OFFICE OF THE INSTITUTIONAL REVIEW BOARD

Standard Operating Procedures		
SOP #307.1 Revision 1	**TITLE: Data and Safety Monitoring Plans**	Effective Date: 3/1/2019
Approved By: OIRB Director	Signature	Date 3/1/2019
Approved By: IRB Chair	Signature	Date 3/1/2019

PURPOSE

To describe Institutional Review Board (IRB) review of data and safety monitoring plan(s) (DSMP) to ensure adequate protection of research participants.

REVISIONS FROM PREVIOUS VERSION

Administrative corrections

POLICY

Researchers develop data and safety monitoring plans as a mechanism for assuring the safety of research participants and associated research data, the validity of data, and the appropriate termination of projects. The IRB requires review and approval of data and safety monitoring plans for projects that present greater than minimal risk to research participants or projects funded by the National Institutes of Health (NIH) or regulated by the Food and Drug Administration (FDA), as applicable.

RESPONSIBILITIES

Execution of SOP: IRB, Researchers.

PROCEDURE

1. At initial review, researchers conducting greater than minimal risk research, or NIH funded/FDA regulated research include a description of the proposed data and safety monitoring plan in the IRB protocol.
2. During initial review, the IRB reviews the general description of the DSMP to determine that adequate protections for research participants are in place (see the Initial Full Review SOP).
3. The IRB recognizes that the elements of a monitoring plan may vary depending on the potential risks, complexity, and nature of the project. The IRB reviews several elements of the DSMP, which may include but are not limited to:
   - Plans for monitoring the progress of projects and the safety of participants;
   - Plans for assuring compliance with requirements regarding the reporting of adverse events;
   - Plans for review or analysis of cumulative safety data to determine whether harm is occurring;
   - Plans for assuring that any action resulting in a temporary or permanent suspension of a project is reported to the appropriate agencies;
   - Plans for assuring data accuracy and protocol compliance;
   - Plans for assuring communication among multi-center sites adequately protect the participants (for multi-center projects where the lead PI is employed by UNM or UNM is the coordinating institution).
4. The IRB may request additional information regarding the DSMP at initial review.

5. After reviewing the plan, the IRB may determine that a formal DSMP is not necessary or that the project requires an independent individual or independent body (e.g. Data and Safety Monitoring Board [DSMB]) for monitoring.
6. If an external sponsor or funding agency has the responsibility for data and safety monitoring, the Office of Sponsored Projects (OSP) administrator negotiates the provision of data and safety monitoring plans and reports (both routine and urgent) by the sponsor to the PI in the funding agreement or contract.
7. If the IRB (or an external entity) determines the DSMP of a researcher-initiated protocol must include a Data and Safety Monitoring Board (DSMB), the IRB evaluates the DSMB for membership, charter, and DSMB responsibilities, all of which include, but are not limited to, the following:

   DSMB Membership
   - Multidisciplinary representation from relevant specialties (this may include experts such as bioethicists, biostatisticians and basic scientists);
   - Membership limited to individuals free of apparent significant conflicts of interest, whether financial, intellectual, professional, or regulatory in nature; and
   - Size appropriate to the type of project.

   DSMB Charter
   - Detailed presentation of the membership composition, including qualifications and experience;
   - Roles and responsibilities of the DSMB; and, if relevant:
   - Authority of the DSMB (e.g. advisory to the sponsor, PI);
   - Timing and purpose of DSMB meetings;
   - Procedures for maintaining confidentiality;
   - Format, content, and frequency of DSMB reports;
   - Specific data to be monitored and statistical procedures, including monitoring guidelines, to monitor the identified primary, secondary, and safety outcome variables;
   - Decision rules and actions to be taken upon specific events, outcomes or end points; and
   - Plans for changing frequency of interim analysis as well as procedures for recommending protocol changes.

   DSMB Responsibilities
   - Initial review of the proposed research to assure quality conduct of the project;
   - Procedures to review and assure quality of conduct of the project including data management and quality control procedures;
   - Evaluation of the quality of ongoing conduct of the project by reviewing the research accrual, compliance with eligibility, subject adherence to project requirements, and accuracy and completeness of data;
   - Consideration of factors external to the project when relevant information becomes available, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the research;
   - Recommendations of early termination based on efficacy results or safety concerns;
   - Recommendations of termination due to unfavorable benefit-to-risk or inability to answer research questions;
   - Recommendations for continuation of ongoing projects;
   - Consideration of overall picture, primary and secondary analysis;
   - Modification of sample sizes based on ongoing assessment of event rates; and
   - Review of final results.

8. The PI submits documentation evidencing DSMP or DSMB activities (e.g. summary report, meeting minutes) to the IRB prior to continuation review if provided to the PI by the sponsor or prepared by the PI, as described in the DSMP. The IRB reviews DSMP or DSMB materials received prior to continuation review as an amendment request.
9. The PI is responsible for acquiring evidence that DSMB activities have occurred if the sponsor has not been providing the documentation. At the time of continuation review of the project, the PI submits documentation representing DSMP or DSMB activities not previously submitted to the IRB.
10. At continuation review, the IRB reassesses the risk category and determines whether the PI should provide additional information in the informed consent document based on the information provided in the DSMP or DSMB materials.

REFERENCES

NIH Policy for Data and Safety Monitoring,
http://grants.nih.gov/grants/guide/notice-files/not98-084.html