How to Successfully Navigate the IRB Application Process

The current fillable pdf IRB application form can be found at http://www.webster.edu/irb/

Section I: General Information

SECTION I: GENERAL INFORMATION

Project Title:

Proposed Start Date: Proposed End Date:

*This date cannot be prior to written IRB approval is obtained.

Tip: Your “Start Date” cannot be prior to IRB approval, so it is recommended that you are conservative here. Make your start date at least 2-3 weeks from the date you submit your application, then add “or following IRB approval”.

For example, you might type “9/30/2017, or following IRB approval”.

Type of Project (check all that apply):

- Faculty Research
- Student Research
- Staff Research
- Thesis/Dissertation
- Course Requirement
- Other (please specify):

Tip: Click every box that applies to your research project. For example, a student might need to click on 3 boxes: “Student Research” and “Thesis/Dissertation” and “Course Requirement”.

Principal Investigator(s): Create entry for each investigator and Faculty Sponsor, if applicable

Name: Phone Number:
Email: Role: Faculty
Campus: Staff
Department: Student

Click to Add Another Investigator

Tip: Fill in each box with your information. Click the button “Click to Add Another Investigator” if you are a student with a Faculty Sponsor or if you have other research collaborators on this project. You do not need to add “Investigators” for community partners, etc. who will simply help facilitate your data collection.

Important Point! Fill in each box, as requested, in this section for each Investigator and the Faculty Sponsor, to facilitate contact with the IRB.
Tip: Click “Yes” or “No” for each of the above 4 questions.

**Question 1:** This question is important because human subjects research supported by a U.S. federal department or agency may be governed by additional regulations as implemented by the respective department or agency.

**Question 2:** This question pertains to your research project if you are conducting research at a site outside of Webster University, such as research involving students at a High School or employees of a local business. If this is the case include the signed off-site letter of support.

**Question 3:** This question pertains to your research project if you are conducting research, for example, at a different University, that also has a registered IRB. If this is the case contact the IRB at irb@webster.edu before proceeding to avoid duplicating efforts.

**Question 4:** This question pertains to any research conducted outside the United States. If this is the case fill out and submit the **Statement of International Research Conduct** with your application.
Section II: Review Determination

The purpose of Section II is to help the IRB Committee determine the level of risk involved in your research project. For example, if your research is a completely anonymous online survey that does not involve a vulnerable population (like children) and the questions are not of a sensitive or risky nature, then your research would be classified as very low risk and would tend to be approved more quickly.

Tip: Carefully answer each of the statements in this section. For any box that you check, additional questions will open that need to be addressed to help explain why the you feel the benefits of your research study outweigh the increase in risk.

- 1. This research will include participants who are under the age of 18.
- 2. This research includes participants who are prisoners, pregnant women, adults who are not legally competent, or other vulnerable populations (e.g., refugees, individuals who are terminally ill, etc.)
- 3. Individuals participating in this research can be identified directly or indirectly (by using codes, pseudonyms, etc.) through the data recorded.
- 4. This research will involve recording participants using audio, video or photographs.
- 5. Disclosure of the participants' responses could potentially place them at risk of criminal or civil liability.
- 6. Disclosure of the participants' responses could be potentially damaging to their financial standing, employability or reputation.
- 7. This research involves the collection of:
- 8. This research involves the collection of previously collected data, documents, records, or biological specimens that can be linked directly or indirectly to the original individuals (e.g., medical chart records, test scores, educational records, etc.)
- 9. This study poses a potential risk to participants greater than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.
- 10. Information from this project will be submitted to the Food and Drug Administration (FDA).
- 11. None of the above apply to my research project.

Tip: Statement 3: It is important to know that this box must be checked for ALL research involving face-to-face interviews, observations, video and voice recording. It must also be checked anytime data is identified with a code that could be used to indirectly identify the research subject. It must also be checked whenever you are using a signed consent form or collecting any data that could be used to directly or indirectly identify the research subject.

Important Point! Use “confidential” (not “anonymous”) throughout your application, if #3 is marked.

