

# UC Davis Policy and Procedure Manual

## Chapter 240, Research Involving Human Subjects

### Section 30, Data Safety Monitoring Plans

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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>).