

Application for Exemption from Institutional Oversight



Institutional Review Board
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Unless qualified as meeting the specific criteria for exemption from Institutional Review Board (IRB) oversight, All LSU research/ projects using living humans as subjects, or samples, or data obtained from humans, directly or indirectly, with or without their consent, must be approved or exempted in advance by the LSU IRB. This form helps the PI determine if a project may be exempted, and is used to request an exemption.

-- Applicant, Please fill out the application in its entirety and include the completed application as well as parts B-F, listed below, when submitting to the IRB. Once the application is completed, please submit the completed application to the IRB Office by e-mail (irb@lsu.edu) for review. If you would like to have your application reviewed by a member of the Human Subjects Screening Committee before submitting it to the IRB office, you can find the list of committee members at <http://sites01.lsu.edu/wp/ored/human-subjects-screening-committee-members/>.

-- A Complete Application Includes All of the Following:

- (A) This completed form
- (B) A brief project description (adequate to evaluate risks to subjects and to explain your responses to Parts 1&2)
- (C) Copies of all instruments to be used.
 - *If this proposal is part of a grant proposal, include a copy of the proposal and all recruitment material.
- (D) The consent form that you will use in the study (see part 3 for more information.)
- (E) Certificate of Completion of Human Subjects Protection Training for all personnel involved in the project, including students who are involved with testing or handling data, unless already on file with the IRB. Training link: <https://about.citiprogram.org/en/homepage/>
- (F) Signed copy of the IRB Security of Data Agreement: <http://www.lsu.edu/research/downloads/IRB-Security-of-Data-Agreement-Form.pdf>

1) Principal Investigator: Rank:

Dept: Ph: E-mail:

2) Co-Investigator(s): please include department, rank, phone and e-mail for each. **If the co-investigator resides in the EU, a GDPR consent form must be signed by the co-investigator prior to study submission for IRB approval.**

*If the Principal Investigator is a student, identify and name supervising professor in this space

3) Project Title:

4) Proposal? (yes or no) ☐ If Yes, LSU Proposal Number

Also, if YES, either ☐ This application completely matches the scope of work in the grant
OR ☐ More IRB Applications will be filed later

5) Subject pool (e.g. Psychology students)

*Indicate any "vulnerable populations" to be used: (children <18 the mentally impaired, the aged, other).

*Projects with incarcerated persons cannot be exempted.

6) Does your study include participants (counting MTurk) in the 28 member states of the EU or the three additional countries? ☐ Yes ☐ No
(Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, UK, Norway, Iceland, Lichtenstein)

7) PI Signature _____ Date _____
(no per signatures)

**** I certify my responses are accurate and complete.** If the project scope or design later changes, I will resubmit for review. I will obtain written approval from the Authorized Representative of all non-LSU institutions in which the study is conducted. I also understand that it is my responsibility to maintain copies of all consent forms at LSU for three years after completion of the study. If I leave LSU before that time, the consent forms should be preserved in the Departmental Office.

Screening Committee Action:	☐ Exempted	☐ Not Exempted	Category/Paragraph	
Signed Consent Waived?:	☐ Yes	or	☐ No	
Reviewer	Signature	Date		

Part 1: Determination of "Research" and Potential for Risk

- This section determines whether the project meets the Department of Health and Human Services (HHS) definition of research involving human subjects, and if not, whether it nevertheless presents more than "minimal risk" to human subjects that makes IRB review prudent and necessary.

1. Is this project involving human subjects a systematic investigation, including research, development, testing, or evaluation, designed to develop or contribute to generalizable knowledge?

(Note some instructional development and service programs will include a "research" component that may fall within HHS' definition of human subject research).

Yes

No

2. Does the project present physical, psychological, social or legal risks to the participants reasonably expected to exceed those risks normally experienced in daily life or in routine diagnostic physical or psychological examination or testing? You must consider the consequences if individual data inadvertently become public.

Yes - Stop. This research cannot be exempted - **submit regular application for IRB review.**

No - Continue to see if research can be exempted from IRB oversight

3. Are any of your participants incarcerated?

Yes - Stop. This research cannot be exempted--**submit regular application for IRB review.**

No - Continue to see if research can be exempted from IRB oversight.

4. Are you obtaining any health information from a health care provider and/or participant (when participant physically resides in an EU country) that contains any of the identifiers listed below?

