

**Institutional Review Board (“IRB”)**

**Application Instructions**

IMPORTANT: Please review the following instructions before preparing your application:

* Read each item carefully and provide the information requested where it is requested.
* Place your response below each item’s description. Please do not copy and paste your literature review from your research study onto this application.
* Do not remove or alter sections of the application that may not be applicable to your study. This document must be provided to the Connecticut State Community College (“CT State”) IRB intact. If a section is not applicable to your study, please type “N/A” below that section.
* Include an identifying header on each page of this application including (i) the application date, (ii) the name of the principal investigator, and (iii) the title of the research study.
* Delete this instruction section in the final version.
* Contact the CT State IRB at CTState-IRB@ct.edu with any questions.

**Application**

1. Application Version Number and Date: (The application version must be revised each time a modification is submitted to the IRB to change the application.)
2. Name of Principal Investigator (“PI”):
3. E-mail Address of PI:
4. Phone Number of PI:
5. Mailing Address of PI:
6. Name of Institution (for which this research study is being conducted):
7. National Institutes of Health (“NIH”), Protecting Human Research Participants (“PHRP”), U.S. Department of Health and Human Services (“HHS”) or other comparable training program certificate number: (This is a requirement. The response to this item cannot be “N/A.” Attach a copy of your human research protection training certificate to this application.)
8. Name of Faculty Advisor:
9. E-mail Address of Faculty Advisor:
10. Please list the names of all other investigators, their institutional affiliation, and their NIH/PHRP/HHS/other comparable training certificate number: (If applicable, attach a copy of their human research protection training certificate to this application.)
11. Title of Research Study:
12. Source of Funding:
13. Proposed Start Date of Research Study:
14. Proposed End Date of Research Study:
15. Do you intend to disseminate, publish, and/or present the results of this research study outside of CT State? If yes, please describe how, where, and when the results of this research study will be shared externally.
16. Introduction and Purpose: State the reason for the study, the research hypothesis, and the goals of the proposed study as related to the research question(s). Provide a clear and succinct summary description of the background information that led to the plan for this study. Do not copy and paste your literature review from your research study onto this application. If available, provide an abstract of the research study. Provide references as appropriate and, when applicable, previous work with human research participants. Also, state how this study is related to the mission of CT State.
17. Design, Procedures, Materials, and Methods: Describe what participants will be asked to do. Be sure to submit copies of surveys, interview questions, focus group scripts, or examples of types of questions to be asked as attachments. Describe the research techniques that will be used to conduct this study (i.e., observations, interviews, surveys, focus groups, collection of artifacts, etc.). Describe the topics or research domains to be covered. Address reliability and validity in your research study. Then, address each of the following sections (a-k), as appropriate.
	1. For field research, explain where the research will be conducted and explain why this particular site was chosen.
	2. Has the PI or other investigator(s) conducted research at this site or with this population previously? If so, briefly describe this experience. Describe the length of time to be spent in the field site(s). If unsure, provide an approximation. If local collaborators will be involved, explain their role.
	3. For research that will be conducted in the field, is governmental or community permission to conduct research required at any of the sites? If so, explain how you will obtain this permission. Sometimes the consent process can be multi-layered in community settings. Describe what the full process is in the setting in which the research will take place. If there is formal documentation of this permission, attach it to the application form or indicate when it will be received and forwarded to the IRB. Also, does your research study require approval from an institution or organization other than CT State (e.g., another IRB, another college or university, or a health care provider)? If yes, attach it to the application, detailing action taken, date of determination, and the name and contact information of the institutional official, or indicate when it will be received and forwarded to the IRB.
	4. If a local collaborator (translator, interpreter, etc.) is used, explain who the collaborator is, what this person’s qualifications are and how they will be involved in the study. Also, will your research study instruments be translated into other languages, such as Spanish, to accommodate non-English speakers? How will you handle non-English speakers? Identify the population’s primary language(s).
	5. With respect to cognitive impairment and physical disability, please describe how your research study will be accessible to all.
	6. Please describe the desired characteristics of the participants (e.g., gender, race/ethnicity, age range, etc.), the desired number of participants, and any criteria for inclusion or exclusion. (If you intend to ask demographic questions, please include an “I prefer not to disclose” option.) Do you intend to study any special or vulnerable populations such as children, minors under 18 years old, pregnant women, minorities, non-English speakers, prisoners, mentally and/or physically disabled persons, cognitively impaired persons, traumatized individuals, terminally ill persons, elderly, and/or educationally and/or economically disadvantaged persons? If yes, please identify the special or vulnerable populations and how you intend to protect them from any physical, psychological, or economic harm resulting from your research study. Also, please describe how you intend to recruit and select participants for your research study.
	7. Explain whether data will be recorded in such a way that it can never be linked to the participants (anonymous data). If you are conducting a survey using the Internet, describe procedures to ensure that the data is not linked to an individual participant (i.e., will participant’s name, e-mail address, or Internet protocol (“IP”) address be recorded?).
	8. Sometimes participants want their identity to be known. If it is anticipated that this will be the case, please describe why and whether it presents any risk to the participant. This should be described in the consent form, if it is known ahead of time.
