AAHRPP DOCUMENT # 18
UNIVERSITY OF ALABAMA
HUMAN RESEARCH PROTECTION PROGRAM

GUIDANCE: DEVELOPING A DATA AND SAFETY MONITORING PLAN (DSMP)
OR A DATA AND SAFETY MONITORING BOARD (DSMB)

A Data Safety And Monitoring Plan (DSMP) is a written description of how participants and accumulating data in a study will be monitored to ensure safety of human subjects and human research data, the validity of data, and the appropriate termination of the study. A Data Safety And Monitoring Board (DSMB) is an independent body composed of clinical research experts and community representatives that reviews data while a clinical trial or study of greater than minimal risk is in progress to ensure that participants are not exposed to undue risk.

Studies needing DSMPs and (sometimes) DSMBs are studies of more than minimal risk, clinical investigations and clinical trials funded by the National Institutes of Health or regulated by the Food and Drug Administration, some studies using vulnerable populations, and studies with private sponsors who require them. Note that data and safety monitoring plans and boards are not limited to medical studies. Investigators are invited to discuss their possible need for a DSMP with a research compliance specialist or the Research Compliance Officer before submitting their applications for review. SEE POLICY: Data Safety and Safety Monitoring in Proposed Research for full description.

Guidelines for Developing a DSMP for Your Proposal
Developed by the University of Kentucky Office of Research Integrity and Used by Permission

Include the following components and describe the essential elements of each component:

1. Monitoring the progress of trials/study and the safety of participants
   a. Procedures for detecting harm promptly and mitigating potential injuries
   b. Who actually implements monitoring procedures and how often
   c. What the monitor(s) will be looking for
   d. Procedures to ensure adequate feedback of information to researchers and medical or other decision-makers
   e. If PI is the sole monitor of the trial, explain how conflict of interest will be averted.

2. Assuring compliance with the requirements regarding the reporting of unanticipated problems or adverse experiences:
   a. Procedures for ensuring appropriate reporting of findings to the IRB
   b. Whether you will use a Data and Safety Monitoring Board
   c. Whether you will report findings to other entities and if so, what will be reported and how.

3. Assuring that any action resulting in a temporary or permanent suspension of the study is reported to the appropriate entities (i.e., funding agency):
a. What will be reported and how  
b. What the criteria will be for suspension of “termination” of the study.

4. Assuring data accuracy and protocol compliance:
   a. Quality control measures and who is responsible for implementing  
   b. What procedures are in place to ensure protocol adherence

5. (If this is a multi-site study in which the University of Alabama is the lead site or a coordinating site), Assuring that communication among multi-center sites adequately protects the participant.
   a. Consider such issues as communicating data safety monitoring reports, unanticipated problems, and protocol modifications.

Guidelines for Investigator-Initiated Protocols Which Require a DSMP and Data and Safety Monitoring (DSM) or a Data and Safety Monitoring Board (DSMB)

Please provide the IRB with the following information for their review:

1. Membership
   a. Multidisciplinary representation from relevant specialties, such as bioethicists, biostatisticians, and basic scientists  
   b. Free of apparent significant financial, intellectual, professional, or regulatory conflicts of interest  
   c. The number of members depends on the type and size of the study

2. The DSM/DSMB charter
   a. A detailed description of the membership, including qualifications and experience  
   b. Roles and responsibilities of the Data Safety Monitor or DSM  
   c. The authority of the DSM/DSMB (e.g., advisory to the sponsor or PI)  
   d. The timing and purpose of DSMB meetings  
   e. The procedures for maintaining confidentiality  
   f. The format, content, and frequency of DSM or DSMB reports  
   g. Statistical procedures including monitoring guidelines, which will be used to monitor the identified safety outcome variables  
   h. Plans for changing the frequency of interim analysis as well as procedures for recommending protocol change

3. DSM/DSMB responsibilities:
   a. Initial review of the proposed research to assure quality study conduct  
   b. Procedures to review and assure quality of study conduct including data management and quality control procedures  
   c. Evaluation of the quality of ongoing study conduct by reviewing the study accrual, compliance with eligibility, participant adherence to study requirements, and accuracy and completeness of data
d. Considering factors external to the study when relevant information becomes available, such as scientific or therapeutic developments that may have an impact on the safety of participants or study ethics


e. recommendation of early termination based on efficacy results

f. Recommendations of termination due to unfavorable benefit-to-risk or inability to answer study questions

g. Recommendations of continuation of ongoing studies

i. Considering overall picture, primary and secondary analyses

g. Modifying sample sizes based on ongoing assessment of events rates and review of final results.

**Additional Resources**

*Note: Each link below opens a new window.*


Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees (FDA)  [http://www.fda.gov/CBER/gdlns/clintrialdmc.pdf](http://www.fda.gov/CBER/gdlns/clintrialdmc.pdf)

Guidelines for Developing a Data and Safety Monitoring Plan (National Institute on Drug Abuse (NIDA))  [http://www.drugabuse.gov/Funding/DSMBSOP.html](http://www.drugabuse.gov/Funding/DSMBSOP.html)