**DATA AND SAFETY MONITORING**

**PLAN TEMPLATE**

SF424 (R&R) – Version F

Last revised 6/10/20

**Content Instructions**

* **For human subjects research that does not involve a clinical trial:** Your study, although it is not a clinical trial, may have significant risks to participants, and it may be appropriate to include a data and safety monitoring plan. If you choose to include a data and safety monitoring plan, follow the content criteria listed below, as appropriate.
* For any proposed clinical trial, NIH requires a data and safety monitoring plan (DSMP) that is commensurate with the risks of the trial, its size, and its complexity. Provide a description of the DSMP, including:
  + Indicate how many people and what type of entity will provide the monitoring. Include such details as whether a single person, multiple people, or a data safety monitoring board will provide monitoring. Also indicate what type of entity will provide the monitoring (e.g., PD/PI, Independent Safety Monitor/Designated Medical Monitor, Independent Monitoring Committee, Safety Monitoring Committee, Data and Safety Monitoring Board, etc.).
  + 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)](https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event) such as deaths, hospitalizations, and life threatening events and Unanticipated Problems (UPs), will be managed and reported, as required, to the IRB, the person or group responsible for monitoring, the awarding IC, the NIH [Office of Biotechnology Activities](https://osp.od.nih.gov/biosafety-biosecurity-and-emerging-biotechnology/), and the [Food and Drug Administration](https://www.fda.gov/).
  + The individual(s) or group that will be responsible for trial monitoring and advising the appointing entity. Because the DSMP 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 approved 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 experts.
    - [Data and Safety Monitoring Board (DSMB)](https://grants.nih.gov/grants/glossary.htm#DataandSafetyMonitoringBoardDSMB): a formal independent board of experts including investigators and biostatisticians. NIH requires the establishment of DSMBs for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally, for all Phase III clinical trials, although Phase I and Phase II clinical trials may also need DSMBs. If a DSMB is used, please describe the general composition of the Board without naming specific individuals.
* Additional instructions for Career Development: **CDA applicants who are proposing to gain clinical trial research experience under a mentor's supervision (i.e., you will not be leading an independent clinical trial)**: Include only the following information in your data and safety monitoring plan (i.e., do not follow the standard instructions for the data and safety monitoring plan):
  + The names of the individual(s) or group that will be responsible for trial monitoring (i.e., the lead investigator of the clinical trial).
  + If applicable, the name of an independent safety monitor or a data and safety monitoring board.
* Additional instructions for Fellowship: **Fellowship applicants who are proposing to gain clinical trial research experience under a sponsor's supervision (i.e., you will not be leading an independent clinical trial)**: Include only the following information in your data and safety monitoring plan (i.e., do not follow the standard instructions for the data and safety monitoring plan):
  + The names of the individual(s) or group that will be responsible for trial monitoring (i.e., the lead investigator of clinical trial).
  + If applicable, the name of an independent safety monitor or a data and safety monitoring board.

**Review Criteria and/or Questions to Consider**

* Is the plan for monitoring progress of trials and safety of participants adequate?
* Is the plan for assuring compliance regarding the reporting of adverse events adequate?
* Is there a plan for assuring the temporary or permanent suspension of the clinical trial if necessary? Is the plan adequate? Does it include reporting the suspension to the appropriate NIH Program Director and other relevant agencies?
* Is the plan for assuring data accuracy and protocol compliance adequate?

**Suggested outline**

We have provided a suggested outline on the third page of this document. If you would like, you can enter your text directly below each subsection header. This document is already formatted appropriately (0.5 inch margins, Arial font, 11 point text). Just delete the first two pages and you are on your way to a complete draft!

**DATA AND SAFETY MONITORING PLAN**

***Framework for Safety Monitoring:***

***Frequency of Monitoring:***

***Adverse Events Reporting Plan:***

***Entities Conducting Monitoring:***

**DATA SAFETY MONITORING BOARD** ***(if applicable)***

***Charge of DSMB:***

***Meetings:***

***Meeting Procedure:***

***Reports of DSMB Deliberations:***

***Discussion of Confidential Material:***