

Creating an IRB Proposal

What is IRB?

Many institutions such as hospitals and universities have Institutional Review Boards (IRB). All research proposals must IRB approval before the research can begin. These institutions must be in compliance with federal regulations from the US Department of Health and Human Services. (<http://www.uco.edu/academic-affairs/research-compliance/files/documents/sops%205-2012.pdf>)

These are some frequently asked questions by those who are new to the IRB process. They are certainly not all inclusive, but are listed here to provide you an idea of some of the areas that you need to consider before engaging in a research project.

Why do I have to have an IRB?

Creating an IRB and receiving institutional approval prior to your research beginning protects those participating in your research by ensuring that the researcher is compliant with the guidelines.

How do I know if I need an IRB?

You will need an IRB if you are doing a research study that involves people or animals from whom you are gathering information with the intent to publish or present the findings of your study.

What should I do?

When you are working with an institution, inquire about their IRB policy and process. These institutions will have forms for you to complete prior to beginning your research.

What if I want to do research with a group and there is no IRB process?

It is important that you have your research proposal reviewed by a professional in the field of your research to ensure that you are following standard guidelines for research – recruiting subjects, obtaining their permission, and having a written informed consent signed by participants. You may consider partnering with an institution that has IRB requirements.

How do I complete the application?

Each form is different, but basically you are asked information about your study, your study participants, how you will collect the information, where you will store the information and for how long, how you will disseminate the information, whether you have written informed consent, and how the data will be destroyed once the study is complete.

General Information for completing and IRB proposal

A. Describe the purpose/hypothesis of the project or the research problem.

- Use enough detail that the reader can ascertain what the project is about.
- Describe why it is being done and the importance of the knowledge expected to result.
- Explain how the project/study fits with and extends current knowledge.

B. Describe the subjects needed for this project.

Who will be in your study, age group, males/females, etc.

C. Describe the procedures (steps) used to recruit subjects, and some examples include:

Community advertisement, Email blast, Direct target, online posting, In-class announcement, Others; you will need to meet the institutional requirements if you are using technology to recruit - for instance if you are recruiting on a college campus, you will need approval from the IT Department.

D. Where will recruitment of subject occur?

Will you be going to certain sites to recruit your subjects – the mall, specific events, gatherings, businesses or other organizations?

E. Are there intentions to use an oral or written script of any materials (flyer, letter, email, advertisement, announcements) as part of the recruitment of research subjects?

If yes, you will need to attach a copy of these scripts/documents.

F. List the maximum number of subjects you expect to participate

How many do you hope to have participate in the study? Are you doing a small pilot study, a focus group, surveys, etc. You will need to provide an explanation for that number.

- Power number for statistical significance, or an explanation as to why you will not reach that number.

G. Will you be specifically including or targeting any of the following groups for research subjects?

Minors, cognitively impaired, pregnant women, prisoners, Native Americans, seniors (65 or older)
If yes, explain the additional safeguards used to protect the welfare of these vulnerable groups.

H. Describe your methods to be used in the study.

Include the study design, measurements or observations of the subjects, and what the subjects will experience. Provide estimated time to complete any surveys/questionnaires, etc. (30 minutes, one hour, etc)

I. Where will data actually be collected?**J. Will tissue or blood samples be collected for data? Yes or No****K. Projected start date:** Upon IRB approval – estimate a date**L. Project end date:** write your anticipated date for the completion of the project

M. Will medical clearance be necessary for subjects to participate because of tissue or blood sampling, or administration of food or drugs, or physical exercise conditioning?

N. Does the research include any:

Physical stress including physical exertion, physiological stress, exposure to radiation, legal risk, economic risk, exposure to infectious disease, personal information about subject or family, degrading materials, confidential records, etc.

O. Describe the amount of risk or harm anticipated.

Describe why the risk is necessary. Explain how the risk will be minimized.

P. Will the subjects be deceived or misled in any way?

It is important to be honest with participants and not mislead them. Provide as much information as possible, keeping in mind you do not want to influence the outcome of our study by leading participants to certain answers or responses.

Q. Will any inducements be offered to the subjects for their participation?

Are you providing gift items to those participating?

R. How will consent be obtained?

Will you be gathering participants together, will you provide them a written informed consent, or if it is a survey, are you assuming they are giving consent when they complete and return the survey?

S. Will any aspect of the data be made part of a record that can be identified with the subject?

Generally, participants are assigned numbers so their responses are not connected back to their names.

T. Who will have access to the data? Only the research team should have access to the data.

U. Who is responsible for secure storage? The research team

V. Describe the benefits to your study.

How will your study contribute to the body of knowledge on your subject?

Invite someone to read your IRB before it is submitted to ensure that you have provided the information and documentation requested. You will need to attach a sample of the Informed Consent that you will provide participants as well as any instructions for participants, and a survey if you plan to use a survey.