

INSTITUTIONAL REVIEW BOARD

APPLICATION FOR APPROVAL TO USE HUMAN SUBJECTS IN RESEARCH

EXPEDITED/FULL REVIEW

**I. 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 [IRB@newhaven.edu](mailto:IRB@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. **All researchers and PI’s involved in the study who will interact with human participants must submit certification from CITI: Collaborative Institutional Training Initiative Research Modules.** To complete the CITI certification, register at <http://www.citiprogram.org>.

* Create an account—search for the University of New Haven as your affiliate program.
* Fill in required fields.
* Select courses
* Basic course
* Faculty course (if you are faculty or PI)
* Social Science and Behavioral Research or the Biological Specimen module, depending on the nature of your study.

CITI certification is valid for five years. If applicable, please append CITI certification to this application.

1. Submit one signed copy of the signature page to the following:
   * If by email: As scanned document to [IRB@newhaven.edu](mailto:IRB@newhaven.edu)
   * Otherwise, signature lines fillable in Word are provided
2. Once received, the IRB processes applications on a first-come, first-served basis.
3. Most applications will require revisions.
4. The entire process may take between 1 and 2 months.
5. *We cannot accept applications in formats other than Microsoft® Word.*

**Upon approval of the study, the consent document will be stamped with an expiration date. Only this document may be used when enrolling subjects. Any changes in the consent form must be submitted as a revision for IRB Approval. Studies extending beyond the expiration date must be submitted for a continuation review.**

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*

EXPEDITED OR FULL IRB REVIEW

II. BASIC PROTOCOL INFORMATION

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| **STUDY/ THESIS/ DISSERTATION TITLE** |
| **Title:** |
| **Does your application require an  expedited or  full IRB review?** |
| ***Note:*** *Request for expedited review may be referred to the full IRB procedure if the Chair deems it appropriate.* |

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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 |
| 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.* | |

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| **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 sIRB?  No  Yes |

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| **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:** |

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| **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):** |

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

**III. OTHER STUDY MATERIALS AND CONSIDERATIONS**

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| **STUDY MATERIALS LIST** | |
| **Please indicate whether your proposed study will include any of the following:** | |
| Recording/photography of participants *(voice, video, or images)*? | No  Yes |
| Participant compensation *(gift cards, meals, extra credit, etc.)*? | No  Yes |
| Advertising for participants *(flyers, TV/Radio advertisements)*? | No  Yes |
| More than minimal psychological stress?\* | No  Yes |
| Confidential data collection *(participant identities known but not revealed)*? | No  Yes |
| Anonymous data collection *(participant identities not known)*? | No  Yes |
| Archival data collection *(data previously collected for another purpose)*? | No  Yes |
| Extra costs to the participants *(tests, hospitalization, etc.)*? | No  Yes |
| The inclusion of pregnant women? | No  Yes |
| More than minimal risk?\* | No  Yes |
| Alcohol consumption? | No  Yes |
| Pilot study procedures *(which will be published/included in data analysis)*? | No  Yes |
| Use of bodily fluids *(e.g., blood, saliva, semen, vaginal fluids, skin cells, etc.)?* | No  Yes |
| Total amount of deposits: |  |
| Blood draws over time period *(days)*: |  |
| The use of rDNA or biohazardous material? | No  Yes |
| The use of human tissue or cell lines? | No  Yes |
| Fluids that could mask the presence of blood *(including urine/feces)*? | No  Yes |
| Use of radiation or radioisotopes? | No  Yes |
| ***\*Note: Minimal risk*** *is defined as “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in everyday life or during the performance of a routine physical or physiological examinations or tests. [45 CFR 46.102(i)]. This includes possible psychological stress. If you are unsure if your study qualifies as minimal risk, contact the IRB.* | |

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| **INVESTIGATIONAL METHODS** |
| **Please indicate whether your proposed study will include any of the following:** |
| The use of an investigational new drug (IND) or an approved drug for an unapproved Use?  No  Yes *(Provide the drug name, IND number, and company)*: |
| The use of an investigational medical device or an approved medical device for an unapproved Use?  No  Yes *(Provide the drug name, IDE number, and company)*: |

