**Application to CCSNH IRB with Outside Approval**

**Using this document:**

* The purpose of this document is to provide you with a guide to provide the information that the CCSNH IRB needs in order to review your protocol.
* Please note, this document is intended for researchers who ***have*** IRB approval. If you do not have IRB approval from another organization, please complete the **Application to Ethical Research Board**.
* We suggest that you contact the CCSNH IRB 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 CCSNH IRB at CCSNHIRB@ccsnh.edu.

**Submitting a protocol:**

* This document has three parts: **Section A “Investigator’s Agreement**,” **Section B “Permissions,”** and **Section C “Protocol Information.”**
* 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 all accompanying materials (i.e. consent forms, recruitment materials, instruments, data collection forms, evidence of human subject ethics education, conflict of interest form, IRB approval, IRB application) to CCSNHIRB@ccsnh.edu.
* For the CCSNH IRB to consider any other IRB approval, you must include the original application and approval from the institution.
* **Please note you must submit your answers within this Microsoft Word format and in this form only.**
* Please submit the electronic form in its entirety as a single PDF. **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 email (scanned document to CCSNHIRB@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 an accepted training in human subjects research. Be sure to include your certificate of completion in your application. A list of accepted trainings can be found on the IRB website.
* 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). **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** fromthe 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 CCSNH IRB 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 CCSNH IRB** 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 CCSNH IRB. If written consent is required, all participants will be consented by signing a copy of the consent form that has a non-expired CCSNH IRB approval number and given a copy of the consent.
7. That the CCSNH IRB will be notified prior to a **change in the Principal Investigator** for the study.
8. That the CCSNH IRB will be notified when **the active study is complete**.

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| **Principal Investigator (print)** | **Date** |
|  |  |
| **Protocol Title** | **Protocol Number (CCSNH IRB only)** |
|  |
| **Principal Investigator’s Signature** |

**The CCSNH IRB 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.**

* **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** fromthe 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 CCSNH IRB** in writing.

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| **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 (CCSNH IRB only)** |
|  |

**The CCSNH IRB 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.**

**Protocol Form**

**B. Protocol Information**

|  |  |
| --- | --- |
| **CCSNH IRB Protocol Number (assigned by CCSNH IRB, 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):** |  |
|  | 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 CCSNHIRB@ccsnh.edu. Proof of training can be submitted via email (****CCSNHIRB@ccsnh.edu****).**