



Clinical and Translational Support Laboratory

Organization: Directorship and Staffing

SOP No./WI No.: CTSI-CRC-PL-101

Department: Processing Laboratory


Version No.: 02

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Review Period: 2 years

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Date	23 Dec 2016	28 Dec 2016	Dec 29, 2016



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1. OBJECTIVE

This Standard Operating Procedure (SOP) describes the personnel organization and directorship to include roles, requirements and responsibilities of each. The Clinical and Translational Support Laboratory (CTSL) provides a management structure for the facility in support of the assigned tasks and duties.

2. SCOPE

The scope of this procedure includes CTSL personnel. The specific job duties for personnel are defined via the individual training file. Institutional position descriptions are maintained through Human Resources.

3. RESPONSIBILITIES

Processing Lab staff is responsible to work in accordance with this procedure.

4. DEFINITIONS

4.1. Principle: The Indiana Clinical and Translational Sciences Institute (ICTSI) CTSL is committed to providing processing, distribution, and temporary storage for Principal Investigators conducting clinical trials and bio specimen collection activities. The CTSL strives to provide quality, cost efficient services to meet the needs of the scientific and medical community that we are formed to serve.

CRC: Clinical Research Center	CRD: Clinical Research Department
CRO: Contract Research Organization	CTSL: Clinical and Translational Support Laboratory
ICTSI: Indiana Clinical and Translational Sciences Institute	IUPUI: Indiana University Purdue University of Indianapolis
PI: Principal Investigator	PL: Processing Lab
SOP: Standard Operating Procedure	QA: Quality Assurance

5. ASSOCIATED DOCUMENTS

- 5.1. SOP No. CTSI-CRC-QA-004 for "Handling of SOP Deviations"
- 5.2. SOP No. CTSI-CRC-PL-121 for "General Safety"



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6. PROCEDURE

- 6.1. Organization Overview: The CTSL operates under the overall guidance of the Director of Indiana CTSL. The laboratory director and laboratory manager ensure that policies and procedures developed for CTSL operation are consistent with CTSI directives.
- 6.2. The CTSL Management Team consists of the following personnel: Director and Operations Manager.
- 6.3. A template for the CTSL Organizational chart is provided in Appendix 01 Template for Processing Lab Organizational Structure.
- 6.4. Updates to the Organizational Chart are to be incorporated during a quarterly review of the current active version of Appendix A. Document quarterly review with initials and date on active appendix A.
- 6.5. Current and obsolete versions of the CTSL Organizational chart are maintained by CTSL.
- 6.6. Current position descriptions are maintained by the IUPUI Human Resources for CTSL personnel.
- 6.7. Key Personnel
 - 6.7.1. Director
 - 6.7.2. Operations Manager
 - 6.7.3. Processing Laboratory Technical Supervisor (Senior Technician)
 - 6.7.4. Technicians
 - 6.7.5. Consultants
 - 6.7.5.1. Technical consultants are utilized periodically to guide policies and procedures. Their role and qualifications shall be documented.
- 6.8. Documentation
 - 6.8.1. Documents are managed per CTSI-CRC-QA-003 Document Control and Management
 - 6.8.2. Deviations to this SOP are managed per CTSI-CRC-.CLN-030 "Handling SOP Deviations"

7. REFERENCES

None

8. APPENDICES

- 8.1. Appendix A: Template for Processing Lab Organizational Structure



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9. AMENDMENT HISTORY

Date of Amendment: 28 Nov 2016

Amendment Request by: Robert Orr

Change Control No, if applicable: CTSI-CRC-PL-DC-2016-001

Details of Amendment:

- Updated to footer file location
- Established quarterly review of Appendix A including update of appendix as needed at quarterly review
- Updated section 4.1 by removing “analysis” and adding “distribution” to services.
- Appendix A added to end of SOP



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Appendix A: Template for Processing Lab Organizational Structure
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