Unit Procedure

Unlabeled/Mislabeled Specimens

SOP No./WI No.: CTSI-CRC-PL-157

Department: Processing Laboratory

Version No.: 02

Effective Date: 05 Jan 2016

Supersedes: No.: CTSI-CRC-PL-157-01 Effective Date: 01 May 2014

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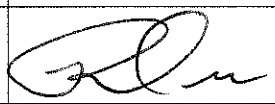
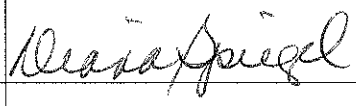
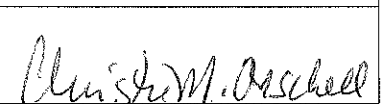
Review Period: 2 years

	Written by	Reviewed by	Approved by
Name	Robert Orr	Diana Spiegel	Christie Orschell
Job Title	Operations Manager	Quality Assurance Manager	ATP Director
Signature			
Date	28 Dec 2016	28 Dec 2016	Dec 29. 2016

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1. OBJECTIVE

This Standard Operating Procedure (SOP) describes the acceptable subject identifiers and the procedure for handling rejection of unlabeled/mislabeled specimens at the Indiana Clinical and Translational Sciences Institute (CTSI) Clinical and Translational Support Laboratory (CTSL).

2. SCOPE

This SOP is applicable to CTSL staff responsible for receiving bio specimens related to clinical research studies.

3. RESPONSIBILITIES

The CTSL personnel are responsible to work with study personnel to ensure compliance with these procedures. CTSL staff is to ensure that every specimen has two patient identifiers on each specimen or is managed by this unlabeled/mislabeled samples procedure.

4. DEFINITIONS

CRC: Clinical Research Center	CTSI: Clinical and Translational Sciences Institute
CTSL: Clinical and Translational Support Laboratory	MRN: Medical Record Number
PID: Protocol Identification Number	SID: Subject Identification Number
SOP: Standard Operating Procedure	VID: Visit Identification Number

5. ASSOCIATED DOCUMENTS

5.1. CTSI-CRC-PL-152 "Protocol Visit Set-up and Labeling"
5.2. Form No: CTSI-CRC-PL-FM516 Unlabeled/Mislabeled Specimen Form"
5.3. CTSI-CRC-PL-104 "Problem Management and Discrepancy Resolution"
5.4. Form No: CTSI-CRC-PL-LG602 "CTSL Processing Problem Log"

6. PROCEDURE

6.1. Upon receipt, inspect each sample to verify at least 2 of the following identifiers are present:
  6.1.1. Full name of patient
  6.1.2. Patient Medical Record Number (MRN)
  6.1.3. Protocol Identification Number (PID)
  6.1.4. Subject Identification Number (SID)
  6.1.5. Visit Identification Number (VID)

6.2. Specimens that are labeled with only one identifier but sufficient information exists to definitively link the sample to a set of processing requirements will be processed. CTSI-CRC-PL-FM516 "Unlabeled/Mislabeled Specimen Form" will be completed, attached to the original processing instructions and returned to study personnel.

6.3. Specimens delivered to the CTSL without a label and/or lacking sufficient information to clearly identify the related study and patient will not be processed until identification can be established.

6.3.1. Laboratory staff will complete the "Laboratory Section" of the CTSI-CRC-PL-GM516 "Unlabeled/Mislabeled Specimen Form" and will retain the specimen in the CTSL in monitored refrigeration. The specimen bag will be marked with the date of receipt.

6.3.2. CTSL personnel will notify the CRC nursing station with all available information to attempt to rectify the error.

6.3.3. CRC Staff will provide contact information for the responsible person if available.

6.3.4. If responsible party is located, the specimen will be returned to them for correction of labeling. The responsible party will also be required to complete the CTSI-CRC-PL-GM516 "Unlabeled/Mislabeled Specimen Form" that was initiated.

6.3.5. If CRC staff cannot identify the responsible party, CTSL will retain the specimen (in monitored refrigeration) and the initiated CTSI-CRC-PL-GM516 "Unlabeled/Mislabeled Specimen Form" for up to one week.

6.3.6. If, after one week, the responsible party is unable to be identified, the specimen will be discarded and the initiated CTSI-CRC-PL-GM516 "Unlabeled/Mislabeled Specimen Form" will be completed.

6.4. At a minimum, the following information will be recorded on CTSI-CRC-PL-GM516 "Unlabeled/Mislabeled Specimen Form":

6.4.1. Specimen receipt date/time, sending location and specimen description.

6.4.2. Description of labeling error.

6.4.3. Time, date, and name of personnel notified of the error.

6.4.4. Final resolution (i.e., held for 1 week and discarded; returned to CRC or study personnel).

6.4.5. Signature of the CTSL personnel responsible for notification and final resolution with date of completion.

NOTE: Documentation of all unacceptable/rejected specimens will be maintained by the CTSL per SOP CTSL-CRC-PL-104 "Problem Management and Discrepancy Resolution".

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7. REFERENCES

7.1. IU Health Specimen Identification and Labeling and Specimen Rejection Policies: http://iuhealth.org/health-professionals/pathology-laboratory/specimen-collection-and-preparation1/

8. APPENDICES

None

9. AMENDMENT HISTORY

Date of Amendment:	2 Mar 2016
Amendment Request by:	Robert Orr
Change Control No, if applicable:	CTSI-CRC-PL-DC-2016-024
Details of Amendment:	Updated to footer file location; Updated link in 7.1

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INDIANACTSI
Clinical and Translational Sciences Institute

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-157	Unlabeled/Mislabeled Specimens

Print Name	Signature*	Date Read
DAVID Pelloso	David Pelloso	04JAN2017
SARA MURPHY	SMurphy	04 JAN 17
Nancy Hoover	Nancy Hoover	04 Jan 2017
Annette Falaschetti	Annette Falaschetti	04Jan2017
TIM NEED	Tim Need	04Jan2017

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