| UC San Diego<br>Altman Clinical and Translational Research Institute<br>Center for Clinical Research | SOP Number | CCR:002<br>Page 1 of 6 |
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| SOP TITLE: ACTRI CLINICAL OPERATIONS | | |

## 1 PURPOSE

1.1 This procedure establishes guidelines and operational standards for research colleagues who utilize the Altman Clinical and Translational Research Center (ACTRI) Center for Clinical Research (CCR), including facilities at La Jolla and Linda Vista.

## 2 REVISIONS FROM PREVIOUS VERSION

2.1 Updated Clinic Appointment Request Form link.

## 3 GUIDANCE

3.1 All study teams utilizing the facilities and services provided by ACTRI CCR will be required to follow the procedures written in this document.

3.2 ACTRI at La Jolla

3.2.1 The ACTR Clinic at La Jolla provides over 20 exam rooms, treatment rooms, infusion rooms, consult rooms, procedure rooms and overnight rooms.

3.2.2 The clinic supports phase 1 studies, overnight studies, and complex studies including viral vector, infectious disease and cannabis studies.

3.2.3 This site supports both adult and pediatric studies.

3.2.4 Services include an onsite Investigational Drug Service (IDS) pharmacy; RN infusion services; complex phlebotomy, specimen processing, and shipping; DEXA and ultrasound services; dietitian services; vital signs; anthropometric measurements; coordinator services; procedural sedation and other services by arrangement.

3.2.5 Staffing at this site include registered nurses (RN), licensed vocational nurses (LVN), lab techs, registered dietitian, ultrasound tech, administrative staff, operations staff, and coordinator services.

3.3 ACTRI at Linda Vista

3.3.1 The ACTRI clinic at Linda Vista provides 7 exam rooms and services to support both adult and pediatric research in collaboration with UC San Diego and Linda Vista.

3.3.2 Participant ages can range from 3 months to geriatrics.

3.3.3 Staffing at this site will include onsite administrative support staff, RN, LVN, and lab technician.

3.3.4 All studies and staff utilizing the ACTRI Clinic at Linda Vista must have UC San Diego affiliation.

3.3.5 This site will provide limited services that include phlebotomy, specimen processing and shipping, vital signs, ECG's, room use only, consult and cognitive testing room, anthropometric measurements, and coordinator services.

## 4 DEFINITIONS

4.1 Study Team staff

4.2 Principal Investigator (PI)

4.3 Clinic Operations team

## 5 RESPONSIBILITIES

5.1 The PI remains responsible for the overall study conduct and for compliance with the principles of Good Clinical Practice (GCP) and applicable local and national regulations and guidance even if study specific tasks are delegated to others.

5.2 The CCR Co-directors and CCR assistant clinical director are responsible for providing the study PI access to relevant CCR standard operating procedures (SOPs).

## 6 PROCEDURE

6.1 Study Initiation

6.1.1 Study Team staff or PI submits all service requests for ACTRI clinic using the link: https://ucsd- actri.jotform.com/200906276270048

6.1.2 The form can also be accessed using the ACTRI website “Request for Clinical Research Services” using the link: Center for Clinical Research "Request CCR Services"

6.2 Study In-Service

6.2.1 Study Team staff or PI submits Study “In-Service” requests regardless of the type of study.

6.2.1.1 In- Service request must be submitted within 60 calendar days of the study start date, even if contract is still pending.

6.2.1.2 To submit the in-service request, a UC San Diego IRB number is required.

6.2.1.3 Submit an ACTRI Study In-Service Request Form using the JotForm link: https://ucsd-actri.jotform.com/form/202016994389060

6.2.1.4 Not all studies require an in-service. The investigator will be notified if the study does not require an in-service.

6.2.1.5 All studies that include investigational product (IP) administration by clinic nurses will require an in-service.

6.2.1.6 All in-service meetings are completed in-person by the study coordinator and scheduled in the afternoons in the clinic from Monday through Friday.

6.3 Clinical Conductor Build

6.3.1 All studies conducted at any ACTRI site will be built in Clinical Conductor by the Clinic Operations team.

6.3.1.1 In general, the study will be built in the order in which the request was received and after the following steps are completed:

6.3.1.1.1 Clinical Research Services Request Form submission

6.3.1.1.2 In-service Request Form submission

6.3.1.1.3 Coverage Analysis completion

6.3.1.1.4 Scientific review (if necessary)

6.3.1.1.5 Meeting with ACTRI Clinical Operations staff to review study visits and budget

6.3.1.1.6 Study active in Velos

6.4 Appointment Requests, Cancellations, and Reschedule Requests

6.4.1 Clinical Conductor will be used as the main scheduling program in the ACTRI clinic. Visits will still be scheduled in Epic by the clinic scheduler.

