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. All decisions that 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> are to be confirmed by the [Organizational Official] or designee.

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.

3.3. The [HRPP Administrator] follows this SOP before placing an item of new information on the IRB agenda.

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. Refer allegations of IRB <Noncompliance> to the [Organizational Official] to complete this procedure and any other applicable policies and procedures.

       4.1.1.2. Evaluate the <Allegation of Noncompliance> to determine whether there is a basis in fact.

       4.1.1.3. 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. Follow any other applicable SOPs.
4.2.3. If an acknowledgement is expected, follow “SOP: Post Review (HRP-111)” to notify the submitter.

4.2.4. No further action is required under this SOP.

4.3. Consider whether any immediate actions might be necessary to protect the rights and welfare of current or future subjects while additional information is gathered.

4.3.1. If so, take those actions, notify the institution, sponsor, CRO, or SMO, as applicable.

4.4. Consider whether immediate notification of the institution, sponsor, CRO, or SMO might be appropriate.

4.4.1. If so, notify the institution, sponsor, CRO, or SMO, as applicable.

4.5. If more information is needed, contact the submitter to gather new information.

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

4.6.1. If the corrective action plan is insufficient, contact the research team to develop a sufficient correction action plan.

4.6.1.1. If the research team is unable to develop a sufficient corrective action, consider the <Noncompliance> to be <Continuing Noncompliance>.

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

4.7. 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>:

4.7.1. Notify the [Organizational Official].

4.7.2. 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.

4.7.3. Send for <Committee Review> to reconsider approval of the study in light of the new information.

5. REFERENCES

5.1. 45 CFR §46.103(b)(5)

5.2. 21 CFR §56.108