Office of Regulatory Affairs

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Description of Services

The Office of Regulatory Affairs (ORA) provides a broad spectrum of support for Clinical Investigators and their study teams in the conduct and navigation of clinical research regulatory requirements.

Services provided by this office include: Scientific and Feasibility Review, Data and Safety Monitoring, internal monitoring and auditing support, FDA and Sponsor inspection/audit preparation and guidance, ClinicalTrials.gov registration and results reporting assistance, FDA IND/IDE guidance and support, regulatory binder preparation, and more.

The mission of the ORA is to guide and support the UCLA clinical research community through the different compliance requirements associated with the conduct of clinical research.

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Scientific Review Committee

Established in September 2016 and formally mandated in July 2022, the UCLA Scientific Review Committee (SRC) provides a scientific and feasibility review for non-oncology studies that meet the National Institutes of Health (NIH) definition of a Clinical Trial and that have not already been reviewed by an external scientific review committee. This scientific review is intended to complement the Institutional Review Board (IRB) review through a detailed review of the required elements of the clinical protocol, statistical applications, adequacy of research staffing, any competing trials, well-constituted data collection forms, and utilization of institutional resources.

The Committee meets on the first and third Wednesday of every month. Meeting Schedule with deadlines.

Investigators are not required to initiate SRC reviews and there is no application process. All study documentation is collected by the ORA staff and provided to the SRC for review. SRC review occurs prior to IRB review.
Data Safety Monitoring Board (DSMB)

A Data and Safety Monitoring Board (DSMB) is a group of individuals with pertinent expertise that reviews accumulating data from an ongoing clinical trial. The CTSI DSMB offers oversight for those investigator initiated trials that do not have an external DSMB oversight mechanism. The DSMB advises investigators regarding the continuing safety of trial subjects and those yet to be recruited to the trial, as well as the continuing validity and scientific merit of the trial.

The CTSI DSMB performs the following general functions:

- Objectively appraise a study’s progress
- Assess data quality via a formal and planned process
- Provide analytical expertise and rigor
- Determine the statistical significance of efficacy and/or risk?benefit ratio

Required forms for submission to DSMB to be submitted to the Office of Regulatory Affairs.

1. CTSI Serious Adverse Event Reporting Form
2. Single Subject Exception Request Form

Learn more about Data & Safety Monitoring at UCLA

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Internal Monitoring and Auditing

Sponsor-Investigators are responsible for the selection of qualified study monitors and ensuring that the trials are adequately monitored throughout the life of the trial. At UCLA, the Office of Regulatory Affairs offers assistance with monitoring and quality assurance auditing for investigator-initiated studies. This service helps ensure compliance with FDA, GCP, and IRB regulations, and UCLA Health System policies and guidance, as related to clinical research. Please contact the Office of Regulatory Affairs for more information.

The ORA monitoring program provides a proactive (rather than “for cause”) regulatory assessment and has a strong educational component. Investigators are required to provide monitoring findings to the IRB according to their policies.

The ORA auditing program includes routine and for-cause reviews (requested by institutional officials). The purpose of routine reviews is to assist investigators with achieving and maintaining regulatory compliance. The reviews are meant
to be educational rather than punitive in nature. The ORA summarizes and reports the findings directly to the investigators and the CTSI DSMB.

When writing a grant proposal, Investigators are encouraged to include costs for monitoring and auditing of their study. Contact the Office of Regulatory Affairs for details.

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Sponsor Monitoring for Clinical Research Studies

For clinical research studies where a study sponsor is obligated by the FDA to monitor study source records, sponsors may now be provided monitoring capability through one of three mechanisms:

1. Remote monitoring through HealthLink (a module within UCLA’s CareConnect Electronic Health Records System) for CareConnect related source records, and UCLA’s secure instance of Box.com for source/study documents not stored in CareConnect;
2. Remote monitoring through UCLA’s secured instance of Zoom video conferencing facilitated by the principal investigator and research team; and/or
3. Safe and compliant on-site monitoring facilitated by the principal investigator & research team as outlined by the following procedures and/or policies (links may require UCLA AD login):
   - UCLA Safety and Masking Guidance
   - UCLA Patients/visitors/vendors Visitation Guidance
   - UCLA Visitor Guidance
   - UCLA Health Temperature and Symptom Screening Guidelines

