



SOP: New Information

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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 Legal.

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. An IRB chair or IRB vice-chair 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 Director of Human Research Protection Program Administrator to complete this procedure.
 - 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. Refer allegations of IRB <Noncompliance> to Director of Human Research Protection Program Administrator to complete this procedure.
 - 4.1.2.2. 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.



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- 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, and notify Legal.
- 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, and notify Legal.
- 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 Legal.
 - 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>.

5. REFERENCES

- 5.1. 45 CFR §46.103
- 5.2. 21 CFR §56.108