

## Hyperglycemia & Adverse Pregnancy Outcome Follow-Up Study

## **HAPO FUS**

**Manual of Operations (MOO)** 

## **Table of Contents**

1.	Overview	1-1
	1.1 Study Overview	1-1
	1.2 Summary of Tasks	1-2
	1.3 HAPO Follow-Up Study Timeline	1-3
	1.4 Field Center Preparation for the HAPO Follow-Up Study	1-4
2.	General Guidelines	2-1
	2.1 Guidelines for Completion of HAPO Follow-Up Study Forms	2-1
	2.1.1 General Instructions	2-1
	2.1.2 Specific Instructions	2-3
	2.2 General Guidelines for Mother/Child Visits	2-4
	2.3 Guidelines for Interviewing	2-5
	2.4 Guidelines for Phlebotomy	2-8
	2.5 Privacy and Confidentiality	2-11
3.	Recruitment	3-1
	3.1 Goals	3-1
	3.2 Waiver of Consent	3-1
	3.3 Forms Used During Screening and Enrollment of Participants	3-1
	3.4 Screening Eligibility	3-2
	3.5 Identifying HAPO Participants for Screening	3-2
	3.6 Initial Contact of HAPO Participants Listed in the Recruiting	2 2
	Register 3.6.1 HAPO Study Summary	3-3 3-5
	3.6.2 HAPO Follow-Up Study Description	3-3 3-8
	3.7 Enrollment Procedures	3-0 3-10
	3.7.1 Recruiting Register	3-10
	3.7.1 Recruiting Register  3.7.2 Phone Call Information	3-11
	3.7.2 Thorse can information 3.7.3 Screening Form	3-11
	3.7.4 Visit Planning Form Instructions	3-21
	3.7.4.1 Instruction Set A: OGTT for Both Mother and Child	3-21
	3.7.4.2 Instruction Set B: OGTT Child, SBD Mother	3-22
	3.7.4.3 Instruction Set C: OGTT Mother, SBD Child	3-23
	3.7.4.4 Instruction Set D: SBD for Both Mother and Child	3-24
	3.7.4.5 Instruction Set E: OGTT Child, Mother Pregnancy	3-25
	3.7.4.6 Instruction Set F: SBD Child, Mother Pregnancy	3-26
	3.7.4.7 Appointment Reminder	3-27
	3.8 Entering Data from the Screening Form and Visit Planning Form	3-27
	3.9 Unwilling to Reschedule a Missed Visit	3-27
	3.10 Recontacting Pregnant Women	3-27
	3.10.1 Recontact Screening Form	3-28
	3.10.2 Recontact Visit Planning Form Instructions	3-35
	3.10.2.1 Instruction Set A: OGTT for Both Mother and Child	3-36
	3.10.2.2 Instruction Set B: OGTT Child, SBD Mother	3-36
	3.10.2.3 Instruction Set C: OGTT Mother, SBD Child	3-36
	3.10.2.4 Instruction Set D: SBD for Both Mother and Child	3-36
	3.10.2.5 Instruction Set G: Child Visit Completed, OGTT Mother	3-36
	3.10.2.6 Instruction Set H: Child Visit Completed, SBD Mother	3-37
	3.11 Entering Data from the Recontact Forms	3-38
	3.12 Unwilling to Reschedule a Missed Visit	3-38
	3.13 Special Circumstances Form	3-38

