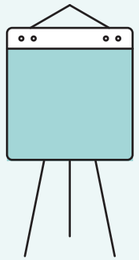
SUBMITTING AN IRB PROTOCOL APPLICATION



Complete your training.

The research team must have context of the history of human subjects research, responsibilities of a researcher and duties of the IRB. The IRB will not review your proposed study prior to researcher training.

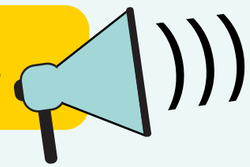
What is your research question?

1. Tell the IRB what specific trait, function or behavior you want to study. Tell us how previous research studies and their results support your study.
2. Give the IRB an example of potential discoveries you hope to make. For example, ple, outline a disease state or behavior that might benefit from the study results. This is required to assess the risk/benefit ratio.

Who will be in your study?

1. Your study should only include those who are able to participate and those who represent the population where your study is relevant. List the criteria that make someone eligible for your study as inclusion criteria.
2. In contrast, there might be individuals who should not participate in your study because it could be too risky or interfere with a condition. List these as exclusion criteria.

How will people find out about your study?



1. It's common for studies to be advertised on fliers, ads or social media. The IRB must know how people find out about the study.
2. It's also important to consider the privacy concerns associated with recruitment. If the study topic may bring up sensitive or potentially embarrassing topics, outline the way that potential participants will contact the research team.

How long will you need to keep study records?

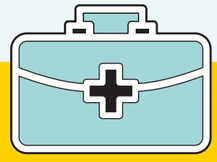
1. When the original research question is answered, you will need to close the study with the IRB. You will need to keep the study records for a minimum of **three** years following the final closure.
2. If your study is sponsored, you should keep the study records for a minimum of **three** years after the closure of the sponsored financial account.
3. If your study involved Protected Health Information (PHI) you will need to keep study records for a minimum of **six** years following the closure of your study or grant.

How will you affirm and document that someone wants to be in your study?

1. Research is voluntary, so consider the investment of time that a participant commits and be certain that they are made aware of any risks, costs, benefits, and procedures. Everyone should know how to contact the principal investigator and the IRB. Informed consent is more than a form; it's a process and a responsibility!
2. If your study involves a vulnerable population (recall the definition from your training!), you will need to have some additional protections in place.

How will you keep the data and records private, anonymous and/or confidential?

1. When you are collecting data, consider the questions and the environment in which you are working. This is a consideration of privacy.
2. If there is a risk of discomfort (either physical or emotional) to the participant, explain the way you will minimize these discomforts. Outline how you will monitor participant safety. Review the IRB requirements to report any recordkeeping concerns (e.g. loss of study records) or unanticipated events.
3. Tell the IRB how you will store hard copy and electronic data. Limit record sharing to only project personnel. Use university-approved, password-protected systems. Store files in locked cabinets in limited access areas. These measures contribute to the confidentiality of a study.



What will you do if something unexpected happens?

1. You need to amend your protocol with the IRB if any of the research procedures change or if there are changes to project personnel.
2. Consider how you would handle and report any unexpected events that may occur. Outline this in the application. If there is a risk of discomfort (either physical or emotional) to the participant, explain the way that you will minimize discomforts. Know how and when to report problems with the research to the IRB.

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