

Protection of Human Subjects for Grant Submissions NC TraCS Institute Data and Safety Monitoring Plan (DSMP) Template

This section should be specific to the research being proposed, should describe the specific risks to subjects who participate, and how risks will be minimized. If the various specific aims are very different and/or involve different populations, this section can be done individually for each specific aim. Be sure to describe IRB approval of the research project will be obtained, that no research will be performed until IRB approval received and that IRB approval for gaining access to the subjects that will be recruited and enrolled into the study will be obtained.

I. RISKS TO SUBJECTS

- a. Human Subjects Involvement and Characteristics:** Describe study population, basic characteristics for inclusion in study
 - i. Proposed involvement of human subjects – describe & justify proposed involvement of human subjects
 - ii. Characteristics of the subject population – include anticipated number, age range, health status if relevant
 - iii. Sampling plan, recruitment & retention strategies:
 - iv. Enrollment criteria - Inclusion/exclusion criteria, exclusion of any subpopulation
 - v. Rationale for involvement of special vulnerable populations, including pregnant women, fetuses, neonates, children, prisoners, institutionalized
 - vi. Study group assignment and treatment, selection of intervention dose, frequency
 - vii. Collaborating sites where research performed, role of sites & investigators; explain how data from site obtained, managed, protected
- b. Source of Materials:** Describe material obtained from living individuals in form of specimens, records or data
 - i. Human research material and data collection: Clinical data, blood samples, safety Labs, questionnaires, other data.
 - ii. Access to individually identifiable information
 - iii. Specimen and data management and protection
- c. Potential Risks** (physical, psychological, financial, legal, other): Describe all risks from study participation - treatments, procedures, interventions, including potential loss of confidentiality

II. ADEQUACY OF PROTECTION AGAINST RISKS

- a. Recruitment and Informed Consent**
 - i. Recruitment - Describe plans for recruitment of subjects, if selection of subjects is random or from some database, advertisements, etc
 - ii. Informed consent process - Describe the consent process, who will seek it, nature of information provided, method of documenting consent, if waiver of consent will be sought, that consent forms will be IRB approved.
 - iii. Informed consent documents DO NOT need to be submitted to the PHS agencies unless requested
- b. Protection against risk**
 - i. Describe plan for protecting against or minimizing risks, including risk to privacy or confidentiality of data.
 - ii. Vulnerable populations, describe protections as relevant (see subparts B-D)
 - iii. Discuss plans for ensuring medical or professional intervention in event of adverse effects. Clinical trials must include description of plan for data and safety monitoring of clinical trial and adverse event reporting to IRB, NIH, and others to ensure safety of subjects.

III. POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE SUBJECTS AND OTHERS

- a. Discuss the potential benefits of the research to research participants and others.
- b. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others.

IV. IMPORTANCE OF THE KNOWLEDGE TO BE GAINED

- a. Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- b. Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

V. DATA AND SAFETY MONITORING: If proposed research includes a clinical trial, create heading entitled "Data and Safety Monitoring Plan." Provide a general description of a monitoring plan you will establish as the overall framework for data and safety monitoring.

A. Adverse Events and serious adverse event collection and reporting: Describe following:

- Process by which Adverse Events (AEs) will be reported to IRB, the funding I/C, the NIH Office of Biotechnology Activities (OBA), DSMBs, and the FDA in accordance with Investigational New Drug (IND) or Investigational Device Exemption (IDE) regulations.
- Timelines for adverse events (AE) and serious adverse events (SAE) collection and reporting (include a decision tree for reporting SAEs if available).
- Definition of AEs, SAEs, and unanticipated problems; include adverse event grading scales/classification system and study relatedness criteria.
- Procedures for documentation of adverse events.
- Specify plans for communication of AEs / SAEs with other sites.

B. Describe entity responsible for monitoring. Options for monitoring trials include, but are not limited to, monitoring by:

- PD/PI (required)
- Institutional Review Board (IRB) (required)
- Independent individual/safety officer
- Designated medical monitor
- Internal Committee or Board with explicit guidelines
- DSMB: NIH specifically requires the establishment of Data and Safety Monitoring Boards (DSMBs) for Phase III clinical trials. Occasionally required for Phase I & II trials. Alternative monitoring may be appropriate for smaller clinical trials

C. Monitoring of Data: The frequency of monitoring will depend on potential risks, complexity, and the nature of the trial. Describe the following:

- Who is responsible for data and safety monitoring, including name of Safety Officer, type of information that will be reviewed and frequency of such reviews.
- Frequency of data and safety monitoring reviews (include specific time or number of subjects as well as monitoring accrual milestones).
- Planned interim analysis, if any, for safety or efficacy monitoring and rules for stopping the study, based on interim analysis or for defined safety events or endpoints.
- Content of data and safety monitoring reports, including type of data reviewed.
- Plans to check the validity and integrity of the data.
- Include a roster of DSMB member names, affiliations; any conflict of interest, their roles & responsibilities. Describe protection of data presented to the DSMB or SO.