Proposal Transmittal Form

University of Hartford

Institutional Review Board

This form should be initiated by the investigator who is proposing to conduct research involving humans. **The investigator should complete all items and submit one PDF Document containing all required components.** Please allow 3 to 4 weeks for the review of your proposal. A letter providing the results of the review will be sent electronically to the email address indicated.

One signed electronic PDF **or** one complete hard copy of the complete proposal should be forwarded to the IRB **(electronic preferred)**. Contact information as follows:

Jessica Pawlik-York
IRB Chair
IRB@hartford.edu
University of Hartford

Office of the Provost
CC BLDG 3rd floor
200 Bloomfield Avenue
West Hartford, CT 06117

Project Title: _____

Principal Investigator Name: _____

University Department/ Program: _____

University office address:_____

Home Street Address*: _____

Home City, State, Zip Code*: _____

Phone Number: _____

Email Address: _____

**Provide only if no University of Hartford office*

Check one of the following:

- ◯ University of Hartford faculty member
- ◯ University of Hartford student
- ◯ Other, please describe:

If a student, please provide the following information:

Research Advisor: _____

Advisor's Campus Address: _____

Advisor's Email Address: _____

Advisor Campus Telephone: _____

PART A (to be completed by the Principal Investigator)

If you are a University of Hartford student, please indicate the following:

Is this proposal related to an undergraduate honors project? Yes ◯ No ◯

If you are a Master's degree or Doctoral degree student, has this research proposal been approved by the appropriate master's thesis or doctoral dissertation committee?
Yes ◯ No ◯

(Proposals must be approved by a dissertation committee prior to submission to the IRB)

If your research involves resources (human participants or data) whose rights are protected by another institution, please provide evidence of permission to engage those resources.

- ◯ Other institution involved, permission attached
- ◯ Other institution involved, permission in process, documentation attached
- ◯ No other institution involved in rights protection of resources

Does your research involve participants younger than 18 years of age, prisoners, pregnant women, person with a cognitive/developmental disability, or economically/educationally disadvantaged persons?

Yes ◯ No ◯ (If yes, Full Committee Review is required)

To be completed by Principal Investigator:
I attest that all information stated in the Proposal Transmittal Form is true.

Signature of Principal Investigator: _____ Date _____

To be completed by Research Advisor (if applicable):
I attest that I have reviewed this proposal and approve the content. To the best of my knowledge, the content is accurate, the study is methodologically sound, and the proposal conforms to all ethical requirements for human participant's research.

Signature of Research Advisor: _____ Date _____

PART B (to be completed by the Principal Investigator)

All proposals that concern research conducted with human participants must be submitted to the IRB for review.

Indicate the type of IRB review you are requesting (see relevant descriptions on pp. 3-5):

Exempt Review - Category #_____

Expedited Review - Category #_____

○ **Full Committee Review (any proposals that do not meet criteria for exempt or expedited review, including research with any special populations)**

Exempt Review (proposals are not exempt from submission to the IRB):

For proposals to be considered exempt, research activities will involve human participants in one or more of the following categories. If you believe your research fits within one of these, please indicate the category number in section B above:

Source: Federal Register Title 45, §46.104 (link)

a) 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.

   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 participants cannot readily be ascertained, directly or through identifiers linked to the participants; **and**
   ii. Any disclosure of the human participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be

damaging to the participants' 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 participants can readily be ascertained, directly or through identifiers linked to the participants, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(Paragraphs (2) (i) and (ii) of this section only may apply to research with children involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section may not be applied to research involving children.)

(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult participant through verbal or written responses (including data entry) or audiovisual recording if the participant prospectively agrees to the intervention and information collection and at least one of the following criteria is met: **(may not be applied to research involving children)**

A. The information obtained is recorded by the investigator in such a manner that the identity of the human participants cannot readily be ascertained, directly or through identifiers linked to the participants;
B. Any disclosure of the human participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' 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 participants can readily be ascertained, directly or through identifiers linked to the participants, 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 participants, and the investigator has no reason to think the participants will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the participants 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 participants regarding the nature or purposes of the research, this exemption is not applicable unless the participant authorizes the deception through a prospective agreement to participate in research in circumstances in which the participant is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable bio-specimens, if at least one of the following criteria is met:

i. The identifiable private information or identifiable bio-specimens are publicly available;
ii. Information, which may include information about bio-specimens, is recorded by the investigator in such a manner that the identity of the human participants cannot readily be ascertained directly or through identifiers linked to the participants, the investigator does not contact the participants, and the investigator will not re-identify participants;
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)

Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise participant to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are 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. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants.

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.