	9. The risk of harm in qualitative or ethnographic research is usually limited to what may result from invasion of privacy, stigmatization, or breach of confidentiality. This harm can affect individuals or entire groups or communities. Identify the risks (including physical, psychological, and/or economic harm) and inconveniences to the participants of this research. Describe what steps will be taken to minimize those risks and inconveniences. Please note that the IRB regards no research involving human participants as risk-free. You may describe minimal risks for your research study, such as discomfort, boredom, and/or fatigue, or state that the research will involve minimal risk like an activity (named) which participants will perform as part of your study.
	10. Will the participants benefit directly from this research? Are there any other types of benefits (i.e., to society or to the body of knowledge being researched/field of study)?
	11. Describe any economic considerations (i.e., cash payment, donations to the community, in-kind goods, or services) provided to participants. Explain how and when participants or the community will receive economic considerations. (If applicable, *see* local and state laws concerning raffles.)
18. Explain how the data (interviews, observations, etc.) will be analyzed (e.g., discourse analysis, document analysis, content analysis).
19. For student-initiated research studies, describe the plan for communication between the PI and student investigators (“SI”) to assure that adverse events and any deviations occurring during studies are identified, evaluated, and communicated to the IRB in a timely manner. The plan should document how communication between SI and PI will occur including the method(s) of contact and the frequency of contact. The plan should also document how the SI will communicate directly with the IRB, if needed. This plan is required for all student-initiated studies at CT State except for studies determined to be exempt from continuing IRB review. It is important to note that researchers may not initiate changes to approved research procedures in the field without first obtaining approval from the IRB.
20. Privacy and Confidentiality: Explain how the privacy interests of participants will be maintained during the study. Describe procedures for protecting confidentiality of data collected during the study and stored after study closure. Describe plans for storage and security of electronic data. If identifiable, sensitive information (illegal drug use, criminal activity, etc.) is collected, state whether a Certificate of Confidentiality will be obtained. Be sure to state whether any limits to confidentiality exist and identify any external agencies (study sponsor, U.S. Food and Drug Administration (“FDA”), etc.) that will have access to the data. Also, describe how and when the data collected will be destroyed. Then, address each of the following sections (a-c), as appropriate.
	1. If private information is stored in the field and transferred when you leave the field, describe what steps will be taken to protect the data.
	2. If this private information is retained, could it lead to the identification of the research site or study participants? If so, describe any negative consequences this may have on participants. If personally identifiable information (“PII”) is collected, justify the need to do so. *See* CT State IRB Data Security Guidelines at <https://ctstate.edu/irb>.
	3. The IRB acknowledges that sometimes it is not possible or desirable to maintain anonymity. For example, when a researcher works with a small group of people only found in a particular region with whom others have worked. In order to advance ethnographic knowledge about the group, their identity must be made known. Sometimes individuals or whole communities do not want to remain anonymous. If this is the case, please describe why. If there are differences in the community about this, describe how this will be handled.
21. Informed Consent: Explain how you will introduce yourself as a researcher to potential participants. If you already know them, explain the circumstances. Describe how you will obtain informed consent including who will obtain consent, where and when it will be obtained, and how much time participants will have to decide. Potential participants have the right to (i) disclosure of all relevant information about the research; (ii) comprehension of the information; and (iii) voluntary agreement, free of coercion and undue influence. Attach a copy of the consent form. *See* CT State IRB Informed Consent Form Template at <https://ctstate.edu/irb>. Also, the consent form should allow participants to attest that they are 18 years of age or older. Otherwise, you will need to obtain child/minor assent and parent consent. Sometimes the consent process can be multi-layered in community settings. Be sure to describe what the full process is in the setting in which the research will take place. Then, address each of the following sections (a-g), as appropriate.
	1. If you plan to obtain signed consent, attach a copy of the consent form.
	2. Why is the study considered to be minimal risk?
	3. The IRB must find that participants’ rights are not adversely affected. For example, participants may choose not to answer any questions they do not want to answer, and they may stop their participation in the research at any time.
	4. How will important information be returned to the participants, if appropriate?
	5. Does a breach of confidentiality constitute the principal risk to participants? Relate this to the risks associated with a breach of confidentiality and indicate how risks will be minimized.
	6. Would the signed consent form be the only record linking the participant to the research? Relate this to the procedures to protect privacy and confidentiality.
	7. Does the research include any activities that would require signed consent in a non-research setting? For example, in non-research settings, normally there is no requirement for written consent for completion of questionnaires.
22. Conflict of Interest: Do you have any direct or indirect financial interest in CT State? Are you an employee of CT State? Disclose any personal, business, or volunteer affiliations or supervisor-supervisee relationships that may give rise to an actual, perceived, or potential conflict of interest. If you are a Connecticut State Colleges and Universities (“CSCU”) employee conducting research at CT State for an external purpose unrelated to official business (e.g., publication, conference presentation, graduate/doctoral research, etc.) you must sign a statement agreeing not to seek out additional student or employee information from any CSCU information system about any student or employee or attempt to re-identify any individual involved in your research study. *See* CT State IRB Employee Statement at <https://ctstate.edu/irb>.