

# INSTRUCTIONS TO COMPLETE APPLICATION FOR EXEMPT REVIEW

THIS IS A NEW APPLICATION FORM WITH A FILL-IN FORMAT. IT IS CURRENTLY IN BETA TESTING.

Proposed educational, behavioral, and social science research submitted for IRB review often presents low risk of harm to participants especially if the participants' identifiers are removed. The federal regulations at [45 CFR 46.104](#) allow for eight categories of minimal risk research activities that may be exempt from formal IRB review. Six of these categories are recognized by the [CSULB IRB](#) (or see Section 2 below).

Research that is greater than minimal risk does not qualify for an exempt determination. Greater than minimal risk means that the probability and magnitude of harm or discomfort anticipated for the proposed research is greater than those risks ordinarily encountered in daily life. Greater than minimal risk research is reviewed by the convened IRB.

Exempt review **does not** apply to research with prisoners except for research aimed at a broader subject population that incidentally includes prisoners. Exempt category 2, subsection 2(iii), and category 3 do not apply to research with children.

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Exempt from IRB review is determined by an IRB member or a qualified professional designated by the CSULB IRB to review an application for exempt review. The reviewer can determine if the application is exempt or deny the application an exempt determination.

After reviewing the application, the reviewer will determine if the application is exempt, the reviewer will indicate the determination in item #38 on the application. The IRB will then send a notice to the PI of the determination decision. There is no IRB expiration date for exempt research. Exempt research can be modified by submitting an amendment.

## **An exempt application can be DENIED:**

- 1) If any student, staff, faculty, etc. named on the application does not have current CITI completed.
- 2) If the proposed research activities are not listed in any of the [six exempt eligible categories](#). (The proposed research will likely require expedited review by the IRB or review by the convened IRB.)
- 3) If the proposed research is a survey or interview of a sensitive topic such as childhood trauma, sexual abuse, domestic violence, suicide, criminal activity, or psychiatric problems.
- 4) If the proposed research activities are more than minimal risk or involve prisoners or involve children for research activities in category 2, subsection 2(iii), or in category 3.

A denied Exempt Review Application can either be revised and resubmitted for another exempt review or a new application can be completed for [Expedited and Standard Review](#).

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The Application for Exempt Review below has two sections. The first section asks for information about the PI, other researchers, and details about the proposed research.

The second section has a list of Proposed Research Activities and exempt categories. The PI will complete the first section and select the Proposed Research Activities choice in the second section that most closely matches their proposed research. Check the exempt category to ensure the category is applicable for the Proposed Research Activities.

If none of the exempt categories apply to the Proposed Research Activities, do not submit the application. Either revise details of the proposed research on the exempt application or submit an [Expedited and Standard Review Form](#) (for Expedited and Full Board Review).

Submission of an application for Exempt Review in IRBNet should only have three attachments: (i) Application for Exempt Review, (ii) Informed Consent Form(s) and, **(iii) Appendices**. In the appendices, please combine all the following items into a single file and list them in alphabetical order, e.g., Appendix-A: Recruitment flyer, Appendix-B: Permission Letter, Appendix-C: Faculty Advisor Letter, Appendix-D: surveys, interview questions, etc.).

# APPLICATION FOR EXEMPT REVIEW

Enter requested information where prompted: "Click or tap here to enter text." or enter text in gray box . Where applicable click on the box . If Not Applicable enter N/A.

## Section 1: People & Research

<b>Study Title:</b>
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### PEOPLE

<b>1. PI's Name: (Last, First, Degree)</b>	
<b>2. CSULB email:</b>	
<b>3. CITI Member ID#:</b>	
<b>4. Department/School:</b>	
<b>5. CSULB Affiliated?</b>	<input type="checkbox"/> Yes (GO TO #6) <input type="checkbox"/> No, <b>enter affiliation:</b> _____ (GO TO #12)
<b>6. CSULB Affiliation</b> (Check all that apply):	<input type="checkbox"/> Student <input type="checkbox"/> Faculty <input type="checkbox"/> Staff <input type="checkbox"/> UHP <input type="checkbox"/> Thesis <input type="checkbox"/> UG Student <input type="checkbox"/> Grad Student <input type="checkbox"/> <b>Other:</b> _____

**STUDENT PI MUST COMPLETE ITEMS #7 THROUGH #11 for FA. NON-STUDENT PI GO TO ITEM #12**

<b>7. Faculty Advisor's (FA) Name: (Last, First, Degree)</b>	
<b>8. FA CSULB email:</b>	
<b>9. FA CITI Member ID#:</b>	
<b>10. FA Department/School:</b>	
<b>11. Signed Faculty Advisor letter attached?</b> <input type="checkbox"/> Yes	
<b>STUDENT PI DO NOT SUBMIT APPLICATION WITHOUT THE SIGNED FA LETTER ATTACHED</b>	

