

Resource Overview

FDA Regulatory Support Provided by the Clinical Research Compliance Office (CRCO) within the Office of the Vice Chancellor for Research at the University of North Carolina at Chapel Hill

Introduction:

The FDA regulatory process is essential for ensuring the safety, efficacy, and quality of drugs, biologics, and medical devices in clinical research. The CRCO provides support to sponsor-investigators by assisting with FDA-related regulatory requirements, including initial submissions, amendments, supplements, and annual reporting requirements. By providing this resource, the CRCO assists sponsor-investigators in ensuring compliance with FDA regulations, streamlining the regulatory process, reducing risks of non-compliance, and supporting successful outcomes for federally funded research projects.

Key FDA Regulatory Support Services:

CRCO's goal is to help ensure that IND and IDE related submissions are complete, properly organized, and submitted in a timely manner, supporting compliance and reducing avoidable delays in clinical research.

CRCO is responsible for:

The CRCO assists with the administrative preparation, compilation, organization, and high-level review of required FDA submissions, including initial IND/IDE submissions. We help ensure that all required components are present, appropriately formatted, and aligned with basic FDA submission expectations.

Activities outside the CRCO's scope:

The CRCO does not develop, write, revise, or interpret scientific, clinical, or regulatory content for INDs, IDEs, amendments, or annual reports. This includes but is not limited to drafting study protocols, risk assessments, preclinical summaries, investigational plans, device descriptions, regulatory rationales, or clinical justifications.

Sponsor-investigators remain fully responsible for determining regulatory strategy and ensuring the accuracy, adequacy, and scientific validity of all content submitted to the FDA.

Initial Submissions to the FDA

The CRCO provides administrative and organizational support for preparing Investigational New Drug (IND) and Investigational Device Exemption (IDE) submissions working with sponsor-investigators to ensure that all necessary documentation is complete and accurate. This includes:

- Investigational New Drug (IND) Applications for drugs and biologics
- Investigational Device Exemptions (IDE) for medical devices
- Ensuring compliance with FDA guidelines for submission requirements, study protocols, informed consent forms, and investigator brochures
- Conducting high-level review to ensure all required components are included.

Value: The CRCO works with the sponsor-investigator to ensure that all necessary regulatory documentation is submitted correctly and on time, helping to avoid delays in the approval process. This facilitates the timely launch of clinical trials and ensures that research can proceed without unnecessary regulatory setbacks.

Amendments and Supplements

During the course of a clinical trial, changes to the study design, protocol, or other aspects of the regulatory filing may be necessary. The CRCO supports sponsor-investigators by ensuring that any amendments or supplements are compliant with FDA requirements. This includes:

- Assisting with the compilation and submission coordination of Amendments or Supplements to INDs or IDEs, ensuring the submission materials are complete and formatted appropriately.
- Providing guidance on what documentation must be included when changes occur (e.g., revised protocol, updated investigator information) and facilitates organization of these materials for submission.
- Performs a high-level administrative review to confirm that required elements are present before submission.

Value: The CRCO helps mitigate risks by working with sponsor-investigators to ensure all necessary amendments and supplements are properly submitted to the FDA. This reduces the risk of trial interruptions or delays due to regulatory issues and ensures continuous compliance with FDA rules.

Annual Reports

The CRCO assists sponsor-investigators in managing the submission of Annual Reports to the FDA. These reports are essential for maintaining active INDs and IDEs, ensuring that clinical trials are progressing according to plan, and identifying any issues early in the process. The CRCO assists with:

- Supporting sponsor-investigators in ensuring timely submission of required annual progress reports for clinical trials under an IND or IDE.
- Compilation and organization of documents that the sponsor-investigator has prepared, such as updated protocols, adverse event reports, investigator information, manufacturing updates, or trial-status summaries.
- Performing a high-level administrative review to confirm that all required components are present and the report is formatted appropriately for FDA submission.

Value: The CRCO helps to ensure that all annual reports meet FDA standards, reducing the risk of regulatory non-compliance, and ensuring the continued progress of research. This proactive approach helps maintain good standing with the FDA and supports ongoing trial operations.

Regulatory Guidance and Training

The CRCO also provides ongoing regulatory education and training to sponsor-investigators, ensuring that they understand the complexities of FDA regulations. This includes:

- Training programs on FDA regulations relevant to clinical research, including the IND/IDE process, clinical trial protocols, and regulatory reporting
- Consultation services to help investigators navigate FDA requirements for specific studies, including preparation for FDA meetings and inspections
- Educating research staff on Good Clinical Practice (GCP) compliance
- Assistance with the preparation and facilitation during FDA inspections

Value: Regular training helps to build internal expertise, ensuring that sponsor-investigators are up to date on FDA guidelines and can respond quickly to any regulatory changes or challenges. It empowers sponsor-investigators to submit accurate, high-quality documentation that supports their studies.

Impact and Value to Federally Funded Grant Success

The CRCO's support in FDA regulatory matters is important to the successful management of federally funded research projects. By providing expert guidance on FDA submissions, amendments, and ongoing regulatory reporting, the CRCO assists with ensuring studies comply with the necessary regulations, reducing risks of delays or non-compliance. This support not only helps maintain the integrity of the research process but also facilitates the smooth progression of clinical trials, ensuring timely access to new treatments and therapies.

The office's proactive approach to regulatory compliance, combined with its support in preparing for FDA inspections and meetings, enhances the likelihood of favorable outcomes during regulatory reviews. These efforts align with the University's goal of advancing public health through safe, effective, and scientifically sound research.

Conclusion

The FDA regulatory support provided by the CRCO is essential for the success of federally funded clinical research. The office assists the sponsor-investigator to ensure that all FDA submissions, amendments, and annual reports are handled in a timely, compliant manner, thus helping sponsor-investigators navigate complex regulatory requirements. By offering ongoing regulatory guidance and support for FDA interactions, the CRCO minimizes risks and helps ensure that federally funded research progresses smoothly, ultimately contributing to the advancement of public health.