3. RECRUITMENT

3.1 Goals

The goals of recruitment are to recontact HAPO participants at each of 10 field centers over a 36 - 39 month period, and to screen and recruit the mother and child to participate in the HAPO Follow-Up Study. The recruitment goal is 800 women and children in each of 8 HAPO field centers, and 300 women and children in the Chicago and Cleveland HAPO field centers.

3.2 Waiver of Consent

Because field centers will contact HAPO participants and ask them to answer questions about their willingness and eligibility to participate in the HAPO Follow-Up Study prior to obtaining written informed consent, it may be necessary to obtain a waiver of consent from the local Institutional Review Board (IRB) or Ethics Committee in order to contact prior HAPO participants and ask them to complete the Screening Form. Each field center needs to carefully explore what is required with their local IRB or Ethics Committee to ensure that HAPO women can complete the Screening Form prior to providing written informed consent.

3.3 Forms Used During Screening and Enrollment of Participants

The data forms, study descriptions, and participant instructions that are used during recruitment and enrollment include:

- Recruiting Register – (see **Sections 3.5, 3.7.1**)
- HAPO Identification Form – (see **Section 3.6**)
- Contact Information Form – (see **Section 3.6**)
- HAPO Study Summary – (see **Section 3.6.1**)
- HAPO Follow-Up Study Description – (see **Section 3.6.2**)
- Phone Call Information – (see **Section 3.7.2)**
- Screening Form – (see **Section 3.7.3**)
- Visit Planning Form – (see **Section 3.7.4**)
- Participant instructions for the visit – (see **Section 3.7.4**)
- Recontact Screening Form – (see **Section 3.10.1**)

- Recontact Visit Planning Form – (see **Section 3.10.2**)
- Special Circumstances Form – (see **Section 3.13**)

3.4 Screening Eligibility

Women who participated in the HAPO Study, along with their HAPO child, are eligible to be screened for enrollment in the HAPO Follow-Up Study if the gestational age at delivery was ≥ 37 weeks and the neonate had no major malformations at birth. HAPO women for whom there was a fetal or neonatal death will not be screened or contacted.

3.5 Identifying HAPO Participants for Screening

It is essential that accurate records be kept of participant recruitment for the Follow-Up Study, including information on refusals, and that study IDs be correctly utilized, i.e. that participants be given the same ID they were given in the original HAPO Study. The DCC has preprinted a Recruiting Register with the HAPO IDs of women who are to be contacted and invited to participate for day-to-day use in each field center. The ordering of the IDs is based on the birth date of the child in order to ensure that mothers with the oldest children are contacted first. All women who meet the eligibility criteria in **Section 3.4** for the follow-up study are listed. The Data Coordinating Center has also preprinted the birth dates of both the mother and child, based on the original HAPO data set, so that field center staff can verify that they are contacting the correct person during screening.

Upon receipt of the Recruiting Register, field center staff should locate their list of names corresponding to HAPO Study IDs and enter the woman's name in the Recruiting Register beside her HAPO ID. A 'Notes' column is also provided for optional use to record information about times to call, alternate phone numbers, etc. The Recruiting Register will not be returned to the Data Coordinating Center.

Each field center must continue recruitment according to the order specified on the Recruiting Register until the end of the HAPO Follow-Up Study, unless they are instructed by the Data Coordinating Center to discontinue recruitment due to meeting or exceeding their recruitment goal.

3.6 Initial Contact of HAPO Participants Listed in the Recruiting Register

Some of the field centers involved in the HAPO Follow-Up Study are already conducting follow-up studies of their own HAPO participants. The approach to locating, contacting, and screening women for the HAPO Follow-Up Study is expected to differ between centers involved in their own follow-up studies and those that are not, since the information necessary for contacting the original HAPO participants is expected to be less up-to-date in those centers not already conducting their own follow-up studies. Women listed on the Recruiting Register as eligible for the HAPO Follow-Up Study are expected to be contacted first by mail, and then by telephone. The mail contact should include a copy of the HAPO Study Summary, a HAPO Follow-Up Study Description, and, a Contact Information Form to fill out indicating whether or not the woman is willing to be contacted for the follow-up study, and if so, the phone number that should be used, and the best time to call. A stamped and addressed envelope for return of the Contact Information Form should also be included.

During each woman's participation in HAPO, she was asked to complete a HAPO Identification Form that asked her for her name, address and phone number, and the names, addresses, and phone numbers of two contacts who were likely to know her address and phone number if she should move or change phone numbers during the study or after delivery. The purpose of this information was to ensure that the field center would be able to maintain contact with her both during the study and subsequent to the study. Collection of this information was also done to facilitate potential follow-up of participants. The form also contained space for the participant's HAPO ID and the participant's local medical record number. Field centers not already engaged in follow-up studies of their HAPO participants need to locate these forms since they represent the starting point for contacting their local participants. It is expected that field centers conducting their own follow-up studies would have updated contact information that would be used as the starting point for making contact with women listed in the Recruiting Register.

Prior to mailing information and/or contacting HAPO participants by phone, field centers should use whatever local means are available to verify that the most recent address and phone number that they have for the woman are correct. This verification may include checking local population registries, searching local medical records using the woman's medical record number that was recorded during HAPO, reviewing local phone directories for updated phone numbers and addresses, or attempting to find the woman on social media, e.g. Facebook. US

field centers may also wish to make use of the National Change of Address (NCOA) Service, which contains changes of address reported to the US Postal Service (USPS), which are stored for 48 months in the NCOA database. Access to this database can be obtained through commercial companies such as Melissa Data, Inc. Melissa Data, Inc. can also provide updated listed telephone numbers through its Residential Telephone Append (RTA) Service. In addition, Melissa Data, Inc. has other address/phone update services that can supplement NCOA and RTA services to increase the likelihood of obtaining updated contact information.

Once field centers have determined the address and phone number for a woman, they should send the HAPO Study Summary translated into the local language, the HAPO Follow-Up Study Description also translated into the local language, and the Contact Information Form for the woman to complete about participating in the Follow-Up Study. They should also be given a number to call if they have any questions about the study. If a field center cannot verify the address that was given during HAPO or obtain and verify a new address by any of the means listed above, they should attempt to call the contacts the woman included on her HAPO Identification Form (completed when she originally enrolled in HAPO). Each field center should develop a script for these phone calls. An example of a script that might be used is given below.

"My name is xxx from zzz and I am trying to reach yyy. She participated in a very important research study called the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) Study several years ago, and I am trying to reach her to invite her to participate in a follow-up study involving herself and her HAPO child. She gave us your name as someone likely to know her current address and phone number. Would you be willing to provide that information to us, so that we might contact her by mail to share with her the results of the original HAPO Study and describe the proposed follow-up study, followed by a phone call inviting her to participate? "

If the contacts listed on the Identification Form cannot be contacted or are unwilling to provide the HAPO participant's current address and phone number or simply do not know them, field center staff should nonetheless send the information about HAPO and the Follow-Up Study to the last known address, requesting that it be forwarded to any new address or returned to the sender if it cannot be delivered. If the material mailed to the woman is returned as undeliverable with no new address listed, field center staff should try to make contact with the woman at the last known phone number since phone numbers can often be retained even if a

person moves. This contact should not be used to request completion of the Screening Form, but to obtain the new address so that the woman can be sent the HAPO Study Summary, the HAPO Follow-Up Study Description, and the Contact Information Form.

