Simmons University, Institutional Review Board
Initial Submission Template

Contents

1- Getting Started

Please note that this template is a replica of the Cayuse IRB Platform, where your proposed study will be submitted for IRB review. This document aims to act as an aid to better prepare your protocol submission prior to submitting it within the actual electronic system. Please do not submit this template as your protocol.

About Cayuse IRB

Cayuse IRB is an interactive web application. As you answer questions, new sections relevant to the type of research being conducted will appear on the left-hand side. Therefore, not all numbered sections may appear. You do not have to finish the application in one sitting. All information can be saved.

Additional information has been added throughout the form for guidance and clarity. That additional information can be found by clicking the question mark in the top-right corner of each section.

Prior to starting your IRB application, please be sure you have read the IRB Manual: Instructions to Investigators and completed CITI Training.

For more information about the IRB submission Process, IRB Tracking, and Cayuse IRB Tasks, please refer to the Cayuse IRB Procedures Manual.

* I have read the information above and am ready to begin my submission

○ Yes

Getting Started

Throughout the submission, you will be required to provide the following, as applicable:

- Detailed Study Information
- Informed Consent Forms
- Study Recruitment Document(s)

Simmons University IRB

- You cannot begin data collection until a formal approval letter from the chair of the IRB has been received.
- Please submit the application as soon as possible.

2- Investigator Information

* 2.1 What is your status at Simmons University?

- ○ Student
- ○ Faculty
- ○ Staff

* 2.2 Principal Investigator

FIND PEOPLE

2.3 Co-Investigator(s)

Your co-investigators will be required to certify this submission prior to review.

FIND PEOPLE

* 2.4 Primary Contact

Who should be contacted for questions or changes regarding this protocol? (Can be the same as Principal Investigator)

FIND PEOPLE

2.5 Faculty Advisor

If you are a student, please select your faculty advisor for this project. Your faculty advisor is required to guide you through the submission process and sign off on your protocol.

FIND PEOPLE

2.6 Other Personnel

Provide names of other personnel in this study who do not need access to this protocol (for example, student research assistants)

FIND PEOPLE

2.7 Personnel at other institutions

Personnel at collaborating institutions cannot have access to our Cayuse database. You may download a copy of your protocol as a PDF and share it with them that way. Please add their names and their roles below.

If you cannot find the appropriate Simmons contacts, please contact the IRB via irbprotocols@simmons.edu

You may also share this form so that they may request a Cayuse account.

3- Project Information

Please note that the questions that appear will depend on the type of project you are submitting.

* 3.1 Do you need assistance determining which type of application you should submit?

Projects include Human Subjects Research Project, Performance/Quality Improvement Project, or Classroom Project.

- ○ Yes
- ○ No

Answering "Yes" to this question will present you with definitions for the three types of projects you may submit.

* 3.2 Please select the type of project you are submitting.

- ○ Human Subjects Research Project
- ○ Classroom Project
- ○ Performance Improvement Project

* 3.3 Is this project being reviewed by another institution's review board? This question will appear only for Human Subjects Research Projects

- ○ Yes
- ○ No

* 3.4 Is this project being submitted to a funding agency/organization? This question will appear only for Human Subjects Research Projects

- ○ Yes
- ○ No

* 3.5 Start and End Dates of Project

Start Date

End Date

* 3.6 Brief description of project

approximately 10 sentences or less

* 3.7 Does your project involve any of the following populations? This question will appear only for Human Subjects Research Projects and Performance Improvement Projects

Projects that involve any of the below "vulnerable" populations and involve greater than minimal risk may receive a full review.

- [ ] Children under 8 years of age
- [ ] Children 8-17 (under 18 years of age)
- [ ] Prisoners
- [ ] Economically disadvantaged
- [ ] Educationally disadvantaged
- [ ] Individuals with impaired decision-making ablity
- [ ] None of the above

* 3.8 Does this project include secondary data analysis? This question will appear only for Human Subjects Research Projects

Secondary data analysis involves the re-use of data and specimens that were or will be collected for non research purposes or from research studies other than the proposed research study. The research materials generally will be publicly available materials, medical records or existing repositories of clinical specimens. Non contact between investigator and subject is allowed.

- ( ) Yes
- ( ) No

3.9 If you will be utilizing any outside agencies to conduct your research, please attach the appropriate permission letters or emails from the agencies indicating their willingness to cooperate with your research.

