9. REDCap Data Entry System and BOD POD Procedures

9.1 Overview

Data entry is done at each field center using the HAPO Follow-Up Study REDCap Data Entry System. REDCap (or Research Electronic Data Capture) is a secure web application designed exclusively to support data capture for research studies. The REDCap Consortium is comprised of many active partners from Clinical and Translational Science Award (CTSA) Institutions, General Clinical Research Centers (GCRC) and other US and international institutions. A description of all REDCap activities, updates, resources and institutional partners is available at http://project-redcap.org/.

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.

Instruction on data entry procedures is included at training meetings. All data forms are entered locally, except for the Identification Form and Contact Information Form which are not entered at all, but retained by the field center for maintaining contact with participants. Data entry personnel will only have access to data from their field center. Entered data will be downloaded by the Data Coordinating Center weekly to undergo logic checks, cross-form consistency, etc. All hard copies of data entry forms should be retained throughout the duration of the HAPO Follow-Up Study.

9.2 Data Entry System Access and Login

Two steps are required to access the HAPO Follow-Up REDCap database.

1) Establish a SSL VPN connection to Northwestern by entering your Northwestern assigned NetID and password at the following link: https://www.vpn.northwestern.edu. The VPN connection must be maintained throughout data entry. Do not log out of the VPN site until data entry is complete.

2) After establishing a SSL VPN connection, click on the link for "NUBIC REDCap (Production)".   On the REDCap page, enter your NetID as your User name and the same password as you entered in Step 1. Click on the "My Projects" tab where you will see "HAPO Database (Single Entry)" and "HAPO Database (Double Entry)".

At regular intervals, you will be alerted by Northwestern University to change your NetID password. Please do not share or circulate your NetID or password.

9.3 Video Training Resources

The REDCap Consortium provides continually updated video tutorials for using REDCap. These videos are available at http://project-redcap.org/ under the Video Resources tab.

9.4 Question Types

The HAPO Follow-Up Study Data Entry System contains several different data types including: dates, times, multiple choice with only one possible answer, multiple choice with multiple answers allowed, numeric values, and in a few cases, free text. Logic checks are built in for numeric values. Skip patterns are also built in to the Data Entry System, making a question available for data entry only if it should be answered based on earlier answers.

9.4.1 Dates

Dates are entered by clicking on the appropriate date in a pop-up calendar. Make sure the month, day and year are specified correctly.

9.4.2 Times

Times may be specified by selecting the appropriate time from a pop-up 24-hour clock. REDCap only handles 5 minute increments from the hour using the pop-up clock feature; however, times like 12:14 may be entered manually.

9.4.3 Multiple Choice with Only One Possible Answer

Multiple choice questions in which only one answer should be specified are represented using either radio buttons when there are only a few options or a drop down menu when there are many possible options. In either case, selection of one item will delete any other selections, forcing a choice of only one answer.

9.4.4 Multiple Choice with Multiple Answers Allowed

Multiple choice questions for which multiple answers are allowed are represented using check boxes. Multiple answers may be selected and selection of one answer will not delete selection of another answer.

9.4.5 Numeric Values

Numeric values should be entered into the field provided. On the data collection forms, spaces are provided for recording numeric data and in some cases leading zeroes may be used. For example, a blood pressure measurement of 160/90 would be recorded as 160/090 on the data collection form so that a number fills each of the spaces on the form. When entering the diastolic blood pressure portion of this value into the Data Entry System, it is not necessary to include the 0 preceding the 90 (i.e. only '90' needs to be entered). Including the leading 0 is not problematic, however. If '090' is entered, REDCap will recognize the leading zero and remove it prior to data export.

Range checks for numeric entries are built into the data entry system. If an entered value falls outside the range, a message will pop up that says 'The value you provided is outside the suggested range. (Range= XX to XX) This value is admissible, but you may wish to verify.' If the entered value is incorrect, it should be changed. If the value is correct and should be verified, select 'Unverified' under 'Complete?' in the Form Status section at the end of the form before saving the entered values. The Participant ID will be available in the drop down menu for Unverified Records on the entry page for the form to indicate that at least one entry for this form requires verification. Make a note on the paper form to indicate that the value needs to be verified. Once the value is checked and either verified or fixed, select 'Complete' or 'Incomplete' as appropriate under 'Complete?' in the Form Status section.

