

<b>University of Rochester</b>	<b>Office for Human Subject Protection</b>		
	<b>Research Subjects Review Board</b>		<b>Effective Date: 02/26/2019</b>
	<b>Data &amp; Safety Monitoring</b>		<b>Policy 506</b>
			<b>Version: 2.2</b>

## POLICY

### 1. Purpose

This policy establishes the requirements for a Data and Safety Monitoring Plan (DSMP) in research involving human subjects.

### 2. Scope

This policy applies to all research protocols utilizing human subjects when the RSRB is the Reviewing IRB.

### 3. Definitions

3.1. *Data and safety monitoring* – The process for reviewing cumulative data throughout an ongoing study to ensure the safety of the study subjects and continued validity and scientific merit.

3.2. *Data and Safety Monitoring Plan (DSMP)* – A written plan outlining the appropriate oversight and monitoring of the conduct and progress of the study to ensure that important information that may affect the safety or welfare of subjects is collected, recognized and acted upon as quickly as possible, and to ensure the validity and integrity of the research data.

3.3. *Data Monitoring Committee (DMC), Safety Monitoring Committee (SMC) or Data and Safety Monitoring Board (DSMB)* – A formal committee of qualified individuals with relevant subject-matter expertise and who do not have any conflicts of interest (i.e., financial, intellectual, professional or regulatory) with the research established to review interim data to assess both safety and efficacy, and issue recommendations regarding the continuation, modification or termination of the study. Functions under a governing charter and membership may include health professionals, laboratory scientists, statisticians, and ethicists, as well as, patient advocates. Depending upon the requirements of the study and the determination of the IRB, this committee/board can either be independent or include individuals involved in the conduct of the study.

3.4. *Independence* – Individuals external to the study organizers, Investigators, and those related to the study who perform the data and safety monitoring. Aside from being paid for their duties, it is expected that these individuals have no ongoing financial relationship with a study’s sponsor and are not involved in the conduct of the study in any role other than that of an SM, DMC, SMC, or DSMB member. Further guidance within the [FDA Guidance for Clinical Trial Sponsors Establishment and Operation of Clinical Trial Data Monitoring Committees](#).

3.5. *Principal Investigator (Investigator)* – The individual who has the full and final responsibility for the conduct of the approved research.

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3.6. *Safety Monitor (SM)* – A qualified professional with relevant subject-matter expertise whose primary responsibility is to provide periodic safety monitoring throughout the conduct of the study. Unless independence is required, the SM may be an individual responsible for conducting the study.

#### 4. References

- 4.1. HHS 45 CFR 46.111(a)(6); FDA 21 CFR 56.111(a)(6); FDA Guidance for Clinical Trial Sponsors Establishment and Operation of Clinical Trial Data Monitoring Committees – March 2006
- 4.2. [Policy 505 Scientific Review of Research](#)
- 4.3. [RSRB Guideline for Reporting Research Events](#)

#### 5. Responsibilities

- 5.1. The Investigator is responsible for the development of a DSMP (or providing an already developed DSMP) that complies with the requirements of this policy.
  - 5.1.1. Additional information to guide Investigators in the development of a safety monitoring plan may be found in the FDA guidance document “[Establishment and Operation of Clinical Trial Data Monitoring Committees](#)” or guidance provided by the appropriate National Institutes of Health department.
- 5.2. The Investigator is responsible for ensuring the activities of the study specific DSMP are carried out and documented appropriately, and that research events are reported to RSRB according to the *RSRB Guideline for Reporting Research Events*.
- 5.3. The RSRB is responsible for review of the DSMP to determine the appropriateness of the DSMP given the nature, size, and complexity of the research protocol and to ensure it is consistent with 45 CFR 46.111(a)(6) and 21 CFR 56.111(a)(6), which states, “where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.”
- 5.4. The scientific reviewer is responsible for ensuring that the data and safety monitoring procedures are appropriate to the design, specific risks and risk level of the study, and are adequate to safeguard the rights and welfare of study subjects, as described in *Policy 505 Scientific Review of Research*.  
*Note: Scientific review complements the regulatory charge of the IRB, which includes assessment of the balance of potential benefit to potential risk to human subjects.*
- 5.5. The respective data monitoring group or committee is responsible for the following, as outlined in the approved study protocol:
  - Interim monitoring;

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- Oversight and analysis of study information and data to assure the continuing safety of research subjects;
- Assessing efficacy of the study intervention;
- Reviewing appropriateness of the study;
- Assessing continued relevance of the study question, and integrity of the accumulating data throughout the life of a research project.

