

and/or by preliminary discussions amongst IRB members prior to a convened meeting.

5. GENERAL INFORMATION ON SUSPENSIONS AND TERMINATIONS

- 5.01 Information indicating that research is not being conducted in accordance with IRB requirements (

- v. Requiring arrangements for care of participants outside the research
 - vi. Requiring or permitting follow-up of participants (e.g., for safety reasons)
 - vii. Arranging for compensation of current and/or former participants
- (3) When participants are to be withdrawn from the research, the IO, IRB Chair, or the convened IRB will evaluate whether the procedures for withdrawal consider the rights and welfare of enrolled participants.
- (4) When study approval is suspended, the reason(s) will be communicated to the investigator(s), along with any actions required to protect the rights and welfare of current or past research participants. Other IRB responsible for

when the research is associated with unexpected serious harm to subjects as actions taken by investigators or sponsors to stop research activities are not terminations as described by this policy.

(2)

