Title: Independent verification that no material changes have occurred

Purpose

This document outlines the procedures which the Princeton Institutional Review Board uses to verify that no material changes have occurred during the approval period of ongoing research. This includes IRB responsibilities to ensure that such change has not occurred after the IRB has issued initial approval.

Regulatory Background

The Princeton IRB recognizes that protecting the rights and welfare of human subjects may require independent verification from sources other than the investigator that no material changes have occurred during the IRB approval period. According to federal regulatory requirements at 45 CFR 46.103(b)(4)(2), the IRB must establish a written procedure which the IRB will follow for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review. Among other things, approved research must be conducted according to IRB determinations, regulatory requirements and University policies. The IRB must ensure that when appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

Scope

This procedure applies to all Investigators, including faculty, students and staff, conducting human subjects research under the jurisdiction of Princeton IRB.

Responsibilities

RIA administrators will conduct internal monitoring of ongoing research protocols and communicate findings to the IRB as appropriate.

Investigators will provide access to relevant documents, labs, equipment and other information per the request of the IRB.

IRB Members may request independent verification and will review audit results at a convened meeting while assessing whether further inquiry may be necessary.

Procedure

The need for verification from independent sources will be initiated on a case-by-case basis by RIA administrators, the IRB Chair or a designee according to the following criteria:

1. Protocols where concern about possible material changes occurring without IRB
approval have been raised based on information provided in continuing review reports or from other sources.

2. Protocols conducted by Principal Investigators who have previously failed to comply with federal regulations and/or the requirements or determinations of the IRB.

3. The probability and magnitude of anticipated risks to subjects.

4. The complexity of projects involving unusual levels or types of risk to subjects;

5. Complaints from a subject or a third party;

6. The probable nature and frequency of changes that may ordinarily be expected in the type of research proposed;

7. Any other instance where the IRB deems verification from outside sources may be relevant.

In making determinations about independent verification, the IRB may require that such verification take place at predetermined intervals during the approval period, at the time of continuing review or may require such verification at any time during the approval period in the light of new information.

The Verification Process

A RIA Administrator, the IRB Chair or designee, or a full convened board may request independent verification of ongoing research activities.

The review will focus on assessing relevant research documents or observing the conduct of the research and/or consent process to verify the accuracy of the information presented to the IRB. This helps to ensure that no material changes have been initiated without IRB approval.

Independent verification may be requested by anyone knowledgeable about the research in question. This request must include the specific reason for the request.

Reporting Results of the Verification Process

1. Results from Independent Verification will be reported to the IRB on a periodic basis.

2. Findings that present increased harm to subjects or others and those requiring immediate action will be presented to the committee by the IRB Chair or RIA administrators at the next convened IRB meeting.

3. Corrective actions and the IRB’s decision will be communicated to the investigator in writing. The IRB will also notify the PI if any additional action is warranted.
4. The Board may suspend or terminate the research as appropriate. However, if the IRB Chair believes that continuation of the research, prior to the Board meeting, may cause harm to subjects, the IRB Chair may suspend or stop research activities pending further review by the Committee.

References

OHRP Guidance on Written IRB Procedures

http://www.hhs.gov/ohrp/policy/irbgd107.html

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