

HAC Policies and Procedures

Data and Safety Monitoring Plans and Boards

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Each clinical research study reviewed by the HAC (except for studies that qualify for exempt review) must include a monitoring plan in its protocol. The Description of Research Proposal (DRP) should include a Data and Safety Monitoring Plan (DSMP) if a Data and Safety Monitoring Board (DSMB) is required.

What is a Data and Safety Monitoring Plan?

A Data and Safety Monitoring Plan (DSMP) is a written plan designed to ensure the safety of clinical research subjects, the validity and integrity of research data and to ensure that clinical research subjects are not exposed to undue risks. Clinical research is defined as any study in which an investigator or other research staff interacts directly with human subjects.

The DSMP should include a description of:

- All anticipated risks.
 - Principal Investigator (PI) must state the level of risk and explain why this designation is appropriate.
- Measures in place to reduce the risk(s).
- Who is responsible for data and safety monitoring?
 - How will they respond to risks (anticipated and unanticipated)?
 - How often will monitoring occur?
 - Will they assess a change to the risk-benefit ratio?
 - If the PI is monitoring, how will conflict of interest be managed/avoided?
 - The level of monitoring should be based on the level of risk.

How Is The Risk Level Determined?

The Principal Investigator (PI) should clearly identify in the protocol the level of risk involved in the study. During the initial review of the study the HAC will review the PI's assessment of risk level.

Minimal Risk Studies - Continuous, close monitoring by the PI may be adequate for studies with minimal risk. The PI is still responsible for reporting all adverse events and serious adverse events to the HAC and sponsor/funding agency.

Studies Involving Greater than Minimal Risk - Depending on the level of risk, some studies will require an independent individual to intermittently monitor the study. The monitor may be an independent safety monitor or an independent group/board.

Risk Level	Definition
Minimal	No more risk than what would occur in daily life or during routine physical and psychological exams
Low	Minor increase over minimal risk

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Moderate	Risks are greater than minimal, but not high
High	Greater than minimal risk due to the increased probability for generating SAEs

What About Studies that Have No Risk Involved?

The HAC Chairperson or designee will make the final determination.

What About Monitoring and Who Does It?

The degree of monitoring involved should be commensurate with the level of risk. The PI should identify the degree and frequency of monitoring based upon the risk level in the protocol. During initial review, the HAC will review the PI's assessment of the degree of monitoring and make the final determination of appropriate monitoring.

What is a Data and Safety Monitoring Board?

A Data and Safety Monitoring Board (DSMB) is an independent committee established to monitor safety and data throughout the life of the study or a specified time period. The DSMB is responsible for making an unbiased assessment of study progress. It also has a role in ensuring that the trial remains on target with meeting projected accrual goals. The DSMB does not replace the role of the HAC. A DSMB is not required for every study and may not be necessary or appropriate if the protocol involves no more than minimal risk. However, the NIH requires a DSMB for all Phase III studies. If a DSMB is not required, this must be addressed in the DRP.

A DSMB may be required if:

- The protocol will generate blinded/randomized data.
- If the protocol is a multi-center trial that presents more than minimal risk to the subjects.
- The protocol uses gene transfer or gene therapy methodology.
- The protocol poses more than minimal risks to the subject.

The DSMB's responsibilities include:

- Monitoring of adverse events.
- Monitoring of data and study quality.
- Recommending continuation or conclusion of a study to the PI and HAC.
- Protection of confidentiality of study data and results of monitoring.
- Quality Control.

What Is A DSMB Composed Of?

The DSMB is usually comprised of a group of individuals who are experts in the field applicable to the study. They should not be affiliated with the study. These experts

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should be willing to be objective in their review of the study data and issues that arise. The members should not have affiliations/interests that could be affected by the study outcome. DSMB membership can also include statisticians, lay people and administrators.

Who Do I Contact if I Have Any Questions?

For additional guidance, contact the HAC Administrative Office at HAC@mcg.edu or call the following extensions:

(706) 721-8397 for PIs whose last names begin with A-G

(706) 721-3110 for PIs whose last names begin with H-P

(706) 721-1482 for PIs whose last names begin with Q-Z

Although the above listing indicates the staff's primary PI assignments, all HAC Administrative Office staff can answer your questions. There may be situations when your questions may require consultation with the HAC or OHRP leadership.