3. EVENT INVESTIGATION

For hospitalized MI, event investigation entails review of the hospital record. Investigation of fatal CHD includes review of the death certificate and hospital record where available, and, for out-of-hospital deaths in Forsyth County, Jackson, and Minneapolis, physician questionnaires, interviews with next-of-kin and collection of other information. In Washington County, the medical examiner adds relevant questions to his routine inquiry but other out-of-hospital investigations are prohibited.

Procedures for the identification and investigation of hospitalized and fatal events in members of the ARIC cohort differ from community surveillance procedures at certain stages and are described in detail in Manual 2, Section 3. In the following paragraphs, general differences between surveillance and the investigation of cohort events are noted. References to specific procedures within Manual 2, Section 3 are identified where appropriate.

3.1 Procedures for Fatal CHD

The Death Certificate (DTH) Form and the Surveillance Event Eligibility (SEL) Form are completed for all eligible fatal events. A worksheet, the Surveillance Event Investigation Summary (SEI) Form, is used locally to monitor completion of investigation forms. One or more of the following data forms may be completed: Hospital Record Abstraction (HRA) Form, Stroke (STR) Form (for cohort members only), Informant Interview (IFI) Form, Physician Questionnaire (PHQ), and the Coroner/Medical Examiner Report (COR) Form. Autopsy reports for cohort members are copied. All forms and instructions are located in Appendix II.

For fatal events meeting ARIC eligibility criteria and sampling fractions, the Surveillance Event Eligibility form and the Death Certificate form are completed. Data from the Death Certificate form are entered into a computerized data base locally at each field center.

Some proportion of fatal events, either in-hospital or out-of-hospital, are coroner/medical examiner cases. This means that the county coroner or state medical examiner has performed an investigation of the circumstances of death in order to ascertain that the causes were natural. In this case, the coroner/medical examiner signs the death certificate. In general, the coroner/medical examiner takes cases of unexpected death where no physician was in attendance during the 24 hours prior to death. During his investigation, the coroner/medical examiner may or may not perform an autopsy. Any death where a legal question is likely to arise (e.g., after surgery, during an automobile accident, etc.) will probably be a coroner/medical examiner case. If the death is certified by a coroner or medical
examiner, the Coroner/Medical Examiner Report Form is completed, the data entered into the database at the field center, and later transferred to the Coordinating Center.

Medical Examiner and coroner reports are generally stored in their offices. The entirety of the documents generally require full review in order to complete the Coroner/Medical Examiner Report Form. Whatever can be retrieved from the records of these inquiries may be used to answer questions on the Coroner/Medical Examiner Form whether the document is called a report, an investigation, findings, or a summary.

Procedures for the investigation of fatal events in cohort members are described in Manual 2, Section 3.2.1. Briefly, a Cohort Eligibility Form and Death Certificate Form are completed for a fatal event occurring in a cohort member. A Coroner's Form is completed if the death is certified by a coroner/medical examiner, and the autopsy report copied if an autopsy is performed.

3.1.1 In-Hospital CHD Deaths

In-hospital deaths, which include deaths on the wards, in the ICU, CCU or operating room, may be identified by screening either the hospital discharges or the death certificates. Both the Hospital Record Abstraction Form (HRA, appendix A-II) and the Death Certificate Form are completed if the in-hospital death is eligible for study either as a hospitalized event (according to the discharge codes and sampling fractions specified in Section 2.2.2) or as a fatal event (according to the cause of death codes and sampling fractions specified in Section 2.3.1).

If the in-hospital death is initially identified from the death index, the hospital may occasionally lie outside the catchment area for the ARIC community. In this case, this fact is recorded on the Death Certificate Form and no attempt is made to obtain the hospital record.

Persons who upon record abstraction are found to have been admitted without vital signs are treated as out-of-hospital deaths (as defined in Section 3.1.2). Only the administrative data of the Hospital Record Abstraction Form are recorded in such cases. If the death is first identified from the death index and the death certificate indicates "dead on arrival", an attempt is made to find the hospital record to verify this information.
If the hospital record indicates that the person was transferred within the study area directly from another acute care hospital, the record for the other hospitalization is found and abstracted onto another Hospital Record Abstraction Form, provided the hospital discharge index contains an eligible ICD-9 discharge code regardless of day of discharge.

