# GUIDANCE FOR STUDENT RESEARCHERS WITH A FACULTY ADVISOR

For student-initiated research the student is designated as a student Principal Investigator (PI) and will need a Faculty Advisor (FA). A PI is the individual responsible for the development and conduct of a research study. The FA for a student PI will mentor the PI from the start of the research project until the its end.

The FA should guide the student PI in formulating a research hypothesis (or research question), developing the research methodology for investigating the hypothesis (or research question), and in procuring or designing supplemental research materials.

Ultimately the student PI can use the results of their research for a thesis or a paper that could be submitted for publication. The focus of this Guidance is on research involving human subjects and the CSULB Institutional Review Board (IRB).

Upon securing the commitment of a FA, the student PI will need to have the FA complete and sign the [Faculty Advisor Letter](https://www.csulb.edu/sites/default/files/2024/documents/Faculty%20Advisor%20Letter%2002.29.24.docx) to submit with the IRB Application to the IRB using [IRBNet](https://www.csulb.edu/sites/default/files/2024/documents/IRBNet%20Guide%2006.11.24%20%28b%29.pdf). The CSULB IRB uses a web-based system, IRBNet, to manage submissions for IRB review and oversight.

The FA should guide the student PI in formulating a research hypothesis (or research question), developing the research methodology for investigating the hypothesis (or research question), and in designing supplemental research materials such as recruitment strategies, informed consent information, and data collection tools. Once the research project plan is complete, the student PI will submit an IRB Application for IRB review.

CSULB does not permit students to conduct any research involving human subjects without the oversight of a Faculty Advisor, Mentor, or a class instructor for class research projects.

# Institutional Review Board (IRB)

An IRB is a committee that is required by federal law to protect the rights and welfare of human subjects participating in research activities. The IRB reviews of all proposed human subjects research at CSULB to ensure that the recruitment strategies, the informed consent information and consent process, study procedures, description of risk/benefits, and data security plan are satisfactory, ethical and comply with federal and state regulations, and CSULB policies. The IRB will also verify that the PI, FA, and any Research Assistants (RA) have completed the [CITI](https://www.csulb.edu/sites/default/files/2023/documents/Instructions%20on%20Navigating%20CITI%20Program%2012.04.23.pdf) human subjects research protection course.

**No research involving human subjects** may be conducted by University faculty, staff, or students prior to approval by the IRB being granted under the appropriate provisions of this policy ([Policy](https://www.csulb.edu/academic-senate/policy-statement-0) [Statement, Protection of Human Subjects, CSULB Academic Senate](https://www.csulb.edu/academic-senate/policy-statement-0)). This restriction applies equally to all three categories of review: standard full board, expedited, and exempt. No contact of any kind may be made for purposes of research with actual or prospective subjects until after the appropriate informed-consent form has been reviewed and approved or a waiver of informed consent has been granted by the IRB.

# Will my research require IRB review?

Proposed research projects that meet the regulatory definition of research with human subjects will require review and approval by the CSULB Institutional Review Board (IRB) **BEFORE** the research (including subject recruitment) can begin. The IRB will also consider the level of risk to subjects who participate in the research. Most research at CSULB is minimal risk.

***Research*** is defined as: “a systematic investigation, including development, testing and evaluation designed to develop or contribute to generalizable knowledge.”

***Systematic investigation*** is a prospective plan that incorporates data collection and data analysis designed to test a hypothesis and permit conclusions to be drawn.

***Generalizable knowledge*** is the extent that research findings and conclusions from a study conducted on a population sample can be applied to the population at large (i.e., the results from a study of computer science graduate students at CSULB applies to computer science graduate students at all CSU campuses.)

***Human subject*** is “a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

***Minimal risk*** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

***More than minimal risk*** means that the probability and magnitude of harm or discomfort anticipated in the research are more than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

# How do I prepare my application submission for IRB review?

Following the final development of a research project proposal with your FA, the next step is preparing the IRB application with the [Faculty Advisor Letter](https://www.csulb.edu/sites/default/files/2024/documents/Faculty%20Advisor%20Letter%2002.29.24.docx) for submission to the IRB for review. You will submit your IRB application in IRBNet which designates the Submission Type as a “New Project”. If appropriate you may want to submit [Permission/Authorization Letters](https://www.csulb.edu/sites/default/files/document/view_a_sample_permission_letter.pdf) when conducting research off-campus or at locations other than a CSULB office/lab or public space. Also include recruitment materials, informed consent materials, the QR code or link for a survey that is activated and referenced in the application, recruitment materials, and informed consent.

