Standard Operating Procedure (SOP)

SOP #: 401.112	HRP-112 New Information	
Executive Owner: Vice President Research Operations		Effective Date: 6/11/2018 Review Date: 09/19/2019

Scope	This standard operating procedure (SOP) applies to the HRPP staff members at AdventHealth Orlando.
Purpose	This procedure establishes the process to manage new information including information related to IRB operations. This procedure begins when an IRB or others receive 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. This procedure ends when an <HRPP Personnel> member or [IRB Executive Chair] has determined whether the information requires reporting to the convened IRB.
Qualified Personnel	HRPP staff members and/or [IRB Executive Chair] carry out these procedures. All individuals who can make decisions about new information carry out these procedures or ensure they are carried out by other personnel. Individuals unsure of a decision in this SOP are to bring new information to higher level official for a determination. An IRB chair or IRB vice-chair follows this SOP before placing an item of new information on the IRB agenda.
Training	Not applicable.
Supplies & Equipment	Not applicable.
Procedure	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 [Research Compliance Senior Manager] and reported to by the Research Oversight Committee. 2. Ask the following six questions. 2.1. Does the information represent an <Allegation of Noncompliance>? If yes: 2.1.1. Refer allegations of IRB <Noncompliance> to the [Research Compliance Senior Manager] to complete this procedure. 2.1.2. Evaluate the <Allegation of Noncompliance> to determine whether there is a basis in fact. 2.1.3. If the final determination is that the <Allegation of Noncompliance> has basis in fact, then this represents <Noncompliance>. 2.2. Does the information represent <Noncompliance>? If yes:

2.2.1. Refer allegations of IRB <Noncompliance> to the [Research Senior Compliance Manager] to complete this procedure.

2.2.2. Evaluate the <Noncompliance> to determine whether it is <Serious Noncompliance> or <Continuing Noncompliance>.

2.3. Does the information represent <Serious Noncompliance>?

2.4. Does the information represent <Continuing Noncompliance>?

2.5. Does the information represent an <Unanticipated Problem Involving Risks to Subjects or Others>?

2.6. Does the information represent a <Suspension of IRB Approval> or a <Termination of IRB Approval>?

3. If the answers to all six questions above are "no":

3.1. Respond as needed to any complaint, query, or input.

3.2. Follow any other applicable SOPs.

3.3. If an acknowledgement is expected, follow "SOP: Post Review (HRP-111)" to notify the submitter.

3.4. No further action is required under this SOP.

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

4.1. If so, take those actions, notify the institution, sponsor, CRO, or SMO, as applicable, and notify the [Research Compliance Senior Manager].

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

5.1. If so, notify the institution, sponsor, CRO, or SMO, as applicable, and notify the [Research Compliance Senior Manager].

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

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

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

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

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

8. 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>:

8.1. Notify the [Research Compliance Senior Manager].
8.2. 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.
8.3. Send for <Committee Review>.

Definition(s)

IRB: Institutional Review Board
HRPP: Human Research Protection Program

Reference(s)

45 CFR §46.103(b)(5)

21 CFR §56.108

Related Documents

Not applicable.

Keywords

IRB, institutional review board, IRB member