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

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