day

6 ☐ 5 or more hours per day

50. On an average WEEKEND day, how many hours does<this child> watch TV?

0 ☐ None

1 ☐ Less than 1 hour per day

2 ☐ 1 hour per day

3 ☐ 2 hours per day

4 ☐ 3 hours per day

5 ☐ 4 hours per day

6 ☐ 5 or more hours per day

51. 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.)
    - 0 ☐ None
    - 1 ☐ Less than 1 hour per day
    - 2 ☐ 1 hour per day
    - 3 ☐ 2 hours per day
    - 4 ☐ 3 hours per day
    - 5 ☐ 4 hours per day
    - 6 ☐ 5 or more hours per day

52. During the past seven days, how often did your family eat breakfast together?
    - 0 ☐ 0 times
    - 1 ☐ 1-2 times
    - 2 ☐ 3-4 times
    - 3 ☐ 5-6 times
    - 4 ☐ 7 times

53. During the past seven days, how often did your family eat lunch together?
    - 0 ☐ 0 times
    - 1 ☐ 1-2 times
    - 2 ☐ 3-4 times
    - 3 ☐ 5-6 times
    - 4 ☐ 7 times

54. During the past seven days, how often did your family eat dinner together?
    - 0 ☐ 0 times
    - 1 ☐ 1-2 times
    - 2 ☐ 3-4 times
    - 3 ☐ 5-6 times
    - 4 ☐ 7 times

55. How would you classify your own weight?

1 ☐ Very Underweight
2 ☐ Underweight
3 ☐ Normal
4 ☐ Overweight
5 ☐ Very Overweight

56. How would you classify <this child>'s current weight?

1 ☐ Very Underweight
2 ☐ Underweight
3 ☐ Normal
4 ☐ Overweight
5 ☐ Very Overweight

Now we would like to know about your household family structure

Please tell me the names, sex and ages of all children and adults living in your household

57. Adult 1 (Respondent)
Relationship to Participant:

1 ☐ Mother
2 ☐ Father
3 ☐ Stepmother
4 ☐ Stepfather
5 ☐ Grandmother
6 ☐ Grandfather
7 ☐ Aunt
8 ☐ Uncle
9 ☐ Cousin
10 ☐ Other relative _____
11 ☐ Other non-relative _____

DOB: ___ /__ / ____ Sex: 1 ☐ Male 2 ☐ Female
mm dd yyyy

Age: ___ ____ years

58. Adult 2
Relationship to Participant:

1 ☐ Mother
2 ☐ Father
3 ☐ Stepmother
4 ☐ Stepfather
5 ☐ Grandmother
6 ☐ Grandfather
7 ☐ Aunt
8 ☐ Uncle
9 ☐ Cousin
10 ☐ Other relative _____
11 ☐ Other non-relative _____

Age: ___ ____ years Sex: 1 ☐ Male 2 ☐ Female

59. Adult 3
Relationship to Participant:

1 ☐ Mother
2 ☐ Father
3 ☐ Stepmother
4 ☐ Stepfather
5 ☐ Grandmother
6 ☐ Grandfather
7 ☐ Aunt
8 ☐ Uncle
9 ☐ Cousin
10 ☐ Other relative _____
11 ☐ Other non-relative _____

Age: ___ ____ years Sex: 1 ☐ Male 2 ☐ Female

60. Adult 4
Relationship to Participant:

1 ☐ Mother
2 ☐ Father
3 ☐ Stepmother
4 ☐ Stepfather
5 ☐ Grandmother
6 ☐ Grandfather
7 ☐ Aunt
8 ☐ Uncle
9 ☐ Cousin
10 ☐ Other relative _____
11 ☐ Other non-relative _____

Age: ___ ____ years Sex: 1 ☐ Male 2 ☐ Female

61. Adult 5 (Respondent)
Relationship to Participant:

1 ☐ Mother
2 ☐ Father
3 ☐ Stepmother
4 ☐ Stepfather
5 ☐ Grandmother
6 ☐ Grandfather
7 ☐ Aunt
8 ☐ Uncle
9 ☐ Cousin
10 ☐ Other relative _____
11 ☐ Other non-relative _____

Age: ___ ____ years Sex: 1 ☐ Male 2 ☐ Female

62. Adult 6
Relationship to Participant:

1 ☐ Mother
2 ☐ Father
3 ☐ Stepmother
4 ☐ Stepfather
5 ☐ Grandmother
6 ☐ Grandfather
7 ☐ Aunt
8 ☐ Uncle
9 ☐ Cousin
10 ☐ Other relative _____
11 ☐ Other non-relative _____

Age: ___ ____ years Sex: 1 ☐ Male 2 ☐ Female

63. Adult 7
Relationship to Participant:

1 ☐ Mother
2 ☐ Father
3 ☐ Stepmother
4 ☐ Stepfather
5 ☐ Grandmother
6 ☐ Grandfather
7 ☐ Aunt
8 ☐ Uncle
9 ☐ Cousin
10 ☐ Other relative _____
11 ☐ Other non-relative _____

Age: ___ ____ years Sex: 1 ☐ Male 2 ☐ Female

64. Adult 8
Relationship to Participant:

1 ☐ Mother
2 ☐ Father
3 ☐ Stepmother
4 ☐ Stepfather
5 ☐ Grandmother
6 ☐ Grandfather
7 ☐ Aunt
8 ☐ Uncle
9 ☐ Cousin
10 ☐ Other relative _____
11 ☐ Other non-relative _____

Age: ___ ____ years Sex: 1 ☐ Male 2 ☐ Female

65. Child 2
Name: _____
Relationship to Participant:

1 ☐ Sibling
2 ☐ Stepsibling
3 ☐ Cousin
4 ☐ Other_____

Age: ___ ____ years Sex: 1 ☐ Male 2 ☐ Female

66. Child 3
Relationship to Participant:

1 ☐ Sibling
2 ☐ Stepsibling
3 ☐ Cousin
4 ☐ Other_____

Age: ___ ____ years Sex: 1 ☐ Male 2 ☐ Female

67. Child 4
Relationship to Participant:

1 ☐ Sibling
2 ☐ Stepsibling
3 ☐ Cousin
4 ☐ Other_____

Age: ___ ____ years Sex: 1 ☐ Male 2 ☐ Female

68. Child 5
Relationship to Participant:
1 ☐ Sibling
2 ☐ Stepsibling
3 ☐ Cousin
4 ☐ Other_____
Age: ___ ____ years Sex: 1 ☐ Male 2 ☐ Female

69. Child 6
Relationship to Participant:
1 ☐ Sibling
2 ☐ Stepsibling
3 ☐ Cousin
4 ☐ Other_____
Age: ___ ____ years Sex: 1 ☐ Male 2 ☐ Female

70. Child 7
Relationship to Participant:
1 ☐ Sibling
2 ☐ Stepsibling
3 ☐ Cousin
4 ☐ Other_____
Age: ___ ____ years Sex: 1 ☐ Male 2 ☐ Female

71. Child 8
Relationship to Participant:
1 ☐ Sibling
2 ☐ Stepsibling
3 ☐ Cousin
4 ☐ Other_____
Age: ___ ____ years Sex: 1 ☐ Male 2 ☐ Female

APPENDIX 3. SURVEY ADMINISTRATION SCRIPT

The survey administration script will be specific to each site and is included in the site-specific protocol. General introductory comments about the mediator and moderator questions that may be provided by survey administration staff are as follows.

As part of the COPTR study at <*University*>, we are collecting information about each family's background, household and lifestyles. These questions include information about you and your family's education, income, racial and ethnic background, living situation, activities, eating patterns, rules, and parenting styles.

Please keep in mind that all of your answers are confidential and will not be shared with anyone outside the research project. There are some researchers who are outside of <*University*> that are a part of the larger research group that we will share some information with. We will take off your name and any other identifying information. The survey is voluntary, so you are free to decide not to answer any question that you do not want to answer. However, the study will be helped if you are able to answer all of the questions as completely as you can.

At any time, if you have questions, please feel free to ask me for help.

Please keep in mind that there are no right or wrong answers. Please answer the questions as honestly as you can.

Do you have any questions before we begin?

APPENDIX 4: FREQUENTLY ASKED QUESTIONS

GENERAL QUESTIONS

1**. What does [WORD] mean?**
NOTE: If the person is asking for a translation from English to another language or vice versa, the translator can provide. The possible acceptable translations should be written in advance and included in the site-specific protocol.

If the person is asking about defining a word in English and is an English speaker, the data collector's response is "Whatever [WORD] means to you."

2. How do I answer if [PARTICIPANT DESCRIBES A SCENARIO]
Answer as best as you can. Choose the response that seems to best show your answer.

3. **What is the reason you are asking about X?**
“It helps us with the research project.”
“It helps us learn about how different families respond to the program/research project.”

4. **I don't understand the question.**
NOTE: If the person is asking for a translation from English to another language or vice versa, the translator can provide. The possible acceptable translations should be written in advance and included in the site-specific protocol.

If the person is an English speaker and is asking the data collector to interpret or rephrase a question:
“Answer as best as you can. Choose the response that seems to best show your answer.”

QUESTIONS

HOUSEHOLD CONFIGURATION
Children may include adopted and foster children.
Relationship may be sibling, step sibling, cousin or other.
Adults living in the household are those who are aged 18 and older.
Relationship may be Mother, Father, Stepmother, Stepfather, other male caregiver, or other female caregiver.

Criteria for ‘living in the household’: Resides at this address on a daily basis.

CHILD (OR PARENT) HISPANIC
Hispanic or Latino: Refers to anyone of Mexican birth or descent, anyone who says they were born in or had ancestors from Spain or one of the western hemisphere territories or countries where Spanish is the primary language (e.g.,

Puerto Rico, Nicaragua, El Salvador, Dominican Republic, Colombia, Peru, etc). From NHANES http://www.cdc.gov/nchs/data/nhanes/int1.pdf

YEARS PARENT LIVED IN USA
Living in the United States is defined as the total number of years that the participant has lived consistently in the United States. If the participant has left the United States for a period of time (1 year or more), do not include this time in the total number of years.

EMPLOYMENT STATUS
'Working full time' is defined as working 35 hours or more per week; 'working part time' is working 1 to 34 hours per week (www.bls.gov). Hours worked per week may be summed across multiple jobs to determine full- or part-time status.

Individuals 'not working for pay' include those who do not have a job for which they are paid. This category also includes individuals who do not have a job and are actively looking for work, who are waiting to be recalled from a job from which they are temporarily laid off, retired persons, students, and those taking care of children or family members. (ref: 'Unemployed categories' and 'not in the labor force' descriptions from http://www.bls.gov/cps/lfcharacteristics.htm#fullpart).

MARITAL STATUS
Participants who are 'married or living as married' include those who are married or are not married but are living with a significant other.
Participants should be marked 'Single' if they have never been married or are separated, divorced or widowed.

ACCESS TO CAR
Is there a car that you can use whenever you need to? This could be during the day or evening hours, weekdays, or weekends. A person who has access to a car and drives the car will respond "Yes and I drive"; a person who has access to a car but does not drive will respond "Yes but I don't drive"; a person who does not have access to a car will respond "no".

EDUCATION COMPLETED
There are TWO education questions. These two questions are to measure the highest level of education of each parent or adult caregiver living in the household. If only one adult lives in the household, then the second question will be answered to indicate Does the 2nd question get asked if you know there is no other adult? there is no second adult caregiver living in the household.

If a grandparent or other relative is completing the survey:
THEN ADD INSTRUCTIONS HERE.
SHOULD THE GRANDPARENT FILL IN QUESTION ONE FOR SELF AND QUESTION 2 FOR PRIMARY PARENT? WHAT IF THERE ARE TWO PRIMARY PARENTS? NEED TO CLARIFY FOR THE PPT WHOSE EDUCATION THEY ARE REPORTING.

**Ideally, the first education question would be filled out by the person who will be the primary parent/caregiver participating in the study—regardless of whether they are the parent, grandparent, etc

HOUSEHOLD INCOME

Household income includes income from adults or working adolescents who live in the household. Include income during the past year from any sources. Sources include paid work, unemployment benefits, disability benefits, food stamps, interest earnings, or any other income source.

USDA FOOD SECURITY QUESTIONS

U.S. Household Food Security Survey Module: Six-Item Short Form July 2008
http://www.ers.usda.gov/Briefing/FoodSecurity/surveytools.htm#household

CHILD HEALTH INSURANCE

FREE/REDUCED BREAKFAST OR LUNCH (TARGET CHILD OR ANY FAMILY CHILD?)

Free or reduced price breakfast or lunch refers to the school meals served at your child's school. Some families are eligible for purchasing these meals at reduced cost, or they may be eligible to receive this meal free of charge. The question refers to ANY child in the household.

CHILD CARE (PAID OR UNPAID: OWN HOME; SOMEONE ELSE'S HOME; CHILD CARE CENTER)

Someone other than the parent/guardian includes (but not limited to) the index child's siblings, relatives (other than parent), roommates or other adults living in the house.

Child care in someone else's home includes both paid and unpaid child care (for example, from relatives).

BREASTFEEDING/PREGNANCY RISK QUESTIONS

These questions are related to the birth mother of the index child.

TV & MEDIA

How many working TVs do you have in your home?

- This includes any TVs that may or may not have cable or satellite connection

Is there a TV in the room where this child sleeps?

- This includes any TVs that may or may not have cable or satellite connection

Is there a computer in your home?

- This includes laptops or tablets, but does not include other hand held devices such as mp3 players (e.g. iPod Touch), or Smartphones.

