IRB FREQUENTLY ASKED QUESTIONS?

Below is a list of questions frequently asked by students and principal investigators submitting applications to the IRB.

Contents

Who must submit a project for IRB review?

The Widener University IRB reviews research studies that are:

- conducted by University faculty, staff, and students
- performed on the premises of the University
- performed with or involves the use of facilities or equipment belonging to the University
- involves University students, staff, or faculty as participants
- new faulty transferring IRB approved research from another institution [BACK]

How do I know if my project is considered research?

Research is a systematic investigation designed to develop or contribute to generalizeable knowledge. This definition also includes pilot research.

A systematic investigation has the following characteristics: (1) represents an attempt to answer a research question, (2) methodologically driven by collecting data or information in a way that is organized and consistent; (3) the data or information collected is analyzed in some way (quantitative or qualitative); and (4) conclusions are drawn from the results.

Generalizable knowledge is defined as one or more of the following: (1) the knowledge contributes to a theoretical framework of an established body of knowledge; (2) the results are expected to be generalized to a larger population beyond the site of data collection or sample studied; (3) the results are intended to be replicated in other settings; and (4) the information gathered will be shared via publication, presentation or other distribution of the results, which can be an indicator of generalizing knowledge. However, it is possible to collect data from human subjects that are not considered research, such as classroom learning exercises.

Classroom research projects **DO NOT** require IRB review. A classroom project is not considered research when:

(1) the exercise is solely to fulfill course requirements or to train students in the use of particular research methods or devices, **AND**
(2) the results will never be distributed outside the classroom and/or institutional setting, **AND**
(3) the project involves minimal risk to subjects, **AND**
(4) the project does not involve vulnerable populations.

In classroom projects, while IRB review is not required, the ethical principles of the Belmont Report still apply. The classroom instructor is responsible for informing students about these principles including the elements of informed consent.

Students can choose to submit classroom research projects for IRB review if the intent is to present the results outside of the University or there is interest in publishing the results. This submission should be done prior to data collection. If a student does not obtain approval prior to data collection they cannot present at a conference or publish the results even if the research was originally just performed as a classroom assignment. [BACK]

I believe my project is exempt, is submission for IRB review still required?

Yes. Only the IRB can make the determination that your project is exempt, or fits within another category of review. [BACK]

Do projects involving the secondary use of data require IRB review?

Projects that involve the analysis of secondary data, that is, data collected for previous research or data collected for non-research purposes, that is not immediately available to the public, must undergo IRB review and approval. [BACK]

What "reading level" should my consent form be?

Since the average reading level for the general population in the United States is about 8th grade, consent forms should be at the 8th grade reading level. However, if the population of participants in your study can reasonably be expected to have a higher reading level (e.g., Participants are all professionals such as doctors, nurses, teachers, etc.), then the reading level for the consent form may be higher. Nonetheless, be careful not to overestimate the reading level of the participants. That is, not all high school graduates can read at a 12th grade level. In addition, if your participants are expected to have reading levels lower than 8th grade (e.g., 9-11 year-old children in 6th grade), then the reading level for the consent form should be correspondingly lower. [BACK]

How do I tell what reading level my consent form is now, as I have it written?

To calculate the readability of your consent form in Microsoft Word:

1. Go to the “tools” menu;
2. Select “Spelling and Grammar”;
3. Choose the “Options” button, and check “Show Readability Statistics”;
4. After finishing the Spelling Check, the final message will provide the Flesch-Kincaid grade level. [BACK]

Also see: http://office.microsoft.com/en-us/word-help/test-your-document-s-readability-HP010148506.aspx

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How can I change the text in the consent form to get it to the needed level?

The best ways to lower the reading level of any text are as follows:

- Use simpler sentence structure (avoid compound sentences, or multiple clauses);
- Use shorter sentences;
- Use simpler, less complex vocabulary;
- Consult the Thesaurus for alternative simpler words.

One hint: You can highlight a segment of your writing, and perform the "spelling and grammar check" on that portion, in order to ascertain what segments of your text may remain problematic for readers at a certain reading level. This can be extremely helpful in identifying what portions of text may need revision. [BACK]

Also see: http://prism.grouphealthresearch.org/start.htm

How long should an investigator allow for approval from the IRB?

Generally, once the signed paper copy of the application comes in for review, the time to distribute, review, and respond to the investigator is approximately three weeks for exempt and expedited reviews. This assumes all signatures and supporting documents are with the application. The timeframe for full reviews is similar from the date of the IRB meeting the application is reviewed.

Although the Widener University IRB strives for an efficient response time, it would be prudent to allow 6-8 weeks for final approval of applications requiring revisions. This would permit the investigator time to respond to reviewers' comments and/or acquire any necessary supporting documents to satisfy the requirements. Allowing adequate time for processing will ultimately minimize your stress level. [BACK]

How can I help shorten the time my application is in review?

