

DELIVERABLES/REPORTING REQUIREMENTS: JHS - EXAM CENTER

All deliverables, COAs, and vouchers shall be submitted to the JHS Director for approval with signature before submission to the NHLBI Project Office and Contracts Office. Note that deliverables in preparation for a possible Exam 4 will be due only if a tentative decision to propose continuation of the study has been made and NHLBI has given approval to proceed with the preparatory work.

- I. The Following shall be delivered to the Coordinating Center, laboratories, and reading centers as required by the protocol:
 - A. Final Protocols for
 1. Pilot test, at least 4 weeks prior to start of pilot examinations
 2. JHS Exam, at least 4 weeks prior to start of the clinical examinations including
 - a. Annual follow-up
 - b. Events ascertainment
 3. Comparability studies, at least 4 weeks prior to start
 4. Participant alert notification and referrals
 - B. All samples, tapes/disks, images and other data on study subjects (i.e., comparability studies) shall be delivered weekly.
 - C. Monthly reports on the examination data during the examination period (begin October 15, 2005 for Exam 2 and October 15, 2009 for Exam 3), including but not limited to:
 1. Participant retention
 2. Completeness of exam data
 3. Reports on alerts and referrals
 4. Events ascertainment
 - D. Quarterly updated list of publications and presentations coming from the **Exam Center** investigators.
 - E. Reports on data collection from
 1. the pilot test, 2 weeks after completion
 2. Comparability studies, monthly during comparability data collection
 - F. Quality Assurance/Control activities, Quarterly updates during clinic exams
 1. Quality Control logs of data transmitted, edit checks conducted, and identified errors
 2. Audit trails for all data entry and data correction activities, including electronically transferred data
 3. Staff training and certification protocol
 - G. Events ascertainment and adjudication of events completed and delivered within two years of their occurrence.

- II. The following shall be delivered to the Undergraduate Training Center
 - A. Assignments for JHS Scholars' field training in all aspects of the planning and execution of the study.
- III. The following shall be delivered to the Project Officer and Contracts Officer, NHLBI: (2 copies, 1 copy to PO and 1 to CO).
 - A. Staff training materials
 - B. ICP/KYN/RRA tasks:
 - 1. Development of materials/protocol, including
 - a. telephone script and calling schedule
 - b. data collection instrument on health care utilization
 - c. lifestyle modifications questionnaire during interim clinic activities
 - d. ICP/KYN post test
 - e. Tracking system of presentations provided and activities conducted
 - 2. Assessment of participant awareness of their cardiovascular health
 - C. Local Laboratory
 - 1. Final subcontract
 - 2. Performance report
 - D. Annual site visits to local laboratory with site visits report due, 3 weeks after visit.
 - E. Deliver raw data without individual identifiers as requested or whenever concerns arise regarding the quality of the database.
 - F. Semi-annual progress reports
 - G. Participant Consent forms for NHLBI approval within 2 weeks of SC approval. Resubmit Participant Consent forms to NHLBI after IRB-approval for re-review and approval of any subsequent modifications.
 - H. Abstracts and manuscripts proposed for publication 4 weeks (2 weeks for abstracts) in advance of submission for NHLBI approval, including at least 3 manuscripts per year for publication with an **Exam Center** investigator as first author.
- IV. The following shall be delivered to the Contracting Officer NHLBI (1 copy):
 - A. Monthly vouchers.
 - B. A final report, documenting and summarizing the results of the **Exam Center** contract work, including salient results (not to exceed 200 words), recommendations and conclusions based on both the general experience and the individual viewpoint of the **Exam Center** during the performance of the contract. Due 4 months following the end of Exam3.