Is there a computer in the room where <this child> sleeps?
- This includes laptops or tablets that are USUALLY kept in the child's room, but does not include other hand held devices such as mp3 players (e.g. iPod Touch), or Smartphones.

Is there a video game player in your home?
- This includes video game consoles (e.g. XBOX, Nintendo Wii), or portable video game players, but does not include other hand held devices such as mp3 players (e.g. iPod Touch), or Smartphones.

Is there a video game player in the room where this child sleeps?
- This includes video game consoles (e.g. XBOX, Nintendo Wii), or portable video game players that are USUALLY kept in the child's room, but does not include other hand held devices such as mp3 players (e.g. iPod Touch), or Smartphones.

Do you have Internet access in your home?
- Internet access means having an internet provider (e.g. Comcast) that a device can connect to OR having a device that connect to the internet without an internet provider (e.g. via 3G or 4G network).
- Does this include smartphone? YES

On an average WEEK day, how many hours does this child watch TV?
- This includes videos on TV, computers, laptops, or tablets.

On an average WEEKEND day, how many hours does this child watch TV?
- This includes videos on TV, computers, laptops, or tablets.

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.)
- This does not include watching videos on computers, laptops, or tablets as this is recorded in the previous questions. However, it does include using other handheld devices when used to play video games (e.g. iPodTouch, Smartphones)

FOOD NORMS
During the past seven days, please tell us how many times all, or most, of your family living in your house ate breakfast together?
- If other family members are present, but not eating with the index child, this should not be included.

During the past seven days, please tell us how many times all, or most, of your family living in your house ate lunch together?

- If other family members are present, but not eating with the index child, this should not be included.

During the past seven days, please tell us how many times all, or most, of your family living in your house ate dinner together?

- If other family members are present, but not eating with the index child, this should not be included.

Please indicate how you would classify your own weight.

-

Please indicate how you would classify this child's current weight.

-

The Blood Pressure MOP was approved by the COPTR Steering Committee on March 10, 2012.
Revisions approved March 2013.

CHILDHOOD OBESITY PREVENTION AND TREATMENT RESEARCH

COPTR

MANUAL OF PROCEDURES

5. BLOOD PRESSURE

JULY 2012
REVISED MARCH 2013

The Blood Pressure MOP was approved by the COPTR Steering Committee on March 10, 2012. Revisions approved March 2013.

SUMMARY OF REVISIONS

Approved March 2013 – Case Western Reserve University will collect 4th blood pressure measurement in large discrepancy found between 2nd and 3rd measurement. The changes are reflected in 2 places --

PROCEDURES MANUAL
5. BLOOD PRESSURE
Table of Contents

1. INTRODUCTION

The purpose of this procedure manual is to provide explicit and detailed instruction on how to collect blood pressure and pulse measurements in the COPTR studies. There will be four common measurement time points – baseline, 12 months, 24 months and 36 months. All baseline blood pressure and pulse measurements will be collected prior to randomization. All common data collection will occur between May 2012 and March 2017. This document was written, edited and approved by the members of the Biomedical Measures Working Group, as well as the Measurement Subcommittee and Steering Committee. Even small deviations from the procedures as they are described here are highly discouraged. Data collectors at all sites should strictly adhere to the main trial procedures outlined in this manual for all common measure. This standardization is crucial to the ultimate goals of our research.

In the COPTR study a "common" measurement is defined as any measurement collected at more than one site. For these variables common procedures are used to collect measurements with the goal of being able to produce comparable data from multiple sites for future analyses.

Systolic and diastolic blood pressure and pulse are assessed in COPTR index children at two sites (Case Western Reserve University and Stanford University). Case Western Reserve University will use the OMRON HEM-705-CP (old model) and the HEM-705-CPN (new model) and Stanford University will use the Dinamap Pro 100 and Dinamap Carescape v100 (new model name) digital blood pressure monitors. Both brands use the oscillometric method of blood pressure measurement. This means the monitor detects blood movement through the brachial artery and converts the movement to a digital reading. No stethoscope is required.

2. TERMINOLOGY TO DESCRIBE RELEVENT INDIVIDUALS

Index child: A child who meets eligibility criteria and is randomized to a study arm with the intention that his or her BMI data will be included in the site's primary outcome analysis as the main exposure.

Master Trainer: The person (or persons) at each site that trains and supervises certification of other blood pressure data collectors or research associates.

Measurement Coordinator: The person (or persons) at each site that organizes blood pressure data collection activities. This person may or may not be a master trainer.

Research Associate/data collection staff: Personnel who collect blood pressure measurements.

Trainee: The person receiving training and seeking certification to participate as a Research Associate/data collector.

3. CONFIDENTIALITY CONSIDERATIONS

Each participant being measured has the right to confidentiality. No form is identified with a participant's name. Every effort should be made to keep observations and data recording as objective and non-judgmental as possible. It is important to not react to any measure, simply observe and record on the form. The staff should be pleasant and

respectful to each person who participates in the study and make the experience a positive one. The staff introduces themselves to the participants, explain all procedures to them, and obtain the participant's approval before taking measurements.

Communication among staff during measurements is done in a quiet and respectful manner so that participants cannot overhear any discussion related to results. It is likely that some participants will ask to be told their measurements results. The blood pressure reading can be easily shown to the participant in a discreet way.

Care should be taken that the physical measures are performed in a private area. Privacy also involves sound, so it is important that data collectors do not speak values aloud in a way that could be overheard.

If a participant's physical injuries or deformities (such as a cast) result in having to alter or omit procedures this should be noted on the data collection form in the comments section.

To assure safety of participants, the measurers should remove rings, bracelets, or other jewelry that could pose a hazard and be cautious when using pens or pencils while taking measurements.

4. EQUIPMENT

Blood pressure monitors are marked with a number for identification. The same brand and model of equipment (OMRON HEM-705-CP, HEM-705-CPN, Dinamap Pro 100, or Dinamap Carescape v100) is used throughout the study. Special attention must be placed on assessment and maintenance of the instrument's accuracy as per the manual that accompanies the instrument.

The Dinamap blood pressure monitor is particularly durable for both the inpatient and outpatient setting and designed for use with adult, pediatric and even neonatal patients who have very low perfusion pressures.

The OMRON and DINAMAP blood pressure monitors has following specifications:

	OMRON	DINAMAP
Display:	LCD Digital Display	LED Digital Display
Measurement Range:	Pressure: 0 to 299 mmHg Pulse: 40 to 180/minute	Systolic: 30 to 245 mmHg MAP: 15 to 215 mmHg Diastolic: 10 to 195 mmHg Pulse: 30 to 240 beats/minute
Accuracy/Calibration:	Pressure: ±3 mmHg Pulse: ±5% of reading	Pressure: mean error ≤ 5 mmHg, s.d. ≤ 8 mmHg Pulse: ±3.5% or 3 bpm
Inflation:	Automatic by electric pump	Automatic by electric pump
Deflation:	Active electronic control valve	Stepped deflation

Rapid Pressure Release:	Active electronic control valve	
Pressure Detection:	Capacitive pressure sensor	Transducer, matched amplitude pulse detection
Measurement Method:	Oscillometric method	Oscillometric method
Pulse Wave Detection:	Capacitive pressure sensor	
Power Source:	4 "AA" batteries or AC adapter	AC input or battery
Battery Life:	Approximately 300 uses	6V; 3.3 Ahr sealed lead battery; 11.5 hours with heavy use
Operating Temperatures/Humidity:	50°F to 104°F (10°C to 40°C) 30 to 85% RH maximum	41°F to 104°F (5°C to 40°C) 700 hPa to 1060 hPa
Storage Temperatures/ Humidity:	–4°F to 140°F (–20°C to 60°C) 10 to 95% RH maximum	–4°F to 122°F (–20°C to 50°C) 5% to 95% noncondensing
Main Unit Weight:	Approximately 13.4 oz (380g) not including batteries	5.4 lbs (2.4 kg) including batteries
Main Unit Dimensions:	Approximately 4 1⁄2" (l) x 7" (w) x 2 4⁄5" (h)	Approximately 21.9cm (w) x 13.5cm (d) x 19.5cm (h)

Blood pressure monitoring device – calibrated, research, precision-grade digital monitor

Case Western-OMRON HEM-705-CP or HEM-705-CPN Digital Blood Pressure Monitor

Stanford – Dinamap Pro 100 or Dinamap Carescape v100

Blood pressure cuff/bladder sets

Case Western - for OMRON automated devices

- Small: for arm circumferences 7 to 9”
- Medium: for arm circumferences 9 to 13"
- Large: for arm circumferences 13 to 17"

Stanford - for Dinamap automated devices

- Infant (8 to13 cm)
- Child (12 to 19 cm)
- Small Adult (17 to 25 cm)
- Adult (23 to 33 cm)
- Large Adult (31 to 40 cm)
- Thigh (38 to 50cm)

The following equipment and supplies may also be needed:

Metric tape

Pens

Clipboard

Timer
Preferably, chair with arm support for blood pressure measurement, or chair and table. Table must provide for a comfortable resting posture of the arm with midcuff at heart level. Chair must have a back for participant's back to be supported during rest and BP determinations.
Circuit breaker (power strip)
Three-pronged adapter for older residences, if appropriate
Blood pressure data collection form or computer
HEM-ADPT1 AC adapter (optional)
Four AA batteries

5. BLOOD PRESSURE DATA COLLECTION FORM

Blood pressure and pulse data are either recorded manually or electronically into a computer database. Regardless of the method used, the blood pressure data collection form in Appendix 2 are used as a template to assist the development of paper form or the electronic format used for the collection of data. The data will then be uploaded to the RCU, using standard procedures (see section 9).

6. TRAINING AND CERTIFICATION FOR BLOOD PRESSURE

COPTR uses a “train the trainer” model. Each Field Site designates two or more “master trainers” who participate in central trainings organized by the RCU. The central training will be conducted in Chapel Hill, NC from April 16 to April 18, 2012. The designated master trainers are responsible for training and certifying the data collection staff at their center. To be certified, a master trainer has significant prior experience collecting blood pressure measurements in research studies (at least 50 measurement episodes), attends all training sessions as designated by the RCU and has read and is familiar with the blood pressure protocol and MOP. For certification, the master trainers are observed measuring five individuals (age does not matter). The five individuals must include both genders and require varying cuff sizes. The master trainer must correctly select the appropriate cuff size and demonstrate consistent compliance with the MOP to be certified and to be able to train the staff at his/her site.

If a site wants to add an additional Master Trainer after the central trainings have been conducted by the RCU, the RCU needs to be notified. Any Master Trainer candidate, who does not participate in the centralized training at the RCU must have significant experience in the measuring blood pressure as stated above, read the blood pressure protocol and MOP, and have another certified Master Trainer available to conduct the certification. The Master Trainer candidate is observed measuring five individuals (age does not matter). The five individuals must include both genders and require varying cuff sizes. The master trainer candidate must correctly select the appropriate cuff size and demonstrate consistent compliance with the MOP to be certified as a Master Trainer and to be able to train the staff at his/her site.

The data collection staff are trained by a certified master trainer. In the training sessions, the master trainer reviews the information in the MOP and demonstrates the technique for determining cuff size and measuring blood pressure to the data collection

staff. During the session, the data collectors practice measurements on each other and on age and body size-appropriate volunteers without assistance from the master trainer or other staff.

For certification, the trainee is observed by the master trainer. The participants must include 5 or more children (boys and girls in the age range being studied at the Field Site) requiring varying cuff sizes. The trainee must correctly select the appropriate cuff size and demonstrate consistent compliance with the MOP to be certified.

Data collectors who do not meet the certification criteria will be offered additional instruction and testing, however, the testing for certification must be completed on a different group of children.

All staff collecting blood pressure measures must be certified before collecting data. Each Field Site will keep a Blood Pressure Certification Training Log (Appendix 3).

Recorders to transcribe/input the results are allowed but not required, during data collection. Recorders do not have to be certified to record the measurements, but should be familiar with the data collection forms, edit requirements and the blood pressure MOP.

7. GENERAL MEASUREMENT PROCEDURES

7.1 Equipment Set-up

Follow set-up instructions according to the manual.

7.2 General Equipment Calibration Procedures

The Omron unit has been validated to remain in calibration for up to 100,000 measurements. The units do not have to be calibrated before their first use. The Field Site does not have to perform the CHECK MODE function during the COPTR studies.

7.3. General Procedures

When possible, blood pressure measurements must be conducted early in the visit and not following potentially stressful exam components such as the blood drawing.

7.4. Participant Preparations

Before measurements commence participants are offered the opportunity to visit a restroom or bathroom. The participants are asked to roll up their right sleeve (if can’t roll up all the way, ask them to remove right arm from sleeve).

7.5. Determining Cuff Size

Proper cuff size must be used to avoid under- or over-estimation of blood pressure. Cuff size refers to the cuff's bladder, not the cloth. Cuff bladder width should be approximately 40% of the circumference of the arm measured at a point midway between the olecranon and the acromion. Cuff bladder length should cover 80-100% of the circumference of the arm.

Blood pressure measurements should usually be taken in the right arm. The left arm may be used if the blood pressure is known to be higher in that arm or in the presence of an anomaly or other circumstance prohibiting use of the right arm (e.g., cast). Note that measurement was taken in left arm on the blood pressure data collection form.

