

NewsFlash!

To facilitate the review and processing of human subjects protocols for extramurally funded projects, USC's Institutional Review Board (IRB) has released the attached "Best Practices Regarding Urgent & Non-Urgent Review."

Below are key highlights:

Considerations for All Extramurally Funded Studies

- To avoid any delays, Investigators should submit an iStar application when funding is likely (i.e., receipt of a fundable score, communication regarding Award, etc.).
- Upon receipt of an Award, Investigators should submit an IRB application within 5 business days in order to prevent delays in the review process.
- If the same project was submitted to various Sponsors, the Investigator may consider submitting an iStar application without the funding information. Once funding is likely, an amendment can be submitted with the relevant revisions, including funding information, study title, etc.
- Investigators should contact the Sponsor directly with any questions regarding the level or type of IRB approval required.

Urgent Review Criteria

An Urgent Review may be requested by an Investigator when it meets the following criteria:

1. A Sponsor requires IRB approval prior to issuing an Award; **and**
2. A Sponsor has issued a ***specific deadline*** for meeting the IRB approval requirement; **and**
3. Sponsor documentation of the above requirement has been received and submitted with the iSTAR application.

For projects that satisfy the Urgent Review criteria, the IRB will review the application within 5 business days. *Please note: this does not imply IRB approval will be received within 5 business days.*

In the event that an application was submitted without an Urgent Review request and the Sponsor informs the Investigator of imminent funding, the IRB should be notified via the "send message to IRB" function in iStar. Supporting documents must be uploaded with the request. Urgent Review requests may be considered or denied at the discretion of the IRB.

Best Practices for Urgent Review Submissions

When considering a request for Urgent Review, the Investigator should:

1. Carefully review the Sponsor's request. It is the responsibility of the Investigator to ensure the Sponsor's request meets the Urgent Review requirements and to ensure all requirements are fulfilled.

2. Ensure the iSTAR application is complete and accurate.
3. Ensure all required documents are uploaded in the iSTAR application. Required documents include, but are not limited to:
 - a. Sponsor documentation that meets the Urgent Review requirements
 - b. Proposal application and budget detail
 - c. Instruments, questionnaires, recruitment, consent documents, etc.
4. Ensure the iStar application indicates an Urgent Review requirement. This is done using the Just in Time (JIT) request and/or the “send message to IRB” functions in iSTAR.
5. Submit and/or update the iSTAR application within 5 business days of a Sponsor’s requirement to obtain IRB approval prior to issuing an Award.

6. Respond to any contingencies in a timely manner.

Please Note: The IRB may not honor the Urgent Review request if the Investigator and/or study team have not submitted the iSTAR application in a timely fashion consistent with these Best Practices and/or IRB procedures.

Questions

If Investigators have questions about the Best Practices document and/or the Urgent Review of iSTAR applications, please contact the IRB Office (323) 442-0114 or irb@usc.edu for guidance.