

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

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Check the website for the most recent information on IRB:

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