

SOP: Group Email Management

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1 PURPOSE

- 1.1 This procedure establishes the process to manage incoming messages that pertain to FSU human subjects protection matters and that are sent to the OHSP group email account in order to ensure that such communications are timely acknowledged, routed appropriately, and documented in accordance with applicable human subjects protection regulations (45 C.F.R. §46.115(a)(4)) and best business practices.
 - 1.1.1 The process begins when an incoming message that pertains to an FSU human subjects protection matter is received in the OHSP group email inbox.
 - 1.1.2 The process ends when the incoming message has been acknowledged, routed appropriately, and documented in accordance with applicable human subjects protection regulations (45 C.F.R. §46.115(a)(4)) and best business practices.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None.

3 POLICY

- 3.1 All queries from researchers will be promptly addressed or forwarded to the respective IRB Coordinator for handling.
- 3.2 Queries from participants will be forwarded to the responsible study investigator or, if applicable, routed to the respective IRB Coordinator for handling.
- 3.3 All other queries will be reviewed on a case-by-case basis and addressed or routed when necessary.
- 3.4 A filing system using sub-folders will be maintained within the group email inbox so all routed queries will be categorized and filed.
 - 3.4.1 The only emails remaining in the inbox should be those that have not been addressed or routed; routing may be discussed with an IRB Coordinator or the OHSP Director.
- 3.5 All emails sent from the OHSP group email inbox must include a complete signature to identify the staff member serving as group email manager.
 - 3.5.1 You may choose to add a message in your signature which refers to RAMP IRB use of the "Add Comment" feature as our primary method of study-related communication. If you do not add this message, make sure that you provide instructions to direct investigators to use RAMP IRB for these communications.
 - 3.5.1.1 Add a line in smaller size text underneath your standard signature block that says: Please use the RAMP IRB "Add Comment" feature to retain study-related communications on your study workspace. Refer to regulatory requirement at [45 C.F.R. §46.115\(a\)\(4\)](#), IRB records.

4 RESPONSIBILITIES

- 4.1 The OHSP group email manager and staff members carry out this procedure.

5 PROCEDURE

- 5.1 Upon receipt of a query, the OHSP group email manager will evaluate the purpose of the message.
 - 5.1.1 For inquiries of a general or simple nature, the OHSP group email manager may respond directly to address the query.
 - 5.1.1.1 Once an original query has been addressed, it will be filed in the OHSP group email 'Addressed' folder.
- 5.2 Queries from researchers or others pertaining to a researcher will be routed to the respective IRB Coordinator.
 - 5.2.1 The OHSP group email manager will confirm with researchers receipt of the query and will notify the researcher to whom the message was forwarded.

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- 5.2.1.1 To minimize redundancy, the respective IRB Coordinator will be included in the message confirming receipt, and this will serve as the routing mechanism.
- 5.2.2 Once a query has been routed, it will be filed in the IRB Coordinator's folder.
 - 5.2.2.1 If a researcher emails to follow-up on a prior group email inquiry that is more than 5 business days old, the OHSP group email manager will confirm with researchers receipt of the query and will re-notify the IRB Coordinator to whom the message was forwarded that the inquiry is still outstanding.
 - 5.2.2.2 If a researcher emails twice to follow-up on a group email inquiry that has been outstanding for 10 business days or more, the inquiry will be forwarded to the OHSP Director for handling.
- 5.2.3 The designated IRB Coordinator will "Reply All" to the forwarded query or otherwise ensure the OHSP group email is copied in the response to the researcher.
 - 5.2.3.1 The OHSP group email manager will file the response in the IRB Coordinator's folder for recordkeeping purposes.
- 5.3 Queries from participants or others pertaining to participants will be routed to the responsible study investigator, unless:
 - 5.3.1 If the participant query represents a concern, complaint, or Allegation of Non-Compliance or Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSOs) related to a specific study, this will be routed to the respective IRB Coordinator for investigation.
 - 5.3.1.1 The OHSP group email manager will confirm with the participant or other pertaining to participants receipt of the query and will notify the participant to whom the message was forwarded.
 - 5.3.1.1.1 To minimize redundancy, the respective IRB Coordinator will be included in the message confirming receipt, and this will serve as the routing mechanism.
 - 5.3.1.2 If a query represents Non-Compliance, UPIRTSOs, Suspensions of IRB Approval, and/or Terminations of IRB Approval these must be managed following HRP-024 - SOP - New Information.
 - 5.3.1.3 If a query requires further investigation, follow HRP-025 - SOP - Investigations.
 - 5.3.2 Once a participant query has been routed, it will be filed in the 'Queries or Complaints' folder and/or in the IRB Coordinator's folder.
- 5.4 Any queries from FSU leadership, such as Deans, Directors, and Department Chairs, an external institution's leadership or a federal agency, and that pertain to a researcher may be forwarded to both the OHSP Director and respective IRB Coordinator; such queries that do not pertain to a researcher but which are neither general nor simple in nature should be routed to the OHSP Director for handling.
- 5.5 The only emails remaining in the inbox should be those that have not been addressed or routed.

6 MATERIALS

- 6.1 None.

7 REFERENCES

- 7.1 HRP-024 - SOP - New Information
- 7.2 HRP-025 - SOP - Investigations
- 7.3 45 C.F.R. §46.115(a)(4), IRB records.