

Guideline Number: 01	Version Number: 1.0
Effective Date: March 14, 2016	
Title: Process to Manage Reportable New Information	

Purpose

This guideline describes the process to evaluate information that is reported under Policy 206: Reporting Requirements for Investigators and to describe the Princeton University IRB reporting requirements to federal agencies.

Regulatory background:

Institutions must promptly report certain information to the federal government. 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

Scope:

This guidance is for the use of the Director of Research Integrity & Assurance, the IRB Chairperson, Assistant Director of Research Integrity & Assurance, and IRB members.

Procedure

This procedure is summarized in the flowchart found on the last page of this guidance document.

When new information is reported to the IRB, the Assistant Director of Research Integrity & Assurance reviews the information. The Assistant Director of Research Integrity & Assurance provides a preliminary assessment of the information to the Director of Research Integrity & Assurance and the IRB Chairperson. These three individuals (“Assessment Team”) determine whether the issue represents any of the following:

1. Noncompliance that is neither serious nor continuing.
2. Serious noncompliance
3. Continuing noncompliance
4. Unanticipated problem involving risks to subject or others.
5. Suspension of IRB approval.
6. Termination of IRB approval
7. None of the above.

The Assessment Team may create a subcommittee to further investigate the issue. The subcommittee may involve IRB members, IRB staff, and other individuals affiliated or unaffiliated with Princeton who have expertise in the relevant area. The Assessment team and any applicable subcommittee are charged with the protection of human subjects who participate in research conducted by Princeton University investigators. The Assessment team and any applicable subcommittee are expected to provide one of the following deliverables:

If the Assessment Team or subcommittee determines that the issue represents noncompliance that is neither serious nor continuing, the item is reviewed under expedited review. The Assessment Team will inform the Board via the expedited review report and may supplement the notification via a summary of the issue at a convened IRB meeting.

If the Assessment Team or subcommittee determines that the issue represents one of the following:

1. Serious noncompliance
2. Continuing noncompliance
3. Unanticipated problem involving risks to subjects or others
4. Suspension of IRB approval
5. Termination of IRB approval

the information item is assigned to a convened IRB meeting to determine whether any additional actions are necessary to protect the rights and welfare of subjects. In the interim, the Assessment Team or applicable subcommittee will consider whether any immediate actions are necessary to protect the rights and welfare of subjects.

The Assessment Team or subcommittee will document its findings.

Actions that the Assessment Team or the convened Board may take include, but are not limited to, the following actions over the protocol and subjects:

1. Modify the protocol.
2. Modify the information disclosed during the consent process.
3. Re-consent subjects.
4. Increase the frequency of continuing review.
5. Observe the research and/or consent process.
6. Require follow-up of subjects.
7. Suspend IRB approval.
8. Terminate IRB approval

In addition to actions over the protocol, the Board may recommend actions against the principal investigator. These recommendations are referred to the Dean for Research

for decision.

