UNIVERSITY OF MIAMI	SOP: Incoming Items			
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1 PURPOSE

1.1 This procedure establishes the process to triage information submitted to the IRB.

1.2 The process begins when any communication is received by the IRB.

1.3 The process ends when an HSRO staff member triages the appropriate action for the received information.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

2.2 Added provisions for submissions from external site and for Central IRB.

2.3 Reconciliation to Huron HRPP Toolkit 4.5, dated 12/10/2021

3 GUIDING PRINCIPLES

3.1 None

4 RESPONSIBILITIES

4.1 HSRO staff members carry out these procedures.

5 PROCEDURE

5.1 If the item is a request for an approval or determination[1], and the submission does not include an external site or external IRB, follow HRP-021 - SOP - Pre-Review.

5.2 If the item is a request either for this IRB to review for another Participating Site (pSite) or for this institution to rely on an external IRB, follow HRP-803 - SOP - Reliance Pre-Review.

5.3 If the item is an update to a study for which an external IRB is the IRB of record, follow HRP-805 - SOP - External IRB Updates.

5.4 If the item is a notification of an emergency use of a test article in a life-threatening situation, follow HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access.

5.5 If the item is an investigator's request to continue subjects in research for which IRB approval has lapsed, have a Designated Reviewer follow HRP-063 - SOP - Expiration of IRB Approval.

5.6 If the item is a Report of New Information and does not fit in a category above, follow "SOP-New Information HRP-024."

5.7 If the item does not fit into the above categories:

5.7.1 If the item is a question, concern, or complaint:

5.7.1.1 Document the nature of the question, concern, or complaint and the contact information of the person contacting the IRB.

5.7.1.2 Respond to any questions or concerns. When appropriate, tell the person that you will call/email him/her once you have been able to find additional information. If necessary, consult with your supervisor.

6 MATERIALS

6.1 HRP-021 - SOP - Pre-Review

6.2 HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access

6.3 HRP-024 - SOP - New Information

6.4 HRP-063 - SOP - Expiration of IRB Approval

7 REFERENCES

7.1 AAHRPP elements I.1.A, I.4.A, I.5.D, I.7.C, I-9, II.2.A, II.2.B, II.2.E-II.2.E.2, II.2.F-II.2.F.3

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[1] A "request for an approval or determination" includes approval of new research, response to modifications required to secure approval, continuing review of research, modification to previously approved research, request for study closure, or a determination whether an activity is exempt Human Research.