To determine cuff size:

1. Have the participant stand, holding forearm horizontal (parallel) to the floor.
2. Measure arm length from the acromion (bony protuberance at the shoulder) to the olecranon (tip of the elbow), using a metric tape. If the skinfold has already been measured from this arm the midpoint has already been identified and the arm does not need to be remeasured or marked.
3. Mark the midpoint on the dorsal surface of the arm or use the skinfold mark.
4. Have participant relax arm along side of the body.
5. To measure the arm circumference, pull the tape snugly around the arm at the midpoint mark. NOTE: Keep the tape horizontal. Tape should not indent the skin.
6. Use the criteria in the table below for determining cuff size. A copy of the table should be attached to the monitor/sphygmomanometer for easy reference.

Cuff Size Indicated by Measured Arm Circumference

OMRON			Dinamap	
Cuff Size	Arm Circumference		Cuff Size	Arm Circumference
Medium	≥ 22 to < 32 cm (9 to 13")		Child	12 – 19 cm
Large	≥ 32 to < 42 cm (13 to 17")		Small Adult	17 – 25 cm
			Adult	23 – 33 cm
			Large Adult	31 – 40 cm
			Thigh	38 – 50 cm

For OMRON monitor used at Case Western Reserve University: If the participant's arm circumference is ≥ 17", then the large cuff size will be used and annotated on the data form that the “arm circumference ≥ 17".

7.6. Wrapping the Blood Pressure Cuff Around the Arm

The participant should be seated with back supported, legs uncrossed, both feet flat on the ground in a quiet room, with:

- the elbow and forearm of the right arm resting comfortably on the armrest of the blood pressure measurement chair (or the table),
- the palm of the hand turned upward,
- the area to which the cuff is to be applied must be bare

If unable to take the BP using the right arm, please note on the BP Form.

Locate the brachial artery by palpation and mark the skin with a little dot. (The brachial artery is usually found at the crease of the arm, under the muscle and slightly toward the body).

Place the appropriate cuff around the upper right arm so that:

1. The midpoint of the length of the bladder lies over the brachial artery and the mid-height of the cuff is at heart level.
   OMRON: Confirm for yourself where the midpoint of the length of the bladder is by folding the bladder in two. Do not trust the marking on the cuff.
   DINAMAP: Line up the arrow on the cuff with the brachial artery in the cubital fossa.
2. The lower edge of the cuff, with its tubing connections, is placed ½ to 1 inch above the natural crease across the inner aspect of the elbow with the mid-height of the cuff at heart level.
3. Wrap the cuff snugly about the arm, with the palm of the participant's hand turned upward. Make sure that the long edges of the cuff lie on top of each other as you wrap the cuff around.
4. Secure the wrapped cuff firmly by applying pressure to the locking fabric fastener over the area where it is applied to the cuff.
5. Do not wrap the cuff too tightly around the arm, but so that you can insert only one or two fingers between the cuff and arm.

7.7. Taking the Seated Blood Pressure and Pulse Measurements

1. The participant should sit comfortably with back supported, legs uncrossed and both feet flat on the floor.
2. The participant should sit quietly for a period of 4-5 minutes (use timer) before the first blood pressure is taken.
3. During the 4-5 minute rest period, participants should be resting and should not be completing questionnaires or speaking with study staff.
4. Push the START button on the blood pressure monitor machine and wait for the output.
5. Record the systolic and diastolic blood pressures and pulse readings on the BP form. (Mean Arterial Pressure will also be recorded at Stanford)
6. After values have been computed by the machine and all the air is out of cuff, have the participant sit still for 1 to 3 minutes (use timer), then hit START button.
7. Repeat until you have obtained three readings.
8. Average of the 2nd and 3rd measures are used in analysis. The calculation of average will be done with software program (Filemaker, RedCap or SAS).
9. If there is a malfunction, press CLEAR and start again.
10. Case only: A 4th measure will be taken if a large discrepancy is observed between the 2nd and 3rd systolic and/or diastolic blood pressure measurements. The average of the 2nd and 3rd measures are used in analysis.

OMRON note: The Omron device will “clear” itself of all previous readings after a 5-min interval. Moreover, the Omron does not permit downloading readings to another electronic device. Thus, recording the blood pressure and pulse readings in a timely manner is essential.

Troubleshooting: Appendix 4 contains the error indicators and troubleshooting tips from the OMRON HEM-705-CP Digital Blood Pressure Monitor Manual and/or the Dinamap Pro 100 manual.

7.8. Alert Values – Stage 2 Hypertension

Stage 2 Hypertension, defined as more than 5mmHg above the 99th blood pressure percentile for age, gender and height percentiles (see tables below), is indication for prompt evaluation and treatment.

99th Blood Pressure Percentile for Boys by Age and Height Percentile

	Systolic Blood Pressure (mmHg)								Diastolic Blood Pressure (mmHg)						
	Percentile of Height								Percentile of Height						
	5th	10th	25th	50th	75th	90th	95th		5th	10th	25th	50th	75th	90th	95th
7	117	118	120	122	124	125	126		82	82	83	84	85	86	86
8	119	120	122	123	125	127	127		83	84	85	86	87	87	88
9	120	121	123	125	127	128	129		84	85	86	87	88	88	89
10	122	123	125	127	128	130	130		85	86	86	88	88	89	90
11	124	125	127	129	130	132	132		86	86	87	88	89	90	90
12	126	127	129	131	133	134	135		86	87	88	89	90	90	91
13	128	130	131	133	135	136	137		87	87	88	89	90	91	91
14	131	132	134	136	138	139	140		87	88	89	90	91	92	92
15	134	135	136	138	140	142	142		88	89	90	91	92	93	93

99th Blood Pressure Percentile for Girls by Age and Height Percentile

	Systolic Blood Pressure (mmHg)								Diastolic Blood Pressure (mmHg)						
	Percentile of Height								Percentile of Height						
	5th	10th	25th	50th	75th	90th	95th		5th	10th	25th	50th	75th	90th	95th
7	117	118	119	120	122	123	124		81	81	82	82	83	84	84
8	119	120	121	122	123	125	125		82	82	83	83	84	85	86
9	121	121	123	124	125	127	127		83	83	84	84	85	86	87
10	123	123	125	126	127	129	129		84	84	85	86	86	87	88
11	125	125	126	128	129	130	131		85	85	86	87	87	88	89
12	127	127	128	130	131	132	133		86	86	87	88	88	89	90
13	128	129	130	132	133	134	135		87	87	88	89	89	90	91
14	130	131	132	133	135	136	136		88	88	89	90	90	91	92
15	131	132	133	134	136	137	138		89	89	90	91	91	92	93

If the measured value indicates Stage 2 Hypertension, follow the instructions below.

1. Repeat the blood pressure measurement over again from the start.
2. If still greatly elevated (Stage 2 Hypertension) and...
    a. If symptoms: nausea, vomiting, headache, altered mental status, visual disturbance, seizure, neurological symptoms, or otherwise feeling ill, call 911 or immediate referral to the emergency room.
    b. If no symptoms (feeling perfectly normal): Refer to primary physician/clinic

or Hypertension clinic within 48 hours. Tell them if they start to have any of the above symptoms or feel ill in any way, they must call 911 to go directly to the emergency room.

8. QUALITY CONTROL PROCEDURES

8.1. Erroneous Measurements

Computer entered data can be deleted and reentered as needed.

8.2. General QC Procedures

All data collection staff will be trained and certified prior to taking blood pressure and pulse measurements. Special training and re-certification may be held for data collection staff that have not collected blood pressure data in approximately one year.

Since the blood pressure and pulse measurement are collected using an automated device, end digit preference (e.g. 0 or 5) should not be an issue. Also, the OMRON blood pressure device does not require calibration. The RCU will calculate the correlations between the 2nd and 3rd blood pressure and pulse measurements within an individual. The Field Sites will receive these reports.

9. Data Processing

All collected blood pressure data should be reviewed for completeness by each Measurement Coordinator and then given to the Data Manager at the site. All blood pressure and pulse values are entered or downloaded into the site's Data Management System within 2 weeks of data collection. The adopted protocol for transferring blood pressure data to the RCU requires a single data upload from each site on a quarterly basis via the RCU Data Capture website. The RCU may request data at other times for purposes of reporting to the DSMB.

The table below shows the start and end dates of each quarter and when the data transfer to the RCU must be completed.

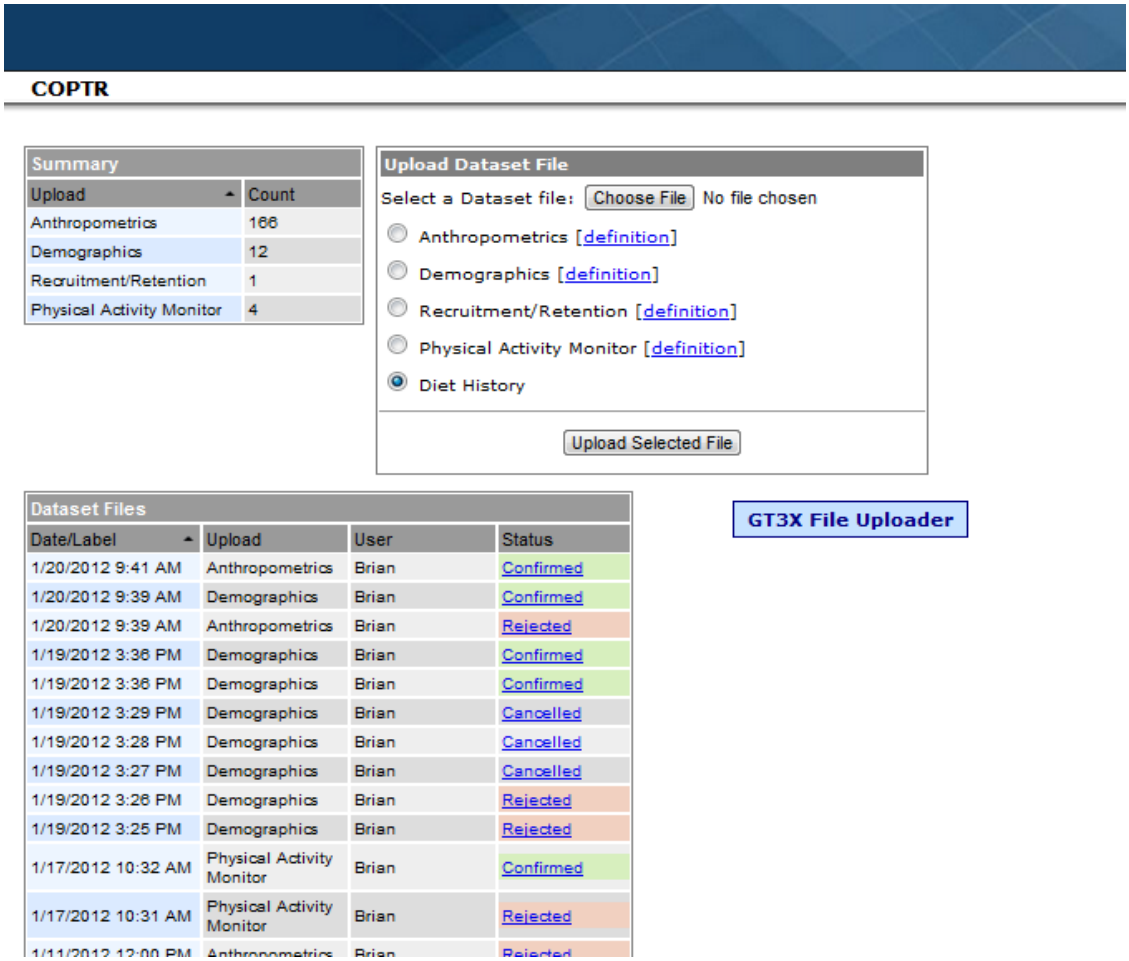
Data upload schedule

Quarter	Measurement		Due to RCU
	Start Date	End Date	
1	January 1	March 31	April 15
2	April 1	June 30	July 15
3	July 1	September 30	October 15
4	October 1	December 31	January 15

The Measurement Coordinator stores all the logs detailed in the appendices in either paper or electronic form. The logs must be available for inspection by the site Principal Investigator, the RCU and other officials related to the COPTR study if requested.

Process for Uploading to the RCU (see screen example below)

visit the RCU Data Center at: www.shepscenter.unc.edu/coptr
login with your user id and password
Browse and select the appropriate quarterly output ZIP file
Select “Blood Pressure” as the dataset type
Select “Upload Selected File”



APPENDIX 1. SITE-SPECIFIC INFORMATION FOR BLOOD PRESSURE

Information on pertinent site-specific procedures may be placed behind this page. These pages are generated by the investigators at the site rather than by the RCU.

The Blood Pressure MOP was approved by the COPTR Steering Committee on March 10, 2012. Revisions approved March 2013.

