CARDIA

Coronary Artery Risk Development in Young Adults

CARDIA Follow-up Contacts

Manual of Operations

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1. Overview

Retention of the CARDIA cohort is a continual focus of the Study. Maintaining contact with the participants is critical to facilitate their re-examination as the Study progresses. Contact efforts are made by mail and/or telephone. Each Field Center (FC) is encouraged to determine which method, or combination of methods, achieves the best results within their cohort. In addition to the follow-up contacts for confirmation of contact information and the Annual Contact Questionnaires, the FC is encouraged to maintain contact with participants using newsletters, greeting cards, etc.

Participant contacts are scheduled at six month intervals using the participant's Year 0 (Y0) Exam date as the beginning date. The "six-month" contact is utilized to confirm contact information, i.e. address and telephone number verification. At this contact, the verification may be obtained from someone other than the participant (spouse, parent, room-mate, friend), although direct contact with the participant is preferable. The "annual" contact, conducted at the yearly anniversary of the Y0 Exam date, requires direct contact with the participant (not family or friend, etc.). During this contact, the ***Annual Contact Questionnaire***, currently *CARDIA 324-Month Follow-Up Questionnaire*, is administered. On September 2, 1993, the CARDIA Steering Committee determined that for all "annual" contacts, the contact may be counted even if the participant refused to complete the questionnaire. However, it is still mandatory that direct contact with the participant be made. Every effort should be made to complete the questionnaire as these data are valuable to the Study.

2. Mortality Reporting

The CARDIA Study attempts to acquire as much data as possible regarding the death and cause(s) of death for any CARDIA participant. Death certificates are requested for all deaths, and depending upon the cause of death, hospital records, autopsy records, coroner's report, and/or emergency room records are sought. It is important to report a death to the coordinating center within 48 hours of discovery, even if details are lacking. This is done by faxing form 33A to the coordinating center with all the currently available information.

2.1 Mortality Review Forms to be Completed When a Participant Dies

The CARDIA Steering Committee approved the implementation of a *Decision Matrix for Forms to be Obtained When a Participant Dies*, along with the associated forms (Form 33A—Form 33D) (Appendix 8) for use in obtaining data on deceased CARDIA participants. The *Decision Matrix* indicates which forms should be completed, depending upon the cause of death. For **all** deaths, Form 33A (***Initial Notification of Death***) and Form 33B (***Final Report of Death***) are required. For cardiovascular, cerebrovascular, reno vascular, pulmonary, and "ambiguous" reasons for death, **Form 33C** (***Interviews with Witness or Next of Kin***) and Form 33D (***Physician Interview***) should be completed—when there is indication to pursue additional information about the death of a participant. If you are unsure about completion of Form 33C and/or Form 33D, consult with your FC's principal investigator (PI).

Full hospital records for all participant deaths occurring in a hospital should be requested **EXCEPT** for those participants who died of AIDS, unintentional injury, or homicide (Appendix 7). Autopsy reports and/or coroner's reports (as indicated on the death certificates) should be requested for all deceased participants. Emergency room records are requested when the participant dies in an emergency room.

It is necessary to obtain written permission from a relative to access the hospital (or emergency room) records and autopsy/coroner's reports. Always use a permission form which requests hospital records, as well as autopsy records. Obtaining consent may take considerable time and effort, as some of these deaths may have occurred years earlier than reported, and it may be difficult to locate the next of kin. However, because this data is very important to the study, every effort should be made to obtain the information. Progress in obtaining records/information will be tracked using the electronic tracking package.

Death certificates should be requested from the family (when appropriate) or from the state health department. These documents, along with Form 33B and the necessary accompanying documents should be forwarded to the coordinating center as soon as possible. Death certificates will be forwarded to a nosologist (coder), who will assign standardized ICD-9 code numbers to

causes of death (on the death certificates). The coordinating center will batch the death certificates and forward them to the nosologist for coding.

In summary, when a participant's death is discovered, Form 33A should be immediately forwarded within 48 hours) to the coordinating center. When the death certificate is obtained, determine which of the series 33 forms should be completed and whether hospital records/emergency room records and/or autopsy/coroner's reports should be pursued. (A copy of the death certificate should be forwarded to the coordinating center when it is received at the field center.) Signed permission from the next of kin to access the hospital records and autopsy records should be sought. Make certain that the memo requesting the hospital records also includes a request for autopsy reports. When all documents are acquired and de-identified, please forward a copy of **all** documents, along with Form 33B placed on the top of the stack, to the coordinating center. Follow guidelines for de-identifying medical records found in Appendix 15. All data entry of this information will occur at the coordinating center. The mortality tracking process is illustrated in the CARDIA Mortality Record Acquisition and Review Process flowchart (Appendix 6).

2.2 Conducting a Vital Status Check

If neither the participant nor any of the contact persons have been contacted, and there is no reliable source of information to determine the participant's vital status, FC staff should run a search for a deceased participants using available internet resources.

A listing of available internet resources follows:

Death records search engines:

- National Death Index* (paid) www.cdc.gov/nchs/ndi.htm
- PublicRecords*Now* (free) www.public-records-now.com
- Social Security Death Index http://ssdi.rootsweb.com/
- Obituaries (free) www.legacy.com
- Ancestry (free) www.ancestry.com
- VitalChek (paid) www.vitalchek.com
- Lexis/Nexis http://www.accurint.com
- Search for death records (free) http://www.archives.com
- Family link (paid) www.familylink.com
- Death records (free) www.knowx.com

- Vital search (free?) http://www.vitalsearch-worldwide.com/

People search engines:

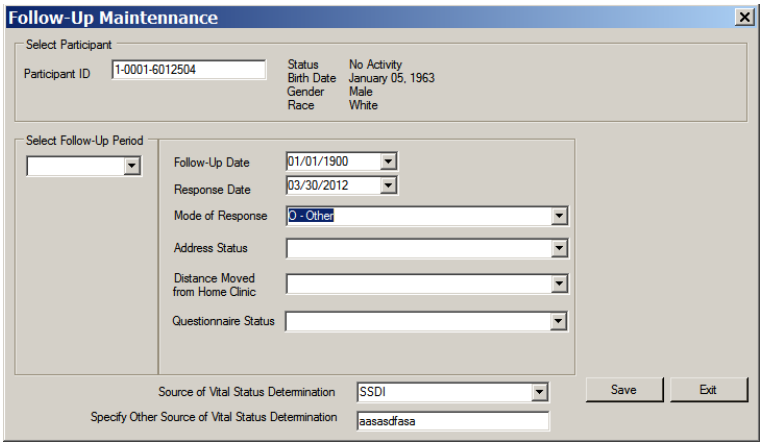
- Pipl www.pipl.com
- PeopleSmart www.peoplesmart.com
- Spokeo www.spokeo.com
- Dogpile www.dogpile.com
- ZabaSearch www.zabasearch.com
- The best people search http://www.searchbug.com
- PeopleFinders (free) www.peoplefinders.com
- USA-People (free) www.usa-people.com
- White Pages (free) http://www.whitepages.com/person
- And Sales Genie/Polk City Directory (paid) https://www.salesgenie.com

*requires CARDIA Steering Committee approval

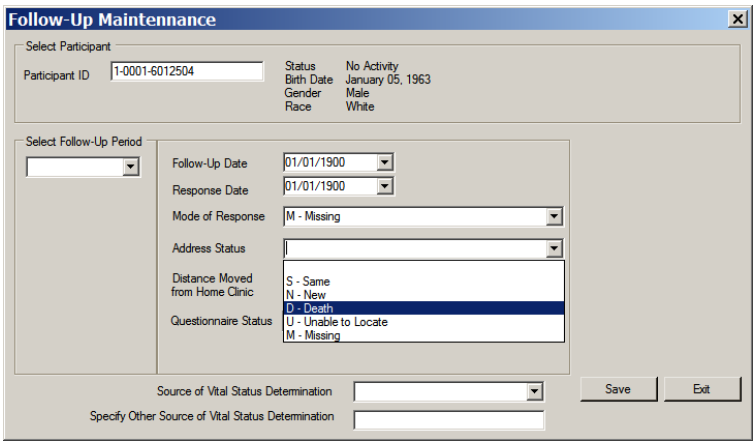
The vital status search must be done once a year during the annual follow-up contact.

If participant **was found deceased** searching one of the resources then in the Follow-Up Maintenance Window of the Scheduling system the FCs staff will enter:

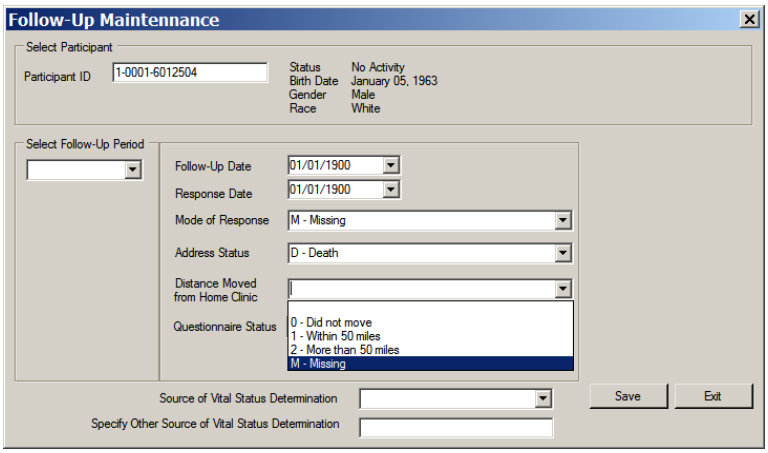
"Mode of Response" as "other";



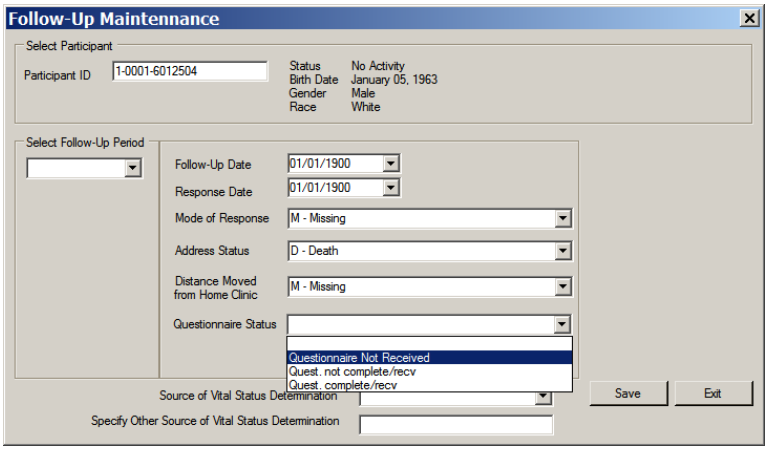
"Address Status" as "death";



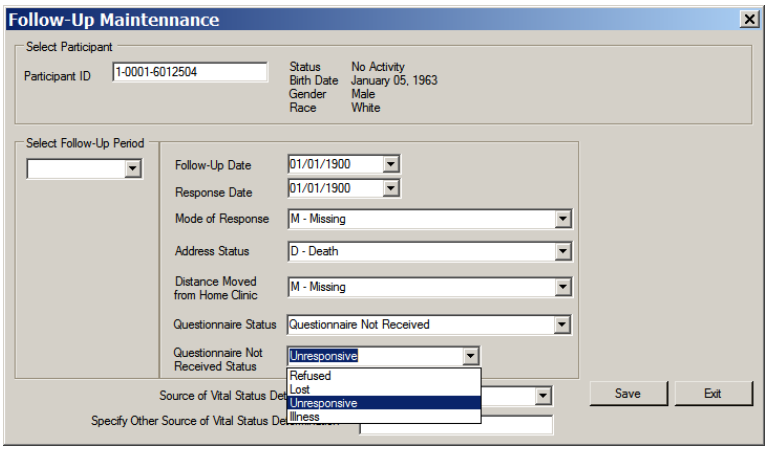
"Distance Moved from Home Clinic" as "missing";



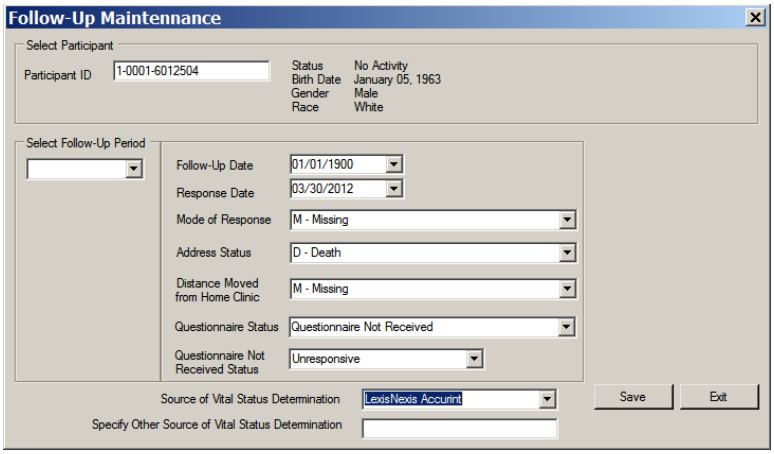
"Questionnaire Status" as "not received";

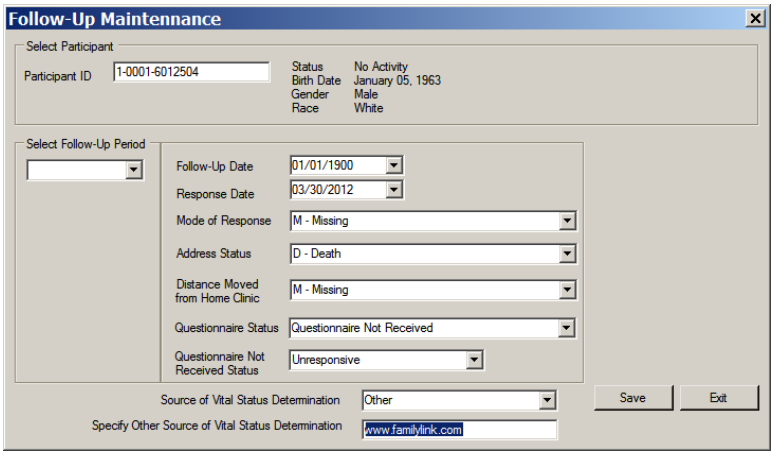


"Questionnaire not received status" as "Unresponsive"



"Vital Status Check Source" as selected one from the drop down menu or typed in if "other".

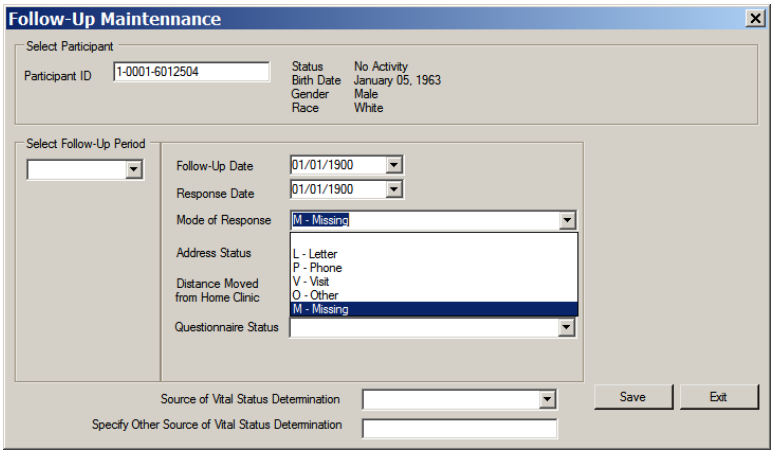




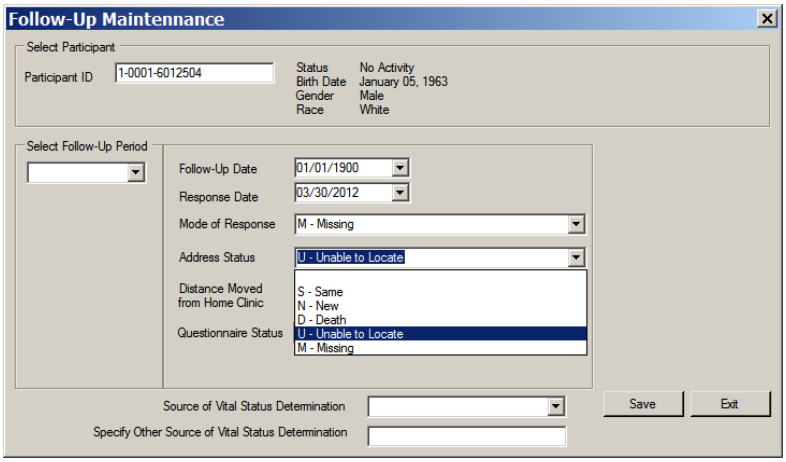
"Response Date" will be automatically entered by system as date of current search.

If participant **<u>was NOT found as deceased</u>** searching one of the resources then in the Follow-Up Maintenance Window of the Scheduling system the FCs staff will enter:

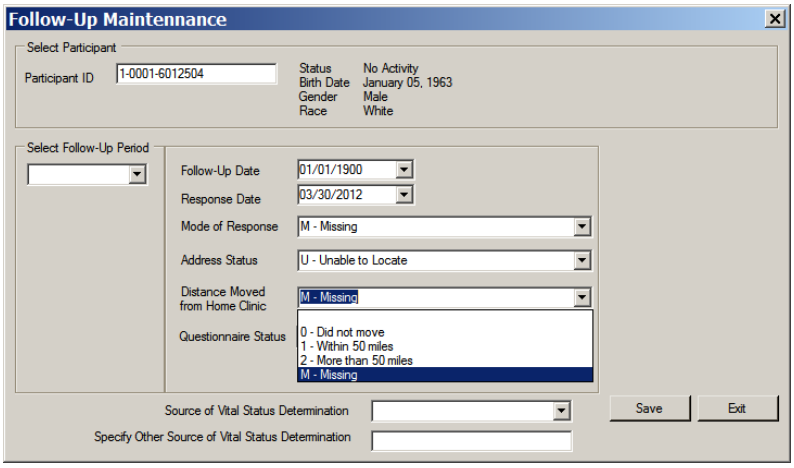
"Mode of Response" as "missing";



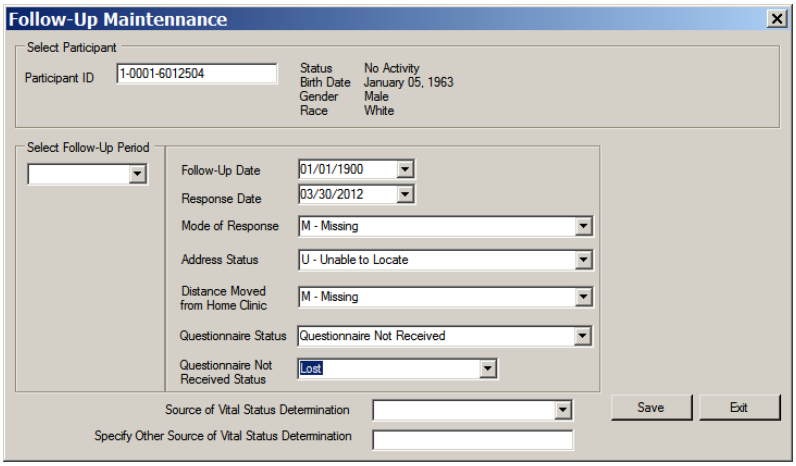
"Address Status" as "unable to locate";



"Distance Moved from Home Clinic" as "missing";

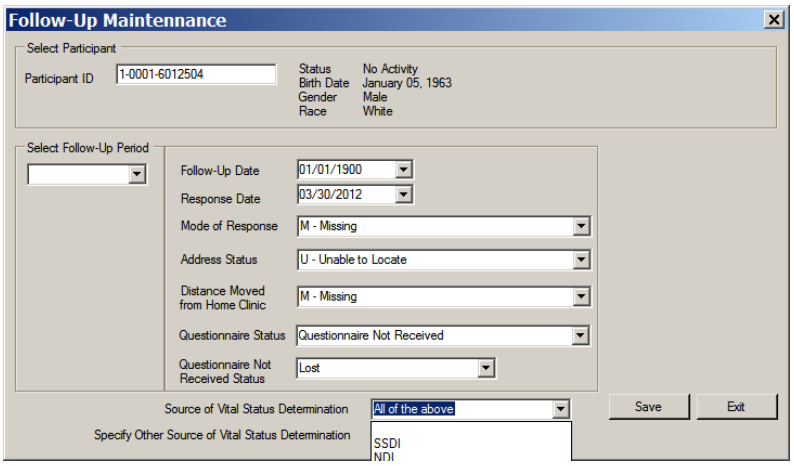


"Questionnaire Status" as "not received";



"Questionnaire not received status" as "Lost"

"Vital Status Check Source" as selected "all of the above" from the drop down menu.



"Response Date" will be automatically entered by system as date of current search.

2.3 Updating of the CARDIA Scheduling System to Reflect Deceased Participants

In order to provide the most up-to-date rates of follow-up contact for CARDIA participants, the *CARDIA Coordinating Center* updates the CARDIA Scheduling System on a regular basis with deceased participant information available from the CARDIA Endpoints system.

PROCEDURE:

1. From the CARDIA Endpoints system, obtain a listing cumulative listing of those participants who have been identified and confirmed as deceased.
2. Send the list of identified and confirmed deceased participants to Data Management (DM) to confirm and compare the information with that information contained within the CARDIA Scheduling System.
3. If participant(s) are on the list from the Endpoints system, but not listed with a status of 'Z' in the Scheduling List, determine the contact period in which the participant was identified as Deceased.
4. DM will compile a list containing the participant's id, death date, the Follow-up Contact period following the notification of the deceased status.
5. This list will be sent to the IS/IT Help Desk with a request to update the listed participants to a status of 'Z' (deceased) in the CARDIA Scheduling System.

