

Request for Exemption Determination

Instructions:

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 may be required.

I. STUDY INFORMATION	
Researcher/Principal Investigator:	
Protocol Number:	
Protocol Title:	
Funding Agency(ies) and/or Sponsor name:	
Grant Number:	

II. CONTACT INFORMATION			
PRIMARY CONTACT: <i>(For phone calls, documents, and correspondence)</i>			
<i>Please check appropriate box:</i>	<input type="checkbox"/> SPONSOR/CRO	<input type="checkbox"/> INVESTIGATIVE SITE	<input type="checkbox"/> OTHER (specify):
Name:	Title:		
Company:			
MAILING ADDRESS:			
Address:			

II. CONTACT INFORMATION			
City:		State:	
Phone:		Fax:	
Email:			
PHYSICAL ADDRESS: (if different than above)			
Address:			
City:		State:	
Zip / Postal code:			
SECONDARY CONTACT:			
Please check appropriate box:		<input type="checkbox"/> SPONSOR/CRO	<input type="checkbox"/> INVESTIGATIVE SITE
		<input type="checkbox"/> OTHER (specify): ____	
Name:		Title:	
Company:			
MAILING ADDRESS:			
Address:			
City:		State:	
Zip / Postal code:			
Phone:		Fax:	
Email:			
PHYSICAL ADDRESS: (if different than above)			
Address:			
City:		State:	
Zip / Postal code:			
ELECTRONIC INVOICES SHOULD BE SENT TO:			
Name:		Title:	
Company:			
Address:			

II. CONTACT INFORMATION

City:

State:

Zip / Postal code:

Phone:

Fax:

Email:

III. PROJECT INFORMATION

1. Has a request for exemption determination been reviewed and disallowed by any other Ethics Review Board for this project? Yes* No

*If Yes, please attach a letter of explanation including written comments from other Ethics Board.

2. Does the researcher hold a position with a hospital, university or other institution that requires review of his/her research by a local Ethics Review Board? Yes* No

*If Yes, Institutional Jurisdiction Waiver must be attached.

3. Is this study funded or supported (in whole or part) by a federal department or agency?
 Yes* No

*If Yes, please list the funding agency:

4. Are you required to submit this study to the FDA prior to the study's initiation or are results of this study going to be submitted to the FDA as part of an application for research or marketing permit?
 Yes No

IV. PROJECTS INVOLVING HUMAN SUBJECTS

1. Does the project involve human subjects? Yes* No

*If Yes, please indicate if the protocol design requires the enrollment of any of the vulnerable populations listed below. Check all that apply.

<input type="checkbox"/> Pregnant Women/Fetuses	<input type="checkbox"/> Prisoners
<input type="checkbox"/> Handicapped	<input type="checkbox"/> Economically Disadvantaged
<input type="checkbox"/> Mentally Disabled	<input type="checkbox"/> Educationally Disadvantaged
<input type="checkbox"/> Pediatric Subjects/Minors; age range:	<input type="checkbox"/> Other (specify):
<input type="checkbox"/> No vulnerable populations will be enrolled	

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 information will be collected related to items a and b above.

V. CATEGORIES OF EXEMPTION UNDER 45 CFR 46.101(B)

The categories of exempt research are found at federal regulation 45 CFR 46.101(b). Refer to the regulation when answering the questions below.

Category 1 [45 CFR 46.101(b)(1)] NA

1. Will this Research be conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
- a. research on regular and special education instructional strategies, or
 - b. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods?

Yes* No

*If Yes, describe how this category applies to the research:

2. Please also explain why you believe this research will be conducted in an established or commonly accepted educational setting:

Categories 2 and 3 [45 CFR 46.101(b)(2 and 3)] NA

1. Check any of 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

2. Will this project include children as research subjects? Yes* No

*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.

V. CATEGORIES OF EXEMPTION UNDER 45 CFR 46.101(B)

3. Will the information obtained be recorded in such a manner that participants CANNOT be identified directly or through identifiers linked to the participants? (Refer to HIPAA Privacy Rule standards for de-identification found at 45 CFR 164.514(b)). Yes No*

*If No, please answer the next question under this category (3a).

- 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? Yes* No

*If Yes, the research is not exempt.

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? Yes* No

*If Yes, please provide a citation to the federal statute.

6. Describe how this category applies to the research:

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 currently exist (not being prospectively collected)? Yes No

2. Are these documents or specimens publicly available? Yes No

V. CATEGORIES OF EXEMPTION UNDER 45 CFR 46.101(B)

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? (*Refer to HIPAA Privacy Rule standards for de-identification found at 45 CFR 45.514(b)*). Yes No

4. Describe how this category applies to the research:

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? Yes* No

*If Yes, please provide documentation of approval.

3. Please check the following statements that are true:

- This project is designed to study, evaluate or otherwise examine a federal public benefit or service programs.
- This project is designed to study, evaluate or otherwise examine procedures for obtaining benefits or services under a federal public benefit or service 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. Is there a statutory requirement for IRB review of research on this benefit program? Yes* No

*If Yes, then this research is not exempt.

5. Describe how this category applies to the research including the a description of the public benefit program or service being studied:

V. CATEGORIES OF EXEMPTION UNDER 45 CFR 46.101(B)
<u>Category 6 [45 CFR 46.101(b)(6)]</u> <input type="checkbox"/> NA
<p>1. Does this research involve a taste and food quality evaluation and/or consumer acceptance studies? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>2. Please check any of the following statements that are true:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Only wholesome foods without additives will be consumed. <input type="checkbox"/> 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. <input type="checkbox"/> 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. <input type="checkbox"/> 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 or by the Food Safety and Inspection Service of the Department of Agriculture.
<p>3. Describe how this category applies to the research:</p>

VI. PERSON COMPLETING FORM	
<p>I certify that the information contained in this form is complete and accurate and that no facts have been suppressed or misstated. I am requesting for Total IRB to review the information submitted and provide approval or disapproval information. I understand that Total IRB has the authority to oversee this study and suspend the research study at this site if necessary to protect the rights and welfare of the study subjects. I agree to provide all information requested to conduct reviews of this study on time.</p>	
<p>_____</p> <p>Form Completed By</p>	<p>_____</p> <p>Date</p>
<p>_____</p> <p>Title, Company</p>	
<p>Phone:</p>	<p>Email:</p>