If a field center is unable to make initial contact by mail or phone with a woman listed in the Recruiting Register, the Screening Form should be completed by marking 'No' for question 1 – 'Able to contact HAPO participant?'. Mark 'Unable to locate correct contact information' for question 2. Enter the date of the last call in question 3, using year/month/day format, entering only the last digit of the year. The recruiter should also enter his or her HAPO staff ID in question 24.

If the woman returns the Contact Information Form included in the mailing, indicating that she does not wish to be contacted about participation in the HAPO Follow-Up Study, the Screening Form should be completed by answering 'Yes' to question 1 – 'Able to contact HAPO participant?'. Enter the date that the Contact Information Form was received by the HAPO Follow-Up Study in question 4, using year/month/day format, entering only the last digit of the year. Mark 'No' for question 5 and mark the appropriate response for question 6. The recruiter should also enter his or her HAPO staff ID in question 24.

3.6.1 HAPO Study Summary

A summary of the HAPO Study has been prepared in lay language. The information it contains is as follows:

YOUR PARTICIPATION IN THE HAPO STUDY

Doctors have known for decades that diabetes poses risks for pregnant women and their babies. And, they have known that the development of diabetes during pregnancy (gestational diabetes) indicates high risk of developing diabetes later in life for many mothers.

Now, thanks to you, they know much more.

Participation in the HAPO (Hyperglycemia and Adverse Pregnancy Outcomes) study by thousands of women, including you, from nine countries, taught doctors that gestational diabetes puts more women and babies at risk than thought previously.

Just as rising cholesterol levels precede heart attacks and rising blood pressure levels preface strokes, doctors now know that rising glucose levels foretell gestational diabetes and its adverse effects.

What is Gestational Diabetes?

Some pregnant women who were not diabetic before their pregnancies develop diabetes during pregnancy. Hormones from the placenta block the action of the mother's natural insulin, which is called insulin resistance. As a result, her body does not process glucose (sugar) properly, and it builds up. This is hyperglycemia, which leads to the diagnosis of gestational diabetes.

Women who begin their pregnancies overweight are more likely to develop gestational diabetes. Since obesity rates are increasing rapidly throughout the world, it makes sense that gestational diabetes has doubled in the last decade.

Gestational diabetes can be controlled and usually disappears after the baby is born. But, for two-thirds of mothers with gestational diabetes, it will occur again in future pregnancies. These women are also more likely to have diabetes later in life.

Gestational diabetes typically occurs in the last half of pregnancy. The baby is formed but growing quickly. Untreated, gestational diabetes can cause glucose to cross the placenta and cause the baby to become overweight, which is known as macrosomia. A baby is considered overweight or large if the baby's weight is in the upper 10 percent of weight of babies born in his or her ethnic group.

Because of their size, large babies are more likely to experience a birth injury or to require a Caesarian section instead of a vaginal birth. Stimulated by the extra sugar they receive from their mothers during pregnancy, they produce extra insulin. This can result in their developing low blood sugar soon after birth. Later, these babies may have a greater risk of becoming obese and having diabetes as adults.

What is the HAPO Study?

From July 2000 to April 2006, you were among approximately 25,000 non-diabetic women who participated in the HAPO study, which was funded by the United States-based National Institutes of Health and the American Diabetes Association.

You and your fellow HAPO participants live in Australia, Barbados, Canada, China, Israel, Singapore, Thailand, United Kingdom and United States. Their average age was 29 years old when they enrolled in the study. They come from all ethnic groups.

The first HAPO baby was born in the United States in September 2000. The others now range in age from 6 to 12 years.

Doctors measured the participants' glucose levels at approximately 28 weeks gestation. Women with diabetic-level glucose levels were excluded from the study and sent to their caregivers for treatment. At delivery, glucose from the babies' umbilical cord blood was measured. Shortly after delivery, the babies' glucose levels were measured. Researchers also recorded the mothers' height, weight, blood pressure and other medical information.

What did the HAPO Study Teach Us?

The HAPO Study showed that the higher the mothers' glucose levels, even before the levels reached the range of diabetes, the more likely their babies were overweight, had high insulin levels and suffered the secondary effects. The glucose-pregnancy outcome link is a continuous link, with no clear threshold at which risks increased.

In addition to large babies, birth injuries and increased rate of Caesarian deliveries, the study also linked rising glucose levels to higher rates of preeclampsia (toxemia of pregnancy) and preterm or early delivery. As anticipated, the fetal and infant death rates in the HAPO study were very low and the study showed no increase in death rate as glucose levels rose.

A very important finding was that the study showed the increased risks of the outcomes that were studied correlated with the mothers' high glucose levels independently of other factors such as the mothers' ages, weights and family histories.

What's Next?

After reviewing the HAPO results, a group of more than 50 experts from around the world who represented an organization named the International Association of Diabetes and Pregnancy Study Groups (IADPSG) published new clinical recommendations for the diagnosis of gestational diabetes in March 2010. It recommended the testing of glucose levels of all pregnant women at 24 to 28 weeks of pregnancy if they were not already found to have diabetes before their pregnancies or earlier in their pregnancies. Because of the worldwide increase in obesity and gestational diabetes, the IADPSG recommended all pregnant women be assessed for gestational diabetes with an oral glucose tolerance test.

In the past, gestational diabetes studies have focused on the long-term effects on the mothers and the link to post-pregnancy diabetes. But the HAPO Study made it clear that gestational diabetes also carries risks for the babies. Other studies have linked diabetes in mothers to higher risks of childhood obesity, the children's increased risk of cardiovascular disease in adult life and in, the female offspring, glucose abnormalities during their own pregnancies. Now, researchers hope that conducting Follow-Up visits on the HAPO children will indicate whether or not the risk for metabolic problems is increased when blood glucose levels in the mothers are at the level defined as gestational diabetes by the new recommendations.

Now that doctors know more about the effects of gestational diabetes on the children, the focus will swing toward the on-going, multigenerational aspects of the problem.

"Our long-term goal is to break the cycle," said HAPO lead researcher, Dr. Boyd Metzger from Northwestern University Medical School and Northwestern Memorial Hospital in Chicago. "The HAPO Study brings us one step closer to understanding how to reach this goal."

3.6.2 HAPO Follow-Up Study Description

Each field center should prepare a script to describe the HAPO Follow-Up Study to HAPO participants. The script should follow very closely the information contained in the local HAPO Follow-Up Study mother and child Consent Forms. The following script is an example of a description that might be sent to HAPO women to introduce them to the Follow-Up Study.

HAPO FOLLOW-UP STUDY

You and your HAPO child are invited to participate in a study being done in 10 of the original 15 HAPO centers from around the world. The study is designed to determine whether your blood sugar levels while you were pregnant are related to your child's growth and blood sugar levels 8 – 12 years later, and if your blood sugar levels during pregnancy are related to your current blood sugar levels.

If you agree to participate in the study, you and your child will both have an office visit. For your child, we will measure weight, height, blood pressure, and skinfolds and we will evaluate where your child is at in puberty. We will measure waist and arm size using a tape measure and we will measure body fat using a special piece of equipment called a BOD POD. The BOD POD will take 5 minutes and will require changing into a bathing suit. If your child is not taking oral medication or insulin for diabetes, the study will require an overnight fast and a 2-hour oral glucose tolerance test, similar to the one you did during HAPO. For this test, we will insert a little tube into a vein and collect blood from it at four time points. The tube will then be removed. If your child currently has diabetes and is taking oral medication or insulin, we will only do a single blood draw on your child, and will not ask that you have your child fast overnight. For you, the office visit will require measurement of height, weight, and blood pressure. We will measure waist and hip size using a tape measure. We will also perform the same 5-minute measurement of body fat using the BOD POD that will require changing into a bathing suit, just like your child. If you are not taking oral medication or insulin for diabetes, the study will require an overnight fast and a 2-hour oral glucose tolerance test. For this test, we will draw blood at two time points. If you currently have diabetes and are taking oral medication or insulin, we will only do a single blood draw, and will not ask you to fast overnight. If you are currently pregnant, we will contact you again six months after your baby's due date to invite you to come in for the study visit, but we would still like to invite you to bring your child for a study visit at this time.