<b>12. List names of other CSULB researchers with their email, CITI Member ID, and CSULB affiliation.</b>			
<input type="checkbox"/> <b>No other CSULB researchers (GO TO #13)</b>			
If the number of researchers exceeds space <b>attach</b> a list of other researchers in the appendices.			
Last, First Name	Email address	CITI Member ID	CSULB Affiliation
			<input type="checkbox"/> Student <input type="checkbox"/> Staff <input type="checkbox"/> Faculty <input type="checkbox"/> Other: _____
			<input type="checkbox"/> Student <input type="checkbox"/> Staff <input type="checkbox"/> Faculty <input type="checkbox"/> Other: _____
			<input type="checkbox"/> Student <input type="checkbox"/> Staff <input type="checkbox"/> Faculty <input type="checkbox"/> Other: _____
			<input type="checkbox"/> Student <input type="checkbox"/> Staff <input type="checkbox"/> Faculty <input type="checkbox"/> Other: _____

<b>13. List names of Non-CSULB affiliated researchers with their email, and CITI Member ID below.</b>			
<input type="checkbox"/> <b>No Non-CSULB affiliated researchers.</b>			
If the number of researchers exceeds space <b>attach</b> a list of other non-CSULB researchers in the appendices.			
Last, First Name	Email address	CITI Member ID	Non-CSULB Affiliation Institution Name(s):
			<input type="checkbox"/> Student <input type="checkbox"/> Staff <input type="checkbox"/> Faculty <input type="checkbox"/> Other: _____
			<input type="checkbox"/> Student <input type="checkbox"/> Staff <input type="checkbox"/> Faculty <input type="checkbox"/> Other: _____

**PROPOSED RESEARCH RECRUITMENT CHARACTERISTICS**

<b>14. Describe the research population:</b>			
<b>AGE</b>	<b>GENDER</b>	<b>CSULB Affiliation</b>	<b>Non-CSULB Affiliated</b>
<input type="checkbox"/> Under age 18 <input type="checkbox"/> 18+	<input type="checkbox"/> All <input type="checkbox"/> Female only <input type="checkbox"/> Male only <input type="checkbox"/> Other: _____	<input type="checkbox"/> Student <input type="checkbox"/> Staff <input type="checkbox"/> Faculty <input type="checkbox"/> Other: _____	<input type="checkbox"/> Student <input type="checkbox"/> Staff <input type="checkbox"/> Faculty <input type="checkbox"/> Other: _____
<b>15. Anticipated number of participants:</b>			
<b>16. Describe Inclusion criteria:</b>			
<b>17. Describe Exclusion criteria:</b>			
<b>18. Is research funded?</b> <input type="checkbox"/> No <input type="checkbox"/> Yes, describe funding source: _____			
<b>19. Recruitment strategies, check all below that apply and attach relevant materials.</b>			
<input type="checkbox"/> Flyers/letters <input type="checkbox"/> Email <input type="checkbox"/> Subject pool <input type="checkbox"/> Tabling in public <input type="checkbox"/> Social media post <input type="checkbox"/> In-class announcement <input type="checkbox"/> Personal network/Snowball sampling (potential subjects to contact PI) <input type="checkbox"/> <b>Other:</b> _____			
<b>20. Is permission needed from a facility, institution, or organization to conduct the research?</b>			
<input type="checkbox"/> No <input type="checkbox"/> Yes, <b>provide facility, institution, or organization name and attach letter:</b>			
<b>21. Describe any known risks to participating in the research (Required if the identity of participants can readily be ascertained, directly or indirectly, through identifiers linked to the participants):</b>			
<b>22. Describe mitigations to the risks in 21. (Required if the identity of the participants can readily be ascertained, directly or indirectly, through identifiers linked to the subjects):</b>			
<b>23. If applicable, describe any <u>direct</u> benefits to participants and any potential benefits to society:</b>			
<b>24. Are incentives/compensation provided to participants?</b> <input type="checkbox"/> No <input type="checkbox"/> Yes, <b>describe incentive type, value, timeline:</b>			
<b>25. Are incentives/compensation funded through CSULB?</b> <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not Applicable (If research targets CSULB students only, offers incentives, and is funded "state side," Financial Management will ask you to submit the name and ID number of student subjects. See <a href="#">PI Guidance Document</a> for further assistance)			
<b>26. Requesting signed informed consent from participants?</b> <input type="checkbox"/> No <input type="checkbox"/> Yes, attach consent form in appendices.			
<b>27. Requesting waiver of signature for informed consent?</b> <input type="checkbox"/> No <input type="checkbox"/> Yes, attach justification in appendices.			
<b>28. Requesting waiver of informed consent?</b> <input type="checkbox"/> No <input type="checkbox"/> Yes, attach justification for waiver in appendices.			
<b>29. Are data publicly available or de-identified? (no consent required)</b> <input type="checkbox"/> No <input type="checkbox"/> Yes, <b>provide name of data source:</b> _____			

**30. Summarize the proposed research intervention or interaction activities involving the participants. This would include collecting data with a survey (online or hardcopy), focus groups, interviews, etc. Include the duration of the intervention or interaction activities and frequency. (i.e., 30-minute interview of high school math teachers every three months of academic year). ATTACH data collection materials.**

## Section 2: Exemption Information

Review the list of **Proposed Research Activities** below. Check the **Proposed Research Activities** box(es) that match your proposed research. The Exempt Reviewer will select the **Exempt Category Determination in #38**.

