How to Fill Out an IRB Form

The Institutional Review Board (IRB) form should be filled out by anyone in the university community doing research on human beings or animals. The form is necessary. Even if you think your research is not dangerous, you still MUST have it approved by the IRB before you can begin collecting research data.

Some instructions are on the IRB form itself. However, this form can be complicated; below is a breakdown of the sections that are most problematic for researcher. This document should clarify what is required. If you have additional questions, contact your advisor (usually your teacher) FIRST. Then contact the head of the IRB.

Application Data Section

In this section you will explain what type of research will be done.

Indicate the type of review
Exempt review is the most common choice for undergraduate researcher. The research under an exempt review involves a very minimal risk to the research subjects. These might include things such as loss of time, a paper cut from a physical paper survey, potentially asking questions that may cause slight emotional disturbances in the subject, and risks that do not require medical intervention.
Expedited review is mainly used when personal health data or personal records are being accessed in relation to the research. Graduate researchers mainly use this.

Full review is used more for drug trials and things that could pose a life threating danger to the research subject.

Applicant Data

In this section you will list your name and the name(s) of research group members, if applicable. You will also disclose your advisor's name and contact information and information pertaining to the research you will be conducting.

Advisor
Every researcher or group of researchers filling out an IRB form MUST have an advisor. This advisor is typically the professor who is overseeing the class that your research is needed for. If for some reason you are not doing the research in a class setting the advisor will be the faculty member who is overseeing the research. Yes an advisor is needed. Always.

Has this research been reviewed by another IRB?
This will be answered, “yes�? if research will be taking place at another school, hospital, or health care facility. Trine’s IRB will not approve your request unless approval has been achieved through the other institution’s IRB first. Make sure to follow all procedures for both IRB forms, as they will be different but equally important.

Research Summary

In this section you will be telling why you want to do this research, how it can benefit or back up research that is already done, the methods and questions you will be using, participant expectations, and time commitment for participants.

Background
The Background subsection is part of the Research Summary section of the IRB form. It is often confusing for researchers. Below are some guidelines for completing it.
In this section you need to use citations to show that you have researched previous studies on your topic. You need to show that your research is building on the work of others, not repeating it. To make this easy, start out by defining the goal of your research or the research question you are asking. Then summarize the research that you have found that pertains to this question. End with why the research you will be doing is useful. First, what does it contribute to knowledge in the field, and second why is that contribution beneficial? Here is an example of an approved background section from an IRB form. Obviously, you should cite sources at the end using the appropriate documentation style for your field.

State the problem or question you are researching.
The physical therapy profession is composed of two distinct health care professionals who practice at differing levels of education and scope of practice: PTAs who must earn an Associate degree, and PTs who must earn a clinical doctoral degree (DPTs). The gap between educational levels and professional development may be a factor in PTAs choosing to return to school in pursuit of an entry-level doctoral degree in physical therapy, however, it is quite plausible that many other factors play into a PTA’s decision to seek further professional development and education.

Incorporate research
Cottrell1 examined motivating factors in certified occupational therapist assistants (COTAs) who chose to pursue additional education to transition to registered occupational therapists (OTRs). The author identified several motivating factors in COTAs currently enrolled in an occupational therapy (OT) program, such as expanding employment options, increasing professional autonomy, and increasing salary, among several others. Kneisley and Heater2 also examined motivating factors in COTAs seeking OT degrees and found the two major factors leading COTAs to pursue additional professional education were desire for professional advancement and cognitive interest.

The nursing profession has several levels of certification, degree, and professional scope within the profession. Megginson3 examined factors leading Associate degreed registered nurses (ADNs) to return to school to seek Bachelor's degrees in nursing (BSN) and determined main motivating factors of 1) being at the right time in life, 2) increasing options, 3) achieving a personal goal, and 4) BSN providing a credible professional identity. A meta analysis performed by Altmann4 examining ADNs transitioning to BSNs identified and reviewed 28 studies related to ADNs attitudes towards seeking further professional development. The author sought to provide information that could potentially aid in identifying gaps in knowledge of reasons behind ADNs choosing to (or choosing not to) return to school. The author stated understanding nurses' attitudes could aid in fostering positive attitudes towards advanced education and enticement of more ADNs to transition to BSN or higher-especially in light of the ongoing nursing shortage.

What new information will you find? How is it beneficial?

Similar to the above allied health professions, the field of PT may benefit from understanding the attitudes and motivation of PTAs choosing to advance their professional development by returning to school to attain a DPT degree. However, unlike the above professions, a recent literature search revealed no peer-reviewed studies examining this phenomenon in the profession of physical therapy. It would benefit the profession of physical therapy to identify and understand motivating factors leading PTAs to choose to return to school to seek a DPT.

