CCTS IND/IDE CONSULTATION TEAM

Providing assistance with initial packet submissions, follow-up, protocol amendments, safety reporting, responses to FDA requests for information, and annual reporting

WHAT TO EXPECT

PRIOR TO AND DURING SUBMISSION TO THE FDA:

- Respond to general requests for information from investigators
- Meet with investigators to provide guidance and answer questions about FDA submissions
- Provide assistance with preparation of packets for submission, including templates, forms, and letters (with institutional signatures)
- Edit for clarity and conformance with FDA expectations
- Format, copy and assemble final documents, including accompanying CDs and copies, and facilitate submission
- Coordinate institutional reviews and signatures

FOLLOWING SUBMISSION TO FDA:

- Assist with FDA communications and questions
- Maintain records of and tracking of all submissions via electronic database and hard copy files
- Coordinate and submit annual reports
- Review and submit amendments or responses required by FDA
- Assist with safety reporting

NEED A CONSULT OR HAVE A GENERAL QUESTION?

Contact Dunia Ritchey at dritchey@peds.uad.edu or 205-492-5703

CCTS
Center for Clinical and Translational Science

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