Expedited review:

For proposals to be considered for expedited review, research activities must present no more than minimal risk to human participants and involve only procedures listed in one or more of the following categories (The activities should not be deemed to be of minimal risk simply because they are included on this list) If you believe your research falls within one of these categories, please indicate the number in Section B:

Source: HHS.gov, OHRP Expedited Review Categories (link)

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met:
   a. Research on drugs for which an investigational new drug application is not required or
   b. Research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling;

2. Collection of blood samples by finger stick, heal stick, ear stick, or venipuncture as follows:
   a. From healthy, non-pregnant adults who weigh at least 110 pounds or
   b. From other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected.

3. Prospective collection of biological specimens for research purposes by noninvasive means, such as:
   a. hair and nail clippings in a non-disfiguring manner;
   b. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
   c. permanent teeth if routine patient care indicates a need for extraction;
   d. excreta and external secretions (including sweat);
   e. un-cannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue;
   f. placenta removed at delivery;
   g. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
   h. supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

PRINCIPAL INVESTIGATOR CHECKLIST:

PLEASE CONFIRM THAT YOUR PROPOSAL INCLUDES ALL OF THE FOLLOWING ITEMS BY CHECKING IN THE APPROPRIATE COLUMN

Document Needed:	Included	N/A
Completed Proposal Transmittal form, including all required signatures	☐	☐
Informed consent form (for participants able to provide consent)	☐	☐
Parental permission form (if using participants under 18 years old)	☐	☐
Assent form (if using participants unable to provide consent)	☐	☐
Copy of all measures (e.g., questionnaires, scales, interview schedules, or focus group questions)	☐	☐
Copy of all recruitment materials (i.e., letter of invitation, ads, flyers, emails, phone script). Include appropriate permissions for recruitment of participants or placement of flyers (particularly if placing flyers on campus).	☐	☐
Proof of Human Participants Training (CITI) for principal investigator(s) and all research personnel	☐	☐
HIPAA Release if collecting medical information See: § 164.514 (link)	☐	☐

Instructions

Depending on the nature of your research, some sections of this proposal form may not be applicable. If so mark as "NA" in the sections (please don't leave them blank). There are some instructions at the beginning of each section, please include all information that is relevant to your study and your participants.

This information should be written in language that IRB members from many backgrounds and disciplines can easily understand. There should be no discipline specific jargon included in the descriptions used in any of the sections.

When you write a protocol, keep an electronic copy for your records. You will need to modify this copy when proposing future changes to your protocol.

There are a number of materials that will need to be included as "appendices" to this document, including: Consent form, parent permission form (as applicable), child assent form (as applicable), recruitment materials (advertisements, scripts, etc.), all paper and pencil measures (questionnaires, etc.), questions that will be used for focus groups or interviews.

1.0 **Purpose of the study:** Briefly describe the basic purpose or the study, including any specific aims, or objectives. State the hypotheses to be tested or the research questions that will guide the study.

2.0 **Background / Literature Review / Rationale for the study:** Briefly (500 words or fewer) describe: The relevant current context of the study and gaps in current knowledge. Provide the scientific or scholarly background for, rationale for, and significance of the proposed research based on the existing literature and how it will add to existing knowledge. Please place your reference list (if applicable) at the end of the proposal.

3.0 **Inclusion and Exclusion Criteria:** Briefly describe the criteria (such as age range, gender, language, etc.) that define who will be included or excluded in your study sample. Indicate specifically whether you will include or exclude the following special populations:

- Adults unable to consent/ person with a cognitive/developmental disability
- Individuals who are not yet adults (under 18 years of age)
- Pregnant women (where the activities of the research may affect the pregnancy or the fetus)
- Prisoners or other detained individuals

4.0 **Sample Size:** Briefly describe the total number of participants (if more than one site is involved, describe the total number of participants at each site) that will be included in the study. Provide a justification for the sample size that will be used (including participants at all sites).

5.0 **Research Locations:** A research location is defined as a location or place where the research procedures will occur. Describe the locations where the research procedures will take place. Examples: lab space at university, schools, community centers, public venues, etc. Indicate that all required permissions and/or approvals are already obtained or will be obtained at each research location prior to project implementation (include obtained permissions as an appendix to this document). Indicate any location-specific regulations or customs affecting your project, including any local scientific and ethical review structure if applicable. If there are no special regulations, indicate this information.

6.0 **Procedures Involved:** Indicate the study design that will be used. Provide a description of all research procedures and activities. If the study involves multiple conditions where each condition involves different procedures, please provide a table that breaks down the procedures by condition and in chronological order. Include when and where they are performed.

