

## Clinical and Translational Support Laboratory

### General Safety

SOP No./WI No.: CTSI-CRC-PL-121

Department: Processing Laboratory

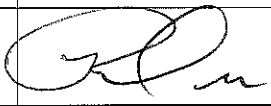
Version No.: 02

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Supersedes: No.: CTSI-CRC-PL-121-01                      Effective Date: 01 May 2014

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Review Period: 2 years

	Written by	Reviewed by	Approved by
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Job Title	Operations Manager	Quality Assurance Manager	ATP Director
Signature			
Date	23 Dec 2016	28 Dec 2016	Dec 29, 2016



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**1. OBJECTIVE**

This Standard Operating Procedure (SOP) defines the procedure used in the Indiana Clinical and Translational Sciences Institute (CTSI), Clinical and Translational Support Laboratory (CTSL) to provide biologic safety for all personnel in the CTSL. The CTSL meets the safety requirements of Indiana University Purdue University Indianapolis (IUPUI) Environmental Health and Safety.

**2. SCOPE**

This SOP applies to personnel working within the CTSL and it is the responsibility of CTSL personnel to assure that non-CTSL staff complies with this SOP upon entry to the CTSL controlled areas. This SOP defines practices applicable to standard laboratory hazards (biologics, chemicals, flammables and toxins).

**3. RESPONSIBILITIES**

CTSL personnel Lab personnel are responsible for following and enforcing the safety procedures defined in 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
PL: Processing Laboratory	PPE: Personal Protective Equipment
QA Quality Assurance	RSO: Radiation Safety Office
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-FM503 Department/Sub-Unit Exposure Determination List
- 5.4. CTSI-CRC-PL-FM504 Annual CTSL Managerial Review of Safety Practices



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**6. PROCEDURE**

- 6.1. Note: IUPUI mandated safety forms are included in appendices and represent current version at date of SOP sign-off. Revised forms (as applicable) will be inserted at each annual safety review.
- 6.2. IUPUI Policies
  - 6.2.1. The IUPUI safety policies are maintained in the IUPUI Employee Health and Safety Handbook accessible at <https://ehs.iupui.edu/index.html>
  - 6.2.2. The IUPUI Radiation Safety policies and procedures are maintained through the Radiation Safety Office (RSO) and can be accessed through the RSO website at: <http://researchcompliance.iu.edu/radsafety/iupui/index.html>
  - 6.2.3. Training- CTSL complies with IUPUI requirement for both initial and on-going safety training.
- 6.3. A copy of the following Safety Procedures are maintained in the CTSL:
  - 6.3.1. Laboratory Specific Safety practices (Appendix B- Blood Borne Pathogens Safety Procedures).
  - 6.3.2. CTSL Phone Tree (Template and instructions for use are contained in Appendix C- Emergency Call CTSL Phone Tree Template)
    - 6.3.2.1. Updates to the Phone Tree are incorporated as necessary.
    - 6.3.2.2. The current version date is recorded on the Phone Tree
    - 6.3.2.3. Retired/obsolete version will be discarded.
  - 6.3.3. Per IUPUI Safety policies, the CTSI-CRC-PL-FM503 Department/Sub-Unit Exposure Determination List is maintained in the department to ensure exposure risk communication during specific job related tasks.
  - 6.3.4. Per IUPUI Safety policies, the CTSI-CRC-PL-FM504 Annual CTSL Managerial Review of Safety Practices will be maintained in the department to ensure that safety practices are reviewed on an annual basis.
- 6.4. Safety Equipment/Personnel Protective Equipment
  - 6.4.1. Easily accessible eyewash fountains and safety showers are provided in areas where chemicals and biologicals are handled. All personnel are required to be familiar with the locations and use of the eyewashes and safety showers.
  - 6.4.2. Eyewash Stations: Test eyewash stations weekly for proper stream flow and to flush the lines of any microbial organisms. Document the weekly test on the CTSI-CRC-PL-LG604 Eye Wash Check and Maintenance Log. Eyewash maintenance records are maintained in the CTSL.
  - 6.4.3. Safety Showers: IUPUI inspects, tests and maintains the safety showers. Inspection and testing are completed according to Plant Engineering policies. Documentation of all information related to the safety showers is maintained by Plant Engineering.
  - 6.4.4. Personal Protective Equipment: all labs are required to maintain applicable PPE as described for use in laboratory specific procedures. (Appendix B- Blood Borne Pathogens Safety Procedures).



