**HRP-503D - Exemption Request**

**Version 2025-1**

**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 Chairs or their 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.

**Important:**

* **VULNERABLE POPULATIONS:**
	+ **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.**
* **INTERNATIONAL RESEARCH:**
	+ **Research conducted at an international location, requires a completed International Checklist found in the IRES IRB library, which must be uploaded in Local Site Documents page in IRES IRB.**
* **MULTI-SITE RESEARCH:**
	+ **Reliance agreements are generally not executed as single IRB review of exempt research is not required.**
	+ **sIRB may be a possibility for exempt research with limited IRB review. Contact HRPP at** **hrpp@yale.edu** **to discuss the possibility of sIRB review.**
* **HIPAA Applicability**
	+ **Research with Protected Health Information will require authorization from participants OR a waiver of HIPAA Authorization. If you need a waiver of authorization, complete** [**the HIPAA Waiver Request**](#_REQUEST_FOR_A_1) **at the end of this form.**

Select one or more 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.

[ ]  ***(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 or tap here to enter text.

1. **Describe the target population.**

Click or tap here to enter text.

1. **Describe the educational setting of the research and the practices that will be studied.**

Click or tap here to enter text.

1. **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 or tap 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 or tap here to enter text.

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

Click or tap here to enter text.

1. **Describe how consent, assent and/or parental permission will be obtained.**

Click or tap here to enter text.

Most research using educational records is subject to FERPA. Use of personally identifiable education records generally cannot be released by schools or school clinics without written permission of the parent (if the student is a minor) or a student (adult). For more information about use of personally identifiable information in research, see HRP-331 - WORKSHEET - FERPA Compliance, in IRES IRB Library.

1. **Describe the location of the study.**

Click or tap here to enter text.

1. **If you are planning sharing of the data with external entities, describe how it will be achieved (what data will be shared, with whom, if sharing deidentified data, describe the deidentification process, etc.).**

Click or tap here to enter text.

**If you are collecting Protected Health Information without a signed authorization of the participant, you must** [**request a HIPAA waiver or alteration**](#_REQUEST_FOR_A_1) **at the end of this form.**

[ ]  **(*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 criterion 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 or tap here to enter text.

1. **Describe the target population.**

Click or tap here to enter text.

1. **Describe the location of the study.**

Click or tap here to enter text.

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

Click or tap here to enter text.

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

Click or tap here to enter text.

1. **Describe the procedures that will be used to conduct the research.**

Click or tap here to enter text.

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.

1. **If subjects’ identity can be readily ascertained directly or through identifiers linked to them, 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:**

Click or tap here to enter text.

1. **If you are planning sharing of the data with external entities, describe how it will be achieved (what data will be shared, with whom, if sharing deidentified data, describe the deidentification process, etc.).**

Click or tap here to enter text.

**If you are collecting Protected Health Information without a signed authorization of the participant, you must** [**request a HIPAA waiver or alteration**](#_REQUEST_FOR_A_1) **at the end of this form.**

***(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 criterion applies)**

[ ] (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 they 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 or tap here to enter text.

1. **Describe the target population.**

Click or tap here to enter text.

1. **Describe the location of the study.**

Click or tap here to enter text.

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

Click or tap here to enter text.

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

Click or tap here to enter text.

1. **Describe the benign behavioral intervention studied in this research.**

Click or tap here to enter text.

1. **Describe the collection of data following the intervention.**

Click or tap here to enter text.

1. **If subjects’ identity can be readily ascertained directly or through identifiers linked to them, 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:**

Click or tap here to enter text.

1. **Will the research involve deception regarding the nature or purposes of the research?** [ ]  **Yes** [ ]  **No**

Deception may include not fully disclosing the purpose of the study or omitting information in order to achieve unbiased research results. Prospective agreement to use of deception must be obtained from participants. If such agreement cannot be obtained, the exemption category will not apply. See the term *Deception* in the Consent Glossary (IRES IRB Library, Consent Forms tab) for an example of how it can be used in the consent forms.

1. **If you are planning sharing of the data with external entities, describe how it will be achieved (what data will be shared, with whom, if sharing deidentified data, describe the deidentification process, etc.).**

Click or tap here to enter text.

**If you are collecting Protected Health Information without a signed authorization of the participant, you must** [**request a HIPAA waiver or alteration**](#_REQUEST_FOR_A_1) **at the end of this form.**

[ ]  **(*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 criterion 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 that is subject to HIPAA. **This category does NOT apply to biospecimens. This category does not apply to investigators from non-HIPAA covered entities.**

[ ] (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that will be maintained in accordance to certain federal privacy standards.

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 or tap here to enter text.

**3) Describe the target population and dates of records to be reviewed.**

Click or tap here to enter text.

**4) Describe where the data/documents, records or specimens will be obtained from.**

Click or tap here to enter text.

* 1. **Is the information publicly available?** [ ] Yes [ ]  No
1. **If applicable, describe how data, including any data about biospecimens, will be recorded so that subjects will not be identified.**

Click or tap here to enter text.

1. **Describe the plan for analysis of the specimens or data.**

Click or tap here to enter text.