9.4.6 Free Text

Free text entries are made only on rare occasions. Enter text as concisely as possible.

9.5 Saving Entered Data

Data entry can be stopped at any point for a form. If data entry is not complete for a form, it will be considered an Incomplete Record. All entered values can be saved for Incomplete Records by selecting 'Incomplete' from the drop-down menu under 'Complete?' in the Form Status section for each form and clicking on 'Save Record'. Participant IDs from these records will be available for selection in the drop down menu labeled Incomplete Records on the entry page for every form.

When data entry is finished for a form, select 'Complete' from the drop-down menu under 'Complete?' in the Form Status section. Then select 'Save Record' to save all entries and automatically exit the form. 'Save and Continue' saves all entries without exiting the form and allows data entry to continue on the same form. 'Save and go to Next Form' saves all entries for the current form and automatically continues to the next form in sequence for the same participant. Since 'Save Record' automatically exits the form and then allows selection of a new form and a new participant for data entry, this may be the most useful option since not all forms are used for all participants.

After a form has been completely entered into the HAPO Follow-Up Study REDCap Data Entry 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' at the end of the 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.

9.6 Making Corrections

If it is necessary to make a correction for either an Incomplete Record or a Complete Record, select the appropriate form from the Data Entry Forms menu and choose the appropriate Participant ID from either the Incomplete Records drop down menu or the Complete Records drop down menu. Make the appropriate change and click on 'Save Record'. REDCap will then return to the entry page for the form and return a message that says 'Participant ID "XXXX" successfully edited'.

9.7 Single v. Double Data Entry

Double data entry is required for a subset of the HAPO Follow-Up data collection forms. For the remaining forms only a single entry is required. A step-by-step process for double and single data entry for a HAPO Follow-Up (HAPO FUS) participant with ID XXXXX is outlined below.

9.7.1 Double Data Entry

1. First, open project titled "HAPO Database (Double Entry)"
2. Enter data for HAPO FUS participant XXXXX first by selecting "XXXXX--1" from the drop down menu for Incomplete Records. You will be entering data from the following forms:
   - Questionnaire
   - Physical Measurements Mother
   - Physical Measurements Child
3. Enter this data again for HAPO FUS participant XXXXX this time by selecting "XXXXX--2" from the drop down menu for Incomplete Records. You will be entering data from the following forms:
   - Questionnaire
   - Physical Measurements Mother
   - Physical Measurements Child
4. Click on the Data Comparison Tool in the left-hand panel. There will be two dropdown menus under Participant ID that will allow you to compare record "XXXXX--1" to record "XXXXX--2". A table will appear showing you *only* differing values across the two records, "XXXXX--1" and "XXXXX--2" with the label (field name) and the form name associated with these differing values.
5. If you need to correct or change the values of one of the records ("XXXXX--1", "XXXXX--2"), simply click on the value(s) displayed in red and it will take you to that form for that particular record.
6. After resolving any discrepancies in Double Data Entry and fixing them in REDCap, run the Data Comparison tool once again to ensure that all discrepancies were in fact addressed.

9.7.2 Single Data Entry

7. Now, open project titled "HAPO Database (Single Entry)".

8. Here you will enter the data for any of the *22* remaining forms that were completed. These do not need to be entered twice. These forms include:

- Screening
- Visit Planning
- Recontact Screening
- Recontact Visit Planning
- Test Qualification Mother
- Test Qualification Child
- OGTT Mother
- OGTT Sample Processing Mother
- OGTT Child
- OGTT Sample Processing Child
- Single Blood Draw Mother
- Single Blood Draw Sample Processing Form Mother
- Single Blood Draw Child
- Single Blood Draw Sample Processing Form Child
- Metformin Use Mother
- Metformin Use Interview Mother
- Metformin Use Child
- Metformin Use Interview Child
- *Special Circumstances*
- *Study Visit Variation*
- *Blood Pressure Remeasurement Mother*
- *Blood Pressure Remeasurement Child*

9. Click on the appropriate form in the left-hand panel, select the Participant ID from the drop down menu and carefully proceed entering data.