- Do not submit an incomplete application.
- If you feel a section is not relevant to your application, do not skip; address the section by providing rationale why it is not relevant to your particular study.
- Make sure you have the application signed by all involved parties (all investigators, faculty advisor).
- Do not submit an application prior to dissertation proposal defense.
- Complete the application fully and respond to all questions.
- Use the consent form template for construction of your consent or informational letter. It contains all the necessary elements of informed consent.
- Complete both the general application checklist and the consent form checklist. [BACK]

Do all studies need a consent form?

No, all studies do not need a consent form. These are alternative methods for consent that can be used in certain circumstances.

- Studies that use anonymous, archival data do not require a consent form. This option is generally for retrospective research. Information must be provided about how the data were collected and prior agreements by the participants to release the data for the purposes of research.
- Some studies that are anonymous, such as written surveys or on-line surveys, may not require consent and voluntary completion of the survey implies consent. However, an information letter is necessary for all anonymous surveys so that participants may make an informed decision as to whether they want to complete the survey. The process of informed consent is completed, but the subject does not need to physically sign the statement to indicate consent. The researcher must document that consent was obtained from the subject, including the date consent is provided.

One of the exceptions to this generalization is a survey that involves minor children. In this case, parental or guardian permission may be needed. [BACK]

Who should I contact if I have questions?

Although Dr. Barbara Patterson and Dr. Robert Wellmon are the chairperson and Secretary & Vice-chairperson of the IRB committee, respectively, any member of the IRB committee is available to assist you. Contact information can be accessed on the IRB web site. [BACK]

If a study is being done in conjunction with another facility that has an IRB committee, which committee do you submit to first?

The order of IRB submission is not a critical issue but final approval by the Widener University IRB may be contingent upon a letter of confirmation from the other institution.

With changes to the Common Rule, it is possible to have only one IRB review your project, when the research is being conducted at multiple sites. An IRB of Record or IRB Authorization Agreement (IAA) is a special agreement between two institutions who are engaged in human subjects research. These agreements help to economize on the IRB review and approval process by limiting the IRB review to one institution. IAAs are sometimes referred to an IRB of Record, but mean the same thing. When signing the IAA, one institution is designated the lead IRB or IRB of Record. Click here for more information about single IRB review. [BACK]

What verb tense is appropriate for the IRB application?

All research proposals should be written in the future tense. For example, “This study proposes to examine the relationship between…” “Data will be collected…”

The study cannot be conducted until it receives IRB approval. [BACK]

Should I submit my IRB application before my dissertation proposal defense?

NO! Your dissertation committee must approve your application prior to IRB review. The correct time to submit your application is following a successful defense of your proposal. [BACK]

What is a certificate of confidentiality?

Confidentiality Certificates are issued by the Department of Health and Human Services to provide special privacy protection to research subjects. This Certificate helps researchers protect the privacy of subjects against forced legal demands such as court orders and subpoenas that seek the names or other identifying characteristics of a research subject. It does not, however, prevent the need for possible disclosure in circumstances necessary to protect the subject or others from serious harm, as in cases of child abuse. Also, a researcher may not rely on a Certificate to withhold data if the subject consents to the disclosure. [BACK]

How do I determine if I need a conflict of interest statement in my proposal?

A conflict of interest statement is required for every proposal submitted to the IRB. The investigator must make a statement that indicates whether or not the research protocol is subject to bias by any conflicting financial interests or other personal situations of the investigator involved in the study. The conflict of interest statement provides the investigator with the opportunity to describe how potential conflicts of interest are managed or prevented. Conflicts of interest can occur when the investigator has dual roles within the research environment such as educator/investigator or clinician/investigator. [BACK]

How does one differentiate confidentiality and anonymity?

Anonymity refers to study participants who cannot be identified by any means. No identifying demographic data exists when collecting the data from the survey or questionnaire. De-identified archival data and mailed or online surveys are potential examples.

On the contrary, confidentiality suggests that the data collected will be maintained and reported without divulging any identifying information; although, the investigator may have access to the study participant's names, gender, and other identifying information. [BACK]

Consent form versus informational letters: What is the difference?

A consent form is a document signed by the participant that contains specific information so that he or she may make an informed decision as to whether to participate in the study or not. The following must be included:

- Purpose of the Research
- What is expected of the participant
- Risks and/or Discomforts
- Potential Benefits
- Alternative Procedure or Treatment
- Confidentiality Provisions
- Liability statement
- IRB Contact for Information
- Voluntary Participation and Right to Discontinue without Penalty
- Signature of Participant and Investigator

An informational letter should contain all of the content from the aforementioned list so that he or she may make an informed decision as to whether to participate in the study or not; however, a signature of the participant is not required. Informational letters are often used with anonymous surveys.

