

UC Davis Policy and Procedure Manual

Chapter 240, Research Involving Human Subjects

Section 30, Data Safety Monitoring Plans

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Responsible Department: Office of Research

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I. Purpose

This section provides the policy and procedures for developing a data safety monitoring plan (DSMP) to provide a mechanism for ensuring subject safety and the validity and integrity of research data.

II. Policy

- A. A DSMP must be developed for all clinical investigations conducted at UC Davis regardless of funding source.
- B. The DSMP must be included as part of the application to the Institutional Review Board (IRB) and must contain, at a minimum:
 - 1. An assessment of the level of risk of the investigation;
 - 2. Identification of the individual or entity responsible for monitoring the study;
 - 3. Description of the steps that will be taken to monitor subject safety and review data accuracy;
 - 4. A statement regarding the frequency of monitoring and review;
 - 5. A discussion of anticipated adverse events (including severity scale and attribution scale); and
 - 6. A plan for reporting adverse events.
- C. All phase III randomized clinical trials supported by the National Institutes of Health require monitoring by a Data Safety Monitoring Board (DSMB).

III. Roles and Responsibilities

- A. Principal Investigators are responsible for:
 - 1. Developing DSMPs for their clinical investigations;
 - 2. Submitting the DSMPs to the IRB; and
 - 3. Convening Data Safety Monitoring Boards when required by the IRB.
- B. The Institutional Review Board:
 - 1. Reviews DSMPs submitted by Principal Investigators;
 - 2. Determines whether the submitted DSMPs are adequate to protect human subjects; and
 - 3. Determines when DSMBs are required to protect human subjects.
- C. Clinical Translational Science Center (CTSC)

The CTSC maintains a list of subject matter experts and serves as a resource to investigators who must recruit a group of experts as members for a Data Safety Monitoring Board.
- D. Data Safety Monitoring Board (DSMB)

When required by the IRB, a DSMB:

 - 1. Develops study specific charges;

2. Reviews the research protocol and other records related to a clinical investigation to determine the risks and benefits to research subjects and to protect the safety of subjects; and
3. Reviews study data to determine whether the investigation should continue as originally designed, should be changed or should be terminated.

IV. Further Information

For further information, contact IRB Administration, (916) 703-9151.

V. References and Related Policies

National Institutes of Health Policy on Data and Safety Monitoring
(<http://grants.nih.gov/grants/guide/notice-files/not98-084.html>).