OMB#: 0925-0281
Exp 3/31/2014

ALERT TRACKING FORM

ID NUMBER: | | | | | | | |

FORM CODE: A T F

DATE: 06/01/2011
Version 1.0

Instructions: *The purpose of this form is to acknowledge receipt of and document resolution of local and central alerts that occur as a result of the exam visit. Listings of these alerts are available in the Alert and Expedited Notification Report in the DMS. This form is completed if an urgent or immediate alert is listed in the Report for the participant. For all alerts (both local and reading center/central), fill in the date the field center was notified of the alert, the date the participant was contacted and the staff code of the person who made the contact.*

Reason for Alert Report	a. Date field center alerted	b. Date participant notified	c. Staff Code
1. Seated blood pressure			
2. Triglyceride			
3. Fasting glucose			
4. Creatinine or eGFR			
5. Albumin:creatinine ratio			
6. White blood count			
7. Hemoglobin			
8. Platelet count			
9. Retinal photography			
10. MRI - local			
11. Echocardiography - local			
12. Echocardiography – central			
13. ECG - local			
14. Abdominal aorta diameter scan - local			
15. Abdominal aorta diameter scan - central			

Reason for Alert Report	a. Date field center alerted	b. Date participant notified	c. Staff Code
16. CES-D – depression			

INSTRUCTIONS FOR THE ALERT TRACKING FORM (ATF)

I. General Instructions

The report tracking form is designed to track when and how referrals were made for medical care. Referrals can occur while the participant is at the field center or when a central lab or reading center (e.g., the MRI Reading Center) notifies field center staff of an immediate or urgent alert or when field center staff run the DMS alerts report. The DMS alerts report should be run once a day to ensure that all alerts are processed and resolved in a timely manner; to run the report, follow the instructions in the DMS MOP or provided by Coordinating Center staff.

Field center staff are responsible for notifying the participant and, as determined from the participant's informed consent, the participant's physician. (Notification of alerts requires that the field center staff member review the instructions for reporting study results provided by the participant in his/her informed consent.) The level of the alert determines the length of time allowed to notify the participant and/or their physician – specific timelines for specific alerts are given in MOP 2. If the participant and/or physician could not be contacted within the time frame specified for an alert value, the Field Center PI must be notified on the day of expiration of that notification time window.

Some study participants do not identify a personal physician or another provider of medical care. Field centers keep a list of local physicians whom participants can call. The local medical society is typically a good source for such a list and one that is acceptable to practitioners in the community.

This form may be accessed more than once, since alert value information may be obtained from the central laboratories or the study reading centers at different times. Similarly, it is possible that notification may take place on a different date than the date of receipt of the alert notification at the field center. Consequently, field center staff should determine whether a copy of this form previously has been entered in the DMS before attempting to enter a new form.

The study participant does not need to be present when this form is completed. The information required is gathered at the time of the study visit or after laboratory tests have been completed or the results of other components processed by reading centers.

Because more than one technician may be involved in filling out the form and performing the referral, only the staff person who implemented the referral enters his/her code number in the boxes provided under column (c), Items 1 through 16.

Alerts will continue to appear in the DMS Alerts Report until the participant and/or physician is notified and the notification details entered in this form. Consequently, field center staff should make every effort to notify participants and/or physicians as soon as possible.

Occasionally a participant who has both an original visit and a QC repeat visit will have an alert at either or both visits. If an alert from the same source e.g. blood pressure appears at both visits it is at field center staff's discretion (after consultation with the field center PI) whether to re-notify the participant. Alert and resolution information for an alert from the original visit should be entered using the original participant ID and alert and resolution information for an alert from the repeat visit should be entered using the repeat visit ID. If the alert appears at both visits and is from the same source and the participant is re-notified then the most recent contact date should be entered for the date the participant was notified. If the alert appears at both visits and is from the same source and the participant is <u>not</u> re-notified field center staff should enter the date the alert was received as the date the participant was contacted (using the repeat

visit ID) and add a notelog to document that the participant was previously notified and record the original notification date in the notelog.

II. Detailed Instructions for Each Item

For all referrals: Look up the informed consent to record the participant's instructions for releasing results to the physician or ophthalmologist. This is documented in Item 2 of the Informed Consent Tracking Form (ICT). Notifications of the results reported should be acted on exactly according the instructions of the participant as provided in the consent. Field center staff may include additional related information in the notification to the participant, if confirmed by the PI.

Items 1 – 16. For all expedited notifications, fill in the date the test result was received at the Field Center in column (a), the date the participant was notified in column (b) and the staff code number who implemented the notification (column (c)). Notifications are classified into "immediate" (requires action within hours or a week after the field center receives the notification) or "urgent" (requires action within a month) based on the report from the source agency or group. Manual 2 contains the "trigger value" levels, the classification of notifications (immediate, urgent), and other related information for all expedited notifications. Some exam components and procedures, such as retinal photography, have multiple expedited notifications which may be "triggered" for a single participant; in such cases, field center staff should notify the participant of all related notifications from a single source at the same time, or, if such is not possible, record the last date and method of notification used in the appropriate row and column.

Note: Expedited notifications reported by the Echocardiography or Abdominal Aorta Scan Reading Centers may have already been reported by the local specialist. Other expedited notifications may recur due to re-runs of lab specimens or re-analysis of other exam data. In such instances, the "Date Field Center Alerted" field may already be completed in the ATF. When this occurs, field center staff should go into the ATF, click on the ">>" next to the "Date Participant Notified" question for the appropriate Reading Center or Lab and enter a notelog documenting the previous date the participant was notified for the same expedited notification; the "Date Participant Notified" value should then be modified based on the current expedited notification information and the form then saved. This will indicate in the DMS that the alert has been resolved and will also document the prior processing of the alert.