Mothers and children who are to have an oral glucose tolerance test will be asked not to eat or drink anything (except plain water) after your evening meal on the night before the visit. They are also asked not to drink anything, including water, for 2 hours before the scheduled appointment. Mothers and children who are having non-fasting blood samples drawn are also asked not to eat or drink anything, including water, for 2 hours before the scheduled appointment. When you and your child come for the visit the next morning, you will both be asked to produce a urine sample and your blood pressure will be measured. For children undergoing an oral glucose tolerance test, we will insert a little tube into the vein and take blood

samples. These children will then drink a sweet solution of sugar in about 10 fluid ounces (300 ml) of water. Additional blood samples will be taken at 30 minutes, and 1 and 2 hours after drinking the sugar water. For mothers undergoing an oral glucose tolerance test, we will draw a blood sample. These mothers will then drink a sweet solution of sugar in water, with additional blood samples taken at 2 hours after drinking the sugar water. Mothers and children who are not fasting will have a single blood draw. You will also be asked questions about your background and you and your child's health habits and medical history, following the first blood draw.

For those mothers and children who have an oral glucose tolerance test, a laboratory located in Chicago will measure the amount of sugar in each of the blood samples. This same laboratory will also measure the amount of fat in the blood for all participating mothers and children. The results of these blood tests will be given to your local center and they will then contact you with the results and advise you to obtain care if any of your results require follow-up.

3.7 Enrollment Procedures

Prior to attempting to make contact by phone with a potential participant, field center staff should affix the woman's HAPO ID labels to each page of the Phone Call Information, the Screening Form and the Visit Planning Form. Before attempting to contact a potential participant, the recruiter should complete questions 1 – 4 on Phone Call Information. Completion of questions 5 and 6 on Phone Call Information is optional. However, it may be helpful for the recruiter to have the current or last known address readily available, or to record the best times to call as indicated on a returned Contact Information Form, alternate phone numbers, previous addresses, etc. Also, both the Screening Form and the Visit Planning Form need to be available for the recruiter's use when attempting to contact a potential participant. The Screening Form is used to determine the willingness and eligibility of mothers and children to participate in the HAPO Follow-Up Study, while the Visit Planning Form is used to indicate whether or not an OGTT will be done or only a single blood draw will be done, if the woman agrees to participate. The Visit Planning Form is also used to record the date and time of the scheduled visit, and indicates which set of instructions should be read and mailed to the participant. These instructions vary depending on what type of blood samples will be collected,

and whether both mother and child will participate in the study visit, or just the child, e.g. because the mother is currently pregnant.

Note: Whenever you are attempting to contact a woman by phone and she is not available, you should only leave your name and number. Information about the nature of the call should not be given to anyone else to preserve confidentiality.

3.7.1 Recruiting Register

As noted above, each field center's Recruiting Register contains the HAPO IDs of the women to be contacted and the order in which they are to be contacted. The birthdates for the mother and child corresponding to each HAPO ID have been pre-entered and should be transcribed onto Phone Call Information prior to attempting contact with a potential participant. The Recruiting Register also has a 'Notes' column for optional use to record best times to call, alternate phone numbers, etc. The Recruiting Register will not be returned to the Data Coordinating Center.

3.7.2 Phone Call Information

Phone Call Information is to be filled out prior to attempting contact for a screening phone call with a potential participant. Information on this form will not be entered into the Data Entry System and will not be viewed by the Data Coordinating Center.

Phone Call Information

Question 1

Enter the woman's name prior to making any phone calls. This is being recorded to ensure that staff know the name of the person they are calling.

Questions 2-3

Enter the birthdates listed on the Recruiting Register for the mother and child, using year/month/day format. Enter the last two digits of the year of birth for the mother, and the last digit of the year of birth for the child. Recording of the birthdates here is to help ensure that the correct HAPO ID is being used for the woman being called.

Question 4

Enter the woman's current or last known phone number prior to making any phone calls. This information is being recorded to ensure that staff know the phone number of the person they are calling.

Question 5

If desired, enter the woman's current or last known address. Space for this information is provided so that all contact information can be recorded in one place.

Question 6

If desired, record any notes pertaining to best times to call as indicated on a returned Contact Information Form, alternate or previous phone numbers, alternate or previous addresses, etc.

Question 7

During the screening phone call, if the mother says she is pregnant or breastfeeding enter an anticipated call back date either six months after the baby's due date if she is pregnant or six months from the current date if she is breastfeeding. Set the form aside and use it as a reminder to call back on or near the anticipated date. The Recontact Screening Form and Recontact Visit Planning Form will be used during recontact phone calls due to pregnancy or breast feeding.

3.7.3 Screening Form

The Screening Form should be completed for all potential Follow-Up Study participants listed on the Recruiting Register, even if they are not successfully contacted. All information on the Screening Form will be entered into the Data Entry System.

Contact and Willingness

Questions 1-6

If the woman completed and returned the Contact Information Form indicating a willingness to participate in the Follow-Up Study and provided a time to call, the recruiter should attempt to call

the woman at the time or times indicated. If the Contact Information Form was not returned, the recruiter should make up to 10 attempts to reach the woman by phone, varying the time of day and days of the week that phone contact is attempted. It might also be helpful for local field centers to have a list of what they believe are the 10 best time periods to call. This list could be stored with the Screening Form and Visit Planning Form in the woman's HAPO folder, and when a call is made, but not completed, staff would then check off the time period that the call was made, so that the next call would be at a different time and/or day of the week.

If a potential participant has not been reached by phone after 10 attempts, mark 'No' for question 1 – 'Able to contact HAPO participant?'. The reason for not contacting the HAPO participant should be indicated in question 2. Enter the date of the last call in question 3, using year/month/day format, entering only the last digit of the year. The recruiter should also enter his or her HAPO staff ID in question 24. The Visit Planning Form is not completed for HAPO participants that the field center is unable to contact.

If the woman completed and returned the Contact Information Form indicating refusal to participate in the Follow-Up Study, mark 'Yes' for question 1 – 'Able to contact HAPO participant?'. Enter the date the Contact Information Form was received by the HAPO Follow-Up Study in question 4, using year/month/day format, entering only the last digit of the year. Mark 'No' for question 5 – 'Would you be willing to answer some questions to determine eligibility for you and your child to participate in a follow-up study of HAPO participants?' and mark the appropriate response to question 6. The recruiter should also enter his or her HAPO staff ID in question 24. The Visit Planning Form is not completed for HAPO participants that indicate refusal to participate.

When Contact is Made

When contact is made with a potential participant, the recruiter should read the following statement at the top of the Screening Form:

> "This is xxx from the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) Follow-Up Study. First, I want to thank you for your participation in HAPO. The results of the study have helped us understand the effects of a mother's blood sugar during pregnancy on the development of her baby. Now we are trying to determine if there is a link between your

blood sugar when you were pregnant and your HAPO child's growth and blood sugar levels. We would also like to know about your health. It will take about 10 minutes to determine if you and your child are eligible to participate in the HAPO Follow-Up Study. Let me assure you that all information you provide will be kept confidential."

