Temple University

SOP: New Information

Document No.:	Edition No.:	Effective Date:	Page:
HRP-112	003	01 MAY 2020	Page 1 of 2

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> may be confirmed by the [Chief Research Compliance Officer] as the [Chief Research Compliance Officer] deems appropriate.

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. Inform the [Chief Research Compliance Officer] of the <Allegation of Noncompliance>.
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. Inform the [Chief Research Compliance Officer] of the <Noncompliance>.
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.

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 the [Chief Research Compliance Officer].

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 the [Chief Research Compliance Officer].

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 [Chief Research Compliance Officer].

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>.

4.8. If the information represents research misconduct, as defined in Policy on Misconduct in Research and Creative Work (Policy Number 02.54.01), the [Chief Research Compliance Officer] will liaise with appropriate entities within the Office for the Vice President for Research in accordance with the policy.

5. REFERENCES

5.1. 45 CFR §46.103

5.2. 21 CFR §56.108