- A. Names
- B. Address: street address, city, county, precinct, ZIP code, and their equivalent geocodes. Exception for Zip codes: the initial three digits of the ZIP Code may be used, if according to 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'. (Note: The 17 currently restricted 3-digit ZIP codes to be replaced with '000' include: 036, 059, 063, 102, 203, 556, 692, 790, 921, 830, 831, 878, 879, 884, 890, and 893.)
- C. Dates related to individuals
 - i. Birth date or date of death
 - ii. Admission date
 - iii. Discharge date
 - iv. And all ages over 89 and all elements of dates (including year) indicative of such ago. Such ages and elements may be aggregated into a single category of age 90 or older.
- D. Telephone or fax numbers
- E. Electronic mail addresses
- F. Social security numbers
- G. Medical record numbers (including prescription numbers and clinical trial numbers)
- H. Health plan beneficiary numbers
- I. Account numbers
- J. Certificate/license numbers
- K. Vehicle identifiers and serial numbers including license plate numbers
- L. Device identifiers and serial numbers
- M. Web Universal Resource Locators (URLs)
- N. Internet Protocol (IP) address numbers
- O. Biometric identifiers, including finger and voice prints
- P. Full face photographic images and any comparable images
- Q. Any other unique identifying number, characteristic, or code; except a code used alone or in combination with other information to identify an individual who is the subject of the information.

Yes - Stop. This research cannot be exempted--**submit regular application for IRB review.**

No - Continue to see if research can be exempted from IRB oversight.

Part 2: Exemption Criteria for Research Projects

Please select any and all categories that relate to your research. Research is exemptible when all research methods are one or more of the following categories. Check statements that apply to your study:

- ☐ 1. In education setting, research to evaluate normal educational practices.
-

- ☐ 2. For research **not involving vulnerable people [prisoner, fetus, children, or mentally impaired]**: observe public behavior (including participatory observation), or do interviews or surveys or educational tests:

The research must also comply with one of the following:

- ☐ a) The participants cannot be identified, directly or statistically;
- ☐ b) The responses/observations could not harm participants if made public;
- ☐ c) Recorded information is identifiable and IRB conducts limited review – **Adults only**
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- ☐ 3. For benign behavioral interventions with collection of information (verbal, written, audiovisual recording) from **adult** subjects who prospectively agrees and one of the following is met

- ☐ a) Recorded information cannot readily identify the subject
- ☐ b) Any disclosure of responses outside of the research would not reasonably place subject at risk
- ☐ c) Recorded information is identifiable and IRB conducts a limited review
-

- ☐ 4. Secondary research for which consent is not required: use of identifiable private information or identifiable biospecimens;

The research must also comply with one of the following:

- ☐ a) Information or biospecimens are publicly available
- ☐ b) Recorded information cannot readily be identified (directly or indirectly/linked); investigator does not contact subjects and will not re-identify the subjects
- ☐ c) Information collection and analysis involving identifiable health information when use is regulated by HIPAA “health care operations” or “research” or “public health activities and purposes”
- ☐ d) Research by or on behalf of Federal department/agency using government-generated or collected information. Compliant with relevant privacy protections.
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- ☐ 5. Research and demonstration projects conducted/supported by a Federal department or agency or subject to approval by dept/agency head and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs

- a) **Prior to commencing**, research must be posted on a Federal Web Site or in other way determined by the Agency.

- ☐ 6. Research to evaluate food quality, taste, or consumer acceptance.

- a) The food has no additives
 - b) The food is certified safe by the USDA, FDA, or EPA
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- ☐ 7. Secondary research for which broad consent is required

- a) Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review
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- ☐ 8. Secondary research for which broad consent is required. Research involving the use of identifiable private information or identifiable biospecimens. **All of the following are required:**

- a) Broad consent for the storage, maintenance, and secondary uses
- b) Documentation of informed consent or waiver of documentation was obtained
- c) Limited IRB review that broad consent is consistent with proposed research
- d) Return of research results not included in the study plan

Part 3: Consent Forms

* The consent form must be written in non-technical language which can be understood by the subjects. It should be free of any exculpatory language through which the participant is made to waive, or appears to be made to waive any legal rights, including any release of the investigator, sponsor, institution or its agents from liability for negligence. (Note: the consent form is not a contract)

* Sample consent forms, can be found on our website under [Consent Forms & Guides](#)

* The IRB prefers using signed informed consent. However, if that is impractical, an application to waive signed consent can be requested below. If this waiver is requested, the **IRB must be provided with the consent script** that will present the information to subjects regarding the study/research. All consent forms or scripts must include a statement that the study was approved or exempted by the IRB and provide IRB contact information to participants.

I am requesting waiver of signed Informed Consent because:

- (a) Having a participant sign the consent form would create the **principal risk** of participating in the study.

or that

- (b) The research presents **no more than minimal risk** of harm to subjects and involves no procedures for which having signed consent is normally required.

Now that your application is complete, please send it to the IRB office by e-mail (irb@lsu.edu) for review. If you would like to have your application reviewed by a member of the Human Subjects Screening Committee before submitting it to the IRB office, this is the list of [committee members](#).