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	<b>Author:</b>	<b>B. Cale P. Moraes</b>
	<b>Approved by:</b>	<b>L. Johnson M. Wallace</b>
<b>SOP TITLE: ACTRI Clinic Laboratory Daily Operations</b>		

## 1 PURPOSE

- 1.1 This procedure will outline the day-to-day operations that are required by All Staff to maintain safe and efficient ACTRI clinic laboratory (lab) operations.
- 1.2 All ACTRI Clinical staff including Nurse Practitioner (NP), Registered Nurses (RN's), Licensed Vocational Nurses (LVN's) and Hospital Laboratory Technicians are expected to comply with this policy.
- 1.3 This SOP will also apply to any study team staff, including Clinical Research Coordinators (CRCs) and Principal Investigators (PIs), who utilize the ACTRI clinic laboratory services.
- 1.4 This SOP will apply to any ACTRI clinic lab location, including the labs at the ACTRI La Jolla clinic and Linda Vista clinic.

## 2 DEFINITIONS

- 2.1 ACTRI Clinical staff – includes NP, RN's, LVN's, laboratory technicians, and clinic leadership.
  - 2.1.1 This does not include other Ancillary clinic staff.
- 2.2 ACTRI Ancillary clinic staff – operations specialist, dietician, ultrasound technician, administrative support.
- 2.3 UCSD Study Team staff – includes PI's, CRCs, project managers, volunteers or anyone who has been approved as part of the study team and has been provided access to the ACTRI clinic.
- 2.4 All Staff – includes UCSD Study Team staff and ACTRI Clinical staff.

## 3 REQUIREMENTS

- 3.1 The requirements listed in this section apply to All Staff unless specified.
- 3.2 All Staff who enter an ACTRI clinic lab to perform study related business or tasks are required to complete the Lab Safety Trainings required by UCSD:
  - 3.2.1 UC Lab Safety Fundamentals
  - 3.2.2 Annual Laboratory Hazards Training
  - 3.2.3 International Air Transportation Association (IATA)
  - 3.2.4 Good Clinical Practice (GCP)
- 3.3 All Staff are required to wear UCSD-issued ID badges.
- 3.4 All Staff are required to wear the proper attire, including long pants and closed toe and heeled shoes.
- 3.5 All Staff are required to don the appropriate PPE, as required, when in an ACTRI clinic lab.
  - 3.5.1 Lab coats must be worn at all times in the lab by staff working with any biohazardous materials including human bodily fluids.
  - 3.5.2 Face shields or plexi-glass dividers must be used when pipetting or transferring biohazard materials, including bodily fluids.
- 3.6 All ACTRI Clinical staff are required to attend In-Services and to review the lab manuals for the studies they are processing.

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3.7 All Staff are required to follow infection control policies including proper hygiene and handwashing.

#### **4 RESPONSIBILITIES**

4.1 ACTRI leadership, including the Assistant Nurse Manager and Assistant Director, are responsible for ensuring All Staff are compliant with this SOP.

4.1.1 Clinic leadership will hold ACTRI Clinical staff accountable for non-compliance of this SOP or other unprofessional behaviors that occur in the laboratory (lab) or clinic.

4.1.2 Non-compliance by UCSD Study Team staff will be reported to their department leadership.

4.1.3 Non-compliance by any staff member may result in loss of ACTRI clinic and lab privileges.

4.2 All Staff are responsible for understanding this SOP and ensuring compliance.

4.3 All Staff are responsible for ensuring safe practice.

4.3.1 Proper specimen handling and hand-off

4.3.2 Timely notification to leadership for any lab issues

4.3.3 IReport notification

4.3.3.1 Lab errors

4.3.3.2 Emergency events

4.3.3.3 Violation of SOP

4.4 All Staff are responsible for ensuring professional communication.

#### **5 PROCEDURE**

5.1 The ACTRI clinic lab in La Jolla is open from 7:00 am to 5:30 pm daily.

5.1.1 Labs in Linda Vista and L2 clinics are open depending on volume and staffing. If there is a visit scheduled at either of these locations that requires Clinical staff, the lab will be open.

5.2 A lab technician will be assigned to the La Jolla lab from 7:00 am to 5:30 pm each day.

5.2.1 The assigned hours will be determined based on clinic and lab volume.

5.2.2 The assigned lab technician will be primarily responsible for all specimen processing and lab kit set-up.

5.2.3 The assigned lab technician may also be assigned to simple blood draws or patient care duties as needed depending on clinic volume.

5.2.4 The other lab technicians on shift are responsible for being in the lab to help the assigned lab technician when not assigned to patient care duties.

