



Yale University School of Medicine
Human Investigation Committee
Request for Exemption from Committee Review

A. Investigator and Project Information

Title of Project: _____

***Principal Investigator:** _____

Dept: _____

Address: _____

Telephone: _____ **E-mail:** _____ **Fax:** _____

PI's Association or Status with Yale: _____

Correspondent:

***Other Investigator(s):** _____

*Please indicate for each investigator listed if there is a protocol or project related conflict of interest (COI). For further information regarding COIs see the HIC policy on the web site at <http://info.med.yale.edu/hic/policy/index.html>

B. Human Subject Protection Training (HSPT) and Health Insurance Portability and Accountability Act (HIPAA) Training:

All individuals involved in the design, conduct or oversight of human research should have knowledge of the relevant ethical principles and federal, state and institutional requirements related to such research, appropriate to their role and obligations in human research. It is strongly recommended that study personnel for exempt projects complete the Yale Human Subject Protection training and the HIPAA for researchers training before initiating the research.

C. Principal Investigator/Faculty Advisor Assurance

As the Principal Investigator of this research project, I certify the following:

- The information provided in this application is complete and accurate.
- That I assume full responsibility for the protection of human subjects and the proper conduct of the research.
- That subject safety will be of paramount concern, and every effort will be made to protect subjects' rights and welfare.
- That all members of the research team will be kept apprised of research goals.
- That I am in compliance with the requirements set forth in the Yale University Faculty Handbook and qualify to serve as the Principal Investigator of this project or have acquired the appropriate approval from the Dean's office or office of the Provost, or Yale-New Haven Hospital general counsel.

Signature of PI

Date

Faculty Advisor (Print or Type Name) (If Applicable)

Date

**Signature of Advisor

Date

**As faculty advisor I assure that this project has scientific value and merit and that the PI has the necessary resources to complete the project and achieve the aims.

D. Instructions:

Certain research activities may be exempt from review, if confirmed by the HIC 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 of the categories noted below.

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.**

E. CATEGORY OF EXEMPTION FROM COMMITTEE REVIEW

(**Category 1**) 45 CFR 46.101(b)(1) Research conducted in established or commonly accepted educational settings, involving *normal educational practices*, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

1) Describe the purpose of the study

2) Describe the target population, including the expected number of subjects and expected duration of the study

3) Describe the educational setting of the research and the practices that will be studied

(**Category 2**) 45 CFR 46.101(b)(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), *survey procedures*, *interview procedures*, or *observation of public behavior*, **unless** the information is obtained and recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects; **and** any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

This exemption regarding educational tests is applicable to minor subjects. However, this exemption for research involving survey or interview procedures or observations of public behavior does not apply to research involving minors, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

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 HIC, will allow you to access Protected Health Information (PHI) without authorization from the subjects. To request the HIPAA waiver, complete question 7

- 1) Describe the purpose of the study**
- 2) Describe the target population including the expected number of subjects and the expected duration of the study**
- 3) Describe the procedures that will be used to recruit subjects, obtain consent, research authorization (or waiver), and conduct the research. Attach a copy of the written consent or research authorization form, if used. If written consent will not be used, give the text of the verbal statement used to obtain consent/assent. If requesting a waiver of HIPAA authorization, complete question 7.**
- 4) Clarify whether data will be recorded with or without identifiers**
- 5) Clarify whether disclosures will place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation**
- 6) Submit the survey(s), instrument or interview questionnaire that will be used.**
- 7) Request for waiver of HIPAA authorization:**

Describe why it would be impracticable to obtain the subject's authorization for use/disclosure of this data;

By signing this request for exemption, 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.

(Category 3) 45 CFR 46.101(b)(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, or observation of public behavior that is not exempt under item (2) above; **if** the human subjects are *elected or appointed public officials or candidates for public office*; **or** federal statute(s) require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

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 HIC, will allow you to access Protected Health Information (PHI) without authorization from the subjects. To request the HIPAA waiver, complete question 7

- 1) Describe the purpose of the study**
- 2) Describe the target population including the expected number of subjects and the**

expected duration of the study

3) Describe the procedures that will be used to recruit subjects, obtain consent, research authorization (or waiver), and conduct the research. Attach a copy of the written consent or research authorization form, if used. If written consent will not be used, give the text of the verbal statement used to obtain consent/assent. If requesting a waiver of HIPAA authorization, complete question 7.

4) Clarify whether data will be recorded with or without identifiers

5) Clarify whether disclosures will place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation

6) Submit the survey(s), instrument or interview questionnaire that will be used.

7) Request for waiver of HIPAA authorization:

Describe why it would be impracticable to obtain the subject's authorization for use/disclosure of this data;

By signing this request for exemption, 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.

- 1) (**Category 4**) 45 CFR 46.101(b)(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects

“Existing” is a key word here. It means that all the data, documents, etc. must already exist when the study is started. Note that any use of additional research material collected after research is initiated will disqualify the study from exempt status. This category solely applies to retrospective data collection, or use of existing samples. Also, “identified” or “linked” are key words. The investigator may not record identifiers.

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 HIC, will allow you to access Protected Health Information (PHI) without authorization from the subjects. To request the HIPAA waiver, complete question 6.

1) Describe the purpose of the study

2) Describe where the data/documents, records or specimens will be obtained from

3) Describe the target population, including the expected number of subjects and

expected duration of the study

4) Describe how data will be recorded so that subjects will not be identified

5) Describe the procedures that will be used

6) Request for waiver of HIPAA authorization:

Describe why it would be impracticable to obtain the subject's authorization for use/disclosure of this data;

By signing this request for exemption, 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.

(**Category 5**) 45 CFR 46.101(b)(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine methods and procedures of *public benefit or service programs*. (For example, a study of identifiable welfare data.)

NOTE: The following criteria must be satisfied to invoke the exemption for research and demonstration projects examining "public benefit or service programs":

- The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).
- The research or demonstration project must be conducted pursuant to specific federal statutory authority.
- There must be no statutory requirement that the project be reviewed by an Institutional Review Board (IRB).
- The project must not involve significant physical invasions or intrusions upon the privacy of participants.

1) Describe the purpose of the study

2) Describe the target population, including the expected number of subjects and expected duration of the study

3) Describe the programs, and/or benefits or services that will be studied, evaluated or examined

(**Category 6**) 45 CFR 46.101(b)(6) Taste and food quality evaluation and consumer acceptance studies, **if** wholesome foods without additives are consumed, **or** a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or an agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the EPA or the USDA.

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 HIC review.

- 1) Describe the purpose of the study**
- 2) Describe the target population, including the expected number of subjects and expected duration of the study**
- 3) Describe the research activities that will be conducted**
- 4) Describe the food and/or food ingredient being studied**