After reading the statement at the top of the form, the recruiter should mark 'Yes' for question 1 and enter the current date in question 4, using year/month/day format, entering only the last digit of the year.

If the woman indicates that she is willing to answer some questions to determine eligibility for her and her child to participate in a follow-up study of HAPO participants, mark 'Yes' for question 5 and skip to question 7 on the Screening Form.

If the woman is unwilling to answer questions to determine eligibility, mark 'No' for question 5. If the woman offers a reason for not participating, mark the appropriate reason in question 6. Do not ask the woman for a reason, only record those that are offered. Thank the woman for her time, and enter your HAPO staff ID in question 24.

Note: If something is encountered that would preclude the mother or child from participating in the study, e.g., a death or recent medical treatment such as chemotherapy, mark "No" for question 5. Then mark "Other" for question 6 and indicate what the circumstance is. Then go to the Special Circumstances Form and record the circumstance in question 3 and/or question 4 (see **Section 3.13**)

Birthdates

Questions 7 – 8:

Read the birthdates that were transcribed from the Recruiting Register onto Phone Call Information (questions 2 and 3). Ask the woman if these birthdates are correct and mark the appropriate answers.

Birthdates are checked to confirm correct identities. If at least one birthdate is correct, continue with the remaining questions.

If the mother has more than one child and does not remember which child was part of HAPO, ask the mother if one of her children was born on the date recorded under question 3 'HAPO child's birthdate on Recruiting Register' on Phone Call Information. If she answers yes and confirms this child participated in HAPO, then continue with the remaining questions.

If both birthdates are incorrect, STOP further questions and try to resolve the discrepancy before continuing with screening.

One possible solution to resolve the discrepancy is to check that the HAPO ID and birthdates on Phone Call Information have been transcribed correctly from the Recruiting Register. Other clerical errors could also arise. If the discrepancy cannot be resolved and 'Yes' was marked for question 5, change the answer to 'No', mark 'Other' for question 6 and write in 'Incorrect birthdates' as the reason. Thank the woman for her time, and enter your HAPO staff ID in question 24.

Physical Measurements - Child, Question 9

'Yes' to Question 9:
If the mother is willing for her child to have measurements of weight, height, blood pressure, skinfolds and waist and arm circumference, evaluation of where her child is at in puberty and the BOD POD assessment, mark 'Yes' to question 9 and continue with the remaining questions.

'No' to Question 9:
If the mother is not willing to have her child have these measurements, mark 'No' to question 9, thank the woman for her time, and enter your HAPO staff ID in question 24.

Diabetes - Child, Questions 10-11

'No' to Question 10:
If the mother indicates that she has not been told by a medical person that her child has diabetes, mark 'No' for question 10 and go on to question 13.

'Yes' to Question 10:

If the mother indicates that she has been told by a medical person that her child has diabetes, mark 'Yes' to question 10, and ask whether the child is currently taking oral medication or insulin for treatment of diabetes.

'No' to Question 11:

If the child is not currently taking medication for diabetes, mark 'No' for question 11, and go on to question 13. These children can be asked to fast and have an OGTT.

'Yes' to Question 11:

If the child is taking medication for diabetes, mark 'Yes' for question 11, and continue with question 12. Children who are being treated for diabetes are not asked to fast, and the mother should not be asked if she is willing to have her child complete an OGTT.

Single Blood Draw – Child, Question 12

'Yes' to Question 12':

If the mother indicates that she is willing for her child to have a single blood draw, mark 'Yes' for question 12 and then mark 'Single blood draw' for question 1 on the Visit Planning Form.

'No' to Question 12:

If the mother is unwilling to have her child have a single blood draw, mark 'No' for question 12, thank the woman for her time and explain that a requirement for her child's participation is the drawing of blood samples. Enter your HAPO staff ID in question 24.

OGTT - Child, Question 13

'Yes' to Question 13:

If the mother is willing to have her child have an OGTT, mark 'Yes' for question 13 and then mark 'OGTT' for question 1 on the Visit Planning Form and continue with question 14,

'No' to Question 13:

If the mother is unwilling for her child have an OGTT, mark 'No' for question 13, thank the woman for her time and explain that an OGTT is a requirement for her child's participation. Enter your HAPO staff ID in question 24.

Pregnancy and Breastfeeding, Questions 14-18

'No' to Question 14:

If the mother indicates that she is not currently pregnant, mark 'No' for question 14, and continue with question 17.

'Yes' to Question 14:

If the mother is currently pregnant, mark 'Yes' to question 14, and tell her that she cannot be invited to participate now.

If there are more than 6 months of recruitment remaining, tell her that we would like to call her again 6 months after the baby is born, and ask her for her expected date of delivery. Enter the date in question 15, using year/month/day format, entering only the last digit of the year. Also, mark 'Pregnancy – recontact' for question 2 on the Visit Planning Form and record the anticipated call back date six months after the baby's due date for question 7 on Phone Call Information using year/month/day format, entering only the last digit of the year.

If there are fewer than 6 months of recruitment remaining, skip question 15, and mark 'Pregnancy, do not recontact' for question 2 on the Visit Planning Form. Ask her if she would be willing to bring her child in at this time for his or her study visit.

'Yes' to Question 16:

If the woman is willing to bring her child in for a study visit at this time, mark 'Yes' to question 16. Schedule the child's appointment, and enter the date and time of the appointment in questions 3 and 4 of the Visit Planning Form. Enter your HAPO staff ID in question 5 of the Visit Planning Form and then proceed to the visit instructions on the Visit Planning Form. If the child is to have an OGTT, read the set of instructions corresponding to the mother being pregnant or breastfeeding, and the child having an OGTT. If the child is to have a single blood draw, read the set of instructions corresponding to the mother being pregnant or breastfeeding, and the child having a single blood draw. Enter your HAPO staff ID in question 24 of the Screening Form.

'No' to Question 16:

If the mother is not willing to have her child participate at this time, thank the woman for her time, and enter your HAPO Staff ID in question 24.

'No' to Question 17:

If the mother indicates that she is not currently breastfeeding, mark 'No' for question 17, and continue with question 19.

'Yes' to Question 17:

If the mother is currently breastfeeding, mark 'Yes' to question 17, and tell her that she cannot be invited to participate now.

If there are more than 6 months of recruitment remaining, tell her that we would like to call her again in 6 months. Mark 'Pregnancy – recontact' for question 2 on the Visit Planning Form and record the anticipated call back date six months after the current date for question 7 on Phone Call Information using year/month/day format, entering only the last digit of the year.

If there are fewer than 6 months of recruitment remaining, mark 'Pregnancy, do not recontact' for question 2 on the Visit Planning Form. Ask her if she would be willing to bring her child in at this time for his or her study visit.

'Yes' to Question 18:

If the woman is willing to bring her child in for a study visit at this time, mark 'Yes' to question 18. Schedule the child's appointment, and enter the date and time of the appointment in questions 3 and 4 of the Visit Planning Form. Enter your HAPO staff ID in question 5 of the Visit Planning Form and then proceed to the visit instructions indicated by the Visit Planning Form. If the child is to have an OGTT, read the set of instructions corresponding to the mother being pregnant or breastfeeding, and the child having an OGTT. If the child is to have a single blood draw, read the set of instructions corresponding to the mother being pregnant or breastfeeding, and the child is having a single blood draw. Enter your HAPO staff ID in question 24 of the Screening Form.