Table 3. Deliverables and Reporting Requirements

#	<u>Description</u>	<u>Delivery Schedule</u>	JHS: Jackson Heart Study; CC : Coordinating Center; EC: Exam Center, PO: Project Office, CO: Contracts Office; SC: Steering Committee		<i>As Referenced in</i>	
			Respondent(s)	Recipient(s)	<i>Text/Deliverables</i>	
1	Pilot Test protocols	4 weeks prior to start of pilot exam: 08/01/05, 07/31/09, *07/31/13	EC, JHS Director	CC	III.A.2.	I.A.1.
2	Final Study Exam protocols	2 weeks prior to start of clinic exam: 09/12/05, 09/13/09, *9/13/13	EC, JHS Director	CC	II.A.3.	I.A.2.
3	Comparability Study protocols	4 weeks prior to start	EC, JHS Director	CC	II.A.3.	I.A.3.
4	Alert notification and Referral Protocols	4 weeks prior to start of clinic exam: 08/26/05, 08/27/09, *8/27/13	EC, JHS Director	CC	II.A.3.	I.A.4..
5	All samples, tapes/disks, images and other data on study subjects using approved examination protocols	Weekly during clinic exams or as directed by the protocol.	EC, JHS Director	CC, laboratories , and reading centers	III.A.3.	I.B.
6	Reports on the examination data	Monthly during Exam period, beginning 10/15/05 for Exam2; 10/15/09 for Exam 3	EC JHS Director	CC	III.A.3.a.	I.C.
7	Publication and Presentation list	Quarterly updates, beginning 10/15/05	EC JHS Director	CC	II.B.13.	I.D.
8	Reports on pilot test data	2 weeks after completion of pilot	EC JHS Director	CC	II.A.2.	I.E.1.

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9	Reports on comparability study data	Monthly, during comparability data collection	EC JHS Director	CC	III.A.3.b.	I.E.2.
10	Quality Assurance/Control data	Quarterly updates beginning 10/15/05 for Exam2; 10/15/09 for Exam 3	EC, JHS Director	CC	II.B.4.	I.F.
11	QC data logs	In place 4 weeks prior to start of clinic exam: 08/26/05, 08/27/09 and *8/27/13, with quarterly updates beginning 10/15/05 for Exam2; 10/15/09 for Exam 3	EC, JHS Director	CC	II.B.8.	I.F.1.
12	Data Audit	In place 4 weeks prior to start of clinic exam: 08/26/05, 08/27/09 and *8/27/13, with quarterly updates beginning 10/15/05 for Exam2; 10/15/09 for Exam 3	EC, JHS Director	CC	II.B.8.	I.F.2.
13	Staff certification protocols	Quarterly updates beginning 10/15/05	EC, JHS Director	CC	II.B.8. III.A.2.	I.F.3.
14	Events ascertainment and adjudication	Completed within two years of their occurrence	EC, JHS Director	CC	II.B.4.	I.G..
15	Assignments for JHS Scholars' field training	Semi-Annually, 10/15 and 4/15 each year of contract term	EC JHS Director	CC	II.B.5.b	II.A..

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16	Staff training materials	Developed 2 weeks prior to start of clinic exam: 09/12/05, 09/13/09, *09/13/13	EC, JHS Director	PO CO	II.A.2. II.B.8.	III.A.
17	ICP/KYN/RRA Protocol/materials	Completed 2 weeks prior to start of ICP exam: 09/15/08, 09/15/12	EC, JHS Director	PO CO	III.B.1.	III.B.1.
18	ICP/KYN/RRA tracking system	Completed 2 weeks prior to start of ICP exam: 09/15/08, 09/15/12	EC, JHS Director	PO CO	III.B.1.	III.B.1.e
19	ICP/KYN/RRA health awareness report	Completed 2 months after ICP exam, 10/30/09, *10/30/13	EC, JHS Director	PO CO	III.B.2.	III.B.2.
20	Local laboratory subcontract	Final subcontract in place 4 weeks prior to start of pilot exam: 08/01/05, 07/31/09, *07/31/13 Semi-annual performance updates: 03/15 and 09/15 each year of contract term	EC, JHS Director	PO CO	III.F.	III.C.
21	Site visit reports	3 weeks after annual visits to local lab	EC, JHS Director	PO (1 copy) CO (1 copy)	II.B.12.	III.D.
22	Raw data without identifiers	As requested or when difficulties arise	EC, JHS Director	PO (1 copy) CO (1 copy)	III.F.	III.E.
23	Progress reports	Semi-annually: 03/15 and 09/15 each year of contract term	EC, JHS Director	PO (1 copy) CO (1 copy)	II.B.11	III.F.

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24	IRB-approved Participant Informed Consent Forms	Within 2 weeks of initial approval and of approval of modifications	EC, JHS Director	PO (1 copy) CO (1 copy)	TABLE 1 III.A.3.	III.G.
25	Manuscripts/ Abstracts.	At least 3 manuscripts/abstracts per year, Submit manuscripts (4 weeks), abstracts(2 weeks) in advance of presentation/publication	EC, JHS Director	PO (1 copy) CO (1 copy)	III.C.2.	III.H.
26	Vouchers	Monthly, throughout the term of the contract.	EC, JHS Director	CO (1 copy)		IV.A.
27	Final Report	4 months following the end of exam 3 cycle: 1/31/13	EC, JHS Director	CO (1 copy)		IV.B.