3.1.2 Out-of-Hospital CHD Deaths

CHD deaths occurring outside of regular acute care hospitals are categorized as "out-of-hospital CHD deaths". This includes deaths in nursing homes and other chronic care facilities. It also includes persons dead on arrival at acute care hospitals, dying in outpatient departments or emergency rooms, or admitted without vital signs. For purposes of defining out-of-hospital death, "no vital signs" means no pulse rate or no systolic blood pressure. A person admitted on a respirator who never had a pulse rate or a systolic blood pressure off the respirator is also considered an out-of-hospital death.

For out-of-hospital deaths in centers other than Washington County, information is sought from the decedent's family and physician(s) within 6 months after death. Prior to contacting the informant or the physician, it is ascertained whether the deceased was a member of the ARIC cohort. If the deceased was a cohort member, the cohort procedures for investigating deaths described in Manual 2, Section 3 are followed instead of the community surveillance procedures.

The family member is contacted for an interview, the physician is sent a questionnaire. Whenever possible, the informant is the spouse or another family member of the decedent. Also, the informant may be someone else who witnessed the death. Some death certificates contain the names of the spouse and a witness.

First an attempt is made to contact and interview the spouse or a first-degree relative (i.e., son, daughter, or sibling) of the decedent, or someone else who lived with the decedent. If another person witnessed the death, this person is interviewed as well. Using name and address information from the death certificate, an attempt is made to find the informant's telephone number in either the regular or the reverse ("crisscross") telephone directory. If the telephone number is available, a Format 1 letter (Appendix III) is sent.

If a telephone number cannot be found, a Format 2 letter (Appendix III) is sent asking the informant to return a telephone number on an enclosed form in a self-addressed, stamped envelope (Format 3: Appendix III) to the Surveillance Supervisor at the Field Center. These letters include a request to the U.S. Post Office for address correction and are sent with both the interviewer and Field Center Principal Investigator's signatures.
After enough time for the Format 1 letter to arrive or upon receipt of a reply form, the interview is conducted over the telephone, or if necessary, in person using the Informant Interview Form. If a Format 2 letter is sent and no reply is received in two weeks, another such letter is sent by registered mail. If no reply is received, a Format 4 letter (Appendix III) is sent to next-door neighbor(s) (identified through the reverse telephone directory) to request information on the whereabouts of the potential informants. A reply is requested on a self-addressed, stamped postcard (Format 5: Appendix III) to the Surveillance Supervisor at the Field Center. Format 2 and Format 4 letters are also sent when a telephone number is initially available, but attempts at telephone contacts with informants are unsuccessful. If no reply is received from the neighbors, no further effort is needed.

When the death is witnessed by someone other than a member of the decedent's family, both a family member and the witness are interviewed. In such a case, the information from both interviews are recorded on separate Informant Interview Forms. Up to three (the three best) Informant Interview Forms may be completed for a given event.

Information is sought from physicians by sending the Physician Questionnaire. One questionnaire is sent to the physician who signed the death certificate, if he/she is not the medical examiner. From the informant interview, an attempt is made to identify the decedent's usual physician and/or a physician who attended the decedent for heart disease during the four weeks prior to death. A questionnaire is sent to these physicians (if any, and if different from the one signing the death certificate). Sample cover letters are provided in Appendix III for each of these physician contacts (Formats 7 and 8, respectively). Up to two (the two best) Physician Questionnaires may be entered into the ARIC database for a given event.

If there is no response after four weeks of the initial mailing to a physician, a follow-up letter and another copy of the Physician Questionnaire are sent. If there is no response after eight weeks of the initial mailing, the physician is contacted by telephone. On occasion, prior to returning the Physician Questionnaire (or prior to answering questions over the telephone), the physician requests a release form signed by the informant, which can be modeled after the Release-of-Information Form for physicians (Format 9: Appendix III) or for nursing homes (Format 6: Appendix III).

If the patient had no physician or no knowledgeable physician can be identified, and the patient's medical record or emergency room record is accessible, then it is permissible for an ARIC abstractor to complete the physician questionnaire using the record.
If the fatal event was a coroner's or medical examiner's case, his/her report is abstracted onto the Coroner Form. The medical examiner/coroner may require a Release of Information Form. If the decedent died in a nursing home, nursing home personnel are asked to complete a Physician Questionnaire based on the nursing home record. Centers may offer to assist with abstraction if this would be helpful. The nursing home may require the family informant to provide a Release-of-Information Form (Format 6, Appendix III).

If information provided by the informants or physicians indicates that a person who died out-of-hospital was admitted to a catchment area hospitalized within 28 days prior to death for MI or heart surgery, an attempt is made to locate the hospital record. If the discharge diagnoses include an ARIC screening code, regardless of day of discharge, the chart is abstracted onto the Hospital Record Abstraction Form.

