Hawaii Pacific Health
55 Merchant Street • Honolulu, Hawaii 96813 • hawaiipacifichealth.org

Request for Exemption Determination

This request form should be used if you wish to obtain a written opinion that a proposed project is exempt from the requirement for IRB review or does not require IRB review because the project does not involve research or does not involve human subjects.

Please submit the completed form together with the following:

- A copy of the protocol or a detailed description of the research;
- Copies of all data collection tools including case report forms and surveys; and
- Copies of any interview or focus group questions that will be used.

If this research will be conducted by a covered entity and involves the use and/or disclosure of protected health information (PHI), an authorization or waiver of authorization for the use/disclosure of the PHI might be required. If you wish to request a waiver of authorization from the HPH Privacy Board, please complete the HPH HIPAA Full Waiver request form.

- Section I of this form asks for general information about the investigator and research staff.
- Sections II and III of this form ask for general information that would exclude the project from an exemption determination. If you are unable to provide the requested confirmations for Sections II and III, the research would not be exempt.
- Section IV of this form asks for information to determine if the research is exempt under the categories of exempt research found at 45 CFR 46(b).
- Section V of this form asks for information to determine if the activity is research. The regulations outlining the requirement for IRB review applies to research involving human subjects. If you wish to obtain an opinion that your project does not involve research, you should complete Section V of the request form.
- Sections VI and VII of this form ask for information to determine whether the activity is research that does not involve human subjects. If you wish to obtain an opinion that your project does not involve human subjects, you should complete Section VI or VII of the request form.

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Request for Exemption Determination

Sponsor _____ Sponsor Protocol No. _____

I. Principal Investigator (PI) Information: Please provide information about the person legally responsible for the conduct of the research.

1.	PI Name:		
2.	PI Company Name:		
3.	PI Mailing Address: (street, city, state/province, zip, country)		
4.	PI Phone: ( )	PI Fax: ( )	PI E-mail:
5.	Preferred method of contact: (mark one) ☐ Fax ☐ E-mail ☐ Regular Mail		

Other contact information (optional):

6.	Study Coordinator or Other Contact Person Name:		
7.	Study Coordinator / Other Contact Person Phone: ( )	Study Coordinator / Other Contact Person Fax: ( )	Study Coordinator / Other Contact Person E-mail:
8.	Study Coordinator's/ Other Contact Person's preferred method of contact: (mark one) ☐ Fax ☐ E-mail		

9.	Title of research project:

II. Please confirm that this investigation does not involve research on an FDA regulated product such as a drug or device. HPH does not provide exemption determinations for investigations of products regulated by the FDA except for taste and food quality evaluation and/or consumer acceptance studies (Category 6 of Section IV below).

III. Please confirm that you do not intend to include prisoners in this research. If prisoners will be included, the research is not exempt under federal regulation 45 CFR 46.101(b).

IV. Categories of Exemption under 45 CFR 46.101(b)

The categories of exempt research are found at federal regulation 45 CFR 46.101(b). This regulation is included at the end of this request form. Please review the requirements and answer the questions below that relate to the exemption category most appropriate for your research.

	Category 1 [45 CFR 46.101(b)(1)] ☐ NA		
1.	Will this research involve 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? *If yes, please explain why you believe this research involves normal educational practices:	*Yes ☐	No ☐
2.	Please also explain why you believe this research will be conducted in an established or commonly accepted educational setting:		

	Category 2 and 3 [45 CFR 46.101(b)(2 and 3)] ☐ NA		
1.	Place an "X" by the following statements that are true: ☐ The research involves educational tests (cognitive, diagnostic, aptitude, achievement) ☐ The research involves survey procedures* ☐ The research involves interview procedures* ☐ The research involves observation of public behavior* *If the research involves children, the exemption for this category is limited to educational tests and observation of public behavior where the investigator(s) will NOT participate in the activities being observed.		
2.	Will this project include children as research subjects? *If the research does involve children, the exemption for this category is limited to educational tests and observation of public behavior where the investigator(s) will NOT participate in the activities being observed.	*Yes ☐	No ☐
3.	Will the information obtained be recorded in such a manner that participants CANNOT be identified directly or through identifiers linked to the participants? *HPH uses the HIPAA Privacy Rule standards for de-identification found at 45 CFR 164.514(b), (the text of the standard is included at the end of this form).* *If no, please answer the next question under this category (3a).	Yes ☐	*No ☐
3a.	If the information would be recorded in such a manner that subjects can be identified directly, or through identifiers linked to the subjects, would 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 or reputation? *HPH believes disclosure of health information could reasonably place participants at risk.* *If yes, the research is not exempt.	*Yes ☐	No ☐
4.	Are all of subjects of the research either elected or appointed public officials or candidates for public office?	Yes ☐	No ☐
5.	Does a federal statute require without exception that the confidentiality of personally identifiable information be maintained throughout the research and thereafter? *If yes, please provide a citation to the federal statute.	*Yes ☐	No ☐

	Category 4 [45 CFR 46.101(b)(4)] ☐ NA		
1.	Does the research involve the use of data, documents, records, pathological specimens, or diagnostic specimens that are currently existing (not being prospectively collected)?	Yes ☐	No ☐