******NOTE:** When you are entering data, if you cannot find the ID you need in the drop down menus please DO NOT enter it into the 'Enter new or existing Participant ID' field. Please contact the Data Coordinating Center to resolve any issues pertaining to missing IDs.

9.8 BOD POD Procedures

9.8.1 BOD POD Identifying Information, ID Fields and Settings

When using the BOD POD during HAPO Follow-Up Study visits, please adhere to the following:

1) Do not enter any identifying information into the "First Name", "Middle Name" or "Last Name" fields.   These fields may be left blank, or they may be filled using field center-specific requirements such as the field center Principal Investigator's last name, the study protocol number, etc. Raw data from the BOD POD will be transmitted to the HAPO Follow-Up Study Data Coordinating Center so it is crucial that all identifying information is not included as part of the study visit.

2) The "Date of Birth" field should be filled in using the mother and child's birth month and year, and then specifying "1" for the day. The "Date of Birth" field is used by the BOD POD to select the appropriate % body fat estimation equation so it needs to be accurate enough to result in the correct age range. Use of a "1" for all days will assist with de-identification of the data.

3) In the field labeled "ID_1", enter the 6-digit ID for the mother/child pair (e.g. V0001A). Note that only the first and last characters of this ID are letters *and they must be capital letters*. The middle four characters are all numbers. For the ID V0001A, the 2nd-4th characters are the number "0" not the letter "O".

4) In the field labeled "ID_2" enter "HAPO MOM" or "HAPO CHILD" as appropriate. Please use all capital letters and make the entries exactly as they are indicated here.

5) For the "Ethnicity" field always select "General Population".

6) For the "Thoracic Gas Volume Model" always select "Predicted".

7) "Body Density Model" will automatically default to "Siri" for mothers and "Lohman" for children based on the entered birthdate. Please use these models. Do not select different models.

9.8.2 BOD POD Refusal

In the rare circumstance that a participant refuses the BOD POD test, you can still obtain a mass measurement in lb or kg using the BOD POD scale without doing a full BOD POD test as follows:

1) From the main menu select "Practice".

2) Select the "Mass" activity.

3) Follow the instructions on the screen.

4) Record the mass measurement that is displayed. You will not be able to export this data.

9.8.3 Exporting Raw BOD POD Data

At the end of each week, raw data from the BOD POD should be exported and transmitted to the Data Coordinating Center. Instructions for exporting results from the BOD POD database are on pages 91-94 of the operator's manual. The following instructions represent what is described there:

1) In the BodPod software, click on "Data Management" and then click on "Export Results".

2) On the next screen, choose which subject(s) results you would like to export - you can sort by name, date, etc. This should be all HAPO participants for whom raw data have not yet been transmitted to the HAPO Follow-Up Study Data Coordinating Center.

3) Click on "Next".

4) Type in the file name for the results that are about to be exported. This should be "HAPO BOD POD Data – XXXX -YYYY-MM-DD" where 'XXXX' is the name of your field center, and 'YYYY-MM-DD' is the date of the data export in year/month/day format.

5) The results will automatically go to the "C" drive and they will be in a .txt file format.

6) Exit the software OR press the windows key - this key is on the lower left row of the keyboard - it looks like the Microsoft symbol.

7) Go to "Computer" or "My Computer".

8) Double click on the "C" drive.

9) Double click on the "BodPod Data" folder.

10) Double click on the "Export Results" folder.

11) Make sure the file you just exported is saved in this folder.

12) Then save this file to a thumb drive and transfer it to another computer where it can be transmitted to the Data Coordinating Center.

13) Upload the raw data onto Vault as follows:

    1. First click on the password protected ticket to Vault that you were sent.

    2. Enter your designated password.

3. Click the upload button on the right hand side towards the top.
4. Upload your raw BOD POD data.