

# UCSF Human Research Protection Program

## Data Safety Monitoring Plans Information Sheet for Principal Investigators

In response to federal regulations,<sup>1</sup> the UCSF HRPP requires an adequate **data and safety monitoring plan (DSMP)** for all **interventional research studies** involving **greater-than-minimal risk**.

Important note: Most, but not all studies (i.e., non-interventional studies) undergoing full committee review will require a DSMP. Interventional studies cannot be placed on a CHR agenda for review unless an adequate DSMP is included within the CHR application submission. CHR staff is available to provide investigators with guidance in developing appropriate DSMPs.

### Investigator Responsibilities:

The Investigator is responsible for ensuring that there is an appropriate DSMP in place at the time of initial CHR approval and for ensuring that the safety-monitoring plan is implemented over the life of the protocol.

### What Type of DSMP is Appropriate?

Development of an appropriate DSMP must include consideration of the following:

- Is the DSMP commensurate with the risks involved with the research?
  - Safety monitoring intensity and frequency should be tailored to fit the expected risk level, complexity, size, type of participant population and type of study (i.e., biomedical vs. behavioral research).
- Where does the DSMP fall along the continuum from monitoring by the principal investigator or group of investigators to the establishment of an independent **Data Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC)**?
  - The DSMP should indicate specifically whether or not there will be a DSMB/DMC.
- Does the DSMP include a specific plan for capturing and reporting [post-approval events](#) to the CHR and other entities such as medical monitors, study sponsors, and/or federal agencies (as appropriate)?

### What should you include in a DSMP?

Key areas that should be included in the plan are:

- An explanation of the plan to monitor study progress and safety.
- A description of who will perform the monitoring reviews and at what frequency.
- The type of data and events (i.e., efficacy data, adverse events, unanticipated problems involving risk to participants or others) that are to be captured under the monitoring plan.
- Procedures for communicating the outcome of reviews by the monitoring entity to the CHR, the study sponsor and/or other appropriate entities.
- As appropriate:
  - a plan for conducting and reporting interim analysis

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<sup>1</sup> CFR 46.111(a)(6) and 21CFR 56.111(a)(6): “where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects”

- clearly defined stopping rules
- clearly defined rules for withdrawing participants from study intervention(s)

### **Studies with a DSMP or DSMB/DMC Required by Other Entities:**

For studies conducted at the [General Clinical Research Center \(GCRC\)](#), Pediatric Clinical Research Center (PCRC), or Cancer Center, a DSMP should already be part of these applications. For purposes of the CHR application, it is acceptable to cut and paste a plan accepted by one of the UCSF Clinical Research Centers (CRC) or Cancer Center into your CHR application.

For studies conducted under the jurisdiction of the FDA, investigators may need to summarize and add supplemental information from the sponsor's protocol for the DSMP section of the CHR application.

### **Investigator-Sponsored IND/IDE Research:**

When an Investigator files an IND or an IDE, the Investigator is considered to be the study Sponsor and as such carries all of the FDA regulatory responsibilities and safety-reporting obligations of both the Investigator *and* the Sponsor as described in the FDA regulations [21 CFR 312](#) (drugs) and [21 CFR 601](#) (biologics) and [21 CFR 812](#) (devices). Please refer to these regulations for complete information regarding reporting responsibilities.

### **Definitions:**

Data Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC) is a formal committee, independent of the trial organizers and investigator(s) that is specifically established to conduct interim monitoring, oversight and analysis of study information and data to assure the continuing safety of research participants, efficacy of the study intervention, appropriateness of the study, continued relevance of the study question, and integrity of the accumulating data throughout the life of a research project . DSMBs/DMCs are typically made up of individuals who have expertise in the field of investigation, experience in the proper conduct of clinical trials, and/or statistical knowledge, and who do not have any serious conflicts of interest (i.e., financial, intellectual, professional or regulatory).

Data and Safety Monitoring Plan (DSMP) is a plan established to assure that each research study has a system in place for appropriate oversight and monitoring of the conduct and progress of the study that ensures: 1. important information that may affect the safety or welfare of participants comes to light and is acted upon as quickly as possible, and 2. the validity and integrity of the data.

Interventional research studies are any prospective, human research studies that are designed to answer specific questions about the effects or impact of a particular biomedical or behavioral intervention, or are designed to answer specific questions about human physiology.

Greater-than-minimal risk research studies are those where the probability and magnitude of harm or discomfort anticipated in the proposed research are greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.