Remote monitoring through HealthLink requires both, a Remote Monitoring Agreement facilitated by Clinical Trial Contracting & Strategic Relations (CTC-SR), as well as budget allocations for applicable Remote Monitoring Set-Up and Provisioning Fees (referenced below) for each sponsor-monitor provisioned with remote monitoring access. The institutional remote monitoring agreement and applicable remote monitoring fees have been standardized to streamline remote monitoring setup and mitigate negotiation. The option for remote monitoring may be made available prospectively during contract negotiations for new clinical trial agreements received by CTC-SR as of October 1, 2020. For existing studies, a process has been established to prioritize study teams and sponsors requiring remote monitoring access with the limited resources available to support remote monitor contracting, set-up and provisioning. For more information, please contact CTSIORA@mednet.ucla.edu.

For source and study documents stored external to CareConnect, such documents should be redacted appropriately of participant Protected Health Information (PHI) and uploaded to UCLA secure Box.

Remote Monitoring for sponsors through Zoom is to be facilitated by the research team. Monitoring language in existing clinical trial agreements would typically not require modification to enable Zoom-based monitoring. Should you have industry clinical trial contract related questions please contact Tamika Merrick, Director of CTC-SR at TMerrick@mednet.ucla.edu.
Remote Monitoring Fee Schedule (Direct Costs)

Fee Classification

Per Study, Per Monitor, Per Visit

Industry Funded Clinical Research Study

*Please note: all fees above are subject to the applicable UCLA indirect rate(s).*

Remote monitoring set-up and provisioning fees may include, but are not limited to, facilitation of the following tasks:

- Remote monitoring terms and obligations contract review and execution with study sponsor(s) and CRO(s) for each applicable clinical research study.
- Study-specific statement of work defining scope and effective timeline for provisioning.
- Individual study monitor terms and obligations agreement review and completion.
- UCLA Healthlink Electronic Health Record (EHR) user access application review and completion.
- Remote study monitor provisional access application completion.
- Remote study monitor online training – scheduling, facilitation, and completion.
- Remote study monitor approval and access provisioning.
- Remote study monitor virtual visit scheduling and research participant linking to Healthlink.
- Remote monitoring use and access compliance – tracking, auditing, maintenance and reporting.

Monitors may not in any way divulge, save, copy, print, record, photograph, download, export, screenshot, release, sell, loan, alter and/or destroy any PHI except as permitted by law and properly authorized by the policies of the Participant. Any breach of the responsibilities and/or conditions of the terms of my access may be subject to access suspension, employer notification and disciplinary action, and may be subject to civil and/or criminal charges, as applicable. Reinstatement of suspended access will be subject to the requirements, training and fees associated with new user access, as determined at UCLA’s discretion.

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- **What is the Remote monitoring set up fee?**
  For Industry (for profit) funded studies the cost is $2500 per study. The $2500 cost covers the provisioning of a study and one monitor for that study. For each additional monitor to be provisioned for that study, it is an additional $2000.

- **Is the $2500 a one-time fee, or is it per remote monitoring visit (RMV)?**
  Yes, the $2500 is a one-time fee. It is the study set up fee and also covers provisioning one monitor for that
study. For each additional monitor to be provisioned for that study, it is an additional $2000. An additional $2000 will be charged each time a new monitor comes onto the study. The cost is not per RMV. If there is staff time on your end, you will need to discuss those charges separately.

- Are the signed forms (healthlink user access form, confidentiality statement form and Individual user access form) a one-time requirement or do they need to be provided prior to each RMV?
  The signed forms are a one-time requirement only.

- If a monitor has already been provisioned for a study (eg. study A) and is now requesting access to another study (study B), are they required to provide the signed forms again?
  No, It is not required. The study team/Sponsor/CRO contact should e-mail Uma Ganapati at uganapati@mednet.ucla.edu requesting access for the monitor for the additional study and provide the following information:
  - i. Name of the previously provisioned monitor
  - ii. IRB# for the study they are requesting access to
  - If the study has a fully executed remote monitoring agreement, the provisioning process will be initiated immediately.

- Do clinical research coordinators need to be trained to provide access to specific patients during the specified time frame?
  Once the CRAs EMR access is provisioned, the study team will be provided with a tip sheet that the clinical coordinators can refer to, for help releasing subjects. There is no additional training.

- Who on the study team can release subject records to CRAs for remote review?
  Only certain study personnel like research nurses or clinical research coordinators are able to release subject records. Data managers are not able to do so. The system has been set up in this manner based on a study personnel’s job description.

