2. GENERAL GUIDELINES

This section of the HAPO Follow-Up Study Manual of Operations provides summary guidelines for several areas of data collection, including completion of HAPO Follow-Up Study forms, mother and child visits, interviewing, handling of blood specimens, and for maintaining HAPO Follow-Up Study participant privacy and confidentiality. Subsequent sections of this manual provide detailed descriptions for all data collection procedures.

2.1 Guidelines for Completion of HAPO Follow-Up Study Forms

2.1.1 General Instructions

- All forms must be completed legibly, in ink. It is preferable to use ink in some color other than black (e.g., blue) to make it easier for the individual responsible for data entry to read the response. Red ink should NOT be used except for making corrections.
- No “white-out” or pencils.
- Do NOT write in shaded areas, unless otherwise instructed.
- Clearly mark boxes by placing an “X” in the box. Do NOT circle a response or the box.
- Write numeric or character values and dates in the spaces provided.
- Please print.
- Use CAPITAL letters and English where space is provided for an answer to a question that is not listed, i.e. “Other”.
- Follow instructions on each form for skipping questions.
- Complete ALL items on each page of each form unless otherwise instructed, making sure to fill in HAPO Staff ID in the Form Completion section at the end of every form.
- If a participant refuses to answer a question and there is a category for “Refused”, this category should be selected. If there is not a category for “Refused”, then leave the answer blank.
- If the participant indicates she does not know the answer to a question, and there is a category for “Don’t know”, this category should be selected. If there is not a category for “Don’t know”, then leave the answer blank.

- If a participant won't choose only one specific answer on an interviewer-administered questionnaire, then leave the answer blank.
- For items where a numeric value is required and the value is unknown, enter "9's" in all available spaces. For example, "999.9" would be recorded to indicate a missing weight, in pounds.
- Dates are recorded using year/month/day format as YYYY/MM/DD (unless otherwise indicated), e.g. for September 10, 2012 use 2012/09/10. Use the number for the month. 4 digits are required to designate the year since dates may be before or after the year 2000. Where a date can only be 2010 or later, e.g., the date a form is completed, 2 0 1 _ appears in the field for year. For the birth date of the mother, 1 9 _ _ appears in the field for year, since no mother can have a birth year of 2000 or later.
- All times on forms are to use the 24-hour clock. Be sure to convert afternoon and evening times to this format, e.g., 2:00 PM is recorded as 14:00, and 6:15 PM as 18:15.
- For items where a numeric value is required, use leading zeros as needed. For example, if the blood pressure measurement is 160/90 but the form contains spaces __ __ __/__ __ __, then record it as 160/090 so that a number fills each of the spaces on the form, and if the blood pressure is 98/65, record it as 098/065. Likewise, zeros should also be used after a decimal point so that all spaces are filled. For example, if you are asked to record a weight and the measurement is 45.4 kg but the form contains spaces __ __ . __ __, then record it as 45.40 so that a number fills each of the spaces on the form.
- Entry of all data into REDCap for all HAPO Follow-Up Study Forms should be completed as soon as possible after the Study Visit, ideally within 2 working/business days of the Study Visit.

Common errors in completing forms are:

- Illegible entries.
- Missing information (blank data fields).
- Incorrect dates.
- Transcription errors.
- Improper, inadequate corrections.

Corrections must include the following elements:

- Each correction must be made in red ink.
- Draw a single line through the incorrect response leaving the original entry readable (do NOT use “white-out”).
- Write the correct response near the incorrect response or, if it’s a checkbox, place a checkmark in the correct box.
- Circle the correct response and place your initials and the date close to the circle.

Note: **Always** review completed data forms prior to data entry.

After a form has been entered into the HAPO Follow-Up Study REDCap data entry and management system, the data entry person should enter his or her staff ID in the spaces marked: “HAPO staff ID of person entering data into Data Entry System,” the last question on every form. In addition, an “X” should be placed in the box at the top of the first page of the form marked “Data entry done” to indicate that the data on the form have been entered.