See the IRB website for a template to construct a consent form. [BACK]

Do I need IRB approval to use archival data? If yes, why?

The answer is YES. When using archival data, an investigator typically submits a request for an 'exempt' status review. IF the original data was NOT collected for a particular research study purpose, an approval to use archival data needs to be provided from the individual who maintains the database. Include a description of how the data is stored and will be accessed in the application. [BACK]

What is the IRB policy on the translation of consent forms into languages other than English?

Translation of research materials, such as consent forms, informational handouts, questionnaires, etc., requires careful conversion to ensure accuracy. The accuracy of the translation must consider cultural meaning, colloquial interpretation within the other language or particular culture speaking that language, in addition to the simple accuracy in translation of specific words. For this reason, it is usually insufficient to have any available person who speaks or writes the language to recreate the material, especially if they are not sensitive to the differences in native speakers' interpretation of vocabulary and phrasing. There are several means to execute an accurate translation.

1. For many languages, such as Spanish, there exist certifications as a translator. You may wish to utilize the services of someone certified in the relevant language. For some other languages, there is no certification. For

translations into these languages, professional translation services will sometimes provide their own certification that the translation is accurate for the relevant purpose.

2. Whether you use a professional translator or not, it is usually necessary to first translate from English to the language of interest, then have a translator take the material in the other language and re-translate it back to English. This provides a second check that the vocabulary and phrasing indeed provide the information accurately. The process is optimal if one person initially translates from English to the other language, then a second person, who was not exposed to the first English text, re-translates from the other language to English. You can then check the second generation English text to see if it has maintained the correct meaning.

Most importantly, describe in your IRB application how you have conducted the translation, as well as how you have checked to ensure that the translation was accurate. The IRB will not require evidence of certification for the translation, but will review the translation process. [BACK]

Do I need IRB approval for a Pilot Study?

The best way to know whether a "Pilot Study" requires IRB review is to ask the question, "Will any human participants be asked to undergo any data collection activity, or to provide any data that may be used in the studies analyses?" If the answer to this question is "Yes," then one needs to submit the "Pilot Study" for IRB review. The examples provided below outlining common "pilot" research activities may help clarify the need for IRB review.

1. Research investigators often refer to a study as a "Pilot Study" if it is a preliminary investigation. That is, the study is a first investigation of a phenomenon or hypothesis with a smaller sample, an abbreviated procedure, or with a human population other than the population for whom the hypothesis is of primary relevance. The data collected will be reviewed, stored, and analyzed by the investigator(s). If this is the case, the activity is indeed research, albeit of less extensive scope than other studies, and ***WILL require IRB review and approval***.

2. If the activity involves collection of data from participants using a newly created measurement device (e.g., a self-report questionnaire, interview questions, observational measure, measurement procedure), and the collected data will be saved and evaluated for psychometric properties (e.g., inter-rater reliability, calculation of Cronbach's alphas for internal consistency, factor analysis, etc.), then this constitutes research regarding the newly devised measurement, and ***WILL require IRB review and approval***.

3. If you are planning to collect data or solicit feedback about a research protocol from human participants (e.g., the measurement items, any important factors missed by the measurement, clarity of self-report or interview question items, feasibility of procedure, etc.) and plan to use all or any of the data provided by these participants in the study, the activity ***WILL need IRB review and approval***. Any changes resulting from participant feedback with an IRB approved research protocol requires a "Change of Protocol" form.

4. If you plan to solicit advice and/or feedback about procedures or measurement devices from experts who will not participate in the study or contribute data to the study, this ***WILL NOT require IRB review***. For example, if you ask teachers or school administrators to review and provide feedback about your questionnaire items or interview questions regarding a bullying experience measurement for school students, if you ask physicians for feedback about questions to ask patients with a particular diagnosis or treatment regimen, if you ask therapists to review and provide feedback about factors you plan to assess about a particular type of therapy, these do not require IRB review.

5. If you ask someone to complete a questionnaire or research procedure in order to solicit feedback or test parameters of the procedure (e.g., how long it takes for a person to complete a questionnaire, etc.), but do not

review, retain, or analyze the content of their answers or performance on the measure, this ***WILL NOT require IRB review***. For example, if you have constructed a questionnaire about shopping for gluten-free foods, and ask people with celiac disease to read and complete the questionnaire, but do not look at, review, or retain their answers but inquire about clarity of items and time required to complete the questionnaire, this will not require IRB approval.

If you believe that you might retain and include the responses as part of your study data, you will require IRB approval and any appropriate consent from these participants to utilize their data (as described in #3 above). [BACK]