HCHS/SOL V2-Report Tracking
RET- QxQ

General Instructions

This administrative form is used to document release of results for the participant and their health care provider (HCP). In addition, the form provides a place to record the contact information for that provider. The report tracking form (RET) is designed to track when and how referrals were made for medical care, and to track the final study results being sent to the participants. Referrals can occur while the participant is at the field center and following receipt by the field center of any study result requiring notification of the participant or his/her provider of primary care . The field center personnel may need to respond to a finding during the clinic visit (such as abnormal blood pressure) or to results received from a central lab or reading center according to the potential clinical or safety impact of the result.

Study results and findings are classified as routine reports to the study participant and/or his/her physician, or alert values that are notified promptly according to the time line for alert values specified in section 20 of 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.

Notification of results and also alert values requires that the field center technician review the instructions for reporting study results provided by the participant in his/her informed consent. These instructions are also to be recorded in Item 2 of the Informed Consent Tracking (ICT) Form. 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.

Q1. From the Informed Consent document, note permission for release of results.

Q1a. If partial release is granted, note the exceptions and circumstances.

Q1b. Record the contact information for the primary Health Care Provider.

Q2. For all expedited alert notifications, fill in the date the test result was received at the Field Center in column 1, the date the notification was made in column 2, the method used in column 3 and the staff code number who implemented the notification (column 4). Triggers for expedited notification are seated blood pressure, triglyceride, fasting glucose, creatinine, WBC counts, Hepatitis B or C tests, ECG, and sleep study according to the levels specified in section 24 of Manual 2. Field center staff may judge that additional information a study participant requires notification, if confirmed by the PI.

Q3. Participants may phone in requesting a summary of the results. Field center staff can act on a request from a participant by printing a partial report if the results are still incomplete. The date on which an incomplete summary report is sent is recorded on the form. Note: only study participants can request access to their data/results; requests from third parties are not honored unless accompanied by a signed authorization from the study participant.

Q4. This field is used to record the date by which all results have been received and the final report is mailed (which would include previously mailed alert values). If it is not possible to obtain all results from a lab or reading center by 3 months after the exam visit, an incomplete report is prepared and mailed.