6.4.1.1 Visits should match in Clinical Conductor and Epic.

6.4.1.2 Clinical Conductor is the source of truth for actual visits.

6.4.2 Coordinators will require access to Clinical Conductor for scheduling. The coordinator will review Clinical Conductor for available visit times to self-schedule their study visits.

6.4.3 Clinic Appointment Request Forms must be submitted for:

6.4.3.1 visits less than 5 days in advance;

6.4.3.2 visits not available in Clinical Conductor;

6.4.3.3 schedule changes;
6.4.3.4 complex visit requests, including overnight visits requiring clinic staff;
6.4.3.5 complex visits that require special resources;
6.4.3.6 NP services;
6.4.3.7 and any other request or requirement that is not available in Clinical Conductor.

6.4.4 Clinic Appointment Request Form link: https://forms.monday.com/forms/52899b211ec1b0a779025c077650d9d8?r=use1

6.5 Special requests and late arrivals

6.5.1 Overnight, weekend visits, and visits that extend past 5:30pm must be requested a minimum of 2 weeks in advance to allow time to secure staffing. These types of requests require an email to and approval from clinic leadership.

6.5.2 Participants must arrive on time. If they will be late, the coordinator must email the clinic administrative coordinator and notify the clinic at 858-534-0001. **If the participant is more than 15 minutes late to the appointment, their visit may be canceled**.

6.6 Current studies in Epic

6.6.1 If the study is currently built in Epic, the study team are responsible to ensure that visits are linked to the research study in Epic. For more information on how to link appointments, follow this training link: https://pulse.ucsd.edu/departments/EMR/ResourceLibrary/Documents/Research/Check%20for%20Appts%20Linked%20to%20Research%20Studies%20from%20the%20Schedule.pdf

6.7 Orders

**6.7.1** For all studies in Clinical Conductor, coordinators must continue to upload orders into Clinical Conductor 48 hours prior to the visit or when the visit has been approved. Studies built in Epic will have the orders built in the EMR. **If orders are not available 24 hours in advance, the visit may be canceled.**

6.7.2 Clinical coordinators are responsible to ensure the orders (paper or on Epic) are correct.

6.7.3 Clinical Conductor Orders

6.7.3.1 All orders must be uploaded to Clinical Conductor a minimum of 48 hours in advance.
6.7.3.2 All orders must include the IRB number, MRN, and PI signature.

6.7.4 Epic Orders

6.7.4.1 Confirm orders against the schedule of events.
6.7.4.2 The physician investigator must have signed the pending orders in Epic. The clinic staff is not responsible for additional or missing tests performed based on Epic orders.
6.7.4.3 Orders must be signed by a physician investigator (if PI is PhD, co-investigator who is an MD must sign the orders) who has medical privileges at UCSD.
6.7.4.4 Orders must be linked to the correct research study. For more information on how to link orders, follow this training link: https://pulse.ucsd.edu/departments/EMR/ResourceLibrary/Documents/Research/Research%20Orders%20Need%20Linked%20to%20Research%20Study.pdf

6.8 Lab Kits
- 6.8.1 Lab kits must be delivered to the lab by 12 noon the day prior to the visit.
  - 6.8.1.1 All tubes must be labeled with the correct subject ID information.
  - **6.8.1.2 <u>If the lab kit is not provided to the clinic on time, the visit may be canceled.</u>**

6.9 General information or questions
- 6.9.1 Email ACTRI ctri-clinic@health.ucsd.edu with questions.
  - 6.9.1.1 This email is checked twice per week.
  - 6.9.1.2 If urgent, contact Clinic leadership.
  - 6.9.1.3 When sending an email with participant information, use "*Secure:"* in the subject line.
- 6.9.2 For immediate needs or questions, contact the clinic nurses' station
- 6.9.3 Take advantage of afternoon or Friday visits
- 6.9.4 Request to be added to the "All Clinic User Email List" to ensure receipt of important clinic updates.

