

**INSTITUTIONAL REVIEW BOARD**

**APPLICATION FOR APPROVAL TO USE HUMAN SUBJECTS IN RESEARCH**

**EXEMPT PROJECT**

**APPLICATION INSTRUCTIONS**

1. Complete each section of this document by checking applicable boxes and filling prompted fields.
2. Email the completed application, with the following supporting documents (as separate Microsoft*®* Word documents) to IRBExempt@newhaven.edu:
	* Consent Forms, Permission Letters, Recruitment Materials
	* Surveys, Questionnaires, Interview Questions, Focus Group Questions
	* Provide any other information that might be pertinent to the IRB's decision.
3. Submit one signed copy of the signature page to the following:
	* If by email: As scanned document to IRBExempt@newhaven.edu
	* Otherwise, signature lines fillable in Word are provided
4. Once received, the IRB processes applications on a first-come, first-served basis.
5. *We cannot accept applications in formats other than Microsoft® Word.*

Note: Applications and supporting documents with the following problems will be returned immediately for revisions:

1. Grammar, spelling, or punctuation errors
2. Lack of professionalism
3. Lack of consistency or clarity
4. Incomplete applications

*Failure to minimize these errors will cause delays in your processing time*

BASIC PROTOCOL INFORMATION

|  |
| --- |
| **STUDY/ THESIS/ DISSERTATION TITLE** |
| **Title:**  |

|  |
| --- |
| 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:  |

|  |
| --- |
| 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 |
| STUDENT RESEARCHERS – If not the PI, who is your research advisor? |
| [ ]  PI is my research advisor |
| Name: |
| 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.* |

**EXEMPT QUESTIONS**

|  |
| --- |
| Please Respond to the Following: |
| Does your study involve the collection of data from a vulnerable population?[ ]  No[ ]  Yes *(Please describe):* |
| Does this study involve deception (research where the subject is purposely mislead)?[ ]  No[ ]  Yes *(Please describe):* |
| If the study involves risk to subjects, is the risk greater than that incurred in ordinary life or tasks?[ ]  This study involves no risk to subjects[ ]  No[ ]  Yes *(Please describe):* |

|  |
| --- |
| **STUDY STATUS** |
| Is this proposal [ ]  **new**, or [ ]  **revised** following a previous IRB review? |
| Has this study ever been previously approved by the UNH Human Subjects IRB?[ ]  No[ ]  Yes ***(Please list Protocol # for that review):*** |
| Has this study ever been previously approved by a **non-**UNH Human Subjects IRB?[ ]  No[ ]  Yes *(Please identify which IRB reviewed):* |
|  **\*\*\*If yes, please append the decision of the other IRB to this application.\*\*\***  |
| Does this protocol include multiple sites?[ ]  No[ ]  Yes ***(Please identify alternative sites, as well as the primary IRB of submission):*** |
| Are you filing for exemption from the Single IRB?[ ]  No[ ]  Yes |

|  |
| --- |
| **USE OF UNIVERSITY OF NEW HAVEN PARTICIPANTS** |
| **Do you intend to use UNH students, staff, or faculty as participants *OR* UNH student, staff, or faculty data in your study?**[ ]  No *(Proceed to Funding Source)*[ ]  Yes *(Complete the section below)* |
| **# Of Participants/Data sets:**  | **Department/Source:**  |
| **Class(es)/Year(s):**  | **Department Chair:**  |

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

|  |
| --- |
| **STUDY DATES** |
| **When do you plan to perform your study?** *(Approximate dates for collection/analysis)***:****Start** *(Month/Year)***:** **Finish** *(Month/Year)***:**  |

|  |
| --- |
| **EXEMPT CATEGORY** |
| **Please review the list of exempt category numbers provided on page 5. Please identify which category you are applying under below.** |

**EXEMPT REVIEW**

A. The following categories of human subject research may be exempt from IRB oversight:

(1) Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(3)

(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

(5) Research that is designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.

 (6) Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

B Only the IRB may grant Exempt status to projects. Therefore all research projects using human subjects must be submitted for IRB review BEFORE data collection commences. The IRB CANNOT approve projects retroactively.

C. If exempt status is granted, the study will no longer be under the jurisdiction of the IRB. However, if procedures are revised which deviate from those originally reviewed by the IRB the project must be resubmitted to the IRB BEFORE data collection commences. The IRB CANNOT approve projects retroactively.

D. Research involving protected populations, e.g., children, prisoners, pregnant women, or fetuses, is **NOT** eligible for exempt status.

|  |
| --- |
| E. I believe my research can be classified as exempt under category number(s): above. |

***F. Please append to this document any surveys, interview questions, or tests you plan to use in your project. While the IRB understands that interviews are often fluid and questions may deviate from those submitted, a list of sample questions and areas of inquiry are essential so that the IRB may properly evaluate your application.***

[ ]  Check this box to confirm you have included a description of your study in your application materials.

[ ]  Check this box to confirm you have included a copy of all surveys, interview questions, or tests that will be used in your study.

[ ]  Check this box to confirm you will use no surveys, interview questions, or tests in your study.

G. I certify that all of the information and materials provided in and in support of this application are to the best of my knowledge and belief true, correct, and complete.

I agree to use procedures with respect to safe-guarding human subjects in this activity that conform to University policy. If significant changes in investigative procedure involving human subjects is called for during the activity covered by this application, I shall seek prior approval for such changes from the IRB and agree to follow the advice of the IRB.

**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**

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

**Add further signatures below as needed:**

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

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

|  |
| --- |
| **FOR IRB USE ONLY:** |
| Date Received:  |
| Protocol #:  |
| Exempt Category(ies): |
| Comments:  |
| Decision:  |
| Date Revision Requested:  |
| Nature of Revision: |
| Date Revision Received:  |
| Date Completed:  |