Application for Exemption from Institutional Oversight

Institutional Review Board
Dr. Robert Mathews, Chair
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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 A-F, listed below, when submitting to the IRB. Once the application is completed, please the completed application to the IRB Office or to a member of the Human Subjects Screening Committee. Members of this committee can be found at http://sites01.lsu.edu/wp/ored/human-subjects-screening-committee-members/

-- A Complete Application Includes All of the Following:

(A) A copy of this completed form and a copy of parts B thru F.
(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: (http://phrp.nihtraining.com/users/login.php)
(F) IRB Security of Data Agreement: (https://sites01.lsu.edu/wp/ored/files/2013/07/Security-of-Data-Agreement.pdf)

1) Principal Investigator: _____ **Rank:** _____

Dept: _____ **Ph:** _____ **E-mail:** _____

2) Co Investigator(s): please include department, rank, phone and e-mail for each
*If student, please identify and name supervising professor in this space

_____

IRB#_____ LSU Proposal #_____

◯ Complete Application
◯ Human Subjects Training
◯ IRB Security of Data Agreement

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) _____

*Circle any **"vulnerable populations" to be used**: (children <18; the mentally impaired, pregnant women, the ages, other). Projects with incarcerated persons cannot be exempted.

6) PI Signature _____ **Date** _____ (no per signatures)

** **I certify my responses are accurate and complete.** If the project scope or design is 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 / 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 (HSS) 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 subjects 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 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
- ii. Admission date
- iii. Discharge date
- iv. Date of death
- v. 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 numbers;
E. Fax numbers;
F. Electronic mail addresses;
G. Social security numbers;
H. Medical record numbers; (including prescription numbers and clinical trial 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; 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.

Continue on the next page

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 five 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, pregnancy, 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;

or that

◯ **b) The responses/observations could not harm participants if made public;**

or that

◯ **c) Federal statue(s) completely protect all participants' confidentiality;**

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

◯ **All respondents are elected, appointed, or candidates for public offices.**

◯ **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.**

The research *must also comply with one of the following:*

◯ **a) Subjects cannot be identified** in the research data directly or statistically, and no-one can trace back from research data to identify a participant;

or that

◯ **b) The sources are publicly available**

◯ **5. Research or demonstration service/care programs, e.g. health care delivery.**

◯ **a) It is directly conducted or approved by the head of a US Govt. department** or agency.

and that

◯ **b) It concerns only issues under usual administrative control** (48 Fed Reg 9268-9). e.g., regulations, eligibility, services, or delivery systems;

and that

◯ **c) Its research/evaluation methods are also exempt from IRB review.**

◯ **6. For research not involving vulnerable volunteers (see "2&3" above), do food research to evaluate quality, taste, or consumer acceptance.**

The research *must also comply with one of the following:*

◯ **a) The food has no additives;**

or that

◯ **b) The food is certified safe by the USDA, FDA, or EPA.**

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.)

* For example consent forms, please refer to our website, www.lsu.edu/irb

* The IRB prefers using signed informed consent; However, if that is impractical, an application to waive signed consent can be requested below. However, even if this waiver is requested, the **IRB must be provided with the consent script** that will present the information to human 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 for review, the address is listed below, OR you can send it to one of the Human Subjects Screening Committee Members. The list of Committee Members can be found here (http://sites01.lsu.edu/wp/ored/human-subjects-screening-committee-members/)

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