5.2.5 It is a shared responsibility amongst all on-duty lab technicians to be in the lab ensuring safe and efficient laboratory operations.

5.2.6 During high volume shifts and when there is complex processing, it is a shared responsibility of the clinic nursing staff (RN's and LVN's) to assist in processing their own specimens if their patient care visit permits. If clinic nursing staff have a 1:1 or complex patient care assignment, they are exempt from specimen processing.

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- 5.2.6.1 Clinic leadership must be notified by the assigned lab technician when volume exceeds the ability for the lab technician(s) to meet the responsibility of the processing and kit set-up.
- 5.2.6.2 If at any time the lab technician(s) feel they need assistance to meet the demands of the lab, they are required to notify clinic leadership.
- 5.2.7 When a study requires specific training prior to processing, only personnel who have completed the required training will perform the processing.
- 5.3 Upon opening of the lab, the Daily Checklist must be completed by the designated ACTRI Clinical staff member.
  - 5.3.1 Daily Checklist:
    - [https://ucsdhs.sharepoint.com/:x/r/teams/ACTRICenterforClinicalResearchCCR/Shared%20Documents/Clinic%20Operations/Internal%20Checklists%20and%20Logs/ACTRI%20Daily%20checklist\\_v4.xlsx?d=wdc63d817f512461a9240d74ace301512&csf=1&web=1&e=I54Ydm](https://ucsdhs.sharepoint.com/:x/r/teams/ACTRICenterforClinicalResearchCCR/Shared%20Documents/Clinic%20Operations/Internal%20Checklists%20and%20Logs/ACTRI%20Daily%20checklist_v4.xlsx?d=wdc63d817f512461a9240d74ace301512&csf=1&web=1&e=I54Ydm)
- 5.4 Daily, upon closing of the clinic, room checks, stocking and biohazard bin removal will be a shared responsibility by all ACTRI Clinical staff, and the Daily Checklist will be completed.
  - 5.4.1 Lab technicians will be primarily responsible, but if the clinic nursing staff have completed their patient care duties, they are expected to assist in the closing procedures.
  - 5.4.2 Lab technicians will be responsible for ensuring that all specimens are properly stored and secured at the end of each day.
    - 5.4.2.1 No specimens left out
    - 5.4.2.2 Specimen log complete
- 5.5 Only ACTRI Clinical staff are permitted to access the freezers and refrigerators in any of the ACTRI labs.
  - 5.5.1 UCSD Study Team staff who need to drop off a sample or remove a sample from any of the freezers or refrigerators must request an ACTRI Clinical staff member to assist.
    - 5.5.1.1 The freezers and refrigerator in the ACTRI labs will be locked after business hours.
      - 5.5.1.1.1 It is the responsibility of the ACTRI clinical lab technician assigned to the lab to ensure that the freezer is locked at the end of the day.
  - 5.5.2 All specimens must be logged in and out of the freezer(s) and refrigerator in the online Specimen Log.
    - 5.5.2.1 The Specimen Log will be maintained by ACTRI Clinical staff.
    - 5.5.2.2 The Specimen Log includes IRB number, subject ID, number of tubes, dates logged in and dates logged out, and name of the Clinical staff member who accessed the samples.
    - 5.5.2.3 Specimens can only be stored for up to 7 days in the ACTRI freezers.

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- 5.5.2.4 ACTRI lab technicians will inventory all samples in the freezers weekly and notify study teams if they need to be removed.
- 5.5.2.5 ACTRI Clinical staff will log this inventory each week in the Specimen Log (in progress).
- 5.5.3 Exceptions may be made for studies that need to have access to an ACTRI clinic lab after-hours.
  - 5.5.3.1 After-hours access must be requested and approved by ACTRI clinic leadership.
  - 5.5.3.2 Once approved, an ACTRI Clinical staff member will be assigned. If the Clinical staff member is coming in on overtime to assist, the study team may be charged \$50.00.
  - 5.5.3.3 After-hours requests must be submitted via the Clinic Appointment Request Form:  
<https://forms.monday.com/forms/52899b211ec1b0a779025c077650d9d8?r=use1>.
- 5.5.4 The freezers and refrigerator will be locked after hours and on weekends in all ACTRI clinic labs.
- 5.6 All specimens collected (blood, saliva, urine, etc.) in an ACTRI clinic must be dropped off in the lab by an ACTRI Clinical staff member, preferably the staff member who collected the specimen.
  - 5.6.1 UCSD Study Team staff are not allowed to bring specimens to the lab.
  - 5.6.2 In the rare instance where an UCSD Study Team staff member needs to bring the specimen(s) to an ACTRI lab, they must provide a verbal hand-off to an ACTRI Clinical staff member and log the following in the Study Team Specimen Drop-Off Exception Log: specimen, date, time, IRB number, subject ID and the name of the Clinical staff member they handed the specimen to.
    - 5.6.2.1 This should be an exception to the SOP and only when an ACTRI Clinical staff member is not available.
- 5.7 The following steps in 5.7.1 through 5.8 apply to ACTRI Clinical staff.
  - 5.7.1 The specimen(s) must be labeled with the correct patient identifier at the bedside before being taken to the lab.
  - 5.7.2 The staff member who collected the specimen must document in the nurses notes the specimen collected, the time of collection and who they handed the specimen to.
    - 5.7.2.1 In the rare instance when there are no lab personnel available at the time of drop-off:
      - 5.7.2.1.1 Use one of the laminated communication signs
        - 5.7.2.1.1.1 Green – Stop, do not process. This will be processed by person who drew specimen.
        - 5.7.2.1.1.2 Yellow – Wait, this needs to be processed but needs additional specimens/time/other.