## 6. Requirements

- 6.1. A Data and Safety Monitoring Plan (DSMP) is required for all research posing greater than minimal risk, and may be required for selected studies involving minimal risk.
  - 6.1.1. The DSMP should be tailored to the nature, size, and complexity of the research protocol, the expected risks of the research, and the type of subject population being studied.
  - 6.1.2. The plan may describe monitoring activities that are conducted by the Investigator or group of Investigators to the establishment of an independent Data and Safety Monitoring Board (DSMB)/Data Monitoring Committee (DMC). *Appendix 1* provides guidance for recommended evaluation criteria based on level of risk.
  - 6.1.3. The DSMP should include the following information, at minimum:
    - the individual(s) responsible for monitoring;
    - the process for conducting the monitoring;
    - the mechanism for documenting the monitoring; and
    - who will be notified of any monitoring activity outcome (e.g., IRB, sites)
- 6.2. During the review of a DSMP, the RSRB will conduct the following activities:
  - 6.2.1. Ensure that the DSMP is described in sufficient detail to permit the RSRB to determine that subjects will be adequately protected. The RSRB may add, revise or delete elements from the DSMP on a study-by-study basis, as appropriate.
  - 6.2.2. Confirm that, as the research progresses through continuing review, the Investigator follows the data monitoring procedures described in the approved protocol (and DSMP).
  - 6.2.3. Determine whether the frequency of continuing review or the DSMP require modification, based on reported results.
  - 6.2.4. Review safety monitoring reports (e.g., DSMB, DMC/SMC, SM).
- 6.3. The Investigator is required to submit all monitoring reports to the RSRB. Any report that indicates an increased risk to subjects (usually reflected as a revision to the consent form and/or protocol) is reported to the RSRB according to the *RSRB Guideline for Reporting Research Events*.

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**Appendices:**

Appendix 1: Recommended Safety Evaluation Criteria

**Revision History:**

8/2014: Revised to format of policy template consistent with Policy 101; Policy number assigned; Sections 3.2, 3.3, and 3.5 definitions; references added to replace footnotes; Sections 5.1 and 5.2 added responsibilities; additional editorial changes.

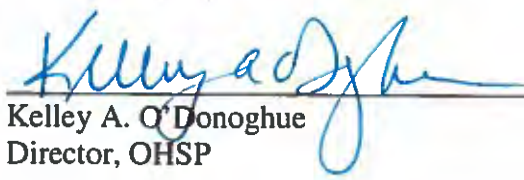
10/2016: Add reference to policy 505, add hyperlinks, editorial changes.

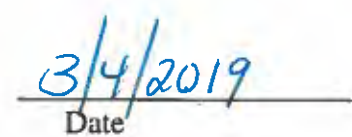
02/2019: Section 5.2 add documentation of DSMP activities; editorial changes; remove T. Gommel as signatory

**Supersedes Date:**

10/26/2016

**Approved By:**

  
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 Kelley A. O'Donoghue  
 Director, OHSP

  
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 Date

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## Appendix 1

### Recommended Safety Evaluation Criteria

***Investigator (or appropriate study team designee) monitoring only:***

This level of monitoring would be appropriate for minimal risk studies and certain single-site greater than minimal risk studies. The prompt submission of reports of new information and other study-related safety information to the RSRB, sponsor, federal agencies, and another other required entities as outlined in the approved protocol. Protocol deviations that involve a safety issue and proposed modification are reported by the Investigator. Examples of study activities that may be appropriate to this level of review:

- Open-label, single-site clinical trials
- Small pilot studies with drugs/devices
- Phase 4 drug or device studies

***Investigator monitoring and independent safety monitor:***

The Investigator monitors the study as noted above, with additional oversight by an independent safety monitor. This individual has appropriate clinical and research expertise and should have no conflicts in monitoring the study. This level of monitoring would be appropriate for studies posing greater than minimal risk that may require independent oversight. Examples of study activities appropriate to this level of review:

- Phase 1 or 2 single-site studies
- Investigator-initiated study involving potential undue influence in a vulnerable population

***Investigator monitoring and formal monitoring committee:***

The Investigator monitors the study as noted above, with oversight by a DMC/SMC/DSMB. The protocol should contain a description of the committee, including its composition (numbers, area of expertise and names of the chair and its members, if known), frequency of meetings, schedule of reports, and specific responsibilities. Examples of study activities appropriate to this level of review:

- Multi-center clinical trials
- Gene transfer studies
- Blinded placebo-controlled clinical trials