Wells College

New Project Application: Human Participants in Research Institutional Review Board

This form is to be completed for new research projects involving the use of human participants. Completed forms and supplementary materials should be submitted as a single PDF to irb@wells.edu.

Please note that all researchers and research assistants must complete the Social/Behavioral Course offered through the Collaborative Institutional Training Initiative (CITI) program prior to submitting this application. The training module is accessible at: https://www.citiprogram.org/. CITI program certification is good for three years from the date of completion.

Project Information

Title of Project: _____

Expected Start Date: _____ Expected Completion Date: _____

Investigator Information

Indicate who will perform this research. If this is a student project, the Primary Investigator is the supervising faculty member (e.g., course instructor, thesis advisor).

	Name	CITI Training Completion Date
Primary Investigator at Wells:	_____	_____
Additional Wells College Investigators:	_____	_____
	_____	_____
	_____	_____

Primary Investigator's Signature: _____ Date: _____

----------FOR IRB USE ONLY----------

IRB Project Identification Number _____

Approved _____ Denied _____ Decision Date: _____ Expiration Date: _____

Rev. 8/2015

PROJECT REVIEW CHECKLIST

Academic research with human participants is reviewed by the Wells College Institutional Board (IRB) to ensure that researchers are taking necessary steps to protect participants from potential harms. Research carrying minimal risk may qualify for expedited review, where an IRB Co-chair serves as the primary reviewer and recommends approval or major substantive changes to the other Co-chairs. Research carrying more than minimal risk requires a full review by the IRB Co-chairs and/or other members of the IRB roster.

To help determine whether this application meets the requirements for expedited review, please indicate which of the following statements apply to this this study:

☐ This research does not involve participants who are prisoners; fetuses; pregnant women; children; economically and/or historically marginalized adults; or physically, mentally, or cognitively impaired adults.

☐ This research does not, through the collection or recording of identifying information or behaviors, expose the participant to potential criminal or civil liability; stigmatization; or damage to financial standing, employability, insurability, or reputation.

☐ The research does not collect information regarding sensitive aspects of the participant's behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).

☐ This research is not funded by external grants.

☐ This research does not involve monetary or material compensation for participation.

☐ The study's procedures present no greater probability or magnitude of harm or discomfort than an individual can reasonably expect to encounter during daily life or the performance of routine physical or psychological examinations.

All applicants must answer the following questions. Please use simple, jargon-free language. Provide sufficient detail so that individuals outside of your discipline will understand the procedures and rationale.

1. **Research Purpose: Why conduct this study?** Provide a brief statement of purpose for this study (1 -2 paragraphs). What is your research question? Why is this question important for your discipline? How will this research contribute to existing knowledge about the topic? How do you expect to use findings from this study (e.g., senior thesis, poster presentation, manuscript for publication, etc.)?

2. **Research Participants: Whom will you study?** Fully describe the relevant characteristics of the people you will ask to participate in your research.

   Indicate if you intend to include participants based on demographic or behavioral criteria such as race, sexual orientation, gender, interest group characteristics, etc. Why have you have chosen this specific group or groups? How will you use this information in the analysis? *In order to guard against unintentional disclosure of personal identity, the IRB encourages applicants to limit the collection of potentially identifying information to only that which is relevant and necessary for your research purpose.*

   Indicate if you intend to include participants under the age of 18 and explain why this group is relevant and necessary for your research. *Proposals that pose more than minimal risk and/or include legal minors from populations other than enrolled college students require justification.*

   Indicate if you intend to include members of vulnerable populations, such as prisoners, fetuses, pregnant women, etc. *Proposals that include members of the populations identified on the previous page require justification.*

3. **Research Participants: How will you recruit participants?** Describe the type of sample you will recruit for this study (e.g., convenience, purposive, simple random, etc.). Fully explain how you will recruit volunteers. *Attach the text for what you plan to communicate to potential volunteers in any oral invitations, emails, online posts, posters, etc.*

4. **Research Methodology: What will you ask participants to do?** Fully describe the research methodology (e.g., survey, interview, experiment, participant observation, etc.) and the specific tasks researchers and volunteers will perform as part of this research. Please be thorough and detail each step of the research process. *Attach copies of any relevant questionnaires, interview guides, or other documents related to your research design.*

Indicate how data will be collected, recorded, and secured. What form or forms will data take (e.g., paper survey, data file, audio recording, etc.), and how will each form be secured? Will data be audio and/or video recorded?

Indicate whether data will be collected with or without identifying information. Will information be anonymous or confidential? *Anonymity means no link exists between participants' identity and their data (e.g., online survey that does not collect direct identifiers). Confidentiality means that a link between individuals' personal identity and their data exists, but the researcher will not disclose this link (e.g., focus group discussions or interviews).*

5. **Informed Consent: How will you ensure that participants have given informed consent?** Informed consent is an essential part of the process of protecting the people who contribute to our research. Describe the steps you will use to obtain informed consent from your participants. If you will use a language other than English, please provide a justification. *Attach a copy of your written consent form. You may use the template available on the IRB webpage.*

   Proposals involving participants under the age of 18 must obtain informed consent from a parent or legal guardian. *Attach a copy of written consent form for a guardian and an assent form for the child.*

   Will you need permission from an organizational official (e.g., school principal or superintendent) or community member (e.g., village elder) to enter your research site? *Describe the steps you will take to gain informed consent.*

Under special circumstances, the IRB may waive the requirement for written informed consent. If you believe that your research qualifies for oral consent, please contact an IRB Co-chair in order to receive additional instructions prior to submitting an application.

6. **Deception: Will you deceive participants?** Some studies require deception. However, deception should only be used when alternative approaches would prevent the study from being conducted. All deceptions must be justified, and participants must be fully debriefed at the conclusion of the study. If deception is a part of your study, please offer a full description of each deception, a justification for each deception, and a description of when and how you will debrief participants about each deception.

7. **Potential Risks to Participants: What risks might participants face as the result of participating?** Research participants may experience adverse effects ranging from discomfort to psychological distress, physical injury, or criminal liability. *Researchers should design studies*

such that they minimize potential risks. Indicate what risks are associated with participation in this study. What steps will you take to minimize these risks?

8. **Potential Benefits to Participants: What benefits will participants receive for participating?** Indicate any potential benefits that participants may accrue as a result of participating in this research. Benefits can range from the satisfaction of participating in research, gained insight into their own behavior, monetary benefits, or professional networking. In the event that participants will be paid, describe all payment arrangements, including how much participants will be paid and how compensation will be structured should a participant choose to withdraw from the study prior to completion of the research. *Is it likely that benefits will create an undue influence over some participants?*

9. **Researcher/Participant Relationship: Will you recruit participants that you already know?** Research involving human participants requires that potential participants have the ability to volunteer for a study, to decline to volunteer, and/or to leave a study without undue influence or enticement. Undue influence can include prior relationship between researcher and recruit, excessive monetary compensation, the promise of special consideration for participation, or the withholding of services. Undue influence or simply the perception of undue influence on the part of recruits may prevent individuals from being able to give consent. Describe any existing relationship between researcher and potential research participants (e.g., teacher/student, academic adviser/advisee, TA/student, etc.). If such relationships exist, will they affect the potential participant's ability to volunteer? What steps will you take to minimize undue influence?

10. **External Funding: Is this study funded by an external agency?** Indicate the source and relevant terms of any funding that supports this project.

11. **External Researchers and IRB Assurance: Are you collaborating with researchers at other institutions?** Provide the name, title, and institutional affiliation for all collaborators from other institutions. Have you applied for or received approval from the IRB at these institutions?