1. PURPOSE

1.1. This procedure establishes the process to manage new information.
1.2. This procedure begins when an IRB receives information that is not a request for a determination (regardless of whether the information is reportable) or receives reportable new information as part of a submission.
1.3. This procedure ends when an HRPP staff member or [IRB Executive Chair] has determined whether the information requires reporting to the convened IRB.

2. POLICY

2.1. None

3. RESPONSIBILITY

3.1. All individuals who can make decisions about new information carry out these procedures or ensure they are carried out by other personnel.
3.2. Individuals unsure of a decision in this SOP are to bring new information to higher level official for a determination.

4. PROCEDURE

4.1. Ask the following six questions.

4.1.1. Does the information represent an <Allegation of Noncompliance>? If yes:
    4.1.1.1. Evaluate the <Allegation of Noncompliance> to determine whether there is a basis in fact.
    4.1.1.2. If the final determination is that the <Allegation of Noncompliance> has basis in fact, then this represents <Noncompliance>.

4.1.2. Does the information represent <Noncompliance>? If yes:
    4.1.2.1. Evaluate the <Noncompliance> to determine whether it is <Serious Noncompliance> or <Continuing Noncompliance>.

4.1.3. Does the information represent <Serious Noncompliance>?
4.1.4. Does the information represent <Continuing Noncompliance>?
4.1.5. Does the information represent an <Unanticipated Problem Involving Risks to Subjects or Others>?
4.1.6. Does the information represent a <Suspension of IRB Approval> or a <Termination of IRB Approval>?

4.2. If the answers to all six questions above are “no:”

4.2.1. Respond as needed to any complaint, query, or input.
4.2.2. If an acknowledgement is expected, follow “SOP: Post Review (HRP-111)” to notify the submitter.
4.2.3. Follow any other applicable SOPs.
4.2.4. No further action is required under this SOP.

4.3. If the information is an unauthorized disclosure of confidential information, immediately notify the Office of Information Privacy and Security.

4.4. If the information represents <Noncompliance> that is neither <Serious Noncompliance>, nor <Continuing Noncompliance>, evaluate any submitted corrective action.

4.4.1. If the corrective action plan is insufficient, contact the research team to develop a sufficient correction action plan.
4.4.1.1. If the research team is unable to develop a sufficient corrective action, consider the <Noncompliance> to be <Continuing Noncompliance> and address as above.

4.4.2. If the research team develops a sufficient corrective action, follow “SOP: Post Review (HRP-111)” to notify the submitter.

4.5. If the information represents <Serious Noncompliance>, <Continuing Noncompliance>, an <Unanticipated Problem Involving Risks to Subjects or Others>, a <Suspension of IRB Approval>, or a <Termination of IRB Approval>:

4.5.1. Obtain confirmation by the [Organizational Official].

4.5.2. Bring the information to the attention of an IRB chair or IRB vice-chair for consideration of whether any immediate actions are necessary to protect the rights and welfare of subjects in advance of the meeting.

4.5.3. Send for <Committee Review>.

5. REFERENCES

5.1. 45 CFR §46.103(b)(5)

5.2. 21 CFR §56.108