### Data Safety Monitoring Plan

The NIH Data and Safety Monitoring Policy is described and referenced in Part II Section 5.3.

If the proposed research includes a clinical trial (See definition of “clinical trial” under Part III Section 3), create a document entitled "Data and Safety Monitoring Plan." For all clinical trials, NIH requires a data and safety monitoring plan (DSMP) that is commensurate with the risks of the trial and its size and complexity. In this attachment, you must provide a description of the DSMP that you are proposing to establish for each clinical trial proposed, including:

* The overall framework for safety monitoring and what information will be monitored.
* The frequency of monitoring, including any plans for interim analysis and stopping rules (if applicable).
* The process by which Adverse Events (AEs), including Serious Adverse Events (SAEs) such as deaths, hospitalizations, and life threatening events and Unanticipated Problems (Ups), will be managed and reported as required to the Institutional Review Board (IRB), the person or group responsible for monitoring, the funding IC, the NIH Office of Biotechnology Activities (OBA; http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines) , and the Food and Drug Administration (FDA; <http://www.fda.gov/>).
* The individual(s) or group that will be responsible for trial monitoring and advising the appointing entity. Because the monitoring plan will depend on potential risks, complexity, and the nature of the trial, a number of options for monitoring are possible. These include, but are not limited to, monitoring by a:
  + PD/PI: While the PD/PI must ensure that the trial is conducted according to the protocol, in some cases (e.g., low risk trials, not blinded), it may be acceptable for the PD/PI to also be responsible for carrying out the DSMP.
  + Independent safety monitor/Designated medical monitor: a physician or other expert who is independent of the study.
  + Independent Monitoring Committee or Safety Monitoring Committee: A small group of independent investigators and biostatisticians.
  + Data and Safety Monitoring Board (DSMB): a formal independent board of experts including investigators and biostatisticians. As noted in Part II Section 5.3, NIH requires the establishment of DSMBs for multi-site clinical trials involving interventions that entail potential risk to the Supplemental Grant Application Instructions II-11 participants, and generally for Phase III clinical trials. Although Phase I and Phase II clinical trials may also need DSMBs, smaller clinical trials may not require this oversight format, and alternative monitoring plans may be appropriate.
    - If a DSMB is used, please describe the general composition of the Board without naming specific individuals.