

[Data & Safety Monitoring for Clinical Trials](#)

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Data & Safety Monitoring

The NIH requires data and safety monitoring for all types of clinical trials, including physiologic, toxicity, and dose-finding studies (phase I); efficacy studies (phase II); efficacy, effectiveness and comparative trials (phase III).

Monitoring should be commensurate with risks. The method and degree of monitoring needed is related to the degree of risk involved. A monitoring committee is usually required to determine safe and effective conduct and to recommend conclusion of the trial when significant benefits or risks have developed or the trial is unlikely to be concluded successfully.

Data Safety Monitoring Plans

[Data and Safety Monitoring Plan \(DSMP\)](#) is just one of the mechanisms used to ensure the safety of study subjects as well as maintain data validity, integrity, and scientific merit. The UCLA Human Research Protection Program requires an adequate [Data and Safety Monitoring Plan \(DSMP\)](#) for all interventional research studies involving greater-than-minimal risk. DSMPs depend upon many variables, such as the degree of risk, disease being studied, subject population, and number of sites where the research is being conducted. Complex DSMPs frequently include a Data Safety Monitoring Board (DSMB).

NIH Data Safety Monitoring Plan Information and Templates

To assist investigators in complying with the NIH data safety monitoring policy, please visit [guidance and sample DSMP templates](#) on the NIH website.

DSMP Checklist

- Primary and secondary outcome measures
- Inclusion/exclusion criteria
- Sample size
- List of participating enrolling clinics or data collection centers
- Projected timetable
- Target population distribution (e.g., women, minorities, etc.)
- Data acquisition and transmission
- Data entry methods
- Data analysis plan
- Quality assurance plan

- Reporting mechanisms of AEs/SAEs to the IRB, FDA, and NIDA.
- Reporting mechanisms of IRB actions to sponsor or funder
- Report of changes or amendments to the protocol
- Trial stopping rules
- Conflict of interest
- Potential risks and benefits for participants
- Collection and reporting of AEs and SAEs
- Management of SAEs or other study risks
- Plans for Interim Analysis of efficacy data
- Responsibility for data and safety monitoring
- Frequency of DSM reviews
- Content of DSM report
- DSM Board Plan (if applicable)

Please contact the [Office of Regulatory Affairs](#) for more information.

Last updated: 17 Jan 2017

The Data Safety Monitoring Board (DSMB)

DSMBs are made up of multidisciplinary members who are knowledgeable in the conduct of research, and should include those with backgrounds in biostatistics, experimental design, bioethics, and experts in the medical field of concern.

The [CTSI DSMB](#) offers oversight for those investigator initiated trials that do not have an external DSMB oversight mechanism. The DSMB advises investigators regarding the continuing safety of trial subjects and those yet to be recruited to the trial, as well as the continuing validity and scientific merit of the trial.

The CTSI DSMB performs the following general functions:

- Objectively appraise a study's progress
- Assess data quality via a formal and planned process
- Provide analytical expertise and rigor
- Determine the statistical significance of efficacy and/or risk?benefit ratio

DSMBs are responsible for reviewing data and endpoints on a timeline set forth by the DSMP in the protocol, and are typically required for the following types of studies:

- More than minimal risk
- Multiple study sites. It is more difficult to recognize a pattern of increased or unusual problems when investigators treat small fractions of the population separately
- Vulnerable population (pediatric, geriatric)
- Blinded studies
- New therapies or science
- Highly toxic therapies or dangerous procedures.
- High expected rates of morbidity or mortality in the study population.
- High chance of early termination of the study.

[NCI guidelines](#) are widely considered to be the most comprehensive and set forth requirements for DSMB composition

and function; note that it is required that a majority of the members be drawn from outside the institution (or institute) conducting the study. DSMB membership is usually comprised of:

- Experts in the fields of medicine and science that are applicable to the study,
- Statistical experts,
- Lay representatives, and
- Other who can offer an unbiased assessment of the study progress

DSMB Collaboration with the IRB

The DSMB is not specifically required to communicate with the IRB, but the intent is clear that the important information get to the IRB: "The study leadership will provide information on cumulative toxicities and relevant recommendations to the local principal investigators, to be shared with their IRBs."

Please contact the [Office of Regulatory Affairs](#) for more information.

Last updated: 21 Nov 2016

DSMPs and DSMBs at UCLA

The UCLA Human Research Protection Program requires an adequate data and safety monitoring plan (DSMP) for all interventional research studies involving greater-than-minimal risk. Please review [Guidance and Procedure: Data Safety Monitoring Plan](#) for more information.

The [CTSI DSMB](#) offers oversight for those investigator initiated trials that do not have an external DSMB oversight mechanism. The DSMB advises investigators regarding the continuing safety of trial subjects and those yet to be recruited to the trial, as well as the continuing validity and scientific merit of the trial.

The CTSI DSMB performs the following general functions:

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[Jonsson Comprehensive Cancer Center DSMB](#)

In response to the National Cancer Institute mandate, the JCCC DSMB was constituted in January 2001 and meets monthly. The JCCC DSMB reviews all Serious Adverse Events (SAEs) occurring in JCCC protocols. In addition, the JCCC DSMB serves as the DSMB for institutional research studies at UCLA that do not have an external DSMB. The JCCC DSMB helps to ensure that adequate safety monitoring will be carried out for all cancer interventional trials offered at the JCCC. The DSMB oversees the implementation of the data monitoring plans approved by ISPRC and on file with the JCCC. The chairman of the JCCC DSMB is Dr. Sven De Vos.

Please contact the [Office of Regulatory Affairs](#) for more information.

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Related Guidance, Tools & Templates

- [FDA Guidance for Clinical Trial Sponsors](#)
- [NIH Policy for Data and Safety Monitoring](#)
- [Further Guidance on a Data and Safety Monitoring for Phase I and Phase II Trials](#)
- [Webinar: Oversight of Clinical Investigations](#)

UCLA Presentations:

- [Data Monitoring: Assuring Safety & Study Integrity in Clinical Research](#)
- [Managing the Practice of Research](#)

Last updated: 7 Mar 2019

Last updated: 15 Apr 2016

- Group 1
 - [Clinical Research Information Systems](#)
 - [Clinical Research Business Partners](#)
- Group 2
 - [Office of Research Administration](#)
 - [Jonsson Comprehensive Cancer Center](#)
- Group 3
 - [Office of Human Subjects Protection](#)
 - [CareConnect Website](#)

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