Clinical and Translational Support Laboratory

Radiation Safety Oversight

SOP No./WI No.: CTSI-CRC-PL-122

Department: Processing Laboratory

Version No.: 02

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	Written by	Reviewed by	Approved by
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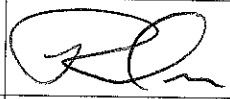
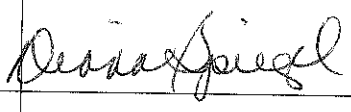
Signature			
Date	28 Dec 2016	28 Dec 2016	Dec 29, 2016

1. OBJECTIVE

This Standard Operating Procedure (SOP) describes the process to ensure that policies, procedures and regulations set forth by Indiana University Purdue University Indianapolis (IUPUI) Radiation Safety Office (RSO) are followed by the Clinical and Translational Support Laboratory (CTSL) processing staff.

2. SCOPE

This SOP applies to all CTSL and Clinical Research Center (CRC) staff providing lab processing activities for radio labeled specimens including processing and separating aliquots. This procedure is intended to provide a brief description of radiation safety oversight, but does not over-ride any procedures provided directly from the IUPUI Radiation Safety Office.

3. RESPONSIBILITIES

3.1. The clinical and lab staff is responsible for appropriately handling radioactive labeled specimens in a manner which complies with the policies, procedures and regulations set forth by the IUPUI Radiation Safety Office.

3.2. The IUPUI Radiation Safety Office is responsible for educating users in the safe handling of radioactive material; reviewing clinical protocols requiring the use of radioactive survey records; maintaining all Nuclear Regulatory Commission (NRC) by-product material and state licenses; and administrator of radiation safety program and University safety committees.

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	mCi: milliCurie
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. IU EHS Policies and Procedures: https://protect.iu.edu/environmental-health/
5.4. CTSI-CRC-PL-121 "General Safety"

6. PROCEDURE

6.1. Processing of Radiolabeled Specimens:
- 6.1.1. Per the RSO, most radiolabeled studies performed in the CRC contain a very low level of radioactivity (below background levels) and therefore no further precautions or procedures beyond universal precautions are required when processing.
  - 6.1.1.1. Refer to Attachment A- Radiation Safety and Procedures for Specimen Processing Staff.
  - 6.1.1.2. A signed copy of the Radiation Safety Process and Procedures for Specimen Processing Staff is on file in the CTSL.
- 6.1.2. Studies that utilize isotopes that are not listed in the RSO Radiation Safety Process and Procedures for Specimen Processing Staff or that will potentially reach higher than background radiation levels will be reviewed by CTSL management to evaluate feasibility and safety issues.
  - 6.1.2.1. All approved technicians must attend Radiation Safety Orientation and Radiation Safety course, if necessary before working with radioactive materials not listed in Appendix A.
  - 6.1.2.2. All laboratories must be authorized by the RSO for use of radioactive processing of isotopes not listed in Appendix A- Radiation Safety Process and Procedures for Specimen Processing Staff by completing and submitting A-4 Form. Application for Radionuclide Laboratory Approval.
  - 6.1.2.3. Processing of protocols that utilize with radioactive materials not listed in Appendix A will follow all applicable procedures and policies as prescribed by the RSO.

7. REFERENCES

7.1. IUPUI Radiation Safety Procedures Manual, available on line at: http://researchcompliance.iu.edu/radsafety/iupui/index.html
7.2. Contact information: 541 Clinical Dive, CL 159 Office Phone 317-274-4797; Fax: 317-274-2332

8. APPENDICES

8.1. Appendix A; RSO Radiation Safety Process and Procedures for Specimen Processing Staff

9. AMENDMENT HISTORY

Date of Amendment:	28 DEC 2016
Amendment Request by:	Robert Orr
Change Control No, if applicable:	CTSI-CRC-PL-DC-2016-008
Details of Amendment:	Updated to footer file location; updated the SOPs in 5.2; Updated links in steps 5.3 and 7.1

Appendix A - RSO Radiation Safety Process and Procedures for Specimen Processing Staff

RADIATION SAFETY PROCESS AND PROCEDURES FOR SPECIMEN PROCESSING STAFF

Scope: This procedure applies to staff processing (i.e., centrifuging, pipetting, and handling containers of blood and other body fluids from patients undergoing research protocols approved by IUPUI Radiation Safety Office (RSO) using the following isotopes: C-14, Ca-41, Ca-45, F-18, Tc-99m, and H-3 . The locations for which processing of these samples is permitted without monitoring for radioactivity or performing cleaning practices above standards for Universal Precautions are UH-AOC 5030 and UH 5582C.

Studies utilizing the C-14 study process and the C-14 laboratory (UH AOC 5049) for analysis are NOT within the scope of this procedure.

Rationale: Exposure to radioactive materials via handling of specimens from patients undergo ing radio-labeling studies is a potential safety hazard. While laboratory staff is aware of the potential hazards presented by blood borne pathogens or from certain drugs used in chemotherapy it is important for staff to also be knowledgeable regarding radioactive exposure in order to manage the risk. Everyone is exposed each day to natural background radiation. Persons receive an exposure of about 360 mrem per year from background radiation.

The administration of radioactive materials by the nuclear medicine and PET departments for diagnostic purposes is common. There are several reasons why these patients present a minimal hazard. The primary reason is that the amount of radioactivity (and the related radiation exposure) is small with the material having a short "half-life." This means the radioactivity disappears rapidly. Standard universal precautions (e.g., wearing disposable gloves) will protect laboratory staff from these radiation hazards. Samples from radiolabeled drug study patients carry an even lower level of radioactive isotopes and are considered by IUPUI RSO to not require precautions above those standardly employed for Universal Precautions.

Procedure:

1. The CTSL will identify studies submitting samples containing radioactive labeling for CTSL services via (a) requesting the information on the sample processing set-up sheet and (b) having this as a standard agenda item in all protocol start-up or modification meetings with CRC.
2. The CTSL will process these samples utilizing Universal Precautions
3. Radioactive labeling of the specimens or processing area is not required
4. Cleaning other than that defined under Universal Precautions is not required.
5. Monitoring of the processing area for radioactivity is not required.
6. Radiation Safety training for technicians processing these samples is not required.
7. Contact Radiation Safety if you do not understand this procedure or if you have further questions.

For any questions, PLEASE CONTACT: Radiation Safety Office at 274-4797 (8 am to 5 pm weekdays, after hours listen for paging instructions)

Clinical Research Center

Form/Log: SOP/WI/Policy Training Memo			
Ref: SOP for Training, CTSI-CRC-GEN-004			
Form/Log No.: CTSI-CRC-GEN-FM009	Version No.: 02	Effective Date: 11 May 2016	Page 1 of 1

SOP/WI/Policy Training Memo

Date: 30Dec2016

The following Standard Operating Procedure(s) is available electronically at box.iu.edu or paper copy at the nurse's station.
Please review and sign off that you have read and understand the SOP noted below by **05 JAN 2017**

Date

SOP/WI/Policy No.	Document Title
CTSI-CRC-PL-122	Radiation Safety Oversight

Print Name	Signature*	Date Read
David Pelloss	David Pelloss	04 JAN 2017
Amber Falaschetti	Amber Falaschetti	04 JAN 2017
Nancy Hoover	Nancy Hoover	04 Jan 2017
SARA MURPHY	SARA MURPHY	04 JAN 2017
TIM NEED	Tim Need	04 JAN 2017

*My signature demonstrates that I have read, understand and agree to comply with the above-referenced procedure(s).