1. Cottrell-Fleming, RP. COTA to OTR: Factors influencing professional development. Am J Occup Ther. 2000 54:413-420.
2. Kneisley, BA, Heater, SL. Factors which motivate the certified occupational therapist assistant (COTA) to become a registered occupational therapist (OTA). Occup Ther Health Care. 1998; 11(3): 39-51.
3. Megginson, LA. RN-BSN education: 21st century barriers and incentives. J Nurs Manage. 2008; 16:47-55.
4. Altmann, TK. Registered nurses returning to school for a bachelor's degree in nursing: Issues emerging from a meta-analysis of the research. Contemp Nurs. 2011; 39(2): 256-272.

Expectations of Participants

The Expectations of Participants subsection is also located in the Research Summary section. This subsection will be a very detailed step-by-step description of what you will be asking people to do.
For example:

> *Spring Semester 2016*
> *A focus group consisting of three-five current Trine University DPT researcher (who are also PTAs) will be conducted in early February, 2016 to refine current survey questions, (attached), to determine any additional questions to be included on the survey, and to determine which questions may not be of benefit to the study on the survey. Once the survey is revised as needed. The survey will be distributed to subjects electronically via public University email addresses. Follow up reminder emails may be sent to encourage participation in the survey to increase response rates.*

Access to Existing Data

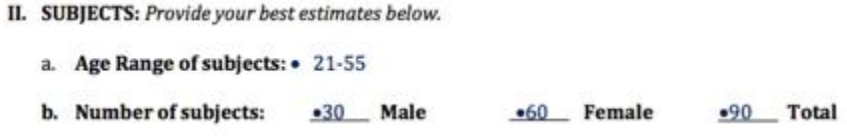
This subsection asks if your project requires personal data on the research subjects, such as health records or any other potentially confidential information. If you are using data that you did not collect yourself, a description of it goes here, including why you need it and how you have obtained access to the information. But do not put the personal data in the IRB form.

Subjects

In this section you will disclose an estimated the number of research participants. Here you will tell the participants age, target population, and if you will need to exclude anyone for any reason.

Number of subjects

When figuring out the number of research subjects that will be participating in the study it is best to aim high. You CANNOT go over this number of subjects in your research, or you will have to file an addendum. You will also describe who will be participating in your research. For example:



II. SUBJECTS: *Provide your best estimates below.*

a. **Age Range of subjects:** • 21-55

b. **Number of subjects:** •30 **Male** •60 **Female** •90 **Total**

1st, 2nd, and 3rd year DPT researcher at the University of Findlay and Trine University who are currently enrolled in the University of Findlay Weekend PTA to DPT program (Findlay, OH) and the Trine DPT

Program. The Findlay program was chosen due to the fact it is the only weekend format PTA to DPT program in the country at the current time.

Recruitment: Location of Subjects

This is where you will tell the recruitment location of research subjects and how you will be contacting them. You also need to tell what recruit method or incentives you will use. Incentives are anything you are giving to research subjects in return for participating in your research.

Risks and Benefits of Participation

Every research project will have some risk, and every research project needs to have some benefit that is more than just adding to the personal understanding of the researcher. Risks can be as simple as a paper cut or loss of time or as severe as a heart attack or unintentional death. Explained below is the most common area that researchers have a difficult time with.

Deception
Deception is intentionally withholding any information from the research subjects for any reason. Sometimes deception is okay, but only if it is done to avoid causing a change in behavior in the research subjects, or if it will prevent a bias. If information is being withheld because it could cause a bias or changes the behavior of the participants, this needs to be documented and explained. For example: If students know that a researcher has come to a class to observe them their behavior may change. In a case like this it may be ok to use deception.

Note: Any subjects participating in the research must be told, before participation, what the project ultimately is trying to do. If deception is to be used, then only the information that will cause the bias is to be left out.

Confidentiality of Data

For this section you will tell how you are protecting the privacy of your research subjects, how your data will be stored, how you will destroy it when you are done, and who will have access to your data. In this section researchers seem to have a difficult time understanding the difference between anonymous and confidential. Below is an explanation of anonymous and confidential and how to decide which fits your project the best.

Anonymous and Confidential

Anonymous means there is no name or no way to tell participants based on their answers or data within the research.

Confidential means that the researcher will not reveal names of the subjects.

The anonymity/confidentiality of the subjects can be maintained by turning the data collected from participants into numerical values, using pseudonyms, ect. You will most likely choose one of the two when doing the research.

Informed Consent

In this section you will describe how you will gain consent from your research subjects and how will you know if they fully understand what they are agreeing to.

Consent Documents

You will need to gain consent from the research participants. This can be verbal or written consent. If gaining verbal consent, it would be best to write up a prompt of what you will be saying to the participants. If gaining written consent, attach the consent form that you have composed to give to the participants. For more detailed explanation, refer to the informed consent checklist on Trine's IRB page.