

Policy Number:	206	Version Number:	4.1
Approval Date:	April 23, 2014		
Title:	Reporting Requirement for Investigators		

Purpose

This policy outlines the information items that an investigator must report to the IRB.

Scope

This policy applies to all investigators under the jurisdiction of Princeton University, including faculty, staff and students conducting research involving human research participants.

Regulatory Background

Institutions must promptly report certain information to the federal government, the IRB, appropriate institutional officials, and the federal department or agency head. These types of information consist of the following:

- Unanticipated Problems Involving Risks to Subjects or Others
- Serious or continuing noncompliance
- Suspension or termination of IRB approval

In an effort to capture the above information, the Princeton University IRB requires that investigators report the information items listed under the heading “Reportable New Information” of this policy to the IRB.

Responsibilities

Investigators: Investigators must report the below information items to the IRB within 5 business days of learning of the information. If the information is not listed below, it should not be reported to the Princeton IRB.

Definitions

Unanticipated Problems Involving Risks to Subjects or Others: any incident, experience, or outcome that meets all of the following criteria:

1. Unexpected in terms of nature, severity, or frequency given the research procedures that are described in the protocol-related documents (such as the IRB-approved research protocol and informed consent document) and the characteristics of the subject population being studied; and

2. Related or possibly related to participation (a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
3. Suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized (including physical, psychological, economic, or social harm).

Noncompliance: Failure to follow the regulations or the requirements or determinations of the IRB and this failure may affect subjects' rights or safety.

Allegation of Noncompliance: An unproven assertion of non-compliance.

Finding of Noncompliance: Non-compliance in fact. Once a finding of noncompliance is proven, it must be categorized as serious noncompliance; continuing noncompliance; or noncompliance that is neither serious nor continuing.

Serious noncompliance: Non-Compliance that adversely affects the rights or welfare of subjects.

Continuing Noncompliance: A pattern of non-compliance that suggests the likelihood that, without intervention, instances of non-compliance will recur; or a repeated unwillingness to comply; or a persistent lack of knowledge of how to comply.

Suspension: Temporarily or permanently withdrawing IRB approval of some or all research procedures short of a termination of IRB approval. Suspended studies remain open and are subject to continuing review. Suspensions can be initiated by the IRB or the investigator. For example, an investigator may voluntarily suspend the study if the investigator determines that preliminary safety or efficacy data warrant suspension. Voluntary suspensions are not reportable to regulatory agencies unless the suspension is a result of an Unanticipated Problem or serious or continuing noncompliance.

Termination: Permanently withdrawing IRB approval of all research procedures. Terminated studies are permanently closed and no longer undergo continuing review.

Reportable New Information

Investigators are required to report the following information items using eRIA to the IRB within 5 business days of learning of the information. :

1. Failure to follow the protocol due to the action or inaction of the investigator or research staff
2. Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.
3. Breach of confidentiality

4. Complaint by a subject that cannot be resolved by the research team
5. Allegation of Noncompliance or a Finding of Noncompliance
6. Information that indicates a new or increased risk or a safety issue. This information may come from an interim data analysis, publication in the literature, sponsor report, or investigator finding.
7. Incarceration of a subject in a study that was not approved to involve prisoners
8. Audit, inspection, or inquiry by a federal agency
9. Written report by a federal agency; a study monitor; a data safety monitoring board; or a study sponsor.
10. Suspension of the study or premature termination of the study by the sponsor, investigator, or institution

The process the IRB uses to evaluate Reportable New Information and potentially report it to federal agencies are outlined in Princeton University IRB Guideline 01.

References

21 CFR §56.108(b)

45 CFR §46.103(b) (5)

Princeton University IRB Guideline 01

Version History

Version Number	Revision Date	Revision Description
4.1	11/9/2020	Revised to reflect IRB change in definition of <i>Noncompliance</i> .
4.0	2/14/2020	Revised to reflect RIA policy template.
3.0	10/1/2017	Revised to reflect reporting via eRIA.
2.0	3/1/2016	Added information items that need to be reported to the IRB; editorial revisions.
1.0	4/23/2014	Initiation.