APPENDIX 2. BLOOD PRESSURE DATA COLLECTION FORM

To be completed by COPTR staff:

Index Child ID: _____

Form Code: **BP** Version:

Device #: _____

1. Today's Date: ___ / ___ / ____
   mm dd yyyy

2. Visit: __ __ __ (e.g. 0 for baseline, 12 for 12 months, 24 for 24 months, 36 for 36 months)

3. Extremity (mark one)

__ (1) Right Arm (preferred)

__ (2) Left Arm - reason: _____

4. Arm circumference

__ __ . __ inches

__ __ . __ cm

5. Cuff size (mark one)

OMRON		Dinamap	
___(1) Small		___(5) Child	12 – 19 cm
___(2) Medium	≥ 22 to < 32 cm (9 to 13")	___(6) Small Adult	17 – 25 cm
___(3) Large	≥ 32 to < 42 cm (13 to 17")	___(7) Adult	23 – 33 cm
___(4) Large	≥ 17"	___(8) Large Adult	31 – 40 cm
		___(9) Thigh	38 – 50 cm

	6. Systolic blood pressure (mmHg) Measured by:_ _ _ Recorded by: _ _ _	**7. Diastolic blood pressure (mmHg)** Measured by:_ _ _ Recorded by: _ _ _	**8. Pulse (bpm)** Measured by:_ _ _ Recorded by: _ _ _
Measure 1	__ __ __ mmHg	__ __ __ mmHg	__ __ __ bpm
Measure 2	__ __ __ mmHg	__ __ __ mmHg	__ __ __ bpm
Measure 3	__ __ __ mmHg	__ __ __ mmHg	__ __ __ bpm
Measure 4	__ __ __ mmHg	__ __ __ mmHg	__ __ __ bpm
Average (calculated by computer)	*2nd & 3rd values* __ __ __ mmHg	*2nd & 3rd values* __ __ __ mmHg	*2nd & 3rd values* __ __ __ bpm

The Blood Pressure MOP was approved by the COPTR Steering Committee on March 10, 2012. Revisions approved March 2013.

APPENDIX 3. COPTR BLOOD PRESSURE TRAINING CERTIFICATION LOG

Name	Training Date(s)	Certification Date	Certified by	Blood pressure certified to measure (*master trainer)

APPENDIX 4. ERROR INDICATORS AND TROUBLESHOOTING TIPS

OMRON:

ERROR INDICATORS

SYMBOL	CAUSE	CORRECTION
E	Monitor did not detect pulse rate	Remove the arm cuff. Refer to "Applying the arm cuff" on page 12. Wait 2-3 minutes. Take another measurement.
EE	Cuff under-inflated	Remove the arm cuff. Read "Taking a Measurement" on page 14. Wait 2-3 minutes. Take another measurement.
E	Cuff over-inflated	
	Batteries are worn	Replace the four batteries. Refer to page 7 for battery installation.

TROUBLESHOOTING TIPS

PROBLEM	CAUSES AND SOLUTIONS
No power. No display appears on the unit	Replace all worn batteries. Check the battery installation for proper placement of the battery polarities.
Measurement values appear too high or too low.	Blood pressure varies constantly. Many factors including stress, time of day, how you wrap the cuff, may affect your blood pressure. Review the sections "Before Taking a Measurement" and "Taking a Measurement".

DINAMAP:

Procedural and Error Alarm Codes						
Alarm Code	**LED Display**	**LCD Display**	**Audible Tone and Volume**	**Effect of Alarm Silence Switch**	**Effect of Clear via SelectKnob**	**Probable Cause**
N99	No change	N99- NIBP FAILED	High priority alarm. Volume adjustable	2 minutes silence	Clear	Unable to make an NIBP determination due to insufficient signal
N55	No change	N55- TIMEOUT: PRESS	High priority alarm. Volume adjustable	2 minutes silence	Clear	One cuff pressure for > 1 minute. Motion artifact
N44	No change	N44- TIMEOUT: TOTAL	High priority alarm. Volume adjustable	2 minutes silence	Clear	Determination time > 2 minutes. Motion artifact
N33	No change	N33- TIMEOUT: INFLT	High priority alarm. Volume adjustable	2 minutes silence	Clear	Inflation time > 40 seconds or air leak detected
NOO	No change	NOO- OVER PRESSURE	High priority alarm. Volume adjustable	2 minutes silence	Clear	Overpressure detected

Procedural and Error Alarm Codes (cont.)						
Alarm Code	**LED Display**	**LCD Description**	**Audible Tone and Volume**	**Effect of Alarm Silence Switch**	**Effect of Clear via SelectKnob**	**Probable Cause**
No Code	No Change	LOW BATTERY, Flashing battery icon	3 beeps every 10 seconds, adjustable volume	2 minutes silence	No effect	Replace or recharge battery. From onset of alarm. 5 NIBP measurements available. Beep rate increases linearly as battery discharges
No Code	Blank	LOW BATTERY - SYSTEM DISABLED	Steady tone, maximum volume	No effect	No effect	Replace or recharge battery. NIBP measurement disabled
No Code	No Change	PRINTER - NO PAPER	High Priority alarm. Volume adjustable	2 minutes silence	Clear	Paper ran out or printer door open
No Code	Values Posted	NIBP RANGE ERROR	High Priority alarm. Volume adjustable	2 minutes silence	Clear	NIBP algorithm returned value outside specified accuracy range
Other: N, P, E, I, S	Blank	Error code, description	Steady tone, maximum volume	No effect	No effect	Internal system fault

The Blood Pressure MOP was approved by the COPTR Steering Committee on March 10, 2012. Revisions approved March 2013.

APPENDIX 5. FREQUENTLY ASKED QUESTIONS

CHILDHOOD OBESITY PREVENTION AND TREATMENT RESEARCH

COPTR

MANUAL OF PROCEDURES

6. BIOMEDICAL MEASURES

MAY 2012
REVISED MARCH 2013

SUMMARY OF REVISIONS

Approved March 2013 – Added field to indicate if LDL was directly measured by the lab. The changes are reflected in 1 place – page 26, item 16 on form.

Procedures Manual
6. BIOMEDICAL MEASURES
Table of Contents

1. Introduction

The purpose of this procedure manual is to provide explicit and detailed instruction on how to the biomedical measures will be collected, processed, shipped and results transferred in the COPTR studies. There will be three common measurement time points – baseline, 12 months, and 36 months. All baseline measurements will be collected prior to randomization. All common data collection will occur between May 2012 and March 2017. The specimen collection, processing and shipment sections of this procedure manual were prepared by the Northwest Lipid Metabolism and Diabetes Research Laboratories. The remaining sections of the document were written by the Biomedical Measures Working Group. The entire document was edited and approved by the members of the Biomedical Measures Working Group, as well as the Measurement Subcommittee and Steering Committee. Even small deviations from the procedures as they are described here are highly discouraged. Data collectors at all sites should strictly adhere to the main trial procedures outlined in this manual for all common measures. This standardization is crucial to the ultimate goals of our research.

In the COPTR study a “common” measurement is defined as any measurement collected at more than one site. For these variables common procedures are used to collect measurements with the goal of being able to combine data from multiple sites for future analyses.

Hemoglobin A1c (HbA1c), Glucose, Total Cholesterol, LDL-cholesterol, HDL-cholesterol, Triglycerides, high-sensitivity C-reactive protein (hs-CRP), Insulin and Alanine Aminotransferase (ALT) are assessed as common measures in the COPTR index children at two sites (Case Western Reserve University and Stanford University). Blood specimen samples will be sent to the Northwest Lipid Metabolism and Diabetes Research Laboratory (NWRL) for analysis. Sections 2, 5, 6, and 9 thru 12 below were provided by NWRL.

2. ABOUT THE LABORATORY

2.1 Brief History

The Northwest Lipid Metabolism and Diabetes Research Laboratories (NWRL) was established in 1971 as one of twelve laboratories involved in the Lipid Research Clinics Program, and subsequent Coronary Primary Prevention Study, funded by the National Heart, Lung, and Blood Institute. During the program, this laboratory participated in the development and standardization of methods for the separation of lipoproteins and for the chemical quantification of their components, and performance was monitored continually through the Lipoprotein Standardization Program of the Centers for Disease Control. The laboratory is directed by Santica Marcovina, PhD, ScD, Research Professor of Medicine, Division of Metabolism, Endocrinology, & Nutrition, Department of Medicine, University of Washington.

The laboratory is an Abell Kendall reference network laboratory of the National Reference System for Cholesterol, and participates in the lipid standardization programs offered by the National Heart, Lung, and Blood Institute, Centers for Disease Control, and the College of American Pathologists. In addition, the laboratory serves as the

reference laboratory for the International Standardization of Apolipoproteins AI, B, and Lp(a) and is one of the five World Health Organization laboratories.

For more than 30 years, the laboratory has participated in studies to identify the prevalence of hyperlipidemia in the population and to evaluate the efficacy of intervention. Reported in 1983, results of the Coronary Primary Prevention Study demonstrated that lowering cholesterol was effective in reducing the risk of premature heart disease; this information was key in the development of treatment recommendations issued by the National Cholesterol Education Program. To maintain a high level of accuracy and consistency in results, we continue to perform the Beta Quantification procedure as outlined in the Manual of Laboratory Operations for the Lipid Research Clinics Program without introducing any technical change. The NWRL has been involved in numerous and varied multi-center investigations throughout the United States and internationally. We currently serve as the Central Laboratory for the following NIH-sponsored studies:

ACCORD – Action to Control Cardiovascular Risk in Diabetes
AIM-HIGH -- Atherothrombosis Intervention in Metabolic Syndrome with Low HDL/High Triglyceride and Impact on Global Health Outcomes
CARDIA - Coronary Artery Risk Development in Young Adults
Clinical Islet Transplantation Consortium
DPPOS – Diabetes Prevention Program Outcomes Study
LABS - Longitudinal Assessment of Bariatric Surgery
Look AHEAD – Action for Health in Diabetes
SEARCH – Search for Diabetes in Youth
SNAP – Study of Novel Approaches for Prevention
STOPP-T2D – Studies to Treat or Prevent Pediatric Type 2 Diabetes
Teen LABS – Teen Longitudinal Assessment of Bariatric Surgery
TrialNet - Anti-CD3, CTLA4-Ig, GAD, IL-Beta 1, Natural History, NIP and Oral Insulin Protocols

2.2. Introduction to the Central Laboratory MOP from NWRL

We have provided basic overviews in the areas where you should have already had training, such as Universal Precautions and Phlebotomy Procedures, but these are provided only as reminders and should be treated as such. If you feel you need additional training in these areas we have provided some resources for you. The sections covering specimen collection, processing and shipping is directly related to the COPTR Study, and are covered in detailed form. This detail is provided for a reason: submission of proper specimens under optimum conditions is very important. *Accurate analyses can seldom be performed on poor specimens.* Once you have familiarized yourself and have repeatedly performed these procedures, it will not be necessary for you to refer to this manual every time you collect specimens. Therefore, we have also included sections that give basic outlines easy to follow. Table 1 on page 12 will be provided in laminated form to be posted for a quick reference.

2.3. Laboratory Contacts

Should question arise, we are happy to answer them or to assist you at any time. Please feel free to contact any one of the following people. We are committed to you and to the study, and we will do what it takes to ensure our combined success!

LABORATORY DIRECTOR

Santica Marcovina, PhD, ScD
Research Professor of Medicine
Director
Principal Investigator, CBL
smm@u.washington.edu
Phone: (206) 685-3331
FAX: (206) 897-1815

Operations Personnel:

SITE LIAISON

Jessica Harting
jjc8@u.washington.edu
Phone: (206) 543-3694
FAX: (206) 616-4889

SUPPLY COORDINATION and SHIPPING

Marlon Ramirez,
marlonrj@u.washington.edu
Phone: (206) 685-3328
FAX: (206) 616-4889

3. TERMINOLOGY TO DESCRIBE RELEVENT INDIVIDUALS

Index child: A child who meets eligibility criteria and is randomized to a study arm with the intention that his or her BMI data will be included in the site's primary outcome analysis as the main exposure.

Master Trainer: The person (or persons) at each site that trains and supervises certification of other biomedical measures data collection staff or research associates.

Measurement Coordinator: The person (or persons) at each site that organizes biomedical measures data collection activities. This person may or may not be a Master Trainer.

D*ata collection staff*: Personnel who collect biomedical measurements.

Trainee: The person receiving training and seeking certification to participate as a Research Associate.

4. CONFIDENTIALITY CONSIDERATIONS

Each participant being measured has the right to confidentiality. No form is identified with a participant's name. Every effort should be made to keep observations and data recording as objective and non-judgmental as possible. It is important to not react to any measure, simply observe and record on the form. The staff should be pleasant and respectful to each person who participates in the study and make the experience a positive one. The staff introduces themselves to the participants, explain all procedures to them, and obtain the participant's approval before taking blood specimen.

Communication among staff during the blood draw is done in a quiet and respectful manner so that participants cannot overhear any discussion related to results. It is likely that many participants will ask when and if they will be told their results. If the biomedical results are requested, each Field Site have individual policies and procedures in place to inform the participant (or his/her parent) of the results in a timely manner.

Care should be taken that the blood draw is performed in a private area. Privacy also involves sound, so it is important that data collection staff do not speak values aloud in a way that could be overheard. To insure that modesty is respected during blood draw these tasks are performed in the presence of another person. Privacy screens are used when appropriate.

To assure safety of participants, the measurers should remove rings, bracelets, or other jewelry that could pose a hazard and be cautious when using pens or pencils while taking measurements.

5. EQUIPMENT

5.1. Supplies Provided by the Central Laboratory

For Blood Collection and Processing:

- Blood Collection Vacutainers
- Disposable plastic transfer pipettes
- 2mL blue caps and cryovials

For Specimen Identification:

- Specimen shipment form (originals provided, clinics to make copies, Appendix 2)
- Bar-coded labels for specimen tubes and shipment forms

For Specimen Shipping:

- Ziploc bags
- Cold packs
- 2" Revco freezer storage boxes with 9x9 dividers
- Polyfoam tube holders with absorbent pad and cardboard outer shell
- Polyfoam shipping containers with cardboard outer shell
- Pre-printed Federal Express air bills
- Biohazard plastic bags

- "EXEMPT HUMAN SPECIMEN" Stickers

All supplies are shipped to the two main clinic sites. Supplies are provided in bulk and should be ordered in quantities to ensure that sites are properly stocked at all times, while bearing in mind that some supplies have expiration dates, as noted above. Please be mindful of dated collection supplies so that you do not order too many at one time, causing expiration before their use. If you need help in determining the quantities needed and/or setting up a supply tracking system, please call our Supply and Shipping Coordinator, Marlon Ramirez, at (206) 685-3328.