If this study is funded by NIH and meets NIH's definition of a clinical trial (a research study in which one or more human participants are prospectively assigned to one or more interventions, which may include placebo or other control, to evaluate the effects of those

interventions on health-related biomedical or behavioral outcomes) you must register this study with Clinicaltrials.gov, per 42 CFR Part 11 (link).

Describe the study timelines including: the duration of an individual participant's participation in the study and the overall anticipated duration of the project. Briefly describe the actual source records or measures that will be used to collect data about participants. Describe what data will be collected and how it will be collected at all measurement/data collection time-points. Describe the data analysis plan, including any statistical procedures. If doing online research, include the URL where the data collection will occur. If the research involves individuals who are vulnerable or susceptible to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.

7.0 **Incomplete Disclosure or Deception and Debriefing:** If the study will use incomplete disclosure of information (e.g. study purpose) or deception of participants, describe the incomplete disclosure or deception, and provide a rationale explaining why it is necessary to the research. Describe the debriefing process that will be used to make participants aware of the incomplete disclosure or deception, including their right to withdraw any record of their participation.

8.0 **Recruitment Methods:** Describe how potential participants will be identified, and then describe when, where, and how potential participants will be invited to participate in the study. Describe the types of strategies and materials that will be used to recruit participants.

9.0 **Consent Process:** Describe how consent (and HIPAA Authorization, if applicable) will be obtained. If a waiver of consent is being requested, state the reasons why the research could not be performed without this waiver. If obtaining consent using a written consent document, describe:

- Where the consent process will take place
- Any process to ensure ongoing consent if appropriate
- The details of the consent process including:
- The role of the individuals listed in the application as being involved in the consent process

- The amount of time that will be devoted to the consent discussion (in order to ensure participants' understanding of the study and procedures)
- Steps that will be taken to ensure the participants' understanding of the study and procedures

There must be specific measures included to ensure that the rights and welfare of minors and other vulnerable populations are considered during the consent process.

Describe whether and how consent (and HIPAA Authorization, if applicable) of the participant will be documented in writing. If you will obtain consent (and HIPAA Authorization, if applicable), but not document consent in writing, please provide a rationale for why you are not obtaining written consent.

If there are Non-English speaking participants who will be enrolled, describe the process to ensure that the oral and written information provided to those participants will be in the language with which they are most comfortable speaking or writing. Indicate the language that will be used by those obtaining consent and the qualifications of the person obtaining consent if consent will be in another language. If you will be using a translator during recruitment, consent, data collection, or data analysis specify how you will identify an appropriate translator and what the provisions will be for protecting the confidentiality of participants.

For participants who are not yet adults (minors under 18 years of age):

- Describe whether parental permission will be obtained
- Describe the process for assent of the participants

For persons with a cognitive/developmental disability:

- Describe the process to determine whether an individual is capable of consent
- Describe the process for assent of the participants

10.0 **Financial Compensation (or class credit):** If applicable, describe any financial or other compensation that will be provided to participants (including any class credit incentives). Describe the payment method and include how much money or what gifts will be provided and for what activities, as well as when (timing) compensation will be provided. Include whether compensation will be prorated if there are multiple research activities or if a participant withdraws from the study before finishing. Describe any costs that participants may be responsible for because of participation in the research.

11.0 **Potential Benefits to Participants:** Indicate if there is no direct benefit to participants. Do not include benefits to society or others. Note: participation in the research itself and compensation from participating in the research are not benefits to be included in this

section. Describe the potential benefits that individual participants may experience from taking part in the research.

12.0 **Risks to Participants:** Describe the reasonably foreseeable risks, discomforts, hazards, or inconveniences related to the participants' participation in the research. Describe the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks as well as community or group harms.

Note: a breach of confidentiality is a common risk in social and behavioral research. If applicable, describe risks to others who are not participants (e.g., group harms, harms to society). Describe procedures that will be followed when participants withdraw from the research, including withdrawal from some of the procedures, but not all. Describe the use of data after withdrawal.

13.0 **Audio/Video Recording/Photography:** If applicable, describe the type of recording being utilized and why the type of recording is necessary to the research. Describe how the recordings will be utilized in the research (e.g., data analysis only or data analysis and presentations). If the intent is to use recordings or images for public presentation or publication, there must be compelling rationale provided for why you are asking the IRB to waive the fundamental right to privacy regarding participation in research. Describe how and where the recordings are stored, who has access to them, and if/when they will be destroyed. If recording is mandatory for participation, a rationale must be provided here and the consent form must include this detail.

