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DSMP

Data and Safety Monitoring Plan

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Outline

- Purpose
- When are they needed?
- What do they contain?

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Purpose

Objective

Monitoring of:

- safety of study participants
- quality of research data
- appropriate conduct of the clinical research

Distinct from:

- **IRB oversight**
- **scientific review**

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When is a DSMP necessary?

In general…

All studies that involve human subjects

Level of monitoring depends on study's

- potential risk
- size
- Complexity

Monitoring level may be decided by

- study sponsor
- IRB
- institution

Type of plans

Embedded in the protocol

- minimal risk
- monitoring done by study PI/team

Separate DSMP

- greater than minimal risk
- monitoring done by Data Safety and Monitoring Board (DSMB)

Who should write/review the plan

Study team

- PI
- study statistician
- other relevant team members

Plan written for DSMB use

- needs to be approved by DSMB
- provides guidance to study team/DSMB
- submitted to the IRB

WCM Institutional policy/guideline

Large, multi-site, randomized, blinded, and Phase III trials

Phase I and II studies for which risk to the subjects appears unusually high

Phase I and II studies for which the principal investigator is the IND/IDE sponsor or manufacturer and independent monitoring is required to maintain the integrity of the trial

Gene transfer studies

Studies with vulnerable populations or risky interventions/procedures or any other factors that might indicate high morbidity/mortality end-points

Studies with high risk of toxicity or other major medical risks

WCM Institutional policy/guideline

Always “write” a DSMP for human subjects

Determine whether the WCM DSMB is required

http://researchintegrity.weill.cornell.edu/DSMB.html

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Preparing a DSMP

Participant safety

DSMP Component	Examples of Monitoring Activities
specific subject safety parameters	vital signs, weight, safety blood tests, cardiac status, anxiety, depression scores, adverse events, etc.
frequency of subject safety observations	weekly telephone FU, monthly appointments, observations of participant while in clinical setting, each treatment cycle, etc.
party responsible for safety monitoring	PI, study coordinator, safety monitor, independent monitor, DSMB, etc.
subject stopping rules	exclusion criteria, including adverse response to study procedure; pregnancy; specific AE grade; cardiac irregularity; non-compliance; etc.
study stopping rules	unanticipated problems involving risk to subjects or others (UPIRTSO), unexplained adverse outcomes, life threatening adverse events,
reporting mechanisms (i.e. deviations, adverse events, UPIRTSOs)	plans for reporting to IRB, FDA, sponsor, participating sites, DSMB, etc.

Data integrity

DSMP Component	Examples of Monitoring Activities
specific data items to be reviewed	participant eligibility, data is accurate and complete, calculations are standardized and performed properly
frequency of monitoring data: points in time, or after specific number of patients	First 3 subjects and every 20th subject, monthly, quarterly, annually, etc.
individual responsible for data monitoring	PI, study coordinator, safety monitor, independent monitor, data manager, statistician, etc.

Participation privacy

DSMP Component	Examples of Monitoring Activities
Under what conditions (time and place) will subject be consented, interviewed, or telephoned?	observations of consenting process, interviewing, or clinical visit performed quarterly on 3 subjects request input from 5 subjects related to their experiences regarding privacy expectations etc.

Data confidentiality

DSMP Component	Examples of Monitoring Activities
What are the conditions that will protect the confidentiality of the data?	Check for locked file cabinets, secure electronic records, secure location with protected health information is stored, etc.

Product accountability

DSMP Component	Examples of Monitoring Activities
Who is responsible for obtaining, storing, preparing, administering, or disposing of the study drug or study device? Who is responsible for overseeing product accountability?	research pharmacy, PI, central pharmacy, research laboratory, nursing, etc.

Study documentation

DSMP Component	Examples of Monitoring Activities
study file management	study file management guidelines and checklists for monitoring (sample of study files annually, etc.)

Study coordination

DSMP Component	Examples of Monitoring Activities
roles and responsibilities are clarified, education needs are addressed, planned meetings or communications with documented meeting notes/minutes	periodic debriefing to determine if expectations are clear and if educational needs exist scheduled meetings are on the calendar, and meeting outcomes are noted and available to staff etc.

DSMP specifics

GOAL: provide a framework by which to reduce harm or injury to participants, in order to further promote a level of conscientious conduct.

Minimum required

Assessment of level of risk

A plan for safety review
- anticipated AEs
- AE grading and attribution
- unanticipated and/or serious AE reporting
- periodic reporting of AEs

Ensure compliance with principles of informed consent

Assessment of protocol compliance, including violations/deviations

A plan for compliance with privacy related regulations (e.g., HIPAA)

Additional considerations

Prospective stopping rules

- unacceptable risk (toxicity stopping rule)
- strong evidence of futility/efficacy (interim analyses)

Plan for on-going review

- information to be provided
- review frequency
- rationale for info provided and frequency

Study enrollment

- observed accrual rate compared to expected accrual rate
- eligibility rate

Safety review questions

- reasons for drop-outs
- AEs too frequent or severe?
- should the protocol be modified?

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Questions?

Please direct any questions to DSMB@med.cornell.edu *for a prompt response!*