1. **List all other information, including health information, that will be recorded. Only those items listed on this application may be recorded.**

Click or tap here to enter text.

1. **If you are planning sharing of the data with external entities, describe how it will be achieved (what data will be shared, with whom, if sharing deidentified data, describe the deidentification process, etc.).**

Click or tap here to enter text.

**If you are collecting Protected Health Information without a signed authorization of the participant, you must** [**request a HIPAA waiver or alteration**](#_REQUEST_FOR_A_1) **at the end of this form.**

[ ]  (***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 or tap here to enter text.

1. **Describe the location of the study.**

Click or tap here to enter text.

1. **Describe the target population.**

Click or tap here to enter text.

1. **Describe the programs, and/or benefits or services that will be studied, evaluated or examined.**

Click or tap here to enter text.

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

Click or tap here to enter text.

1. **If you are planning sharing of the data with external entities, describe how it will be achieved (what data will be shared, with whom, if sharing deidentified data, describe the deidentification process, etc.).**

Click or tap here to enter text.

**If you are collecting Protected Health Information without a signed authorization of the participant, you must** [**request a HIPAA waiver or alteration**](#_REQUEST_FOR_A_1) **at the end of this form.**

**(*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 or tap here to enter text.

1. **Describe the location of the study.**

Click or tap here to enter text.

1. **Describe the target population.**

Click or tap here to enter text.

1. **Describe the research activities that will be conducted.**

Click or tap here to enter text.

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

Click or tap here to enter text.

1. **If you are planning sharing of the data with external entities, describe how it will be achieved (what data will be shared, with whom, if sharing deidentified data, describe the deidentification process, etc.).**

Click or tap here to enter text.

# REQUEST FOR A HIPAA WAIVER

**If you are collecting Protected Health Information without a signed authorization of the participant, you must** [**request a HIPAA waiver or alteration**](#_REQUEST_FOR_A_1) **at the end of this form.**

|  |
| --- |
| **Type of Waiver:**  |
| [ ]  **Full Waiver**The investigator will access, use, or disclose research participants’ PHI for the research study ***without obtaining authorization*** for that use or disclosure. | [ ]  **Alteration**The investigator will access, use, or disclose research participants’ PHI for the research study ***with verbal authorization*** for that use or disclosure or with a written authorization that does not include all of the required HIPAA statements.[[1]](#footnote-1) | [ ]  **Partial Waiver**The investigator will access, use, or disclose research participants’ PHI for ***a portion of the research*** e.g. for recruitment or identification of potential participants without obtaining authorization for that use or disclosure. |

**All questions below must be answered.**

|  |
| --- |
| 1. **What is the purpose for which you are requesting the HIPAA waiver/alteration?**
 |
|  |
| 1. **Describe Protected Health Information that is needed for this study** *[Include the anticipated data locations as well as the type of information that will be required]:*
 |
| **Data Location:** |
|  |
| **List Health Information:** |
|  |
| **Select HIPAA Identifiers:** |
| [ ] Name[ ] Address (all geographic subdivisions smaller than state, including street address, city county, and zip code)[ ] All elements (except years) of dates related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89)[ ] Telephone numbers[ ] Fax number[ ] Email address[ ] Social Security Number[ ] Medical record number | [ ] Health plan beneficiary number[ ] Account number[ ] Certificate or license number[ ] Vehicle identifiers and serial numbers, including license plate numbers[ ] Device identifiers and serial numbers[ ] Web URL[ ] Internet Protocol (IP) Address[ ] Finger or voice print[ ] Photographic image - Photographic images are not limited to images of the face.[ ] Any other characteristic that could uniquely identify the individual (please describe):  |
| 1. **Who Will Have Access to the Protected Health Information** *[Describe each person and organization by name or category. Examples include the research sponsor, the investigator, the research staff, and all research monitors.]***:**
 |
|  |
| 1. **Does the use or disclosure of protected health information involve no more than a minimal risk to the privacy of individuals?**
 |
| [ ] **YES** [ ] **NO** |
| 1. **Plan for Protecting Identifiers:** *[Describe how access to study data is controlled; who will monitor access to study data; where will identified information be stored]*

**Note:** All portable devices must contain encryption software, per University Policy 5100. If there is a technical reason a device cannot be encrypted please submit an exception request to the Information Security, Policy and Compliance Office by clicking on url http://its.yale.edu/egrc or email it.compliance@yale.edu. |
|  |
| 1. **Plan for Destroying Identifiers:** [Describe how, by whom and when identifiers will be destroyed; or provide justification for retaining the identifiers]
 |
|  |
| 1. **Explain why the research could NOT be practicably conducted without the waiver or alteration:**
 |
|  |
| 1. **Explain why the research could NOT be practicably conducted without access to and use of the protected health information:**
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|  |

**By submitting this form, you attest to the Privacy Board that the protected health information for which you have requested this Waiver of Authorization will not be reused or disclosed to any person or entity other than those listed above, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by an IRB.**

1. For HIPAA Required Statements, refer to HRPP Worksheet, HRP-330, HIPAA Authorization available in the IRES IRB Library. [↑](#footnote-ref-1)