**IV. PURPOSE**

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| **PURPOSE OF RESEARCH** | |
| **Write an original, brief, non-technical description of the purpose of your research.**  Include in your description your research hypothesis/question, a narrative that explains the major constructs of your study, and how the data will advance your research hypothesis or question. This section should be easy to read for someone not familiar with your academic discipline: | |
| **Check if this proposal is new**  **or revised**  **in response to previous IRB review.** | |
| **Is this study a part of a larger study?** | No  Yes |
| **If yes, has it received IRB approval?** | No  Yes |
| **If yes, provide a brief description of larger study:** | |

**V. PARTICIPANT INCLUSION/EXCLUSION CRITERIA**

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| **STUDY POPULATION** |
| **Provide the inclusion criteria for the participant population** *(e.g., gender, age range, ethnic background, health status, occupation, etc.)***:** |
| **Provide a rationale for selecting the above population** *(i.e., Why will this specific population enable you to answer your research question?)***:** |
| **Will your participant population be divided into****experimental and control groups?**  No  Yes |
| **Do you have a relationship to any of your participants** *(e.g., spouse, romantic partner, or advisor.)***?**  No  Yes *(Explain)*: |
| **Indicate who will be excluded from your study population** *(e.g., persons under 18 years of age)***:** |
| **If applicable, provide rationale for involving any special populations** *(e.g., children, ethnic groups, individuals with impaired decision-making ability or low socio-economic status, or prisoners)***:** |

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| **TYPES OF PARTICIPANTS** | |
| **Who will be the focus of your study?** *(Check all that apply)* | |
| Typical Participants (Age 18-65) | Pregnant Women |
| Minors (Under Age 18) | Fetuses |
| Over Age 65 | Cognitively Disabled |
| College/University Students | Physically Disabled |
| Active-Duty Military Personnel | Participants Incapable of Giving Consent |
| Discharged/Retired Military Personnel | Individuals under judicial jurisdiction (Prisoners) |
| Inpatients | Specific Ethnic/Racial Group(s) |
| Outpatients | Participant(s) related to the researcher |
| Patient Controls | Other: |
| ***Note:*** *Only check the boxes if the participants will be the focus (for example, ONLY military or ONLY students). If they just happen to be a part of a broad group you are studying, you only need to check “Normal Participants.” Some studies may require that you check multiple boxes (e.g., African American males, aged 65+).* | |

**VI. RECRUITMENT OF PARTICIPANTS**

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| **CONTACTING PARTICIPANTS** |
| **Describe in detail how you will contact participants regarding this study** *(include the method(s) used—email, phone call, social media, snowball sampling, etc..)***:** |

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| **SUBMISSION OF RECRUITMENT MATERIALS** |
| **Submit a copy of all recruitment letters, scripts, emails, flyers, advertisements, or social media posts you plan to use to recruit participants for your study as separate Word documents with your application.** |
| **Check the appropriate box:** |
| All the necessary recruitment materials will be submitted with my application. |
| My study strictly uses **archival** data, so recruitment materials are not applicable. |
| My study as described does not use recruitment materials. |
| **If you plan to provide documents in a language other than English:** |
| I will submit a translated copy of my recruitment materials along with the English version(s). |

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| **LOCATION OF RECRUITMENT** |
| **Describe the location, setting, and timing of recruitment:** |

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| **SCREENING PROCEDURES** |
| **Describe any procedures you will use to ensure that your participants meet your study criteria** *(e.g., a screening survey or verbal confirmation to verify that participants are 18 or older)***:** |

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| **CONFLICTS OF INTEREST** |
| **Do you have a position of academic or professional authority over the participants** *(e.g., You are the participants’ teacher, principal, supervisor, or district/school administrator.)***?**  No  Yes *(Explain what safeguards are in place to reduce the likelihood of compromising the integrity of the research, e.g., addressing the conflicts in the consent process and/or emphasizing the pre-existing relationship will not be impacted by participation in the research.)***:** |
| **Do you have any financial or personal conflicts of interest to disclose** *(e.g., Do you or an immediate family member receive income or other payments, own investments in, or have a relationship with a non-profit organization that could benefit from this research?)***?**  No  Yes *(State the funding source/financial conflict and then explain what safeguards are in place to reduce the likelihood of compromising the integrity of the research.)***:** |