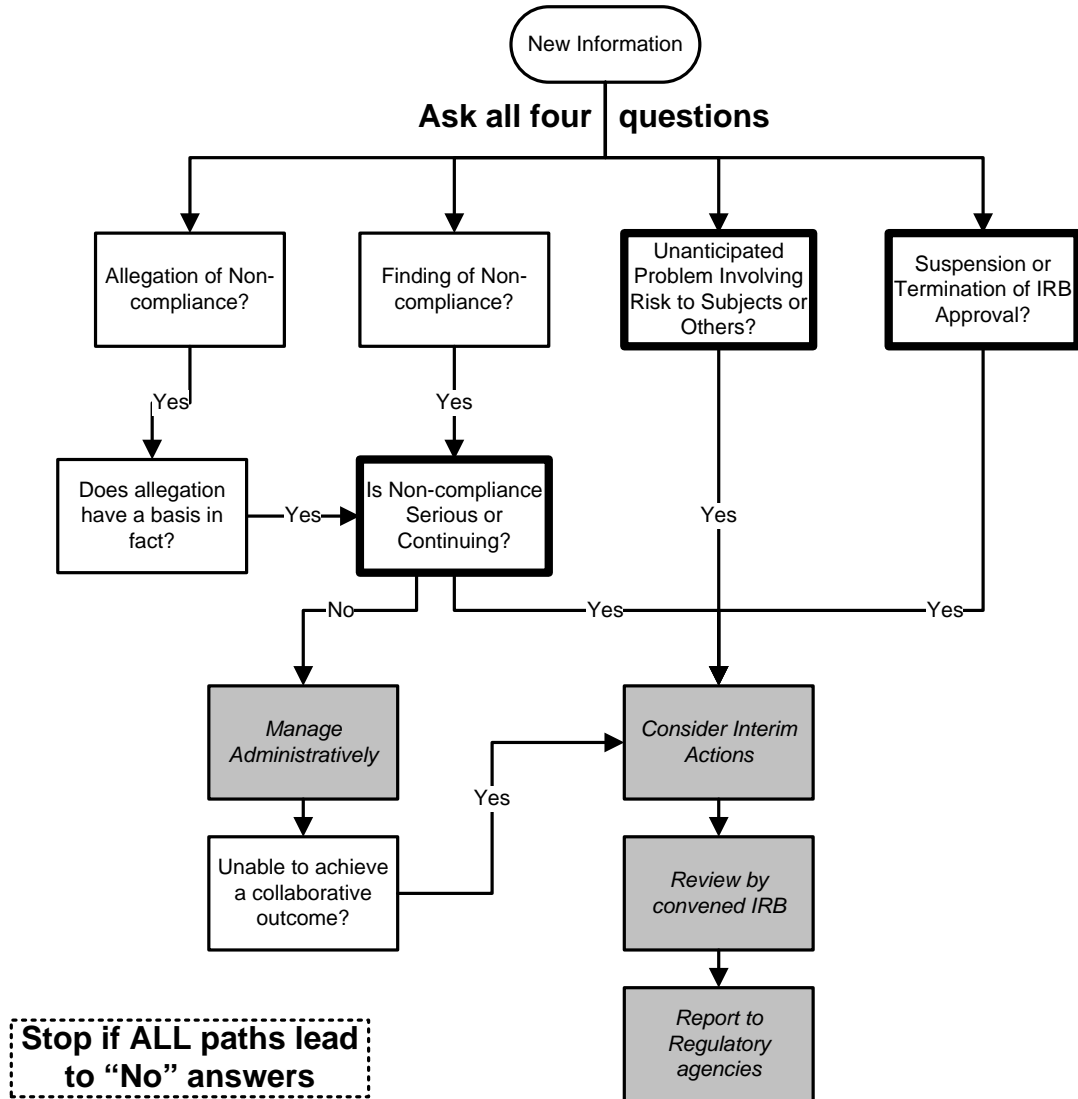
IRB Reporting Obligations to Government Agencies

Finding	Ensure Reporting to FDA¹?	Ensure Reporting to OHRP²?
Noncompliance that is not serious and not continuing	no	no
Serious noncompliance	If study is FDA-regulated	If study is federally sponsored and related to the local research context
Continuing noncompliance	If study is FDA-regulated	If study is federally sponsored and related to the local research context
Unanticipated Problem Involving Risks to Subjects or Others	If study is FDA-regulated	If study is federally sponsored and related to the local research context
Suspension of IRB approval	If study is FDA-regulated	If study is federally sponsored and related to the local research context
Termination of IRB approval	If study is FDA-regulated	If study is federally sponsored and related to the local research context

¹ If another entity, e.g., the study sponsor or another institution, reported the finding, Princeton University IRB does not report.

² With the exception of some federal sponsors such as DOD, DOE, if another entity, e.g., the study sponsor or another institution, reported the finding, Princeton University IRB does not report.

Flowchart



REFERENCES

21 CFR §56.108(b)

45 CFR §46.103(b)(5), 45 CFR §46.108(a)