'No' to Question 18:

If the mother is not willing to have her child participate at this time, thank the woman for her time, and enter your HAPO Staff ID in question 24.

Physical Measurements - Mother, Question 19

'Yes' to Question 19:
If the mother is willing have measurements of weight, height, blood pressure, waist and hip circumference, and the BOD POD assessment, mark 'Yes' to question 19 and continue with the remaining questions.

'No' to Question 19:
If the mother is not willing to have these measurements, mark 'No' to question 19 and continue with the remaining questions.

Diabetes - Mother, Questions 20-21

'No' to Question 20:
If the mother indicates that she has not been told by a medical person, when she was not pregnant, that she has diabetes, mark 'No' for question 20 and go on to question 23.

'Yes' to Question 20:
If the mother indicates that she has been told by a medical person, when she was not pregnant, that she has diabetes, mark 'Yes' to question 20, and ask whether she is currently taking oral medication or insulin for treatment of diabetes.

> 'No' to Question 21:
> If the mother is not currently taking medication for diabetes, mark 'No' for question 21, and go on to question 23. These women can be asked to fast and have an OGTT.
>
> 'Yes' to Question 21:
> If the mother is taking medication for diabetes, mark 'Yes' for question 21, and continue with question 22. Women who are being treated for diabetes are not asked to fast, and should not be asked to complete an OGTT.

Single Blood Draw – Mother, Question 22

'Yes' to Question 22:
If the mother indicates that she is willing to have a single blood draw, mark 'Yes' for question 22 and then mark 'Single blood draw' for question 2 on the Visit Planning Form.

Schedule the appointment for the mother and child, and enter the date and time of the appointment in questions 3 and 4 of the Visit Planning Form. Enter your HAPO staff ID in question 5 of the Visit Planning Form and then proceed to the visit instructions indicated by the Visit Planning Form. If the child is to have an OGTT, read the set of instructions corresponding to the mother having a single blood draw, and the child having an OGTT. If the child is also to have a single blood draw, read the set of instructions corresponding to both mother and child having a single blood draw. Enter your HAPO staff ID in question 24 of the Screening Form.

'No' to Question 22:
If the mother is unwilling to have a single blood draw, mark 'No' for question 22, thank the woman for her time and explain that a requirement for her participation is the drawing of blood samples. Enter your HAPO staff ID in question 24.

OGTT - Mother, Question 23

'Yes' to Question 23:
If the mother is willing to have an OGTT, mark 'Yes' for question 23 and then mark 'OGTT' for question 2 on the Visit Planning Form.

Schedule the appointment for the mother and child, and enter the date and time of the appointment in questions 3 and 4 of the Visit Planning Form. Enter your HAPO staff ID in question 5 of the Visit Planning Form and then proceed to the visit instructions indicated by the Visit Planning Form. If the child is to have an OGTT, read the set of instructions corresponding to both mother and child having an OGTT. If the child is to have a single blood draw, read the set of instructions corresponding to the mother having an OGTT and the child having a single blood draw. Enter your HAPO staff ID in question 24 of the Screening Form.

'No' to Question 23:

If the mother is unwilling to have an OGTT, mark 'No' for question 23, thank the woman for her time and explain that an OGTT is a requirement for her participation. Enter your HAPO staff ID in question 24.

Form Completion, Questions 24-25

Make sure that you have entered your HAPO staff ID in question 24.

When data entry of the Screening Form is complete, the person entering the form should enter their HAPO staff ID in question 25.

3.7.4 Visit Planning Form Instructions

The instructions that are to be given for the visit depend on type of blood samples that will be obtained for the mother and child, and whether only the child is scheduled for a study visit due to the mother currently being pregnant or breastfeeding. The Visit Planning Form indicates which set of instructions is appropriate for the participants. These instructions are to be read to the mother during the screening phone call and then a copy mailed.

3.7.4.1 Instruction Set A: OGTT for Both Mother and Child

- Both you and your child should follow your usual diet for three days before the visit. Do not eat more or less bread, pasta, rice, potatoes, baked goods, sweets or other carbohydrates than you normally do.
- Bring all medications that either you or your child are currently taking to the visit. If there are medications that either you or your child normally take in the morning, do not take them on the morning of your visit. Bring them with you so you can take them after the visit is finished.
- Neither you nor your child should use any products containing caffeine or nicotine the morning of the appointment.
- Neither you nor your child should engage in vigorous activity for 10 hours prior to the visit.
- Both you and your child should wear a loose shirt or sweater so that the clinic personnel can easily obtain blood and measure blood pressure. You and your child may bring a

tight-fitting bathing suit or exercise shorts/top for the BOD POD. If not, we will have bathing suits available for you and your child.

- If you or your child use inhalers for asthma or allergies, do NOT use them after bedtime the night before the visit and until after the visit has been completed
- Bring information about the height and weight of your child's father to the visit since questions will be asked about this important information.
- If you or your child is ill with chills, fever, vomiting or diarrhea within three days of your appointment, please call and reschedule the study visit; if you or your child has been ill during that period, not all parts of the study for you and/or your child can be completed if you come to the clinic.
- 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.
- In addition, both of you should not drink anything at all, including water, for 2 hours before the visit.

3.7.4.2 Instruction Set B: OGTT for Child, Single Blood Draw for Mother

- Both you and your child should follow your usual diet for three days before the visit. Do not eat more or less bread, pasta, rice, potatoes, baked goods, sweets or other carbohydrates than you normally do.
- Bring all medications that either you or your child are currently taking to the visit. If there are medications that either you or your child normally take in the morning, do not take them on the morning of your visit. Bring them with you so you can take them after the visit is finished.
- Neither you nor your child should use any products containing caffeine or nicotine the morning of the appointment.
- Neither you nor your child should engage in vigorous activity for 10 hours prior to the visit.
- Both you and your child should wear a loose shirt or sweater so that the clinic personnel can easily obtain blood and measure blood pressure. You and your child may bring a tight-fitting bathing suit or exercise shorts/top for the BOD POD. If not, we will have bathing suits available for you and your child.

- If you or your child use inhalers for asthma or allergies, do NOT use them after bedtime the night before the visit and until after the visit has been completed.
- Bring information about the height and weight of your child's father to the visit since questions will be asked about this important information.
- If you or your child is ill with chills, fever, vomiting or diarrhea within three days of your appointment, please call and reschedule the study visit; if you or your child has been ill during that period, not all parts of the study for you and/or your child can be completed if you come to the clinic.
- Your child should eat and drink nothing except water (including alcohol, medications and chewing gum) for 12-14 hours before the visit; your child should not eat any food after the evening meal the night before the visit.
- In addition, your child should not drink anything at all, including water, for 2 hours before the visit.
- You may eat normally the night before the visit and eat a normal breakfast. But you should not eat or drink anything, including water, for 2 hours before the visit.

3.7.4.3 Instruction Set C: OGTT for Mother and Single Blood Draw for Child

- Both you and your child should follow your usual diet for three days before the visit. Do not eat more or less bread, pasta, rice, potatoes, baked goods, sweets or other carbohydrates than you normally do.
- Bring all medications that either you or your child are currently taking to the visit. If there are medications that either you or your child normally take in the morning, do not take them on the morning of your visit. Bring them with you so you can take them after the visit is finished.
- Neither you nor your child should use any products containing caffeine or nicotine the morning of the appointment.
- Neither you nor your child should engage in vigorous activity for 10 hours prior to the visit.
- Both you and your child should wear a loose shirt or sweater so that the clinic personnel can easily obtain blood and measure blood pressure. You and your child may bring a tight-fitting bathing suit or exercise shorts/top for the BOD POD. If not, we will have bathing suits available for you and your child.