Tip: You would NOT check the box for statement 3 if you are doing a truly anonymous research project, such as an anonymous online survey using Qualtrics.

See page 10 for the requirements that must be satisfied to conduct an anonymous online survey.
Section III: Project Description

**Purpose:**
Provide a summary of the proposed research describing the specific objectives, including background information and rationale of the proposed research. Remember, this summary should be in language understandable to IRB committee members with varied backgrounds. Many of them will not understand terms that are commonly used in your specialization. Also use this space to justify why the expected or anticipated benefits of this research merits the potential risks to human subjects.

**Tip:** Provide an overview of your project in order to help the IRB understand your project and to determine that the potential benefits outweigh the risks to human subjects.

Keep your description straightforward and avoid using specialized jargon, abbreviations, etc without carefully defining such terms first.

Address each of the following sub-topics:

1. **Goal:** Why are you doing this study? Is it based on anything? What is your hypothesis or goal?
2. **Literature Review:** Provide citations to previous research to convey that what you are proposing has a scientific basis and that it is sensible within this field. (Do NOT include an entire thesis bibliography.)
3. **Expected Benefits:** Describe the potential benefits of your proposed research study.

**Methodology**

1. Describe any procedures used in this study. Describe all interactions with human subjects and all activities in which the human subjects will be asked to participate.

**Tip:**
Describe the methods and procedures to be used in your research project to accomplish the objectives stated in the purpose section of the application.

Provide a description of your study design. What will you do?

Describe all interactions with human subjects such as manipulations, intervention, observations, or any other type of interactions such as communication or interpersonal contact between investigator and subject.
2. How will you be obtaining informed consent from your participants? (Check all that apply)
   Please attach a copy of the script or form that you will be using. (Click here for a generic informed consent script or form.)
   
   - Verbal consent
   - Implied consent (through voluntary participation in the research)
   - Verbal assent (for children under the age of 18)
   - Parental permission
   - Signed consent form

   Tip: For human subjects over age 18, select Verbal consent, Implied Consent, or Signed Consent Form. For children under the age of 18, select BOTH Parental permission AND Assent.

   Tip: For help in creating your Informed Consent document or script, and to ensure that your document contains all the required elements, visit the IRB website:
   http://www.webster.edu/irb/policy/informed_consent.html

3. How will you gather the data from participants? Describe any measures such as surveys, questionnaires, interviews, videotapes, audiotapes, field notes, etc. Provide a brief description of your measures in this section and include these documents in the appendix.

   Tip: Describe any measures that you are using to gather data from the study participants.

   Provide a brief description of your measures in this section and if you are not the author, provide evidence that you have permission to use the tool.

   Include the documents for each measure in the appendix.

   Important Point! The IRB strongly advises researchers to use Qualtrics, the university’s official web-based survey software for online data collection.

   Important Point! If one of your measures is an anonymous survey, in this section you should also indicate that you have addressed items (a) through (g) as listed on page 10.

   For example, you might type “In my Qualtrics survey I am not collecting IP addresses by using the “Anonymize Responses” option. I am not collecting any information that could be used to directly or indirectly identify an individual. Research subjects will have the ability to skip questions as well as the ability to ask to have their data removed at the end of the survey. I will use an implied consent form as the first page of the survey. For the gift card drawing, after the participant completes (or decides to quit) the survey, he or she will be re-directed to a second survey before being asked for any contact information. The data gathered in this second survey will not be connected to the first survey’s data in any way.”
4a. Please describe the plan for data storage. This includes electronic data, traditional paper-and-pencil measures, audio and video recordings.

**Tip:** Explain how the data will be stored in some form (paper and/or digital form) in secure locations on campus. Particular care should be taken to protect data on lap-top computers, external hard drives and other portable devices. Study information containing personal identifiers stored on these devices should be encrypted or password protected to prevent unintentional breaches of confidentiality in the event the storage device is lost or stolen. Similarly, paper records identifying research participants including consent forms should be kept in a secure location with access restricted to key study personnel.

