Data and Safety Monitoring (HRPP 3.2)

Description:

This policy describes UNMC's requirements for data and safety monitoring for non-exempt research.

Policy:

All non-exempt research must have an appropriate plan for data and safety monitoring in consideration of the nature and risk level of the research.

The Data and Safety Monitoring Plan (DSMP) may or may not include a formal Data and Safety Monitoring Board (DSMB).

Data and Safety Monitoring Plan (DSMP)

The DSMP should include elements such as:

- The specific data that will be reviewed.
- The frequency and duration of review (when monitoring will start and end).
- The identities of persons or groups conducting the review.
- The conditions under which specific subjects should be withdrawn.
- The conditions under which the study will be halted.

The DSMP may include monitoring by any of the following:

- An investigator and/or study staff.
- A faculty advisor.
- A sponsor appointed medical monitor or CRO.
- An independent monitor or monitoring group (not directly involved with design and conduct of study).
- A formal Data and Safety Monitoring Board (DSMB).

DSMB Required For:

1) Phase III Clinical Trials, with the exception of low-risk behavioral and nutritional studies.
2) Multicenter Randomized Phase II Clinical Trials, with the exception of low-risk behavioral and nutritional studies.
3) High Risk Phase II Clinical Trials.

DSMB Considered For:

- Research involving a large study population, or multiple site studies.
- Research intended to provide definitive information about the effectiveness and/or safety of a medical intervention.
- Research that involves an intervention with potential to induce unacceptable toxicity.
- Research which evaluates mortality or another major endpoint.
- Research for which it would ethically be important for a trial to stop early if the primary question addressed has been definitively answered.
- Research involving a particularly vulnerable population.

Review of a DSMP by the IRB:

An investigator must provide:

- A DSMB charter, or
- Describe the composition of the DSMB membership and frequency of the DSMB meetings and protocols.

Review of DSMB Reports by the IRB:

An investigator must:

- Obtain copies of, and review, the DSMB reports as produced at a frequency described in the approved IRB application.
- Submit copies of all DSMB reports to the IRB at the time of continuing review.
- Report promptly to the IRB if the DSMB report finds serious risks to the welfare of subjects, or recommends substantive changes to the protocol or ICF.

If the DSMB report is due and not submitted by the time of continuing review, the IRB may table or suspend the study.