### 31. Proposed Research Activities

Evaluate/Compare instructional techniques, curricula or classroom management methods. **Examples:** Evaluating the use of accepted or revised standardized tests, testing or comparing a curriculum or lesson, a program evaluation of computer programming continuing education.

#### Exempt Category 1

Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

### 32. Proposed Research Activities (Choose all that apply)

Educational Testing/Assessment  Cognitive, Diagnostic, Aptitude, Achievement Testing/Assessment  
 Survey/Questionnaire  Interview  Focus groups  Observation of public behavior  Audio recording  
 Video recording

**Examples:** Surveying teachers, nurses, or doctors about a technique or an intervention outcome, interviewing managers about a management style or best practice, conducting a focus group about the opinion of a community program.

#### Exempt Category 2

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

- (i) The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects cannot be readily ascertained, directly or indirectly through identifiers linked to the subjects; OR
- (ii) Any disclosure of Human Subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; OR
- (iii) The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects can be readily ascertained, directly or indirectly through identifiers linked to the subjects, **AND an IRB Member conducts limited IRB review.**

### 33. Proposed Research Activities (Choose all that apply)

- Benign behavioral intervention with **adult** subject
- Benign behavioral intervention with collection of data from **adult** subject
- Benign behavioral intervention with audiovisual recording with **adult** subject

**Example:** Healthy adult subjects are asked to take part in two hour-long assessments of memory, attention and information processing speed before and after 1 hour of cognitive enhancement exercise using specially designed computer software. Adult students undergoing a vigorous workout for 10 minutes then completing a math puzzle.

#### Exempt Category 3 (*Children excluded from this category*)

Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

- A. The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects cannot readily be ascertained, directly or indirectly, through identifiers linked to the subjects; OR

B. Any disclosure of the Human Subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; OR

C. The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects can be readily ascertained, directly or indirectly through identifiers linked to the subjects, **AND an IRB member conducts a limited IRB review to ensure there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.**

(i) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(ii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

### 34. Proposed Research Activities (Choose only one)

Secondary research for which consent is not required

Secondary research use of identifiable private information or identifiable biospecimens that are **publicly available**

Secondary research use of identifiable private information or identifiable biospecimens that are **de-identified**

Secondary research use of identifiable private information or identifiable biospecimens **for "health care operations," "research," or "public health activities and purposes"** as defined by 45 CFR parts 160 & 164

Secondary research use of identifiable private information or identifiable biospecimens **on behalf of a federal department or agency** and using government collected data, in compliance with federal law

**Example:** A researcher is given two datasets that contain private, identifiable information. The researcher uses the identifiers to merge the two datasets but strips the resulting (merged) data of identifiers immediately after the merger and before conducting data analysis. The resulting data used for the analysis is completely de-identified with no link to identifiers.

### Exempt Category 4

Secondary research for which consent is not required: Secondary research use of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available; OR

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; OR

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164 (HIPAA), subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); OR

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

**Note:** Exemption Category 4 only applies to the re-use of data and specimens that were or will be collected for non-research purposes or from research studies other than the proposed research study. The research materials typically will be publicly available materials, medical records, or existing repositories of clinical specimens. No contact between investigator and subject is allowed. If an investigator wants to collect information/specimens directly from research subjects, then another IRB review path will be required. Exemption Category 4(iii) only applies to the use of data (when HIPAA applies).

**35. Proposed Research Activities**

Any federally-supported evaluation of federal public programs

**Exempt Category 5**

Research and demonstration projects which are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine: public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

**36. Proposed Research Activities**

Any food quality/consumer study of foods found to be safe by the FDA

**Exempt Category 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 Dept. of Agriculture

**37. Proposed Research Activities**

None of the Exempt Categories apply to the Proposed Research Activities.

**Note: If none of the exempt categories apply to the research, it does not qualify for exempt review.** Please submit using an [Expedited and Standard Review form](#).

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**ONLY THE EXEMPT REVIEWER COMPLETES THE FOLLOWING**

**38. Exempt Reviewer Determination**

The Exempt Reviewer will check one box for the review decision. If the first box is checked, the reviewer will also enter the appropriate exempt category number.

- 1.  Research is Exempt based on Category – Enter exempt category number: \_\_\_\_\_
- 2.  Research is Exempt for Category 3(C) Limited IRB Approval
- 3.  Research is Not Exempt – **Reason:** \_\_\_\_\_
- 4.  Research Application is not complete – **Reason:** \_\_\_\_\_

**Exempt Review Determination Date:** \_\_\_\_\_