



LIBERTY IRB
An Independent Central IRB



Request for Determination of Exemption

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
- Signed Submission letter requesting exemption
- Signed and dated curriculum vitae
- Medical license (if applicable)

There is no expiration date on its IRB exemption determinations; however, any future changes to the project may affect its exempt status. You should contact Liberty IRB regarding these changes before implementing them.

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.

- 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). If you wish to obtain an opinion that you are doing research, it does involve human subjects, but that it should be exempt under these categories, you should complete Section IV of the request form.
- 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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Sponsor _____

Section 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) <input type="checkbox"/> Fax <input type="checkbox"/> E-mail <input type="checkbox"/> Regular Mail		

Other contact information:

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) <input type="checkbox"/> Fax <input type="checkbox"/> E-mail		

9.	Title of research project:
10.	Study is: Single Center <input type="checkbox"/> Multi-center <input type="checkbox"/> You are the PI of the multi-center trial <input type="checkbox"/>



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

Section 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).

Section 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)		<input type="checkbox"/> NA	
1.	<p>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?</p> <p>*If yes, please explain why you believe this research involves normal educational practices:</p>	*Yes <input type="checkbox"/>	No <input type="checkbox"/>
2.	<p>Please also explain why you believe this research will be conducted in an established or commonly accepted educational setting:</p>		



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Category 2 and 3: 45 CFR 46.101(b)(2 and 3)		<input type="checkbox"/> NA	
1.	Place an "X" by the following statements that are true: <input type="checkbox"/> The research involves educational tests (cognitive, diagnostic, aptitude, achievement) <input type="checkbox"/> The research involves survey procedures* <input type="checkbox"/> The research involves interview procedures* <input type="checkbox"/> 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 <input type="checkbox"/>	No <input type="checkbox"/>
3.	Will the information obtained be recorded in such a manner that participants CANNOT be identified directly or through identifiers linked to the participants? *If no, please answer the next question under this category (3a).	Yes <input type="checkbox"/>	*No <input type="checkbox"/>
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? . *If yes, the research is not exempt.	*Yes <input type="checkbox"/>	No <input type="checkbox"/>
4.	Are all of subjects of the research either elected or appointed public officials or candidates for public office?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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 <input type="checkbox"/>	No <input type="checkbox"/>



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Category 4: 45 CFR 46.101(b)(4)		<input type="checkbox"/> NA	
1.	Does the research involve the use of data, documents, records, pathological specimens, or diagnostic specimens that are <u>currently</u> existing (not being prospectively collected)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
2.	Are these documents or specimens publicly available?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Category 5: 45 CFR 46.101(b)(5)		<input type="checkbox"/> NA	
1.	Is this research being conducted by a <u>federal</u> Department or Agency head?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
2.	Has the research been approved by a <u>federal</u> Department or Agency head? *If yes, please provide documentation of approval.	*Yes <input type="checkbox"/>	No <input type="checkbox"/>
3.	Please place an "X" by the following statements that are true: <ul style="list-style-type: none"> <input type="checkbox"/> This project is designed to study, evaluate or otherwise examine a federal public benefit or service program. <input type="checkbox"/> This project is designed to study, evaluate or otherwise examine procedures for obtaining benefits or services under a federal public benefit program. <input type="checkbox"/> 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. <input type="checkbox"/> 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.		



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5.	Is there a statutory requirement for IRB review of research on this benefit program? *If yes, then this research is not exempt.	*Yes <input type="checkbox"/>	No <input type="checkbox"/>
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Category 6: 45 CFR 46.101(b)(6)	<input type="checkbox"/> NA
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1.	Does this research involve a taste and food quality evaluation and/or consumer acceptance studies?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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2.	<p>Please place an "X" by the following statements that are true:</p> <p><input type="checkbox"/> Only wholesome foods without additives will be consumed.</p> <p><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.</p> <p><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.</p> <p><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.</p> <p><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 Food Safety and Inspection Service of the Department of Agriculture.</p>		
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Section V Projects that do not involve research			
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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 <input type="checkbox"/>	*No <input type="checkbox"/>
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Section VI Projects not involving human subjects			
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1.	Does the project involve any intervention or interaction with a living individual?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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2.	Does the project involve obtaining information about living individuals?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
3.	Will the information obtained include any of the following? a. <input type="checkbox"/> Information about behavior that occurs in a situation in which an individual can reasonably expect that no observation or recording is taking place. b. <input type="checkbox"/> 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. <input type="checkbox"/> No, no information will be collected that fits into boxes a and b above.		

Section 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 <input type="checkbox"/>	No <input type="checkbox"/>
2.	Was the information or samples collected specifically for this project or were they collected for another purpose? <input type="checkbox"/> They were collected for this project. <input type="checkbox"/> They were collected for another purpose.		
3.	Will the investigator be able to discover the identity of the individual?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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): <input type="checkbox"/> The key to decipher the code will be destroyed before the research begins. <input type="checkbox"/> 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. <input type="checkbox"/> 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; <input type="checkbox"/> There are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased. <input type="checkbox"/> Other (specify): _____	*Yes <input type="checkbox"/>	No <input type="checkbox"/>



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NAME OF PERSON COMPLETING THIS FORM:		
<hr/>		
Printed or Typed Name of Person Completing This Form		Company & title
()	()	
Phone number	Fax number	E-mail address (optional)