2.1.2 Specific Instructions

It is up to the HAPO Follow-Up Study Research Nurse to make the forms **PERFECT** for the data entry person by reviewing all forms prior to transmission to the data entry person for data entry. The HAPO Follow-up Study Future Contact Form, which is the only self-administered form and is not entered into the data system, is to be reviewed **BEFORE** the participant leaves the clinic to ensure that the participant has provided all of the requested information.

In reviewing forms, check for:

- Missing data.
- Illegible entries.
- Multiple boxes checked, or checks between boxes.

If a form contains any of these problems, seek clarification of the items in question from the HAPO Follow-Up Study staff member who completed the form. If the staff member is unable to resolve the problem and the participant would not be able to provide the correct data, and the item requires a numeric value, enter “9’s” in the spaces. For other types of questions, if the staff

member is unable to resolve the problem and the participant would not be able to provide the correct data, circle the answers in red ink and write the letters NR beside the answers for “Not Resolvable”, and initial it. Also, if there is a category for “Not answered” this category should be selected for data entry. This will allow the data entry system to enter the appropriate “missing value” code for this question. If the form was an interviewer-administered questionnaire, and the participant has left the clinic, attempt to obtain the data as soon as possible. Set the form aside until the correct data are obtained and entered on the form. If, for some reason, the correct data cannot be obtained, circle the answers with red ink, write the letters NR beside the answers, initial it, and proceed as above depending on the type of question.

Complete only the appropriate questions and be sure to follow the instructions on the form for skipping of questions.

2.2 General Guidelines for Mother/Child Visits

Mothers and their children will have a study visit where specific HAPO Follow-Up Study data are collected. At this visit, questionnaires will be completed, height, weight, and blood pressure will be obtained for both the mother and the child, skinfolds and waist and mid-arm circumference will be measured for the child, waist and hip circumference will be measured for the mother, a BOD POD assessment of body size and fat mass will be obtained for both the mother and child, a pubertal assessment will be made of the child, and blood and urine specimens will be obtained, including a child and maternal OGTT. For some children and/or mothers, there will only be a single blood draw.

Research participants rightly expect the study visit to start promptly and to finish as quickly as possible. Prolonged delays, down-time when nothing is happening, or a general sense of disorganization during this visit will waste their time and undermine their confidence in the study as a whole. Thus, scheduling procedures should take into account how many participants can be accommodated at one time. Staff should also give participants a realistic estimate of how long the visit will take when making an appointment for the visit. Do not underestimate the length of the visit: participants will be happy to leave early, but unhappy to stay late.

Written and telephone communications in preparation for the mother/child visit should also include the very specific list of conditions that the mother and child must meet for the visit, e.g.,

"Both you and your child should eat and drink nothing except water (including alcohol, medications and chewing gum) for 12-14 hours before the visit; don't eat any food after your evening meal the night before the visit.", "Neither you nor your child should engage in vigorous activity for 10 hours prior to the visit.", etc.

To the extent possible, all materials required for the visit should be prepared in advance, including forms with attached HAPO ID labels, blood tubes with HAPO ID Bar-code labels, etc.

2.3 Guidelines for Interviewing

Interviewing is an important component of the HAPO Follow-Up Study. Therefore, it is essential that interviewers present questions appropriately, record mothers' replies precisely and accurately and probe for additional information meaningfully. To maintain an objective information gathering atmosphere, the interviewer must convey that he/she is an understanding interested person capable of accepting information in a non-judgmental manner. The participant feels comfortable in talking to a receptive, supportive person without fear of appearing inadequate.

Increasing Cooperativeness

Previous studies have identified several factors that increase the respondent's responsiveness.

- Be prepared and know your material. Participants need to feel that you are interested in the study and interested in their responses. Be an active listener and establish comfortable eye contact with the participant.
- Offer convincing statements about the purpose of the study.
- Describe the beneficial uses of the research findings to both the participant and the community.

Types of Questions

There are two main types of questions:

- Pre-coded questions: With pre-coded questions the appropriate answer box is checked.

- Open questions: Where there are blanks to be filled in, you record the participant's answer. In this study, all questions of this type require numeric answers, for example, 220 pounds.