**VII. RESEARCH PROCEDURES**

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| **PROCEDURES** | | |
| **Write an original, non-technical, step-by-step description of what your participants will be asked to do during your study and data collection process.** If you have multiple participant groups, *(e.g., parents, teachers, and students)* or control and experimental groups, please specify which group you are asking to complete which task(s). **You do not need to list signing/reading consent as a step.** | | |
| **Step/Task/Procedure** | **Time to Complete Procedure** *(Approx.)* | **Participant Group(s)**  *(All, Group A, Group B, Control Group, Experimental Group, etc.)* |
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| ***Note:*** *For complex study designs, additional diagrams, timelines, or figures may be submitted separately.* | | |

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| **SUBMISSION OF DATA COLLECTION INSTRUMENTS/MATERIALS** |
| **Submit a copy of all instruments, surveys, interview questions, outlines, observation checklists, prompts, etc. that you plan to use to collect data for your study as separate Microsoft® Word documents with your application.** |
| **Check the appropriate box:** |
| All of the necessary data collection instruments will be submitted with my application. |
| My study strictly uses **archival** data, so data collection instruments are not applicable. |
| **If you plan to provide documents in a language other than English:** |
| I will submit a translated copy of my study instrument(s) along with the English version(s). |

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| **STUDY LOCATION** |
| **Please state the actual location(s)/site(s) in which the study will be conducted.** Be specific *(include city, state, school/district, clinic, etc.)*: |
| ***Note:*** *Investigators must submit documentation of permission from some research sites to the IRB prior to receiving approval. If your study involves K-12 public schools, district-level approval is acceptable as opposed to submitting separate permission documentation from each school. If your study involves colleges or universities, hospitals, or prisons, you may also need to seek IRB approval from those institutions. You may seek permission prior to submitting your IRB application; however,* ***do not*** *begin recruiting participants. If you find that you need a conditional approval letter from the IRB to obtain permission the IRB will provide one after you have completed all requested revisions.* |

**VIII. DATA ANALYSIS**

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| **ANALYSIS METHODS** |
| **Describe *how* the data will be analyzed:** |
| **Please describe what will be done with the data and the resulting analysis** *(Include any plans for publication or presentation)***:** |

**IX. PARENETAL/GUARDIAN CONSENT**

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| **PARENTAL/GUARDIAN CONSENT REQUIREMENTS** |
| **Does your study require parental/guardian consent?** *(If your participants are under 18, parental/guardian consent is required in most cases.)*  No  Yes *(Answer the following question)* |
| **Does your study entail greater than minimal risk without the potential for benefits to the participant?**  No *(Proceed to Child Assent)*  Yes *(Consent of both parents is required)* |

**X. ASSENT FROM CHILDREN**

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| **CHILD ASSENT** |
| **Is assent required for your study?** *(Assent is required unless the child is not capable of assenting due to age, psychological state, or sedation OR the research holds out the prospect of a direct benefit that is only available within the context of the research.)*  No *(My study meets one of the above exclusions)*  Yes *(Children must consent to their own participation in this study)* |

**XI. PROCESS OF OBTAINING INFORMED CONSENT**

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| **CONSENT PROCEDURES** |
| **Describe in detail *how* and *when* you will provide consent/assent/parental consent information** *(e.g., as an attachment to your recruitment email, as the first page participants see after clicking on the survey link, etc.)***:** |
| **Unless your study qualifies for a waiver of signatures, describe in detail *how* and *when* consent forms will be signed and returned to you** *(e.g., participants will type their names and the date on the consent form before completing the online survey, participants will sign and return the consent forms when you meet for their interview, etc.)***:** |
| ***Note:*** *A waiver of signatures is only applicable if you will not be able to link participant responses to participants (i.e., anonymous surveys).* |