For example, you might type “*Raw data will be stored online via a secure data collection website, Qualtrics.com. Once downloaded, the data will be managed and stored on a password-protected drive on a university computer located within the locked Behavioral and Social Sciences laboratory in the ISB building at Webster University or on a password-protected USB drive/laptop belonging to the Principle Investigator.”.

4b. What will be done with the data after the study is complete? This includes electronic data, traditional paper-and-pencil measures, audio and video recordings.

**Tip:** Indicate how long you intend to keep the data after the study is complete. Explain how you will remove all identifiers (if any) and securely store the data. Indicate when you will remove the data from an external server, if used, such as Qualtrics.com. If you intend to destroy any data, explain when and how you will do so.

**Important Point!** It is acceptable to indicate that data will be kept “indefinitely”, if that is the case.

4c. Please describe the plan for the analysis of the data. This includes electronic data, traditional paper-and-pencil measures, audio and video recordings.

**Tip:** Explain how the collected data will be analyzed or studied quantitatively and/or qualitatively. Identify the descriptive statistics and/or statistical tests of hypothesis you plan on using. Explain how the analysis will address the research questions.
4d. Please describe the plan for the dissemination of results.

Tip: State how you plan to share the results of your research project.

For example, you might type “Findings from the proposed study will be presented to the university community and reported in a document in order to meet course requirements for the Senior Thesis class. I may also seek out appropriate opportunities to present my findings at professional research conferences. I also plan to submit a paper about my research to one or more scientific journals.”

**Population**

1. Describe the general characteristics of the target sample to be studied in terms of makeup and size. What inclusion/exclusion criteria will be used? Please justify exclusions.

Tip: List the characteristics of your study population (e.g., age, occupation, gender, etc.). Why did you choose to study this population?

How many people will you include in your sample selected from this population? Why are you using this number for your sample size?

What characteristics would make someone ineligible for participation in your study?

Justify your inclusion/exclusion rules.

2. How will subjects be recruited to your study? Please attach any materials used for recruitment (advertisements, email/verbal scripts, graphics).

Tip: The IRB needs to understand the details of all recruitment activities that will be used in your study. Identify all recruitment methods that will be used. If your recruitment plan involves using any email, address and/or telephone lists, how will those lists be obtained?

How and when will potential participants be approached/ contacted about study participation? Who will conduct these activities and where will they occur?

Remember to include ALL recruitment materials in the appendix of your application document.

Important Point! To fully protect subjects, the IRB must approve a project before investigators start to work on it – even before they begin to recruit subjects, since recruitment strategies are part of the review.
3. Will participants be compensated for participating?  

**Tip:**  
If you have grant monies to pay a participant an “honorarium”, indicate that here.  
If a professor has stated that students who volunteer as research subjects can earn extra credit, indicate that here.  
If you are holding some sort of drawing for a prize, etc., indicate that compensation and protocol for selection here.  
Payment for participation in research may not be offered to the subject as a means of undue influence, where it causes someone to assume risks he or she would not otherwise assume. Rather, it should be in a form of recognition for the investment of the subject’s time, loss of wages, or other inconvenience incurred.  
Payment should be given on a reasonable prorated basis to avoid the impression of undue influence for the subject to continue in the study or punishing the subject for choosing to withdraw. You may not withhold all compensation from a participant who withdraws from the study!  

**Important Point!**  
The words 'raffle' and 'lottery' have specific legal meanings. Avoid using these terms and use “drawing” instead.

**Section IV: Appendix Materials**

Check all of the materials below that are part of this application. Please include them as attachments when submitting by email.

