Contact Us

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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

Last updated: 6 Nov 2023

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