

## Unit Procedure

### Management of Requests for Sample Processing Support

SOP No./WI No.: CTSI-CRC-PL-151

Department: Processing Laboratory


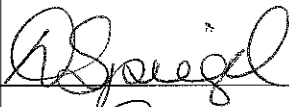
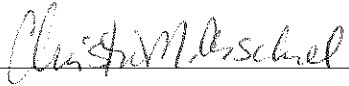
Version No.: 02

Effective Date: 25 Jan 2017

Supersedes: No.: CTSI-CRC-PL-151-01      Effective Date: 08 May 2014

Page No: 1 of 5

Review Period: 2 years

	Written by	Reviewed by	Approved by
Name	Robert Orr	Diana Spiegel	Christie Orschell
Job Title	CTSL Operations Manager	CRC Quality Assurance Manager	ATP Director
Signature			
Date	06 JAN 2017	6 Jan 2017	Jan 6, 2017



SOP/WI No.: CTSI-CRC-PL-151	Version 02
Title: Management of Requests for Sample Processing Support	Page 2 of 5

**1. OBJECTIVE**

This Standard Operating Procedure (SOP) establishes a process for gathering, documenting and applying protocol specific processing to be performed by the Clinical and Translational Support Laboratory (CTSL) at the Indiana Clinical and Translational Sciences Institute (CTSI).

**2. SCOPE**

- 2.1. This SOP applies to CTSL Personnel receiving, approving, and/or processing samples.
- 2.2. This SOP applies to CTSL Personnel managing the storage of samples within the Indiana CTSI Specimen Storage Facility (SSF) in support of investigator managed protocols.
- 2.3. The scope of this SOP is limited to sample support requests processed after the implementation date of this initial SOP version.

**3. RESPONSIBILITIES**

- 3.1. The lab staff is responsible for following IUPUI biosafety practices in relation to all samples.
- 3.2. The lab staff is responsible for appropriately handling specimens in a safe and compliant manner.
- 3.3. CTSL Management is responsible for supporting compliance with this SOP.

**4. DEFINITIONS**

CRC: Clinical Research Center	CTSI: Clinical and Translational Sciences Institute
CTSL: Clinical and Translational Support Laboratory	IUPUI: Indiana University Purdue University Indianapolis
PI: Principal Investigator	PL: Processing Lab
RSO: Radiation Safety Office	SOP: Standard Operating Procedure
SSF: Specimen Storage Facility	

**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-153 “Sample Receipt, Log-in and/Tracking”



SOP/WI No.: CTSI-CRC-PL-151	Version 02
Title: Management of Requests for Sample Processing Support	Page 3 of 5

**6. PROCEDURE**

6.1. New Protocol Requests

6.1.1. Complete the CTSI-CRC-PL-FM505 “Request for CTSL Sample Processing Support”.

6.1.1.1. All questions must be answered as yes or no to confirm requests.

6.1.1.2. Alternatively, CTSL personnel can collect and record all of the required information for initiating a new request and document as needed either on CTSI-CRC-PL-FM505 “Request for CTSL Sample Processing Support” or by retaining email correspondence detailing the request and filing them in a study specific folder, electronically and paper form.

6.1.2. CTSL Management reviews request for completeness.

6.1.3. Refer all requests to CTSL Director, or designee, for final approval, if applicable.

6.1.4. Obtain final approval of completed request from the PI and/or coordinator of study. Alternatively, payment for services rendered may be considered as acceptance and approval of CTSL services.

6.1.5. Non-CRC Protocols

6.1.5.1. Once study has been approved for processing support, CTSL personnel assign a CTSL Master Study ID number and enter it on CTSI-CRC-PL-LG605 “CTSL Master Study Log”.

6.1.5.2. Master Study IDs for Non –CRC studies are assigned using the following format: PYY-###, where YY is the year study support was begun and the ### is a three digit unique identifier.

6.1.6. CTSL Staff and Protocol personnel complete a draft of the protocol specific form CTSI-CRC-PL-508 “Lab Processing Sheet” from the protocol application or study lab manual.

6.1.6.1. Complete the Protocol ID name.

6.1.6.2. Complete the visit time point.

6.1.6.3. Create a separate Lab Processing Sheet for each visit that has unique specifications. Multiple visits with same or similar collections may be combined on one sheet.