2.	Are these documents or specimens publicly available?	Yes ☐	No ☐
3.	Will the investigator record any information in a manner such that subjects can be identified either directly or through identifiers linked to the subjects? *HPH uses the HIPAA Privacy Rule standards for de-identification found at 45 CFR 164.514(b) (the text is included at the end of this form).*	Yes ☐	No ☐

	Category 5 [45 CFR 46.101(b)(5)] ☐ NA		
1.	Is this research being conducted by a federal Department or Agency head?	Yes ☐	No ☐
2.	Has the research been approved by a federal Department or Agency head? *If yes, please provide documentation of approval.	*Yes ☐	No ☐
3.	Please place an "X" by the following statements that are true: ☐ This project is designed to study, evaluate or otherwise examine a federal public benefit or service program. ☐ This project is designed to study, evaluate or otherwise examine procedures for obtaining benefits or services under a federal public benefit program. ☐ This project is designed to study, evaluate or otherwise examine possible changes in or alternatives to a federal public benefit or service program or procedures used by the program. ☐ This project is designed to study, evaluate or otherwise examine possible changes in methods or levels of payment for benefits or services under a federal public benefit or service program.		
4.	The program being studied must deliver a public benefit program or service. Please describe the program or service being studied.		
5.	Is there a statutory requirement for IRB review of research on this benefit program? *If yes, then this research is not exempt.	*Yes ☐	No ☐

	Category 6 [45 CFR 46.101(b)(6)] ☐ NA		
1.	Does this research involve a taste and food quality evaluation and/or consumer acceptance studies?	Yes ☐	No ☐

2.	Please place an "X" by the following statements that are true: ☐ Only wholesome foods without additives will be consumed. ☐ The food consumed will contain a food ingredient that is at or below the level found to be safe and is for a use found to be safe. ☐ A food will be consumed that contains an agricultural chemical or environmental contaminant that is at or below the level found to be safe by the Food and Drug Administration. ☐ A food will be consumed that contains an agricultural chemical or environmental contaminant that is at or below the level approved by the Environmental Protection Agency. ☐ A food will be consumed that contains an agricultural chemical or environmental contaminant that is at or below the level approved by the Food Safety and Inspection Service of the Department of Agriculture.

V. Projects that do not involve research			
1.	Is the project a systematic investigation designed to develop or contribute to generalizable knowledge? *If no, please provide an explanation of why the project is not research under the definition above.	Yes ☐	*No ☐

VI. Projects not involving human subjects			
1.	Does the project involve any intervention or interaction with a living individual?	Yes ☐	No ☐
2.	Does the project involve obtaining information about living individuals?	Yes ☐	No ☐
3.	Will the information obtained include any of the following? a. ☐ Information about behavior that occurs in a situation in which an individual can reasonably expect that no observation or recording is taking place. b. ☐ Information provided for specific purposes by an individual in a setting in which the individual could reasonably expect the information would not be made public. c. ☐ No, no information will be collected that fits into boxes a and b above.		

VII. Projects not involving human subjects because anonymous or coded samples will be used (based on the OHRP guidance of the same title)			
1.	Does the project involve obtaining biological samples from living individuals?	Yes ☐	No ☐

2.	Was the information or samples collected specifically for this project or were they collected for another purpose? ☐ They were collected for this project. ☐ They were collected for another purpose.		
3.	Will the investigator be able to discover the identity of the individual?	Yes ☐	No ☐
4.	Will the information or samples include any codes with links to the identity of the individual? *If yes, place an "X" by the following statements that are true (at least one must be selected): ☐ The key to decipher the code will be destroyed before the research begins. ☐ There is an agreement between the investigator and the holder of the key that prohibits the release of the key to the investigators under any circumstances, until the individuals are deceased. ☐ There are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; ☐ There are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased. ☐ Other (specify):_____	*Yes ☐	No ☐

NAME OF PERSON COMPLETING THIS FORM: Please tell us who you are and how we can contact you if we have questions about the information in this form.

_____ Printed or Typed Name of Person Completing This Form

_____ Company & title

( ) _____ Phone number

( ) _____ Fax number

_____ E-mail address (optional)

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Categories of Exempt Research found at Federal Regulation 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.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

ii) 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.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) The human subjects are elected or appointed public officials or candidates for public office; or

(ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(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.

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:

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.

(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.

HIPAA Privacy Rule Standard for De-identification found at 45 CFR 164.514(b):

The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:

(A) Names;

(B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:

(*1*) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and

(*2*) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

(C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;

(D) Telephone numbers;

(E) Fax numbers;

(F) Electronic mail addresses;

(G) Social security numbers;

(H) Medical record numbers;

(I) Health plan beneficiary numbers;

(J) Account numbers;

(K) Certificate/license numbers;

(L) Vehicle identifiers and serial numbers, including license plate numbers;

(M) Device identifiers and serial numbers;

(N) Web Universal Resource Locators (URLs);

(O) Internet Protocol (IP) address numbers;

(P) Biometric identifiers, including finger and voice prints;

(Q) Full face photographic images and any comparable images; and

(R) Any other unique identifying number, characteristic, or code; and (ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.