- [ ] IRB training documentation for you (and your Faculty Sponsor, if applicable) (required, if you have not done so in the past three years)
- [ ] Informed consent script/form (required)
- [ ] Assent script (required, if participants are under the age of 18)
- [ ] Parental permission form (required, if participants are under the age of 18)
- [ ] Scripts/Questionnaires for data collection (required, if you are utilizing these tools in your research)
- [ ] Subject recruitment materials (required, if you are utilizing these in your research)
- [ ] Off-site letter of support (required, if you are carrying out your research outside of Webster University)
- [ ] Off-site IRB approval (required, if the location at which you are doing research requires their own IRB approval)
- [ ] International Research Statement (required, if you are carrying out your research outside of the United States)

**Tip:**  
Check carefully that you have both checked the box and attached all needed forms in your submission packet.  
When a form is missed, it slows down the approval process.  
If you can create a single supplemental file for the Consent Form, Scripts/Questionnaires, Recruitment materials, and other items, that is much preferred over submitting several different attachments.
Finalizing your Student Application

Once you have a polished, final IRB application file, you will need your Faculty Sponsor to review your application for correctness. Ideally, you will send a single email to your Faculty Sponsor with two attachments (1) the completed IRB application and (2) a Supplemental Materials file.

Ideally, your Faculty Sponsor will carefully read your application and possibly suggest improvements for you to make before the packet is approved by the Faculty Sponsor.

After your Faculty Sponsor approves your application, the Faculty Sponsor will submit it on your behalf to irb@webster.edu.

How to Write an IRB Application that Gets Approved Faster!

- Write in a way that clearly communicates your project to the IRB committee. Your reviewer may well be from a different field of study than yours.

- Provide a convincing rationale for the scientific merits of the study, as well as a clear discussion of the safeguards you will put into place in order to conduct this project within established ethical guidelines.

- When feasible, opt for collecting as little personally identifiable information as possible and for reducing the risk to human subjects in every possible manner.

- When your research involves any slight increase in risk (as indicated in Section II – Review Determination), carefully explain why you feel the benefits of your research study outweigh the increase in risk.

- Keep in mind that research projects with increased risk will take more time because these applications will need to be reviewed by more than one person or even possibly the entire Review Board at a scheduled meeting.

- Double check that you have thoughtfully answered each question or prompt and that you have submitted all required documentation in the appendix. If you are missing any documents, the expeditor waits to assign a reviewer to your application until all documentation has arrived. This oversight can greatly delay the time it takes for approval of your application.

- When you get feedback from an IRB Reviewer, try to address the indicated issues quickly and get the revised application re-approved by your faculty sponsor and back to the reviewer. If you do not understand a directive from the reviewer, you can always ask for clarification.

- Please follow up with the IRB committee on the status of your application, if you have concerns. This helps to confirm that any communications and documents are received and that the process is proceeding in a timely manner.
Anonymous Online Qualtrics Survey Requirements

If you are conducting an online survey, and your survey is intended to be anonymous, you must ensure that:

a) Your survey tool is not collecting Internet Protocol (IP) information from respondents.
   - In Qualtrics, use Masked IP addresses so that the source of the data cannot be traced
     - Under the Edit Survey tab, click the Survey Options button. Check the box next to "Anonymize Response."
     - Under the Edit Survey tab, click the Survey Flow, then add End of Survey, then Customize buttons. Select: "Do NOT record any personal information and remove panel association."
     - Click the Save Changes button

b) No individually identifiable information (e.g., name, birth date, identification numbers, mailing address, email address, etc.) is being collected as part of the survey instrument.

c) No combination of indirect identifiers is being collected which would reasonably allow the investigator or anyone else to identify participants.

d) For each question in your survey include the ability to withhold the answer with a “no response” choice or the ability to move to the next item without providing an answer. Subjects may not be forced to answer a question in order to proceed. A research subject must be able to proceed without answering the question, otherwise it is a violation of the subject’s right to withdraw from the research study or to withhold information.

e) At the end of your survey, include an option to withdraw from the survey and a statement regarding the fate of that participant’s data.

f) Include an “implied informed consent” as the first page of your survey which includes all elements of a typical informed consent document.

g) If an incentive (e.g., gift card drawing) is used with an otherwise anonymous survey, all participant contact information must be gathered outside of the primary data collection instrument (for example: through a second separate survey linked to from the first).

Tip: Acknowledge that each of the above items have been addressed for your anonymous survey in the Methodology section, #3 (see page 5 of this document for suggested language).

Tip: Even if your survey is NOT anonymous, you must acknowledge that you have addressed items d, e, and f, above, in the Methodology section, #3.