

California Baptist University IS MY RESEARCH EXEMPT?

Exemption Categories under Federal Regulations: 45 CFR 46.101(b)

I. Introduction and instructions

“Exempt” is a federal research classification established in federal regulation 45 CFR 46.101(b), which identifies six exempt categories (listed at the end of this document) for human-subjects research. A copy of the entire federal regulation is available on the OIRPA/IRB website. If federally sponsored and/or funded research fits the exempt category it does not require a formal IRB review. However, at CBU **ALL** research conducted by CBU students, faculty, and staff—whether or not the research is sponsored or funded by the federal government—requires IRB review and approval *prior* to beginning the research. But, research qualifying as exempt faces fewer requirements and restrictions. For example, research projects confirmed by the IRB as exempt do not have a one-year time limit and, consequently, do not require submitting an application to continue the research if it extends beyond one year.

Please review the federal exempt requirements and answer the applicable questions below to determine if your research might qualify as exempt. CBU research qualifying as exempt typically does so by conforming to one of the first two, maybe three federal categories.

If it appears your research is exempt, *please submit a complete Form A* (available on the OIRPA/IRB website) to the IRB for review and potential confirmation; this application process is explained in the CBU *IRB Handbook*.

IMPORTANT: Faculty members who **require their students to complete a class assignment involving exempt research with human subjects** must consult the *IRB Handbook* for the appropriate IRB instructions and actions. Using a Form A, B, or C, cited in this document, is **not** appropriate; an *Exempt Student Research Declaration* is the required form.

CATEGORY 1 - 45 CFR 46.101(b)(1)

Not Applicable

(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.	Does the 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 make certain these facts are explained clearly in <i>Research Description</i> accompanying the completed Form A submitted to the CBU IRB.	*Yes <input type="checkbox"/>	No <input type="checkbox"/>
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CATEGORIES 2 and 3 - 45 CFR 46.101(b)(2 and 3)

Not Applicable

(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.

1.	One or more of the following statements <i>must be true</i> : <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 observing public behavior If at least one category listed above is true, now determine if the research complies with the additional conditions appearing on the next page.		
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2.	Does this project include children (minors under age 18) as research subjects? *If the research <i>involves minor children</i> , use Form B (or C, if appropriate); EXCEPT if the research is limited to educational tests and observation of public behavior where the investigator(s) do NOT participate in the activities being observed, then Form A is appropriate.	*Yes <input type="checkbox"/>	No <input type="checkbox"/>
3.	Is the data/information obtained recorded in such a manner that participants CANNOT be identified directly or through identifiers linked to the participants? <i>CBU uses the HIPAA Privacy Rule standards for de-identification found at 45 CFR 164.514(b), (the standard is included at the end of this document)</i> . Please note, if a code is kept that links the information to the subject, then subjects can be identified and the appropriate answer here is "no." *If no , please answer the next question, (3a).	Yes <input type="checkbox"/>	*No <input type="checkbox"/>
3a.	If the data/information are recorded in such a manner that subjects <i>can be</i> 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? <i>CBU believes disclosing health information could reasonably place participants at risk.</i> *If yes , the research is not exempt, use Form B (or C, if appropriate).	*Yes <input type="checkbox"/>	No <input type="checkbox"/>
Even if research is not exempt under Category 2, in certain cases it may still be exempt under CATEGORY 3 : (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), <i>if</i> : (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 is maintained throughout the research and thereafter.			
1.	Are subjects in the research either elected or appointed public officials or candidates for public office?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
2.	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 federal statute number citation in the <i>Research Description</i> accompanying the completed Form A submitted to the CBU IRB.	*Yes <input type="checkbox"/>	No <input type="checkbox"/>

CATEGORY 4 - 45 CFR 46.101(b)(4) <input type="checkbox"/> Not Applicable (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.			
1.	Does the research involve the use of data, documents, records, pathological specimens, or diagnostic specimens that currently exist? (this means that no information is being prospectively collected, and all the information is already in existence at this time).	*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.	Does the investigator record any information in a manner such that subjects can be identified either directly or through identifiers linked to the subjects? <i>CBU 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)</i> . Please note that if a code is kept that links the information to the subject, then subjects can be identified and the answer is "yes," and the research is not exempt.	Yes <input type="checkbox"/>	No <input type="checkbox"/>