6. IS personnel will update the necessary tables within the CARDIA Scheduling System with a status of 'Z' for the deceased participant.
7. IS will send a confirmation of the update when the task is completed.
8. Upon receipt of the confirmation of completion, DM will be responsible for verifying that all participants who were identified as deceased have a status of 'Z' in the CARDIA Scheduling System.
9. DM will notify CARDIA personnel when the updates have been completed and confirmed.
10. It is recommended that the list be compiled after the 15th of the month, but before the 25th of each month to allow ample time for review and completion of the work so that the updates will be reflected in the next month's CARDIA Follow-Up Contact Summary Reports.

3. Morbidity Reporting

3.1 Follow-up Windows

A participant is eligible to be contacted for a period of six months at each follow-up window: two months preceding the anniversary month (based upon his/her Y0 Exam date), the anniversary month, and three months following the anniversary month. For example, if the participant's anniversary month is June, the participant's "annual contact" window would open April 1st (two months prior to June) and would close September 30th (three months following June), and the participant's "six-month contact" window would open October 1st (two months prior to December) and would close March 31st (three months following December). A participant not yet contacted is eligible for only one follow-up contact at any point in time. A sample of the CARDIA follow-up windows is included in Appendix 16; the full listing of follow-up windows can be found on the CARDIA Internal Website.

Monthly follow-up tables which enumerate the follow-up status for each FC and CARDIA as a whole are generated at the coordinating center and are available on the CARDIA Internal Website. Information regarding eligibility for contact, total contacted, deaths, pending contacts,

mode of response, number of participants moved (≤50 miles and >50 miles from the FC), contacts by demographics (age, race, sex, and education), etc., is available on these reports.

3.2 Annual Contact Questionnaire (Anniversary Month)

Medical history information is a vital component in CARDIA. The CARDIA Study began as a study of cardiovascular risk development. Therefore, assessment of such conditions as self-report of physician diagnosed hypertension, and use of medications for its treatment are important for achieving this objective and serving in analyses as endpoints. In addition, use of certain medications or presence of specific medical conditions could affect lifestyle, cardiovascular risk factor levels, or increase risk for clinical outcomes.

The CARDIA Study tracks major health events (i.e., injuries, surgeries, illnesses) requiring hospitalization or outpatient treatment reported by participants. The Annual Contact Questionnaire, conducted annually between CARDIA exams, provides a mechanism for the Study to learn of events of interest, and to track longitudinal change in cardiovascular risk.

While CVD morbidity and mortality has been relatively low due to the young age of the CARDIA cohort at the start of the study, there has been a steady increase in the number of possible endpoints requiring adjudication, and this trend is expected to continue. The CARDIA FC staff member(s) will contact each participant to collect information about health care since the last CARDIA contact, whether a follow-up contact or an exam visit. Participants will be asked specific questions about hospitalizations, selected outpatient episodes of care, and other health history-related information since their last CARDIA follow-up contact or exam visit. The information will be recorded on the Annual Contact Questionnaire.

A **hospitalization** is defined as an admission which involves an **overnight** stay in a hospital, alcohol or drug abuse treatment center, or a mental institution. Emergency room visits with no admission, same day surgery, and outpatient clinic services will not be considered hospitalizations, but will be queried separately. Sleep studies are considered outpatient procedures, even though they may take place overnight and in a hospital facility.

An Annual Contact Questionnaire, designed to collect information about hospitalizations, outpatient procedures, and medical conditions that are of interest to the CARDIA Study, will be generated for each participant according to the follow-up contact window. The Hospitalizations Checksheet (Form 324B) and Procedures Checksheet (Form 324C) will give the FC direction about which medical records to pursue and forward to the Coordinating Center, and which do not require medical records. Form A can be administered by an interviewer or it may be mailed to the participant for completion. In either case, the form should be carefully reviewed for completeness, and in some cases the FC staff may need to contact the participant for clarification of information.

3.3 Instructions for Administering the Annual Contact Questionnaire

Question 1: Hospitalizations

The participant will be asked if he/she has been a patient in a hospital overnight since his/her last CARDIA contact. Response options include ***No*** and ***Yes***. If the participant answers ***No***, proceed to Question 2 (Q2).

If the participant answers ***Yes*** and reports overnight hospitalizations, the number of times he/she was hospitalized will be entered. The details about each hospitalization should then be recorded on page 5 of the questionnaire. There are spaces for three hospitalizations on pages 5 and 6. Should the participant report more than three hospitalizations since the last contact, Supplemental Form A will be required. If the follow-up interview is completed by the participant and mailed in to the FC, the Supplemental Form will require a follow-up phone call. ***More instructions about the hospitalization information will follow***. The *Date Admitted*, *Hospital Name and Location*, and *Reason for Stay* should be recorded on the lines provided. If the participant does not recall the exact hospital name or admission date, he/she should be encouraged to be as precise as possible, as this information is vital when obtaining medical records.

Question 2: Outpatient procedures related to the heart.

This question refers to procedures that include coronary angiography or heart catheterization performed as an **outpatient**. Procedures that were once performed only during an inpatient stay are now often performed on an outpatient basis. Response options include ***No*** and ***Yes***. If the

response if ***Yes***, the procedure(s) should be recorded on page 7 of this form There are spaces for 3 procedures on pages 7 and 8. Should the participant report more than 3 procedures since the last contact, Supplemental Form A will be required. If the follow-up interview is completed by the participant and mailed to the FC, the Supplemental Form A will require a follow up phone call. **Additional instructions for reporting procedures will follow**.

Question 3: Outpatient procedures related to opening a blocked artery, such as in the heart (coronary artery), neck (carotid artery) or leg.

This question is specifically looking at the interventional procedure on any artery. The response options are ***No*** and ***Yes***. A response of ***Yes*** triggers an entry on page 7 of this questionnaire.

Question 4: Overnight stay for a sleep test

Response options include ***No*** and ***Yes***. Even though this information is collected, the FCs are no longer asked to acquire medical records of sleep studies.

Question 5: Surgery or other procedure for weight loss

Response options include ***No*** and ***Yes***. Procedures for weight loss include gastric banding (also called LAP-BAND® surgery), gastric bypass, and stomach stapling, among others. If the response is ***Yes***, complete whether the procedure involved at least a one night admission to the hospital or was done as an outpatient. For hospitalizations, please enter the information on page 5 or 6 of Form A. If it was an outpatient procedure, please complete the information on page 7 or 8 of Form A.

Question 6: Doctor's office or outpatient clinic visits

This question refers to doctor's visits that have occurred **since the last CARDIA contact or exam.** The response options are *No* and *Yes.* The respondent should record the exact number of visits in the space provided. If he/she does not recall the exact number, the participant should provide the number believed to be accurate. Please note that Emergency Department visits are not included in Q6.

Question 7: Medical History

Q7a through Q7e require a **No** or **Yes** response only.

Q7f through Q7j require additional responses to sub-questions if the participant responds ***Yes***. For each ***Yes*** response, all sub-questions in the box should be marked ***Yes*** *or* ***No.***

Q7h (Kidney problems) asks about kidney transplant and dialysis and will require additional information on **page 5** for transplant or **page 7** for dialysis. "Kidney dialysis treatment" is referring to the initiation of either hemodialysis or peritoneal dialysis for end stage renal disease and not for acute renal failure that may occur during a hospitalization. It is not necessary to collect records of all dialysis treatments. The respondent should also answer whether he/she is currently on dialysis. In addition, there is a space for other kidney problems

Q7i (**B**lood clot) refers to clots in either the lung (pulmonary embolism) or the legs (deep vein thrombosis), or other, and will require additional information on page 7 if the response is ***Yes.***

Q7j (Cancer) asks for the type or location of the cancer.

Question 8 through Question 9: Have you ever been told by a doctor or nurse

A ***Yes*** to Question 8a, 8b requires additional responses to sub-questions. These sub-questions are listed in the box beside each queried diagnosis. For each ***Yes*** response, all sub-questions in the box should be marked ***Yes*** or ***No***. For 8a, the type of liver disease is elicited. The sub-questions in question 8b refer to recommended treatment for sleep apnea.

Q9 asks the participant **if** he/she has **ever** been told by a doctor or nurse that diabetes has affected the back of the eye (retina). This question does not discriminate between Type I or Type II diabetes or whether the participant is taking insulin, oral medications, or is diet/exercise-controlled. The interviewer should mark the participant's ***Yes, No,*** **or** ***Do not have diabetes*** response. If the participant answers ***Yes,*** the sub-question indicated in the box should also be asked.

Question 10 through Question 11: Medications:

Q10 refers to prescribed medications for blood pressure, cholesterol or diabetes treatment. The interviewer should mark the participant's ***Yes, No***, or ***Don't know*** response. **Q11** asks about aspirin use and the reasons for taking aspirin.

Question 12: Cigarette Smoking

Read Q15 and record the number of cigarettes the participant reports smoking per day, on the average. This question asks specifically about **cigarettes**, not cigars or other forms of tobacco. If the participant reports not smoking cigarettes, record "00." **This is the end of the questionnaire for male participants.**

Question 13 through Question 16. WOMEN only Men should proceed to the bottom of the page.

These questions refer to the reproductive status of women, and men will bypass these questions. They should be answered by all women, regardless of their menopausal status.

Questions 13—16: Menopause

Q13—Q16 are menopause-related questions, and only apply to female participants. Q13 and record the participant's *yes*, *no*, or *not sure* response. If the participant's response to Q17 is *no* (menopause or the change of life NOT reported), then that is the end of the questionnaire. Otherwise, read Q18 and record the participant's response. Read Q19 and record the participant's response. If the participant cannot recall her exact age when her periods stopped, encourage her to provide the age she believes is accurate. **This is the end of the questionnaire for female participants.**

If the participant asks about a *Became more regular* option for Q16, the interviewer can prompt: "*Did this mean your periods became closer together or farther apart?"* The participant's answer to this prompt should help her choose an appropriate option.

Pages 5 through 8: Hospitalizations and Procedures

CARDIA is gathering information about hospitalizations and procedures for events of interest to CARDIA. For hospitalizations recorded on pages 5 and 6, **Follow-Up Questionnaire Form B** will need to be completed by the FC. For procedures/events recorded on pages 7 and 8, **Follow-up Questionnaire Form C** will need to be completed by the FC. **These two follow-up forms are not completed by the participant.** In many cases, the follow-up forms can be completed without additional input from the participant, because all of the relevant information is in Form A. There may be occasions where information is incomplete or missing and the FC will need to make a follow-up phone call. In addition, there are spaces for three hospitalizations and three procedures on Form A. If more than three admissions or events are reported, a **Follow-up Questionnaire Supplemental Form A** will be required.

If the participant reports no hospitalizations or procedures (***No*** responses on all questions **Q1, Q2, Q3, Q5, Q7h and Q7i**), the questionnaire is complete and should be returned to the FC **including all 7 pages.**

Permission to Obtain Medical Records

Q17. The first question asks consent to obtain and review medical records of certain hospitalizations or procedures. Since records from these hospitalizations and procedures may contain information vital to the CARDIA study, every effort should be made to convey their importance to the participant.

When requesting a medical record, the participant should be assured that the record will be reviewed by CARDIA investigators only after the removal of personally identifying information. Reassure the participant that this includes not only name, but also medical record number, birth date, other identifying numbers, address and telephone numbers. Attention should be given to the manner in which consent for the medical record is requested.

Examples of a release form are in Appendices 1-3. It is the responsibility of the FC to assure that the participant understands the consent that he/she is giving. If the participant responds ***No***, and does not agree to allow the Study to obtain medical record(s), check the ***No*** box. See Appendix 12 for Suggested Script and Time Line for Requesting Medical Records.

Hospitalizations

Yes responses to **Q1, Q5, or Q7h** should be associated with entry(ies) on pages 5-6. The Illness or Reason, hospital name and address should be recorded on the lines provided. The reason should be documented exactly as it was reported by the participant. If the participant mailed the questionnaire to the FC with insufficient information, a follow-up phone call should be made to gain as much detail as possible, including specific body part affected and type of injury, if applicable. If a participant reports multiple reasons for a single hospitalization, all should be recorded (using the margins of the form if needed). The interviewer should then attempt to determine the *primary* reason for the hospitalization. If the name of the hospital is missing and not easily obtained, a follow-up phone call may be required. The participant must provide at least an estimate of the date of admission as this is required when requesting medical records.

Finally, each hospitalization asks the location to which the participant was discharged. Be aware that in some cases, a participant may have been admitted to one hospital and transferred to another facility for specific procedures or more specialized care. The participant may omit this information or may report it as **Hospitalization 2**. Information from the second hospital is as important as or more important than that from the original hospital, so be very attentive when records are received to look for evidence of a transfer if one was not reported by the participant.

A CARDIA Code should be assigned as soon as possible following the interview in order to perform quality control monitoring. For each hospitalization, there is a box that states **For Clinic Staff Only** with spaces for up to three CARDIA codes, along with a space for assigning the case number. The first five spaces are the CARDIA ID number. The next three numbers are the form, 324. The next two numbers represent the hospitalization or procedure # - (i.e. procedure 1 =01) the final letter is an H for hospitalizations and a P for procedures. Assigning CARDIA codes is described in Section 5 of the MOO.

Hospitalizations 2 and 3 will be recorded the same way, and if there are more hospitalizations, a check will be entered at the end of page 6. The additional information will be recorded on **Follow-up Supplemental (Form A) (**Appendix 14)

Responses from this part of the questionnaire will determine the responses to **Form B** for the 324 Month Follow-up.

Procedures or Events

Pages 7 and 8 of Form 324 refer to procedures or events, including coronary angiogram, heart catheterizations, outpatient procedures to open a blocked artery or arteries, kidney dialysis or blood clots, or weight loss surgery. The participant will be prompted to enter events in these places from his/her responses to **Q2, Q3, Q5, Q7h or Q7i.**

The first question requests permission to obtain medical records in order to review the events.

There are places for 3 procedures or events, each requesting the type of procedure, the facility name and address and the date. The information listed here will prompt the FC to fill out **Form C** for the 324 Month Follow-up. For each procedure, there is a box that states **For Clinic Staff Only** with spaces for up to three CARDIA codes, along with a space for assigning a case number. The first five spaces are the CARDIA ID number. The next three numbers are the Form 324. The next two numbers represent the hospitalization or procedure # - (i.e. procedure 1 =01) the final letter is an H for hospitalizations and a P for procedures. Assigning CARDIA codes is described in Section 5.

It is important when reviewing Form A to ensure that the questions that required additional information on pages 5 through 7 were completed.

Hospitalizations Checksheet (Form 324B)

Form B is to be completed by the FC only, and is completed when a participant reports a hospitalization. In most cases, the FC will be able to complete Form B with the information that the participant provided on Form A. In some cases, more information will need to be obtained, and an additional phone call will be required. Form B will give the FC guidance about which medical records to obtain and forward to the coordinating center for review and adjudication. Each hospitalization reported on Form A will require the FC to answer Q1 through Q13, or until another stopping point is reached, such as at Q8, Q9, or Q11.

Question 1: Heart, circulation or blood clot

The responses are ***No*** or ***Yes***. A ***Yes*** response will prompt the staff to clarify which of these problems was the reason for the hospitalization. Please answer ***No*** *or* ***Yes*** to each of the problems listed in the box.

Question 2 through Question 7: Stroke/TIA, Kidney failure or transplant, Chronic lung disease/COPD/emphysema, Hypertension/high blood pressure, Diabetes, or Asthma

The response can be ***No*** or ***Yes.***

Question 8: Psychiatric Care

The responses can be ***No*** or ***Yes***. If the response is No, go to **Q9.** If the response is ***Yes***, but no other reason or illness is listed for this hospitalization**, do not collect medical records. CARDIA is not collecting psychiatric records if there is no other diagnosis or procedure associated with the admission.** Questions for this hospitalization number are now complete. Go to the next hospitalization.

Question 9: Pregnancy/Delivery

The response can be ***No*** or ***Yes***. If the response is No, go to **Q10.** If the response is ***Yes,*** but no other reason or illness, (such as a significant complication lengthening the stay) is listed for this hospitalization, e.g., Hospitalization 1, **do not collect medical records. CARDIA is not collecting records of pregnancy or delivery unless there is an associated reason or illness.** Questions for this hospitalization number are now complete. Go to the next hospitalization.

Question 10: Other (specify)

The response can be ***No*** or ***Yes***. If the only reason for Hospitalization was captured in Q1-Q9, the response will be ***No.*** If the response is ***No***, go to Q11. If the response is ***Yes***, answer the questions in **Q10A**.

Q10A (a through z) will give direction about whether the FC needs to collect medical records on ***other*** reasons for hospitalizations. Each diagnosis in **Q10A (a)** (sleep apnea) through **10A (k)** (treatment for previously diagnosed cancer) should be answered ***No*** or ***Yes.*** **Q10A (z)** (Other than listed above) will capture reasons for hospitalization not captured in any of the questions preceding. Answer ***No*** *or* ***Yes to Q10A(z).***

Question 11 through Question 13

Q11: The responses can be ***No*** *or* ***Yes***. If ***Yes***, the participant was hospitalized for one of the reasons included in **Q1** (Heart, etc.) through **Q7** (asthma) of Form B, the FC must attempt to **collect medical records**. If the reason was not one of these, proceed to **Q12**, where the length of stay was answered. The response can be ***3 or less, 4 or more,*** or ***unknown***.

Q13 directs the decision for a hospitalization captured in **Q10**. If the reason for Hospitalization 1 was only for one of the conditions or events in **Q10A (a) through (k)**, **and the length of stay was 3 or fewer nights, do not collect medical records.** If the reason for Hospitalization 1 was one of the conditions or events in Q10A (a) through (k), **and the length of stay was 4 or more nights or unknown**, **collect medical records.** If the reason for Hospitalization 1 was **10A (z)** (Other than listed above)**, collect medical records.**)

If more than one hospitalization was reported on Form A, repeat the above process with each admission to determine the need for obtaining medical records. Form B has room for three hospitalizations. If there were more than 3 reported on Form A, and captured on a Supplemental Form A, the FC will need to use Supplemental Form (Form B) (Appendix 14), as well.

Procedures Checksheet (Form 324C)

Form C is to be completed by the FC only, and is completed when a participant reports a procedure/event on Form A. In most cases, the FC will be able to complete Form C with the information that the participant provided on Form A. In some cases, more information will need to be obtained, and an additional phone call will be required. Form C will give the FC guidance about which medical records to obtain and forward to the coordinating center for review and adjudication. Each hospitalization reported on Form A will require the FC to answer **Q1**

through Q4. There are spaces for three outpatient procedures or events on Form C. If more were reported or discovered, and captured on Follow-Up Supplemental Form (Form A, Follow-Up Supplemental Form (Form C) (Appendix 14), will be required.

Question 1 through Question 4

The CARDIA study is collecting reports of certain outpatient procedures or events of interest to the study analyses. **Q1** asks about problems with the heart, circulation or a blood clot. These procedures would have been reported in **Form A Q2, Q3, Q5H, or Q5I**. **Q2** asks about kidney. **Q3** is for any other procedures not captured in Q1 of Q2. If the answer is ***Yes*** to **Form C Q1, Q2,** or an answer to **Q3** which could involve one of these conditions**, collect medical records.** Repeat this process for additional procedures or events. In the event more than three procedures were reported on Form A, a supplemental form (Form C) will be required.

3.4 Using the Follow-up Log

In the top right corner of the log is the date the log was generated. If you have more than one copy of a log, you can check the date to confirm which the latest version is.

The second line of the title provides the month (mm) and year (yyyy) the participants listed are due for follow-up in the mm/yyyy format. Three dates are listed: *Minimum Month* (the first month the participant can be contacted); *Expected Month* (the ideal month for contacting the participant); and *Maximum Month* (the last month during which the participant can be contacted). The next three lines list the allowable codes and their meaning for parts of the log concerning the follow-up information collected.

CARDIA ID column lists the participants due for follow-up for the month stated in the order of their CARDIA ID.

Date of Follow-up is the date follow-up is initiated for a participant such as the date the first phone call is made or the first letter is mailed.

Date of Response is the date the participant responds to the follow-up and the follow-up is completed.

Mode of Response is the method used to obtain information for completion of the participant's follow-up contact. This may be a letter received from the participant, a telephone call to or from the participant or a visit to the participant. Some participants may have an exam during the time

they are eligible for contact. Information from their exit interview can be used to complete the follow-up. In this event, the mode should be coded as O for *other*.

Address Status indicates whether the participant has moved since his/her last exam or contact.

Distance Moved refers to the distance the participant currently lives from the clinic. If the participant has not moved since his/her first exam, the code is 0. If the participant has moved since the first exam and lives 50 miles or less from the clinic, the code is 1. If the participant lives more than 50 miles from the clinic, the code is 2.

3.5 Editing the Follow-Up Questionnaire

Prior to scanning the follow-up questionnaires to the coordinating center, the FC should review responses to the questionnaire for missing information, discrepancies, and inconsistencies. Contact the participant to clarify responses or obtain more detailed information. **The standard way of editing a document is to draw a single line through the incorrect response on the original form, enter the correct data and circle the correct response. The person making corrections writes his/her initials and the date the correction was made.** The original information should not be obscured.

a. Participant errors on reporting Sleep Studies

Often a participant will report that he/she was hospitalized for a sleep study, even though CARDIA considers a sleep study to be an outpatient procedure. In this case, **Do Not Change** the participant's response. Complete a **Form B** and collect the appropriate records. If the participant reports the sleep study as a outpatient procedure correctly, complete a **Form C**. In either case, the records will be obtained.

3.6 Scanning the Follow-up Questionnaire

Follow-Up Form 324 A, A(supplemental), and proxy form should be scanned to the coordinating center. Fill out scan list (Appendix 4) and send it to the Coordinating Center. ***Follow-up Form 324 B, B (supplemental), C, and C (supplemental)*** are internal forms for clinic use only and **not supposed** to be scanned to the Coordinating Center.

4. Interviewing Principles and Procedures

Interviewing is, in part, a science. There are definite rules that produce valid results. Interviewing is also an art. Frequently there are only general guidelines to follow, and much depends on the sensitivity of the interviewer. The procedures and techniques that follow will help interviewers conduct interviews which will yield valid data.

