**HRP-503D - Protocol for Exemption Request**

**Version 2019-1**



**Protocol Title:** Click or tap here to enter text.

**Principal Investigator:** Click or tap here to enter text.

**Version Date:** Click or tap here to enter text.

**Instructions**:

Certain research activities may be exempt from review, if confirmed by the IRB Chair or his/her designee and confirmed in writing to the Investigator. Research may be exempt from review when the only involvement of human subjects in the research falls into one or more of the categories noted below. The regulations allow for two additional exemption categories that are not currently implemented at Yale.

**Note:**

* **The IRB does not exempt studies that involve the Introductory Psychology Subject Pool.**
* **Exemption categories apply to research involving pregnant women.**
* **Exempt categories DO NOT apply to research with prisoners, except for research aimed at involving a broader subject population that only incidentally includes prisoners.**
* **Exempt categories generally apply to research with minors, except when specifically stated otherwise.**

Choose one of the following exemption categories for consideration and provide the information as requested under the corresponding category. **Delete all other categories that do not apply.** Upload the survey(s), instrument, or interview questionnaire/focus group guides to the Supporting Documents section of IRES IRB.

**FOR HIPAA ONLY - The investigator assures that the protected health information for which a Waiver of Authorization has been requested will not be reused or disclosed to any person or entity other than those listed in this application, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by an IRB.**

*Researchers are reminded that unauthorized disclosures of PHI to individuals outside of the Yale HIPAA-Covered entity must be accounted for in the “accounting for disclosures log”, by subject name, purpose, date, recipients, and a description of information provided. Logs are to be forwarded to the Deputy HIPAA Privacy Officer.*

**CHOOSE YOUR Category(IES) of EXEMPTION FROM FULL IRB REVIEW**

[ ]  ***(Category 1)*** 45 CFR 46.104(d)(1) Research not regulated by the FDA, 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.

1. **Describe the purpose of the study.**

Click here to enter text.

1. **Describe the target population.**

Click here to enter text.

1. **Describe the educational setting of the research and the practices that will be studied.** **If applicable, describe measures in place to ensure that educational practices subject to this research will not adversely impact the students' opportunity to learn required educational content or the assessment of the educators who provide instruction.**

Click here to enter text.

1. **Describe the procedures involved in the study, including how subjects will be accessed, and whether the project is evaluating an established educational program, or a novel program implemented as part of this project.**

Click here to enter text.

1. **Describe measures in place to ensure confidentiality of the data and privacy of subjects.**

Click here to enter text.

1. **How will consent, assent and/or parental permission be secured? Upload a copy of any documents/materials given to subjects.**

Click here to enter text.

1. **Describe the location of the study.** Click here to enter text.
	1. **Does this study include an international location?** [ ] Yes [ ]  No

**If yes, specify location:** Click here to enter text.

**(*Category 2*)** 45 CFR 46.104(d)(2) Research not regulated by the FDA 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: (Please indicate which criteria applies)

[ ] (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.

***This exemption category applies to research with minors ONLY if the research involves educational tests*** ***or the observation of public behavior when the investigator(s) do not participate in the activities being observed.***

1. **Describe the purpose of the study.** Click here to enter text.
2. **Describe the target population.** Click here to enter text.
3. **Describe the location of the study.**

Click here to enter text.

* 1. **Does this study include an international location?** [ ] Yes [ ]  No

**If yes, specify location:** Click here to enter text.

1. **Describe the procedures that will be used to recruit subjects.**

Click here to enter text.

1. **Describe how subjects will provide consent (and/or research authorization) to participate in the study.**

Click here to enter text.

1. **Describe the procedures that will be used to conduct the research. *(NOTE - If using enumerators, include the name of the agency, training provided to individuals at the agency, and the specific role in this research. If using a survey platform, name the platform.)***

Click here to enter text.

1. **If subjects’ identity can be readily ascertained directly or through identifiers linked to them, could any disclosure of their responses outside the research reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, educational advancement, or reputation?** [ ]  **Yes** [ ]  **No** [ ]  **NA**

**If YES –**provide the list of identifiers and describe how data will be secured to protect the privacy of subjects and maintain the confidentiality of the data, and, if applicable, the coding system that will be used.:

1. **If you are from Yale School of Medicine, School of Nursing, or another HIPAA covered entity (such as Psychology clinics) and wish to collect PHI without obtaining written HIPAA authorization, *–* a HIPAA waiver must be obtained. Describe why it would be impracticable to obtain the subject’s authorization for use/disclosure of this data:**

***(Category 3)* 45 CFR 46.104(d)(3)** 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: (please indicate which criteria applies-note: it may be more than one)

* (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.

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.

**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.**

**This category does not apply to research involving minors.**

1. **Describe the purpose of the study.** Click here to enter text.
2. **Describe the target population.** Click here to enter text.
3. **Describe the location of the study.**

Click here to enter text.