14.0 **Provisions to Protect the Privacy and Confidentiality of Participants and the Research Data:** Describe the steps that will be taken to protect participants' privacy interests. "Privacy" refers to a person's desire to place limits on whom they interact or whom they provide personal information. Describe what steps you will take to make the participants feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a participant might experience in response to questions, examinations, and procedures. Indicate who on the research team is permitted to access any sources of information about the participants. Also indicate how the research team has access to the sources of information about the participants. If participants will be re-

contacted for any reason, please describe this process, including a rationale explaining why participants may need to be re-contacted. If you anticipate re-contacting participants, you must be disclose this in the consent form.

Describe how data (and if applicable, biological specimens) will be handled study-wide including: "Data" includes all information collected in the conduct of the research, such as but not limited to: consents, surveys, interview notes, audio or video recordings, photographs, notes of observations, field notes, etc.

- What information will be included as data (or associated with the specimens)?
- Where and how will data (or specimens) be stored?
- How will data be transported from the point of collection to where they will be stored?

Note: electronic storage of data in both domestic and international research must be secured using adequate protections.

- How long will the data or specimens be stored? (Note: Federal regulations require a minimum of 3 years after the completion of the study. However, there are circumstance when other time periods may apply.)
- Who will have access to the stored data or specimens?
- Who is responsible for receipt or transmission of the data or specimens?
- Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.

15.0 **Data Monitoring Plan to Ensure the Safety of Participants:** Describe the plan to periodically evaluate the information collected regarding risks or harms to determine whether participants remain safe.

For example, if you are collecting depression or suicidality data, what is your plan for monitoring severity? Note: the plan might include establishing a data monitoring committee and a plan for reporting their findings to the IRB and the sponsor. It also could include referral to an appropriate resource.

Include the following:

- What information / data are reviewed to ensure safety of participants?
- How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).
- The frequency of data collection, including when safety data collection starts.
- Who will review the data and what their credentials are?

- The statistical tests for analyzing the safety data to determine whether harm is occurring.
- Describe any conditions where the research team may intervene and what the plan is for intervening. (For example, if a participant identifies harm to self or others.)
- Describe any conditions that might trigger an immediate suspension of the research.

16.0 **Data, and if applicable, Specimen Banking:** If data or specimens will be stored for future use, describe why the data will be stored for future use, where the data or specimens will be stored, how long they will be stored, how the data or specimens will be accessed, and who will have access to the specimens. If storing data electronically, include a plan for managing the long-term storage of the data if appropriate. List the data to be stored or, in the case of specimens, what information will be associated with each specimen, specifically with regard to identifiability of specimens. Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

17.0 **Data Sharing:** If data will be shared, describe whether the data being shared is identifiable (if identifiable data will be shared, you must provide a justification), who will be able to access the data (e.g. other researchers), what the data will be used for (e.g. research purposes, teaching, etc.), and what privacy and confidentiality protections are in place.

18.0 **Qualifications of Research Team to Conduct the Research:** Describe the qualifications of the research team to conduct this research. The IRB is looking for information such as area(s) of expertise, past research experience, relevant certifications, etc. For international research or research with vulnerable populations, describe the qualifications (e.g., training, experience, and oversight) of you and your staff as required to conduct the research. CITI training certificates must be submitted with all proposals (as part of the appendix).

19.0 **Multiple sites:** A site is defined as an institution/organization/university that is collaborating on a research study. If this research involves multiple sites, specify which is the lead site is and describe the roles of each site in the study. (The lead site is often determined by the primary grant awardee or the lead investigator on the project.) Indicate that all required IRB approvals are already obtained (attach in an appendix) or will be obtained at each site prior to project implementation. In addition, describe the processes you have in place to ensure successful coordination of activities among sites. For example, do all sites have the most current version of the protocol, consent document, and HIPAA authorization? How will modifications be communicated to sites and approved prior to implementation? How will participating sites be kept abreast of any problems, interim results, or the eventual closure of the study? Describe the mechanisms you have in place to ensure that all local site investigators conduct the study appropriately and that engaged participating sites safeguard data as required by local information security policies. Please confirm that all non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.

20.0 **Reliance Agreements/Single IRB:** Reliance agreements (i.e. IRB Authorization Agreement (IAA)) are formal arrangements between institutions allowing the IRB of one institution to rely on the IRB of another institution for review of human participant's research. Reliance agreements are a formal agreement between IRBs and not the choice of the investigator. However, investigators working with multiple institutions, each having an IRB, may seek to have one IRB become the IRB of record with oversight over some or all participating sites. This means that the investigator should consult with the U of H IRB about being either the reviewing IRB (IRB of Record) or is relying on another IRB for IRB oversight of the research activity. If the study team will seek to utilize a reliance agreement or a single IRB, please describe which institution(s) will be relying on another IRB for review and which institution will be responsible for the IRB oversight of the relying IRB(s)