- If you or your child use inhalers for asthma or allergies, do NOT use them after bedtime the night before the visit and until after the visit has been completed
- Bring information about the height and weight of your child's father to the visit since questions will be asked about this important information.
- If you or your child is ill with chills, fever, vomiting or diarrhea within three days of your appointment, please call and reschedule the study visit; if you or your child has been ill during that period, not all parts of the study for you and/or your child can be completed if you come to the clinic.
- You 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.
- In addition, you should not drink anything at all, including water, for 2 hours before the visit.
- Your child may eat normally the night before the visit and may eat a normal breakfast. But, your child should not eat or drink anything at all, including water, for 2 hours before the visit.

3.7.4.4 Instruction Set D: Single Blood Draw for Mother and Child

- Both you and your child should follow your usual diet for three days before the visit. Do not eat more or less bread, pasta, rice, potatoes, baked goods, sweets or other carbohydrates than you normally do.
- Bring all medications that either you or your child are currently taking to the visit. If there are medications that either you or your child normally take in the morning, do not take them on the morning of your visit. Bring them with you so you can take them after the visit is finished.
- Neither you nor your child should use any products containing caffeine or nicotine the morning of the appointment.
- Neither you nor your child should engage in vigorous activity for 10 hours prior to the visit.
- Both you and your child should wear a loose shirt or sweater so that the clinic personnel can easily obtain blood and measure blood pressure. You and your child may bring a tight-fitting bathing suit or exercise shorts/top for the BOD POD. If not, we will have bathing suits available for you and your child.

- If you or your child use inhalers for asthma or allergies, do NOT use them after bedtime the night before the visit and until after the visit has been completed.
- Bring information about the height and weight of your child's father to the visit since questions will be asked about this important information.
- If you or your child is ill with chills, fever, vomiting or diarrhea within three days of your appointment, please call and reschedule the study visit; if you or your child has been ill during that period, not all parts of the study for you and/or your child can be completed if you come to the clinic.
- You and your child should not eat or drink anything at all, including water, for 2 hours before the visit.

3.7.4.5 Instruction Set E: OGTT for Child, Mother Pregnancy

- Your child should follow his or her usual diet for three days before the visit. Your child should not eat more or less bread, pasta, rice, potatoes, baked goods, sweets or other carbohydrates than he or she normally does.
- Bring all medications that your child is currently taking to the visit. If there are medications that your child normally takes in the morning, your child should not take them on the morning of the visit. Bring them with you so they can be taken after the visit is finished.
- Your child should not use any products containing caffeine or nicotine the morning of the appointment.
- Your child should not engage in vigorous activity for 10 hours prior to the visit.
- Your child should wear a loose shirt or sweater so that the clinic personnel can easily obtain blood and measure blood pressure. Your child may bring a tight-fitting bathing suit or exercise shorts/top for the BOD POD. If not, we will have a bathing suit available for your child.
- If your child use inhalers for asthma or allergies, your child should NOT use them after bedtime the night before the visit and until after the visit has been completed.
- Bring information about the height and weight of your child's father to the visit since questions will be asked about this important information.
- If your child is ill with chills, fever, vomiting or diarrhea within three days of your appointment, please call and reschedule the study visit; if your child has been ill during

that period, not all parts of the study for your child can be completed if you come to the clinic.

- Your child should eat and drink nothing except water (including 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.
- In addition, your child should not drink anything at all, including water, for 2 hours before the visit.

3.7.4.6 Instruction Set F: Single Blood Draw for Child, Mother Pregnancy

- Your child should follow his or her usual diet for three days before the visit. Your child should not eat more or less bread, pasta, rice, potatoes, baked goods, sweets or other carbohydrates than he or she normally does.
- Bring all medications that your child is currently taking to the visit. If there are medications that your child normally takes in the morning, your child should not take them on the morning of the visit. Bring them with you so they can be taken after the visit is finished.
- Your child should not use any products containing caffeine or nicotine the morning of the appointment.
- Your child should not engage in vigorous activity for 10 hours prior to the visit.
- Your child should wear a loose shirt or sweater so that the clinic personnel can easily obtain blood and measure blood pressure. Your child may bring a tight-fitting bathing suit or exercise shorts/top for the BOD POD. If not, we will have a bathing suit available for your child.
- If your child uses inhalers for asthma or allergies, your child should NOT use them after bedtime the night before the visit and until after the visit has been completed.
- Bring information about the height and weight of your child's father to the visit since questions will be asked about this important information.
- If your child is ill with chills, fever, vomiting or diarrhea within three days of your appointment, please call and reschedule the study visit; if your child has been ill during that period, not all parts of the study for your child can be completed if you come to the clinic.
- Your child may eat normally the night before the visit and may eat a normal breakfast. But, your child should not eat or drink anything at all, including water, for 2 hours before the visit.

3.7.4.7 Appointment Reminder

The participant should also receive a reminder call at least four days before the scheduled visit, re-emphasizing the instructions for the visit. Participants should also be given a phone number to call if they have any questions about the study visit or if they need to reschedule. Participants who work night shift should have the study visit done on a day off from work.

3.8 Entering Data from the Screening Form and Visit Planning Form

At each field center, the information from the completed Screening Form and Visit Planning Form will be entered using the REDCap Data Entry System. Specific instructions for this process have been developed by the Data Coordinating Center and are specified in Chapter 9.

3.9 Unwilling to Reschedule a Missed Visit

If the mother and/or child misses a scheduled visit and is unwilling to reschedule the missed visit, question 1 and question 2 on the Special Circumstances Form should be completed (see **Section 3.13**) and entered into the REDCap Data Entry System along with the Screening Form and Visit Planning Form.

3.10 Recontacting Pregnant Women

Women who were pregnant or breastfeeding when initially contacted, are to be recontacted 6 months after the expected delivery date if pregnant, or 6 months after the date of the screening phone call if breastfeeding, provided that recruitment is ongoing at that time. The anticipated call back date should have been recorded in question 7 on Phone Call Information and the form set aside for recontact. Prior to attempting phone recontact with a woman who was pregnant or breastfeeding, field center staff should affix the woman's HAPO ID labels to each page of the Recontact Screening Form and the Recontact Visit Planning Form. When attempting to recontact a potential participant, Phone Call Information and both the Recontact Screening Form and the Recontact Visit Planning Form need to be available for the recruiter's use. The Recontact Screening Form is used to reassess the willingness and eligibility of the mother and child, if not previously examined, to participate in the HAPO Follow-Up Study, while the

Recontact Visit Planning Form is used to indicate whether both the mother and child will attend the study visit, or only one of them will attend, and whether or not an OGTT will be done or only a single blood draw is to be done. The Recontact Visit Planning Form is also used to record the date and time for the scheduled visit, and indicates which set of verbal instructions should be read and mailed to the participant. These instructions vary depending on what type of blood samples will be collected, and whether both mother and child will complete the study visit, or only one of them.

Note: Whenever you are attempting to contact a woman by phone and she is not available, you should only leave your name and number. Information about the nature of the call should not be given to anyone else to preserve confidentiality.

3.10.1 Recontact Screening Form

Preliminary Information

Question 1:
Prior to attempting recontact, mark the appropriate answer ('Yes' or 'No') for whether the HAPO child already completed the Follow-Up Study Visit.

