Issuing Department: Human Subjects Protection Program (HSPP)
Policy Number: 2011-009.9
Policy Title: Institutional Review Board (IRB) - Verification of No Material Changes

Purpose

The purpose of this policy is to describe situations for which verification from sources other than an investigator may be required to ensure that no material changes have occurred since previous IRB review and to describe the process for obtaining such verification.

Definitions

See policy 2011-007.0 for definition of the following terms:

Conflict of Interest Suspension Termination

Policy

The IRB will require independent verification from sources other than the Principal Investigator (PI) that no material changes (i.e. changes that are both relevant and consequential) have occurred since previous IRB review in the following situations:

- When there is inconsistency in the information presented by the PI to the IRB and those inconsistencies cannot be easily resolved.
- When the IRB questions the ability or the willingness of the PI to provide accurate information.
- When concerns have been raised, through continuing review or from other sources, that material changes have been implemented without IRB approval.
- Other circumstances for which the IRB deems independent verification is needed.

In most cases a Research Compliance Monitor (RCM) from within the HSPP will conduct the verification. The RCM has complete access to all research data and may observe the research and consent process.

The IRB may require that a consultant with particular expertise review the research activity. Such consultants will not have a conflict of interest in the research.

Procedure

The IRB Chair, an assigned reviewer through the IRB Chair, or the convened board may request that the RCM or a consultant review the relevant research documents or observe the conduct of the research and / or consent process to verify the accuracy of the information presented to the IRB and to ensure that no material changes have been instituted without IRB approval.

- The request may be made prior to the IRB meeting or requested at the IRB meeting and documented in the minutes.
    - If requested at or prior to the meeting, approval or contingent approval may still be granted pending outcome of the review (e.g. approved contingent upon confirmation of accuracy).
- If a consultant is to be called upon, the IRB Chair may determine who will act as the consultant and will confirm that no conflicts exist.

- The individual performing the verification will provide the IRB Chair with a written summary of the verification.
    - If after evaluation it is established that here may have been material changes made, the IRB Chair will direct the IRB Regulatory Specialist (RS) to place the item on the agenda for the next convened board meeting for further review and discussion and determination as to whether the findings constitutes serious or continuing non-compliance or an unanticipated problem involving risk to subjects or others.
        - the IRB may require corrective actions such as imposing a suspension or termination of approval, requiring additional education, review of policies or other mechanisms to prevent subsequent occurrences.
        - The RS will communicate the determination of the board back to the PI through the correspondence section of the study file in the electronic submission system.
        - The RS will also upload and attach a copy of the evaluation report and the outcome letter to the "Review Board Internal Documents" section of the study file within the electronic system.

    - If after evaluation it is established that there have been no material changes made, the Chair will review and sign off on the report and the issue will be considered resolved.
        - The Chair will forward the report to the RS for processing.
        - The RS will communicate to the PI through the correspondence section of the study file in the electronic submission system that the issues has been resolved.
        - The RS will also upload and attach a copy of the evaluation report and the outcome letter to the "Review Board Internal Documents" section of the study file within the electronic system.
        - For informational purposes, the RS will include the outcome on the agenda of the next board meeting for which the submission deadline has not passed.

Related Policies

2009-003 – Imposing and Lifting Suspensions of IRB Approval or Imposing Terminations of IRB Approval
2009-004.0 - Required Reporting to Institutional Officials and External Agencies
2009-005.0 – Monitoring of IRB Approved Studies
2011-007.0 – Definitions Applied to Policies
2011-009.6 – Institutional Review Board – Consultants

Basis

45 CFR 46
21 CFR 56

Document Attributes

Date Created: 4/26/2017

Replaced Version: 7/8/2011

Reviewed and Approved By: *Richard H. Simon* **Date:** *1 May 2017*
Richard H. Simon, MD
Director Human Subjects Protection Office