- Will monitors only have access to the subject records they are assigned to review or all the subjects. For example, if monitor A is assigned to review subjects 001 and 002 on a study and Monitor B is assigned to review subjects 003 and 004 on the same study, will both monitors have access to all 4 subjects on the study?
  Yes. Coordinators release patients to a specific HL (Healthlink) patient list (the Patient Group), which is built by study. The research monitors are given access to specific studies (the User Context, which is linked to the Patient Group). A research monitor who has been provisioned with a User Context for a specific study will have access to all the patients who have been released to the study. In this scenario if a monitor should not access specific patient charts, this should be a training point to instruct the monitor to not open the charts they should not open. Every access is fully auditable, so if anything ever gets called into question there is an audit trail that the Healthlink team can look back on.

- How long is each remote monitoring visit (RMV)?
  Each RMV is capped at 5 days. The system will generate an error message if the coordinator tries to release subject records for longer than 5 consecutive days. After 5 days (or shorter if set for less time by the study team), the subject records will no longer be able to be seen by the monitor. This ensures the CRAs’ EMR access is limited to the dates specified for the RMV.

- Is there a way to undo release of a subject for monitoring? For example, if we learn that a monitor doesn’t need to review screen fails, how would we remove their access from those patients, so that we can minimize PHI access?
  Yes, if you need any records unreleased prior to the expiration (duration when remote access to the subject records is available to the CRA) please e-mail Uma Ganapati at uganapati@mednet.ucla.edu. A ticket will be opened and assigned to the CC Link team. It is a tool the Healthlink team can run on the backend.

- How long is the EMR access valid?
  Once provisioned, the monitor will have approved access to the system for up to one year, that can be renewed annually for the life of the study or up until the monitor is no longer associated with the study, whichever
• How often can monitors schedule these RMVs?
  Monitors can schedule RMV as many times as necessary depending on the study teams availability. Once the
  monitor has access to the study, they should communicate with the study team to schedule RMV. The study
  team connects the subject records to the study monitor and sets the remote review dates based on the mutually
  agreed upon remote monitoring dates.

• Once approved to remote monitor, how would monitors go about scheduling these RMVs?
  The local team would handle the scheduling of the monitoring and connecting of subjects with the monitoring
  visit. Once the CRA has EMR access, they should reach out to the study team to schedule remote monitoring
  visits. Once they mutually agree to the dates, the study personnel authorized to release subject records will go
  into the system to release subject records for that particular remote visit. Subject records may be released for
  review for up to a max of 5 days. If the remote visit is only scheduled for 2 days, the release of records can be
  restricted to only those 2 days or as many days as the visit is scheduled for, but may not exceed 5 consecutive
days. The system will generate an error message when attempting to release records beyond 5 days.

• Once in-person monitoring visits are re-instated, will CRAs lose access to the remote EMR?
  There are no current plans to stop remote visits.

• What does the monitoring training for CRAs entail?
  It is an online training for CRAs on navigating HealthLink. It is pretty quick and easy to complete. The study
  team will be provided with a tip sheet that they can use to link the subject to the RMV and release records to
  the CRA for remote review.

• Does the Remote monitoring access include the use of Box or any other systems to share files that
  wouldn’t normally be in CC (such as questionnaires or regulatory files)?
  Documents that are not in CareConnect can be redacted for subject identifying information and uploaded to the
  UCLA Health Box system. You must limit the monitor’s view to read only. The ORA office is not involved in this
  process. If there is staff time on your end for setting this up, you will need to discuss those charges separately
  with the sponsor.

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Preparing for an FDA or Sponsor Inspection

Upon notification of an FDA inspection, please contact the Office of Regulatory Affairs immediately for guidance and
assistance. The ORA provides one-on-one inspection/audit preparation guidance, education on how to interact with
the FDA, and provides support for responding to the FDA’s findings, if needed.

If there is a concern about the study preparedness for a Sponsor audit, contact the Office of Regulatory Affairs to
request an audit readiness assessment for both industry and investigator-initiated studies. This program helps ensure
compliance with FDA, GCP, and IRB regulations, and UCLA Health System policies and guidance, as related to clinical
research. The results of the pre-audit assessment will be provided for investigators and teams.

Visit FDA Inspections & Alerts to learn more.

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Regulatory Consultations

The Office of Regulatory Affairs offers a wide variety of regulatory consultations to Clinical Investigators and their study teams in the navigation of the regulatory process.