# What are the IRB Review Types for a New Project Application?

The CSULB IRB has four review types for New Project applications: Exempt, Expedited Review, Full Board Review, and Not Humans Subjects Research (NHSR). The majority of applications submitted for IRB review undergo exempt review. A Full Board Review is rare.

1. An Exempt Review applies to minimal risk research and the only involvement of human subjects is in one of six [exempt categories.](https://www.csulb.edu/sites/default/files/2023/documents/Exempt%20Categories%20v1.pdf) An exempt determination is conducted by a single IRB member or an IRB staff member. Average review time: 2 days to 1 week.
2. An Expedited Review is also minimal risk and the research only involves procedures listed in one or more of the [expedited categories.](https://www.csulb.edu/sites/default/files/2023/documents/Expedited%20Categories%20v1.pdf) An expedited review is conducted by a single IRB member. Average review time: 5 days to 1½ weeks.
3. A Full Board Review is for research that is more than minimal risk and for some minimal risk research with vulnerable populations or research on sensitive topics. The review is conducted at an IRB meeting. The IRB meets monthly except for the months of January, June and July. When an application is to be reviewed at an IRB meeting the student PI and FA are asked to attend the meeting to answer questions about the proposed research.
4. Not Humans Subjects Research (NHSR) is proposed research involving unidentifiable/de- identified or coded private information or biological specimens. It is not considered human subjects research when investigators cannot readily ascertain the identities of the individuals to whom the data or samples belong. This determination is usually conducted by IRB staff.

# Which IRB Application do I need to submit for IRB review of a New Project?

The student PI should submit the IRB Application form the falls within the appropriate IRB Review Type listed above. The student PI can choose from the following application forms to submit for IRB review:

[IRB Application for Exempt Review (formattable)](https://www.csulb.edu/sites/default/files/2024/documents/IRB%20Application%20for%20Exempt%20Review%20BETA%2005.20.24.docx)

[IRB Application for Administrative and Limited Review (formattable) (v.3)](https://www.csulb.edu/sites/default/files/2024/documents/Administrative%20%26%20Limited%20%28Exempt%29%20Review%2006.04.24.docx) – older version

[Expedited and Standard Review Form (Expedited and Full Board Review),](https://www.csulb.edu/sites/default/files/2023/documents/IRB%20Application%20for%20Expedited%20and%20Standard%20Review%20%28formattable%29%20%28v.3%29.docx) and

[Existing and](https://www.csulb.edu/sites/default/files/2024/documents/IRB%20Application%20for%20Exempt%20Review%2013.Feb_.24.docx) [Secondary Data Form](https://www.csulb.edu/sites/default/files/2024/documents/IRB%20Application%20for%20Exempt%20Review%2013.Feb_.24.docx) for (Non-Human Subject Research).

# What are the outcomes of an IRB Review?

The are eight primary outcomes of an IRB review:

**Acknowledged** – This is the same as approved although typically is a review decision by IRB staff.

**Approved** – A review decision by a single IRB member or by the Full Board.

**Approved** **with Conditions** – A review decision by a single IRB member for an Expedited and Standard Review application. The research may begin for all activities except those listed as conditions. The PI **WILL NOT NEED** to submit the revisions to the IRB for the conditions outlined in the IRB notification letter of approved with conditions.

**Approved** **with Conditions** – A review decision by a single IRB member for an Expedited and Standard Review application. The PI  **WILL NEED** to submit the revisions to the IRB for the conditions outlined in the IRB notification letter of approved with conditions.

**Exempt** – A determination by a single IRB member or an IRB staff member.

**Research Not Human Subject Research (NHSR)** – A determination that the proposed research does NOT involve human subjects or data with identifiers or activity is not research.

**Information Required** – Following a pre-review by IRB staff a notice of Information Required is sent to the PI requesting additional information or a revision of some part of the application that is needed to continue review of the submission.

**Modifications Required** – Following a review by an IRB member or at a convened IRB meeting a notice of Modifications Required is sent to the PI requesting additional information or revision of some part of the application. The revision or additional information is required for IRB approval of the submission.

