Application for Research

Using this document:

- The purpose of this document is to provide you with a guide to provide the information that the Ethical Research Board (ERB) needs in order to review your protocol. After every **Instruction** section, there is a **Response** area; please provide your answer in **Response** box.

- Please note, this document is intended for researchers who do not have IRB approval. If you have IRB approval from another organization, please complete the **Application with Outside Approval**.

- We suggest that you contact the ERB during the creation process to ensure the proposal follows the principles and guidelines for human subjects research. If you have any questions regarding this document, creation of your proposal, or how to contact the appropriate department chair, please contact the ERB at nccerb@ccsnh.edu.

Submitting a protocol:

- This document has four parts: **Section A "Investigator's Agreement**," **Section B "Permissions," Section C "Protocol Information,"** and **Section D "Description of the Research Study."**

- Be sure to contact the Department chair in the department you intend to do research in, then the Vice President of Academic Affairs for permissions signatures.

- **To submit a protocol,** complete this document and email it and any accompanying materials (i.e. consent forms, recruitment materials, instruments, data collection forms, evidence of human subject ethics education, conflict of interest form) to nccerb@ccsnh.edu.

- **Please note that we only accept forms in Microsoft Word format and in this form only. Do not submit your responses in a separate document.** We do not accept hand-written documents (with the exception of signatures). Please submit the electronic form in its entirety; do not remove the signature pages from the document even though you will submit these pages as a pdf/hard copy. Do not alter this form; simply provide your responses in the **Response** area. **Forms that are not completed correctly will be returned to you and you will be required to complete them correctly before they are accepted. No exceptions!** If you need help using our form, please contact our office.

- **Sections A & B** must be submitted with signatures. Signed materials can be submitted by mail, fax (603-882-8690), or email (scanned document to nccerb@ccsnh.edu). **Your study cannot be approved until we receive these documents.**

- In order to not delay your review, make sure that you (and any researcher listed on the protocol) have completed the PHRP course in human subjects research. Be sure to include your certificate of completion in your application.

- You **cannot** begin any recruitment or portion of your study until your protocol is accepted. You will be contacted within 5 business days regarding your submission and the approximate date of review (depending on the protocol queue).

Nashua Community College

A. Investigator Agreement

BY SIGNING THIS DOCUMENT, THE INVESTIGATOR AGREES:

1. That **no participants will be recruited** or data accessed under the protocol **until** the Investigator has received the **final approval or exemption determination** from the Chair of the Ethical Research Board or designee.
2. That **no participants will be recruited** or entered under the protocol **until** all researchers for the project have completed their **human investigation research ethics educational requirement and submitted the completion certificate.**
3. That any **modifications of the protocol or consent form** will not be implemented without prior **written approval** from the ERB Chair or designee except when necessary to eliminate immediate hazards to the participants.
4. That any **deviation from the protocol and/or consent form** that is serious, unexpected and related to the study **will be reported promptly to the ERB** in writing.
5. That all protocol forms for **continuations of this protocol** will be **completed** and returned **within the time limit stated** on the renewal notification letter.
6. That **all participants will be recruited and consented as stated in the protocol approved or exempted** by the ERB. If written consent is required, all participants will be consented by signing a copy of the consent form that has a non-expired ERB approval number and given a copy of the consent.
7. That the ERB will be notified prior to a **change in the Principal Investigator** for the study.
8. That the ERB will be notified when **the active study is complete**.

Principal Investigator (print)	**Date**
Protocol Title	**Protocol Number (ERB only)**
Principal Investigator's Signature	

The ERB reserves the right to terminate this study at any time if, in its opinion, (1) the risks of further research are prohibitive, or (2) the above agreement is breached.

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• B. Permissions

BY SIGNING THIS DOCUMENT, THE DEPARTMENT CHAIR AGREES:

1. That the principal investigator has provided notification of intent to research.
2. That **no participants will be recruited** or data accessed under the protocol **until** the department chair has received notification of **final approval or exemption determination** from the Chair of the Ethical Research Board or designee.
3. That any observed **deviation from the protocol and/or consent form** during the study **will be reported promptly to the ERB** in writing.

Principal Investigator (print)	**Date**
Department Chair (print)	**Date**
Department Chair signature	
Vice President of Academic Affairs (print)	**Date**
Vice President of Academic Affairs signature	
Protocol Title	**Protocol Number (ERB only)**

The ERB reserves the right to terminate this study at any time if, in its opinion, (1) the risks of further research are prohibitive, or (2) the above agreement is breached.