Interviewer-administered Questionnaires

Follow standard procedures for reading questions:

- Read slowly in a natural conversation rhythm and in a normal tone of voice.
- Be aware of the participant's facial expressions, e.g., puzzled, confused.
- Repeat the question if it is answered inappropriately, but repeat it exactly as written.
- Offer to re-read a questionnaire item if you believe the participant did not understand what was said.

Follow standard procedures for administering the questionnaire:

- Each question must be asked of each participant in the same way, and in the same order to insure that comparable information is being obtained from all participants in the study.
- Read only those code categories (response options) which appear in the questionnaire. **Note:** Do **not** read "Refused" or "Unknown" as possible response categories. These are provided for you to use **only** if the participant does not select one of the other categories.
- Ask questionnaire items in order and exactly as worded in the forms. Unless each interviewer asks the questions exactly as shown, the answers may be meaningless.
- Ask every question unless you are instructed to skip to another question, in which case you should skip to the specific question indicated. Often a previous statement by the participant will partially answer another question, but rarely does it answer that question completely. Do **not** omit any questionnaire items.

How to Get Satisfactory Responses

To obtain satisfactory responses:

- Learn the intent of each questionnaire item. You need to understand the information we are trying to obtain through each question. Unless you understand its intent, you

may not be able to judge when a response is adequate. During training, ask for clarification if the intent of any question is unclear to you.

- Maintain neutrality. If a participant does not seem to understand a question, repeat the question slowly and clearly. Give the participant time to think about the question (while simultaneously being aware of time allowed for administering the questionnaire). If needed, you can explain the possible responses to a question using the response definitions in the instructions for that question.
- Don't leave a questionnaire item until you have an adequate answer or have determined that a participant cannot give a clearer answer or refuses to answer the question.

Probing Techniques

The two most effective neutral probes are silence and repeating the original question.

- Silence. The value of silence cannot be overestimated. The interviewer who can wait quietly and patiently will soon find that 15 seconds of silence will often allow a participant to expand or clarify a previously inadequate waver.
- Repeating the question or answer categories. Be sure to repeat the question as stated in the questionnaire. This is particularly useful when the participant answers a question irrelevantly. In some cases it will be necessary to remind the participant of your frame of reference, i.e. to acknowledge what the participant has said and then bring the participant back to the topic by repeating the question.
- Do **not** accept a "Don't Know" answer without probing at least once. If a response is a "Don't Know", probe by asking: "Well what do you think". If the question deals with facts, we prefer an approximation to no answer at all. You might probe "what's your best guess approximately?" or convey the idea that 100% accuracy is not required.
- Use neutral probes that do not suggest answers. Probes are needed to obtain more complete, accurate answers. All probes must be non-directive, i.e., the probe must not suggest any particular answer to the participant. Probes should be used whenever the participant is hesitant in answering questions; when she seems to have trouble expressing herself; when she seems too shy to speak at length; whenever there is any reason for the interviewer to believe that the participant has not given a complete report of her thoughts; and, finally, reassuring probes are needed when a participant seems to lack confidence.

- Always cross reference. When you probe to clarify a response, always indicate which response you are clarifying. There will be times when a participant will say something ambiguous and continue talking. Do **not** ask "do you mean" because people tend to say "yes" to any suggestion either because it's easy or because they think it's the right answer.
- Make probes consistent with the purpose of the question. Any probe which does not suggest answers and which is non-threatening is acceptable provided it is appropriate to the particular interviewing problem.
- Watch for vague, incomplete answers. A probe such as "tell me more about…" is effective.
- Avoid "depends" or "qualified" answers. When the participant gives a response of this nature, it is advisable to use probes such as repeating the question; preface the question with a phrase such as "well, in general…".

2.4 Guidelines for Phlebotomy

The proper handling of blood samples is critical to the success of the HAPO Follow-Up Study. Deviation from HAPO Follow-Up Study protocol and procedures can significantly affect the parameter being measured. It is particularly important that time deadlines and transport conditions are strictly adhered to. It is also very important to adhere to the following:

- Before taking any blood specimens, read the procedures carefully and ensure that the correct tubes and HAPO ID labels are available.
- Blood samples may be drawn either by a butterfly, an indwelling catheter, a traditional needle and syringe, or by vacuum present in the sample tube. If a syringe and needle are used **DO NOT FORCE THE BLOOD INTO THE TUBE THROUGH THE NEEDLE**.
- If blood is put into an incorrect tube **DO NOT TRANSFER THE BLOOD TO THE CORRECT TUBE**. A fresh sample must be taken.
- All samples must be sent to a field center laboratory for processing accompanied by the HAPO Follow-Up Study Processing form.

