INSTITUTIONAL REVIEW BOARD

APPLICATION FOR APPROVAL TO USE HUMAN SUBJECTS IN RESEARCH

CONTINUING REVIEW FORM

**Dear Principal Investigator(s):**

**Federal regulations require that full and expedited research protocols previously reviewed by the IRB submit a report annually if the research project continues beyond the expiration date. If you are planning to continue with your research beyond its expiration date (for expiration date, see your approval form), you must first submit a report to the IRB. No data may be collected after expiration date of the protocol until the continuing review form has been approved by the IRB. Exempt protocols DO NOT require continuing review.**

**Please attach a copy of your new consent form to this application.**

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| **STUDY/ THESIS/ DISSERTATION TITLE** |
| **Title:**  |
| **Protocol #:** |
| **Protocol Expiration Date (found on stamped consent form):**  |

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| **PRINCIPAL INVESTIGATOR & PROTOCOL INFORMATION** |
| **Principal Investigator** *(Must be a faculty/staff member at the University of New Haven)*: |
| Title:  |
| Department/Division/Unit :  |
| Phone:  | UNH Email:  |
| **Check all that apply:** |
| [ ]  Faculty | [ ]  Staff |
| **This research is for:** |
| [ ]  Scholarship | [ ]  Master’s Thesis |
| [ ]  Undergraduate Research | [ ]  Graduate Research |
| [ ]  Senior Thesis | [ ]  Honor’s Thesis |
| [ ]  Doctoral Dissertation  | [ ]  Institutional Monitoring Research |
| [ ]  SURF  | [ ]  Other:  |

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| **ASSOCIATED PERSONNEL INFORMATION** |
| **Co-Researcher(s):**  |
| Organization (if non-University New Haven):  |
| Department/Division/Unit  |
| Phone:  | UNH/Other Email:  |
| **Check all that apply:** |
| [ ]  Faculty | [ ]  Graduate Student |
| [ ]  Staff | [ ]  Undergraduate Student |
| **Research Advisor/Mentor(s) if different from PI:**  |
| Organization/Department/Division/Unit:  |
| Phone:  | UNH/Other Email:  |
| **Non-Key Personnel** *(Reader, Assistant, etc.)***:**  |
| Organization/Department/Division/Unit:  |
| Phone:  | UNH/ Other Email:  |
| **Consultant/Methodologist** *(required for PhD candidates)***:**  |
| Organization/Department/Division/Unit:  |
| Phone:  | UNH/ Other Email:  |
| ***Note:*** *The IRB will not review protocols submitted by students without the signature of a faculty advisor on signature page.* |

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| **FUNDING SOURCE** |
| **Will you be seeking non-university or outside funding for the research?** [ ] No[ ]  Yes *(Complete section below)* |
| **Grant Name/Funding Source:**  |
| **Funding Period (Month & Year):**  |

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| **CONTINUING REVIEW** |
| **Please Respond to the Following:** |
| What type of study was this last approved as?[ ]  Full[ ]  Expedited**Submission Date of this Application:** |
| Briefly summarize your research findings thus far, including findings of recent significant literature in the field relevant to research risks (if any): |
| How many subjects have accrued to your project since its last review?: |
| How many subjects have signed consent forms? |
| Have there been any adverse events, unanticipated problems, or breaches of privacy/confidentiality involving risks to subjects or others since the last review?[ ] No[ ]  Yes *(Explain):* |
| Have there been any voluntary or involuntary withdrawals of subjects from research or any complaints about the research?[ ] No[ ]  Yes *(Explain):* |
| Has the risk to participant increased since the last IRB review? [ ] No[ ]  Yes *(Explain):* |
| Has the design of the study changed?[ ] No[ ]  Yes *(Explain):* |
| Have the data gathering instruments changed?[ ] No[ ]  Yes *(Explain, and attach new or revised instruments):* |
| Have any new research materials been developed since the last IRB review? [ ]  No[ ]  Yes *(please attach a copy of all new materials)* |
| Has the selection/recruitment process changed? [ ]  No[ ]  Yes *(Explain):* |
| Has the risk/benefits balance for participants changed?[ ]  No[ ]  Yes *(Explain):* |
| Has the informed consent/ assent/ parental permission process changed?[ ]  No[ ]  Yes *(briefly explain, and* attach old and new forms*):* |
| Has the process for insuring privacy and confidentiality changed? [ ]  No[ ]  Yes *(Explain):* |
| Have any questions regarding the safeguards in place for protection of vulnerable populations arisen?[ ] No[ ]  Yes *(Explain):* |
| Have there been any grievances or complaints about this research?[ ]  No[ ]  Yes *(Explain):* |
| Have there been any adverse events in the conduct of the research? [ ]  No[ ]  Yes *(Explain; an Adverse Event form[s] should have been submitted to the IRB at the time of the incident):* |
| Have any new personnel joined this project since the last IRB review? [ ] No[ ]  Yes *(please attach a copy of each new group member’s NIH or CITI certificate)* |
| Have any CITI certificates expired since the last IRB review? [ ]  No[ ]  Yes *(please attach a copy of the updated CITI certificate)* |
| Provide a brief explanation of research plans for the upcoming year: |

**Reminder:** Proposed changes in the study protocol, consent process or research instruments including questionnaires must be submitted for review and receive approval before they can be utilized.

Failure to submit this report on time may result in the temporary suspension of a study’s approval and a halt to the study until approval is given.

**The faculty sponsor's signature indicates that they have reviewed this application and accept the responsibility of ensuring that the procedures approved by the IRB are followed.**

**SIGNATURES**

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| PI Signature: | Date: |
| Co-PI Signature: | Date: |
| Faculty Advisor Signature: | Date: |

**Add further signatures below as needed:**

**Please email all applications and supporting documents to**

**IRB Chair at** **IRB@newhaven.edu**

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| **FOR IRB USE ONLY:** |
| Date Received:  |
| Protocol #:  |
| [ ]  Expedited ReviewReviewed By: [ ]  Full ReviewCommittee Meet Date:  |
| Comments:  |
| Decision:  |
| Date Revision Requested:  |
| Nature of Revision:  |
| Date Revision Received:  |
| Date Completed:  |
| [ ]  Received Required Citi Training Documentation |