4.1 Developing a Good Interviewing Relationship

Interviewing is one of the major components of the CARDIA Study, and therefore it is crucial that interviewers present questions appropriately, record participant responses precisely and accurately, and probe meaningfully. To promote an objective information-gathering atmosphere, the interviewer must convey an understanding persona accepting of information in a non-judgmental manner, as well as interest in what the participant is saying. The participant must find satisfaction in talking to a receptive person without the fear of judgment.

It is the interviewer's responsibility to obtain full and accurate information by eliciting cooperation from each participant by establishing and maintaining rapport, and encouraging the participant to answer honestly in a strictly neutral way. Interviewers with professional skills make it possible for participants to give frank, complete, relevant answers to questions.

In general, the majority of participants are willing to be interviewed. A confident, enthusiastic approach that assumes people are willing to be interviewed is a most effective technique. Previous studies have identified several factors that increase a participant's receptiveness:

- The interviewer must be prepared by knowing the material. Participants need to feel that the interviewer is interested in the Study and interested in what information they have to give. The interviewer must be an active listener and establish comfortable eye contact with the participant.
- The interviewer must offer convincing statements about the purpose of the Study and show appreciation for the participant’s cooperation.
- The interviewer must describe the beneficial uses of the research findings to both the participant and to the community.

4.2 Two Main Kinds of Questions

a. Pre-coded Questions: An "X" is placed in the box that matches the participant's answer. Whenever there is any question about which response option is appropriate, it is very important that the interviewer record the participant's verbatim response.

b. Open-ended Questions: The question is followed by a blank box for the interviewer to record the participant's answer verbatim. This kind of question suggests no possible answers, so the participant's own words must be recorded in the box provided. The interviewer should encourage him/her to express ideas as fully and as clearly as possible.

4.3 Interviewer Procedures for Reading Questions

There are several standard procedures for reading questions. The interviewer should read in a natural conversation rhythm and in a normal tone of voice. The interviewer should read as speaking, but be cautious of reading questions too rapidly, as a participant may not feel comfortable asking that a question be repeated. If a participant answers a question inappropriately, the interviewer should repeat the question as written.

- Interviewer instructions appear in all capital letters on interviewer-administered questionnaires. These instructions are intended to guide the interviewer and are not to be read to participants.
- Only those code categories which appear in the question should be read, unless:
  - the interviewer has special instructions to the contrary;
  - there is an instruction to READ CHOICES; or
  - a question ends with a dash or colon and it is obvious that the codes must be read for the question to make sense.
- Questions are to be asked exactly as worded and in the same order as they appear in the questionnaires. Minor changes in wording can completely change the meaning of a question. This will help to ensure that comparable information is being obtained from all the participants in the Study. The interviewer should not ask questions out of order unless given special instructions.
- Every question should be asked, unless instructed to SKIP TO another question. Often a previous statement by the participant will partially answer another question, but rarely does it answer that question completely. The interviewer must not omit questions and not

assume answers to questions.

4.4 How to Get Satisfactory Answers

- Learn the Purpose of Each Question. In order to do a good job of interviewing, the interviewer needs to understand the kind of information sought by each question. Unless the question's purpose is understood, the interviewer will not be able to judge when a response is adequate and when a probe for clarification is necessary.
- Don't Attempt to Explain the Question—Maintain Neutrality. If a participant does not seem to understand a question, the interviewer should repeat the question slowly, clearly, and exactly as written. The participant should be given time to think about the question. Unless instructed otherwise, the acceptable reply to a participant asking what a question means is *whatever it means to you*. The interviewer should not attempt to explain the purpose of a question.
- Don't Define Terms Used in Questions. Some participants may ask what is meant by a word or phrase used in a question. The interviewer must leave the matter of definition to the participant, suggesting *whatever you think XYZ means* or *however you use the term XYZ*.
- The interviewer should not leave a question until 1) an adequate answer has been given, 2) the participant cannot give a clearer answer, or 3) *No response* is a response category option.

4.5 Probing Techniques

- Silence. The value of silence cannot be overestimated. Many people, including interviewers, react to silence as a vacuum that must be filled with constant chatter. The interviewer who can wait quietly and patiently will soon find that fifteen seconds of silence is sufficient for a participant to expand or clarify a previously inadequate answer.
- Repeat the Question. When repeating a question, the interviewer should read the question verbatim. This probing technique is particularly useful when a participant answers a question irrelevantly. The interviewer should acknowledge the participant's

answer and then repeat the question.

- Do Not Accept a "Don't Know" Answer Without Probing at Least Once. If a response is *Don't know*, the interviewer should probe by asking *Well, what do you think?* or *I'd like to know your opinion*. If the question requires a factual answer (rather than opinion), an approximation is preferred to no answer at all. The interviewer might probe by asking *What's your best guess?* or *Approximately?* to convey that 100% accuracy is not required.
- Neutral Probes. Probes are needed to obtain more complete, accurate answers. All probes must be non-directive and not suggest any particular answer. The interviewer should use a neutral probe when a participant is hesitant to answer a question, seems to have trouble expressing him/herself, seems too shy to speak at length, or has not given a complete report of his/her thoughts. Additionally, the interviewer should use reassuring probes if a participant seems to lack confidence. Probes that are leading should be avoided, as participants tend to say *yes* to any suggestion, either because it's easy or because they think it's the right answer. A listing of sample neutral probes and leading probes follows:

Acceptable Neutral Probes	**Unacceptable Leading Probes**
In what way?	*Do you mean...?*
Why do you feel that way?	*Then you feel...?*
I would like your opinion.	*So, you think…?*
What do you think?	*For example, …*
Can you give me an example?	
Can you explain that in a little more detail?	
What else can you tell me about that?	

4.6 How to Record Participant Responses onto Exam Forms

Interviewer Recommendations:

- Use black ink pen.
- Be prepared to write.
- Periodically establish eye contact with the participant while writing.
- Use abbreviations to help record as much as possible.
- Always record responses in participant's exact words. If the response is too wordy, the participant should be asked to summarize his/her response.
- If a response is recorded incorrectly, use CARDIA's usual procedures for editing: mark through (with a single line) the incorrect response on the form, initial and date next to the marked-through incorrect response, enter the correct response, and indicate (by circling) the correct response.
- If no answer is given by a participant, the interviewer should mark the *No answer* response, if available; if this option is not available, the interviewer should circle the question number and write *M* (for missing) to the left of the question number.

4.7 Proxy Form

Proxy Respondents for CARDIA Cohort Members

For purposes of the CARDIA annual follow-up a proxy is defined as a well-informed individual who can answer health related questions on behalf of a CARDIA cohort member and/or authorize the release of medical records should the participant be unable to do either. Examples of a proxy are: legal next-of-kin (spouse, son or daughter, brother or sister, or their doctor), power of attorney, or a Legal Health Care Proxy. If a Power of Attorney (POA) has been designated, a photocopy of the documentation may be necessary for some hospital's medical records department to release records in the event the participant becomes cognitively impaired and the proxy signs a release form. Other options for a well-informed proxy include partners and close friends. The proxy may be one of the persons initially named by the study participant as a contact. It may also be the case that CARDIA field center staff has already recorded a proxy and his/her contact information for a cohort participant.

The proxy may or may not be someone previously designated as a contact by the participant. For example, the participant may have designated his/her spouse as a primary contact, but the participant's son or daughter actually ends up being the person to complete the questionnaire. This is fine, as long as the new person is knowledgeable regarding the participant's medical condition, procedures of interest, etc.

a. Role of a Proxy

It is important not to confuse the role of a proxy with that of an assistant. Study participants at times request the help of a family member or friend to answer some of the questions. An assistant might be a spouse or relative living in the house that keeps track of the participant's activities. The assistant's role is different than that of the proxy identified by the participant in that the assistant merely helps the participant locate or remember needed information. The assistant does not respond to opinion questions for the participant. Instead, a proxy responds to both the factual and assessment questions on behalf of the study participant.

b. Conducting an Interview with a Proxy

When an interview is completed by a proxy, the proxy is asked to answer for the participant (to the best of his/her knowledge) instead of the participant responding him/herself with the help of the "proxy." If the proxy does not know the answer, "Unknown" is recorded rather than a guess. During the interview the participant's name or "him/her" should replace "you" in the specific questions, where appropriate. When an interview is completed by a proxy this is recorded on the FU 324 Proxy Form.

c. Reasons When a Proxy Is Needed

If the interviewer has indications that the participant:

- has cognitive decline
- is in nursing home
- has catastrophic health event
- has significant hearing impairment
- has disability
- has been incarcerated

If the interviewer has indications that the participant may have cognitive problems the interviewer uses his/her judgment to determine if the participant is cognitively impaired and unable to answer questions reliably.

The CARDIA study does not track mental status in its cohort participants with a screener. Instead, through their interaction with the participants (or based on the use of a proxy in a previous follow up interview) the CARDIA interviewer determines whether the participant has the ability to respond.

Before scheduling a follow up interview CARDIA personnel determines whether the previous annual follow-up interview was conducted with a proxy, in order to contact him/her to schedule the call. Other criteria available to the follow up interviewer to determine whether a proxy is needed are a history of clinical stroke or a diagnosis of dementia or cognitive impairment noted on hospital records. If either if these conditions are noted, or if it is apparent that the study participant has difficulty answering health related questions, a proxy should be used.

4.8 Medical Records Disposal

Once the case was reviewed and adjudicated, the CC will inform the FC about the adjudication results. After that the FC can destroy medical records that have been already sent to the CC, reviewed, and adjudicated. The FCs should create and fill out a tracking log for destroyed medical records. The tracking log must have participant's ID, admission and discharge dates, admission number, date of adjudication, adjudication results, date when shredded, and technician ID (Appendix 17).

5. CARDIA Morbidity Coding and Processing Medical Records

5.1 CARDIA Morbidity Coding Schemes

A Hospitalization Coding Scheme has been developed to facilitate systematic and consistent identification of hospitalization records of interest to the Study. The coding scheme also provides standardized information about the reasons for hospitalization, facilitating data entry and retrieval of information about CARDIA participants. The goal of the coding is to classify

illnesses in a broad sense, with greater specificity in coding cardiovascular and cerebrovascular diseases. The standardized coding permits identification of the hospitalizations for which the Study will request more detailed information (medical records). Information collected by the interviewer on the Annual Contact Questionnaire is the basis for the coding, and in some instances, may be the only information available for use in identifying endpoints (those diagnoses of special interest to the Study).

Interviewers must be familiar with the CARDIA Hospitalization Coding Scheme to ensure accurate collection of information during the interview (see Tables 1-3). CARDIA coding is included in the Interviewer Training. All interviewers are required to pass a written test using the CARDIA Hospitalization Coding Scheme to become *certified* to perform CARDIA coding.

There are two types of CARDIA coding:

a. **CARDIA Coding Scheme One** permits commonly occurring reasons for hospitalization (e.g., heart attack, pregnancy delivery, diabetes, asthma, pneumonia, AIDS) to be coded using only one code (Table 1). The reasons for hospitalizations listed in Table 1 were included for three reasons: 1) the systemic nature of the illness (e.g., diabetes, AIDS); 2) the regular association of a specific illness with a specific body part (e.g., heart attack, stroke, pneumonia); and 3) the frequency of occurrence in CARDIA participants. In general, these codes are grouped according to body systems. The following are examples of these types of hospitalizations: pregnancy with a vaginal delivery (code P2), diabetes (code E1), hypertension (code V2), stroke (code V1), lupus (code R2), depression (code M1), AIDS (code G1) and pneumonia/bronchitis (code L2).

b. **CARDIA Coding Scheme Two** requires a minimum of two codes; the first code identifies the general or medical problem (e.g., cancer, fracture/broken bone, burn). The second code identifies the body part affected (e.g., breast, leg, foot/ankle). For example, breast cancer would be coded as 51 (cancer) and 32 (breast).

   When the hospitalization is the result of an injury or surgery, the cause code should be listed first, followed by the problem, and the body part. For example, an automobile

accident resulting in a broken leg would be coded W4 (auto accident); 75 (fracture); 45 (leg).

If the participant does not provide enough information for the specific coding, the injury would be coded as injury, unspecified. This coding scheme is flexible, permitting a degree of detail, but without requiring an extensive list of codes.

In review, many hospitalizations require a code for illness or injury and additional codes for affected body part. When coding these hospitalizations, the **illness or injury codes are placed first, followed by the body part codes.** In the case of surgery, the illness code is placed first, followed by the surgery code, and the body part code.

5.2 Coding Hospitalizations

The Annual Contact Questionnaire provides space for coding three two-digit codes for each reported hospitalization. The *primary* (main) reason for the hospitalization should be coded first, followed by secondary reasons. **If any of the reasons for hospitalization result in code: H1–H7, V1-V6, V9, 01, or 02, the code should be listed among the codes whether or not it was the primary reason for the hospitalization**. In the event that more than the provided spaces are required for documenting CARDIA codes, additional codes may be documented in the margin of the Annual Contact Questionnaire.

Interviewer questions regarding the coding of a hospitalization should be directed to the Field Center clinic coordinator. If questions remain, the Coordinating Center follow-up coordinator should be contacted. The Coordinating Center follow-up coordinator will notify all field centers of identified problems or questions about the coding schemes.

Table 1. Codes for Specific Problems

Codes in this section do not require body part affected, unless otherwise noted.

Blood
- B1 Anemia (low blood)
- B2 Sickle cell anemia
- B3 Leukemia

Digestive
- D1 Gastritis
- D2 Ulcerative colitis
- D3 Regional enteritis/Crohn's Disease
- D4 Diverticulitis
- D5 Hepatitis
- D6 Cirrhosis
- D7 Gallstone

Endocrine and Fluid/Metabolism
- E1 Diabetes/high blood sugar
- E2 Hypoglycemia/low blood sugar
- E3 Hyperthyroidism/Graves' Disease
- E4 Hypothyroidism
- E5 Goiter
- E6 Dehydration
- E7 Electrolyte problem
- E8 Fever

Female
- F1 Fibroids (uterus)
- F2 Vaginitis
- F3 Endometriosis
- F4 Menstrual problem

Infection
- G1 AIDS
- G2 Influenza
- G3 Tuberculosis
- G4 Meningitis
- G5 Pelvic inflammatory disease

Heart
- H1 Chest Pain
- H2 Angina/angina pectoris
- H3 Heart attack/myocardial infarction
- H4 Tachycardia/rapid, fast heart rate
- H5 Other abnormal heart rhythm
- H6 Heart failure/congestive heart failure
- H7 Heart valve

Kidney and Prostate
- K1 Pyelonephritis/kidney infections
- K2 Glomerulonephritis
- K3 Kidney failure/end stage renal disease
- K4 Benign prostatic hypertrophy (BPH)

Kidney and Prostate (cont.)
- K5 Kidney stone
- K6 Kidney (renal) transplant

Lung
- L1 Asthma
- L2 Pneumonia/bronchitis
- L3 Pneumothorax (collapsed lung)
- L4 Chronic lung disease/emphysema
- L5 Pulmonary infarction/embolism (blood clot in lung)
- L6 Shortness of breath
- L7 Sleep apnea/sleep disordered breathing/sleep study

Mental and Nervous Problems
- M1 Depression/bipolar (including mania)
- M2 Dementia/senility
- M3 Multiple sclerosis
- M4 Epilepsy/seizure
- M5 Schizophrenia
- M6 Personality disorder (problem)
- M7 Sleep disorder
- M8 Headache
- M9 Anxiety
- MA Mental/Nervous Breakdown

Pregnancy
- P1 Pregnancy-not delivery/complication
- P2 Pregnancy delivery-vaginal/natural
- P3 Pregnancy delivery-caesarean/c-section/surgery
- P4 Miscarriage/abortion/ectopic pregnancy/still birth

Rheumatic Disease
- R1 Arthritis
- R2 Lupus
- R3 Other rheumatic disease (e.g., scleroderma)

Blood Vessel
- V1 Stroke/TIA
- V2 Hypertension
- V3 Ischemia/poor blood supply/poor

circulation (add body part, if known)

V4 Infarction/blockage of artery (add body part, if known)

V5 Aneurysm/ballooning of an artery (add body part, if known)

Blood Vessel (cont.)

V6 Peripheral vascular disease (add body part, if known)

V7 Varicose veins

V8 Hemorrhoids

V9 Slurred speech; left- or right-side weakness; numbness or tingling; sudden difficulty speaking; sudden onset blurred or double vision

Other Causes

W1 Alcohol related/alcoholism

W2 Drug related-not doctor prescribed/illicit

W3 Drug related-doctor prescribed

W4 Automobile

W5 Gun

W6 Knife/blade

W7 Assault/fight

Surgery

X1 Coronary artery bypass (CABG)

X2 Heart Surgery

X3 Hysterectomy (total or partial)

X4 Appendicitis/appendectomy

X5 Lipectomy/liposuction

X6 Cholecystectomy/gallbladder removal

X7 Tubal ligation

X8 Herniated disk (slipped disk)

X9 Post-operative complication

XA Breast reduction

XB Thyroidectomy (thyroid removal)

XC Knee surgery

XD Hemorrhoidectomy (hemorrhoid removal)

XE Myomectomy (fibroid removal)

XF Hernia repair

XG Dilation and Curettage

XH Stomach or Intestinal surgery for obesity (bariatric)

XI Vascular surgery/angioplasty

Table 2. Codes for General Problems or Medical Procedures, Illness/Injuries

Most codes in this section require body part(s) affected.

Diagnosis	Code
Failure (other than heart)/blockage/dysfunction	50
Cancer	51
Other tumor/cyst/polyp	52
Inflammation (itis)	53
Hemorrhage/bleeding	54
Thrombosis/blood clot/embolism	55
Infection, viral/virus	56
Infection (bacterial/other)	57
Abscess/boil/cellulitis	58
Overactive/high	59
Underactive/low	60
Spasm/cramp/pain	61
Stone	62
Rhythm problem	63
Ulcer	64
Metabolic problem	65
Allergic reaction	66
Weakness	67
Paralysis	68
Hernia	69
Surgery	70
Transplant/replacement	71
Obesity	72
Injury	73
Sprain/strain	74
Broken bone/fracture	75
Burn	76
Crush/blunt trauma	77
Puncture/cut/laceration/wound	78
Attempted suicide	79
Poisoning	80
Testing	81
Edema	82
Biopsy	83
Scars/adhesions	84
Other	97
Reason not specified	98
Unsure or unknown	99

Table 3A. Codes for Part of the Body Affected by the Injury or Illness—Listed Alphabetically by Body Part

Body Part	Code	Body Part	Code
Abdomen	19	Lung	14
Ankle/foot/toe	47	Lymph nodes	38
Arm/shoulder/hand/finger/elbow/wrist	44	Mental/emotional	06
Artery	03	Mouth/teeth/lip/chin/jaw	16
Back/spine/disc/sacrum/coccyx/tail bone	43	Muscle	39
Bladder	27	Neck	42
Bone	41	Nerve	08
Brain	05	Nose/throat/sinus/tonsil/upper respiratory	13
Breast	32	Ovary	33
Cervix/vagina	35	Pancreas	30
Chest/rib/side	15	Parotid Gland	17
Ear	12	Pituitary/adrenal/parathyroid	29
Esophagus	18	Prostate	28
Eye	11	Red blood cell/blood	36
Face	10	Skin	40
Gallbladder	25	Small intestine (duodenum)	21
Head/skull	09	Spinal cord	07
Heart	01	Spleen	24
Heart valve	02	Stomach	20
Hip/leg	45	Systemic/entire body	48
Kidney	26	Thyroid	31
Knee	46	Uterus/Fallopian Tubes	34
Large Bowel (include rectum)	22	Vein	04
Liver	23	White blood cell	37

Table 3B. Codes for Part of the Body Affected by the Injury or Illness—Listed Numerically by Code

Body Part	Code	Body Part	Code
Heart	01	Gallbladder	25
Heart valve	02	Kidney	26
Artery	03	Bladder	27
Vein	04	Prostate	28
Brain	05	Pituitary/adrenal/parathyroid	29
Mental/emotional	06	Pancreas	30
Spinal cord	07	Thyroid	31
Nerve	08	Breast	32
Head/skull	09	Ovary	33
Face	10	Uterus/Fallopian Tubes	34
Eye	11	Cervix/Vagina	35
Ear	12	Red blood cell/blood	36
Nose/throat/sinus/tonsil/upper respiratory	13	White blood cell	37
Lung	14	Lymph nodes	38
Chest/rib/side	15	Muscle	39
Mouth/teeth/lip/chin/jaw	16	Skin	40
Parotid Gland	17	Bone	41
Esophagus	18	Neck	42
Abdomen	19	Back/spine/disc/sacrum/coccyx/tail bone	43
Stomach	20	Arm/shoulder/hand/finger/elbow/wrist	44
Small intestine (duodenum)	21	Hip/leg	45
Large Bowel (include rectum)	22	Knee	46
Liver	23	Ankle/foot/toe	47
Spleen	24	Systemic/entire body	48

Table 4. Examples of Hospitalization Coding Scheme

Illness/Injury	Classification	Code
Asthma	lung	L1
Back pain	pain/back	61, 43
Bell's Palsy	paralysis/facial	68, 10
Bladder infection	infection bacterial/other, bladder	57,27
Blood clot in lung	lung: pulmonary infarction/embolism	L5
Breast surgery	surgery/breast	70, 32
Broken leg	broken bone/leg	75, 45
Cancer	cancer/specify organ (e.g., cancer/breast)	51, 32
Cholecystitis	infection/gallbladder	57, 25
Diabetes/high blood sugar	Endocrine	E1
Drug reaction	allergic reaction, prescription drug-related	66, W3
Eclampsia	pregnancy/hypertension	P1, V2
Fibroid removal (myomectomy)	surgery	XE
Food poisoning	poisoning	80
Gallstone	digestive	D7
Gestational Diabetes	pregnancy/diabetes	P1, E1
Gout	metabolic/body part (e.g., gout/ankle)	65, 47
Gunshot wound	gunshot/body part (e.g., gunshot/chest)	W5, 15
Heart Attack/MI	heart	H3
Heart Failure/Congestive	heart	H6
Hernia Repair	surgery	XF
Hodgkin's Disease	cancer/lymph nodes	51, 38
Hypertension	blood vessel	V2
Hysterectomy	surgery	X3
Kidney stone	kidney and prostate	K5
Melanoma	cancer/skin	51, 40
Myeloma	cancer/white blood cells	51, 37
Non-Hodgkin's Lymphoma	cancer/lymph nodes	51, 38
Pneumonia/Bronchitis	lung	L2
Pregnancy delivery-vaginal	pregnancy	P2
Pregnancy delivery-caesarean	pregnancy	P3
Severed finger	blade/hand (with lawnmower)	W6, 44
Toxemia	pregnancy/hypertension	P1, V2
Ulcer	ulcer/stomach/duodenal/small bowel	64, 20, 21
Venous thrombosis	vein/thrombosis/blood clot/embolism	55, 04
Viral Lung infection	infection viral/virus, lung	56, 14

5.3 Requesting Medical Records

With an institution-specific Medical Release Form, records should be requested for the events or procedures identified from Form 31, and 31B or 31C. If the participant has NOT given consent, the medical record will not be requested. If the participant has given consent, clinic staff may pursue the hospitalization record.

