## 1 PURPOSE

1.1. This procedure establishes the process to triage information submitted to the Office of IRB Administration (OIA). Information may be submitted directly in the electronic submission system or it may be submitted via other methodologies including, but not limited to, email, phone, or ticketing systems.

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

1.3. The process ends when an OIA staff member determines the appropriate action for the submitted information.

## 2 REVISIONS FROM PREVIOUS VERSION

2.1. None

## 3 GUIDANCE

3.1. Investigators may independently determine whether a proposed project is not "human subjects research" (NHSR). However, investigators who are uncertain about the project status or who need IRB documentation that the project is NHSR may submit a project to the OIA through UCSD OIA's electronic submission system and an OIA staff member will make said determination.

3.1.1. At UCSD, the Aligning and Coordinating Quality Improvement, Research, and Evaluation (ACQUIRE) committee is also delegated to make NHSR determinations on behalf of the institution. ACQUIRE's primary focus is biomedical projects.

3.1.2. At Rady Children's Hospital San Diego, the Evidence Based Practice – Quality Improvement (E-QUAL) committee is also delegated to make NHSR determinations on behalf of their institution. E-QUAL's primary focus is biomedical projects.

3.2. While information may come to the OIA via phone, email, ticketing system, electronic submission system, or other means, official determinations will only be issued for items submitted via the electronic submission system. However, general questions and requests for clarification, advice, or guidance need not be received in the electronic submission system and may be handled via any communication methodology appropriate for the sensitivity of the information.

## 4 RESPONSIBILITIES

4.1. Designated OIA staff members carry out these procedures.

## 5 PROCEDURE

5.1. If the item is a request to withdraw a submission from consideration, the OIA staff member may withdraw the submission and/or provide information to the requestor on how the submission may be withdrawn.

5.2. If the item is a request for an approval or determination,[1] the OIA staff member will first determine whether a submission has been made in the electronic submission system.

5.2.1. If a submission has not been made, instruct the requestor on how to do so.

5.2.2. If a submission has been made, follow *OIA-021 SOP: Pre-Review* when beginning the review process.

5.3. If the submission includes a request to serve as the single IRB (sIRB) for an independent investigator or external investigator, notify the reliance team of the submission so that they are aware of the submission and can follow procedures in *OIA-059 SOP: UCSD Serving as the IRB of Record*. Approval for the relying site(s)/investigator(s) may not be issued until the reliance team confirms that an appropriate reliance agreement is in place.

5.4. If the item is a request to rely on an external IRB for review and oversight of non-exempt human subjects research, determine whether a submission has been made in the electronic submission system.

5.4.1. If a submission has not been made, instruct the requestor on how to do so.

5.4.2. If a submission has been made, refer the request to the reliance team for application of procedures in

[1] A request for an approval or determination includes approval of new research, new expanded access or humanitarian use device (HUD) protocol; response to approve pending determination; response to a deferral; continuing review of research, expanded access or HUD protocol; modification to previously approved research, expanded access or HUD protocol; determination whether an activity is exempt human research, is not human research, or is human research that does not engage the institution.

*OIA-058 SOP: UCSD Relying on an External IRB*.

5.5. If the item is a notification of an emergency use of a test article in a life-threatening situation, refer to a designated reviewer for application of procedures under *OIA-023 SOP: Emergency Use*.

5.6. If the item is an investigator's request to continue human subjects in expired research, refer to a designated reviewer for application of procedures in *OIA-063 SOP: Expiration of IRB Approval*.

5.7. If the item is a technical submission:

5.7.1.1. Ensure that the submission will meet the criteria for a technical submission and that the information received will satisfy the reason for the submission. For example, if consent form was not stamped due to incorrect format, ensure that the correctly formatted document is included in the submission. If not, request changes accordingly.

5.7.1.2. When the submission will adequately address/satisfy the reason for the submission, follow *OIA-052 SOP: Post-Review*.

5.8. If the item does not fit into the above categories:

5.8.1. If the item is a question, concern, or complaint:

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

5.8.1.2. Respond to any questions or concerns. When appropriate, tell the person that OIA staff will call or email them once they have been able to obtain additional information. If necessary, consult with the supervisor.

5.8.2. Follow *OIA-024 SOP: Reportable Events*.

**6** MATERIALS

6.1. *OIA-001 SOP: Definitions*

6.2. *OIA-021 SOP: Pre-Review*

6.3. *OIA-023 SOP: Emergency Use*

6.4. *OIA-024 SOP: Reportable Events*

6.5. *OIA-052 SOP: Post-Review*

6.6. *OIA-058 SOP: UCSD Relying on an External IRB*

6.7. *OIA-059 SOP: UCSD Serving as the IRB of Record*

6.8. *OIA-063 SOP: Expiration of IRB Approval*

**7. REFERENCES**

7.1. None