If neither an Informant Interview (IFI) nor a Physician Questionnaire (PHQ) form can be completed, then the Hospital Discharge Indices from eligible hospitals are checked for the period covering 28 days before death. If an ICD code eligible hospitalization is found, a HRA is abstracted, regardless of discharge day.

Procedures for the investigation of out-of-hospital deaths occurring in cohort members are described in Manual 2, Section 3.2.1.2. Procedures for contacting informants are similar to those described above, except that the letters refer to the decedent's participation in the ARIC Study (letters are in Manual 2, Appendix VII). A copy of the Release-of-Information forms signed by deceased accompany the Physician Questionnaire.

3.2 Procedures for Hospitalized MI

The Hospital Record Abstraction Form is used to abstract events meeting ARIC eligibility criteria for age, residence, date, hospital discharge code and sampling fraction (Section 2.2.2). If a patient was discharged alive without an ICD9 410 or 411 discharge code and with no ECGs taken and no cardiac enzymes measured, only the administrative information on the Hospital Record Abstraction Form is completed. Otherwise, the entire form is completed. There are a few cases in which the ICD9 code is recorded incorrectly, so that a code on the diagnostic index meets the ARIC criteria but none of the diagnoses recorded on the discharge summary of the medical record meet the study criteria. The HRA Form is still completed in such a case.

Prior to abstracting a record from a hospital for ARIC, information is collected on the normal ranges used for each of the cardiac enzymes abstracted. Many hospitals report use of more than one upper limit of normal for a particular enzyme, for example, when a different laboratory is used for determinations at night or on weekends.
If an eligible hospital record indicates that the patient was transferred directly from another acute care hospital in the catchment area, or that the patient upon discharge is being transferred directly to another acute care hospital in the catchment area, the record for the other hospitalization is found and abstracted if it has ARIC screening codes regardless of day of discharge.

Procedures for investigation of hospitalized events with a discharge diagnosis code for MI or stroke occurring in cohort members are described in Manual 2, Section 3.2.2. Selection codes are listed in Section 3.1.1.2. A Hospital Record Abstraction Form and/or Stroke Form may be used.

3.3 Summary of CHD Event Investigations

The following scheme summarizes the forms completed for eligible surveillance events:

1. Out-of-hospital CHD death, as defined in Section 3.1.2
   a) Death Certificate Form, Surveillance Event Eligibility Form
   b) Up to two Physician Questionnaires and three Informant Interview Forms
   c) Coroner Form on all coroner/medical examiner's cases and Hospital Record Abstraction Form on cases admitted to a catchment area hospital in past 28 days with heart conditions meeting ARIC screening codes regardless of day of discharge.

2. *Hospital CHD deaths, no vital signs in-hospital
   a) Surveillance Event Eligibility Form
   b) First part of Hospital Record Abstraction Form, then investigate as 1, above.

3. *Hospital CHD death, vital signs sometime in hospital
   a) Surveillance Event Eligibility Form, Death Certificate Form, Hospital Record Abstraction Form.

4. *Hospitalized CHD case, discharged alive
   a) Surveillance Event Eligibility Form, Hospital Record Abstraction Form.

*If a patient also transferred to or from a catchment area hospital, complete the additional Hospital Record Abstraction forms.
3.4 Correction of Erroneous Event Investigation Procedures

A fatal or hospitalized CHD event may be identified by surveillance procedures (death certificates or hospital discharge indices) and investigated as a surveillance event, then discovered at a later time to have occurred in a cohort member. In the case of a hospitalized event, a second Hospital Record Abstraction Form is completed independently by a second abstractor (see Section 8.1). Twelve-lead ECGs have to be copied and sent to the Minnesota ECG Reading Center for coding. In addition, certain surveillance forms have to be replaced by cohort forms, certain items on other forms changed, and possibly additional forms appropriate for cohort members completed. Specifically, the Cohort Eligibility Form must replace the Surveillance Eligibility Form. Additional forms required for cohort members have to be indicated on the Death Certificate Form if the death occurred in an out-of-catchment area hospital. The Physician Questionnaire and Informant Interview Form remain unchanged.

If an eligible event has been investigated erroneously as a cohort event, the Cohort Eligibility Form must be deleted and replaced by the Surveillance Eligibility Form. If the event investigated was a stroke, the Stroke Form must be deleted.