UC DAVIS
UNIVERSITY OF CALIFORNIA

| **SOP:** Incoming Items Directed to the IRB | | | | |
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| HRP-020 | 06.15.2017 | L. Smith | C. Kiel | 1 of 1 |

## 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 IRB staff member determines the appropriate action for the received information.

## 2 REVISIONS FROM PREVIOUS VERSION

2.1 Administrative Updates

## 3 POLICY

3.1 Investigators may independently determine whether a proposed project is not "human subject research" (NHSR); however investigators who are uncertain or need IRB documentation that the project is not human subject research may submit a project to the IRB through IRBNet and an IRB staff member will make said determination.

## 4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

## 5 PROCEDURE

5.1 If the item includes new or modified contact information, ensure the Initial Review Application has been updated.

5.2 If the item includes an updated list of study personnel:

5.2.1 Ensure the Initial Review Application has been updated.

5.2.2 Send "TEMPLATE LETTER: Acknowledgement of Personnel Update (HRP-524)" or equivalent.

5.2.3 If there are financial disclosures, follow "SOP: Financial Conflicts of Interests (HRP-055)".

5.3 If the item is a request to withdraw a submission from consideration, withdraw the submission.

5.4 If the item is a request for an approval or determination[1], follow "SOP: Pre-Review (HRP-021)."

5.5 If the item is a notification of an emergency use of a test article in a life-threatening situation have a Designated Reviewer follow "SOP: Emergency Use (HRP-023)."

5.6 If the item is an investigator's request to continue subjects in expired research have a Designated Reviewer follow "SOP: Expiration of IRB Approval (HRP-063)."

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.

5.7.2 Follow "SOP: New Information (HRP-024)."

## 6 MATERIALS

6.1 SOP: Emergency Use (HRP-023)

6.2 SOP: Expiration of IRB Approval (HRP-063)

6.3 SOP: Financial Conflicts of Interests (HRP-055)

6.4 SOP: New Information (HRP-024)

6.5 SOP: Pre-Review (HRP-021)

6.6 TEMPLATE LETTER: Acknowledgement of Personnel Update (HRP-524)

## 7 REFERENCES

7.1 None

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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 or is not Human Research. Submission of an updated list study personnel is not considered a modification of research and is therefore not a "request for an approval or determination."