**XII. USE OF DECEPTION**

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| **DECEPTION** |
| **Are there any aspects of the study kept secret from the participants** *(e.g., the full purpose of the study, assignment, or use of experimental/control groups, etc.)***?**  No  Yes *(Describe the deception involved and the debriefing procedures)*: |
| **Is deception used in the study procedures?**  No  Yes *(Describe the deception involved and the debriefing procedures)*: |
| ***Note:*** *Submit a post-experiment debriefing statement and consent form offering participants the option of having their data destroyed when possible.* |

**XIII. WAIVER OF INFORMED CONSENT OR MODIFICATION OF REQUIRED ELEMENTS IN THE INFORMED CONSENT PROCESS**

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| **WAIVER OF INFORMED CONSENT ELEMENTS** |
| **Are you seeking a waiver of consent from participants in your study?**  No, *continue to the next section.*  Yes, *please complete this section in its entirety.* |
| **Does the research pose no more than minimal risk to participants** *(i.e., no more risk than that of everyday activities)***?**  No, *the study is greater than minimal risk.*  Yes, *the study is minimal risk.* |
| **Will the waiver have adverse effects on participants rights and welfare?**  No, *the waiver will not have adverse effects on participants rights and welfare.*  Yes, *the waiver will adversely affect participants rights and welfare.* |
| **Would the research be feasible without the waiver?**  No, *not having a waiver would make the study unfeasible.* Explain:  Yes, *there are other ways of performing the research without the waiver.* |
| **Will participant debriefing occur** *(i.e., Will the true purpose and/or deceptive procedures used in the study be reported to participants at a later date?)***?**  No, *participants will not be debriefed.*  Yes, *participants will be debriefed.* |
| ***Note:*** *A waiver or modification of some or all of the required elements of informed consent is sometimes used in research involving deception or archival data.* |

**XIV. WAIVER OF THE REQUIREMENT FOR PARTICIPANTS TO SIGN THE INFORMED CONSENT DOCUMENT**

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| **WAIVER OF SIGNED CONSENT** |
| **Are you seeking a waiver of participant signatures on informed consent documents for your study?**  No, *continue to the next section.*  Yes, *please complete this section in its entirety.* |
| **Would a signed consent form be the only record linking the participant to the research?**  No, *there are other records/study questions linking the participants to the study.*  Yes, *only the signed form would link the participant to the study.* |
| **Does a breach of confidentiality constitute the principal risk to participants?**  No, *there are other risks involved greater than a breach of confidentiality.*  Yes, *the main risk is a breach of confidentiality.* |
| **Does the research pose no more than minimal risk to participants** *(i.e., no more risk than that of everyday activities)***?**  No, *the study is greater than minimal risk.*  Yes, *the study is minimal risk.* |
| **Does the research include any activities that would require signed consent in a non-research context** *(e.g., liability waivers)***?**  No, *there are not any study related activities that would normally require signed consent.*  Yes, *there are study related activities that would normally require signed consent.* |
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| **Are the subjects or their legally authorized representatives (LARs) members of a distinct cultural group or community in which signing forms is not the norm?**  No, *the subjects/their LARs are not members of a distinct cultural group or community in which signing forms is not the norm.*  Yes, *the subjects/their LARs are members of a distinct cultural group or community in which signing forms is not the norm, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.* |
| **Will you provide the participants with a written statement about the research** *(i.e., an information sheet that contains all of the elements of an informed consent form but without the signature lines)***?**  No, *participants will not receive written information about the research.*  Yes, *participants will receive written information about the research.* |
| ***Note:*** *A waiver of signed consent is sometimes used in anonymous surveys or research involving secondary data. This does not eliminate the need for a consent document, but it eliminates the need to obtain participant signatures.* |