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6.5. CTSL Procedures

- 6.5.1. The CTSL will post the current laboratory specific practices (Appendix B- Blood Borne Pathogens Safety Procedures).
- 6.5.2. Applicable biosafety precautions are identified for specimens accepted in the CTSL and all specimens are managed using biosafety level 2 (BL2) or Universal Precautions. The CTSL facilities and equipment are not suitable for materials above BL2
- 6.5.3. Applicable radiations safety procedures are identified and directed by the RSO through appropriate safety training and survey testing. CTSI-CRC-PL-122 Radiation Safety Oversight details responsibilities for radiation safety.

6.6. Documentation

- 6.6.1. Safety practice files are retained according to IUPUI safety policies and procedures.
- 6.6.2. Deviations are managed per CTSI-CRC-CLN-030 “Handling of SOP Deviations”

**7. REFERENCES**

- 7.1. IU EHS Policies and Procedures: <https://protect.iu.edu/environmental-health/>
- 7.2. IU EHS Biosafety Manual: <https://protect.iu.edu/environmental-health/biological/biosafety-manual/index.html>

**8. APPENDICES**

- 8.1. Appendix A Record of Exposure Control Plan
- 8.2. Appendix B Blood Borne Pathogens Safety Procedures
- 8.3. Appendix C Emergency Call CTSL Phone Tree Template

