Regulatory Consultations

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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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