DATA AND SAFETY MONITORING PLANS

Unit: Human Research Protections Program (HRPP), Office of Research

incident, experience, or outcome may have been caused by the procedures involved in the research) or test article; and
Suggests that the research places subjects or others at a greater risk of harm (including *physical, psych*ological, *economic, or social harm*) than was previously known or recognized.

PROCEDURE:

Scope of the information to be provided to the IRB at interval of not less than one year.

4. Monitoring Mechanisms
    a. DSMPs may include safety monitoring of the data depending upon the type of research and the level of risk. The type of monitoring may range from monitoring and review by the Principal Investigator or by a group of Investigators to the establishment of an independent Data and Safety Monitoring Board (DSMB). Safety monitoring may be accomplished as follows:
        - The Investigator performs the safety monitoring (i.e. a single site open label trial.)
        - An uninvolved expert in the research performs the safety monitoring (i.e. a single site blinded trial.)
        - The sponsor's medical monitor performs safety monitoring
        - The sponsor's safety monitoring committee performs safety monitoring
        - An independent Data and Safety Monitoring Board (DSMB) performs safety monitoring

For Department of Defense supported projects that are greater than minimal risk, the project may identify 1 or more research monitors depending upon the type of research. The eBridge study submission should include the following:

Identification of the monitor(s). Please note that a monitor may be an ombudsman or a member of the data safety monitoring board. The IRB or HRPP official shall communicate with research monitors to confirm their duties, authorities, and responsibilities.

The duties of the research monitor are determined on the basis of specific risks or concerns about the research, such as:

- Perform oversight functions (e.g. observe recruitment, enrollment procedures, and the consent process, oversee study interventions and interactions, review monitoring plans and unanticipated problems involving risks to participants or others, oversee data matching, data collection and analysis).
- Discuss the research protocol with researchers, interview human subjects, and consult with others outside of the study.
- Report observations and findings to the IRB or designated official

5. Data Safety Monitoring Boards (DSMB) or Committees (DSMC)
    a. A DSM Board or Committee is an independent, impartial group set up specifically to monitor a clinical trial (or other study) throughout its duration to determine where continuation of the study is appropriate scientifically and ethically.
    b. If a DSMB/C will be used as a part of the DSMP, the following must be provided in the eBridge Study SmartForm:

DSMB/C membership

Member expertise

DSMB/C contact and their contact information

Whether the members are independent of the sponsors/researchers

Expected frequency of their meetings

Written assurance that the DSMB/C will provide the MCW/FH IRB with a written overall study safety report at intervals of not less than one year

d. DSMB/C Responsibilities

The primary responsibility of the DSMB/C is to safeguard the interests of study subjects. Therefore, the DSMB/C should:

Approve the safety measures in the protocol to 1) preserve the study integrity and credibility; and 2) to facilitate the availability of timely as well as reliable findings to the broader clinical community.

Provide written documentation confirming that they have read the protocol and agree with the study design and the DSMP.

Continually review quality of study conduct including data management and