to the REB at its next Full Board meeting. The REB is authorized to terminate REB approval following its review at a Full Board meeting.

The REB Chair or designee shall notify the Researcher, and the Organizational Official(s), of any suspension or termination of REB approval of the research and has the authority to notify the regulatory authorities (as applicable) and the Sponsor. The REB may delegate regulatory authority reporting to the University.

See Glossary of Terms.

As a result of ongoing review activities, 1 (po[(y)4 0.

5.1.2 The Researcher must immediately notify the REB of any suspensions or terminations of the research and the reasons for the action;

5.1.3 Reports of suspensions or terminations of the research by the sponsor will be forwarded to the REB Chair or designee for review;

5.1.4 If the REB Chair or designee decides to suspend REB approval of the research, he/she must notify the REB at its next Full Board meeting;

5.1.5 If REB approval is suspended, a subsequent review must be conducted and the REB suspension must be lifted prior to resumption of the research following the sponsor's lifting of a suspension.

5.2.1 If any concerns are raised during the REB's oversight of the research that are related to new information or to the conduct of the research, the REB may suspend or terminate its approval of the research as appropriate. These concerns may include:

- The research not being conducted in accordance with the REB-approved protocol or REB requirements,
- The research is associated with unexpected serious harm to participants (i.e., as may be determined following REB review of reportable events or DSMB reports),
- Falsification of research records or data,
- Failure to comply with prior conditions imposed by the REB (i.e., under a suspension or approval with modifications),
- Repeated or deliberate failure to properly obtain or document consent from participants,
- Repeated or deliberate failure to limit administration of the investigational drug or device to those participants under the Researcher's supervision,
- Repeated or deliberate failure to comply with conditions placed on the research by the REB, by the sponsor, or by regulatory agencies,
- Repeated or deliberate failure to obtain prior REB review and approval of amendments or modifications to the research, or
- Repeated or deliberate failure to maintain accurate research records or submit required reportable event reports to the REB;

5.2.2 The REB Chair or designee is authorized to suspend REB approval of research. If the Chair or designee suspends approval of the research, he/she must notify the REB as per applicable requirements;

5.2.3 The REB is authorized to terminate its approval of the research following a review at a Full Board meeting;

5.2.4 Prior to suspending or terminating REB approval, the REB must consider:

- Risks to current participants,
- Actions to protect the safety, rights and well-being of currently enrolled participants,
- The appropriate care and monitoring of participants,
- Whether withdrawal of enrolled participants is warranted and the specific procedures for their safe withdrawal,
- Whether participants should be informed of the termination or suspension,
- Whether adverse events or outcomes should be reported to the REB,
- Identification of a time frame in which the corrective measures are to be implemented;

5.2.5 The REB Chair or designee will