**Additional IRB Review Considerations**

**Noncompliance**

**Noncompliance** is defined as conducting research in a manner that disregards and/or violates federal regulations or institutional policies and procedures applicable to human subjects research. Noncompliance includes failure to adhere to the approved research protocol, except for minor or technical violations resulting from inadvertent errors, inattention to detail, or failure to follow operational procedures that do not pose risk to subjects and/or violate subject’s rights and welfare.

**Serious noncompliance** is a failure to adhere to the laws, regulations, and/or university policies governing human research that may reasonably be regarded as:

1. Involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research staff, or others; or
2. Substantively compromising the effectiveness of a facility’s human research protection or human research oversight programs.

**Continuing noncompliance** is a persistent failure to adhere to the laws, regulations, or university policies governing human research including persistent failure to adhere to an approved research protocol.

**Considerations:**

1. Does the allegation of noncompliance have no basis in fact with no further action required?
2. If the allegation of noncompliance is substantiated, is there sufficient information available for review to determine if it constitutes serious, and/or continuing and the appropriate associated actions?
3. Should the review and determination be tabled pending receipt of additional information?

**Determinations:**

1. Did the report constitute serious and/or continuing noncompliance according to the definitions above?
2. Is the reported event an Unanticipated Problem?
3. Are the proposed corrective actions adequate to prevent future recurrence?

**Potential actions in response to the event:**

* 1. No further actions required; proposed corrective actions are adequate as submitted
  2. Confirmation of administrative hold
  3. Suspension of enrollment or all research procedures for the research study(ies)\*
  4. Termination of the research \*
  5. Initiate audits of all or some part of the investigator's active protocols
  6. Modification of the protocol or related materials
  7. Modification of the information disclosed during the consent process
  8. Requirement to provide information to current participants whenever such information might relate to the participant's willingness to continue to part in the research
  9. Require re-consent to continue participation
  10. Additional information provided to past participants
  11. Modification of the continuing review schedule
  12. Obtain more information pending final decision or require a response from the investigator with a modified corrective action plan
  13. Conference with other IRB’s involved with the research
  14. Monitoring of the research
  15. Monitoring of the consent process
  16. Training for the PI and/or research team
  17. When appropriate, applying any corrective action to all similar protocols
  18. Referral of the matter to the University entities (e.g. Office of General Counsel, Risk Management, etc.)
  19. Recommendation to the Institutional Official that sanctions be placed on the investigator or department acting in noncompliance (e.g., limitations on the number of active studies an investigator can conduct or prohibiting conduct of research); and/or
  20. Referral of the matter to the University’s Research Integrity Officer if the IRB investigation determines there is just cause to suspect scientific misconduct has occurred.

21. Other actions as deemed appropriate

\*If IRB approval is suspended or terminated, consider actions including, but not limited to, the following to protect the rights and welfare of participants:

1. Notification of current and/or former participants
2. Requiring transfer of responsibility for the research and participants to another investigator
3. Continuation of participants in the research with an independent monitor
4. Withdrawal of current participants from the research, with confirmation the procedures for withdrawal consider the rights and welfare of enrolled participants
5. Requiring arrangements for care of participants outside the research
6. Requiring or permitting follow-up of participants (e.g., for safety reasons); and/or
7. Arranging for compensation of current and/or former participants