* 1. **Does this study include an international location?** [ ] Yes [ ]  No

**If yes, specify location:** Click here to enter text.

1. **Describe the procedures that will be used to recruit subjects.** Click here to enter text.
2. **Describe how subjects will provide consent (and research authorization) to participate in the study.** Click here to enter text.
3. **Describe the benign behavioral intervention studied in this research.** Click here to enter text.
4. **Describe the collection of data following the intervention.** Click here to enter text.

Click here to enter text.

1. **If subjects’ identity can be readily ascertained directly or through identifiers linked to them could any disclosure of the participants’ responses outside the research reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, educational advancement, or reputation?** [ ]  **Yes** [ ]  **No**

**If YES –**provide the list of identifiers and describe how data will be secured to protect the privacy of subjects and maintain the confidentiality of the data, and if applicable the coding system**:**

1. **Will the research involve deception regarding the nature or purposes of the research? \*Note this may include not fully disclosing the purpose of the study or omitting information in order to achieve unbiased research results\*** [ ]  **Yes** [ ]  **No**

**If YES - how will you inform the subjects of the potential use of deception?**

**Note: If such an agreement cannot be obtained, the exemption category will not apply. A non-exempt protocol must be submitted for IRB review.**

1. **If you are from Yale School of Medicine, School of Nursing, or another HIPAA covered entity and wish to collect PHI without obtaining written HIPAA authorization, HIPAA waiver must be obtained. Describe why it would be impracticable to obtain the subject’s authorization for use/disclosure of this data:**

Click here to enter text.

[ ]  **(*Category 4*)** **45 CFR 46.104(d)(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 (choose which one applies):

[ ] (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](https://www.federalregister.gov/select-citation/2017/01/19/45-CFR-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](https://www.federalregister.gov/select-citation/2017/01/19/45-CFR-164.501) or for “public health activities and purposes” as described under [45 CFR 164.512](https://www.federalregister.gov/select-citation/2017/01/19/45-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](https://api.fdsys.gov/link?collection=uscode&title=44&year=mostrecent&section=3501&type=usc&link-type=html) 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. 552](https://api.fdsys.gov/link?collection=uscode&title=5&year=mostrecent&section=552&type=usc&link-type=html)a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, [44 U.S.C. 3501](https://api.fdsys.gov/link?collection=uscode&title=44&year=mostrecent&section=3501&type=usc&link-type=html) *et seq.*

***Note: This exempt category will require a Waiver of HIPAA Authorization whenever the researcher does not have a direct healthcare relationship with the potential subjects and wishes to view identifiable records or samples. The waiver, if approved by the IRB, will allow you to access Protected Health Information (PHI) without authorization from the subjects.***

1. **Is an investigational drug or device being used to test the specimens in this research?**

[ ] Yes [ ]  No

*If you answered yes to this, under FDA regulations an exemption from IRB review cannot be given. You must complete a full application.*

1. **Describe the purpose of the study.**

Click here to enter text.

1. **List the information that will be recorded. Only those items listed on this application may be recorded.** Click here to enter text.
2. **Describe where the data/documents, records or specimens will be obtained from.** Click here to enter text.
	1. **Is the information publicly available?** [ ] Yes [ ]  No
	2. **Does this study include data from an international location?** [ ] Yes [ ]  No

 **If yes, specify location:** Click here to enter text.

**Describe the target population.**

1. **Describe how data will be recorded so that subjects will not be identified.**

Click here to enter text.

1. **Describe the procedures that will be used (e.g. what analysis will be performed on specimens or data).**

Click here to enter text.

1. **Request for waiver of HIPAA authorization:** *If applicable -* Describe why it would be impracticable to obtain the subject’s authorization for use/disclosure of this data

Click here to enter text.

[ ]  (***Category 5*) 45 CFR 46.104(d)(5)** Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval a governmental 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 (i)public benefit or service programs,(ii) procedures for obtaining benefits or services under those programs, (iii) possible changes in or alternatives to those programs or procedures, or (iv) 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.

***Note:*** *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.*

1. **Describe the purpose of the study.**

Click here to enter text.

1. **Describe the location of the study.** Click here to enter text.
	1. **Does this study include an international location?** [ ] Yes [ ]  No

**If yes, specify location:** Click here to enter text.

1. **Describe the target population.** Click here to enter text.
2. **Describe the programs, and/or benefits or services that will be studied, evaluated or examined.**

Click here to enter text.

1. **Provide URL to the website listing the project by the agency/department.**

Click here to enter text.

**(*Category 6*)** 45 CFR 46.104(d)(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.

***This category applies to those studies that do not involve the consumption by the subject of any type or volume of food that has any potential risk such as indigestion or vitamin deficiencies. This implies that the food ingested be considered a reasonable eating pattern. A study that involves the use of alcoholic beverages, vitamins, or supplements does not qualify as exempt from IRB review.***

1. **Describe the purpose of the study.**

Click here to enter text.

1. **Describe the location of the study.** Click here to enter text.
	1. **Does this study include an international location?** [ ] Yes [ ]  No

**If yes, specify location:** Click here to enter text.

1. **Describe the target population.** Click here to enter text.
2. **Describe the research activities that will be conducted.**

Click here to enter text.

1. **Describe the food(s) and/or food ingredient(s) being studied.**

Click here to enter text.