To order supplies, use the ***Supply Request Form*** (Appendix 3).
Follow the instructions on the form and, once completed, Fax to: **206-616-4889**.
If you have questions, contact Marlon Ramirez at: **206-685-3328**.

5.2. Equipment, Supplies & Facilities Required At Collection Sites

These are suggested supplies only; clinics may use equivalent substitutions, if desired.

For Blood Collection:

- Alcohol wipes
- Ammonia spirits ampules
- Arm boards
- Band-Aids
- Cold compresses
- Disposable gloves (powder-free, to avoid possible cross-contamination from powder)
- Finger Lancets (with tip length no greater than 2.4 mm)
- Needle (Vacutainer) holders – adult and pediatric
- Paper and/or other dermatological tape
- Sterile and non-sterile gauze pads
- Sterile, 19, 21, 23 & 25 gauge, 1" needles (multiple-sampling)
- Sterile, 21, 23, 25 gauge butterfly needles (multiple-sampling)
- Syringes, 10 cc
- Tourniquets
- Tegaderm
- Topical Anesthetic (EMLA, lidocaine/prilocaine)

For Blood Processing/Shipping/Storage:

- Tube racks
- Plastic-backed table covers
- Pipetman with disposable tips, capable of adjustment in 1µL increments
- Waterproof pens (such as laundry markers, fine-point, for scribing on labels)
- Centrifuge: refrigerated swinging-bucket type with Microtainer holding capability
- Freezer: -20°C, non-cycling for freezing of C-peptide vials and shipment cold packs
- Dry Ice: a standing order should be made so that there is always a supply on hand

- Wide (3") packing tape for sealing shipping containers

For Specimen Handling:

- Lab coat
- Goggles or face shield
- Paper towels
- Bleach decontaminant -1 part Clorox to 9 parts water, stored in a labeled bottle
- Biohazard waste containers with orange or red-plastic liners
- Sharps/biohazard containers - rigid red or orange plastic containers for sharps waste

For Phlebotomy Area:

- chair for the subject,
- table for blood collection supplies,
- bed, exam table, or treatment chair that flattens out
- phone/ intercom/physical access to emergency equipment.

6. UNIVERSAL PRECAUTIONS

Universal Precautions was mandated into standards December 6, 1991, by the Occupational Safety and Health Administration (OSHA) in response to increasing public concern over possible transmission of the Acquired Immune Deficiency Syndrome (AIDS) virus and Hepatitis B virus. This standard states that any health care worker who might potentially come into contact with body fluids should be educated in infection control and treat all body fluids as though they are potentially infected.

It is assumed that you have already had training in universal precautions. The following is a summary of the basic knowledge required by health care workers, and is not intended to be a complete picture of universal precautions but only the basics. For a more complete overview of universal precautions, you can visit the following web sites:

- http://www.osha.gov
- http://www.niehs.nih.gov

According to OSHA, the following is the recommended protective barrier: gloves, gown, mask and goggles, or face-shield, and they should be used when handling any body fluids.

6.1. Gloves

1. Wear gloves for all patient contact when body fluids are involved.
2. Change gloves between patients and when gloves are soiled or torn.
3. Wash hands thoroughly after removing gloves.
4. Remove gloves before touching telephones, charts, computers, monitors, doorknobs, refrigerator handles, food, pens/pencils, and elevator buttons. The only exception to this is telephones designated as contaminated.
5. Carry spare non-sterile vinyl exam gloves in uniform/lab coat pocket for use with unexpected contact with blood and body fluids.

6.2. Gowns
Wear water-repellent gowns, plastic disposable aprons, etc. when soiling with blood or body fluids is anticipated.

6.3. Face-Shields
Protect mucous membranes (eyes, nose, mouth) by wearing a mask and/or glasses/goggles, or use a counter-top splashguard, etc. when performing procedures where splashing of the face is likely to occur (de-capping, decanting, etc.).

7. BIOMEDICAL MEASURES DATA COLLECTION FORM
The biomedical medical measures data collection form in Appendix 4 is used as a template to assist the development of paper form or the electronic format used for the collection of the data. The fasting data and lab results are be transferred to the RCU Data using standard procedures (see section 12.2).

8. TRAINING AND CERTIFICATION FOR BIOMEDICAL MEASURES
Both sites are utilizing trained phlebotomists to collect the blood specimens. COPTR uses a “train the trainer” model. Each Field Site designates two or more “Master Trainers” who participate in central training and certification webinar conducted by the NWRL. The webinar will be conducted in April or May, 2012. The webinar focuses on sample processing and shipping procedures. To be certified, a master trainer attends all training sessions and has read and is familiar with the biomedical measures protocol and MOP.

As part of staff training and certification process, the data collection staff are trained by a certified master trainer. In the training sessions, the master trainer reviews the information in the MOP and demonstrates the sample processing and shipping procedure. During the session, the data collectors practice the procedures.

All staff collecting, processing and shipping biomedical specimens to NWRL must be certified. Each Field Site will keep a Biomedical Measures Certification Training Log (Appendix 5).

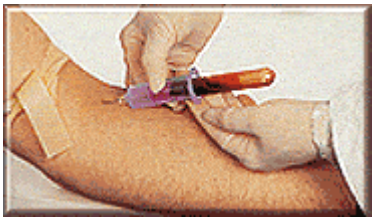
9. COLLECTION PROCEDURES
9.1. Participant Preparations
Accommodations should ensure that the subject can sit quietly in a chair for 5 minutes prior to the venous blood draw, as recommended by NCEP guidelines, and be adjacent to or near by a lavatory which will be used for urine specimen collections. The biomedical measures data collection form (Appendix 4) is used to ascertain fasting time before blood collection.

9.2. Blood Collection Procedures
As with universal precautions, it is assumed that you have already had training in blood collection and completed a phlebotomy course. This section is designed as a brief review of the basics, and also includes information specific to this study. For a more complete overview of blood collection procedures,

you can visit a number of web sites. These sites are suggested only, and their usefulness must be determined individually. To choose from a list of sites, go to the following URL:

- http://phlebotomy.com/

It is understood that universal precautions will be employed during any specimen collection. The following is a suggested method of performing blood specimen collection by venipuncture.



1. Make positive patient identification.
2. Gather necessary equipment.
3. Wash your hands.
4. Don non-sterile exam gloves.
5. Explain planned procedure to patient.
6. Position patient's arm in comfortable position.
7. Select appropriate collection site.
8. Place the tourniquet above the selected collection site. Do not leave tourniquet on for longer than one minute.
9. Clean site with alcohol using circular motion from center outward; allow to air dry (using a gauze pad may re-contaminate the area).
10. Grasp arm 1-2 inches below the site to decrease vein rolling.
11. Enter the vein with the vacutainer needle bevel up at a 15 degree angle.
12. Fill necessary blood tubes and mix each specimen as required.
13. If venipuncture using regular size blood collection tubes does not provide a sufficient sample volume, continue specimen collection using microtainer tubes.
14. For younger participants, use the pediatric microtainer system for collecting blood by venipuncture.
15. Use skin puncture for blood collection only when strictly necessary.
16. Place sharps in puncture resistant sharps container.
17. Apply gauze and tape holding pressure for 2 to 3 minutes to minimize the formation of a hematoma.
18. Remove gloves and wash hands.

Table 1. Collection Chart – Baseline, 12 Months and 36 Months

Analyses	Fasting Condition	Blood Collection Tube	Visual Reference	Clinic Instructions
HbA1c	Non-Fasting Acceptable	2.0mL EDTA purple-top		1. Do **NOT** centrifuge 2. Freeze **Label: HbA1c**
Lipid Profile Glucose ALT Insulin hsCRP	Fasting	7.5mL SST tiger-top		1. Room temp 20-30 min. 2. Centrifuge 3. Transfer 1.5mL into 2.0mL blue top. Freeze and ship on dry ice. **Label: Lipid/Glu/ALT** 4. Transfer 0.5mL into 2mL vial blue top. Freeze and ship on dry ice. **Label: Insulin** 5. Transfer 0.5mL into 2.0mL blue to. Freeze and ship on dry ice. **Label: CRP**

9.3. Detailed Instructions

It is the phlebotomist's responsibility to determine the appropriate procedure to use for blood collection. Once determined, strict adherence to the instructions outlined below should be followed, referencing the appropriate table above for guidance.

Briefly, the steps to take are as follows:

1. Label specimen tubes and vials.
2. Verify that the participant has reported as fasting: **8 hours minimum**, 10 hours recommended *(if noncompliant, if you choose to draw blood anyway, make sure to indicate actual number of hours on the specimen shipment form in comments section; Appendix 2).*
3. Collect specimens.
4. Centrifuge and process.
5. Freeze specimens.
6. Ship frozen specimens.

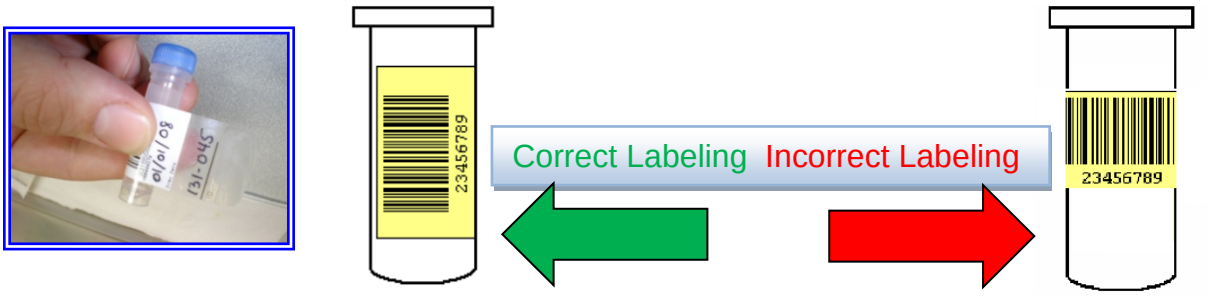
9.4. How should the specimens be labeled?

The Central Laboratory provides labels to clinics. Participant ID and draw date information must be hand-written on the labels for the Baseline visit, where indicated. Do this before removing labels from their page, and use an indelible pen. Follow up

visit labels will be pre-printed with the subject ID numbers and shipped to the sites prior to the participant visits.

Affix the appropriate label (as denoted on the label) to each of the blood tubes and sample vials according to the instructions provided on the Collection Chart (Table 1, page 12).

Label orientation is important for proper scanning of the barcode. Please affix labels to the collection tube and transfer tubes as shown here, with the barcode number running vertically.



9.5. In which order do I collect specimens?
Specimens should be collected in the order they are listed in Table 1 provided on page 12. This order was developed to ensure that the most crucial specimens are collected with priority.

Additionally, the following rules should be adhered to when collecting specimens:

As you draw blood, remember to:

- Mix each blood tube (purple-top) **8-10 times immediately** after collection by inverting the tube gently and evenly. This assures adequate mixing with the anticoagulant.

- The same needs to be performed with the serum tiger-top tubes to assure adequate mixing of silica particles with the blood, which is required to activate clot formation. Gently invert these tubes **5 times**.

- **Avoid under-filling** the collection tubes. Purple-top collection tubes containing EDTA must be filled to at least 30% of the fill volume of the tube. If the tube is not filled to at least 30% of fill volume, there will be a dilutional effect from the anticoagulant and the specimen will be unsatisfactory for testing.

Once blood has been collected and mixed:

- To allow clot formation prior to their transfer to the centrifuge, the serum tiger-top tubes must stand upright at **room temperature for at least 20 minutes, but no longer than 30 minutes**. <u>If there is a deviation of +/- 10 minutes, this fact should be noted on the specimen requisition form under comments.</u>

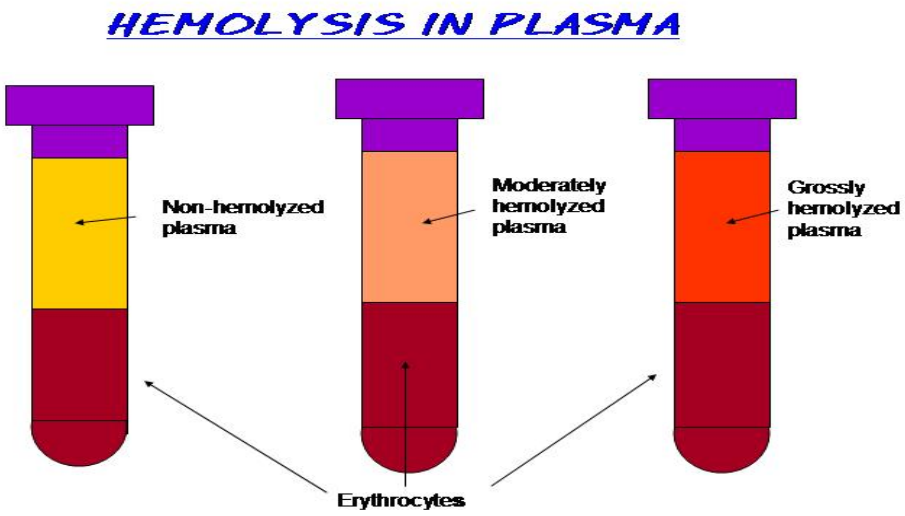
9.6. What causes hemolysis?