<p>Even if the research uses information or biological specimens not qualifying as exempt under b(4), it may still qualify as exempt research based on the OHRP guidance entitled "Guidance on Research Involving Coded Private Information or Biological Specimens." See: http://www.hhs.gov/ohrp/policy/cdebiol.html</p>			
1.	<p>Does the project involve obtaining biological samples from living individuals? *If yes, the research does not qualify as exempt; use Form B (or C, if appropriate).</p>	*Yes <input type="checkbox"/>	No <input type="checkbox"/>
2.	<p>Are the information or samples collected specifically for this research project or were they collected previously for another purpose? <input type="checkbox"/> *They are collected for this project. <input type="checkbox"/> They were collected for another purpose. *If collected for this project, the research does not quality as exempt; use Form B (or C, if appropriate).</p>		
3.	<p>Can the investigator discover the identity of the individuals providing the information or biological specimens? *If yes, the research does not qualify as exempt; use Form B (or C, if appropriate).</p>	*Yes <input type="checkbox"/>	No <input type="checkbox"/>
4.	<p>Does 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 is 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:</p>	*Yes <input type="checkbox"/>	No <input type="checkbox"/>

<p>CATEGORY 5 - 45 CFR 46.101(b)(5) <input type="checkbox"/> Not Applicable (5) Research and demonstration projects which are conducted by or subject to the approval of a federal 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.</p>			
1.	<p>Is this research being conducted for or sponsored by a <u>federal</u> department or agency?</p>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
2.	<p>Is the research project approved by a <u>federal</u> department or agency head? *If yes, please attach the approval documentation to the submitted Form A.</p>	*Yes <input type="checkbox"/>	No <input type="checkbox"/>

3.	<p>Does the research comply with one or more of the following statements:</p> <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. <p>*If yes, then the research is exempt; if no, use Form B (or C, if appropriate).</p>	*Yes <input type="checkbox"/>	No <input type="checkbox"/>
4.	<p>The program being studied must deliver a public benefit program or service. Please fully describe the program or service being studied in the <i>Research Description</i> accompanying the Form A submitted to the CBU IRB.</p>		
5.	<p>Is there a statutory requirement for IRB to review research on this demonstration project?</p> <p>*If yes, then this research is not exempt; use Form B (or C, if appropriate).</p>	*Yes <input type="checkbox"/>	No <input type="checkbox"/>

<p>CATEGORY 6 - 45 CFR 46.101(b)(6) <input type="checkbox"/> Not Applicable</p> <p>(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.</p>			
1.	<p>Does this research involve taste and food quality evaluation and/or consumer acceptance studies?</p>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
2.	<p>Does the proposed research comply with all the following statements:</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. <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>*If yes, then the research is exempt; if no, use Form B (or C, if appropriate).</p>	*Yes <input type="checkbox"/>	No <input type="checkbox"/>

II. PROJECTS THAT DO NOT INVOLVE RESEARCH The definition of research is “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” If the project is not research, then IRB review is not required and, therefore, is exempt.			
1.	Is the project a systematic investigation designed to develop or contribute to generalizable knowledge? *If no , a Form A is still required; based on the above definition, provide an explanation for why the project is not research in the <i>Research Description</i> accompanying the Form A submitted to the CBU IRB.	Yes <input type="checkbox"/>	*No <input type="checkbox"/>

III. PROJECTS NOT INVOLVING HUMAN SUBJECTS If a research project does not involve human subjects, then IRB review is not required, but submitting a Form A is still required. The definition of a human subject is “a living individual about whom an investigator conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.			
1.	Does the project involve any intervention or interaction with a living individual? *The answer must be “ No ” in order for the research to qualify as exempt.	Yes <input type="checkbox"/>	*No <input type="checkbox"/>
2.	Does the project involve obtaining identifiable private information from <i>living</i> individuals? *The answer must be “ No ” in order for the research to qualify as exempt.	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Exempt Research Categories 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 a federal 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 in 45 CFR 164.514(b)

The following identifiers for individuals, 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.