The request for records will be initiated by sending a photocopy of the participant's signed Medical Record Release Form, along with a cover letter, to the appropriate hospital's (healthcare agency) medical records department, or to the provider, if the procedure or event involved only outpatient treatment or diagnosis. Examples of the latter may diagnosis of deep vein thrombosis, initiation of dialysis, or sleep studies that were not considered an "admission." The cover letter should include a request for all admitting medical history and physical exam documentation; daily lab work; ECG tracings; radiology reports; results of all special procedures performed (CT scans, ultrasounds, MRI, etc.); face sheet, ICD-9 codes or CPT codes and discharge summary. A separate request should be made to each hospital or facility in which the participant has had a procedure performed. (Refer to Appendix 3 for an example of a medical records request cover letter.) (Refer to Appendix 10 for Medical Documentation Requirements for CARDIA Endpoints.)

If medical records are not received within two to three weeks of the initial request, follow-up telephone calls should be made. The original request may have been lost or misdirected within the hospital; there may be confusion regarding the specific information requested; and study requests often receive low priority in busy medical records departments. A telephone call may stimulate a search for the records and will certainly be a reminder of the request.

Many hospitals have established time-frames for considering a consent signature as valid. It is important to request the medical records as quickly as possible after the hospitalization has been reported and the Medical Record Release Form has been signed by the participant. The Morbidity and Mortality Tracking Program was designed in the Scheduling System to assist in tracking requests and responses.

5.4 Processing Medical Records

Once the clinic has received the requested record, it should be reviewed for completeness by comparing the record with the request letter. If the FC finds that important documents are missing, but were mentioned in the History and Physical or Discharge Summary, the FC should re-request those documents. Examples may be missing lab reports, missing ECG/EKGs, or missing cardiac catheterization report. A

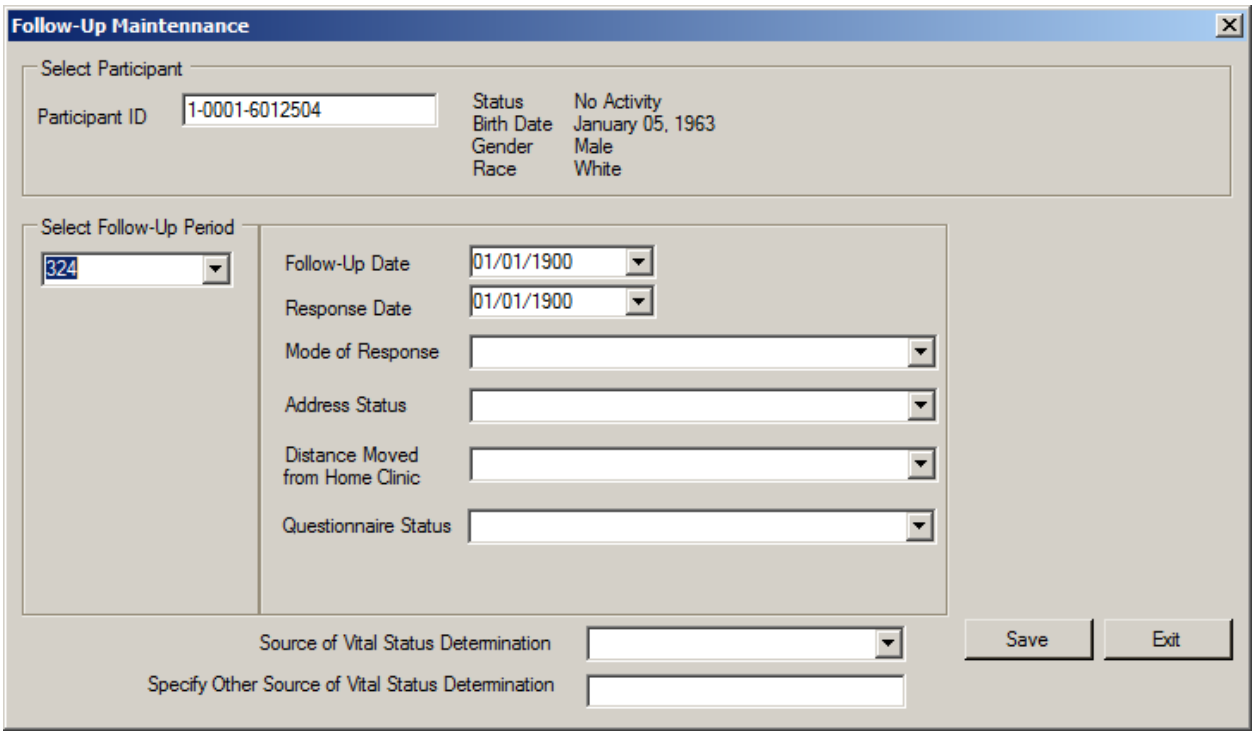
copy of the appropriate pages of the Annual Contact Questionnaire, e.g., pages 5-8, should be placed at the front of the medical record and a copy of both should be made.

5.5 De-Identifying Medical Records

Coordinating center staff may NOT have access to any personally identifying information about a participant. See Appendix 15 for information considered protected health information (PHI). The medical record should be *de-identified* before reaching the coordinating center. The participant's name, social security number, address, date of birth, telephone numbers, medical record number, and any other PHI must be removed from the record prior to forwarding to the coordinating center. All PHI should be removed thoroughly using a grease pencil ONLY. The participant's twelve-digit CARDIA ID, however, must be recorded on appropriate forms. The participant's ID should be included on each page of the medical record. In addition the dates of hospitalization or procedure MUST be retained. The coordinating center must be able to connect the CARDIA ID to the date of hospital admission for tracking. (Refer to Appendix 5 for step-by-step instructions on managing medical records.)

6. CARDIA Follow-up System

Enter CARDIA follow-up maintenance clicking on “Follow-Up/M&M” button in Scheduling system main menu.



Select participant.

The participant ID field is populated automatically by the PID selected from the participant list.

Select follow-up period.

- XXX Month - Select the radio button of the follow-up period you with to enter
- Follow-up date - Enter the date follow-up is initiated for a participant (e.g. the date the first phone call is made, the date the first letter is mailed)
- Response date - Enter the date of the participant’s initial response.

Mode of response

Enter the method that is used to complete the participant’s follow-up information.

- Letter – follow-up is completed through a letter, fax, or e-mail from the participant
- Phone – follow-up is completed through a telephone call to or from the participant

- Visit – follow-up is completed through a visit to or from the participant for the express purpose of follow-up (NOT AN EXAM VISIT)
- Other – follow-up is completed through an exam visit interview (when a participant has an exam during his/her follow-up window) or by any method not otherwise specified
- Missing – follow-up is not completed; follow-up information is not received; the participant does not respond (e.g. letter mailed to participant is returned as undeliverable; participant does not return phone calls; the participant is deceased)

Address Status

Enter the participant's address status (whether the participant has moved or not) since his/her last exam or contact

- Same – the participant has not moved since his/her last exam or contact
- New – the participant has moved since his/her last exam or contact
- Death – the participant has passed away since his/her last exam or contact
- Unable to locate – there is no current address information for the participant; the clinic has no way of attempting contact with the participant (e.g. letter mailed to participant is returned as undeliverable)
- Missing – address status is not verified; the participant does not provide address status; the participant does not respond

Distance moved

Enter the distance the participant has moved **from his/her home clinic** since the baseline exam

- Did not move – the participant has not moved since the baseline exam
- Within 50 miles – the participant has moved 50 miles or less from his/her home clinic since the baseline exam
- More than 50 miles - the participant has moved more than 50 miles or less from his/her home clinic since the baseline exam
- Missing – distance moved is not verified; the participant does not provide information on distance moved; the participant does not respond

Questionnaire status

Enter the final status of the follow-up questionnaire (whether the participant completed and returned the questionnaire or not). The *Questionnaire Status* field will only appear when an annual follow-up period is selected, as questionnaires are not administered during semi-annual follow-up periods.

- Questionnaire Not Received - the participant refused to complete the questionnaire; the participant did not return the questionnaire to the clinic; the participant was not able to be reached; the participant is deceased
- Questionnaire Not Completed/Received - the participant did not complete any part of the questionnaire and it was received by the clinic
- Questionnaire Completed/Received - the participant completed, or partially completed, the questionnaire and it was received by the clinic

Questionnaire not received status

If the *Questionnaire Status* field is marked *Questionnaire Not Received,* enter the reason in this field.

- Refused - the participant refused to complete the questionnaire
- Lost - the participant was not able to be reached; contact information unknown
- Unresponsive - the participant was not able to be reached; contact information known
- Illness - the participant was not able to complete the questionnaire due to health condition

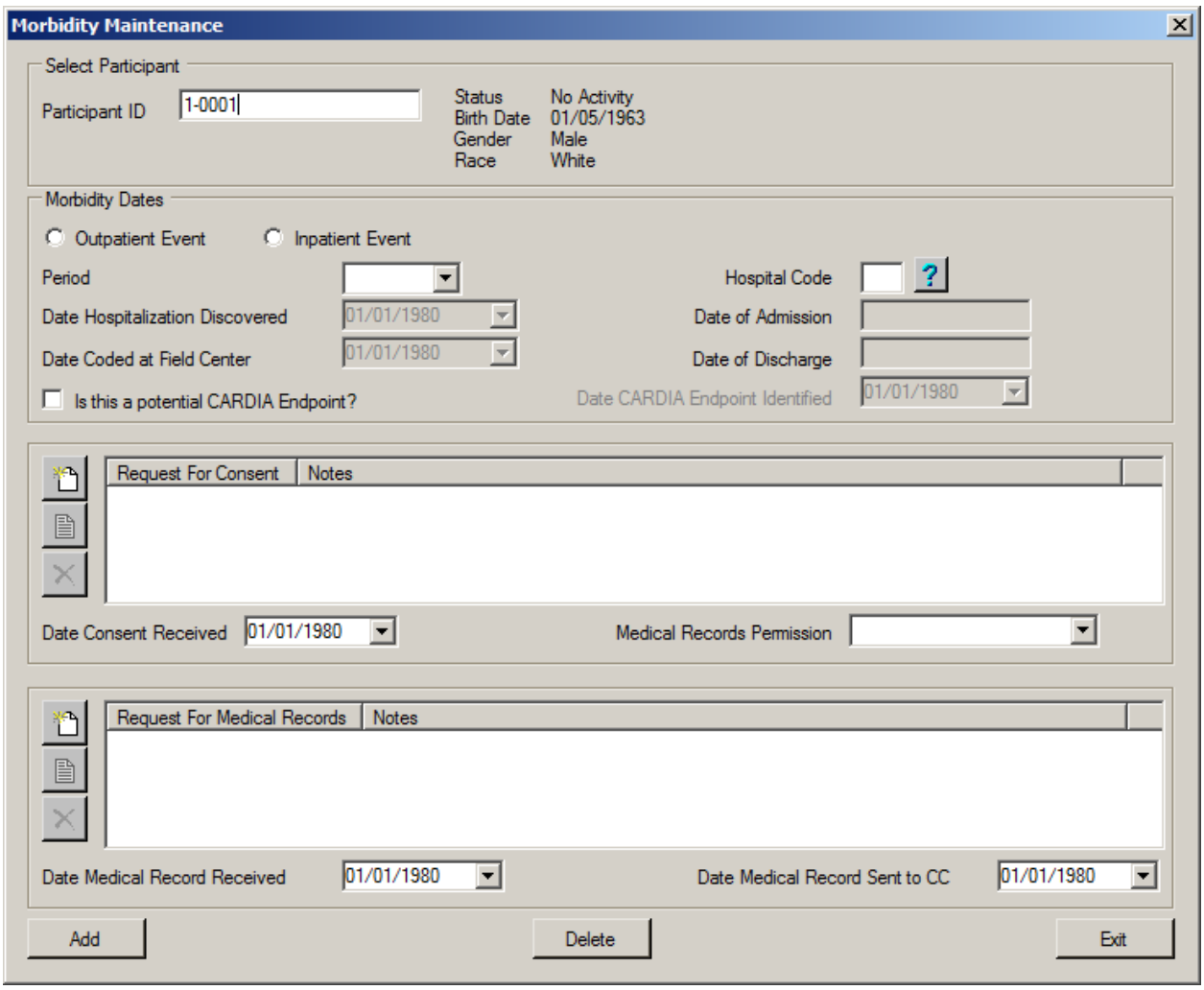
7. CARDIA Endpoints System

7.1 CARDIA Electronic Morbidity Tracking

The CARDIA Electronic Morbidity Tracking program was designed to facilitate monitoring of the process by the FCs. The program can be accessed by the FCs as part of the CARDIA Scheduling System.

The program allows the FC staffs to enter information about the identification and tracking of hospitalization and outpatient records and provides a mechanism for generation of extemporaneous reports.

Instructions for CARDIA Electronic M&M Database – Morbidity Entry



I. Enter Scheduling Program

II. Select Follow-up/M&M tab

III. Right click on Participant ID

IV. Select Morbidity Entry from drop-down box:

1. Participant ID (confirm accuracy)*
2. Select Outpatient or Inpatient Event *

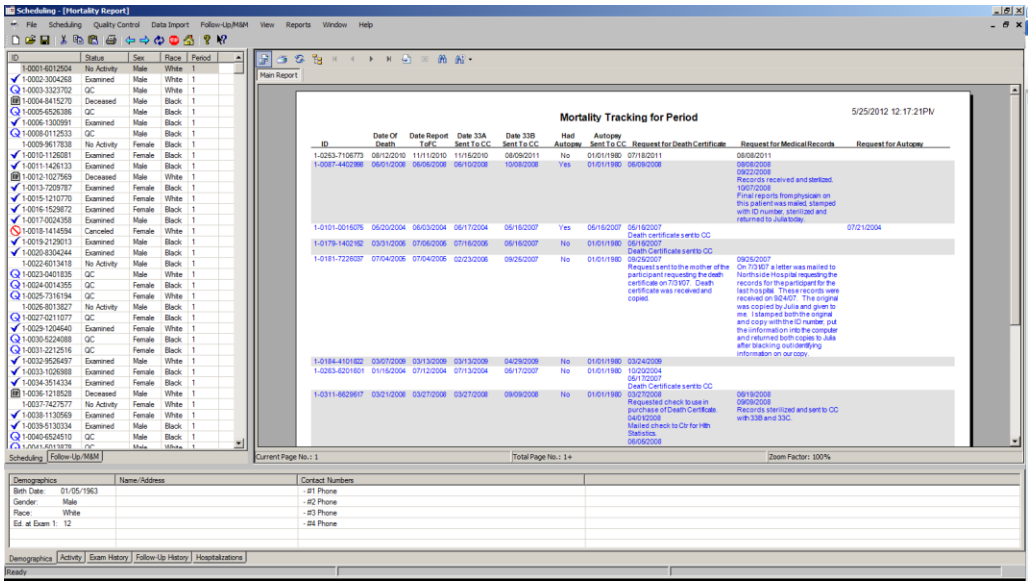
3. Period (click on drop down box; select period)*
4. Hospital Code (actually hospitalization number)*
4. Date hospitalization discovered
5. Date of admission
6. Date of discharge
7. Date coded by FC
8. Is this an endpoint (check box)
9. Date CARDIA Endpoint identified – box will open if item 8 is checked; enter date endpoint identified
10. Click icon at top left of "Request for Consent" to enter date of request; you may enter multiple dates for request for consent. You may also add notes related to request for consent in the notes box.
11. Date consent received
12. Click icon at top/left of "Request for Medical Records" to enter the date of request; you may enter multiple dates for request for records. You may also add notes regarding request for medical records
13. Date medical records received
14. Date medical records forwarded to coordinating center

- Items 1, 2, 3, and 4 **must** be entered in this order.

Click the Add button to Save the entry.

7.2 CARDIA Real Time Mortality Cases Tracking Reports

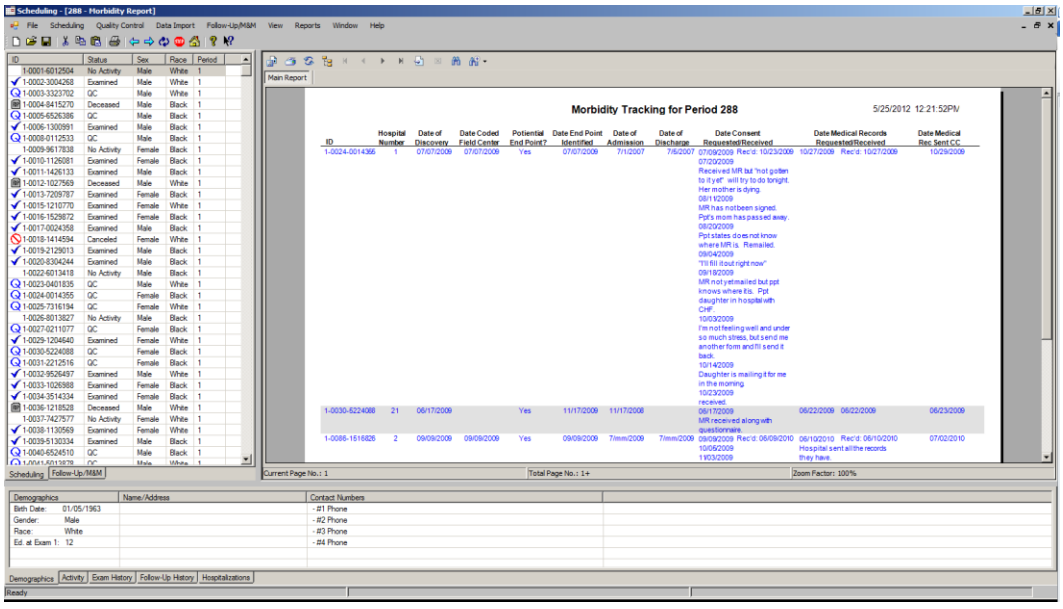
In the Scheduling System main window click on "Reports" and select "Mortality report" from the drop down menu. Mortality tracking report will be populated.



This report could be exported in different formats and printed out. Use submenu to select necessary option.

7.3 CARDIA Real Time Morbidity Records Tracking Reports

In the Scheduling System main window click on “Reports” and select “Morbidity report” from the drop down menu. Then select follow-up period and click OK. Morbidity tracking report for specified follow-up period will be populated.



This report could be exported in different formats and printed out. Use submenu to select necessary option.

Appendix 1

Sample Letter Requesting Signed Medical Records Release Form

UAB SCHOOL OF MEDICINE

Department of Medicine

[DATE]

[PARTICIANT NAME]
[ADDRESS]
[CITY, STATE, ZIP]

Dear [PARTICIPANT NAME],

Thank you for staying in touch with the CARDIA Study. Even though you have been unable to attend the last several exams, your continued participation is still very important to us. The health information that you and our other participants provide each year is helping us to understand more about how cardiovascular disease develops and relates to other medical conditions. Because of the information you participants have shared, over 300 articles have been published in scientific journals to date from the CARDIA data.

On your last questionnaire you reported a hospitalization for [ex. ruptured aneurysm of your right middle cerebral artery with SAH]. Because this is a [ex. vascular] event, obtaining these medical records is vital. The study needs your permission in order to request your medical records, but I understand that you have elected not to give it. I am hoping that you will reconsider. I want to assure you that if you allow us access to your records, they will always be kept **strictly confidential** – no one outside of CARDIA will see them. We will remove all identifying information from them and use them for **research purposes only**. We will not release any information about you without your written permission.

Would you please sign the enclosed Medical Release Form and return it in the postage paid envelope provided? Fill in the **highlighted areas only**. Be sure to initial all three highlighted lines in the box, and sign the highlighted line on the bottom.

Thank you again for your continued support of CARDIA. If you have questions or concerns, please call me anytime at 205-934-6330. Your prompt attention to this matter is greatly appreciated.

Sincerely,

Cora E. Lewis, MD, MSPH
Principal Investigator
CARDIA
Birmingham, AL

Division of Preventive Medicine
401 Medical Towers
1717 11th Avenue South
205.934.0786
Fax 205.934.0777

The University of
Alabama at Birmingham
Mailing Address:
MT 401
1530 3RD AVE S
BIRMINGHAM AL 35294-4410

Appendix 2

Sample Letter Requesting Mortality Records

UAB SCHOOL OF MEDICINE

Department of Medicine

[DATE]

ATTN: Medical Records Department
[HOSPITAL NAME]
[ADDRESS]
[CITY, STATE, ZIP]

Re: [PARTICIPANT NAME]

To Whom It May Concern:

Coronary Artery Risk Development in Young Adults (CARDIA) is an important study funded by the National Institutes of Health to learn how the beginning stages of heart disease develop in healthy young adults. [PARTICIPANT NAME] has been a participant in this study since the mid 1980's. In order for CARDIA to have the highest quality information about the development of heart disease, it is very important that we obtain medical records of hospitalizations from the providers who treat our study participants. Without them we would be seriously hindered in our ability to answer the research questions.