Causes of Hemolysis and/or Red Blood Cell Contamination

Please note that the accuracy of analysis depends on the quality of the samples.
Hemolysis can interfere with many of the laboratory analysis. To reduce the rate of hemolyzed or contaminated specimens, please review your specimen handling procedures with the rules shown below in mind. Please ensure that all centrifuged specimens are inspected for erythrocyte contamination. If erythrocytes (red blood cells) are observed floating in the serum or plasma layer, re-centrifugation is required. If the specimen is grossly hemolyzed (as shown below), collect a fresh specimen, and discard the old one. If there is an indication of sample hemolysis, this should be noted on the Specimen Shipment form.

The usual causes of hemolysis and or erythrocyte contamination are as follows:

1. *Specimen collection with needles smaller than 21 gauge*
2. *Prolonged tourniquet application*
3. *Improper centrifuge speed—all centrifuges need to be inspected annually to verify proper RPM ~ 3,000 +/-300 or 3500 RPM for free rotor centrifuges*
4. *Improper or non- balancing of the centrifuge*
5. *Prolonged centrifugation time which can lead to a heat build-up*
6.



Centrifugation prior to clotting of the specimen

9.7. How do I process specimens?

Centrifuge blood tubes (except the purple-top for HbA1c):

After a strictly followed ***20 to 30 minutes*** standing at room temperature, transfer the SST tiger-tops to the centrifuge, loading the centrifuge according to the manufacturer's instructions.

Centrifuge at 1200 - 1500 RCF (g) [~3500 RPM] for 10 minutes.

Refrigerated Centrifuge
If using a refrigerated centrifuge, set the temperature to 4°C. Following centrifugation, transfer the tubes to a refrigerator set at 4°C or prepare the appropriate tubes for immediate shipment (as described in the next section).

Non-refrigerated Centrifuge
If using a non-refrigerated centrifuge, it is *imperative* that blood tubes not be allowed to sit unattended after rotation has ceased. This process generates heat and tubes must be immediately transferred to the refrigerator once spinning has stopped. It is recommended that a timer pinned to the lab coat be used to alert you when tubes will need to be transferred. ***Leaving tubes in a non-refrigerated centrifuge or at room temperature will compromise the accuracy of the analyses***.

Prepare frozen vials soon after centrifugation is complete:

To avoid sample degradation, the entire procedure of collecting, processing and solidly freezing specimens (at -20°C, -70°C or buried in dry ice) must be completed ideally within 1 hour but never exceeding 2 hours.

To avoid aerosol or possible splashing that may occur while uncapping the tubes, we strongly recommend using a face-shield or counter-top splashguard during this procedure.

Obtain the SST tiger-top tube after centrifugation and twist off the caps, ensuring that the last movement opens the stopper away from the face. Hold the tube upright in one hand. Obtain a disposable transfer pipette and decant the appropriate volumes listed on the collection chart (Table 1) on page 12. Use a clean pipette for each vacutainer.

Be extremely careful to not disturb the cell border with the pipette tip as this may allow red cells to contaminate the serum.

Recap the cryovial tightly; gently invert it several times to mix the sample, and place it in a Revco freezer storage box (vials from multiple participants should be kept in the same Revco box to maximize efficiency). The Revco box should be immediately placed at -20°C, -70°C or buried in dry ice, until its shipment to the Central Laboratory. Re-cap vacutainer and discard in a biohazard waste container.

10. PREPARING SPECIMENS FOR SHIPMENT?

10.1. Frozen Specimens

Serum and plasma vials being stored in Revco boxes at -20°C or -70°C should be shipped to the Central Laboratory on dry ice. If the vials have been stored in dry ice only, due to no freezer access, they should be shipped **on the day of collection**. When possible, avoid shipping frozen specimens on Friday. **NEVER SHIP SAMPLES ON FRIDAY OR SATURDAY!**

Please follow this procedure to prepare frozen specimens for shipment:

- On an on-going basis, the *Frozen Specimen Shipment Form* (Appendix 2) should be filled-in as specimens are processed and transferred to the freezer. This way, when it is time to ship to the Central Laboratory, all that needs to be done is to verify the completed shipment forms with the vials included in the shipment.
- Do this by removing the lid of the Revco box, keeping the bottom half on dry ice, and quickly comparing the box contents to the shipment forms. Once the contents have been confirmed, replace the lid, keeping the Revco box on dry ice, and ready the shipping container as described in the Shipping Frozen Specimens section.

11. SHIPPING INSTRUCTIONS

11.1. General Procedures

The guidelines for shipping patient specimens are outlined in detail in Appendix 6.

Frozen vials are shipped in batches on dry ice. In-the-field collection sites that do not have access to a -20°C freezer should place the processed frozen vials in dry ice and ship on the day of collection.

Shipment Forms

Master copies of the Frozen Specimen Shipment Form are in Appendix 2. Make multiple copies for your use.

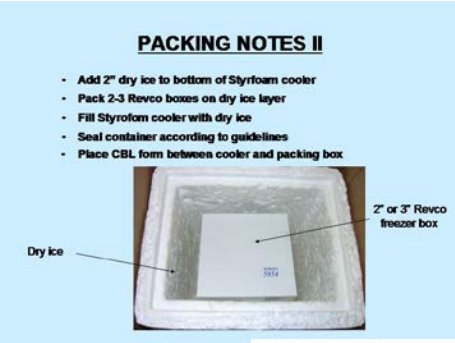
This form is used to indicate the number and types of vials included in the shipment, the identity of the samples, and pertinent clinic and visit information. The forms are organized so that one form must be filled out per subject per visit for the frozen samples. When a shipment is made, a photocopy of the form(s) should be produced and retained at the clinic. The original(s) are placed in a ziploc bag and included with the specimens.

Shipping Containers and Coolant

Polyfoam shipping containers and cold-packs are provided by the Central Laboratory. ***Please freeze cold-packs in a -20°C freezer, as opposed to a -70°C freezer, as excessive freezing of the cold-packs may cause partial freezing of the specimens during transport, compromising the accuracy of analysis.***

To ship FROZEN specimen vials, follow these steps:

- Obtain a polyfoam shipping container and place one to two Revco freezer storage boxes containing the specimen vials inside (the Revco boxes should be placed inside biohazard bags first), fill the shipping container with dry ice to capacity, and fit the polyfoam lid on tightly. Label the shipping box with dry ice labels and "Exempt Human Specimen" label prior to shipping.



- Make a copy of the *Frozen Shipment Form(s)* and retain at the clinic. Place the original(s) in a ziploc bag, positioning it inside the polyfoam shipping container. Close the cardboard exterior shell around the polyfoam container and tape shut. Affix completed air bill to the container, choose **Priority Overnight**, and call FedEx for pickup.

Shipments should be addressed to:

COPTR Central Laboratory
Northwest Lipid Metabolism & Diabetes Research Laboratories
401 Queen Anne Avenue N.
Seattle, WA 98109
Phone: (206) 616-6474

FAX the Central Laboratory with the FedEx tracking number(s):

Any day a shipment is made, FAX the Central Laboratory, using a copy of the *Shipment Notification Fax* form (Appendix 7), to alert of a shipment's pending arrival. This will allow laboratory personnel to investigate and track packages if there are delays or problems with the courier. Make multiple copies of this form for your use since one will be used each day a shipment is made. **Fax the completed form to: 206-685-6880**.

11.2. Shipping Schedule

Shipments can be made **Monday through Thursday** of the week.

Do not ship frozen samples on a Friday, for Saturday Delivery.
NEVER SHIP SAMPLES ON SATURDAY.

11.3. Holiday Schedule

The CCL is officially closed on all US federal holidays and, more importantly, **FedEx will NOT deliver on these days.** Therefore, avoid shipping on any day preceding a US federal holiday (see calendar below).

When a holiday falls on a Monday or Tuesday, the last day to ship samples is the Thursday of the preceding week. The samples are expected to be delivered on Friday, but if there is a delay we will receive the samples on Saturday. When a holiday falls on a Friday, the last day to ship samples is the Wednesday of that week.

Due to the length of the **Thanksgiving holiday**, the last day to ship samples is the Monday of Thanksgiving week. The samples are expected to be delivered on Tuesday, but if there is a delay we will receive the samples on Wednesday.

Federal Holiday	2012	2013	2014
New Year's Day	Monday, January 2	Tuesday, January 1	Wednesday, Janurary 1
MLK Jr's Birthday	Monday, January 16	Monday, January 21	Monday, January 20
President's Day	Monday, February 20	Monday, February 18	Monday, February 17
Memorial Day	Monday, May 28	Monday, May 27	Monday, May 26
Independence Day	Wednesday, July 4	Thursday, July 4	Friday, July 4
Labor Day	Monday, September 3	Monday, September 2	Monday, September 1
Veterans Day	Monday, November 12	Monday, November 11	Tuesday, November 11
Thanksgiving	Thursday, November 22 Friday, November 23	Thursday, November 28 Friday, November 29	Thursday, November 27 Friday, November 28
Christmas Day	Tuesday, December 25	Wednesday, December 25	Thursday, December 25

Federal Holiday	2015	2016
New Year's Day	Thursday, January 1	Friday, January 1
MLK Jr's Birthday	Monday, January 19	Monday, January 18
President's Day	Monday, February 16	Monday, February 15
Memorial Day	Monday, May 25	Monday, May 30
Independence Day	Friday, July 3	Monday, July 4
Labor Day	Monday, September 7	Monday, September 2
Veterans Day	Wednesday, November 11	Friday, November 11
Thanksgiving	Thursday, November 26 Friday, November 27	Thursday, November 24 Friday, November 25
Christmas Day	Friday, December 25	Monday, December 26

12.1. Assays and Quality Control

12.1 Hemoglobin A1c

The measurement of the relative proportion of hemoglobin subclasses and calculation of the HbA1c levels are performed by an NGSP-certified auto-analyzer (G-8 Tosoh, Biosciences, Inc.) using non-porous ion exchange high performance chromatography to achieve rapid and precise separation of stable HBa1c from other hemoglobin fractions. The system calibration is maintained using two point calibration reagents. A set of quality control samples are analyzed twice daily. The acceptance allowance for quality control is + 0.1% variance from the target value for the low level, and + 0.2% variance from the target value for the high level. The inter-assay CVs for the low and high quality control samples are 0.9% and 0.6%, respectively.

12.2. Glucose

Analysis of fasting and post glucose intake samples is performed enzymatically on a Roche Hitachi Modular P chemistry autoanalyzer. This instrument executes the glucose hexokinase method described by Schmidt and Bergmeyer (1974) and Peterson and Young (1958) and recognized as the most specific method for the determination of glucose. Quality control samples with normal and high glucose levels are used for monitoring glucose assay performance. The inter-assay CV is <3%. Lyophilized samples at two different glucose concentrations are used to monitor possible analytical drift.

12.3. Lipid Profile

Measurements of total plasma cholesterol in plasma, cholesterol in the lipoprotein fractions and triglycerides are performed enzymatically on the Roche Modular P autoanalyzer using methods standardized to the Centers for Disease Control and Prevention Reference Methods. Determination of HDL-cholesterol is performed after precipitation of apo B-containing particles by dextran sulfate Mg2+. LDL-cholesterol is calculated by the Friedewald equation. This approach for measuring LDL-cholesterol is clinically reliable if the measurements of total cholesterol, HDL-cholesterol and triglycerides are performed with a high level of accuracy and precision. However, the Friedewald equation for the estimation of LDL-cholesterol is inaccurate when triglycerides are >400 mg/dl. In this case, a complete lipoprotein separation by ultracentrifugation which allows quantitation of the individual lipoprotein classes is performed using the Lipid Research Clinics Beta Quantification procedure.

Quality control materials (BCL-Low, BCL-High (Biocell Laboratories) and L1-Medium (In-house prepared fresh frozen pool) are used at the beginning and at the end of each run.

The inter-assay CVs are consistently <1.5% for total cholesterol and triglycerides and <2% for HDL cholesterol.

Long-term Drift: A large quantity of two lyophilized quality control materials was acquired from Bio Rad for lipids. Values for each analyte were assigned by analyzing the samples daily for at least two weeks to achieve a minimum of 50 values. The mean of all the values constitutes the target value for each analyte. These materials are stored at -70°C and analyzed monthly to monitor for analysis drift. Actions are taken if the values are consistently above or below the 2 SD limit on two consecutive months.

12.4. C-Reactive Protein

Levels of C-reactive protein (CRP) in plasma are measured immunochemically on a nephelometer autoanalyzer (BNII). The reagents are obtained from Siemens Inc. This high sensitivity method is based on polystyrene particles coated with monoclonal antibodies specific to CRP which form immunocomplexes with CRP in plasma samples.The intensity of the scattered light in the nephelometer is directly proportional to the concentration of CRP which is determined versus dilutions of a standard of a

known CRP concentration. The method is standardized against the IFCC/BCR/CAP reference preparation.