Contact

Questions 2-5:
If the woman has not been reached by phone after 10 attempts, mark 'No' for question 2 – 'Able to contact HAPO participant?', and enter a reason for question 3. Enter the date of the last call in question 4, using year/month/day format, entering only the last digit of the year. The recruiter should also enter his or her HAPO staff ID in question 21. The Recontact Visit Planning Form is not completed for HAPO participants that the field center is unable to contact.

When Contact is Made

When contact is made, the recruiter should read the pertinent statement at the top of the Recontact Screening Form:

Introduction A (child already completed visit, mom visit to be done)

"This is xxx from the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) Follow-Up Study. First, I want to thank you for your participation in HAPO. The results of the study have helped us understand the effects of a mother's blood sugar during pregnancy on the development of her baby. As you know, now we are trying to determine if there is a link between your blood sugar when you were pregnant and your HAPO child's growth and blood sugar levels. Thank you again for bringing your child to their study visit. Now we would like to know about your health. It will take about 10 minutes to determine if you and your child are eligible to participate in the HAPO Follow-Up Study. Let me assure you that all information you provide will be kept confidential."

Introduction B (mom and child visit to be done)

"This is xxx from the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) Follow-Up Study. First, I want to thank you for your participation in HAPO. The results of the study have helped us understand the effects of a mother's blood sugar during pregnancy on the development of her baby. Now we are trying to determine if there is a link between your blood sugar when you were pregnant and your HAPO child's growth and blood sugar levels. We would also like to know about your health. It will take about 10 minutes to determine if you and your child are eligible to participate in the HAPO Follow-Up Study. Let me assure you that all information you provide will be kept confidential."

After reading the statement at the top of the form, the recruiter should mark 'Yes' for question 2 and enter the current date in question 5, using year/month/day format, entering only the last digit of the year.

Willingness, Questions 6-7

If the woman indicates that she is willing to answer some questions to determine current eligibility to participate in a follow-up study of HAPO participants, mark 'Yes' for question 6 and skip to question 8 on the Recontact Screening Form.

If the woman is unwilling to answer questions to determine her current eligibility, mark 'No' for question 6. If the woman offers a reason for not participating, mark the appropriate reason in

question 7. Do not ask the woman for a reason, only record those that are offered. Thank the woman for her time, and enter your HAPO staff ID in question 21.

Note: If something is encountered that would preclude the mother or child from participating in the study, e.g., a death or recent medical treatment such as chemotherapy, mark "No" for question 6. Then mark "Other" for question 7 and indicate what the circumstance is. Then go to the Special Circumstances Form and record the circumstance in question 3 and/or question 4 (see **Section 3.13**)

Pregnancy and Breastfeeding, Questions 8-10

'No' to Question 8:
If the mother indicates that she is not currently pregnant, mark 'No' for question 8, and continue with question 10.

'Yes' to Question 8:
If the mother is currently pregnant, mark 'Yes' to question 8, and tell her that she cannot be invited to participate now.

Question 9, 6 months or more of recruitment remaining
Tell her that we would like to call her again 6 months after the baby is born, and ask her for her expected date of delivery. Enter the date in question 9, using year/month/day format, entering only the last digit of the year. Mark 'Pregnancy – recontact' for question 2 on the Recontact Visit Planning Form and record a new anticipated call back date six months after the baby's due date for question 7 on Phone Call Information using year/month/day format, entering only the last digit of the year.

Enter your HAPO staff ID in question 21 on the Recontact Screening Form and in question 5 on the Recontact Visit Planning Form.

Question 9, fewer than 6 months of recruitment remaining
Thank the woman for her time, skip question 10, and mark 'Pregnancy – do not recontact' for question 2 on the Recontact Visit Planning Form.

Enter your HAPO staff ID in question 21 on the Recontact Screening Form and in question 5 on the Recontact Visit Planning Form.

'No' to Question 10:

If the mother indicates that she is not currently breastfeeding, mark 'No' for question 10, and continue with question 11, if the child has not completed the study visit, or with question 16, if the child has completed the visit.

'Yes' to Question 10, more than 6 months of recruitment remaining

If the mother is currently breastfeeding, mark 'Yes' to question 10, and tell her that she cannot be invited to participate now. Mark 'Pregnancy – recontact' for question 2 on the Recontact Visit Planning Form and record a new anticipated call back date six months after the current date for question 7 on Phone Call Information using year/month/day format, entering only the last digit of the year.

Enter your HAPO staff ID in question 21 on the Recontact Screening Form and in question 5 on the Recontact Visit Planning Form.

'Yes' to Question 10, fewer than 6 months of recruitment remaining

Thank the woman for her time, and mark 'Pregnancy – do not recontact' for question 2 on the Recontact Visit Planning Form.

Enter your HAPO staff ID in question 21 on the Recontact Screening Form and in question 5 on the Recontact Visit Planning Form.

Measurements - Child, Question 11

'Yes' to Question 11:

If the mother is willing for her child to have measurements of weight, height, blood pressure, skinfolds and waist and arm circumference, evaluation of where her child is at in puberty and the BOD POD assessment, mark 'Yes' to question 11 and continue with the remaining questions.

'No' to Question 11:

If the mother is not willing to have her child have these measurements, mark 'No' to question 11, thank the woman for her time, and enter your HAPO staff ID in question 21.

Diabetes - Child, Questions 12-13

'No' to Question 12:
If the mother indicates that she has not been told by a medical person that her child has diabetes, mark 'No' for question 12 and go on to question 15.

'Yes' to Question 12:
If the mother indicates that she has been told by a medical person that her child has diabetes, mark 'Yes' to question 12, and ask whether the child is currently taking oral medication or insulin for treatment of diabetes.

'No' to Question 13:
If the child is not currently taking medication for diabetes, mark 'No' for question 13, and go on to question 15. These children can be asked to fast and have an OGTT.

'Yes' to Question 13:
If the child is taking medication for diabetes, mark 'Yes' for question 13, and continue with question 14. Children who are being treated for diabetes are not asked to fast, and the mother should not be asked if she is willing to have her child complete an OGTT.

Single Blood Draw – Child, Question 14

'Yes' to Question 14:
If the mother indicates that she is willing to have a single blood draw taken from her child, mark 'Yes' for question 14 and then mark 'Single blood draw' for question 1 on the Recontact Visit Planning Form.

'No' to Question 14:

If the mother is unwilling to have her child have a single blood draw, mark 'No' for question 14, thank the woman for her time and explain that a requirement for her child's participation is the drawing of a blood sample. Enter your HAPO staff ID in question 21.

OGTT - Child, Question 15

'Yes' to Question 15:

If the mother is willing to have her child to have an OGTT, mark 'Yes' for question 15 and then mark 'OGTT' for question 1 on the Recontact Visit Planning Form and continue with question 16.

'No' to Question 15:

If the mother is unwilling for her child to have an OGTT, mark 'No' for question 15, thank the woman for her time and explain that an OGTT is a requirement for her child's participation. Enter your HAPO staff ID in question 21.

Physical Measurements - Mother, Question 16

'Yes' to Question 16

If the mother is willing have measurements of weight, height, blood pressure, waist and hip circumference, and the BOD POD assessment, mark 'Yes' to question 16 and continue with the remaining questions.

'No' to Question 16:

If the mother is not willing to have these measurements, mark 'No' to question 16 and continue with the remaining questions.

Diabetes - Mother, Questions 17-18

'No' to Question 17:

If the mother indicates that she has not been told by a medical person, when she was not pregnant, that she has diabetes, mark 'No' for question 17 and go on to question 20.

