SOP#: PM-14	**Non-NIH Laboratory Sample Management in Clinical Research Trials**
Version #: 1.1	**Next Review Date: 11/2025**
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NCI Clinical Director Signature/ Effective Date:	James Gulley, M.D., Ph.D. Digitally signed by James Gulley, M.D., Ph.D. Date: 2024.07.15 10:31:40 -04'00'

POLICY

A Decentralized Clinical Trial (DCT) refers to a clinical trial where some or all trial-related activities occur at locations external to the main clinical research site. These trial-related activities may take place at the homes of trial participants or in local health care facilities that are convenient for trial participants.

Currently, clinical trials may already include decentralized elements that are not conducted at main clinical research sites. For example, laboratory tests are often conducted by clinical laboratory facilities at locations more convenient to the participant versus the main research site.

All clinical laboratory testing performed on humans in the United States, including clinical labs required on a protocol, is subject to Clinical Laboratory Improvement Amendment (CLIA) regulations which requires laboratories to be certified. CLIA regulations ensure the accuracy, reliability, and timeliness of participant test results regardless of where the test is performed. CLIA Certificates (or appropriate state/country equivalent) for all laboratory sites, including external sites, must be maintained in the protocol's Investigator Site File [(ISF) or regulatory file].

Technicians and other personnel working for external clinical laboratory facilities should not be added to the delegation log. If the study is regulated by the FDA, all external laboratory locations must be listed on Form FDA 1572, Section 4, or the investigational plan for device studies under an investigational device exemption (IDE). For clinical laboratory faculties outside of the U.S or its territories, please consult with the sponsor. Individual laboratory personnel do not need to be listed on the Form 1572.

The Principal Investigator must ensure that:

- Protocol allows for required labs be done at an external site.
- Clinical laboratory results are promptly received and reviewed in a timely manner.
- The clinical significance of abnormal laboratory results is documented in the medical record.
- Any adverse events (AE), serious adverse events (SAE) and/or adverse events of special interest (AESI) are promptly identified, managed and reported as per protocol requirements.
- External laboratory results are available in the participant's medical record.
- Case report forms include the name of the external laboratory, date specimens were collected, laboratory results, reference ranges, and units of measure (UOM).

PURPOSE

To establish processes utilized when protocol-directed clinical laboratory samples are collected at a site other than the main research site (e.g., NIH Clinical Center), including how to order, reviewing results, documenting in the medical record, and managing the data.

RESOURCES

- FDA draft guidance document (May 2023) *Decentralized Clinical Trials for Drugs, Biological Products, and Devices*
- Clinical Laboratory Improvement Amendments (CLIA) FDA website
- Search for a CLIA Laboratory (select "CLIA Laboratory Lookup" link on left upper section of page)

PROCEDURE:

STEP 1: Planning and Documentation for Outside Laboratory Work by Research Team

- Ask participant where they will go for labs. Note the name of the lab and the laboratory's phone and fax numbers.
- Clinical Research Coordinator (CRC) will confirm that laboratory is CLIA certified or has appropriate state/country equivalent.
    - Search for a CLIA Laboratory and send CLIA certificate to PSO Manager for uploading into the ISF.
    - If not CLIA certified, assist participant with finding a laboratory that is CLIA certified and convenient for them.
- Instruct participant:
    - When labs are to be drawn keeping in mind protocol required timepoints and any "window."
    - To inform a member of the research team what day they will be having the labs drawn.
- Include fax number on laboratory requisition to return results to research team.
- Ensure participant has order/requisition and understands what is required of them – document participant education for outside lab work in CRIS.

Note: Please refer to SOP ADCR-14 *Authorization for Outside Medical Services (AOMS) for Research Participants* for information about payment for lab drawn at an outside laboratory, if applicable.

STEP 2: Reviewing Results

2a: When results have been returned to the research team

- Provider delegated to review the lab results per delegation log reviews results as soon as possible but no later than 24 hours of receipt. Please see SOP PM-3 *Clinical Research Documentation* for information about documentation in CRIS.

Reminders:

- If abnormal lab is potentially an AE/SAE/AESI, provider must discuss event with PI/PI designee and plan for any treatment if needed.
- If an SAE/AESI is identified, the research team must report to sponsor in timeframe outlined in protocol.

2b: If results are not returned within one business day from when the participant indicated they would be drawn:

- Contact the participant to confirm if labs were done, when and where.
  - If labs were not done as required, instruct participant to obtain labs as soon as possible.
  - If drawn, contact the lab directly and request results.
- Once results are returned, see Step 2a above.

Reminder*:* Document in CRIS all conversations with participant and/or lab.

STEP 3: Uploaded Lab Results to CRIS

- See SOP PM-4 *Submitting Outside Record for Entry into CRIS*

STEP 4: Data Entry of Laboratory Results

- Prior to data entry, Data Manager (DM) or CRC will submit a ticket requesting to add Laboratory Name to the database Lab CRF picklist if not already available.
- DM will abstract lab data from outside lab reports once they are uploaded in CRIS.
- DM will enter the name of the laboratory, date drawn, lab result, reference range, and unit of measure (UOM) for labs that are required per the protocol and in accordance with the applicable database manual.
- CRC will perform a quality control check (e.g., verify) of the data entry values against source document from outside laboratory report to ensure accuracy.

STEP 5: Regulatory

- CRC will send CLIA certificate and reference ranges to PSO Manager for uploading into the ISF.

  Note: For reference ranges for external lab, CRC can remove Personally Identifiable Information (PII) about the patient from the lab results report.
- PSO Manager will update the FDA Form 1572, secure PI signature, send to sponsor and upload into the ISF.