

## Meet The Deadline!

For research that requires review by the convened committee, vIRB applications must be submitted on or before 4:00pm of the deadline date. To view the deadline and meeting dates go to:

<http://gra.sdsu.edu/research/irb>

and click on the link

IRB Committee Meeting Calendar

## Understanding Review Levels

The appropriate review procedure (exempt, expedited or convened committee) is determined by federal regulations and applied based on how human subjects are involved in the research. Risk associated with participation in the research, the study intervention/interaction and how informed consent is obtained and documented are all part of determining the review type. Within the vIRB, you will indicate the review level most appropriate for your research in order to develop a vIRB protocol. If you are in doubt, please contact an IRB analyst for assistance. Additional detail about review type follows:

**Exempt—Existing Data:** The analysis of existing or secondary data is usually exempt if no identifiers are recorded.

**Exempt—Prospective Data Collection:** Data collected from adults via survey or interview unless the questions deal with a sensitive aspect of a subject's behavior such as illegal conduct, drug use, sexual behavior, or the use of alcohol.

**Expedited:** The collection of blood or biological specimens, recording weight, height, voice, or image; electrocardiography or ultrasound; testing of muscle strength, sensory acuity, individual or group characteristics and/or behaviors (minimal risk only!).

**Full Committee:** All human subjects research that does not meet exempt or expedited requirements.

## Get the Details!

Find out about subject recruitment, informed consent, writing a protocol, analyzing existing data and more. Details can be found within the Research Integrity/Regulatory Compliance section of the website.

## Remember to:

- Know the code.** Familiarize yourself with the code of ethics for your discipline.
- Formalize your thesis committee.**
- Review the Guidebook prior to submitting your protocol.**
- Pass the tutorial.** A score of 90% or better is required to pass. Save the confirmation email and print it out for your records.
- Submit your protocol AFTER your Thesis Chair/Faculty Sponsor and your committee has reviewed and approved it.** Use the Full Document Viewer feature to disseminate your protocol to your committee for feedback prior to submission.
- Upload all applicable documents to vIRB.** Click on the "Supporting Documents" tab on the top of the vIRB page; select your document type; use the Browser to locate your file; click "Open" and then click "Upload."

*What to include in the Supporting Documents module:*

- Letters of Authorization:** Required permission can be documented in a letter from an agency (or data owner) directed to the Principal Investigator.
- Recruitment Materials:** Include text of advertising, flyers, telephone scripts or other recruitment materials proposed for use in subject recruitment.
- Informed Consent Forms:** Create forms to document consent by using the appropriate [SDSU Consent Templates](#) (available on-line) for your research:

Exempt Prospective research requires a Consent Script.

Expedited or Full Committee research usually requires a (formal) Informed Consent Document.

Research involving children usually requires a Parental Consent Document and an Assent Document.

- Study Instruments:** The IRB will review all research instruments such as surveys, interviews or questionnaires planned for use in data collection. The IRB must review the final instruments prior to approving the use of those instruments for data collection.



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## The IRB Quick Reference Guide

For

## Graduate Students

## Institutional Review Board

<http://gra.sdsu.edu/research/irb>

Division of Research Affairs  
Graduate and Research Affairs  
5500 Campanile Drive, MC 8220  
San Diego, CA 92182-8220

### Contact Information

Phone: 619-594-6622

Office: Student Services East # 1410

E-mail: [irb@mail.sdsu.edu](mailto:irb@mail.sdsu.edu)

## How to Use This Guide

The *IRB Quick Reference Guide for Graduate Students* provides basic information on conducting human subjects research, how to navigate the IRB (Institutional Review Board) process and the web based protocol development system, the *virtual* IRB (vIRB).

### Your Responsibilities

**Review the SDSU Human Subjects Guidebook:** Ultimately, you are responsible for the conduct of your study. To ensure your protocol is designed and carried out in an ethical manner, review the SDSU Human Subjects Guidebook prior to developing your protocol.

**Review and Pass the Tutorial:** You are required to pass the online tutorial that provides training for the ethical conduct of human subjects research PRIOR to protocol submission. To access the online training, go to the Education and Training section located on the IRB webpage and click *Human Subjects Tutorial*.

**Read all IRB correspondence:** You will receive messages via email confirming the submission of your protocol and informing you of review outcome. If you don't receive either of these, or if you have questions— please contact us!

### Enrollment into 799A

If you have been advanced to candidacy and you have an officially appointed thesis committee, you are permitted to enroll in 799A. To enroll, you must obtain clearance from the Institutional Review Board (IRB) if you plan to involve human subjects in your research.

**(Optional) Use of an Approval in Principle:** An Approval in Principle is appropriate when plans for involvement of human subjects in a thesis research project are not fully developed prior to the Thesis 799A deadline. This application allows you to provide a tentative description of the planned thesis research. Once the Approval in Principle is reviewed *and* accepted, you receive an auto-generated email that can be used to permit enrollment in 799A. **Please note:** The Approval in Principle does not constitute an IRB approval.

**(Required) IRB Protocol Review:** Once your research protocol is developed and approved by your Thesis Committee Chair or Faculty Sponsor, it must be submitted for IRB review and approval. **Plan ahead!** The IRB review process may require 3-6 weeks depending on the nature of the research.

## Frequently Asked Questions

**Does my project involve research and human subjects?** Research in which information is obtained about a person through survey, interview, observation or experimentation, or that involves the analysis of previously collected human tissues, records, samples or other existing or secondary data collected from an individual must be approved by the IRB in advance of initiating recruitment, data collection and/or analysis. If you are not sure, submit a vIRB questionnaire – an online tool that allows the IRB to determine whether your project requires IRB review. Simply log in to the vIRB through the WebPortal and choose “Yes. Create New Protocol;” then respond to the questions accordingly. You will be notified within 5-7 days about whether IRB review is needed.

**I think my project is exempt. Do I have to submit an IRB protocol?** Yes! All human subjects research requires review. The Division of Research Affairs, in consultation with the IRB, will review and verify new protocols that are identified as exempt.

**What if the research protocol has been approved at another institution?** The SDSU IRB review and approval must occur in advance of initiating human subjects research, regardless of review requirements imposed by other institutions.

**How long does the IRB review process take?** Research reviewed by the convened committee (not Exempt or Expedited) occurs on scheduled meeting dates listed on the website. You will be notified electronically of the review decision within one week following the scheduled meeting date. Exempt and expedited reviews are conducted in the order received. Don't delay! Submit your completed protocol application upon approval from your Thesis Committee Chair or Faculty Sponsor.

**What may delay approval?** Failure to follow instructions provided in each section of the protocol document or an inadequate informed consent document are common reasons for delay. To avoid unnecessary delay in approval, please review the SDSU Human Research Protection Guidebook to assist in preparing your protocol.

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**SDSU IRB approval is REQUIRED for students conducting research involving human subjects.**

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## Navigating the vIRB

**How do I access the vIRB?** Login to the WebPortal using your RedID and password; click “Activate Research Role;” then click “Launch IRB.”

**How do I submit an IRB protocol?** The vIRB is a fully automated, web based system that allows you, the Principal Investigator (PI), to submit all relevant protocol documents needed for IRB review of new protocols, modifications, renewals and adverse events. The Approval in Principle application is also located within the vIRB. Simply access the vIRB and read the guidance tailored for each section.

*If your study is conditionally approved,*

**Respond to conditions within 90 days:** In advance of initiating any involvement of human subjects in a study (i.e., contact, recruitment, and enrollment), the IRB must review and accept your response to all of the comments included in the review. To view IRB comments: access your protocol through vIRB, click “Protocol Document,” click the title of the section(s) marked conditional; click “IRB COMMENTS” (in red text); then use the scroll bar on the right side of the comment box to view the entire comment.

*If you make changes to an approved study,*

**Submit a modification:** You will need to receive IRB approval in advance of implementation of any revision (e.g., changes to the consent document, study procedures, risks and benefits to study participation, etc), except when necessary to eliminate apparent immediate hazards to the subject (see the Human Subjects Guidebook for details). To submit a modification request: access your protocol through vIRB and on the Protocol Main page, click “Modifications” under Protocol Maintenance; click “Enter Modification;” finally, complete and submit the request.

*If you need to renew your approval or close your protocol,*

**Submit a Report of Progress:** IRB approved protocols must be reviewed at least annually. A continuation of approval is needed if: 1) subject recruitment and/or data collection is continuing or 2) data is being analyzed. A final report is necessary if all procedures are completed that involve human subjects (e.g., recruitment, data collection and analysis). To Submit a Progress Report: access your protocol through the vIRB and on the Protocol Main Page, click “Progress Reports” under Protocol Maintenance; click “Enter Report;” then complete and submit the report.