**XV. CHECKLIST OF INFORMED CONSENT/ASSENT**

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| **STATEMENT** |
| **Submit a copy of all informed consent/assent documents as separate Word documents with your application.** |
| **Check the appropriate box:** |
| All of the necessary consent/assent documents will be submitted with my application. |
| My study strictly uses **archival** data, so consent documents are not required. |
| My study as described uses no consent documents |
| **If you plan to provide documents in a language other than English:** |
| I will submit a translated copy of my consent material(s) along with the English version(s). |
| ***Note:*** *Consent forms must be collected and stored on file. For projects requiring multiple data collection times, informed consent forms must be signed at every data collection session.* |

**XVI. PARTICIPANT PRIVACY, DATA SECURITY, & MEDIA USE**

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| **PRIVACY** |
| **Describe the steps you will take to protect the privacy of your participants** *(e.g., If you plan to interview participants, will you conduct your interviews in a setting where others cannot easily overhear?)***:** |
| ***Note:*** *Privacy refers to persons and their interests in controlling access to their information.* |

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| **DATA SECURITY** |
| **How will you keep your data secure** *(i.e., password-locked computer, locked desk, locked filing cabinet, etc.)***?** |
| **Who will have access to the data** *(i.e., the researcher and faculty mentor/chair, only the researcher, etc.)***?** |
| **Will you destroy the data once the three-year retention period required by federal regulations expires?**  No  Yes *(Explain how the data will be destroyed.):* |
| ***Note:*** *All research-related data must be stored for a minimum of three years after the end date of the study, as required by federal regulations.* |

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| **ARCHIVAL DATA (SECONDARY DATA)** |
| **Are all or part of the data archival** *(i.e., previously collected for another purpose)***?**  No *(proceed to Non-Archival Data.)*  Yes *(Answer the questions below.)* |
| **Are the archival data publicly accessible?**  No *(Explain how you will obtain access to this data.)*:  Yes *(Indicate where the data is accessible from, i.e., a website, etc.)*: |
| **Will you receive the raw data stripped of identifying information** *(e.g., names, addresses, phone numbers, email addresses, social security numbers, birth dates, etc.)***?**  No *(Describe what data will remain identifiable and why this information will not be removed.)*:  Yes *(Describe who will link and/or strip the data—this person should have regular access to the data and should be a neutral party not involved in the study.)*: |
| **Can the names or identities of the participants be deducted from the raw data?**  No *(Write your initials following this statement: I will not attempt to deduce the identity of the participants in this study.)*:  Yes *(Describe)*: |
| **Please provide the list of data fields you intend to use for your analysis and/or provide the original instruments used in the study:** |
| ***Note:*** *If the archival data is not publicly available, submit proof of permission to access the data (i.e., school district letter or email). If you will receive data stripped of identifiers, this must be stated in the proof of permission letter or email.* |

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| **NON-ARCHIVAL DATA (PRIMARY DATA)** |
| **If you are using non-archival data, will the data be anonymous** *(i.e., Raw data does not contain identifying information and cannot be linked to an individual/organization by use of pseudonyms, codes, or other means.)***? Note:** For studies involving audio/video recording or photography, select “No”  N/A: I will only use archival data. *(Skip to Media.)*  No: My data will contain identifiers. *(Complete the “No” section below.)*  Yes: My data will not contain identifiers. *(Complete the “Yes” section below.)* |
| **\*\*COMPLETE THIS SECTION IF YOU ANSWERED “NO: MY DATA WILL CONTAIN IDENTIFIERS.”\*\*** |
| **Can participant names or identities be deduced from the raw data?**  No  Yes *(Describe)*: |
|  |
| **Will a person be able to identify a participant based on other information in the raw data** *(i.e., title, position, sex, etc.)***?**  No  Yes *(Describe)*: |
| **Describe the process you will use to ensure the confidentiality of the participants during the data collection and in any publication(s)** *(i.e., You may be able to link individuals/organizations to identifiable data; however, you will use pseudonyms or a coding system to conceal their identities.)***:** |
| **Do you plan to maintain a list or codebook linking pseudonyms or codes to participant identities?**  No  Yes *(Please describe where this list/codebook will be stored and who will have access to the list/codebook. Explicitly state that the list will not be stored with the data.)*: |
| **\*\*COMPLETE THIS SECTION IF YOU ANSWERED “YES: MY DATA WILL NOT CONTAIN IDENTIFIERS.”\*\*** |
| **Describe the process you will use to collect the data to ensure that it is anonymous:** |
| **Please Initial -** I will not attempt to deduce the identity of the participants in this study: |
| ***Note:*** *If you plan to use participant data (i.e., photos, recordings, videos, drawings) for presentations beyond data analysis for the research study (e.g., classroom presentations, library archive, or conference presentations) you will need to provide a materials release form to the participant.* |