**9. AMENDMENT HISTORY**

Date of Amendment: 9 Dec 2016

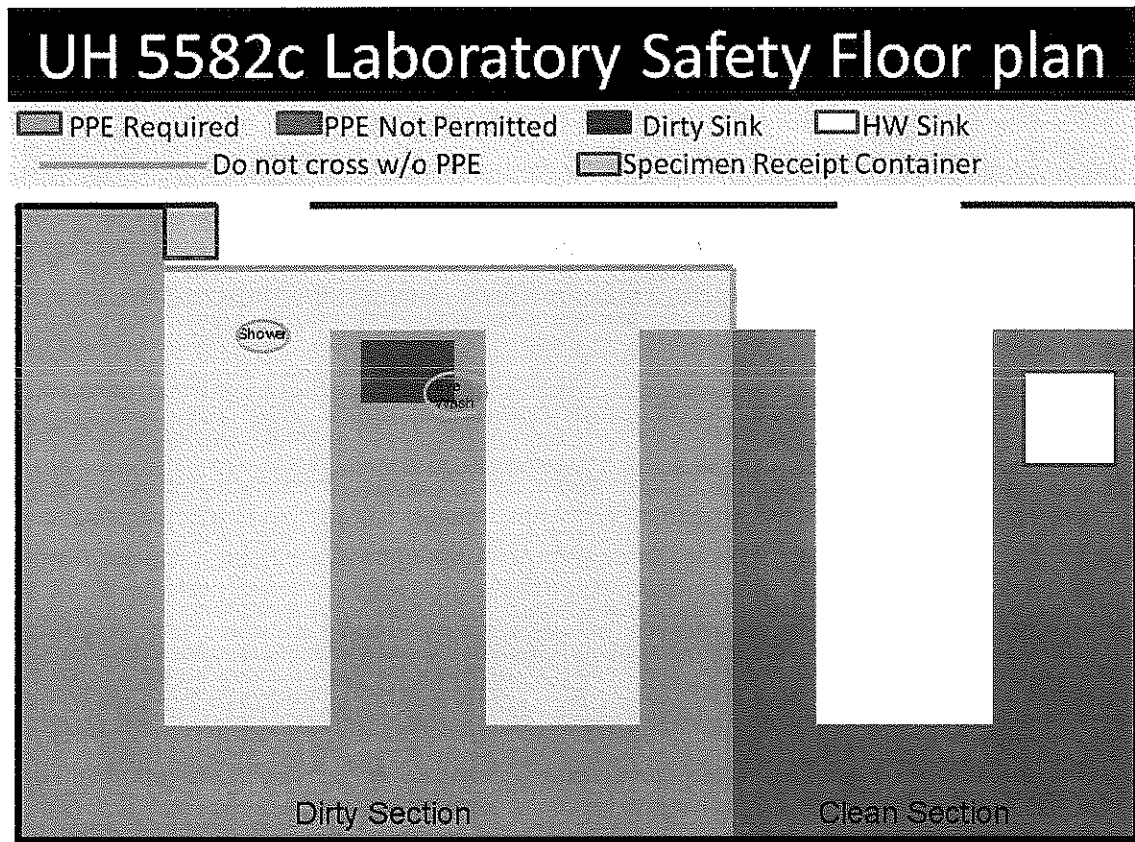
Amendment Request by: Robert Orr

Change Control No, if applicable: CTSI-CRC-PL-DC-2016-007

Details of Amendment: Updated to footer file location; Updated the SOPs in 5.2 and 6.6.2.; Updated Appendix A; Updated all links

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**Appendix A**  
 Record of Exposure Control Plan  
 Department/Sub-Unit Work Practice Controls



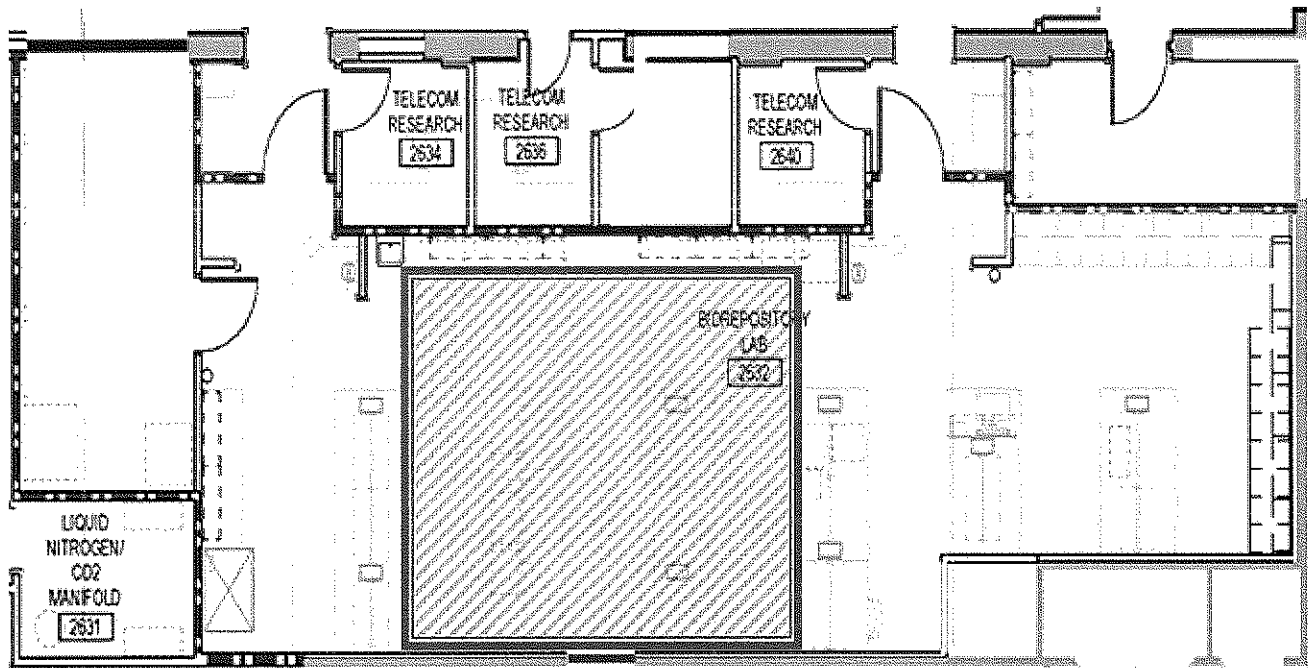
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**Appendix A**  
 Record of Exposure Control Plan  
 Department/Sub-Unit Work Practice Controls