'Yes' to Question 17:

If the mother indicates that she has been told by a medical person, when she was not pregnant, that she has diabetes, mark 'Yes' to question 17, and ask whether she is currently taking oral medication or insulin for treatment of diabetes.

'No to Question 18:

If the mother is not currently taking medication for diabetes, mark 'No' for question 18, and go on to question 20. These women can be asked to fast and have an OGTT.

'Yes' to Question 18:

If the mother is taking medication for diabetes, mark 'Yes' for question 18, and continue with question 19. Women who are being treated for diabetes are not asked to fast, and should not be asked to complete an OGTT.

Single Blood Draw – Mother, Question 19

'Yes' to Question 19:

If the mother indicates that she is willing to have a single blood draw mark 'Yes' for question 19 and then mark 'Single blood draw' for question 2 on the Recontact Visit Planning Form.

Schedule the appointment for the mother and child, if the child has not completed the study visit, and enter the date and time of the appointment in questions 3 and 4 of the Recontact Visit Planning Form. Enter your HAPO staff ID in question 5 of the Recontact Visit Planning Form and then proceed to the visit instructions indicated by the Recontact Visit Planning Form. If the child has not completed the study visit and is to have an OGTT, read the set of instructions corresponding to the mother having a single blood draw, and the child having an OGTT. If the child has not completed the visit and is also to have a single blood draw, read the set of instructions corresponding to both mother and child having a single blood draw. If the child has already completed the visit, read the instructions corresponding to the mother having a single blood draw. Enter your HAPO staff ID in question 21 of the Recontact Screening Form.

'No' to Question 19:

If the mother is unwilling to have a single blood draw, mark 'No' for question 19, thank the woman for her time and explain that a requirement for her participation is the drawing of blood samples. Enter your HAPO staff ID in question 21.

OGTT - Mother, Question 20

'Yes' to Question 20:
If the mother is willing to have an OGTT, mark 'Yes' for question 20 and then mark 'OGTT' for question 2 on the Recontact Visit Planning Form.

Schedule the appointment for the mother and child, if the child has not completed the study visit, and enter the date and time of the appointment in questions 3 and 4 of the Recontact Visit Planning Form. Enter your HAPO staff ID in question 5 of the Recontact Visit Planning Form and then proceed to the visit instructions indicated by the Recontact Visit Planning Form. If the child has not completed the study visit and is to have an OGTT, read the set of instructions corresponding to both the mother and the child having an OGTT. If the child has not completed the visit and is to have a single blood draw, read the set of instructions corresponding to the mother having an OGTT and child having a single blood draw. If the child has already completed the visit, read the instructions corresponding to the mother having an OGTT. Enter your HAPO staff ID in question 21 of the Recontact Screening Form.

'No' to Question 20:
If the mother is unwilling to have an OGTT, mark 'No' for question 20, thank the woman for her time and explain that an OGTT is a requirement for her participation. Enter your HAPO staff ID in question 21.

Form Completion, Questions 21-22

Make sure that you have entered your HAPO staff ID in question 21.

When data entry of the Recontact Screening Form is complete, the person entering the form should enter their HAPO staff ID in question 22.

3.10.2 Recontact Visit Planning Form Instructions

The instructions that are to be given for the visit depend on type of blood samples that will be obtained for the mother and/or child, and whether the child has already completed the study visit. The Recontact Visit Planning Form indicates which set of instructions is appropriate for

the participants. These instructions are to be read to the mother during the screening phone call and then a copy mailed.

3.10.2.1 Instruction Set A: OGTT for Both Mother and Child

See Section 3.7.4.1.

3.10.2.2 Instruction Set B: OGTT for Child, Single Blood Draw for Mother

See Section 3.7.4.2

3.10.2.3 Instruction Set C: OGTT for Mother, Single Blood Draw for Child

See Section 3.7.4.3

3.10.2.4 Instruction Set D: Single Blood Draw for Mother and Child

See Section 3.7.4.4

3.10.2.5 Instruction Set G: Child Visit Completed, OGTT for Mother

- You should follow your usual diet for three days before the visit. Do not eat more or less bread, pasta, rice, potatoes, baked goods, sweets or other carbohydrates than you normally do.
- Bring all medications that you are currently taking to the visit. If there are medications that you normally take in the morning, do not take them on the morning of your visit. Bring them with you so you can take them after the visit is finished.
- Do not consume anything or use any products containing caffeine or nicotine the morning of the appointment.
- You should not engage in vigorous activity for 10 hours prior to the visit.
- You should wear a loose shirt or sweater so that the clinic personnel can easily obtain blood and measure blood pressure. You may bring a tight-fitting bathing suit or exercise shorts/top for the BOD POD. If not, we will have a bathing suit available for you.

- If you use inhalers for asthma or allergies, do NOT use them after bedtime the night before the visit and until after the visit has been completed
- Bring information about the height and weight of your child's father to the visit since questions will be asked about this important information.
- If you are ill with chills, fever, vomiting or diarrhea within three days of your appointment, please call and reschedule the study visit; if you have been ill during that period, not all parts of the study for you can be completed if you come to the clinic.
- You 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.
- In addition, you should not drink anything at all, including water, for 2 hours before the visit.

3.10.2.6 Instruction Set H: Child Visit Completed, Single Blood Draw for Mother

- You and should follow your usual diet for three days before the visit. Do not eat more or less bread, pasta, rice, potatoes, baked goods, sweets or other carbohydrates than you normally do.
- Bring all medications that either you are currently taking to the visit. If there are medications that you normally take in the morning, do not take them on the morning of your visit. Bring them with you so you can take them after the visit is finished.
- Do not consume anything or use any products containing caffeine or nicotine the morning of the appointment.
- You should not engage in vigorous activity for 10 hours prior to the visit.
- You should wear a loose shirt or sweater so that the clinic personnel can easily obtain blood and measure blood pressure.
- If you use inhalers for asthma or allergies, do NOT use them after bedtime the night before the visit and until after the visit has been completed
- Bring information about the height and weight of your child's father to the visit since questions will be asked about this important information.
- If you are ill with chills, fever, vomiting or diarrhea within three days of your appointment, please call and reschedule the study visit; if you have been ill during that period, not all parts of the study for you can be completed if you come to the clinic.

- You should not eat or drink anything at all, including water, for 2 hours before the visit.

3.11 Entering Data from the Recontact Forms

At each field center, the information from completed Recontact Screening Form and Recontact Visit Planning Form will be entered using the REDCap Data Entry System When data entry is complete, the person who entered the data should record their HAPO ID at the end of each form. Then they should check the box labeled 'Data Entry Done' on the front page of each form.

3.12 Unwilling to Reschedule a Missed Visit

If the mother and/or child misses a scheduled visit and is unwilling to reschedule the missed visit, question 1 and question 2 on the Special Circumstances Form should be completed (see **Section 3.13**) and entered into the REDCap Data Entry System along with the Recontact Screening Form and Recontact Visit Planning Form.

3.13 Special Circumstances Form

This form is intended to record special circumstances encountered while recruiting participants to the HAPO Follow-Up Study. One special circumstance might include participants who miss a scheduled study visit and are unable or unwilling to be rescheduled (question 1 and question 2). Other circumstances might include something that is encountered that would preclude the mother or child from participating in the study such as a death or recent medical treatment, e.g. chemotherapy (question 3 and question 4). The person completing this form should record their HAPO staff ID. When data entry is complete, the person who entered the data should record their HAPO ID at the end of the form. They should then check the box labeled "Data Entry Done" at the top of the page.