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Protocol Form

B. Protocol Information

ERB Protocol Number (assigned by ERB, leave blank):

Submission Date:

Submission Type (delete all those that don't apply):

New Protocol
Resubmission of previously rejected protocol
Updated protocol form (includes all previous modifications)
Reopening expired protocol
Continuing review

Protocol Title:

Principal Investigator:

Professional Title:

Mailing Address:

Telephone:

Email address

You are (delete all those that don't apply):

Faculty
Graduate Student
Undergraduate Student
Postdoctoral Trainee
Staff

This research is for (delete all those that don't apply):

Master's Thesis
Doctoral Dissertation
Faculty Research
Other (please describe)

Human Subjects training completion date (attach certificate to form):

Primary contact for the protocol (if other than the principal investigator):

Contact's Email:

Contact's Phone:

Faculty Advisor (if applicable):

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Title: _____

Affiliation: _____

Telephone: _____

Email address: _____

Human Subjects training completion date (attach certificate to form): _____

Other Researchers*:

Please list all other researchers* in this study. Please provide the following information for each researcher: Name, Email address, Phone Number. _____

Funding Source: If research is funded, please provide the following:

Grant name (or name of the funding source): _____

Funding period (month/year): _____

Grant number: _____

Estimated timeline:

(E.g. anticipated start and completion dates for collecting and analyzing data) _____

*** Please only list researchers that are working directly with human subjects and/or their data. All researchers listed on the protocol must complete and submit proof of the NIH Training or provide proof of completing human subjects research training at their institution. If you have any questions about whether a researcher should be listed on the protocol or if a researcher has completed training, please contact nccerb@ccsnh.edu. Proof of training can be submitted via fax (603-882-8690), by mail (505 Amherst St, Nashua NH 03063, attn.: Aimee Huard) or by email (nccerb@ccsnh.edu).**

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C. Description of the Research Study

1. **Study Overview:** Give a brief overview of your project. Consider the following when framing your response:
    - What is your purpose in conducting this research? How does the project contribute to the advancement of knowledge and why is it worth doing? What is the general benefit of the knowledge you expect to gain?
    - Include information about the study's logistics (where and when it will be conducted, etc.). What will you ask participants to do, and what do you hope to learn from these activities?
    - Will participants be compensated for taking part in your study? If so, how much will they receive?
    - If your study has more than one phase, please clearly map out the different phases.

Response 1: (enter response below this header, in the box)

2. **Participants: Please respond to questions a and b in this section.**
    a. **Please describe as best you can the population(s) you plan to work with.** Please describe them in the terms that are most pertinent to your project. We need to understand how working with them will further your research objectives and what steps need to be taken in order to minimize risk to them. Consider the following bullet points when reframing your response:
        - Where do they live? Where will you interact with them while gathering information for your study?
        - Are they men, women, children, elderly people, others?
        - Are they members of a particular sub-community?
        - What is their social status, locally and in their wider society?

Response 2-a: (enter response below this header)

    b. What special experience or knowledge do you have that will allow you to work productively and respectfully with your participants? If you are working with a faculty sponsor and/or other researchers, how does their experience support your study?

Response 2-b: (enter response below this header)

3. **Consent:** Consent is an on-going process that starts when you first inform your participant about the study through your initial interaction with the participant (i.e. recruitment/advertising) and ends when the participant's materials are no longer needed. The federal regulations require that a formal consent process takes place in which you provide participants with specific information about the study (usually provided through a consent form, see General Consent Template) which the participants are required to sign.

   Not every study will fit this mold and in appropriate circumstances alternative methods for conducting the formal consent procedure are permissible. For example, participants are better served if they receive the consent information through an informative conversation (Oral Consent), or they may not be willing or able to sign a consent form. **In general, the ERB needs to understand how participants will be recruited and consented to participate in the study and you will need to provide justification for altering the traditional method for the consent process.** Please note that if your study qualifies for exemption (see Exemption Checklist), you will not be required to follow the federal regulations for documenting consent, but the Board may require that you provide information about the study to the participant. **Please respond to questions a-e in this section.**

   a. How will you identify and approach participants to participate in your research? **Please provide all materials used to contact participants in this study. These materials could include letters, emails, flyers, advertisements, etc. If you will contact participants verbally, please provide a script that outlines what you will say to participants.**

Response 3-a: (enter response below this header)

   b. What is your consent process? Please describe your process for documenting consent. Who will present the consent information and how will it be presented? Is there anything about the study population, your methods, or the nature of your research questions that makes written consent impossible, difficult, or inappropriate to obtain? Are your participants able to sign a form, and if not, what method will you use to document consent? If you are using an alternative method for documenting consent or you are requesting not to document consent, please provide justification for doing so.