## CTSL Processing Lab RI 2632



PPE required within this area while performing sample processing operations





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**Appendix B**

**Blood Borne Pathogens Safety Procedures:** RI2632, RI2632A, UH5582C

Ref. CTSI-CRC-PL-121 General Safety

**Implemented Clinical and Translational Support Lab Specific Bio-safety Practices**

Access to the laboratory is limited when work is being conducted, and certain procedures in which infectious aerosols are created are conducted using appropriate PPE or performed under operating bio-safety cabinets when available.

**Laboratory Safety Procedures List –**

1. Only persons who have been advised of the potential hazard, who are not at increased risk of acquiring infection and meet any specific entry requirements (e.g., immunization) may enter the laboratory. The laboratory director will limit access to the laboratory by posted signage.
2. A biosafety manual and/or special safety operating procedures (SOPs) for the Blood Borne Pathogens and equipment used are prepared and adopted. All personnel potentially exposed to the Blood Borne Pathogens agent are required to read the biosafety manual/SOPs and to follow them.
3. A hazard warning sign is posted outside of the laboratory when Blood Borne Pathogens experimentation is conducted. The hazard warning sign identifies the infectious agent, name and telephone number of the laboratory director and/or other responsible person and indicates special requirements for entering the laboratory (such as immunization).
4. All potentially infectious wastes from laboratories are properly decontaminated prior to disposal. Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable leak-proof container which is closed before being removed from the laboratory and are stored in a secure location prior to decontamination. Liquid biological wastes may be disposed of via a utility sink followed by 10% bleach. Solid biological waste are appropriately packaged and labeled and removed from the laboratory by Environmental Services.
5. Work surfaces will be decontaminated each work day using the following disinfectant(s): 10% bleach (prepared fresh daily), dispatch or other disinfectant deemed suitable by IU Environmental Health and Safety.
6. Personal protective equipment (PPE) is worn to protect eyes, mucous membranes and skin from contamination. Disposable lab coats and gloves must be worn while performing functions in the designated PPE required work area. Lab coats must be closed and must provide full coverage over clothing. Use full face protection whenever the risk of splash exists. Before leaving the laboratory or BBP work area for non-laboratory areas, PPE is removed and left in the laboratory.
7. Operations such as pipetting, mixing, shaking, grinding, sonicating, flaming, and centrifuging have a high potential for aerosol formation. All procedures involving these operations are performed with caution to minimize the creation of aerosols.
8. Mechanical pipetting devices shall be used; mouth pipetting is **prohibited**.
9. Eating, drinking, application of cosmetics, and the storage of food and drink are prohibited within the laboratory. Food storage refrigerators and cabinets are located outside of the laboratory.
10. Persons wash their hands after handling infectious materials and when they leave the laboratory.
11. Biological safety cabinets (a.k.a., tissue culture hoods or laminar flow hoods) are appropriate containment devices to be used during procedures creating aerosols or while using high concentrations or large volumes



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of BL2 materials. The following procedures will be conducted in a biological safety cabinet: Not applicable.

