3.2 Data and Safety Monitoring

1.0 Purpose

The purpose of this policy is to describe the Organization’s requirements for data and safety monitoring for non-exempt research.

2.0 Policy

It is the policy of the Organization that 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).

3.0 Data and Safety Monitoring Plan (DSMP)

- 3.1. The DSMP must be developed to fit the design and risk profile of the research. It should include, as appropriate, elements such as:
  - 3.1.1. The specific data that will be reviewed
  - 3.1.2. The frequency and duration of review (when monitoring wil start and when it will end).
  - 3.1.3. The identities of the persons or groups conducting the review
  - 3.1.4. The conditions under which specific subjects should be withdrawn
  - 3.1.5. As appropriate based on the design and risk profile of the research, the conditions under which the study will be halted (that is, study stopping rules based on efficacy, toxicity and futility)
- 3.2. The DSMP may include monitoring by the investigator and/or study staff, by faculty advisor, by a sponsor appointed medical monitor or CRO, by an independent monitor or monitoring group (not directly involved with the design and conduct of the study), or by a formal DSMB.

4.0 Data Safety Monitoring Board (DSMB)

- 4.1. Under certain circumstances, the IRB or the investigator may decide that the DSMP should include a formal DSMB.
  - 4.1.1. In general a formal DSMB is required for:

        - 4.1.1.1. Phase III clinical trials, with the exception of low-risk behavioral and nutritional studies (such as those where subjects are expected to experience only minor side effects, and interim analyses are not crucial for the protection of subjects).
        - 4.1.1.2. Multicenter randomized phase II clinical trials, with the exception of low-risk behavioral and nutritional studies.
        - 4.1.1.3. High risk phase II clinical trials (such as those involving interventions associated with risk of serious morbidity or death, studies involving diseases associated with high mortality or morbidity, and research involving highly experimental therapies).
    - 4.1.2. In consideration of other trials, a formal DSMB should be considered for the following types of research:
        - 4.1.2.1. Research involving a large study population, or multiple study sites.
        - 4.1.2.2. Research intended to provide definitive information about effectiveness and/or safety of a medical intervention.
        - 4.1.2.3. Research which involves an intervention with the potential to induce unacceptable toxicity.
        - 4.1.2.4. Research which evaluates mortality or another major endpoint, such that inferiority of one treatment arm has safety as well as effectiveness implications.
        - 4.1.2.5. Research for which it would ethically be important for the trial to stop early if the primary question addressed has been definitively answered, even if secondary questions or complete safety information were not yet fully addressed.
        - 4.1.2.6. Research involving a particularly vulnerable population, for whom closer monitoring will provide additional meaningful protection.

5.0 Review of the DSMP by the IRB

- 5.1. The IRB will consider the adequacy of the DSMP based on the conditions described in section 3.1 above.
- 5.2. For studies that do not have a data monitoring committee the IRB will carefully review the data and safety monitoring plan and determine whether a data monitoring committee would provide meaningful additional protection for subjects.
- 5.3. If the research design or risk profile warrants a formal DSMB the investigator must provide the DSMB charter, or describe (1) the composition of the DSMB membership, (2) the frequency of DSMB meetings and reports. It is expected that most studies which require a formal DSMB will also have formal stopping rules for efficacy and toxicity.
- 5.4. The IRB will evaluate the DSMP in order to ensure that it represents adequate provision for monitoring the data collected to ensure the safety of subjects.

6.0 Review of DSMB Reports by the IRB

- 6.1. It is the responsibility of the investigator to obtain copies of, and review, DSMB reports, as they are produced, at the frequency described in the approved IRB application.

- 6.2. The PI is responsible for submitting copies of all DSMB reports to the IRB at the time of continuing review (or interim reporting period as mandated by the IRB).
- 6.3. If the DSMB report finds serious risks to the welfare of subjects, or recommends substantive changes to the protocol (including but not limited to halting of the protocol or accrual) or substantive changes to the informed consent document, then the investigator must submit the report promptly to the IRB. It is expected that such DSMB reports will be followed promptly by a Request for Change in protocol.
- 6.4. If the DSMB finds serious risks to the welfare of subjects, the IRB will take action in accordance with HRPP policy 8.6 (Study Hold, Suspension, and Termination).
- 6.5. If the DSMB report is due but has not been submitted at the time of continuing review (or interim reporting period as mandated by the IRB), the IRB may table the Continuing Review, or may suspend the study in accordance with HRPP policy 8.6 (Study Hold, Suspension, and Termination.

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