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

A 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)

Plese contact the Office of Regulatory Affairs for more information.

Last updated: 10 Aug 2026

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.

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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.

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

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.

Last updated: 10 Aug 2026

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
- FDA Guidance: Oversight of Clinical Investigations - A Risk-Based Approach to Monitoring
- FDA Webinar: Risk-based Approach to Monitoring Clinical Investigations

UCLA Presentations:

- Data Monitoring: Assuring Safety & Study Integrity in Clinical Research
- Managing the Practice of Research

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Sponsor Monitoring and Auditing for Clinical Research Studies

For clinical research studies where a study sponsor is obligated by the FDA to monitor study source records, sponsors may be provided monitoring capability through one of three mechanisms:

1. Remote monitoring through HealthLink (a module within UCLA's CareConnect Electronic Health Records System) for CareConnect related source records, eBinders for regulatory documents, and UCLA's secure instance of Box.com for source documents not stored in CareConnect;
2. Remote monitoring through UCLA's secured instance of Zoom video conferencing facilitated by the principal investigator and research team; and/or
3. Safe and compliant on-site monitoring facilitated by the principal investigator & research team as outlined by the following procedures and/or policies (links may require UCLA AD login):
    - UCLA Safety and Masking Guidance
    - UCLA Patients/visitors/vendors Visitation Guidance
    - UCLA Visitor Guidance
    - UCLA Health Temperature and Symptom Screening Guidelines

Remote monitoring through HealthLink requires both, a Remote Monitoring Agreement facilitated by Clinical Trial Contracting & Strategic Relations (CTC-SR), as well as budget allocations for applicable Remote Monitoring Set-Up and Provisioning Fees (referenced below) for each sponsor-monitor provisioned with remote monitoring access. The institutional remote monitoring agreement and applicable remote monitoring fees have been standardized to streamline remote monitoring setup and mitigate negotiation. The option for remote monitoring may be made available prospectively during contract negotiations for new clinical trial agreements received by CTC-SR as of October 1, 2020. For existing studies, a process has been established to prioritize study teams and sponsors requiring remote monitoring access with the limited resources available to support remote monitor contracting, set-up and provisioning. For more information, please contact CTSIORA@mednet.ucla.edu.

Remote monitoring of regulatory documents through eBinders requires budget allocations for applicable Remote Monitoring Set-Up and Provisioning Fees (referenced below) for each sponsor-monitor provisioned with remote

monitoring access. The remote monitoring fees have been standardized to streamline remote monitoring setup and mitigate negotiation.

For source and study documents stored external to CareConnect, such documents should be redacted appropriately of participant Protected Health Information (PHI) and uploaded to UCLA secure Box.
Remote Monitoring for sponsors through Zoom is to be facilitated by the research team. Monitoring language in existing clinical trial agreements would typically not require modification to enable Zoom-based monitoring. Should you have industry clinical trial contract related questions please contact Tamika Merrick, Director of CTC-SR at TMerrick@mednet.ucla.edu.

On-site Monitoring has traditionally been the primary method for sponsor monitoring of clinical trials at UCLA. However, on-site monitoring should be limited to only rare instances when the remote monitoring arrangements referenced in (1) and (2) above cannot be achieved with sponsor(s).

- On-site monitoring can occur in space where the on-site monitoring access is deemed essential to comply with applicable laws and study teams and monitors strictly adhere to the appropriate UCLA health **visitor** requirements. Investigators must obtain Department Chair or Division Chief (or designee) written approval permitting the request for an on-site visit.

For research studies where a study sponsor is NOT obligated by the FDA to monitor/audit the study source records, sponsors are generally not allowed to conduct monitoring of study records. Sponsors may request a special exception with the Office of Compliance. If approved, sponsors may only conduct monitoring through the remote access process.
Remote monitoring set-up and provisioning fees may include, but are not limited to, facilitation of the following tasks:

- Remote monitoring terms and obligations contract review and execution with study sponsor(s) and CRO(s) for each applicable clinical research study.
- Study-specific statement of work defining scope and effective timeline for provisioning.
- Individual study monitor terms and obligations agreement review and completion.
- UCLA Healthlink Electronic Health Record (EHR) user access application review and completion.
- Remote study monitor provisional access application completion.
- Remote study monitor online training – scheduling, facilitation, and completion.
- Remote study monitor approval and access provisioning.
- Remote study monitor virtual visit scheduling and research participant linking to Healthlink.
- Remote monitoring use and access compliance – tracking, auditing, maintenance and reporting.

Monitors may not in any way divulge, save, copy, print, record, photograph, download, export, screenshot, release, sell, loan, alter and/or destroy any PHI except as permitted by law and properly authorized by the policies of the Participant. Any breach of the responsibilities and/or conditions of the terms of access may be subject to access suspension, employer notification and disciplinary action, and may be subject to civil and/or criminal charges, as applicable. Reinstatement of suspended access will be subject to the requirements, training and fees associated with new user access, as determined at UCLA's discretion.

Please see the "UCLA Clinical Research External Monitoring & Auditing Policy HS 9207" for more information.

For access to HealthLink, once the Remote Monitoring Agreement has been executed with Clinical Trial Contracting & Strategic Relations (CTC-SR), please complete the following forms and submit them via Qualtrics application form https://uclahs.az1.qualtrics.com/jfe/form/SV_brLKnbxUOOKH6HI:

1. Monitor HealthLink Request Form
2. User Agreement - UCLA Health EHR Access Agreement
3. Confidentiality Statement
4. Instructions for Completing Monitoring Forms

Requests will only be accepted via Qualtrics. Please do not submit forms via email.

For access to eBinders, please complete the following forms and submit via Qualtrics application form https://uclahs.az1.qualtrics.com/jfe/form/SV_brLKnbxUOOKH6HI:

1. Monitor eBinders Request Form
2. eBinders Training Certificate

Requests will only be accepted via Qualtrics. Please do not submit forms via email.

Please see the charge master for current rates for access provisioning.

***Provisioning cannot be completed until all forms and certificates are submitted. Please submit all documents at one time. Incomplete applications will be returned.**

****Monitors will only be provisioned for studies listed on the application form.**

*****Monitors provisioned for eBinders only first, will be charged the full monitor rate should they later need access to HealthLink.**

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