

## [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.

Last updated: 30 Oct 2017

### **Scientific Review Committee**

Established in September 2016, the Clinical and Translational Science Institute (CTSI) Scientific Review Committee (SRC) provides a scientific and feasibility review of non-oncology clinical research to ensure that UCLA clinical research is of the utmost quality,

The degree of review required varies based on the type of research, funding, and institutional factors. CTSI SRC review is conducted on those clinical trial protocols that have not already received documented full peer review.

The Committee meets on the first and third Wednesday of every month.

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 in parallel with IRB review.

Please email the [CTSI SRC](#) with any questions.

Last updated: 30 Oct 2017

## 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

Last updated: 24 Feb 2017

## 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 informaton.

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.

Last updated: 14 Nov 2016

## 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.

Last updated: 14 Sep 2016

## 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](#).

Last updated: 17 Jan 2017

## 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 and Navigation Support

- [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](#)

Last updated: 9 Jan 2017

Last updated: 31 Aug 2016

- Group 1
  - [Clinical Research Information Systems](#)
  - [Clinical Research Business Partners](#)
- Group 2
  - [Office of Research Administration](#)
  - [Jonsson Comprehensive Cancer Center](#)
- Group 3
  - [Office of Human Subjects Protection](#)
  - [CareConnect Website](#)

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