12.5. Insulin

The Insulin assay is a two site immuno-enzymometeric assay performed using Tosoh 2000 auto-analyzer. The assay is calibrated to WHO IRP 66/304 standard. The assay has a sensitivity level of 0.5 uU/mL and the standard curve linearity is up to 330 uU/mL. A set of high, medium and low insulin level controls are included in each batch of samples to monitor assay performance. The inter assay CVs for Low, Medium and High insulin level controls are 2.8%, 2.5% and 2.0% respectively. The assay has high specificity as cross- reactivity with Human C-peptide, intact Proinsulin, split (32, 33) Proinsulin and Des (64,65) proinsulin is 0%, 2 %, 2.6% and 39.8 % respectively. A Reference Interval for apparently healthy donors has been established at <17.0 uU/mL. The laboratory has participated in external proficiency evaluation program by the College of American Pathologists (CAP). Additionally, the laboratory has participated in the ADA sponsored Insulin Standardization workshops in 2007 and 2011. In the 2007 insulin standardization workshop this assay was reported as top performer with high sensitivity and specificity. Most recently, in 2011, ADA Insulin standard prepared and target level assigned by IDMS reference method was distributed to the laboratories. The ADA criteria of individual laboratory performance was set at up to 15.5% measurement bias from the assigned target level. Using the current insulin assay our laboratory achieved a bias less than 8.5%.

12.6. Alanine Aminotransferase (ALT)

This assay is performed on a Roche Double Modular P Analytics automated analyzer using Roche Diagnostics reagents. L-alanine reacts with alphaketoglutarate in the presence of ALT to form pyruvate and Lglutamate. NADH is then added to the pyruvate in the presence ofLDH to form L-lactate and NAD+. The rate of NADH oxidation to form NAD+ is directly proportional to the rate of pyruvate formation indicating ALT activity. The rate of decrease in absorbance at 340nm due to the formation of NAD is directly proportional to the rate of pyruvate formation and proportional to the ALT activity of the sample. The normal reference ranges for adults are: 17–67U/L (Male) and 13–50U/L (Female).

13. DATA MANAGEMENT

13.1 Transfer of Lab Results to Field Sites

The NWRL will send a report of the lab results to the Field Site within a week of receipt of shipment.

13.2 Transfer of Biomedical measures data to RCU

The sites receive the lab results from the NWRL and the information is entered or downloaded into the site's Data Management System within 2 weeks after being received from NWRL. The fasting time is also entered into the sites data management system and is transferred to the RCU with the lab results (Appendix 4). The adopted protocol for transferring biomedical measures data to the RCU requires a single data upload from each

site on a quarterly basis via the RCU Data Capture website. The RCU may request data at other times for purposes of reporting to the DSMB.

The table below shows the start and end dates of each quarter and when the data transfer to the RCU must be completed.

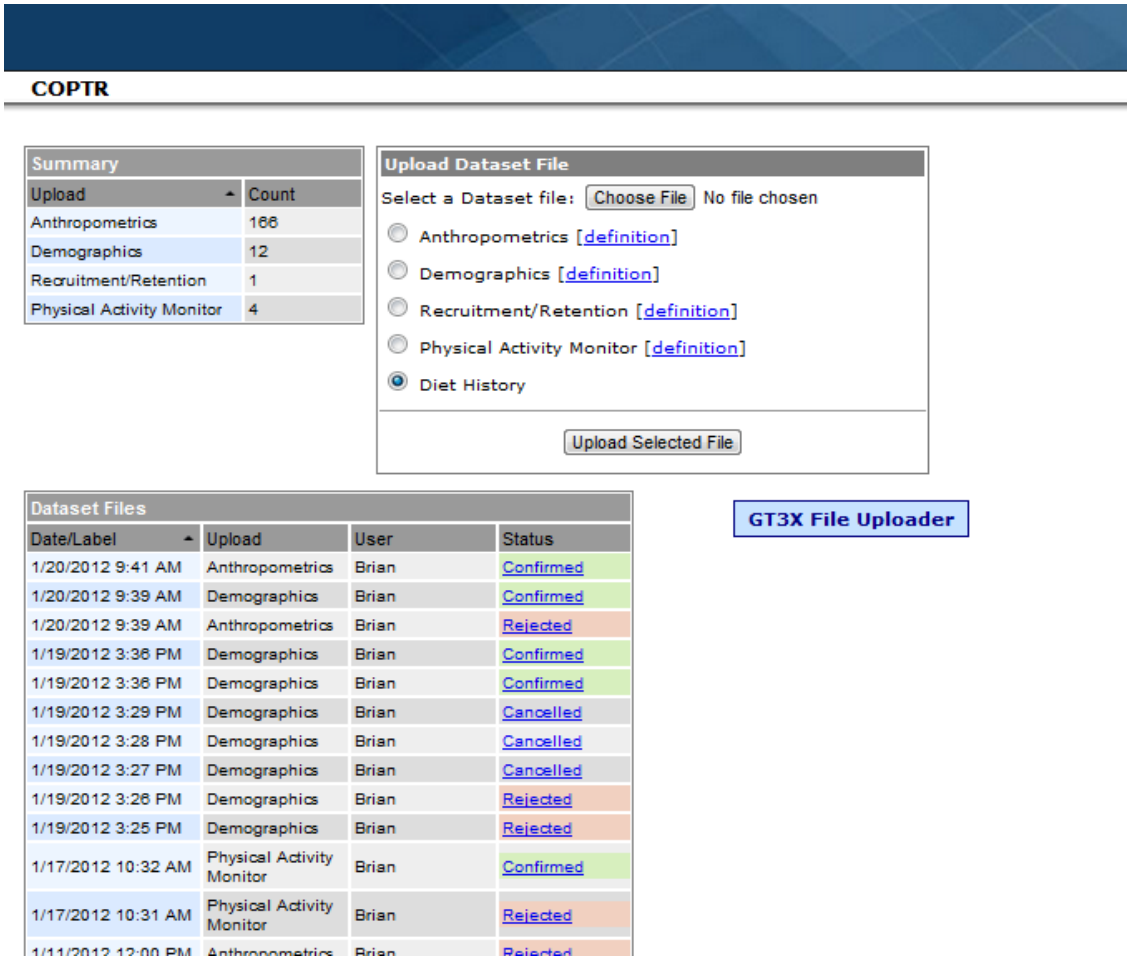
Data upload schedule

Quarter	Measurement		Due to RCU
	Start Date	End Date	
1	January 1	March 31	April 15
2	April 1	June 30	July 15
3	July 1	September 30	October 15
4	October 1	December 31	January 15

The Measurement Coordinator stores all the logs detailed in the appendices in either paper or electronic form. The logs must be available for inspection by the site Principal Investigator, the RCU and other officials related to the COPTR study if requested.

Process for Uploading to the RCU (see screen example below)

visit the RCU Data Center at: www.shepscenter.unc.edu/coptr
login with your user id and password
Browse and select the appropriate quarterly output ZIP file
Select “Biomedical” as the dataset type
Select “Upload Selected File”



COPTR

Summary

Upload	Count
Anthropometrics	166
Demographics	12
Recruitment/Retention	1
Physical Activity Monitor	4

Upload Dataset File

Select a Dataset file: Choose File No file chosen

- Anthropometrics [definition]
- Demographics [definition]
- Recruitment/Retention [definition]
- Physical Activity Monitor [definition]
- Diet History

Upload Selected File

Dataset Files

Date/Label	Upload	User	Status
1/20/2012 9:41 AM	Anthropometrics	Brian	Confirmed
1/20/2012 9:39 AM	Demographics	Brian	Confirmed
1/20/2012 9:39 AM	Anthropometrics	Brian	Rejected
1/19/2012 3:36 PM	Demographics	Brian	Confirmed
1/19/2012 3:36 PM	Demographics	Brian	Confirmed
1/19/2012 3:29 PM	Demographics	Brian	Cancelled
1/19/2012 3:28 PM	Demographics	Brian	Cancelled
1/19/2012 3:27 PM	Demographics	Brian	Cancelled
1/19/2012 3:26 PM	Demographics	Brian	Rejected
1/19/2012 3:25 PM	Demographics	Brian	Rejected
1/17/2012 10:32 AM	Physical Activity Monitor	Brian	Confirmed
1/17/2012 10:31 AM	Physical Activity Monitor	Brian	Rejected
1/11/2012 12:00 PM	Anthropometrics	Brian	Rejected

GT3X File Uploader

APPENDIX 1.SITE-SPECIFIC INFORMATION FOR BIOMEDICAL MEASURES

Information on pertinent site specific procedures may be placed behind this page. These pages are generated by the investigators at the site rather than by the RCU.

APPENDIX 2. FROZEN SPECIMEN SHIPMENT FORM

Shipment Form Barcode Label

The COPTR Central Laboratory
Northwest Lipid Metabolism and Diabetes Research Laboratories – University of Washington
401 Queen Anne Avenue North, Seattle, WA 98109-4517
Phone: (206) 616-6474 FAX: (206) 685-6880

FROZEN SPECIMEN SHIPMENT FORM

This form is used to accompany specimen(s) drawn from a single subject and shipped to the Central Laboratory for analysis. Refer to the Laboratory Manual of Procedures for detailed instructions – **This form is not an instructional sheet**. Once completed, photocopy this form and retain at the clinic. The original should be placed into a Ziploc bag, inside the polyfoam shipping container.

Participant Information:

Site:	☐☐
Participant ID:	☐☐☐☐☐
Acrostic:	☐☐☐☐
Visit:	❑ Baseline ❑ Month 12 ❑ Month 36 ❑ Redraw for Visit _____
Collection Date:	☐☐ / ☐☐ / ☐☐ (Month / Day / Year)

Check ✓ Items Included in Shipment:

HbA1c	Whole Blood	❑ 2.0mL EDTA Purple-top	❑ Missed
Glucose Lipid Profile ALT	Serum	❑ 2.0mL Blue Cap Cryovial	❑ Missed
Insulin	Serum	❑ 2.0mL Blue Cap Cryovial	❑ Missed
CRP	Serum	❑ 2.0mL Blue Cap Cryovial	❑ Missed

It is important that the laboratory be able to contact the person who performed this visit and completed this form:

Contact: _____

Phone: _____

Email: _____

Comments:

_____

_____

_____

_____

APPENDIX 3. SUPPLY REQUEST ORDER FORM

The COPTR Central Laboratory

SUPPLY REQUEST FORM

✵ALL REQUESTS FOR SUPPLIES SHOULD BE MADE AT LEAST✵

***TWO WEEKS* PRIOR TO THEIR ANTICIPATED NEED**

Clinic: _____ Order Completed by: _____ Phone: _____

Date Ordered: _____/_____/_____ Date Needed: _____/_____/_____
MM DD YY MM DD YY

Date Request Received by Lab: ____/____/____ Date Supplies Shipped from Lab: ____/____/____
MM DD YY MM DD YY

ITEM	QUANTITY DESIRED	QUANTITY SHIPPED	QUANTITY PENDING
2.0mL Purple-top Vac.			
7.5mL Tiger SST Vac.			
Transfer Pipettes			
2mL blue-cap Cryo Vial			
Absorbent Pad			
Shipping Container			
2" Revco Freezer Box			
Ziploc Bags			
Biohazard Plastic Bags			
Barcode Labels			
FedEx Air bills			

Question: Please call:
Marlon Ramirez 206-685-3328

- Fill in the amount of each item desired on the table to the left.
- Fax the completed form to the Lab: **206-616-4889**
- Your order will be pr**ocessed and s**hipped to you with a copy of this form enclosed.
- Upon receipt, verify that the contents exactly match the supplies specified on this form.
- If there are no discrepancies, sign the form and fax back to the Lab.
- If there are problems, please call: **206-685-3328**

Comments:

_____

_____

_____

_____

I have reviewed the contents of my shipment and confirm that all supplies listed have been received.

