Verification that no material changes have occurred since the last IRB review

The IRB will determine which studies need verification from sources other than the investigator that no material changes have occurred since the previous IRB review. The IRB may also request periodic progress reports from the investigator(s) in order to oversee the conduct of the study. This procedure may be initiated at any time due to information derived from any source. The IRB may consider independent assessment from sources other than the investigator that there have been no changes to the conduct of the research since the last IRB review including, when the following circumstances occur, but not limited to:

- review of complex projects involving high risks to subjects, including novel therapies and studies where the risk to participants may be uncertain
- when the investigator(s) are under review or corrective action by the IRB or Research Integrity Officer or there is a history of noncompliance
- when projected rate of enrollment warrants monitoring
- when previous audits, either not-for-cause or for-cause, have revealed that the investigators implemented changes to the conduct of the study without IRB approval
- when concerns have been raised about possible material changes occurring without IRB approval or there have been complaints from participants
- other circumstances that may apply for which the IRB deems it necessary to require independent verification

Procedure

The IRB Chair, reviewing members, or the convened IRB may request that an independent agent review the study documents or observe the conduct of the study / consent process to verify the accuracy of the information presented to the IRB at continuing review and to ensure no material changes have been implemented without IRB approval. The request should include the specific reason for the request and the material to be verified. Potential agents who may conduct the verification include:

IRB Staff
IRB Chair or members
R&D Committee members
Others, as appropriate

The agent(s) conducting the verification will present their findings at the next convened IRB meeting. Findings may also be reported to the Institutional Official, Vice President of Research, and the R&D Committee. If the findings indicate that material changes were made without prior IRB approval, the following actions include, but are not limited to:

- Require submission of all revisions for full board review
- Require continuing review more frequently than annually
- Report as research misconduct, if the findings rise to the level of serious or continuing noncompliance
- Other actions, as deemed appropriate by the IRB

The investigator will be notified in writing of any findings and any corrective actions required.