



Standard Operating Procedure: #7
IRB Review of Human Subjects Research - Expedited
Revision Date: October 2020

Overview:

The IRB may review research through the expedited review procedures if the research is minimal risk and involves procedures in the following research as designated by the federal regulations at:

Click [HERE](#) for the categories of expedited review research designated by the federal regulations.

NOTE: The LLNL IRB will not review any study involving administration of a drug under the expedited review process. However, upon review the IRB may permit an expedited review for minimal risk research involving a device that meets Category 1 of the expedited review categories.

Procedures:

1. Principal Investigator (PI): Submits application

The PI submits the *Human Subjects Research Application* form (Form LL6652) and any pertinent documentation to the IRB Office.

2. IRB Office: Pre-review of application

Upon receipt of the application package, the IRB office will assign a protocol number and perform a pre-review of the package. The IRB Chair and Program Manager will follow one of the two actions below:

- Determine that the application meets the expedited review criteria as stipulated in the Regulations and identify two (2) IRB reviewers to review the application.
- OR-
- If required, request revisions and/or clarification from the PI. Upon verification of revisions and determining that the application meets the expedited review criteria as stipulated in the Regulations, two (2) IRB reviewers will be identified to review the application

3. IRB Reviewers: Reviews application for determination

In reviewing the application, the reviewers will follow one of the four actions below:

- Approve the application as submitted.
- OR-
- Request clarification or revisions:
 - This is communicated to the PI through the IRB Program Manager.
 - Upon acceptance of revisions or clarification, the reviewer will proceed with one of the other three actions listed here.
- Request an additional reviewer(s) be assigned to review:
 - The IRB Chair and IRB Program Manager will validate the request and assign reviewer(s) as applicable
- OR -

- The IRB Chair and IRB Program Manager will determine that a full board review is required. The IRB Program Manager will send an email to notify PI that this study will require a full board review and will provide details for attending the next regular IRB meeting (SOP #8: *IRB Review of Human Subjects – Full Board*).
- Refer the application to a Full Board review for further determination:
 - The IRB Program Manager will send an email to notify PI that this study will require a full board review and will provide details for attending the next regular IRB meeting (SOP #8: *IRB Review of Human Subjects – Full Board*).

NOTE: The reviewers may not disapprove the application. Not approving the application would serve as a referral to a full board review.

4. IRB Office: Process approved applications

- a) An approval letter will be generated and signed by the IRB Chair.
- b) The approved protocol package will include:
 - i) Signed approval letter
 - ii) Submitted application
 - iii) Pertinent documentation related to the application (i.e. consent forms, study materials, etc.)
- c) The IRB Program Manager will send an email to notify PI that the study has been approved. The email will have the approved protocol package attached.
- d) The approved protocol will be entered into the DOE IRB database.
- e) All applications approved under expedited review will be communicated to the IRB at the next regularly scheduled meeting. If the meeting is cancelled, the information will be distributed to the IRB via email. The *Expedited Review Summaries* will include:
 - i) Protocol Number and Title of Study
 - ii) Names(s) of Principal Investigators(s)
 - iii) IRB Reviewers and their comments, if applicable
 - iv) Applicable Expedited Review Category(ies)
 - v) Study synopsis
 - vi) Protocol approval date

5. The protocol and all application documentation will follow SOP #18: *Retention of IRB Records*.

References:

45 CFR 46.110
21 CFR 56.110



Document Review History

Revision Number	Date	Author	Summary of Changes
01	September 2017	Ann-Marie Dake	Complete Revision
02	November 2018	Dawn Whalen	Document control process added
03	November 2019	IRB Office	Complete Revision
04	October 2020	Ann-Marie Dake	Revisions and updates