

= Priority Item for SC Approval by August 30th

SOL Visit 2 Forms, Procedures and Manuals – Approval by Steering Committee: August 29-30

	Specific Components of the SOL Visit 2	SOW App. I *	Status			Comment	Steering Cmte. Approval		
			Form	Status §	Lead		Apprvd. 8/29-30	Pending	Due Date
A	<i>Cohort Follow-up Interviews</i>								
1	AFU Y04	a.ii	FE4	-	Marston	Harmonize outcomes & medication	-	-	-
2	AFU Y05	a.iv.2	FE5	✓	Laura	qxs with V2	-	-	-
B	<i>Retention, Recruitment & Scheduling</i>								
1	Retention materials and protocol	-	--	✓	Krista	Recommendations submitted	-	-	-
2	Update contact information, recruit and schedule visits	a.i	IDE,ARE	✓	Nana		-	-	-
C	<i>Field Center Interviews/Questionnaires</i>								
1	Signed informed consent	a.i	ICT	✓	Gerardo	Update per approved V2 Qx.			
2	Medical releases	a.1	-	✓	Nana	Harmonize AFU & V2 instruments	-		
3	Updated personal and contacts' information	a.ii	IDE	✓	Nana		-		
4	Ppt. safety screening	-	PSE	✓	Marston		-		
5	Personal and family medical history	a.iii	MHE	✓	Laura	Address sensitive & low priority qxs.			
6	HX of GDM, pre-eclampsia, eclampsia dx + reprod. Hx @ V2	a.iv.1	-	✓	Alison				
7	Reassess the V1 sociocultural measures	a.v.2	SCE	✓	Linda G.				
8	Expand on V1 sociocultural measures	a.v.1	-	✓	Linda G.				
9	Reassess V1 access to and utilization of health care services	a.vi	HCE	✓	Larissa				
10	Expand on the access to and utilization of health care services	a.vi.	-	✓	Larissa	Address low priority qxs.			
11	Reassess V1 measures of socioeconomic factors	a.vii	ECE	✓	Greg				
12	Abbrev. medication use	a.viii	-	✓	Gerardo				
13	Depression scale and anxiety symptoms	a.ix	?	✗	Neil	Opportunity for an ancillary study		X	
14	Cigarette smoking	--	TBE	✓	Sheila				
15	Alcohol intake	--	ALE	✓	Sheila				
16	Employment/Occupation		ECE	X	Linda G.	Covered under C.11?	C.11		
17	Household income		OCE	X	Linda G.	Covered under C.11?	C.11		
18	Exit interview	a.xi	EXE	X	Marston		-		
15	TBD: 'other questionnaires/ancillary study instruments'	a.x	-	-	-		-	-	-
D	<i>Field Center Exam Procedures</i>								
1	Reassess V1 anthropometry	b.i	ANT	✓	Carmen I.				
2	Reassess seated BP	b.ii	SBP	✓	Gerardo				
3	Determination of fasting status and blood draw	b.iv.1	BIO	✓	Marston				
4	Determination of blood glucose levels – glucose load	b.iv.2	BIO	-	Larissa				
5	Spot urine specimen	b.iv.3	BIO	✓	Annie L.				
6	2-hr. blood draw	b.iv.4	BIO	✓	Annie L.				
7	Biospecimen processing	b.iv.5	BIO	✓	Annie L.				
8	Echocardiography – Field Center	b.iii	-	✓	Susan C.				
9	Echocardiography – Reading Center	b.iii	-	✓	Susan C.				

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E	Adverse Events and Deviations from Protocol								
1	AE reporting (serious and minor)	-	S/MAE	X	Marston	As in Visit 1 – Concept approval needed		-	-
2	Log of deviations from safety protocol	-	-	X	Marston			-	-
F	QC Forms and Logs								
1	Lab QC/phantom ppts.	-	-	✓	Bharat	As in Visit 1 – Concept approval needed			
2	Repeat interview / procedure forms	-	-	X	Marston				
3	Equipment calibration logs	-	-	✓	Marston	Internal	-		
4	Shipping logs	-	-	✓	Annie L.	Internal	-		
G	Reporting of Study Results								
1	Alert result designation and communication – a. Lab Assays	-	-	✓	Bharat				
	b. Echocardiography	-	-	✓	Scott				
	c. BP, other	-	-	X	Gerardo	As in Visit 1 – Concept approval			
2	Processing of alerts, distribution & follow-up	-	-		Marston		-		
3	Report of study results	-	-	X	Marston		-		
F	Event Identification								
1	GDM, pre-eclampsia, eclampsia dx since baseline, + follow-up	a.iv.2	-	✓	Laura	Case definitions and form submitted			
2	Pulmonary, cardiovascular and fatal outcomes	-	-	X	Wayne		-	X	
H	Event Classification								
1	GDM, pre-eclampsia and eclampsia	a.iv.3	-	X	Laura			-	-
2	Pulmonary, cardiovascular and fatal outcomes	-	-	X	Wayne	In progress - Different time line	-		-

* RFP No.: NHLBI-HV-13-05 - APPENDIX I – Specific Components of Visit 2

§ X= Form/instrument under development; ✓ = Form/instrument delivered to SOL CC

Laboratory Assays. Per the revised SOW the following assays will be done in real time: 1) GGT, ALT and AST; 2) Cystatin C; 3) Serum creatinine; 4) Fasting plasma glucose, insulin and Hemoglobin A1c; 5) Oral glucose tolerance test and 2-h post OGTT plasma glucose; 6) Hepatitis C RNA for participants with positive Hepatitis C virology in Visit 1; 7) Urine creatinine and albumin; 8) CBC and 9) Lipid Panel.

The following assays will be deferred/done only for case-control study designs: 1) Hs-troponin1; 2) NT-proBNP; 3) Iron and Transferrin; 4) All other inflammatory or cardiac biomarkers mentioned in the SOW.

Per the revised specimen storage scheme the total number of vials to be stored is 163,350.