      You may have reason to present information orally to one set of participants and in written form to another; if you intend to use multiple methods, please give your rationale and make sure the process is adequately defined.

      Note: Please include your consent form(s) with your protocol. If you use more than one version of the consent form, each form needs to have a unique title.

Response 3-b: (enter response below this header)

c. Are any of your participants unable to consent (i.e. vulnerable population)? These populations include (but are not limited to): minors (participants under the legal age of consent), prisoners, and participants with diminished mental capacity. These participants generally need a parent (or surrogate) consent form and a participant assent form (prisoners being the likely exception unless they are minors too).

Response 3-c: (enter response below this header)

d. What is your relationship to your participants? Do you know them personally or hold any position of authority over them? Do any of the researchers (including the faculty advisor) have positions of authority over the participants, such as grading authority, professional authority, etc.? Are there any relevant financial relationships?

Response 3-d: (enter response below this header)

4. **Materials/Data collected**: For most studies, the risk to participants often lies in the information that is collected from them. Thus the manner in which the materials are collected, how they are stored, and how the information is reported in your research is an important part of determining the risk to participants. When you develop your procedures, consider **minimizing or eliminating the collection of identifying information** where possible and **provide justification** as to why it needs to be collected. **Please respond to questions a-d in this section.**

   a. Describe your methodology for your study. Be specific in the description of your data collection methods, any specific materials or tools that will be used to collect the data, the timeline of the procedures and how long each will last, and the analysis of the data (including any scientific or scholarly justifications for the use of these analyses).

Response 4-a: (enter response below this header)

b. Are any of the data already collected? Are the data publicly available or part of a private collection? Please describe the data set(s) and provide a list of data fields you will use (when applicable). What will you do to protect the confidentiality of the pre-existing data? What will you do to protect the privacy and confidentiality of your participants? Describe the process for collecting data from your participants, focusing on the kinds of information you will gather and the material forms it will take.

Describe the level to which participants will be identifiable, why this information is necessary for you to collect, and how the identifying information will be linked with the participant's data. If you don't intend to collect identifying information, describe your process for keeping the data anonymous.

Note: Please include your data collection form(s) with your protocol.

Response 4-b: (enter response below this header)

c. Will you use audio recordings, photographs, video recordings or other similar data recording devices? Please justify why it is necessary to use data recording devices, how you will use them, and what you will do with the data after they are collected. If you are collecting photographs, audio recordings, or video in which individuals are highly identifiable and you are providing oral consent, how will you document that the people you record agree to let you to maintain and use the resulting materials?

Response 4-c: (enter response below this header)

d. How will your materials be stored? Discuss both how you plan to store it while you are collecting and actively analyzing it, and your long-term plan for maintaining it when the active research phase is finished. How will your study materials be reported in your study? Will you report the results in aggregate or will individual data be discussed?

Response 4-d: (enter response below this header)

5. **Risks**: Almost any intervention into other people's lives carries with it the potential to cause them social, psychological, physical, or legal harm. However, not every interaction will put a participant at risk beyond what is considered minimal. **Please describe to the Board the potential risks and the probability of harm to the participants in your study.** In this section, consider the following when framing your response:
    - Describe the risks to the participants in your study. Does your study include "risk-sensitive" participants? What is the probability that harm could occur?
    - Describe what you will do to minimize those risks. Describe what you will do if a harmful situation occurs.

- Would a loss of confidentiality of any of your materials put participants at risk? If so, how will you prevent this from happening?

Response 5: (enter response below this header)

6. **Benefits**: Benefits help to outweigh the risks to the participants, though not every study will have direct benefits to the participants. Will there be any direct benefits to the participants in your study? If so, what are they? (The Board also considers the general benefits of the study, as described in section 1).

Response 6: (enter response below this header)