4.		4-1
	4.1 Introduction	4-1
	4.2 General Instructions	4-1
	4.3 Supplies	4-2
	4.4 Sample Processing	4-2
	4.5 Recommended Precautions for Preventing Transmission of	
	Bloodborn Infectious Diseases	4-3
	4.6 Storage and Shipping	4-4
5.	Visit – Mother	5-1
٠.	5.1 Forms Used for the Visit – Mother	5-1
	5.2 Consent	5-2
	5.3 Call Back Register	5-3
	5.4 Completing the Test Qualification Form – Mother	5-4
	5.4.1 Special Situations Precluding the OGTT	5-11
	5.5 Rescheduling the Visit	5-12
	5.5.1 Procedures for Mothers Unable to Keep the Original	
	Appointment	5-12
	5.5.2 Procedures for Mothers who Fail to Appear for the Visit	5-12
	5.5.3 Procedures for Women not Meeting OGTT Requirements	5-13
	5.6 Physical Measurements – Mother	5-13
	5.6.1 Urine Sample	5-13
	5.6.2 Measurement of Blood Pressure	5-14
	5.6.2.1 Description and Preparation	5-14
	5.6.2.2 Instructions – Omron 705 Electronic Machine	5-15
	5.6.2.3 Instructions – Manual Sphygmomanometer	5-17
	5.6.2.4 Omron 705 Electronic Machine	5-19
	5.6.2.5 Training	5-20
	5.6.2.6 Blood Pressure Remeasurement	5-20
	5.6.3 Measurement of Height	5-21
	5.6.4 BOD POD Measurements of Weight and Percent Fat	5-22
	5.6.4.1 Measurement of Weight if BOD POD Test Refused	5-23
	5.6.5 Waist Circumference Measurements	5-24
	5.6.5.1 Top of the Iliac Crest	5-24
	5.6.5.2 Midpoint between Lowest Rib and the Iliac Crest	5-25
	5.6.6 Hip Circumference Measurement	5-26
	5.6.7 Data Entry Completion – Physical Measurements – Mother	5-27
	5.6.8 Training	5-28
	5.6.9 Measurement Results	5-28
	5.7 OGTT Procedures	5-28
	5.7.1 75g Glucose Drink	5-29
	5.7.2 Blood Drawing Procedure	5-30
	5.7.3 OGTT Stopped – Not Rescheduled	5-30
	5.7.4 OGTT Stopped – Rescheduled	5-31
	5.7.5 OGTT Blood Handling	5-31
	5.7.5.1 Fasting Blood Samples	5-31
	5.7.5.2 2-Hour Blood Samples	5-32
	5.7.6 OGTT Form Completion	5-33
	5.7.7 Aliquotting/Labeling	5-34
	5.7.7.1 General Instructions	5-34
	5.7.7.2 Urine Sample	5-35
	5.7.7.3 Fasting Blood Glucose Sample	5-36
	5.7.7.4 Fasting Insulin/C-Peptide Sample	5-37
	5.7.7.5 Fasting Lipids Sample	5-38
	5.7.7.6 Fasting Storage Sample	5-39
	5.7.7.7 Fasting DNA Sample	5-40
	5.7.7.8 Fasting A1c Sample	5-40
	5 7 7 9 2-Hour Blood Glucose Sample	5_/1