According to The Department of Health & Human Services – USA (the government office which issued the "Privacy Rule" Federal regulation under the Health Insurance Portability and Accountability Act of 1996 [HIPAA]), in their document "Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule," on page 17, "To use or disclose PHI of the deceased for research, covered entities are not required to obtain Authorizations from the personal representative or next of kin, a waiver or an alteration of the Authorization or a data use agreement. However, the covered entity must obtain from the researcher who is seeking access to decedents' PHI (1) oral or written representations that the use and disclosure is sought solely for research on the PHI of decedents, (2) oral or written representations that the PHI for which use or disclosure is sought is necessary for the research purposes, and (3) documentation, at the request of the covered entity, of the death of the individuals whose PHI is sought by the researchers."

Since (1) this research regards the PHI of deceased participants and (2) disclosure of the PHI is necessary for research purposes, we have (3) enclosed a copy of the participant's death certificate, and ask that you consider this sufficient authorization to release the records we are requesting.

Thank you for your continued support of CARDIA. Please contact me if you have any questions or require further information.

Sincerely,

Cora E. Lewis, MD, MSPH
Principal Investigator
CARDIA
Birmingham, AL

Division of Preventive Medicine
401 Medical Towers
1717 11th Avenue South
205.934.0786
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BIRMINGHAM AL 35294-4410

Appendix 3

Sample Letter Requesting Signed Medical Records Release Form

UAB SCHOOL OF MEDICINE

Department of Medicine

[DATE]

[PARTICIANT NAME]
[ADDRESS]
[CITY, STATE, ZIP]

Dear [PARTICIANT NAME],

As a participant in the CARDIA Study, you reported during your recent telephone interview that you have had a hospitalization or outpatient procedure since your last CARDIA exam. We would like to collect information about this hospital visit or procedure and need your permission to request these medical records.

Please sign the enclosed Medical Release Form which will authorize the release of your medical record and return it in the postage paid envelope that we have provided for your convenience. Fill in the **highlighted areas only**. Remember that all participant information (copies of medical records, etc.) obtained by the CARDIA research staff is **strictly confidential** and is used for **research purposes only**.

If you have any questions, please call me anytime at 205-934-6330. Your prompt attention to this matter is greatly appreciated.

Thank you again for being a part of this study.

Sincerely,

Julia Wilkoff
Recruitment Coordinator and Data Manager
CARDIA Study

Division of Preventive Medicine
401 Medical Towers
1717 11th Avenue South
205.934.0786
Fax 205.934.0777

The University of
Alabama at Birmingham
Mailing Address:
MT 401
1530 3RD AVE S
BIRMINGHAM AL 35294-4410

Appendix 4

Scan List

SCAN LIST
CARDIA: [FIELD CENTER NAME]

Site Staff: _____ **Date:** _____ **Page #:** _____

Please list each PID (first five digits) that you are scanning in this batch and the form(s) scanned and page number(s) scanned for each

	PID	Forms scanned	Page #'s scanned
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			
15.			

_____ (initials) I have reviewed the data, and no PHI is being scanned in this batch.

Appendix 5

Step-by-Step Instructions for Personnel on How to Manage Medical Records

Step-by-Step Instructions for Personnel on How to Manage Medical Records

Mortality Endpoints Checklist (For Death Records)

- Complete Form 33A – Initial Notification of Death.
- Send 33A to coordinating center within 1-2 days of discovery of the event, even if the information is incomplete.
- Enter death into the Mortality Tracking System.
- Record death in Follow-Up system under currently open window.
- Request Death Certificate.
- Log date of Death Certificate request into Mortality Tracking System.
- Process Received Death Certificate:
  - Stamp or write participant ID onto Death Certificate.
  - Copy Death Certificate.
  - De-Identify copy, completely blacking out all protected health information (PHI) except **date of death.**
  - Send de-identified copy to coordinating center.
- Check Death Certificate for Hospitalization information.
- Review "Decision matrix for Forms to be Obtained When Participant Dies," to see if hospital records are needed.
- Request records from hospital/MD office, if applicable.
  - Use Medical Release already signed by participant, **AND/OR**
  - Use letter explaining why Medical Release not needed for research records of deceased participants, and include copy of Death Certificate, **OR**
  - Request signed Medical Release from Next of Kin:
    - Call to verify receipt of Medical Release request (1-2 weeks)
    - Repeat at intervals as needed until signed Medical Release is received or Next of Kin refuses.
  - Log date Hospital Record requested into Mortality Tracking System.
  - Call to verify receipt of request if hospital record is not received in 1-2 weeks.
  - Repeat at intervals as needed until hospital record is received.
- Process received hospital record
  - Review for completeness.
  - Re-request any missing documents which are needed.
  - Call to verify receipt of re-request if not received within 1-2 weeks.

1 of 3

- Log date hospital record received into the Mortality Tracking system.
- Stamp or write participant ID on each page of completed Hospital record.
- Copy records.
- De-Identify the coy, completely marking out all PHI.

- Review "Decision matrix for Forms to be Obtained When Participant Dies" to see if Form 33C – CARDIA Interviews with Witness or Next of Kin - is needed.
- Complete Form(s) 33C for Next of Kin and/or as many witnesses to death as have information which may aid in adjudication of the records.
  - Copy 33C
  - Black out all the Next of Kin PHI on the copy.
- Complete Form 33B – Final Report of Death.
  - Attach a copy of the de-identified hospital record.
  - Attach a copy of all the Forms 33C.
  - Attach death certificate.
  - Attach autopsy report, if applicable.
  - Send to the Endpoints Coordinator at the coordinating center.
- Log date sent to the coordinating center in the Mortality Tracking System.

Hospital/Outpatient Records

- Review participant questionnaire for endpoints or other events requiring record retrieval.
- Code hospitalizations. (requires certification in CARDIA codes)
- Scan completed form(s) to coordinating center.
- Enter each event into the M&M Tracking System.
- Request signed Medical Release from participant.
- Log date of Medical Release request into M&M system
- Call to verify receipt of Medical Release request (1-2 weeks).
- Repeat at intervals as needed until signed Medical Release is received or participant refuses
- Log date Medical Release received into M&M system.
- Request records from hospital/MD office using signed Medical Release. Refer to list of required documents for each event.
- Log date hospital record requested into M&M system.
- Call to verify receipt of request if records are not received in 1-2 weeks.
- Repeat at intervals as needed until record is received.
- Review medical record for completeness.

- Re-request any missing documents which are needed.
- Call to verify receipt of re-request if not received within 1-2 weeks.
- Log date medical record is received into the M&M system.
- Stamp or write CARDIA ID on each page of completed hospital record.
- Copy Hospital Record.
- De-Identify the copy, completely marking out ALL PHI.
- Attach a copy of the questionnaire page that is relevant to the particular hospitalization/outpatient procedure.
- Send complete package of questionnaire and copied, de-identified medical record to the coordinating center.
- Log date the endpoint package was sent to the coordinating center in the M&M system.
- Interviewers at the field centers will identify hospitalizations or outpatient procedures at interim contacts or at clinic visits. Using the Follow-up Contact Forms or Form 31 enter CARDIA codes, complete the Follow-up forms B and C relating to hospitalizations or procedures, making sure that each event has been captured. Following the algorithms on Forms B and/or C ascertain whether records need to be requested, or if they are not relevant to CARDIA. Scan all completed forms to the coordinating center.

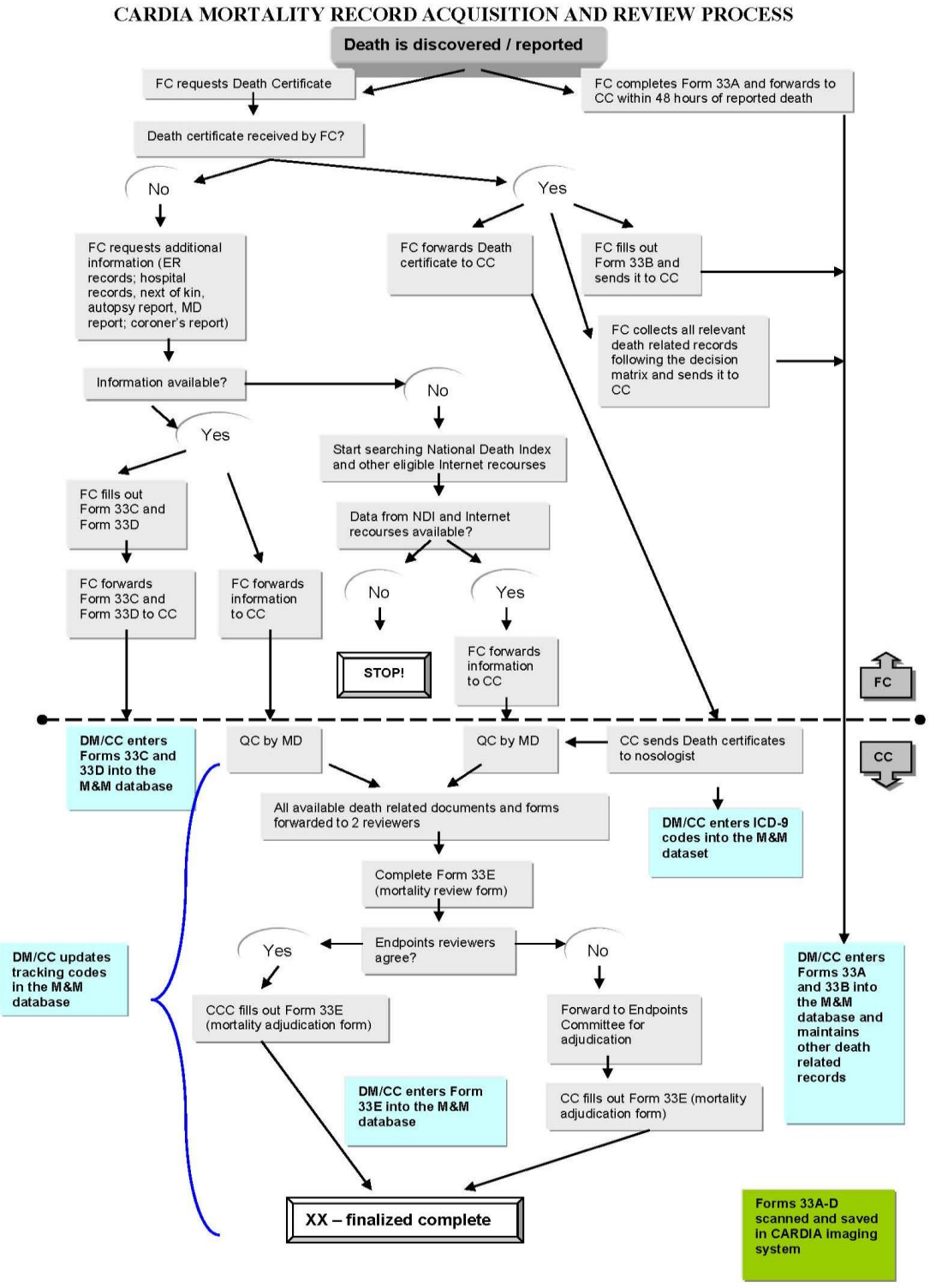
After receiving notification of an event and determining that records should be retrieved, the field center will request written permission to obtain medical records from the participant. Using the list of records needed to adjudicate events in the appendix, request medical records from the health care facility.

When the records are received, review the records for completeness and for discovered events. In the event of incomplete records, e.g., no ECG or cardiac enzymes in a heart-related event, ask for additional records. In the event of a discovered event that was sent to the field center but for about which the field center has no prior knowledge, contact the participant and ask for permission to have the records. If permission is denied, shred the documents that do not relate. If permission is granted, amend the Follow-up form and rescan the corrected form to add additional events.

Copy records and remove all PHI using a grease pencil prior to scanning the records to the coordinating center. Along with the records, scan the appropriate Follow-up form that matches the event. A date that is incorrect on the Follow-up Form, because of a misreport by the participant, does not need to be corrected.

Appendix 6

CARDIA Mortality Record Acquisition and Review Process Flow Chart



Appendix 7

Decision Matrix for Forms to be obtained when Participant Dies

CAUSE OF DEATH	FORM 33 A	B	C	D	HR	AU
Heart Disease	*	*	(*)	(*)	*	*
Sudden Death	*	*	(*)	(*)	*	*
Stroke/Cerebrovascular	*	*	(*)	(*)	*	*
Hypertension	*	*	(*)	(*)	*	*
Renovascular (Kidney)	*	*	(*)	(*)	*	*
Pulmonary	*	*	(*)	(*)	*	*
Cancer	*	*			*	*
Liver Disease	*	*			*	*
Infection	*	*			*	*
Pneumonia	*	*			*	*
Influenza	*	*			*	*
AIDS	*	*				*
Injury-unintentional	*	*				*
Homicide	*	*				*
Suicide	*	*			*	*
Other	*	*			*	*
Ambiguous	*	*	(*)	(*)	*	*

Legend
Form 33A Initial Notification of Death Form
Form 33B Final Report of Death Form
Form 33C Next of Kin/Witness (when indicated)
Form 33D Physicians Form (when indicated)
Hospital record (all admitting medical history and physical exam; daily lab work; ECG tracings; chest x-ray reports; results of all special procedures performed; e.g., scans, any other angiographic reports, graded exercise test, MRI; face sheet; discharge summary)
AU Autopsy record (if autopsy was performed)/coroner's report

Appendix 8

Mortality Review Forms (Form 33A – Form 33D)

Form 33A Page 1 of 2

CARDIA ID: __ - __ __ __ __ - __ __ __ __ __ __ __

Date: __ __ / __ __ / __ __ __ __
Mo Day Year

CARDIA INITIAL NOTIFICATION OF DEATH FORM

This form should be completed and a copy mailed to Coordinating Center within 48 hours after CARDIA learned of the death of any participant. The Final Report of Death Form should be completed and sent as soon as possible to the Coordinating Center with appropriate materials attached.

1. Participant's Name: ☐ (First - Initial) ☐☐☐ (Last Name - First 3 letters)

2. Date of Death: __ __ / __ __ / __ __ __ __
Mo Day Year

3. Date the CARDIA staff learned of the Death: __ __ / __ __ / __ __ __ __
Mo Day Year

4. Place of Death: _____ City _____ County __ __ State __ __ __ __ __ __ - __ __ __ __ Zip Code

5. Was the participant under a physician's care for the condition that led to his/her death?

1☐ No

2☐ Yes → _____ Physician's First Name ___ M.I. _____ Last Name

_____ Street Address

_____ Street Address

_____ City __ __ State __ __ __ __ __ - __ __ __ __ Zip Code

8☐ Unknown at this time

Telephone: __ __ __ - __ __ __ - __ __ __ __

6. Was the participant hospitalized prior to death?

1☐ No

2☐ Yes → _____ Hospital Name _____ Department Name

_____ Street Address

_____ Street Address

_____ City __ __ State __ __ __ __ __ - __ __ __ __ Zip Code

8☐ Unknown at this time

Form 33A
Version 2: 12/1999

7. Non-cardiovascular disease

01☐ Accident

02☐ Homicide

03☐ Suicide

04☐ AIDS

05☐ Heart Attack, Coronary Heart Disease, Other Cardiovascular Disease

06☐ Cardiac Arrest

07☐ Cerebrovascular (e.g., Stroke/Transient Ischemic Attack)

08☐ Cancer

09☐ Kidney Disease

10☐ Liver Disease

11☐ Diabetes

12☐ Lung Disease

13☐ Other, Specify:_____

_____

_____

14☐ Unknown

CARDIA Staff ID: __ __ __

CARDIA ID: __ - __ __ __ __ - __ __ __ __ __ __ __

Date: __ __ / __ __ / __ __ __ __
Mo Day Year

CARDIA FINAL REPORT OF DEATH FORM

This form is to be completed and forwarded to the Coordinating Center. Copies of other appropriate documents noted below should accompany this form. Each of the documents should be carefully reviewed for completeness prior to being forwarded to the Coordinating Center.

1. Participant's Name: ☐ First - Initial ☐☐☐ Last Name - First 3 letters

2. Date of Death: __ __ / __ __ / __ __ __ __
Mo Day Year

3. Time of day of the death if known: __ __ : __ __
1☐ A.M.
2☐ P.M.

4. Was an autopsy performed?
1☐ No
2☐ Yes → Has a copy been made of the autopsy report and enclosed with this form?
1☐ No, copy not available
2☐ Yes, copy enclosed

5. Was the participant hospitalized or seen in the Emergency Room prior to death?
1☐ No 2☐ Yes 8☐ Unable to determine

6. The following potential sources of available information about circumstances leading up to the terminal event should be consulted according to the decision matrix and where available, copies should be made and sent to the Coordinating Center.
According to the decision matrix, should a medical record be obtained?
1☐ No (GO TO CARDIA Staff ID) 2☐ Yes (GO TO 7)

7. Was permission to request medical records obtained from next of kin?
1☐ No → 1☐ Unable to locate (GO TO 9)
2☐ Refused (GO TO 9)
2☐ Yes

Form 33B
Version 1: 06/1999

8. Please indicate status of medical records below:

HOSPITAL RECORDS:	Original exists/ copy enclosed	Original does NOT exist	Original exists/ copy NOT available
			Explain:
a. Emergency Room records	1 ☐	2 ☐	3 ☐ → _____
b. Hospital – Inpatient	1 ☐	2 ☐ (GO TO 8c)	3 ☐ → _____ (GO TO 8c)
i) discharge summary	1 ☐	2 ☐	3 ☐ → _____
ii) discharge diagnosis	1 ☐	2 ☐	3 ☐ → _____
iii) ECG's	1 ☐	2 ☐	3 ☐ → _____
iv) lab reports	1 ☐	2 ☐	3 ☐ → _____
v) x-rays, CAT scan, angiography reports	1 ☐	2 ☐	3 ☐ → _____
vi) surgical pathology report	1 ☐ (GO TO 9)	2 ☐ (GO TO 9)	3 ☐ → _____ (GO TO 9)
Pursue c. and d. only if hospital or ER records are unavailable.			
c. Personal physician records	1 ☐	2 ☐	3 ☐ → _____
d. Ambulance records	1 ☐	2 ☐	3 ☐ → _____

9. According to the decision matrix, should Forms 33C and 33D be completed?

1 ☐ No (GO TO CARDIA Staff ID) 2 ☐ Yes →

	Enclosed	Not Enclosed, explain:
a. Form 33C	1 ☐	2 ☐ → _____
b. Form 33D	1 ☐	2 ☐ → _____

CARDIA Staff ID: __ __ __

CARDIA ID: __ - _ _ _ _ _ - _ _ _ _ _ _ _ _

Date of interview: _ _ / _ _ / _ _ _ _
Mo Day Year

CARDIA INTERVIEWS WITH WITNESS OR NEXT OF KIN

These interviews should be carried out where appropriate, according to the decision matrix. The interviews can usually be done by telephone, and should follow the specified sequence (e.g., using open-ended questions first). More than one form may be completed if several relevant interviews were done.

1. Participant's Name: ☐ (First - Initial) ☐☐☐ (Last Name - First 3 letters)

Interview with witness to death or last person to see the participant alive.

Respondent: _____ ___ _____
First Name M.I. Last Name

_____
Street Address

_____
Street Address

_____ _ _ _ _ _ _ _ - _ _ _ _
City State Zip Code

Telephone: _ _ _ - _ _ _ - _ _ _ _

Relationship to Participant: _____

2. Was the respondent with the participant when he/she died?

1 ☐ No → When was the death discovered?

Date: _ _ / _ _ / _ _ _ _
Mo Day Year

Time: _ _ : _ _ 1 ☐ A.M.
2 ☐ P.M.

(GO TO QUESTION 3)

2 ☐ Yes → When did the death occur?

Date: _ _ / _ _ / _ _ _ _
Mo Day Year

Time: _ _ : _ _ 1 ☐ A.M.
2 ☐ P.M.

(SKIP TO QUESTION 4)

3. When was the participant last seen alive?

   Date: __ __ / __ __ / __ __ __ __
   Mo Day Year

   Time: __ __ : __ __ 1☐ A.M.
   2☐ P.M.

4. Where did the death occur? _____

5. Was the participant seen by a physician?

   1☐ No

   2☐ Yes →

   _____ ___ _____
   Physician's First Name M.I. Last Name

   _____
   Street Address

   _____
   Street Address

   _____ __ __ __ __ __ __ - __ __ __ __
   City State Zip Code

   Telephone: __ __ __ - __ __ __ - __ __ __ __

6. In the words of the respondent, describe the events leading up to the death (attach extra pages if needed).

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

7. Did this respondent identify others who might have additional information?

1 ☐ No

2 ☐ Yes ⟶ Please provide the information below:

First Name M.I. Last Name

Street Address

Street Address

City State Zip Code

Telephone: ___-___-____

First Name M.I. Last Name

Street Address

Street Address

City State Zip Code

Telephone: ___-___-____

First Name M.I. Last Name

Street Address

Street Address

City State Zip Code

Telephone: ___-___-____

CARDIA Staff ID: ___

CARDIA ID: __ - __ __ __ __ - __ __ __ __ __ __ __

Date: __ __ / __ __ / __ __ __ __
Mo Day Year

CARDIA INTERVIEW WITH PARTICIPANT'S PHYSICIAN

This form should be completed according to the decision matrix (at the discretion of the Principal Investigator). The interview should be carried out by the Principal Investigator or Medical Director with the participant's personal physician (or other regular source of medical care). More than one form may be filled out if more than one physician was involved in the terminal care that was provided.

