**Dartmouth College**

**COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS**

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**APPLICATION FOR EXEMPTION**

CPHS template v.0208/2024

**PI:**

**Study Title:**

* **All investigators and key personnel (co-investigators, coordinators, etc.) must have completed education in human subject protections before a study can be approved.**
* **For research to be eligible for Exemption from further IRB review the research must be minimal risk, and fit into one or more of the categories which are summarized below.**

**Check the category(s) you believe describes your research:**

**(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 Sec.111(a)(7).

Note: The surveying or interviewing of prisoners or individuals under the age of 18 does not qualify for exemption.

**(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 Sec.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 they 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 nonresearch 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 and demonstration projects that are **conducted or supported by a Federal department or agency**, or otherwise subject 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. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

1. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

**(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.

**For All Studies:**

**In addition to the brief description of your research in Rapport, please provide the following information:**

1. **Study Design and Objectives**

**Describe study objectives, procedures, materials, and methods of data collection. Please upload any study instruments and funding or other proposals to Rapport:**

1. **Risks & Benefits**

Note: Risks may be physical, psychological, social, legal, educational, economic, to reputation, or others.

* 1. **Describe any potential risks, their likelihood and seriousness:**
  2. **Confirm that risks to subjects are no greater than minimal risk, have been minimized, and use procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk:**
  3. **Describe why all the risks to subjects are reasonable in relation to both anticipated benefits and the knowledge expected to be gained from the study:**

1. **Deception**

**Does any part of this study involve deception or withholding of information from participants?**

**Yes  No**

**If Yes, provide an explanation which addresses the following:**

* A description of the deception being used
* Why the deception is necessary
* A plan for notification that there are undisclosed purposes, and agreement of the subject prior to participation in the study.
* A plan for debriefing, (or providing subjects with the pertinent information after participation), and a timeline for the debriefing.

1. **Study Population and Recruitment Process**

Describe method(s) of recruitment. Any materials to be used for recruitment should be uploaded to the ‘Consent Forms and Recruitment Materials’ page in Rapport.

1. **Informed Consent, Assent, and Authorization**

**All forms discussed in this section should be uploaded to the ‘Consent Forms and Recruitment Materials’ page in Rapport**

* 1. **Please describe and justify the consent process, addressing the following:**
* Who will obtain consent from participants, and whether the process will involve a signed form, script, or other documentation
* Any precautions taken to minimize the possibility of coercion or undue influence

In minimal risk research, it may be acceptable *not* to require a signature on a consent form. It may also be acceptable to use an information sheet in order to provide a description of the study to potential subjects. An information sheet template is available in the IRB Library in Rapport and on the CPHS website. Please upload any information sheets to the Consent Form and Recruitment materials page in Rapport.

1. **Privacy of Participants and Confidentiality of Data**

Describe procedures to protect participant privacy and protection of any potentially sensitive data to be collected.