	5.7.7.10 2-Hour Storage Sample	5-42
	5.7.8 OGTT Sample Processing Form Completion	5-43
	5.7.9 OGTT Blood Flow Chart	5-45
	5.7.10 Quality Control	5-45
	5.8 Single Blood Draw Procedures	5-45
	5.8.1 Single Blood Draw – Blood Handling	5-46
	5.8.2 Single Blood Draw Form Completion	5-46
	5.8.3 Processing Single Blood Draw Samples	5-47
	5.9 Storage of Specimens	5-48
	5.10 Questionnaire	5-49
	5.10.1 Instructions for Administering the Questionnaire	5-49
	5.10.2 Entering Data from the Questionnaire	5-56
	5.10.3 Training	5-56
	5.11 Study Visit Variation	5-56
	5.12 2-Hour Glucometer Measurement	5-56
	5.13 Blood Pressure Remeasurement	5-57
	5.13.1 Completing the Blood Pressure Remeasurement Form	5-57
	Trutol Volume by Weight Chart	5-60
6.	Visit – Child	6-1
•-	6.1 Forms Used for the Visit – Child	6-1
	6.2 Consent	6-2
	6.3 Call Back Register	6-3
	6.4 Completing the Test Qualification Form – Child	6-4
	6.4.1 Special Situations Precluding the OGTT	6-11
	6.5 Rescheduling the Visit	6-12
	6.5.1 Procedures for Children Unable to Keep the Original	
	Appointment	6-12
	6.5.2 Procedures for Children who Fail to Appear for the Visit	6-12
	6.5.3 Procedures for Children not Meeting OGTT Requirements	6-12
	6.6 Physical Measurements – Child	6-13
	6.6.1 Urine Sample	6-13
	6.6.2 Measurement of Blood Pressure	6-14 6-14
	6.6.2.1 Blood Pressure Remeasurement	6-14
	6.6.3 Measurement of Height 6.6.4 BOD POD Measurements of Weight and Percent Fat	6-14
	6.6.5 Waist Circumference Measurements	6-15
	6.6.6 Mid-Arm Circumference Measurement	6-15
	6.6.7 Skinfolds Measurements	6-17
	6.6.8 Pubertal Assessment	6-17
	6.6.8.1 Self Assessment	6-19
	6.6.8.2 Pubertal Assessment – Boy	6-20
	6.6.8.3 Pubertal Assessment – Girl	6-21
	6.6.8.4 Completion of Pubertal Assessment	6-22
	6.6.9 Data Entry Completion – Physical Measurements – Child	6-22
	6.6.10 Training	6-23
	6.6.11 Measurement Results	6-23
	6.7 OGTT Procedures	6-23
	6.7.1 75g Glucose Drink	6-24
	6.7.2 Blood Drawing Procedure	6-24
	6.7.3 OGTT Stopped – Not Rescheduled	6-25
	6.7.4 OGTT Blood Handling	6-26
	6.7.4.1 Fasting Blood Samples	6-26
	6.7.4.2 30-Minute Blood Samples	6-27
	6.7.4.3 1-Hour Blood Samples	6-28
	6.7.4.4 2-Hour Blood Samples	6-28
	6.7.5 OGTT Form Completion	6-29
	6.7.6 Aliquotting/Labeling	6-30
	6.7.6.1 General Instructions	6-30

	6.7.6.2 Urine Sample	6-31
	6.7.6.3 Fasting Blood Glucose Sample	6-32
	6.7.6.4 Fasting Insulin/C-Peptide Sample	6-33
	6.7.6.5 Fasting hsCRP and Lipids Sample	6-34
	6.7.6.6 Fasting Storage Sample	6-35
	6.7.6.7 Fasting DNA Sample	6-36
	6.7.6.8 Fasting A1c Sample	6-36
	6.7.6.9 30-Minute and 1- and 2-Hour Blood Glucose and	
	Insulin/C-Peptide Samples	6-37
	6.7.7 OGTT Sample Processing Form Completion	6-37
	6.7.8 OGTT Blood Flow Chart	6-39
	6.7.9 Quality Control	6-39
	6.8 Single Blood Draw Procedures	6-39
	6.8.1 Single Blood Draw – Blood Handling	6-40
	6.8.2 Single Blood Draw Form Completion	6-40
	6.8.3 Single Blood Draw Sample Processing Form Completion	6-41
	6.9 Storage of Specimens	6-42
	6.10 Questionnaire	6-43
	6.11 Study Visit Variation	6-43
	6.12 2-Hour Glucometer Measurement	6-44
	6.13 Blood Pressure Alert Protocol for Children	6-44
		6-50
	6.13.1 Completing the Blood Pressure Remeasurement Form	6-52
	Trutol Volume by Weight Chart	0-32
7.	Storage and Shipment of Specimens	7-1
٠.	7.1 Storage at the Field Center Laboratory	7-1 7-1
		7-1 7-2
	7.1.1 Storage Labels	7-2 7-4
	7.1.2 The Shipping Grid	7-4
	7.1.3 Storage of Cryovials for Laboratory Coordinating	77
	Center Analysis	7-7 7-0
	7.1.4 Storage of Backup Cryovials	7-9
	7.1.5 Placement of Blood Samples	7-9
	7.1.6 Storage of DNA Samples	7-12
	7.2 Sample Shipment	7-13
	7.2.1 Shipment of Samples to the Laboratory Coordinating Center	7-13
	7.2.1.1 Packing Instructions	7-14
	7.2.1.2 Guidelines for Handling Dry Ice	7-16
	7.2.1.3 Initial Preparation for Shipping via FedEx	7-16
	7.2.1.4 US Shipments to the Laboratory Coordinating Center	7-17
	7.2.1.5 International Shipments to the Laboratory Coordinating	
	Center	7-18
_	Laboration Occasion Contra Describer	
8.		
	(for internal Coordinating Center use only)	
^	DEDCon Data Fatau Custom and DOD DOD Broadures	0.4
9.		9-1
	9.1 Overview	9-1
	9.2 Data Entry System Access and Login	9-2
	9.3 Video Training Resources	9-2
	9.4 Question Types	9-2
	9.4.1 Dates	9-2
	9.4.2 Times	9-2
	9.4.3 Multiple Choice with Only One Possible Answer	9-2
	9.4.4 Multiple Choice with Multiple Answers Allowed	9-3
	9.4.5 Numeric Values	9-3
	9.4.6 Free Text	9-3
	9.5 Saving Entered Data	9-3
	9.6 Making Corrections	9-4
	9.7 Single v. Double Data Entry	9-4

