Unit Procedure

Protocol Visit Set Up and Labeling

SOP No./WI No.: CTSI-CRC-PL-152

Department: Processing Laboratory

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Date	06 JAN 2017	6 Jan 2017	Jan 6, 2017

1. OBJECTIVE

This Standard Operating Procedure (SOP) describes the process for the set up and labeling of protocol specific study visits according to the requirements for studies at the Indiana Clinical and Translational Sciences Institute (CTSI) Clinical and Translational Support Laboratory (CTSL).

2. SCOPE

This SOP applies to all CTSL and Clinical Research Center (CRC) staff providing lab processing services including processing and aliquots. This procedure is intended to provide the basic procedure but does not over-ride protocol defined processing.

3. RESPONSIBILITIES

The clinical and lab staff are responsible for appropriately handling specimens in a safe and compliant manner.

4. DEFINITIONS

CRC: Clinical Research Center	CTSI: Clinical and Translational Sciences Institute
CTSL: Clinical and Translational Support Laboratory	ID: Identification
IUPUI: Indiana University Purdue University Indianapolis	MRN: Medical Record Number
PL: Processing Lab	SOP: Standard Operating Procedure

5. ASSOCIATED DOCUMENTS

5.1. CTSI-CRC-QA-003 Document Control and Management
5.2. CTSI-CRC-CLN-030 Handling of SOP Deviations
5.3. CTSI-CRC-PL-121 General Safety
5.4. CTSI-CRC-PL-151 Management of Requests for Sample Processing Support

6. PROCEDURE

6.1. Protocol collection set up is performed at least one day prior to the scheduled visit(s) when visits are prescheduled. In the instance that a visit is not known by the CTSL a full day in advance or kits are not supplied by study staff in time, set ups are performed as soon as possible.
6.2. Run a visit schedule report for the following workday (or day setups are being prepared for) from the CRC scheduling system (WebCamp) or equivalent.
6.2.1. Print the report and document the time the report was first run at the top.
6.2.2. Review report for study visits requiring CTSL support.

6.2.3. Mark each visit that does not require support by documenting no labs or by highlighting the visit to indicate no CTSL processing required.

6.3. Print the protocol specific form CTSI-CRC-PL-FM508 Lab Processing Sheet that corresponds with the scheduled protocol and visit that is on the schedule report and that requires CTSL processing.

6.3.1. Protocol specific CTSI-CRC-PL-FM508 Lab Processing Sheets is located on the O drive in the PCIR/Lab folder filed by each individual CRC protocol number.

6.3.2. Contact study personnel whenever visit identification is unavailable.

6.4. Set up collection kits per the protocol specific from CTSI-CRC-PL-FM508 Lab Processing Sheet and/or physician orders.

6.4.1. Resolve conflicts between orders and processing instructions by contacting study staff for clarification.

6.4.1.1. Document resolution on protocol specific form CTSI-CRC-PL-FM508 Lab Processing Sheet as appropriate.

6.4.2. Kits may be provided by study staff or by CTSL.

6.4.3. Contact study staff if a kit is not available.

6.4.4. Single time point collection tubes will be set up from left to right in the tube rack according to the order on the protocol specific form CTSI-CRC-PL-FM508 Lab Processing Sheet.

6.4.5. Multiple time point collection visits are organized in the tube rack according to the time of collection.

6.4.5.1. Each set of tubes collected at each time point are placed in the rack from front to back according to the order on the protocol specific form CTSI-CRC-PL-FM508 Lab Processing Sheet.

6.4.5.2. The first time point set of tubes is placed in the left side of the rack with each subsequent time point placed to the right according to the order on the protocol specific CTSI-CRC-PL-FM508 Lab Processing Sheet.

6.5. Print patient specific labels which must include at least two of the following: Patient name, MRN, protocol participant ID (PPI), date of birth and/or ICRC protocol number.

6.5.1. Place one label on each draw tube.

6.5.1.1. If the protocol requests that CTSL printed labels not be placed on the draw tubes, the tubes are still required to have two identifiers such as name, MRN, study specific ID number, protocol number, date of birth, etc.

6.5.2. Place one label on each page of the protocol specific form CTSI-CRC-PL-FM508 Lab Processing Sheet.

6.5.3. Place one label on the Kit QC Check sticker (Appendix A).

6.5.3.1. Complete Kit QC Check sticker with initials of technician who performed kit set up and the date of set up.

6.5.3.2. Place Kit QC Check sticker on rack with kit draws tubes.

6.5.4. If the visit has multiple collection time points, place one label on each page, as needed, of CTSI-CRC-PL-LG616 Multiple Collection Visit Specimen Receipt Log.

6.5.4.1. Complete log by indicating visit ID, date of visit, MCV number and time points expected based on the protocol specific CTSI-CRC-PL-FM508 Lab Processing Sheet.

6.5.4.2. Attach at least one additional label to the kit's tube rack for the nursing staff.

6.6. Prepare a copy of the CTSI-CRC-PL-LG615 Specimen Receipt Log for scheduled visits by copying data from a report pulled from the CRC scheduling system.

6.6.1. Add any other visits that are not on the CRC scheduling system report but CTSL has been informed of in advance.

6.6.2. If a visit on the log in copy of the visit schedule is a multiple collection visit, enter MCV- # on the visit's log entry line in the "Collection Time" box. (# assigned during setup and is only a reference for which tab the MCV sheet will be located in the log in binder for the visit day).

6.6.3. Document "Clinic Visit" in the comments box on each visit's log entry line for those visits not being conducted in the CRC.

6.7. Prepare a copy of the CTSI-CRC-PL-LG615 Specimen Receipt Log for unscheduled visits.

6.8. Check for late additions to the visit schedule as late in the day as possible.

6.8.1. Refer to steps 6.3 through 6.5 above to prepare for the late addition visits.

6.8.2. Document the time of the additional schedule checks on the original printed schedule from step 6.2.

6.9. Place the prepared CTSI-CRC-PL-LG615 Specimen Receipt Logs (scheduled and unscheduled) in the log in binder in preparation of the following day's work.

6.10. Place prepared CTSI-CRC-PL-LG616 Multiple Collection Visit Specimen Receipt Log(s) in the assigned numbered sections of the log in binder in preparation of the following day's work.

6.11. When set ups are complete, transport all collection tube racks to a designated drop-off area at the CRC.

6.12. Deliver any uncompleted collection kits to the CRC for overnight/weekend processing needs.

6.12.1. Review processing instructions with the nursing staff if non-standard processing is required for overnight or weekend processing.

6.12.2. Ensure all supplies such as storage bags/boxes, pipettes and/or cryovials are available for CRC staff to complete processing as required.

7. REFERENCES

None

8. APPENDICES

8.1. Appendix A: Kit QC Check Label Format.

9. AMENDMENT HISTORY

Date of Amendment:	04 Jan 2017
Amendment Request by:	Robert Orr
Change Control No, if applicable:	CTSI-CRC-PL-DC-2016-020
Details of Amendment:	Updated to footer file location; Updated 5.2 with corrected SOP; Updated multiple steps for clarity; Removed step 6.5 as color coding kits with tape is no longer required; Updated 6.6 with new process steps; Updated 6.12 to clarify responsibilities for overnight/weekend processing.

APPENDIX A: Kit QC Check Label Format

Set up Date: _____
Set up By: _____
Checked by: _____