6.1.6.4. Indicate each sample type to be received by the CTSL Staff for each collection time point within each visit on a separate line.

6.1.6.5. Write a brief description of the processing instructions for each sample collected based upon the lab manual or other provided processing detail.

6.1.6.6. Indicate the storage condition for each processed sample and estimated number of aliquots.

6.1.6.7. CTSL staff completes the initial version of the protocol specific form(s) CTSI-CRC-PL-FM508 “Lab Processing Sheet” and sends to the protocol personnel for review.



SOP/WI No.: CTSI-CRC-PL-151	Version 02
Title: Management of Requests for Sample Processing Support	Page 4 of 5

- 6.1.6.7.1. Obtain approved and signed hard copies of each protocol specific form CTSI-CRC-PL-FM508 “Lab Processing Sheet” and file in the designated CTSL protocol folder.
- 6.1.6.7.2. An email from study staff indicating that all lab instruction sheets are approved may be used as final approval in lieu of signed protocol specific form CTSI-CRC-PL-FM508 “Lab Processing Sheet”. File hard copy of email in the designated CTSL protocol folder.
- 6.1.6.7.3. If no formal approval has been obtained, payment for processing services will serve as acceptance of the protocol specific form CTSI-CRC-PL-FM508 “Lab Processing Sheet”(s).
- 6.1.6.7.4. Editable versions of approved protocol specific form CTSI-CRC-PL-FM508 “Lab Processing Sheet” will be kept electronically in study specific folders in the PCIR server (CRC studies) or DMCT server (CTSL studies).
- 6.1.6.7.5. Should a sample be received prior to development of the lab sheets, every attempt will be made to process in compliance with the protocol and all processing data will be recorded on a sheet of paper.
  - 6.1.6.7.5.1. Processing data such as draw time, centrifuge time, freeze time, tech, etc. will be transferred to a formal lab processing sheet once they have been drafted.
  - 6.1.6.7.5.2. Retain the original document/sheet of paper by attaching it to the newly drafted protocol specific form CTSI-CRC-PL-FM508 “Lab Processing Sheet”.
- 6.2. Modifications of CTSI-CRC-PL-FM508 “Lab Processing Sheet”.
  - 6.2.1. Study personnel shall notify CTSL staff of a protocol change in written form.
  - 6.2.2. Modifications may also be made at the time of setup due to changes in kit supplies or protocol amendments that have not been announced formally.
  - 6.2.3. The protocol specific form CTSI-CRC-PL-FM508 “Lab Processing Sheet” is modified as requested or as needed. Date of modifications, version number and initials of modifier are documented on the updated form.
  - 6.2.4. CTSL staff sends modified protocol specific form CTSI-CRC-PL-FM508 “Lab Processing Sheet” to study personnel for review as soon as possible.
    - 6.2.4.1. Time may not allow for formal approval of the updated form prior to use.
    - 6.2.4.2. Refer to 6.1.6.7.3 if approval is not received from study staff prior to visit date.



SOP/WI No.: CTSI-CRC-PL-151	Version 02
Title: Management of Requests for Sample Processing Support	Page 5 of 5

**7. REFERENCES**

None

**8. APPENDICES**

None

**9. AMENDMENT HISTORY**

Date of Amendment: 04 Jan 2017

Amendment Request by: Robert Orr

Change Control No, if applicable: CTSI-CRC-PL-DC-2016-019

Details of Amendment: Updated to footer file location; Updated 5.2 and 6.2.6.7.4 with corrected SOP; Modified 6.1.1.2, 6.1.4 and 6.1.6.3 for clarity; Added 6.1.6.7.3 as a provision for not receiving formal acceptance acknowledgement from study staff; Added 6.1.6.7.5 process to allow for rapid processing of samples that arrive prior to draft of official lab sheets to ensure sample viability; Modified 6.2.2 to provide needed flexibility for adapting to unannounced/unexpected changes to protocol collections at the last minute; Updated step reference in 6.2.4.2

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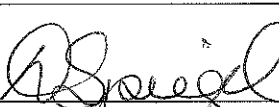

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