1. Participant's Name: ☐ (First - Initial) ☐☐☐ (Last Name - First 3 letters)

2. Physician Interviewed:

_____ ___ _____
First Name M.I. Last Name

_____
Street Address

_____
Street Address

_____ __ __ __ __ __ __ __ - __ __ __ __
City State Zip Code

Telephone: __ __ __ - __ __ __ - __ __ __ __

3. To your knowledge, was the patient suffering from a terminal or life threatening disease prior to death?

1 ☐ No

2 ☐ Yes → Please indicate how long he/she had been ill prior to death and the nature of the medical condition:

_____

_____

_____

_____

4. Did you see the patient during the two weeks prior to his/her death?

1☐ No → If the patient had not seen you in the two weeks prior to his/her death, please indicate the date of the last contact prior to death:

__ __ / __ __ / __ __ __ __
Mo Day Year

2☐ Yes ↓

Please summarize any contacts with the participant during the two weeks prior to his/her death, listing date, reason for contact, diagnosis and treatment:

1. Date: __ __ / __ __ / __ __ __ __
Mo Day Year

Reason: _____

_____

Diagnosis: _____

Treatment: _____

_____

_____

2. Date: __ __ / __ __ / __ __ __ __
Mo Day Year

Reason: _____

_____

Diagnosis: _____

Treatment: _____

_____

_____

(Use the back of this page for further listing)

5. According to your records did the patient ever have or were you treating the patient for:

	If Yes			If **YES** is checked			
				Give length of time in **MONTHS** (rounded to 1st decimal place) patient had this condition	Was he/she currently being treated for this condition?		
	(1) No	(2) Yes	(8) Un-known		(1) No	(2) Yes	Date of last treatment
1. Angina Pectoris							
2. Myocardial Infarction							
3. Other clinical coronary disease							
4. Rheumatic Heart Disease							
5. Cardiomyopathy							
6. Diabetes Mellitus							
7. Hypertension							
8. Stroke or Cerebrovascular Disease							
9. Cancer							
10. Obesity							
11. Headaches							
12. Inability to sleep							

5a. Other major illnesses or conditions patient was treated for:

1.							
2.							
3.							
4.							
5.							

6. Please give a brief narrative of the circumstances surrounding the death of the patient:

_____

_____

_____

_____

_____

_____

7. Was an ECG taken just prior to the patient's death?

1 ☐ No

2 ☐ Yes → If yes, we would appreciate having a copy of this tracing for our follow-up. (IF THE PHYSICIAN BEING INTERVIEWED DOES NOT HAVE RESPONSIBILITY FOR THIS ECG, PLEASE INDICATE BELOW WHOM WE MAY CONTACT TO OBTAIN A COPY):

8 ☐ Address Unknown

_____ ___ _____
First Name (or Institution) M.I. Last Name

_____
Street Address

_____
Street Address

_____ __ __ __ __ __ __ - __ __ __ __
City State Zip Code

Telephone: __ __ __ - __ __ __ - __ __ __ __

8. Did the physician interviewed pronounce the participant dead?

1 ☐ No → Who did?

2 ☐ Yes

_____ ___ _____
First Name M.I. Last Name

_____
Street Address

_____
Street Address

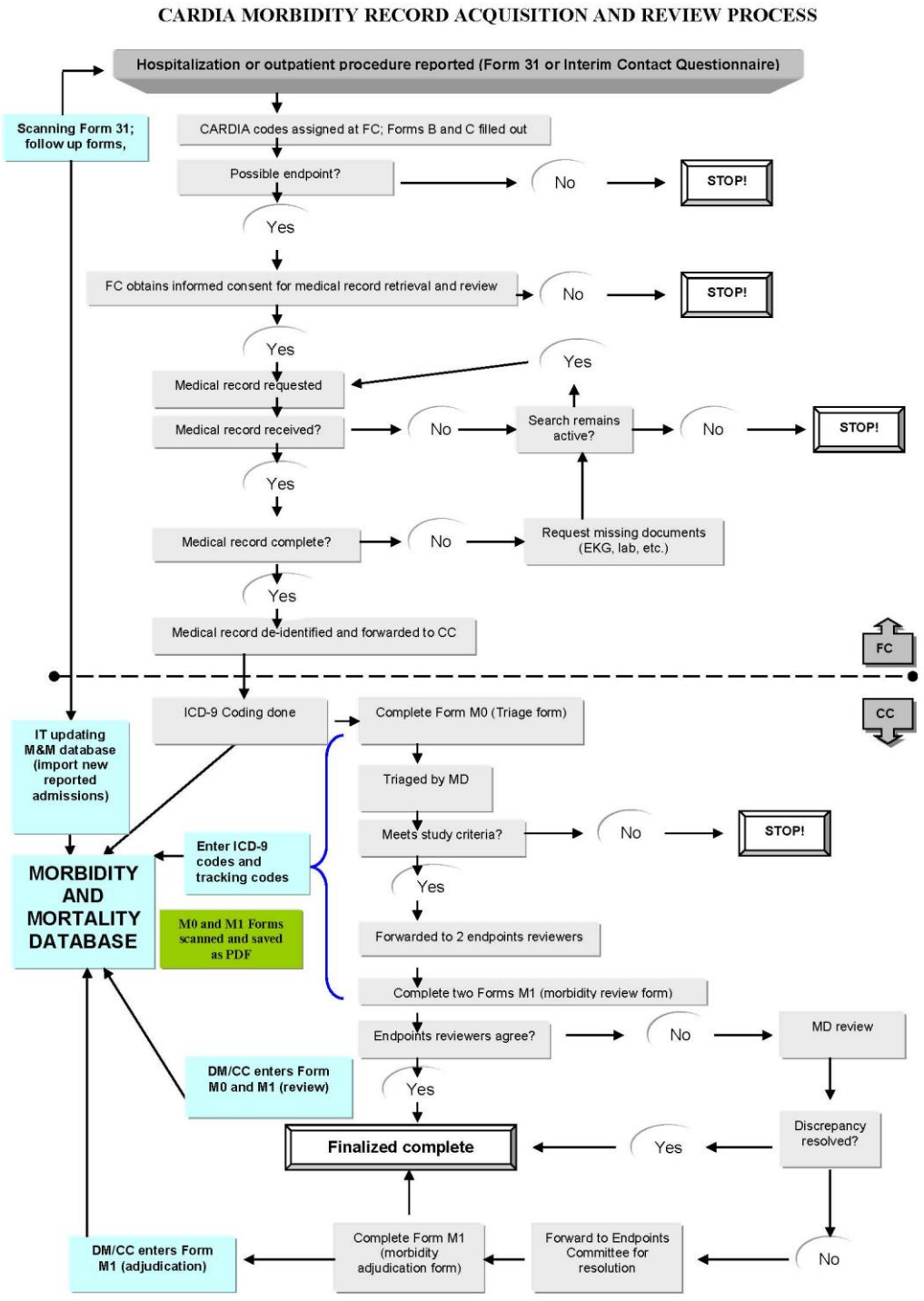
_____ __ __ __ __ __ __ - __ __ __ __
City State Zip Code

Telephone: __ __ __ - __ __ __ - __ __ __ __

CARDIA Staff ID: __ __ __

Appendix 9

CARDIA Morbidity Record Acquisition and Review Process Flow Chart



Appendix 10

Medical Documentation Requirements for CARDIA Endpoints

Medical Documentation Requirements for CARDIA Endpoints

*****DE-IDENTIFY ALL MEDICAL RECORDS BEFORE SENDING TO THE COORDINATING CENTER*****

Coronary Heart Disease (CAD, CHD, MI, Angina); Revascularization

1. Face Sheet physician attestation statement with ICD-9 or ICD-10 diagnosis and procedure codes
2. Discharge summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. ER reports
5. Consultation reports
6. Labs (Cardiac enzymes: Troponin, CK/CPK, CK-MB, myoglobin). **Include reference ranges for enzymes.**
7. 12-lead EKG/ECGs: **ALL. Ensure date and time is on tracing.**
8. Diagnostic procedures, scans: Echocardiogram, stress test, perfusion scintography report, Chest X-ray, MUGA or RVG
9. Catheterization report (angiogram/ arteriogram, contrast ventriculogram)
10. Operative or procedural report {PTCA/PCI (angioplasty or stent) or CABG}; coronary atherectomy; thrombolytic therapy

Congestive Heart Failure (CHF)

1. Face Sheet physician attestation statement with ICD-9 or ICD-10 diagnosis and procedure codes
2. Discharge summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. ER Reports
5. 12-lead EKG/ECGs
6. Labs: Cardiac Enzymes; BNP or Pro-BNP (Brain-type natriuretic peptide)
7. Chest X-ray; Chest CT; magnetic resonance imaging (MRI)
8. Diagnostic procedures, scans: Echocardiogram; radionuclide ventriculography (RVG); multigated acquisition (MUGA); contrast ventriculography
9. Cardiac catheterization

Stroke/TIA

1. Face Sheet physician attestation statement with ICD-9 or ICD-10 diagnosis and procedure codes
2. Discharge summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. ER reports
5. Physician notes/consultation reports/nursing notes
6. Diagnostic procedures, scans: CT scan; CT angiography, MRI, MRA, Echocardiogram, Transesophageal echocardiogram (TEE), Duplex ultrasound, angiography, Lumbar puncture, Carotid Doppler ultrasound
7. Thrombolytic therapy
8. Surgery (operative) reports, carotid angioplasty and stenting
9. EKG/ECGs, rhythm strips

CARDIA Medical Documentation for Endpoints 8/22/2011 1 of 4

Carotid Artery Disease

1. Face Sheet physician attestation statement with ICD-9 or ICD-10 diagnosis and procedure codes
2. Discharge summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. Diagnostic procedures: Duplex ultrasound; Doppler flow study; CT angiography; Magnetic Resonance Angiography (MRA); arteriogram
5. Operative reports: carotid endarterectomy, carotid angioplasty and stenting
6. Physicians notes/consultation reports

Peripheral Artery Disease

1. Face Sheet physician attestation statement with ICD-9 or ICD-10 diagnosis and procedure codes
2. Discharge summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. Angiogram/ arteriogram report; MRA; CT angiography
5. RE reports
6. Doppler flow studies/ultrasound
7. Operative or procedural report: angioplasty or stent; bypass surgery; Abdominal aortic aneurysm repair; amputation for ischemia
8. Exercise test for lower extremity claudification
9. Thrombolytic therapy
10. Ankle-arm systolic pressure ratio

Deep Vein Thrombosis

1. Face Sheet physician attestation statement with ICD-9 or ICD-10 diagnosis and procedure codes
2. Discharge summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. ER Reports
5. Physician notes/Consultation reports
6. Pulmonary arteriogram/CT angiogram/spiral CT scan
7. Ventilation-perfusion lung scan report
8. Diagnostic procedures: Venogram; Impedance plethysmography, isotope scan, Doppler flow study
9. IVC filters, thrombolytic therapy
10. Operative and procedure reports for extracting embolus

Pulmonary Embolism

1. Face Sheet physician attestation statement with ICD-9 or ICD-10 diagnosis and procedure codes
2. Discharge summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. ER Reports
5. Physician/Consultation reports
6. Pulmonary arteriogram/CT angiogram/spiral CT scan, venogram, isotope scan
7. Ventilation-perfusion lung scan report, Impedance plethysmography, Doppler flow study
8. Operative and procedure reports for extracting embolus
9. Thrombolytic therapy
10. Vena cava filter

Diabetes Mellitus

1. Face Sheet physician attestation statement with ICD-9 or ICD-10 diagnosis and procedure codes
2. Discharge summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. ER Reports
5. Physician/Consultation reports
6. Lab reports: blood glucose (fasting; other); HbA1c
7. Oral glucose tolerance test (OGTT)

Asthma

1. Face Sheet physician attestation statement with ICD-9 or ICD-10 diagnosis and procedure codes
2. Discharge summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. ER Reports
5. Chest X-ray
6. Physician/Consultation reports
7. Spirometry

Hypertension

1. Face Sheet physician attestation statement with ICD-9 or ICD-10 diagnosis and procedure codes
2. Discharge summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. ER Notes
5. Labs: chemistries, including creatinine, electrolytes

End-Stage Renal Disease

1. Face Sheet physician attestation statement with ICD-9 or ICD-10 diagnosis and procedure codes
2. Discharge summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. Procedure reports, including dialysis initiation; catheter insertion or AV fistula or graft access
5. Operative reports, including kidney transplant, fistula or graft placement
6. Labs: chemistries, including creatinine, electrolytes
7. Inpatient or outpatient physician notes with start dates

Chronic obstructive pulmonary disease (COPD)

1. Face Sheet physician attestation statement with ICD-9 or ICD-10 diagnosis and procedure codes
2. Discharge summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. ER Reports
5. Physician/Consultation reports
6. Imaging: Chest x-ray; chest CT
7. Spirometry

Other Hospitalizations

1. Face Sheet physician attestation statement with ICD-9 or ICD-10 diagnosis and procedure codes
2. Discharge summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. Physician/Consultation reports
5. ER reports
6. Reports of all diagnostic procedures, including scans, x-rays
7. Operative reports
8. 12-lead EKG/ECG
9. Labs, including pathology reports

Weight Loss Surgery

1. Face Sheet physician attestation statement with ICD-9 or ICD-10 diagnosis and procedure codes
2. Discharge Summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. Operative report(s)

Sleep Apnea

NOTE: do not collect for FU312 and beyond

1. Report of sleep study
2. Clinic progress note

Atrial Fibrillation/Atrial Flutter

1. Face Sheet physician attestation statement with ICD-9 or ICD-10 diagnosis and procedure codes
2. Discharge summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. ER reports
5. Consultation reports
6. Labs (Cardiac enzymes: Troponin, CK/CPK, CK-MB, myoglobin). **Include reference ranges for enzymes.**
7. 12-lead EKG/ECGs: ALL. Ensure date and time is on tracing. If 12-lead ECG is not available, include rhythm strip
8. Procedure notes, including cardioversion attempts

Appendix 11

Sample Medical Records Request Form

CARDIA

To: Medical Records: [FACILITY]
[ADDRESS]

From:

Date:

Pages:

RE: [Patient:]
[DOB:]
[SSN:]

Approximate Date of Service:_____

Attached is a signed authorization from the above patient to release medical records to the CARDIA Study. The patient reported medical treatment for the following reason:

HEART DISEASE (Chest pain, angina, myocardial infarction, coronary artery disease) or Revascularization

Please send the following records to the address below:
CARDIA Study, [Attention; Address]

Document	Requested	Reason not included	Received at CARDIA
Face Sheet physician attestation statement with ICD-9 codes or other coding abstracts			
Discharge Summary			
Admission History and Physical			
ER/ED reports (if applicable)			
Consultations			
12-lead ECGs/EKGs – ALL – *(must have date and time)*			
Procedure reports for cardiac catheterization, arteriogram, angiogram, contrast ventriculogram			
Cardiac Stress test reports, including perfusion scintography report (with thallium, technetium or other isotope) / MUGA scan			
Echocardiogram report			
Procedure report for PCI/ angioplasty/PTCA/ stent/atherectomy			
Operative report for CABG			
Chest x-ray			
Lab reports including **Cardiac Enzymes***(look for troponin, CK, CPK, myoglobin),* **BNP** *(brain natriuretic peptide)*			

IMPORTANT NOTIFICATION: The information transmitted with this facsimile is intended for the use of the person or entity to which it is addressed and may contain information that is privileged and confidential, the disclosure of which Please call me at_____if you have any questions. Thank you for your assistance.
is governed by applicable law. If the reader of this message is not the intended recipient, or the employee or agent responsible to deliver it to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this information is **STRICTLY PROHIBITED**. If you have received this message by error, please notify us immediately and destroy the related message.

Appendix 12

Suggested Script/Timeline for Medical Release Requests

Upon learning about the event:

CARDIA Staff: "CARDIA is looking at how heart disease and its risk factors develop over time and also how other medical conditions may relate to general health and heart disease. Letting us get your medical records helps us find those answers. Your records are always kept strictly confidential – no one outside of CARDIA sees them, and we remove all identifying information as soon as we get them."

[FROM FOLLOW-UP FORM] "May we have your permission to obtain and review your medical records from the above hospitalization/outpatient procedure?"

If Participant response: YES

CARDIA Staff: "Thank you. I'll be mailing a Medical Release for you to sign and return to us in a postage paid envelope. Please mail it back as soon as possible."

CARDIA Staff: "Would you share your concerns about allowing us to get your records?" **[**LISTEN ATTENTIVELY, ADDRESS CONCERNS GENTLY] "Heart disease is still the number one killer in America; what we learn from CARDIA can help our children and grandchildren live longer healthier lives. It would really help the study to have them."

If the participant still responds "no" you may choose to mail a medical release form with a "Sample Letter Requesting Signed Medical Records Release Form" within 24 hours.

Within 5 – 7 days after mailing MR:

CARDIA Staff: "I'm calling to make sure you received the medical release form we mailed to you the other day".

If Participant response: YES

"Great! Have you signed it and put it back in the mail yet?

YES - Thank you!	**No -** If you could do that as soon as you can, we would really appreciate it.

If Participant response: No

"Let's make sure I mailed it to the correct address [VERIFY ADDRESS] and I'll put another one in the mail to you today."

If Participant response: "I don't Know/Remember" – "Why don't I mail you another one just to be sure you have it." [VERIFY ADDRESS**].** "I'll put it in the mail to you today." [RE-MAIL]

If No Answer/Not in – Keep attempting daily to reach ppt. Re-mail MR after one week of inability to contact **(**2 weeks from original MR mail date**).**

One week later call again to see if it was received and/or sent back, using the same script as above. This time if no answer, keep trying daily for up to two weeks to reach the participant and verify receipt of MR before re-mailing**.**

If MR not received one week after they said they had mailed/were going to mail it back, call again

If stated previously that it was already mailed: "I still have not received the medical release form you sent back to us. It could have gotten lost in the mail so why don't I send you another one?" **[**VERIFY ADDRESS, REMAIL]

If stated previously that they have it and would mail back: "I still have not received the medical release form you were going to send back to us. Did you get a chance to put that in the mail to us yet? [FOLLOW SCRIPT ABOVE]

Appendix 13

Sample Medical Records Release Form

UAB SCHOOL OF MEDICINE
Department of Medicine, Division of Preventive Medicine
1530 3rd Avenue South, MT 700, Birmingham, AL 35294-4410
Phone:(205) 934-2294
Fax: (205) 934-1851

AUTHORIZATION TO OBTAIN MEDICAL RECORDS (Protected Health Information)

By signing this document, I authorize the release and disclosure of all of my medical information/protected health information (PHI), whether contained in my medical record or otherwise, by the health care facility listed below, including its doctors, nurses or staff. I further authorize the University of Alabama at Birmingham Division of Preventive Medicine and the research staff involved to use or disclose for the purposes described in my original consent to participate in the **CARDIA Study** and as stated below. This authorization has no expiration date. My signature is further acknowledgement that I have read and understand this document. I also agree to permit my doctors and other health care providers, including those listed below, to disclose PHI to these Researchers for the purposes in this accompanying request.

Participant Name: _____ Date of Birth: _____

Legal representative Name: _____ Relationship: _____

Participant Social Security #: _____

Reports requested inclusive for procedures or hospitalization From ____/____/____ To ____/____/____

Name of Healthcare Provider	Name of Healthcare Institution	Full Address/Phone

Initial _____

Initial _____

Initial _____

Right to Revoke: I understand that I may revoke (take back) this authorization at any time by submitting my written request to Cora E. Lewis, MD, at the above address. I also understand that my revocation will not affect any actions taken by CARDIA researchers in reliance upon this authorization before it was revoked.

Right not to Sign: I also acknowledge my right not to sign this document but that my refusal to do so will not prevent my participation in the CARDIA study.

Re-disclosure: I acknowledge that there is a potential risk that PHI will be re-disclosed by the recipient and no longer protected by the Privacy Rule. However, I understand that when a research study is the recipient, it is required by law to de-identify (remove personal identifiers) before re-disclosing for research purposes. Further information on confidentiality of study records is covered in my study consent form.

TYPE OF RECORD REQUESTED

☐ Electrocardiogram	☐ Outpatient Record	☐ Stress Test
☐ Cardiac Cath/ Angiogram/ Arteriogram	☐ Consult (Oncology/Radiology)	☐ CT Scan and/or MRI Report
☐ Venogram	☐ Radiology Scan/Bone Scan	☐ Carotid Studies
☐ Face sheet	☐ Lab ERA/PRA	☐ Pulmonary Angiogram
☐ Physicians Attestation – Coding Abstract	☐ X-ray Report _____	☐ Echocardiograph Report
☐ Operative or Procedure Report	☐ Cardiac Enzyme Lab Report	☐ Lumbar Puncture
☐ ER Report	☐ Coronary Artery Bypass Graft	☐ History and Physical
☐ Transfer Record	☐ RVG or MUGA	☐ Death Certificate
☐ PTCA, Stent, Artherectomy Report	☐ Pathology Report	☐ Discharge Summary
☐ Other _____	☐ _____	☐ _____

I authorize all health care facilities to accept a **photocopy** of this document as my official consent to release medical records.

Those who may have access to and review this information include the **Division of Preventive Medicine CARDIA Study Researchers and Staff. You may RELEASE this INFORMATION and records obtained as a part of my CARDIA** research participation to:

Name of person/organization **UAB Preventive Medicine/ Cora E. Lewis, MD, MSPH, Principal Investigator**

_____ _____

Signature of participant or legal representative **Date**

Appendix 14

CARDIA 324-Month Follow-up Questionnaire and Check Sheets

324

FOLLOW-UP QUESTIONNAIRE
CARDIA 324-Month Follow-Up Period

Date Completed: ___ ___/___ ___/___ ___ ___ ___

This questionnaire refers to hospitalizations, procedures, or events that have occurred since your last CARDIA contact or exam on .

1. Since your last CARDIA-related contact or exam, have you been a patient in a hospital overnight?

   1 ☐ No
   2 ☐ Yes → 1a. How many times? ☐☐☐ times → RECORD ON PAGE 5

2. Since your last CARDIA-related contact or exam, have you had a coronary angiogram or heart catheterization as an outpatient? (A coronary angiogram is a procedure in which dye is injected into an artery, usually in the upper thigh, to take pictures of the heart.)

   1 ☐ No
   2 ☐ Yes → RECORD ON PAGE 7

3. Since your last CARDIA-related contact or exam, have you had an outpatient procedure to open a blocked artery or arteries, such as an artery in your heart (coronary artery), neck (carotid), or your leg?

   1 ☐ No
   2 ☐ Yes → RECORD ON PAGE 7

4. Since your last CARDIA-related contact or exam, have you had an overnight sleep test where you were tested for sleep apnea or any other sleep-related conditions?