ATTACH This question will appear only for Human Subjects Research Projects

These questions will appear only for Human Subjects Research Projects

* 3.10 Will you be recording identifiable, private information about individual subjects?

Private information is considered to be identifiable when it can be linked to specific individuals either directly or indirectly through a coding system. For example, collecting detailed demographic information or information on personal experiences qualifies the data collected as identifiable private information

- ○ Yes
- ○ No

* 3.11 Will you be utilizing audiotapes or videotapes in your research?

- ○ Yes
- ○ No

* 3.12 When you have completed your contact with the research participant, will there be a debriefing session?

- ○ Yes
- ○ No

* 3.13 Will the data you gather be sensitive in nature? (i.e. have the ability to cause emotional distress, potentially put someone in financial, legal, physical or other harm)? This question will appear only for Performance Improvement and Classroom Projects

- ○ Yes
- ○ No

* 3.14 Do you intend the data that will be collected to be of widespread interest or usefulness to a larger audience than the subjects you collect data from, or widespread interest beyond your department?

This question will appear only for Performance Improvement Projects

- ○ Yes
- ○ No

* 3.15 Will you be publishing or presenting the results outside of Simmons University? This question will appear only for Performance Improvement Projects

- ○ Yes
- ○ No

These questions will appear only for Classroom Projects

* 3.16 Do you intend the data that will be collected to be of widespread interest or usefulness to a larger audience than the subjects you collect data from, or widespread interest beyond your class project?

- ○ Yes
- ○ No

* 3.17 Will you be publishing or presenting the results outside of Simmons University or your class?

- ○ Yes
- ○ No

* 3.18 Will subjects to be used in the project come from a vulnerable population including economically and/or educationally disadvantaged persons, prisoners, persons with impaired decision-making ability, and/or children under the age of 18, except when they are in an educational setting?

- ○ Yes
- ○ No

4- Project Description

Section 4 will only appear if you select "Human Subjects Research Project" or "Performance Improvement Project." Section 4 is not applicable to Classroom Projects.

4.1. *General Description. Briefly describe the overall goals of the proposed research and the general procedures you plan to use in conducting your research project.

4.2. *Significance of the Study. Provide a brief theoretical and empirical rationale for why you believe this study is important. Include a concise review of literature including conceptual framework, and specific hypotheses to be tested and/or research questions to be addressed.

4.3. *Participant Population. Describe the characteristics of the participant population, highlighting any potential vulnerabilities in this research project. If your participant population includes vulnerable populations, please express rational for including these populations in your study.

4.3a. *Participant Recruitment. Describe plans and procedures for the recruitment of participants and the steps to obtain informed consent. Outline who will be recruited, by whom, from where, and how it will be accomplished. Include recruitment script and any recruitment materials in your attachments.

4.4. *Research Procedures and Sources of Research Material. Describe your research data collection procedures and identify the sources of research material obtained from individually identifiable living human participants in the form of specimens, records, or other data.

4.5. *Risks. It is very unusual for human participants? research to have zero risk to them. Describe any potential risks (For example, confidentiality and privacy matters; physical, psychological and social well-being; legal and financial risks, etc.) and assess their likelihood and seriousness.

4.5a. * Protection Against Risks. Describe the procedures for protecting against or minimizing any potential risks and assess their likely effectiveness. Where appropriate, describe provisions for secure storage of data.

4.6. *Benefits. Discuss any direct, specific benefits to participants.

4.7. Informed Consent: Describe your consent process. (How and when you will distribute the informed consent document, when will it be collected, etc.)
If uploading consent form(s) please submit PDFs.

Attach your consent form(s)

ATTACH

4.8 *Recruitment Materials*: Attach the materials (e.g. flyers, messages/emails, script(s)) that you will use to recruit participants.

ATTACH

4.9 *Study Tools*: Please attached any survey or interview questions, or other study tools relevant to your project.

ATTACH

5- Section 5

Thank you for completing your protocol. Please be sure to click "complete submission" on the bottom of the blue navigation panel to the left.

Your protocol will not be submitted for review until you, your faculty advisor, if applicable, and co-PIs, have "certified" the submission.

Once you submit your protocol for review, please allow 5 business days for initial feedback, and 10 business days for review.

If you have any questions please contact irbprotocols@simmons.edu.