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| **MEDIA USE** | |
| **Will your participants be audio recorded?** | No  Yes |
| **Will your participants be video recorded?** | No  Yes |
| **Will your participants be photographed?** | No  Yes |
| **\*\*COMPLETE THIS SECTION IF YOU ANSWERED “YES” TO ANY MEDIA USE\*\*** | |
| **Include information regarding how participant data will be withdrawn if they choose to leave the study\*:** | |
| **Will your participants be audio recorded, video recorded, or photographed without their knowledge?\*\***  No  Yes *(Describe the deception and debriefing procedures.)*: | |
| ***\*Note on Withdrawal:*** *Add the heading “How to Withdraw from the Study” on the consent document and include a description of the procedures a participant must perform to be withdrawn.*  ***\*\*Note on Deception:*** *Attach a post-experiment debriefing statement and a post-deception consent form, offering the participants the option of having their recording/photograph destroyed and removed from the study.* | |

**XVI. PARTICIPANT COMPENSATION**

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| **COMPENSATION** |
| **Will participants be compensated** *(e.g., class credit, gift cards, drawing entry, reimbursement, food)***?**  No *(Proceed to Risks.)*  Yes *(Describe.)*: |
| **Will compensation be pro-rated if the participant does not complete all aspects of the study?**  No  Yes *(Describe.)*: |
| ***Note:*** *Certain states outlaw the use of lotteries, raffles, or drawings as a means of compensating research participants. Research compensation exceeding $600 per participant within a one-year period is considered income and will need to be filed on the participant’s income tax returns. If your study is grant funded, the University of New Haven’s policies might affect how you compensate participants. Contact the IRB for additional information.* |

**XVII. PARTICIPANT RISKS AND BENEFITS**

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| **RISKS** |
| **Describe the risks to participants and any steps that will be taken to minimize those risks.** *(Risks can be physical, psychological, economic, social, or legal. If the only potential risk is a breach in confidentiality if the data is lost or stolen, state that here.)***:** |
| **Will alternative procedures or treatments that might be advantageous to the participants be made available?**  No  Yes *(Describe.)*: |
| **ANSWER THE FOLLOWING QUESTION ONLY IF YOUR STUDY IS CONSIDERED GREATER THAN MINIMAL RISK:** |
| **Describe provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the participants** *(e.g., proximity of the research location to medical facilities or your ability to provide counseling referrals in the event of emotional distress)***:** |

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| **BENEFITS** |
| **Describe the possible direct benefits to the participants.** *(If participants are not expected to receive direct benefits, please state “No direct benefits.” Completing a survey or participating in an interview will not typically result in direct benefits to participants.)***:** |
| **Describe any possible benefits to society:** |
| **Evaluate the risk-benefit ratio.** *(Explain why you believe this study is worth doing, even with any identified risks.)***:** |

**Please continue to next page to complete required signatures**

**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: |
| Research Advisor Signature: | Date: |

**Add further signatures below as needed:**

**Please email all applications and supporting documents to: IRB Chair at** [**IRB@newhaven.edu**](mailto:IRB@newhaven.edu)

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| **FOR IRB USE ONLY:** |
| Date Received: |
| Protocol #: |
| Expedited Review  Reviewed By:  Full Review  Committee Meet Date: |
| Comments: |
| Decision: |
| Date Revision Requested: |
| Nature of Revision: |
| Date Revision Received: |
| Date Completed: |
| Received Required Citi Training Documentation |