9.7.1 Double Data Entry	9-5
9.7.2 Single Data Entry	9-5
9.8 BOD POD Procedures	9-6
9.8.1 BOD POD Identifying Information, ID Fields and Settings	9-7
9.8.2 BOD POD Refusal	9-7
9.8.3 Exporting Raw BOD POD Data	9-8
10. Quality Control	10-1
10.1 Introduction	10-1
10.2 Standardized Central Training	10-2 10-3
10.3 Dry Run 10.3.1 Preparation for the Dry Run	10-3
10.3.2 Dry Run Procedures	10-4
10.4 Site Visits	10-5
10.5 Quality Control of Physical Measurements	10-6
10.5.1 Blood Pressure	10-6
10.5.1.1 Procedure for Comparison Blood Pressure	
Measurements	10-6
10.5.1.2 Blood Pressure Quality Assurance Form Completion	10-7
10.5.2 Anthropometric Measurements	10-11
10.6 Data Forms	10-12
10.7 Standardized Equipment and Supplies	10-13
10.8 Data Editing	10-13
10.9 Documentation of Recruitment	10-14
10.10 Data Entry	10-15
10.11 Processing Field Center Data at the Data Coordinating Center	10-16
10.11.1 Communication of Errors to Field Centers	10-16
10.11.2 Correction of Errors 10.12 Communications	10-17
10.13 Retraining	10-17 10-17
10.14 Laboratory Coordinating Center	10-17
10.14.1 Notification of Biological Sample Shipments	10-18
10.14.2 Quality Control Procedures	10-19
10.15 Processing Laboratory Coordinating Center Data	10-20
10.16 Quality Control Reports	10-21
10.16.1 Reports on Study Progress	10-21
10.16.2 Reports on Laboratory Performancy	10-21
11. Policies	11-1
11.1 Informed Consent	11-1
11.2 Training	11-2
11.3 Privacy of Records	11-2
11.4 Field Center Data Access	11-2
11.5 Publications and Presentations	11-2 11-3
11.5.1 Main Final Paper(s) 11.5.2 Other Study-Wide Papers	11-3
11.5.3 Local Papers	11-3
11.6 Ancillary Studies Policies	11-3
11.6.1 General Policy	11-3
11.6.2 Definition of an Ancillary Study	11-4
11.6.3 Requirements and Procedures for Approval of an	• • •
Ancillary Study	11-4
11.6.3.1 Overview	11-4
11.6.3.2 Considerations for Approval	11-5
11.6.3.3 IRB Review of Local Ancillary Studies	11-6
11.6.3.4 Instructions for Completion of the Ancillary	
Study Proposal Form	11-6
11.6.3.5 Changes to an Approved Ancillary Study	11-8
11.6.3.6 Ancillary Proposal Budget	11-8

11.6.4 Ancillary Study Papers	11-9
11.7 Data Sharing	11-9