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 include a Data and Safety Monitoring Plan (DSMP) that is proportionate to the risk level and design of the study.

The DSMP may or may not include a formal Data and Safety Monitoring Board (DSMB), depending on the nature of the research.

Data and Safety Monitoring Plan (DSMP)

DSMP Requirements:

The DSMP should include, where appropriate:

- The specific data that will be reviewed
- Frequency and duration of review (when monitoring will start and end)
- Identities of persons or groups conducting the review
- Criteria for withdrawing subjects from the study
- Stopping rules, if applicable *(e.g. for efficacy, toxicity, futility)*

Who May Monitor:

Monitoring may be conducted by:

- The investigator and/or study staff
- A faculty advisor
- A sponsor appointed medical monitor or CRO
- An independent monitor or monitoring group not directly involved in study design/conduct
- A formal DSMB

Data and Safety Monitoring Board (DSMB)

When a DSMB is REQUIRED:

A formal DSMB is generally required for:

- **Phase III clinical trials,** except low-risk behavioral and nutritional studies
- **Multicenter randomized Phase II trials,** except low-risk behavioral and nutritional studies
- **High-risk Phase II trials**

When Should a DSMB be Considered:

A DSMB should be considered for:

- Research involving large populations or multiple study sites
- Research intended to provide information about the effectiveness and/or safety of a medical intervention
- Research involving an intervention with potential to induce unacceptable toxicity
- Research evaluating mortality or other major safety endpoints
- Research for which it would be ethically imperative to stop early if the primary question addressed have been answered
- Research involving a particularly vulnerable population

Review of a DSMP by the IRB:

If the research warrants a formal DSMB, the investigator must provide:

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

Review of DSMB Reports by the IRB:

An investigator must:

- Obtain copies of, and review, the DSMB reports are 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.