   1 ☐ No
   2 ☐ Yes

5. Since your last CARDIA-related contact or exam, have you had a surgery or any procedure for weight loss (e.g., gastric bypass, LAP-BAND®, stomach stapling)?

   1 ☐ No
   2 ☐ Yes →
   5a. Was this done as an outpatient procedure or were you admitted to the hospital for at least one night?
   1 ☐ Admitted to the hospital for at least one night → RECORD ON PAGE 5
   2 ☐ Done as an outpatient procedure → RECORD ON PAGE 7

6. Since your last CARDIA-related contact or exam, have you visited a doctor's office or an outpatient clinic (**NOT** in the ER)?

   1 ☐ No
   2 ☐ Yes → 6a. How many times? ☐☐☐ times

___ ___ ___ INTERVIEWER ID

2/06/2012 Page 1 of 7

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FOLLOW-UP QUESTIONNAIRE
CARDIA 324-Month Follow-Up Period

7. **Since your last CARDIA-related contact or exam**, has a doctor or nurse said that you have…?

7a.	High blood pressure or hypertension	1 ☐ No	2 ☐ Yes
7b.	High blood cholesterol	1 ☐ No	2 ☐ Yes
7c.	Diabetes	1 ☐ No	2 ☐ Yes
7d.	Stroke or TIA (transient ischemic attack)	1 ☐ No	2 ☐ Yes
7e.	Peripheral vascular disease (blocked arteries in your arms or legs)	1 ☐ No	2 ☐ Yes
7f.	Heart problems (If response is "No" – mark "No" then skip to 7g)	1 ☐ No	2 ☐ Yes ↓
7f1.	Was this angina or chest pain?	1 ☐ No	2 ☐ Yes
7f2.	Was this a heart attack?	1 ☐ No	2 ☐ Yes
7f3.	Was this heart failure?	1 ☐ No	2 ☐ Yes
7f4.	Other (specify) _____	1 ☐ No	2 ☐ Yes
7g.	Lung disease (If response is "No" – mark "No" then skip to 7h)	1 ☐ No	2 ☐ Yes ↓
7g1.	Was this emphysema?	1 ☐ No	2 ☐ Yes
7g2.	Was this COPD (chronic obstructive pulmonary disease)?	1 ☐ No	2 ☐ Yes
7g3.	Was this chronic bronchitis?	1 ☐ No	2 ☐ Yes
7g4.	Was this asthma?	1 ☐ No	2 ☐ Yes
7g5.	Other (specify) _____	1 ☐ No	2 ☐ Yes
7h.	Kidney problems (If response is "No" – mark "No" then skip to 7i)	1 ☐ No	2 ☐ Yes ↓
7h1.	Have you had a kidney transplant? → RECORD ON PAGE 5	1 ☐ No	2 ☐ Yes
7h2.	Have you ever had kidney dialysis treatments? → RECORD ON PAGE 7	1 ☐ No	2 ☐ Yes
7h3.	Are you on dialysis now?	1 ☐ No	2 ☐ Yes
7h4.	Other (specify) _____	1 ☐ No	2 ☐ Yes
7i.	Blood clot (If response is "No" – mark "No" then skip to 7j)	1 ☐ No	2 ☐ Yes ↓
7i1.	Was this in your lung (pulmonary embolism)? → RECORD ON PAGE 7	1 ☐ No	2 ☐ Yes
7i2.	Was this in your legs (deep vein thrombosis)? → RECORD ON PAGE 7	1 ☐ No	2 ☐ Yes
7i3.	Other (specify) _____ → RECORD ON PAGE 7	1 ☐ No	2 ☐ Yes
7j.	Cancer (If response is "No"- mark "No" then skip to 8)	1 ☐ No	2 ☐ Yes ↓
7j1.	Lung	1 ☐ No	2 ☐ Yes
7j2.	Breast	1 ☐ No	2 ☐ Yes
7j3.	Blood/lymph glands	1 ☐ No	2 ☐ Yes
7j4.	Melanoma	1 ☐ No	2 ☐ Yes
7j5.	Skin (NOT melanoma)	1 ☐ No	2 ☐ Yes
7j6.	Colon	1 ☐ No	2 ☐ Yes
7j7.	Prostate	1 ☐ No	2 ☐ Yes
7j8.	Other (specify) _____	1 ☐ No	2 ☐ Yes

8. **Have you ever** been told by a doctor or nurse that you have…?

8a.	Liver disease	1 ☐ No	2 ☐ Yes
8a1.	Hepatitis	1 ☐ No	2 ☐ Yes
8a2.	Cirrhosis	1 ☐ No	2 ☐ Yes
8a3.	Fatty liver	1 ☐ No	2 ☐ Yes
8a4.	Other (specify) _____	1 ☐ No	2 ☐ Yes
8b.	Sleep apnea (a condition where breathing stops during sleep)	1 ☐ No	2 ☐ Yes
8b1.	Was a CPAP or other pressure device recommended?	1 ☐ No	2 ☐ Yes
8b2.	Was a dental device recommended?	1 ☐ No	2 ☐ Yes
8b3.	Was surgery recommended?	1 ☐ No	2 ☐ Yes
8b4.	Was no treatment recommended?	1 ☐ No	2 ☐ Yes
8b5.	Other (specify) _____	1 ☐ No	2 ☐ Yes

9. If you have diabetes, **have you ever** been told by a doctor or nurse that your diabetes has affected the back of your eye, the retina?

3 ☐ Do not have diabetes
1 ☐ No
2 ☐ Yes → 9a. Have you ever had laser photocoagulation or laser procedure for this problem? (Do not include treatment for glaucoma or cataracts.)
1 ☐ No
2 ☐ Yes

We would like to know about medications you are currently taking.

10. Do you currently take medication prescribed by a doctor…?

10a.	To lower your blood pressure	1 ☐ No	2 ☐ Yes	8 ☐ Don't know
10b.	To lower your blood cholesterol	1 ☐ No	2 ☐ Yes	8 ☐ Don't know
10c.	For treatment of diabetes or high blood sugar	1 ☐ No	2 ☐ Yes	8 ☐ Don't know

11. Do you take aspirin regularly (daily or every-other-day), either because your doctor recommended it or on your own?

8 ☐ Don't know
1 ☐ No
2 ☐ Yes → 11a. What do you take aspirin for?

11a1.	Heart attack or stroke prevention	1 ☐ No	2 ☐ Yes
11a2.	Arthritis	1 ☐ No	2 ☐ Yes
11a3.	Other (specify) _____	1 ☐ No	2 ☐ Yes

12. **On the average**, how many cigarettes do you usually smoke per day? ☐☐ cigarettes
(If you do not smoke cigarettes, please record 00.)

MEN: GO TO BOTTOM OF PAGE 4 | **WOMEN:** GO TO QUESTION 13

13. Have you gone through menopause or the change of life?

1 ☐ No
2 ☐ Yes
8 ☐ Not sure

14. If your periods have stopped, how did they stop?

1 ☐ Naturally
2 ☐ By surgery
3 ☐ Other (specify) _____
4 ☐ I am still having periods → GO TO QUESTION 16

15. How old were you when this occurred? ☐☐ years old

16. During the **past 12 months**, have your periods…? (CHECK ONE)

1 ☐ Become farther apart
2 ☐ Become closer together
3 ☐ Occurred at more variable intervals
4 ☐ Stayed the same
5 ☐ Stopped completely
6 ☐ No periods in more than 12 months
8 ☐ Not sure

If you DO NOT have hospitalizations or procedures to record → **END OF QUESTIONNAIRE**
OR
If you have hospitalizations/procedures to record → **GO TO QUESTION 17 and/or QUESTION 18**

Please return all pages of this questionnaire, even if some are left blank.

Thank you so much for being such an important part of CARDIA!

324

FOLLOW-UP QUESTIONNAIRE
CARDIA 324-Month Follow-Up Period

HOSPITALIZATIONS

17. May we have your permission to obtain and review your medical records from the hospitalization(s) listed below?

1 ☐ No
2 ☐ Yes → Complete Medical Records Release Form

Hospitalization 1

Illness or reason: _____

Hospital name: _____

Street address: _____

_____

City _____ State _____ Zip Code

Date of admission: ___ ___/___ ___/___ ___ ___ ___

After this hospitalization, were you…?

1 ☐ Discharged home
2 ☐ Transferred to a nursing home or rehabilitation hospital (inpatient facility)
3 ☐ Transferred to another acute care hospital

FOR CLINIC STAFF ONLY

CARDIA CODES: 1. ☐☐ 2. ☐☐ 3. ☐☐ CASE NO.: ☐☐☐☐☐ 3 2 4 0 1 H

Hospitalization 2

Illness or reason:

Hospital name:

Street address:

City State Zip Code

Date of admission: ___ ___/___ ___/___ ___ ___ ___

After this hospitalization, were you…?

1 ☐ Discharged home
2 ☐ Transferred to a nursing home or rehabilitation hospital (inpatient facility)
3 ☐ Transferred to another acute care hospital

FOR CLINIC STAFF ONLY

CARDIA CODES: 1. ☐☐ 2. ☐☐ 3. ☐☐ CASE NO.: ☐☐☐☐☐3240 2H

Hospitalization 3

Illness or reason:

Hospital name:

Street address:

City State Zip Code

Date of admission: ___ ___/___ ___/___ ___ ___ ___

After this hospitalization, were you…?

1 ☐ Discharged home
2 ☐ Transferred to a nursing home or rehabilitation hospital (inpatient facility)
3 ☐ Transferred to another acute care hospital

FOR CLINIC STAFF ONLY

CARDIA CODES: 1. ☐☐ 2. ☐☐ 3. ☐☐ CASE NO.: ☐☐☐☐☐3240 3H

☐ **Check here if more than three hospitalizations are reported and use supplemental form**

324

FOLLOW-UP QUESTIONNAIRE
CARDIA 324-Month Follow-Up Period

CORONARY ANGIOGRAM, HEART CATHETERIZATIONS, OUTPATIENT PROCEDURES TO OPEN A BLOCKED ARTERY OR ARTERIES, WEIGHT LOSS SURGERY, BLOOD CLOTS , OR KIDNEY DIALYSIS

18. May we have your permission to obtain and review your medical records from the procedure(s) listed below?

1 ☐ No
2 ☐ Yes → Complete Medical Records Release Form

Procedure 1 **FOR CLINIC STAFF ONLY** CASE NO.: | | | | | | 3 | 2 | 4 | 0 | 1 | P |

Procedure type:
Facility name:
Street address:
City State Zip Code
Date of procedure: ___ ___/___ ___/___ ___ ___ ___

Procedure 2 **FOR CLINIC STAFF ONLY** CASE NO.: | | | | | | 3 | 2 | 4 | 0 | 2 | P |

Procedure type:
Facility name:
Street address:
City State Zip Code
Date of procedure: ___ ___/___ ___/___ ___ ___ ___

Procedure 3 **FOR CLINIC STAFF ONLY** CASE NO.: | | | | | | 3 | 2 | 4 | 0 | 3 | P |

Procedure type:
Facility name:
Street address:
City State Zip Code
Date of procedure: ___ ___/___ ___/___ ___ ___ ___

☐ **Check here if more than three procedures are reported and use supplemental form**

324A (Supplemental)

FOLLOW-UP QUESTIONNAIRE
CARDIA 324-Month Follow-Up Period

Hospitalization __ __

Illness or reason:

Hospital name:

Street address:

City State Zip Code

Date of admission: ___ ___/___ ___/___ ___ ___ ___

After this hospitalization, were you…?

1 ☐ Discharged home
2 ☐ Transferred to a nursing home or rehabilitation hospital (inpatient facility)
3 ☐ Transferred to another acute care hospital

FOR CLINIC STAFF ONLY

CARDIA CODES: 1. ☐☐ 2. ☐☐ 3. ☐☐ CASE NO.: ☐☐☐☐☐3 2 4☐☐H

Hospitalization __ __

Illness or reason:

Hospital name:

Street address:

City State Zip Code

Date of admission: ___ ___/___ ___/___ ___ ___ ___

After this hospitalization, were you…?

1 ☐ Discharged home
2 ☐ Transferred to a nursing home or rehabilitation hospital (inpatient facility)
3 ☐ Transferred to another acute care hospital

FOR CLINIC STAFF ONLY

CARDIA CODES: 1. ☐☐ 2. ☐☐ 3. ☐☐ CASE NO.: ☐☐☐☐☐3 2 4☐☐H

☐ **Check here if more hospitalizations are reported and use another supplemental form**

2/06/2012 Page 1 of 2

324A (Supplemental)

FOLLOW-UP QUESTIONNAIRE
CARDIA 324-Month Follow-Up Period

Procedure __ __	**FOR CLINIC STAFF ONLY** CASE NO.: _ _ _ _ _ 3 2 4 _ _ P
Procedure type:	
Facility name:	
Street address:	
	City State Zip Code
Date of procedure: ___ ___/___ ___/___ ___ ___ ___	

Procedure __ __	**FOR CLINIC STAFF ONLY** CASE NO.: _ _ _ _ _ 3 2 4 _ _ P
Procedure type:	
Facility name:	
Street address:	
	City State Zip Code
Date of procedure: ___ ___/___ ___/___ ___ ___ ___	

Procedure __ __	**FOR CLINIC STAFF ONLY** CASE NO.: _ _ _ _ _ 3 2 4 _ _ P
Procedure type:	
Facility name:	
Street address:	
	City State Zip Code
Date of procedure: ___ ___/___ ___/___ ___ ___ ___	

☐ **Check here if more procedures are reported and use another supplemental form**

324B

HOSPITALIZATIONS CHECKSHEET
CARDIA 324-Month Follow-Up Period

Date Completed: ___ ___/___ ___/___ ___ ___ ___

HOSPITALIZATION 1	CASE NO.:						3	2	4	0	1	H

Has the participant indicated any of the following reasons for being admitted overnight for this case?

1. Suspected or confirmed problems with the heart, circulation, or a blood clot 1☐ No 2☐ Yes ↓

1a. For which specific problem?

- Chest pain or angina 1☐ No 2☐ Yes
- Heart attack (coronary, myocardial infarction or MI) 1☐ No 2☐ Yes
- Atrial fibrillation or abnormal heart rhythm 1☐ No 2☐ Yes
- Heart valve 1☐ No 2☐ Yes
- Congestive heart failure 1☐ No 2☐ Yes
- Heart bypass operation (coronary bypass or CABG) 1☐ No 2☐ Yes
- Heart (cardiac) catheterization, angiogram 1☐ No 2☐ Yes
- PTCA, angioplasty, stent, atherectomy (cardiac or peripheral) 1☐ No 2☐ Yes
- Carotid endarterectomy 1☐ No 2☐ Yes
- Claudication, PAD, PVD, gangrene, or Buerger's disease 1☐ No 2☐ Yes
- Aneurysm 1☐ No 2☐ Yes
- Blood clot in the lung (pulmonary embolism) or leg (DVT) 1☐ No 2☐ Yes
- Ischemia, poor blood circulation 1☐ No 2☐ Yes
- Other (specify) _____ 1☐ No 2☐ Yes

2. Suspected or confirmed stroke or transient ischemic attack (TIA) 1☐ No 2☐ Yes
3. Kidney failure or transplant 1☐ No 2☐ Yes
4. Chronic lung disease/COPD/emphysema 1☐ No 2☐ Yes
5. Hypertension/High Blood Pressure 1☐ No 2☐ Yes
6. Diabetes 1☐ No 2☐ Yes
7. Asthma/ Shortness of breath 1☐ No 2☐ Yes
8. Bariatric surgery (e.g., gastric bypass or laparoscopic banding) 1☐ No 2☐ Yes
9. Other (specify) _____ 1☐ No 2☐ Yes
10. Did any of the problems or conditions include a YES response to Q1 – Q8 or a Q9 response that could be a potential CARDIA endpoint? 1☐ No 2☐ Yes ↓

END OF HOSPITALIZATION 1, IF RESPONSE IS YES TO Q10 COLLECT MEDICAL RECORDS

___ ___ ___ INTERVIEWER ID

2/06/2012

FOR CLINIC USE ONLY

324B

HOSPITALIZATIONS CHECKSHEET
CARDIA 324-Month Follow-Up Period

HOSPITALIZATION 2	CASE NO.:						3	2	4	0	2	H

Has the participant indicated any of the following reasons for being admitted overnight for this case?

1. Suspected or confirmed problems with the heart, circulation, or a blood clot 1 ☐ No 2 ☐ Yes ↓

1a. For which specific problem?

- Chest pain or angina 1 ☐ No 2 ☐ Yes
- Heart attack (coronary, myocardial infarction or MI) 1 ☐ No 2 ☐ Yes
- Atrial fibrillation or abnormal heart rhythm 1 ☐ No 2 ☐ Yes
- Heart valve 1 ☐ No 2 ☐ Yes
- Congestive heart failure 1 ☐ No 2 ☐ Yes
- Heart bypass operation (coronary bypass or CABG) 1 ☐ No 2 ☐ Yes
- Heart (cardiac) catheterization, angiogram 1 ☐ No 2 ☐ Yes
- PTCA, angioplasty, stent, atherectomy (cardiac or peripheral) 1 ☐ No 2 ☐ Yes
- Carotid endarterectomy 1 ☐ No 2 ☐ Yes
- Claudication, PAD, PVD, gangrene, or Buerger's disease 1 ☐ No 2 ☐ Yes
- Aneurysm 1 ☐ No 2 ☐ Yes
- Blood clot in the lung (pulmonary embolism) or leg (DVT) 1 ☐ No 2 ☐ Yes
- Ischemia, poor blood circulation 1 ☐ No 2 ☐ Yes
- Other (specify) _____ 1 ☐ No 2 ☐ Yes

2. Suspected or confirmed stroke or transient ischemic attack (TIA) 1 ☐ No 2 ☐ Yes
3. Kidney failure or transplant 1 ☐ No 2 ☐ Yes
4. Chronic lung disease/COPD/emphysema 1 ☐ No 2 ☐ Yes
5. Hypertension/High Blood Pressure 1 ☐ No 2 ☐ Yes
6. Diabetes 1 ☐ No 2 ☐ Yes
7. Asthma/ Shortness of breath 1 ☐ No 2 ☐ Yes
8. Bariatric surgery (e.g., gastric bypass or laparoscopic banding) 1 ☐ No 2 ☐ Yes
9. Other (specify) _____ 1 ☐ No 2 ☐ Yes
10. Did any of the problems or conditions include a YES response to Q1 – Q8 or a Q9 response that could be a potential CARDIA endpoint? 1 ☐ No 2 ☐ Yes ↓

END OF HOSPITALIZATION 2, IF RESPONSE IS YES TO Q10 COLLECT MEDICAL RECORDS

2/06/2012 **FOR CLINIC USE ONLY** Page 2 of 3

324B

HOSPITALIZATIONS CHECKSHEET
CARDIA 324-Month Follow-Up Period

HOSPITALIZATION 3	CASE NO.:						3	2	4	0	3	H

Has the participant indicated any of the following reasons for being admitted overnight for this case?

1. Suspected or confirmed problems with the heart, circulation, or a blood clot 1 ☐ No 2 ☐ Yes ↓

1a. For which specific problem?

- Chest pain or angina 1 ☐ No 2 ☐ Yes
- Heart attack (coronary, myocardial infarction or MI) 1 ☐ No 2 ☐ Yes
- Atrial fibrillation or abnormal heart rhythm 1 ☐ No 2 ☐ Yes
- Heart valve 1 ☐ No 2 ☐ Yes
- Congestive heart failure 1 ☐ No 2 ☐ Yes
- Heart bypass operation (coronary bypass or CABG) 1 ☐ No 2 ☐ Yes
- Heart (cardiac) catheterization, angiogram 1 ☐ No 2 ☐ Yes
- PTCA, angioplasty, stent, atherectomy (cardiac or peripheral) 1 ☐ No 2 ☐ Yes
- Carotid endarterectomy 1 ☐ No 2 ☐ Yes
- Claudication, PAD, PVD, gangrene, or Buerger's disease 1 ☐ No 2 ☐ Yes
- Aneurysm 1 ☐ No 2 ☐ Yes
- Blood clot in the lung (pulmonary embolism) or leg (DVT) 1 ☐ No 2 ☐ Yes
- Ischemia, poor blood circulation 1 ☐ No 2 ☐ Yes
- Other (specify) _____ 1 ☐ No 2 ☐ Yes

2. Suspected or confirmed stroke or transient ischemic attack (TIA) 1 ☐ No 2 ☐ Yes
3. Kidney failure or transplant 1 ☐ No 2 ☐ Yes
4. Chronic lung disease/COPD/emphysema 1 ☐ No 2 ☐ Yes
5. Hypertension/High Blood Pressure 1 ☐ No 2 ☐ Yes
6. Diabetes 1 ☐ No 2 ☐ Yes
7. Asthma/ Shortness of breath 1 ☐ No 2 ☐ Yes
8. Bariatric surgery (e.g., gastric bypass or laparoscopic banding) 1 ☐ No 2 ☐ Yes
9. Other (specify) _____ 1 ☐ No 2 ☐ Yes
10. Did any of the problems or conditions include a YES response to Q1 – Q8 or a Q9 response that could be a potential CARDIA endpoint? 1 ☐ No 2 ☐ Yes ↓

END OF HOSPITALIZATION 3, IF RESPONSE IS YES TO Q10 COLLECT MEDICAL RECORDS

☐ **Check here if more than three hospitalizations are reported and use supplemental form**

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324B (Supplemental)

HOSPITALIZATIONS CHECKSHEET
CARDIA 324-Month Follow-Up Period

Date Completed: ___ ___/___ ___/___ ___ ___ ___

HOSPITALIZATION __ __	CASE NO.:						3	2	4			H

Has the participant indicated any of the following reasons for being <u>admitted overnight</u> for this case?