Signed: _____ Date: _____

APPENDIX 4. BIOMEDICAL MEASURES DATA COLLECTION FORM

To be completed by COPTR staff:
Index Child ID: _____
Form Code: **BIO** Version:

1. Today's Date: ___ / ___ / ____
mm dd yyyy

2. Visit: __ (e.g. 0 for baseline 12 for 12 months, 36 for 36 months)

3. Time: ___: ___ 1 ☐ AM 2 ☐ PM
hh mm

4. When was the last time you ate or drank anything except water:
Day last consumed: 1 ☐ Today
2 ☐ Yesterday

Time last consumed: Time: ___: ___ 1 ☐ AM 2 ☐ PM
hh mm

5. Computed fasting time: _____ hours (see attached table if not calculated automatically)

BIOMEDICAL LAB MEASURES

6. Hemoglobin A1c (HbA1c)	__ __ . __ %
7. Glucose	__ __ __ __ __ mg/dL
8. Total Cholesterol	__ __ __ __ mg/dL
9. VLDL Cholesterol-Estimated (Trig/5)	__ __ __ __ mg/dL
10. LDL-cholesterol-derived	__ __ __ __ mg/dL
11. HDL-cholesterol	__ __ __ __ mg/dL
12. Triglycerides	__ __ __ __ mg/dL
13. high-sensitivity C-reactive protein (hs-CRP)	__ __ __ . __ __ __ mg/L
14. Insulin	__ __ __ __ . __ uU/mL
15. Alanine Aminotransferase (ALT)	__ __ __ __ . __U/L

16. Was LD-cholesterol directly measured? 1 ☐ Yes

Fasting Time Computation Table

Time Last Consumed		Time of Visit: AM 7-7:59	8-8:59	9-9:59	10-10:59	11-11:59	PM 12-12:59	1-1:59	2-2:59	3-3:59	4-4:59	5-5:59	6
Yesterday...													
PM	Earlier	13	14	15	16	17	18	19	20	21	22	23	
	7-7:59	12	13	14	15	16	17	18	19	20	21	22	
	8-8:59	11	12	13	14	15	16	17	18	19	20	21	
	9-9:59	10	11	12	13	14	15	16	17	18	19	20	
	10-10:59	9	10	11	12	13	14	15	16	17	18	19	
	11-11:59	8	9	10	11	12	13	14	15	16	17	18	
Today...													
AM	12-12:59	7	8	9	10	11	12	13	14	15	16	17	
	1-1:59	6	7	8	9	10	11	12	13	14	15	16	
	2-2:59	5	6	7	8	9	10	11	12	13	14	15	
	3-3:59	4	5	6	7	8	9	10	11	12	13	14	
	4-4:59	3	4	5	6	7	8	9	10	11	12	13	
	5-5:59	2	3	4	5	6	7	8	9	10	11	12	
	6-6:59	1	2	3	4	5	6	7	8	9	10	11	
	7-7:59	0	1	2	3	4	5	6	7	8	9	10	
	8-8:59		0	1	2	3	4	5	6	7	8	9	
	9-9:59			0	1	2	3	4	5	6	7	8	
	10-10:59				0	1	2	3	4	5	6	7	
	11-11:59					0	1	2	3	4	5	6	
PM	12-12:59						0	1	2	3	4	5	
	1-1:59							0	1	2	3	4	
	2-2:59								0	1	2	3	
	3-3:59									0	1	2	
	4-4:59										0	1	
	5-5:59											0	

APPENDIX 5. COPTR BIOMEDICAL MEASURES TRAINING CERTIFICATION LOG

Name	Training Date(s)	Certification Date	Certified by	Biomedical measures certified to measure (*master trainer)

APPENDIX 6. GUIDELINES FOR SHIPPING PATIENT SPECIMENS

GENERAL INFORMATION

Summary of Patient Specimen Exemptions: Under IATA DGR 2007, Section 3.6.2.2.3.6 permits certain types of patient specimens to be shipped with reduced documentation, labeling, and packaging if the specimens meet the standards for the exemption. Specimens that meet the following definitions and other criteria are qualified for the exemption; specimens that fail to meet the definition and other criteria must continue to be meet the 2007 rules:

1. Specimen must meet the following definition:

Specimens are those collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components …being transported for purposes such as research, diagnosis, investigational activities, disease treatment, and prevention.

2. Minimal likelihood that the specimen contains a pathogen:

A patient …specimen is considered exempt if there is a minimal likelihood that pathogens are present. In determining whether a patient …specimen has a minimal likelihood that pathogens are present, an element of professional judgment is required to determine if a substance is exempt. This judgment should be based on the known medical history, symptoms, and individual circumstances of the source …and endemic local conditions.

Examples of specimens which MAY be transported under the exemption include the blood or urine tests to monitor cholesterol levels, glucose levels, or hormone levels, …tests required to monitor organ function such as heart, liver, or kidney function for humans…and antibody detection in humans…

Patient …specimens, for which there is minimal likelihood that pathogens are present may utilize the exemption, provided the specimen is in a packaging which will prevent any leakage. The packaging must meet the following conditions:

1. The packaging must consist of three components:

(a) a leak-proof primary receptacle (s);
(b) a leak-proof secondary packaging, and
(c) an outer packaging of adequate strength for its capacity, mass and intended use, and with at least one surface having minimum dimensions of 100 mm x 100 mm.

2. For liquids, absorbent material in sufficient quantity to absorb the entire contents must be placed between the primary receptacle(s) and the secondary packaging so that during transport, any release or leak of a liquid substance will not reach the outer

packaging and will not compromise the integrity of the cushioning material.

3. When multiple fragile primary receptacles are placed in a single secondary packaging, they must be individually wrapped or separated to prevent contact between them.

DOCUMENTATION

1. If dry ice is used as a refrigerant, mark "Dry ice, 9, UN1845, III on the air bill (check the dry ice checkbox on the FedEx air bill).

2. Check the "no" checkbox on the FedEx air bill in response to the question: "Does this shipment contain Dangerous Goods"

PACKAGING and LABELING

1. Place the "Exempt Human Specimen" label on the outside of the shipping box if the specimen contains no known pathogen.

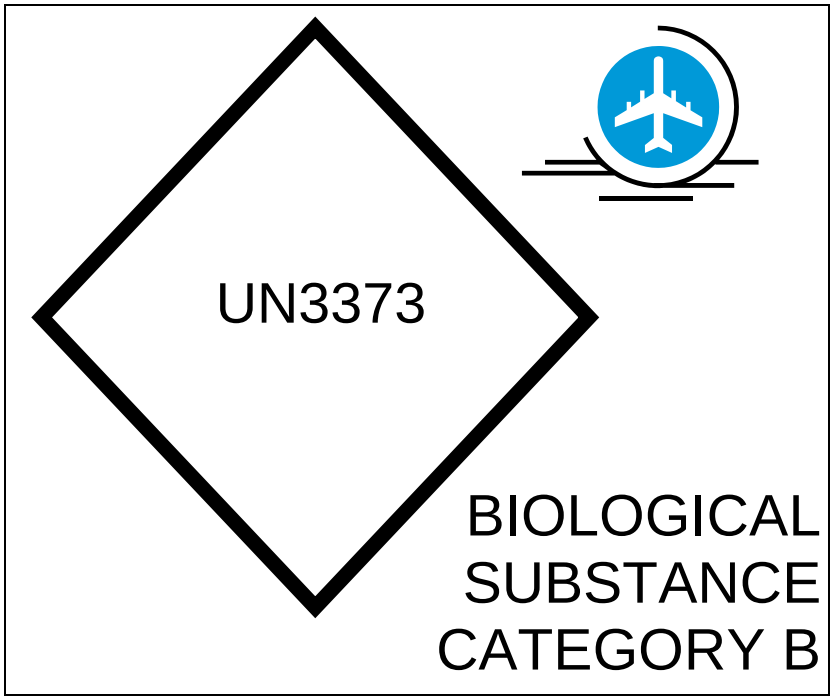
2. DO NOT use the "Biological Substance, Category B UN3373" label on the outer container unless you ARE aware the specimen contains a pathogen.

3. If dry ice is used as a refrigerant place the standard Dry Ice label on the outside of the shipping box and complete the required information on it.

Be certain to review these policies with your institution to assure compliance with your local policies or determinations. The information provided here is our recommendation for clinical sites to expedite shipments in the most efficient manner while maintaining compliance with IATA regulations.

Affix "Exempt Human Specimen" label on all shipments that have NO KNOWN PATHOGENS.

Affix this label to the outside box ONLY when you are AWARE you are sending specimens that contain **known** pathogens.



SHIPPING DRY ICE REFRIGERATING A NON-DANGEROUS COMMODITY[1]

Step 1 Understand that Dry ice is a listed Dangerous Good. "Dry Ice" appears in bold print and is therefore a Proper Shipping Name. ("Carbon dioxide, solid" may also be used.)

UN/ ID No.	Proper Shipping Name/Description	Class or Div.	Sub Risk	Hazard Label(s)	PG	Passenger and Cargo Aircraft				Cargo Aircraft Only		S.P. see 4.4	ERG Code
						Ltd Qty							
						Pkg Inst	Max Qty per Pkg	Pkg Inst	Max Qty per Pkg	Pkg Inst	Max Qty per Pkg		
A	B	C		E	F	G	H	I	J	K	L	M	N
1845	Dry Ice†	9		Miscel-laneous	III	—	—	904	200 Kg	904	200 Kg	A48	9L

Step 2 As a listed dangerous good packaging must conform to Packing Instruction #904. The Special Provision in Column M ("A48") states that packaging tests are not considered necessary. (No UN packaging is required.)

[1] This information is intended to promote safe shipping and handling by the University of Washington and those entities that conduct business with the University of Washington. It is not intended to meet any training requirements or to constitute a determination of compliance with the law. Any non-University of Washington entity must make an independent determination of compliance with the law.

Step 3 The General Packing Requirements (See Below) must be followed, but we may use any good, strong non-spec outer packaging designed to allow the outflow of dry ice vapors. The Shipper's Declaration is not required for Dry ice and non-dangerous goods. Dry ice may be included in an over pack, provided the over pack meets the requirements of Packing Instruction 904.

IATA Dangerous Goods Regulations

PACKING INSTRUCTION 904

STATE VARIATIONS: USG-13

OPERATOR VARIATIONS: HP-02, IC-08, VN-11

☐ This instruction applies to UN 1845 on passenger and cargo aircraft and CAO.

The General Packing Requirements of 5.0.2 must be met.

Carbon dioxide, solid (dry ice), when offered for transport by air, must be in packaging designed and constructed to permi the release of carbon dioxide gas and to prevent a build-up of pressure that could rupture the packaging.

Arrangements between shipper and operator(s) must be made for each shipment, to ensure ventilation safety procedures are followed.

The Shipper's Declaration requirements of Subsections 8.1 and 10.8.1 are only applicable when the Carbon dioxide, solic (dry ice) is used as a refrigerant for dangerous goods that require a Shipper's Declaration.

△ When a Shipper's Declaration is not required, the following information, as required by 8.2.3 for the Carbon dioxide, solic (dry ice), must be contained in the "Nature and Quantity of Goods" box on the air waybill:

- proper shipping name (**Dry ice** or **Carbon dioxide, solid**);
- UN 1845;
- the number of packages; and
- the net quantity of dry ice in each package.

The net weight of the Carbon dioxide, solid (dry ice) must be marked on the outside of the package.

Note 1: *Refer to the relevant airline's loading procedures for Carbon dioxide, solid (dry ice) limitations.*

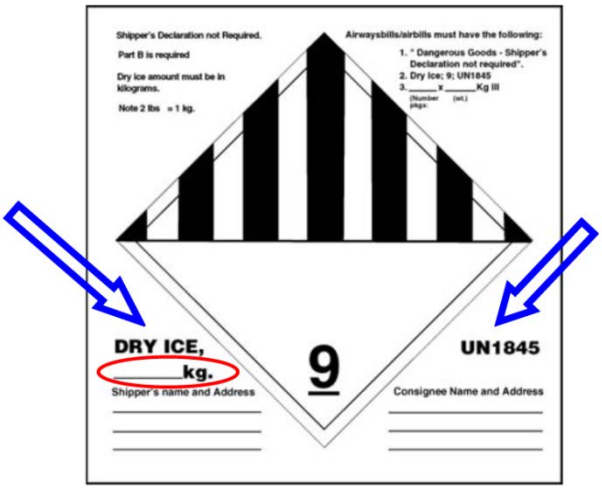
Note 2: *For Air Waybill requirements see 8.2.3. For loading instructions see 9.3.12.*

Note 3: *For cooling purposes, an overpack may contain Carbon dioxide, solid (dry ice), provided that the overpack meets the requirements of Packing Instruction 904.*

5
904

Step 4 Mark and label the package. While you don't need a UN specification package or a DDG, the package must be marked and labeled. Mark the outside of the outer package with the gross weight of dry ice inside.

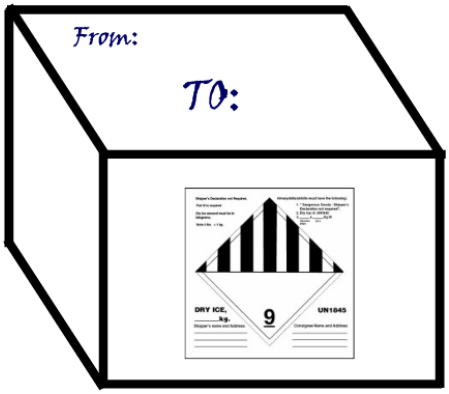
If you have one of these labels that has the proper shipping name and ID number pre-printed on it (See the arrows) then all you need to do is fill in the weight in Kg of the dry ice inside and list it in the encircled area.



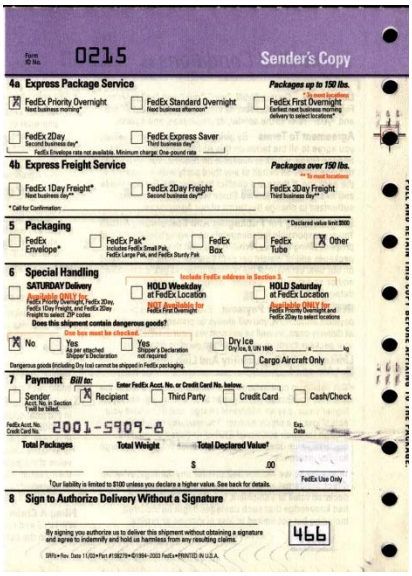
If you use a regular class 9 label you will need to mark the box with the proper shipping name, UN number and the weight of dry ice in kilograms.

"Dry Ice"
"UN1845"
"___ Kg"

The Finished box should look like this:



In the “Special Handling” area of the waybill, you need to check the “Dry Ice” box and list the number of packages and net quantity of dry ice per package.



APPENDIX 7. FAX NOTIFICATION FORM

FAX NOTIFICATION

The COPTR Central Laboratory

Northwest Lipid Metabolism and Diabetes Research Laboratories – University of Washington

TO: **Specimen Processing**
FAX: **(206) 685-6880**
Phone: (206) 616-6474

FROM: Contact: _____

Phone: _____

FAX: _____

PLEASE BE ADVISED OF THE FOLLOWING SHIPMENT ARRIVAL:

Clinical Site: _____

Number of boxes shipped: _____

Date specimens shipped: _____

Fed Ex Tracking Numbers: _____

_____

_____

_____

Remarks: