

I am doing a survey to evaluate a program or a class. Does this need IRB approval?

If it is designed to produce generalizable knowledge (e.g., get published) then it needs IRB approval.

What is the difference between IRB approval and exemption?

Federal law allows certain categories of research to be exempted. Download the exemption form and see if your research fits into one or more of these categories. If it does, apply for an exemption. Exemptions are quicker and last three years before needing renewal, regular approvals must be renewed every 12 months.

How long does it take to get IRB approval?

We can process exemptions in about two weeks, expedited reviews in about three weeks, and regular review takes about two months.

What is expedited review?

Research that cannot be exempted but is minimal risk and does not involve prisoners can usually be approved by expedited review. This means one member of the IRB reviews the proposal and can approve it. All protocols that are submitted and seem to fit this category are sent out for expedited review automatically-you do not have to request it.

Where do I get forms for IRB approval or continuation?

From the IRB website. www.lsu.edu/irb

Who has to take the human subjects training?

All LSU faculty, students, and staff who are involved in the design or conduct of research with human subjects. The IRB will not approve any protocol until all PI's certificates are received by the IRB office.

How do I do the human subjects training?

Take the on-line course at this [link](#). When you complete the training (about two hours) print the certificate and send a copy to the IRB office. You only need to do this one time.

Do Co-PI's at other institutions need to do the human subjects training?

No. We assume they have their own human subjects training course.

What is developmental approval?

When a grant is obtained that calls for developing a survey or instrument and then use it later. Developmental approval allows you to get your funds and develop the instrument. However, all instruments and consent forms must be approved before actually collecting data.

I want my students to conduct a class project where they will administer surveys/interviews. Do I need IRB approval?

If the project will not lead to generalizable knowledge it is not considered research by the federal standard. However, some instructional development and service program projects may involve a “research” component that falls under the HHS definition of human subjects research. Please send an inquiry to the IRB office that outlines your prospective project. We will decide if an application is needed. In the case of research methods courses, you are still strongly encouraged to get IRB approval for class projects so that students have the experience. Please consider if there is a chance that you or your students will ever utilize the data collected in the future for other purposes.

Can projects be given retroactive approval?

No. All projects involving the manipulation/intervention with human subjects must receive approval before any work with subjects can begin.

Are blanket approvals given for recurring projects, such as those done each semester in classes?

No. Blanket approvals are not given. For recurring projects such as those done in classes, the PI, who is probably the instructor, should submit an application (most likely an exempt application) containing all the necessary elements. In succeeding semesters, the PI can file a modification that contains the names of the new student investigators, their NIH certificates, consent forms, and any procedures that differ from those originally approved.

If I want to videotape public behavior, or activity, do I need IRB approval?

It is POSSIBLE that videotaping public behavior, as in ethnographic studies, will not need IRB approval. Investigators should send an email which summarizes the project to the IRB office. Investigators will receive a reply to either confirm there is no need to submit an application or that IRB review will be needed. Generally, if a project will go beyond simple videotaping and include any form of intervention with, or manipulation of, the subjects then IRB review will be needed.

Additional information for NIH-funded research involving human subjects

If you are conducting NIH-funded research that involves human subjects, or are considering applying to NIH for support of such research, we want to call your attention to important changes that may affect how you:

- select the right NIH funding opportunity announcement
- write the research strategy and human subjects sections of your application
- comply with appropriate policies and regulations

First, familiarize yourself with the new PHS Human Subject and Clinical Trial Information form. For application due dates of January 25, 2018, and beyond, you will be required to use an updated application forms package (FORMS-E), which includes the new human subject and clinical trial form. This form requests human subject and clinical trials information at the study level using discrete form fields, which is a change from current practice. Contract proposals will also require this information. [Learn about the new form here.](#)

Second, take a moment to answer these four questions about your current or proposed research:

- 1) Does the study involve human participants?
- 2) Are the participants prospectively assigned to an intervention?
- 3) Is the study designed to evaluate the effect of the intervention on the participants?
- 4) Is the effect that will be evaluated a health-related biomedical or behavioral outcome?

If the answer to all four questions is yes, then your proposed research meets [the NIH definition of a clinical trial](#). Clarified and broadened in 2014, the definition encompasses a wide range of trial types: mechanistic, exploratory/developmental, pilot/feasibility, behavioral, and more. NIH expanded the clinical trial definition in response to widespread calls from diverse stakeholders for improved reporting of research milestones and outcomes, and for assuring maximal transparency.

Need help determining whether your study would be considered by NIH to be a clinical trial? See the NIH [webpage on the definition](#) that includes case studies, FAQs and other resources that can help. Still unsure? Contact your NIH program official or the scientific point of contact listed on the funding opportunity announcement to which you are applying.

Third, familiarize yourself with NIH policy changes related to enhancing stewardship of clinical trials.

NIH made a number of policy changes to improve the stewardship of clinical trials across the life cycle of the trial. We encourage you to familiarize yourself with all that is changing, including:

- the requirement to apply to an FOA that specifically allows for the submission of clinical trial applications for due dates beginning January 25, 2018.
- Good Clinical Practice training expectations for NIH staff, grantees, and contractors that went into effect January 2017.
- updated peer review criteria that will be included in FOAs for clinical trial applications and solicitations for due dates on/after January 25, 2018.

- new Human Subject Information form requirements for clinical trials that will be included in updated application forms (FORMS-E) for due dates on/after January 25, 2018, and contract solicitations published as of January 25, 2018.
- use of a single IRB for non-exempt, multi-site clinical trials for application due dates on/after January 25, 2018.
- expanded [ClinicalTrials.gov](https://clinicaltrials.gov) registration and reporting to include all NIH supported clinical trials.

Improving the design, efficiency, and transparency of clinical trials is important because it:

- respects our ethical obligation to participants to maximize the use of the knowledge from the trials in which they participate
- facilitates design of clinical trials while reducing unnecessary duplication
- promotes broad, timely, and responsible dissemination of research information and results
- fosters responsible stewardship of the public's investment in biomedical research

NIH developed a new [Clinical Trial Requirements for NIH Grantees and Contractors web page](#) to bring together all the information you need to know. Please review this information carefully. Your attention to detail will be critical to ensuring successful funding of your clinical trial awards.

The NIH will be putting out a series of reminder policy notices, training opportunities, and other resources in the [NIH Guide to Grants and Contracts](#), in the [NIH Extramural Nexus](#), and on Dr. Michael Lauer's [blog](#).