An IRB review outcome of Acknowledged, Approved, Approved with Conditions, Exempt, or NHSR is final, and the research project can be initiated.

For an IRB review outcome of Information Required or Modifications Required, research activities cannot be initiated. The student PI will need to respond to the requested information or modifications by submitting a revisions package via IRBNet. The IRB will review the revision package and either approve or acknowledge the project or request additional information or modifications.

# How do I apply for an IRB review?

## First complete the [CITI](https://www.csulb.edu/sites/default/files/2023/documents/Instructions%20on%20Navigating%20CITI%20Program%2012.04.23.pdf) Social & Behavioral Research or the Biomedical Research Basic Course

All CSULB researchers (including Faculty Advisors/Mentors) must complete this course.

***Meet with your Faculty Advisor –***Your Faculty Advisor will advise you on finalizing your research application materials for review by the IRB and on creating an [IRBNet](https://www.csulb.edu/sites/default/files/2024/documents/IRBNet%20Guide%2006.11.24%20%28b%29.pdf) account.

## Have your hypothesis (or research question) formulated and the research project design finalized in your IRB Application

This will include defining your subject population, eligibility criteria, possible risks with mitigations, direct benefits if any and possible benefits to society or community, [recruitment strategies,](https://www.csulb.edu/sites/default/files/2024/documents/GUIDANCE%20Recruitment%20Material%2007Feb2024.docx) compensation/incentives, data collection methods such as survey instruments or interview protocols, plans for securing data and for protecting personal identifiers, and if needed letters of permission/authorization ([sample permission letter](https://www.csulb.edu/sites/default/files/document/view_a_sample_permission_letter.pdf)). Also include any funding information and additional personnel.

## In the IRB Application describe how you will obtain informed consent and include the consent

(see [Consent guidance](https://www.csulb.edu/sites/default/files/2024/documents/GUIDANCE%20Consent%20Guidance%20%26%20Template%2003.04.24.docx)), **templates and sample documents.**

1. ***Submit your IRB application via IRBNet –*** You will need to submit the following materials as organized below:
	* IRB Application Form;
	* Informed Consent document; and
	* Appendices (all other submission materials in a single file and labeled, e.g., Appendix A – Recruitment Materials, Appendix B – Faculty Advisor Letter, Appendix C – Survey, etc.)

Additionally, in IRBNet, under the “Project Administration”, column on the left side of the screen, the student PI must “Share this Project” with the FA and give the FA “Full” access. This will allow the FA to receive the same communications from the IRB as the student PI.

1. ***Monitor your email –*** IRBNet notices are sent to your email when an action on your part is required. Respond promptly to any requested modifications to your application or requests for information. Your IRB approval will also be sent via an IRBNet email notice.
2. ***Conduct your research as approved by the IRB –*** Any changes to research projects that have already been approved by the IRB must be reviewed and approved by the IRB before implementation. For review consideration of any changes by the IRB submit an [Amendment Form](https://www.csulb.edu/sites/default/files/2024/documents/Request%20for%20Amendment%20to%20an%20Approved%20Protocol%20%28formattable%29%20%28v.3%29%20%2002.27.24.docx) via IRBNet.
3. ***Renew your IRB approval prior to the expiration date –*** Research projects approved by IRB expedited review or approved by the Full Board will have an approval expiration date of 12 months from the date of the initial IRB approval. To continue the approved research activities for another 12 months submission of an [Annual Check-In Form](https://www.csulb.edu/sites/default/files/2023/documents/IRB%20Application%20for%20Annual%20Check%20In%20%20%28formattable%29%20%28v.3%29.docx) is needed for research approved by expedited review or submission of a [Continuing Review Form](https://www.csulb.edu/sites/default/files/2023/documents/IRB%20Application%20for%20Continuing%20Review%20%28formattable%29%20%28v.3%29.docx) is needed for research approved by the Full Board. Research projects determined to be exempt have no expiration date and do not require any submission to continue after 12 months.

**Key Resources**

For any questions or to request information contact the IRB at IRB@csulb.edu

[CSULB IRB](https://www.csulb.edu/office-of-research-and-economic-development/institutional-review-board-irb) website

[Instructions on Navigating CITI](https://www.csulb.edu/sites/default/files/2023/documents/Instructions%20on%20Navigating%20CITI%20Program%2012.04.23.pdf)