6.10 Special medication orders
- 6.10.1 If specific medications or supplies are required for the study, notify the clinic manager at least a week in advance.
- 6.10.2 If controlled substances are needed, notify clinic manager at least two weeks in advance

6.11 Recharge rates
- 6.11.1 All recharge rates are available via email request or on the ACTRI website.

6.12 Pharmacy Guidelines
- 6.12.1 IDS Pharmacy is located within ACTRI and works together with the clinic but the units maintain separate workflows. For all pharmacy questions, services, or inquires, email CTRI-IDSPharm@ucsd.edu
- 6.12.2 Send IDS prescriptions and orders separately to pharmacy at least 24 hours in advance
- 6.12.3 Pharmacy requires a separate in-service
- 6.12.4 Email pharmacy for cancellations that include medications
- 6.12.5 Pharmacy begins preparing medications upon patient arrival

6.13 Clinic Access
- 6.13.1 All UC San Diego staff who require clinic access must complete required training and obtain approval.
  - 6.13.1.1 Request clinic access at this link: https://ucsd-actri.jotform.com/211674870051857
  - 6.13.1.2 Complete required training
    - 6.13.1.2.1 Good Clinical Practice
      - 6.13.1.2.1.1 The organization is University of California, San Diego
      - 6.13.1.2.1.2 Additional reading about good clinical practices:

https://blink.ucsd.edu/research/policies-compliance-ethics/compliance/gcp.html

6.13.1.2.2 Laboratory training on the UC Learning Center
6.13.1.2.2.1 Biosafety: Bloodborne Pathogens Training and Annual Refresher
6.13.1.2.2.2 Annual Laboratory Hazards Training
5.13.1.2.2.3 UC Laboratory Safety Fundamentals
6.13.1.2.3 Clinical Conductor Training.
6.13.1.2.3.1 The CCR management team will reach out to schedule the training.
6.13.1.3 Answer questions as prompted
6.13.1.4 Upload proof of required training

6.14 Clinic Orientation – Clinical Research Coordinator (CRC)
6.14.1 All CRC's new to the ACTRI Clinics will be required to spend 4-6 hours shadowing ACTRI coordinators and clinic staff prior to scheduling visits in the clinic.
6.14.1.1 2 hours with ACTRI CRC
6.14.1.2 1 hour with ACTRI Clinic staff
6.14.1.3 1 hour of Clinical Conductor training
6.14.1.4 1 hour with front desk admin
6.14.2 All CRC's will be required to complete required training:
6.14.2.1 CITI GCP training
6.14.2.2 Epic training
6.14.2.3 Clinical Conductor training

6.15 COVID-19 Guidelines
6.15.1 The ACTRI Clinics will follow UC San Diego ambulatory care policies in regard to social distancing and masking guidelines.

6.16 Is the study ready to go?
6.16.1 Have you completed your in-service?
6.16.2 Have you completed your pharmacy in-service?
6.16.3 Has your study been built in Epic?
6.16.4 Do you have all of your supplies?
6.16.5 Are your visits scheduled correctly?
6.16.6 If required, are your orders uploaded in Clinical Conductor?
6.16.7 Have you reviewed and confirmed accurate orders in Epic?
6.16.8 Are you orders linked to research?
6.16.9 Is your study participant's visit linked to research?
6.16.10 Are your orders sent to pharmacy?
6.16.11 Do you have all of your special requests?
6.16.12 Does your participant require meals or snacks? If so, notify the clinic dietitian - Cindy Knott cknott@health.ucsd.edu for special requests.

6.17 Friendly reminders for coordinators:

6.17.1 ACTRI La Jolla Main Clinic Hours are from 7:00am to 5:30pm
6.17.1.1
6.17.2 Make sure you are prepared for your visit with all supplies, orders uploaded, kits with correct number of tubes and orders, shipping labels, and Epic orders entered.
6.17.3 Make sure there are signed orders uploaded in Clinical Conductor board, or signed and linked orders and signed consent uploaded in Epic for studies built in Epic.
6.17.4 Make sure you have provided the lab manual to the Clinic lab manager.
6.17.5 Epic Clinical Research Coordinator Quick Start Guide

## 7 MATERIALS

7.1 ACTRI Clinic JotForm Service Request
7.2 Study In-Service Request JotForm
7.3 Clinic Appointment Request Form
7.4 Epic training: Appointments Linked to Research Studies
7.5 Epic training: Orders Linked to Research Studies
7.6 Clinic Access Request JotForm
7.7 CITI Program: Good Clinical Practice Training
7.8 GCP Information – Research Compliance

## 8 REFERENCES


8.1 ACTRI SOP CCR:012 ACTRI Study Build Workflow
8.2 ICH E6 (R2) Guidelines for Good Clinical Practice
8.3 Quick Start Guide: Clinical Research Coordinators