2.5 Guidelines for ID Labels

There are two sets of labels for each HAPO ID. One set contains ID labels that are to be applied to each page of all forms and questionnaires. These are 6 characters in length and do not contain a Bar-code. A second set of labels that does contain a Bar-code is to be applied to blood sample tubes, urine specimen cups, cryovials, and any shipping documentation as requested.

Each blood sample tube and cryovial is to have a 8-character code that includes the first 5 characters of the participant ID, plus a three-digit code that identifies the sample. The three-digit codes for all blood samples and cryovials are listed below.

Child fasting or single blood draw samples:

- 600 – Glucose
- 601 – Insulin/C-peptide
- 602 – hsCRP and lipids
- 603 – Storage
- 604 – DNA
- 605 – A1c
- 606 – Urine

Mother fasting or single blood draw samples:

- 700 – Glucose
- 701 – Insulin
- 702 – Lipids
- 703 – Storage
- 704 – DNA
- 705 – A1c
- 706 – Urine

Child OGTT samples:

- 650 – 30-minute Glucose
- 651 – 30 minute Insulin/C-peptide
- 610 – 1-hour Glucose

- 611 – 1-hour Insulin/C-peptide
- 620 – 2-hour Glucose
- 621 – 2-hour Insulin/C-peptide

Mother OGTT samples:

- 720 – 2-hour Glucose
- 723 – 2-hour Storage sample

The same color tube and cryovial is also always used for each type of blood sample. The colors are as follows:

Child tubes and cryovials:

- Glucose – 2 ml grey top tube, yellow top cryovial.
- Insulin/C-peptide – 2 ml red top tube, green top cryovial
- hsCRP and lipids – 4 ml red top tube, clear top cryovial
- Storage – 4 ml red top tube, blue top cryovial
- DNA – 3 ml purple top tube
- A1c – 3 ml purple top tube, red top cryovial
- Urine – Specimen cup, orange top cryovial

Mother tubes and cryovials:

- Glucose – 4 ml grey top tube, yellow top cryovial.
- Insulin/C-peptide – 6 ml red top tube, green top cryovial
- Lipids – 6 ml red top tube, clear top cryovial
- Storage – 6 ml red top tube, blue top cryovial
- DNA – 4 ml purple top tube
- A1c – 4 ml purple top tube, red top cryovial
- Urine – Specimen cup, orange top cryovial

Because cryovials that are stored locally for backup are also to be shipped to the Laboratory Coordinating Center after the original cryovials have been analyzed at the Laboratory Coordinating Center for long-term storage, it is necessary to have some means of distinguishing the original sample from the backup, since both are identified by the same three-digit code, e.g.,

600 for child fasting glucose. To help the Laboratory Coordinating Center readily distinguish the original cryovial from the backup, all backup cryovials are to contain white plastic inserts. When a cryovial with a white plastic insert arrives at the Laboratory Coordinating Center, staff will know that the sample is a backup and the original sample was previously sent for analysis. This will help ensure that the Laboratory Coordinating Center does not analyze the sample a second time, but instead places it in long-term storage.

2.5 Privacy and Confidentiality

In all respects, confidentiality of the data regarding individuals is to be maintained. HAPO Follow-Up Study investigators and research staff must regard all data concerning Follow-Up Study participants as confidential and must not divulge any information concerning individual participants. None of the Coordinating Centers are to receive names of study participants. Only HAPO ID codes are to be forwarded. Names on any records or forms are to be removed before copies are forwarded to the Data Coordinating Center. Only HAPO field center investigators and HAPO research staff are to have the names of HAPO Follow-Up Study participants. Any HAPO Follow-Up Study data on computers at the field centers should be safeguarded by passwords known only by authorized personnel, and participant names will not be entered into the REDCap data entry and data management system.