

Institutional
Review Board
(IRB)

General Review Process
for IRB Applications

What happens after I submit my application?

1. Researchers submit through IRBNet



2. Assigned analyst completes the Intake Review (approx. 1-14 days)



3. Researchers complete the revisions and “Mark Revisions Complete”



Exempt

- 4. Analyst reviews revisions
- 4a. If complete, the project is approved, and the exempt letter is published.
- 4b. If incomplete, the revisions are sent back to the researcher. Steps 3 and 4 repeat until the analyst approves.



Expedited

- 4. Analyst reviews revisions
- 5. When complete, faculty IRB reviewer is assigned and has ten business days to conduct review. Researchers work directly with faculty IRB reviewer until approval is recommended.
- 6. Analyst publishes approval letter.



Full Board

- 4. Analyst reviews revisions
- 5. When complete, the application is assigned to the next available IRB meeting.
- 6. IRB reviews and issues decision.
- 7. Analyst communicates the decision in writing to investigators after the IRB meeting.

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Ok, Now, What Do I
Need to Submit
to the IRB?

What Do I Need to Submit to the IRB?

To ensure compliance, IRBs require that all researchers submit a standard set of documents designed to procure all essential information about a particular study prior to initiation of the research. All documents and materials that are submitted to the IRB are what constitute the **IRB Project**.

All IRB applications are found and completed through IRBNet.org using the Smart Form “Wizard”.

<https://www.calstatela.edu/orsca/irb-submission-process>

Required Documents for Exempt Applications: Initial Submissions as of Fall 2024

- o IRBNet Application (Smart Form)
- o CITI Training Certificates for all researchers on the IRB application
- o Instruments / Surveys / Interviews
- o Informational Cover Letter
- o Debriefing statement, if applicable.
- o Electronic Signatures from Principal Investigator and Department Head

Exempt Applications: Documents No Longer Required for Initial Submission as of Fall 2024

The following are items that the investigator should develop as part of conducting ethical research. These items generally *do not* need to be submitted with the IRB application but should be maintained by the research team as part of the research records:

- Recruitment Materials: emails, letters, scripts, flyers, posters, brochures, etc.
- Permissions, support letters, and other approval documentation as applicable
- Translations or back translations

Attachments for Exempt Projects

Required for Initial Submission

- **Survey and interview instruments**
- **Informational cover letter**
- **Debriefing statement, if applicable**
- **CITI Training Certificates**

Not required for submission, but recommended to be developed

- **Recruitment materials**
- **Letters of permission**
- **Translations or back translations**



Attachments for your IRB application will depend entirely on your proposed research.

Check the Smart List at the end of your IRB application.

Modifications for Exempt Research as of Fall 2024

- **Modifications** – If the proposed changes constitute any of the following, a modification application for an exempt project must be submitted:
 - Add procedures that could affect risks to participants
 - Add procedures that do not fit with the exemption categories
 - Add new types of participants to your study that include vulnerable populations (e.g., adding children, individuals with cognitive impairments, prisoners, etc.)
- **Modifications are NOT required to:**
 - Add and remove investigators; PI is responsible for ensuring CITI training is completed.
 - Make changes to recruitment materials or instruments
 - Make changes to informational cover letter

IRB Contact Information

Dr. Sharon Ulanoff, IRB Chair

Dr. Allison Mattheis, Faculty IRB Liaison (resource for **faculty**)

Claire Riner, Research Support Services Coordinator

Karina Martinez, Research Support Analyst

LaTreshia Scott, Research Affairs Analyst

Dr. Jason Shiotsugu, Director of Research

Office of Research, Scholarship, and Creative Activities

Main Phone: 323-343-3792

Check the website for the most recent information on IRB:

<http://www.calstatela.edu/orsca/research-human-subjects-irb>