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- 5.7.2.1.1.3 Pink – Help, this specimen needs processing.
- 5.7.2.1.2 Notify clinic leadership or designee either in person, via text or email that the specimen was dropped off in the lab and pink sign filled out.
  - 5.7.2.1.2.1 Notify in person
  - 5.7.2.1.2.2 Notify via text
  - 5.7.2.1.2.3 Notify via email
- 5.7.2.1.3 Document the study IRB, the time of drop off time and actions in the patient chart/nurses' notes.
- 5.7.2.1.4 Follow-up in lab within 30 minutes to ensure the lab specimen was acknowledged.
- 5.7.3 The staff member who dropped off the specimen(s) is responsible for following up with the assigned lab technician to confirm the specimens were processed.
- 5.7.4 All lab specimen collection times, chain of custody handoffs and disposition must be documented in the nurses' notes.
- 5.8 All ACTRI Clinical staff are expected to be proactive.
  - 5.8.1 If a specimen has been dropped off and you notice it sitting on the lab counter with the pink sign filled out, please investigate and inquire with nursing staff or clinic leadership to identify what the status is.
  - 5.8.2 Unattended specimens must have the laminated communication sheet filled out and immediate notification to the dedicated lab technician, nursing staff or clinic leadership.

## 6 MATERIALS

- 6.1 Laboratory supplies, including but not limited to phlebotomy tubes, urine specimen cups, vacutainers, needles, gloves, antiseptic wipes, Coban, patient records, lab communication signs
- 6.2 Study specific chemicals stored in UCSD approved containers
- 6.3 Specimen Log
- 6.4 ACTRI Daily Checklist:  
[https://ucsdhs.sharepoint.com/:x:/r/teams/ACTRICenterforClinicalResearchCCR/Shared Documents/Clinic Operations/Internal Checklists and Logs/ACTRI Daily checklist\\_v4.xlsx?d=wdc63d817f512461a9240d74ace301512&csf=1&web=1&e=I54Ydm](https://ucsdhs.sharepoint.com/:x:/r/teams/ACTRICenterforClinicalResearchCCR/Shared%20Documents/Clinic%20Operations/Internal%20Checklists%20and%20Logs/ACTRI%20Daily%20checklist_v4.xlsx?d=wdc63d817f512461a9240d74ace301512&csf=1&web=1&e=I54Ydm)
- 6.5 Study Team Specimen Drop-Off Exception Log:  
[https://ucsdhs.sharepoint.com/:x:/r/teams/ACTRICenterforClinicalResearchCCR/Shared%20Documents/Clinic%20Operations/Internal%20Checklists%20and%20Logs/Study%20Team%20Specimen%20Drop%20Exception%20Log\\_v2.xlsx?d=wee3fd9de3541417abd87f6a98e28f3b3&csf=1&web=1&e=86DLI](https://ucsdhs.sharepoint.com/:x:/r/teams/ACTRICenterforClinicalResearchCCR/Shared%20Documents/Clinic%20Operations/Internal%20Checklists%20and%20Logs/Study%20Team%20Specimen%20Drop%20Exception%20Log_v2.xlsx?d=wee3fd9de3541417abd87f6a98e28f3b3&csf=1&web=1&e=86DLI)

## 7 REFERENCES

- 7.1 UC Laboratory Safety Policies: <https://blink.ucsd.edu/safety/research-lab/ucop-labsafety.html>

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7.2 Clinic protocol for Blood Sample Drop-off and Documentation email 8/26/2025