DATA AND SAFETY MONITORING PLAN for NCATS PRIOR APPROVAL

**OVERVIEW OF REGULATION**

It is the policy of the NIH that each Institute and Center (IC) should have a system for the appropriate oversight and monitoring of the conduct of clinical trials to ensure the safety of participants and the validity and integrity of the data for all NIH-supported clinical trials. The establishment of the data safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risk to the participants. The data and safety monitoring functions and oversight of such activities are distinct from the requirement for study review and approval by an Institutional Review Board (IRB).

**DESCRIPTION OF PLAN**

*If the proposed research includes a clinical trial, describe an appropriate Data and Safety Monitoring Plan that includes:*

1. *a description of a monitoring plan*
2. *identification and description of who will be responsible for monitoring*
3. *the process by which Adverse Events (AEs) and Unanticipated Problems (UP) will be reported to all relevant regulatory bodies.*