I. GENERAL INSTRUCTIONS

The Report and Referral Form (REF) is an internal document completed during review of results received from the Central Laboratory and Reading Centers. The JHS clinician must be certified with working knowledge of results reporting and alert procedures. S/he should be familiar with the data entry procedures for electronic form versions and understand the document titled “General Instructions for Completing Paper Forms” prior to completing this form. JHS ID Number, Contact Year, and Name should be completed as described in that document.

The purpose of this form is to keep a record of notifications to JHS participants of alert values and/or study results which led to a medical referral. These alert values and referrals are those defined in the study protocol and are standardized throughout the JHS study. Changing a referral value or alert action requires a revision of the JHS study protocol, and approval by the Steering Committee. However, referrals of JHS study participants to their provider of medical care occur also for conditions not contemplated in the study protocol, and based on the clinical judgment of the JHS nurse clinician, after review by the JHS physician or medical director. These types of referrals are also recorded on this form, under "other conditions."

Alert values reported, result in expedited notification to the participant and the provider of care, and these values/actions are recorded on this form. If any emergent or urgent referrals were made at the time of the examination, these too are recorded on this form. Once the majority of the reports and study results have been obtained from the local laboratory, the central laboratory and the central reading agencies (ECG, ultrasound), a final report to the participant and provider of medical care is printed, and mailed. A summary of the medical alerts and referrals which have resulted from the baseline clinic visit is collected on the REF. The optimal time to fill out and/or key in the REF is once the majority of the results have been received at the Exam Center and a final report to the study participant is prepared.

The daily management and tracking of alert values and participant reports as they are received is done on the Alert/Referral Log (ALT). Once all reports and study results have been obtained from the local laboratory, the central laboratory and the central reading agencies (ECG, ultrasound, echo and pulmonary function) a summary of the medical alerts and referrals which have resulted from a participant clinic visit is collected on the REF. The optimal time to fill out and/or key in the REF is once all results have been received at the Exam Center and a
final report to the study participant is being prepared. At this time, all the information needed to record whether an alert and/or medical referral has been made is available, and can be recorded in Section A for the Baseline Cohort Examination Visit.

At the time of preparing the final report on study results to the participant, the possible alerts and referrals for the current visit are reviewed in order to select the appropriate letter and report to the participant.

A response category (Delayed) has been included in the response categories for ultrasound studies on the REF to permit the provisional documentation of a delay in its receipt when all other study results have been received and a participant results report would routinely be prepared. This information in turn triggers the inclusion of the paragraph in the results report which informs participants that there has been a delay in the receipt of their ultrasound results and they will be notified only if there is an abnormal finding.

In addition to tracking alerts and referrals, the REF is used to record medical and safety events. Occasionally a participant may report the onset of symptoms while at the Exam Center, or other medical or safety events may occur (such as falling). These are annotated on the REF to allow tracking by the data entry system (DES). The event is recorded in the note log for Item 1 whenever a participant experiences a medical or safety event at the Exam Center, or contacts the Exam Center to report a symptom occurring shortly after the clinic examination.

II. SPECIFIC INSTRUCTIONS

A. Baseline Visit Clinic Examination

1. Item 1 is a summary of Baseline Visit Clinic Examination referrals and/or alerts. Record YES if either an alert value or a medical referral has been given or sent to the participant and/or sent to his/her provider of medical care. No distinction is made on this form between an alert or medical referral, the time at which it was made (i.e., during the Medical Data Review or in a subsequent results report), nor is any difference made between the degree of urgency indicated on the medical referral. "At this time" refers to the time when the Exam Center clinician has determined that all study results have been received for the participant, from all laboratories and central reading agencies. If no routine reporting of results is expected from a central reading agency, "at this time" implies that sufficient time has elapsed for the receipt of any possible alert notifications from that agency for this participant.

If any referral and/or alert notifications were made for the Baseline Visit, or are being made at this time, record YES, and continue with Item 2. Otherwise, record NO and complete the administrative items (Items 3-7) in
Section B if the participant is a prior ARIC study participant.

When medical or safety incidents occur, attach a note log to Item 1. In this note log, provide as much detail and clarifying information as possible. If you are uncertain as to whether or not a particular circumstance should be recorded as a medical or safety issue, enter the information. Please note that this process is independent of the Report and Referral system, and one should err on the side of completeness. The note log can be attached to Item 1 regardless of whether the response to this item is "Yes" or "No." Since item 1 on REF can trigger a skip, care should be taken to verify that the note log is entered for Item 1, and not another item.

2-11 In recording the type of referral and/or alert in items 2 through 11, answer YES or NO for every type of report. For this purpose, consider an alert or medical referral as any notification in a letter, phone call, or report calling the participant's or his/her health care provider's attention to a value measured in the clinic, in a local laboratory, or in a central reading agency/laboratory, and identifying it as a value which is either outside of the expected range or requiring follow-up and/or treatment. Typically, medical referrals by the JHS suggest that a measurement should be repeated (within a recommended period of time) or brought to the attention of the participant's health care provider for verification and/or follow-up. This constitutes a medical referral to be recorded on this form, for the specific type of study result listed under 2 through 11. Item 11 (other conditions) serves to record any examination or laboratory findings not contemplated in the study protocol referral guidelines, which prompted a notification of the participant and/or her/his health care provider. Specifically included under Item 11 are referrals due to uterine bleeding.

B. Administrative Information

13. Enter the date on which this referral form is being completed.

14. Record "C" if the form was completed on the computerized data entry system, or "P" if the paper form was used. If the form was completed partially on paper and partially on the computer, code as "C."

15. Enter the three-digit JHS code of the person at the clinic completing this in the boxes provided.

16. Record the result of the participant's baseline visit ultrasound scan ("N" for normal, "A" for abnormal) as soon as the report is received from the Ultrasound Reading Center. Record "U" when no scan was performed, or "D" for delayed receipt if the ultrasound reading is not available when the REF form is keyed and the results report is generated. The outcome status of the ultrasound study (Item 16), and if the study is abnormal, the
referral/alert status (Item 1) and the referral indicator (Item 9) are revised in the DES update mode when the result is received from the Ultrasound Reading Center.