This template is based on the NIH instructions here https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#3.3

A "Data and Safety Monitoring Plan" attachment is required if you answered "Yes" to all the questions in the "Clinical Trial Questionnaire." (i.e. your study is an NIH-defined clinical trial).

The "Data and Safety Monitoring Plan" attachment is optional for all other human subjects research. Your study, although it is not an NIH-defined 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, you may follow the content criteria listed below, as appropriate.

When document is complete, delete this box and save as PI LAST NAME_3.3 Data and Safety Monitoring Plan_DDMONYEAR (example-01JAN2022)

NIH-recommended fonts: Arial, Georgia, Helvetica, Palatino Linotype, 11 pt or larger, margins .05 or larger https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm

For more information:

- NIH Grants Policy Statement, Section 4.1.15.6: Data and Safety Monitoring
- NIH Data and Safety Monitoring Policies
- NIH Policies and IC Guidance for Data and Safety Monitoring of Clinical Trials

3.3 DATA AND SAFETY MONITORING PLAN

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:

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) 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 and the Food and Drug Administration.

- 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): 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.