ClinicalTrials.gov

The Food and Drug Administration Amendments Act of 2007, Section 801 (FDAAA 801) requires Responsible Parties to register and submit summary results of clinical trials with ClinicalTrials.gov and applies to certain Clinical Trials of drugs (including biological products) and medical devices. The International Committee of Medical Journal Editors (ICMJE) requires trial registration as a condition of the publication of research results generated by a clinical trial as required by ICMJE. Finally, Centers for Medicare & Medicaid Services (CMS) require inclusion of an 8-digit Clinical Trial number from ClinicalTrials.gov on claims associated with Clinical Trial participation.

The ORA provides support, for non-cancer studies, to assist and advise Principal Investigators with their obligations. Please contact Elaine Cooperstein for guidance on registration, results reporting, and a PRS account.

Regulatory Binder Preparation

A Regulatory Binder assists sites in achieving and maintaining regulatory compliance and ensuring the highest standards of human subject research. Regulatory binders house all study documentation including, but not limited to, the study protocol, staff CVs, licenses, logs, IRB documents, consent forms, data collection/CRFs, lab documents, sponsor documents, drug/device accountability, FDA documentation, financial disclosure documentation, DSMB information, and more.

For guidance on developing a regulatory binder or evaluation of your current binder, please contact Associate Director, Uma Ganapati PhD.

FDA IND/IDE Guidance and Support

Support for investigators holding an IND or IDE at all stages of an investigation including:

- Determination of product classification (i.e., drug, device, combination product, biologic)
- Applicability of an IND or IDE
- Assistance with IND or IDE application and subsequent submissions (amendments, safety reports, annual and final reports)
- Preparation, coordination, facilitation, and attendance at FDA meetings
- Preparation for and regulatory support during FDA inspections of investigator-sponsored clinical trials
- Update regarding new guidance documents, inspection trends, inspection actions and new regulatory actions taken by FDA relating to clinical trials

Please contact Director of FDA Affairs, Marlene Berro MS, RAC for additional information.

More

Individual and small group trainings and lectures covering good clinical practice and the conduct of clinical research. To request a training or for other clinical trial regulatory affairs questions, please contact us.

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FDA Affairs
Located in the CTSI Office of Clinical Research, the FDA Affairs team provides FDA support and guidance for investigators submitting or holding an IND or IDE at all stages of an investigation. In addition, the FDA Affairs team has created a virtual clinical research platform called ResearchGo that provides a single portal to a wealth of resources, expertise, and best practices for investigators and research staff to facilitate efficient, compliant and ethical study conduct and management.

**What We Do**

- Determination of product classification (e.g., drug, device, combination product, biologic)
- Applicability of an IND or IDE
- Assistance with IND or IDE application and subsequent submissions (e.g., amendments, safety reports, annual and final reports)
- Preparation, coordination, facilitation, and attendance at FDA meetings
- Preparation for and regulatory support during FDA inspections of investigator-sponsored clinical trials
- Update UCLA research community regarding new guidance documents, inspection trends, inspection actions and new regulatory actions taken by FDA relating to clinical trials
- Drug, Device, and Biologic Protocol Development
- Consult with TDG and other campus entities including UCLA Anderson School and School of Bioengineering regarding Drug and Device Development

**Who We Are**

- Marlene Berro, MS, RAC - Director, FDA Affairs
- Jenny Ahn, BSN, RN - FDA Specialist
- Amanda Gonzales, MPH, CCRP - FDA Specialist

Last updated: 13 Apr 2023

**Contact Us**

- Terra Hughes, M.S., Director, CTSI Office of Regulatory Affairs

- Scientific Review Committee
- Data and Safety Monitoring Board
- Training and Lectures
- General Questions

- Uma Ganapati, Ph.D., Associate Director, CTSI Office of Regulatory Affairs

- Internal Auditing and Monitoring
- FDA and Sponsor Inspection/Audit Preparation
- Regulatory Binder Preparation

- Elaine Cooperstein, MS, CCRP, ClinicalTrials.gov Liaison, CTSI Office of Regulatory Affairs

- ClinicalTrials.gov, including PRS account access, registration, and resulting reporting
Marlene Berro, MS, RAC, Director, FDA Affairs

- FDA IND/IDE Guidance
- ResearchGo Site

Required forms for submission to DSMB to be submitted to the Office of Regulatory Affairs.

1. CTSI Serious Adverse Event Reporting Form
2. Single Subject Exception Request Form

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