12. Spills and accidents which result in potential exposure to infectious materials are immediately reported to the laboratory director and the Institutional Biosafety Officer. Spills are cleaned up using the disinfectant listed in item 4 above. Medical evaluation and treatment are provided by Occupational Health Services

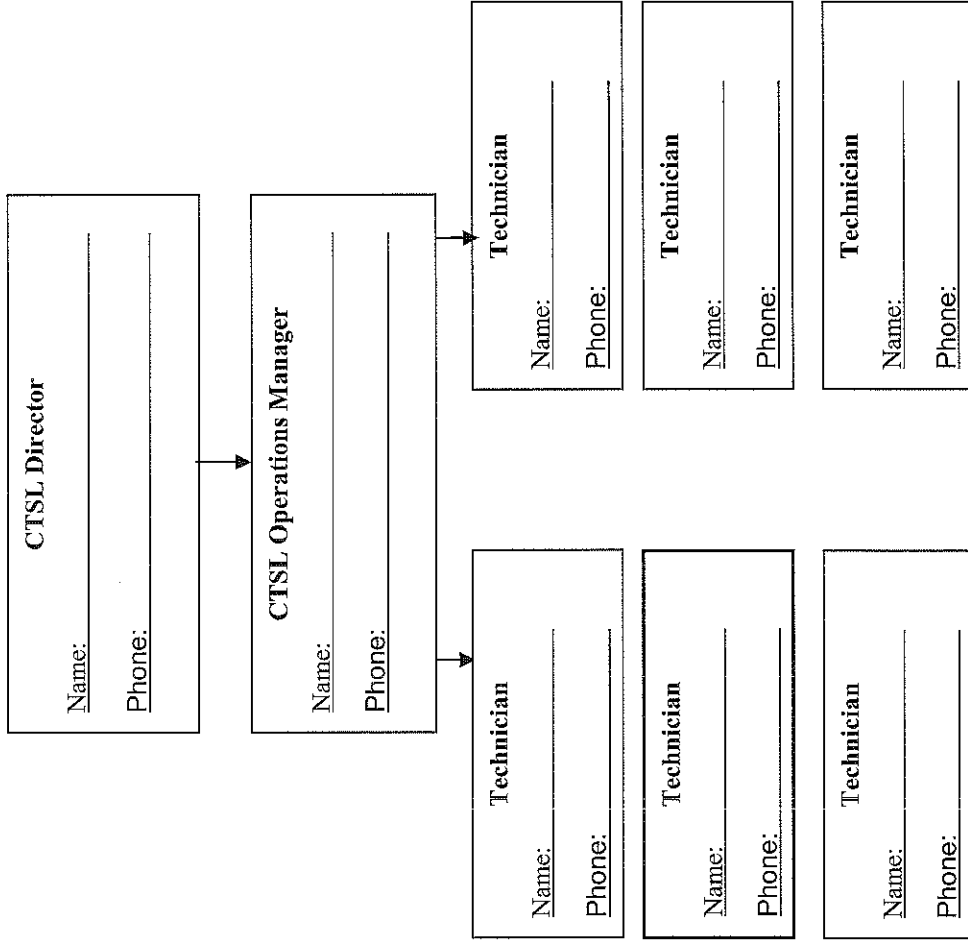


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Emergency Call CTSL Phone Tree Template  
Ref: CTSI-CRC-PL-121 General Safety

**Indiana CTSL CTSL  
EMERGENCY PHONE TREE**

Version Date: \_\_\_\_\_  
Replaces Version: \_\_\_\_\_



**Note:**  
IUPUI Wide emergency notifications are made via IUPUI phone/e-mail notifications. Use of this tree is limited to CTSL Specific emergency notifications outside of the Alarm Response notifications.  
Responsible individuals are to contact respective personnel as indicated by the directional arrow(s). Proceed to the next contact indicated if the first attempt is unsuccessful.  
CTSL Personnel are required to respond to the directives relayed.

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