1.	Suspected or confirmed problems with the heart, circulation, or a blood clot	1 ☐ No	2 ☐ Yes ↓
	1a. For which specific problem?		
	Chest pain or angina	1 ☐ No	2 ☐ Yes
	Heart attack (coronary, myocardial infarction or MI)	1 ☐ No	2 ☐ Yes
	Atrial fibrillation or abnormal heart rhythm	1 ☐ No	2 ☐ Yes
	Heart valve	1 ☐ No	2 ☐ Yes
	Congestive heart failure	1 ☐ No	2 ☐ Yes
	Heart bypass operation (coronary bypass or CABG)	1 ☐ No	2 ☐ Yes
	Heart (cardiac) catheterization, angiogram	1 ☐ No	2 ☐ Yes
	PTCA, angioplasty, stent, atherectomy (cardiac or peripheral)	1 ☐ No	2 ☐ Yes
	Carotid endarterectomy	1 ☐ No	2 ☐ Yes
	Claudication, PAD, PVD, gangrene, or Buerger's disease	1 ☐ No	2 ☐ Yes
	Aneurysm	1 ☐ No	2 ☐ Yes
	Blood clot in the lung (pulmonary embolism) or leg (DVT)	1 ☐ No	2 ☐ Yes
	Ischemia, poor blood circulation	1 ☐ No	2 ☐ Yes
	Other (specify) _____	1 ☐ No	2 ☐ Yes
2.	Suspected or confirmed stroke or transient ischemic attack (TIA)	1 ☐ No	2 ☐ Yes
3.	Kidney failure or transplant	1 ☐ No	2 ☐ Yes
4.	Chronic lung disease/COPD/emphysema	1 ☐ No	2 ☐ Yes
5.	Hypertension/High Blood Pressure	1 ☐ No	2 ☐ Yes
6.	Diabetes	1 ☐ No	2 ☐ Yes
7.	Asthma/ Shortness of breath	1 ☐ No	2 ☐ Yes
8.	Bariatric surgery (e.g., gastric bypass or laparoscopic banding)	1 ☐ No	2 ☐ Yes
9.	Other (specify) _____	1 ☐ No	2 ☐ Yes
10.	Did any of the problems or conditions include a YES response to Q1 – Q8 or a Q9 response that could be a potential CARDIA endpoint?	1 ☐ No	2 ☐ Yes ↓

END OF HOSPITALIZATION, IF RESPONSE IS YES TO Q10 COLLECT MEDICAL RECORDS

☐ **Check here if more hospitalizations are reported and use another supplemental form**

___ ___ ___ INTERVIEWER ID

2/06/2012

FOR CLINIC USE ONLY

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324C

PROCEDURES CHECKSHEET
CARDIA 324-Month Follow-Up Period

Date Completed: ___ ___/___ ___/___ ___ ___ ___

PROCEDURE/EVENT 1	CASE NO.:						3	2	4	0	1	P

Has the participant indicated any of the following reasons for this outpatient procedure or event visit?

1. Suspected or confirmed problems with the heart, circulation, or a blood clot 1 ☐ No 2 ☐ Yes ↓

   1a. For which specific problem?

   - Heart (cardiac) catheterization, angiogram 1 ☐ No 2 ☐ Yes
   - Blood clot in the lung (pulmonary embolism) or leg (DVT) 1 ☐ No 2 ☐ Yes
   - PTCA, angioplasty, stent, atherectomy (cardiac or peripheral) 1 ☐ No 2 ☐ Yes
   - Carotid endarterectomy 1 ☐ No 2 ☐ Yes
   - Cardioversion 1 ☐ No 2 ☐ Yes
   - Other (specify) _____ 1 ☐ No 2 ☐ Yes

2. Kidney failure, start dialysis, or have kidney transplant 1 ☐ No 2 ☐ Yes
3. Bariatric surgery (e.g., gastric bypass or laparoscopic banding) 1 ☐ No 2 ☐ Yes
4. Other (specify) _____ 1 ☐ No 2 ☐ Yes
5. Did any of the problems or conditions include a YES response to Q1 – Q3 or a Q4 response that could involve one of these conditions? 1 ☐ No 2 ☐ Yes ↓

END OF PROCEDURE 1, IF RESPONSE IS YES TO Q5, COLLECT MEDICAL RECORDS

___ ___ ___ INTERVIEWER ID

2/06/2012 FOR CLINIC USE ONLY

324C

PROCEDURES CHECKSHEET
CARDIA 324-Month Follow-Up Period

PROCEDURE/EVENT 2	CASE NO.:						3	2	4	0	2	P

Has the participant indicated any of the following reasons for this outpatient procedure or event visit?

1. Suspected or confirmed problems with the heart, circulation, or a blood clot 1 ☐ No 2 ☐ Yes ↓

   1a. For which specific problem?
   - Heart (cardiac) catheterization, angiogram 1 ☐ No 2 ☐ Yes
   - Blood clot in the lung (pulmonary embolism) or leg (DVT) 1 ☐ No 2 ☐ Yes
   - PTCA, angioplasty, stent, atherectomy (cardiac or peripheral) 1 ☐ No 2 ☐ Yes
   - Carotid endarterectomy 1 ☐ No 2 ☐ Yes
   - Cardioversion 1 ☐ No 2 ☐ Yes
   - Other (specify) _____ 1 ☐ No 2 ☐ Yes

2. Kidney failure, start dialysis, or have kidney transplant 1 ☐ No 2 ☐ Yes
3. Bariatric surgery (e.g., gastric bypass or laparoscopic banding) 1 ☐ No 2 ☐ Yes
4. Other (specify) _____ 1 ☐ No 2 ☐ Yes
5. Did any of the problems or conditions include a YES response to Q1 – Q3 or a Q4 response that could involve one of these conditions? 1 ☐ No 2 ☐ Yes ↓

END OF PROCEDURE 2, IF RESPONSE IS YES TO Q5, COLLECT MEDICAL RECORDS

PROCEDURE/EVENT 3	CASE NO.:						3	2	4	0	3	P

Has the participant indicated any of the following reasons for this outpatient procedure or event visit?

1. Suspected or confirmed problems with the heart, circulation, or a blood clot 1 ☐ No 2 ☐ Yes ↓

   1a. For which specific problem?
   - Heart (cardiac) catheterization, angiogram 1 ☐ No 2 ☐ Yes
   - Blood clot in the lung (pulmonary embolism) or leg (DVT) 1 ☐ No 2 ☐ Yes
   - PTCA, angioplasty, stent, atherectomy (cardiac or peripheral) 1 ☐ No 2 ☐ Yes
   - Carotid endarterectomy 1 ☐ No 2 ☐ Yes
   - Cardioversion 1 ☐ No 2 ☐ Yes
   - Other (specify) _____ 1 ☐ No 2 ☐ Yes

2. Kidney failure, start dialysis, or have kidney transplant 1 ☐ No 2 ☐ Yes
3. Bariatric surgery (e.g., gastric bypass or laparoscopic banding) 1 ☐ No 2 ☐ Yes
4. Other (specify) _____ 1 ☐ No 2 ☐ Yes
5. Did any of the problems or conditions include a YES response to Q1 – Q3 or a Q4 response that could involve one of these conditions? 1 ☐ No 2 ☐ Yes ↓

END OF PROCEDURE 3, IF RESPONSE IS YES TO Q5, COLLECT MEDICAL RECORDS

☐ **Check here if more than three procedures are reported and use supplemental form**

324C (Supplemental)

PROCEDURES CHECKSHEET
CARDIA 324-Month Follow-Up Period

Date Completed: ___ ___/___ ___/___ ___ ___ ___

PROCEDURE/EVENT __ __	CASE NO.:						3	2	4			P

Has the participant indicated any of the following reasons for this outpatient procedure or event visit?

1. Suspected or confirmed problems with the heart, circulation, or a blood clot 1 ☐ No 2 ☐ Yes ↓

   1a. For which specific problem?

   - Heart (cardiac) catheterization 1 ☐ No 2 ☐ Yes
   - Blood clot in the lung (pulmonary embolism) or leg (DVT) 1 ☐ No 2 ☐ Yes
   - PTCA, angioplasty, stent, atherectomy (cardiac or peripheral) 1 ☐ No 2 ☐ Yes
   - Carotid endarterectomy 1 ☐ No 2 ☐ Yes
   - Cardioversion 1 ☐ No 2 ☐ Yes
   - Other (specify) _____ 1 ☐ No 2 ☐ Yes

2. Kidney failure, start dialysis, or have kidney transplant 1 ☐ No 2 ☐ Yes
3. Bariatric surgery (e.g., gastric bypass or laparoscopic banding) 1 ☐ No 2 ☐ Yes
4. Other (specify) _____ 1 ☐ No 2 ☐ Yes
5. Did any of the problems or conditions include a YES response to Q1 – Q3 or a Q4 response that could involve one of these conditions? 1 ☐ No 2 ☐ Yes ↓

END OF PROCEDURE, IF RESPONSE IS YES TO Q5, COLLECT MEDICAL RECORDS

☐ **Check here if more procedures are reported and use another supplemental form**

___ ___ ___ INTERVIEWER ID

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324

PROXY FOLLOW-UP QUESTIONNAIRE
CARDIA 324-Month Follow-Up Period

Date Completed: ___ ___/___ ___/___ ___ ___ ___

This questionnaire refers to hospitalizations, procedures, or events that have occurred since the participant's last CARDIA contact or exam on [DATE]. This questionnaire is to be administered by telephone only.

Reason for using proxy: (CHECK ALL THAT APPLY)

2 ☐ Nursing home
2 ☐ Incarceration
2 ☐ Cognitive decline
2 ☐ Catastrophic health event
2 ☐ Significant hearing impairment
2 ☐ Disability (specify) _____

1. Since [NAME's] last CARDIA-related contact or exam, was he/she a patient in a hospital overnight?

1 ☐ No
2 ☐ Yes → 1a. How many times? ☐☐☐ → RECORD ON PAGE 4
8 ☐ Unknown

2. Since [NAME's] last CARDIA-related contact or exam, has he/she had a coronary angiogram or heart catheterization as an outpatient? (A coronary angiogram is a procedure in which dye is injected into an artery, usually in the upper thigh, to take pictures of the heart.)

1 ☐ No
2 ☐ Yes → RECORD ON PAGE 6
8 ☐ Unknown

3. Since [NAME's] last CARDIA-related contact or exam, has he/she had an outpatient procedure to open a blocked artery or arteries, such as an artery in the heart (coronary artery), neck (carotid), or leg?

1 ☐ No
2 ☐ Yes → RECORD ON PAGE 6
8 ☐ Unknown

4. Since [NAME's] last CARDIA-related contact or exam, has he/she had an overnight sleep test where tested for sleep apnea or any other sleep-related conditions?

1 ☐ No
2 ☐ Yes
8 ☐ Unknown

5. Since [NAME's] last CARDIA-related contact or exam, has he/she had a surgery or any procedure for weight loss (e.g., gastric bypass, LAP-BAND®, stomach stapling)?

1 ☐ No
2 ☐ Yes → 5a. Was this done as an outpatient procedure or was he/she admitted to the hospital for at least one night?
  1 ☐ Admitted to the hospital for at least one night → RECORD ON PAGE 4
  2 ☐ Done as an outpatient procedure → RECORD ON PAGE 6
8 ☐ Unknown

___ ___ ___ INTERVIEWER ID

324

PROXY FOLLOW-UP QUESTIONNAIRE
CARDIA 324-Month Follow-Up Period

6. Since [NAME's] last CARDIA-related contact or exam, has a doctor or nurse said that he/she has…?

6a.	High blood pressure or hypertension	1 ☐ No	2 ☐ Yes	8 ☐ UNK
6b.	Diabetes	1 ☐ No	2 ☐ Yes	8 ☐ UNK
6c.	Stroke or TIA (transient ischemic attack)	1 ☐ No	2 ☐ Yes	8 ☐ UNK
6d.	Peripheral vascular disease (blocked arteries in arms or legs)	1 ☐ No	2 ☐ Yes	8 ☐ UNK
6e.	Heart problems	1 ☐ No	2 ☐ Yes ↓	8 ☐ UNK
6e1.	Was this angina or chest pain?	1 ☐ No	2 ☐ Yes	
6e2.	Was this a heart attack?	1 ☐ No	2 ☐ Yes	
6e3.	Was this heart failure?	1 ☐ No	2 ☐ Yes	
6e4.	Other (specify) _____	1 ☐ No	2 ☐ Yes	
6f.	Lung disease	1 ☐ No	2 ☐ Yes ↓	8 ☐ UNK
6f1.	Was this emphysema?	1 ☐ No	2 ☐ Yes	
6f2.	Was this COPD (chronic obstructive pulmonary disease)?	1 ☐ No	2 ☐ Yes	
6f3.	Was this chronic bronchitis?	1 ☐ No	2 ☐ Yes	
6f4.	Was this asthma?	1 ☐ No	2 ☐ Yes	
6f5.	Other (specify) _____	1 ☐ No	2 ☐ Yes	
6g.	Kidney problems	1 ☐ No	2 ☐ Yes ↓	8 ☐ UNK
6g1.	Has he/she had a kidney transplant? → RECORD ON PAGE 4	1 ☐ No	2 ☐ Yes	
6g2.	Has he/she ever had kidney dialysis treatments? → RECORD ON PAGE 6	1 ☐ No	2 ☐ Yes	
6g3.	Is he/she on dialysis now?	1 ☐ No	2 ☐ Yes	
6g4.	Other (specify) _____	1 ☐ No	2 ☐ Yes	
6h.	Blood clot	1 ☐ No	2 ☐ Yes ↓	8 ☐ UNK
6h1.	Was this in the lung (pulmonary embolism)? → RECORD ON PAGE 6	1 ☐ No	2 ☐ Yes	
6h2.	Was this in the legs (deep vein thrombosis)? → RECORD ON PAGE 6	1 ☐ No	2 ☐ Yes	
6h3.	Other (specify) _____ → RECORD ON PAGE 6	1 ☐ No	2 ☐ Yes	
6i.	Cancer	1 ☐ No	2 ☐ Yes ↓	8 ☐ UNK
6i1.	Lung	1 ☐ No	2 ☐ Yes	
6i2.	Breast	1 ☐ No	2 ☐ Yes	
6i3.	Blood/lymph glands	1 ☐ No	2 ☐ Yes	
6i4.	Melanoma	1 ☐ No	2 ☐ Yes	
6i5.	Skin (NOT melanoma)	1 ☐ No	2 ☐ Yes	
6i6.	Colon	1 ☐ No	2 ☐ Yes	
6i7.	Prostate	1 ☐ No	2 ☐ Yes	
6i8.	Other (specify) _____	1 ☐ No	2 ☐ Yes	

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PROXY FOLLOW-UP QUESTIONNAIRE
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We would like to know about medications [NAME] is currently taking.

7. Does [NAME] currently take medication prescribed by a doctor…?

7a.	To lower his/her blood pressure	1 ☐ No	2 ☐ Yes	8 ☐ Don't know
7b.	To lower his/her blood cholesterol	1 ☐ No	2 ☐ Yes	8 ☐ Don't know
7c.	For treatment of diabetes or high blood sugar	1 ☐ No	2 ☐ Yes	8 ☐ Don't know

If DO NOT have hospitalizations or procedures to record → **END OF QUESTIONNAIRE**
OR
If have hospitalizations/procedures to record → **GO TO QUESTION 8 and/or QUESTION 9**

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PROXY FOLLOW-UP QUESTIONNAIRE
CARDIA 324-Month Follow-Up Period

INTERVIEWER READ TO PROXY:

Collecting medical records for hospitalizations and procedures is a very important part of the CARDIA Study. The medical records are kept confidential and are stored in locked facilities. Thank you for assisting CARDIA and efforts to advance scientific knowledge in the area of cardiovascular health.

HOSPITALIZATIONS

8. May we have your permission to obtain and review [NAME's] medical records from the hospitalization(s) listed below?

1 ☐ No
2 ☐ Yes →

8a. Is [NAME] able to sign a Medical Records Release Form?
2 ☐ Yes → Mail Medical Records Release Form to Participant
1 ☐ No

8a1. Do you have power of attorney for [NAME]?
2 ☐ Yes → Mail Medical Records Release Form to Proxy
1 ☐ No

8a1a. Does someone else have power of attorney for [NAME]?
2 ☐ Yes → Mail Medical Records Release Form to Power of Attorney
1 ☐ No

Hospitalization 1

Illness or reason: _____

Hospital name: _____

Street address: _____

_____

City State Zip Code

Date of admission: ___ ___/___ ___/___ ___ ___ ___

After this hospitalization, was [NAME]…?
1 ☐ Discharged home
2 ☐ Transferred to a nursing home or rehabilitation hospital (inpatient facility)
3 ☐ Transferred to another acute care hospital

FOR CLINIC STAFF ONLY

CARDIA CODES: 1. ☐☐ 2. ☐☐ 3. ☐☐ CASE NO.: ☐☐☐☐☐ 3 2 4 0 1 H

Hospitalization 2

Illness or reason: _____

Hospital name: _____

Street address: _____

_____

City _____ State _____ Zip Code

Date of admission: ___ ___/___ ___/___ ___ ___ ___

After this hospitalization, was [NAME]…?

1 ☐ Discharged home
2 ☐ Transferred to a nursing home or rehabilitation hospital (inpatient facility)
3 ☐ Transferred to another acute care hospital

FOR CLINIC STAFF ONLY

CARDIA CODES: 1. ☐☐ 2. ☐☐ 3. ☐☐ CASE NO.: ☐☐☐☐☐ 3 2 4 0 2 H

Hospitalization 3

Illness or reason: _____

Hospital name: _____

Street address: _____

_____

City _____ State _____ Zip Code

Date of admission: ___ ___/___ ___/___ ___ ___ ___

After this hospitalization, was [NAME]…?

1 ☐ Discharged home
2 ☐ Transferred to a nursing home or rehabilitation hospital (inpatient facility)
3 ☐ Transferred to another acute care hospital

FOR CLINIC STAFF ONLY

CARDIA CODES: 1. ☐☐ 2. ☐☐ 3. ☐☐ CASE NO.: ☐☐☐☐☐ 3 2 4 0 3 H

☐ **Check here if more than three procedures are reported and use supplemental form**

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PROXY FOLLOW-UP QUESTIONNAIRE
CARDIA 324-Month Follow-Up Period

CORONARY ANGIOGRAM, HEART CATHETERIZATIONS, OUTPATIENT PROCEDURES TO OPEN A BLOCKED ARTERY OR ARTERIES, WEIGHT LOSS SURGERY, BLOOD CLOTS, OR KIDNEY DIALYSIS

9. May we have your permission to obtain and review [NAME's] medical records from the procedures(s) listed below?

Procedure 1 **FOR CLINIC STAFF ONLY** CASE NO.: | | | | | | 3 | 2 | 4 | 0 | 1 | P |

Procedure type:
Facility name:
Street address:
City State Zip Code
Date of procedure: ___ ___/___ ___/___ ___ ___ ___

Procedure 2 **FOR CLINIC STAFF ONLY** CASE NO.: | | | | | | 3 | 2 | 4 | 0 | 2 | P |

Procedure type:
Facility name:
Street address:
City State Zip Code
Date of procedure: ___ ___/___ ___/___ ___ ___ ___

Procedure 3 **FOR CLINIC STAFF ONLY** CASE NO.: | | | | | | 3 | 2 | 4 | 0 | 3 | P |

Procedure type:
Facility name:
Street address:
City State Zip Code
Date of procedure: ___ ___/___ ___/___ ___ ___ ___

☐ **Check here if more than three procedures are reported and use supplemental form**

Appendix 15

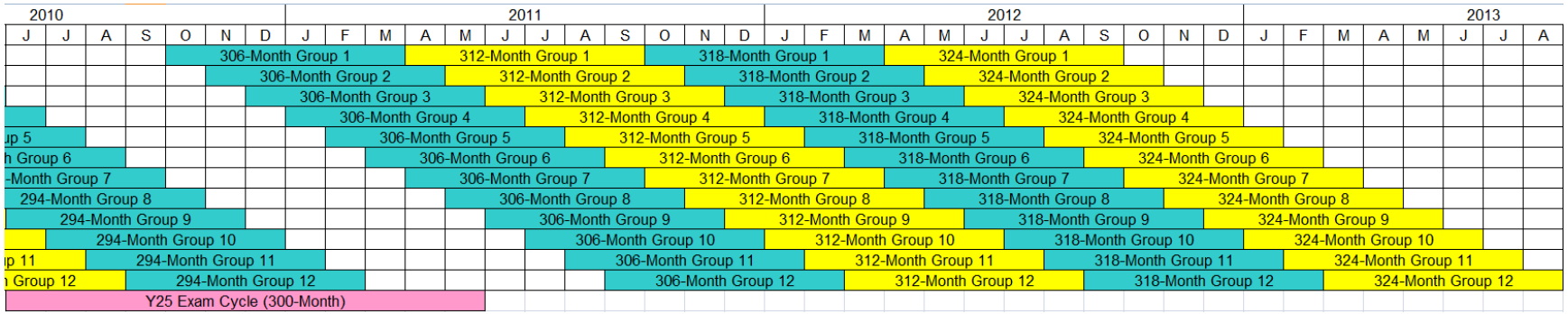
Protected Health Information for CARDIA Participants and Next of Kin in ALL Medical Records

Information that Must be Marked Out*
Name (first, middle, last)
AKA (Also known as, alias)
Date of Birth
Social Security Number
Home Address
Home Phone Number
Cell Phone Number
E-mail Address
Fax Number
Driver License Number/Commercial Driver License Number
Account Number(s)
Medical Record Number
Dictation Number
Lab Number
Clinic Number
Patient Room Number
Information that Must be Available
Date of Death
Place of Death (if participant died in a medical facility)
Cause of Death
Race
Gender
Age
Height
Weight
Admission and Discharge Dates
Outpatient Procedure Date(s)

***use a grease pencil to de-identify all medical records**

Appendix 16

CARDIA Follow-up Windows (Currently Open)



Target Month By Group:	
Group 1	June
Group 2	July
Group 3	August
Group 4	September
Group 5	October
Group 6	November
Group 7	December
Group 8	January
Group 9	February
Group 10	March
Group 11	April
Group 12	May

exam window

annual contact window

mid-year contact window

Appendix 17

Tracking Log for Destroyed Medical Records

N	ID	Admission date	Discharge date	Admission number	Date of adjudication	Adjudication results	Date shredded	Tech ID
1								
2								
3								
4								