Application for Approval of Projects Which Use Human Subjects

This application is used for projects/studies that cannot be reviewed through the exemption process.

Dr. Dennis Landin, Chair
130 David Boyd Hall
Baton Rouge, LA 70803
P: 225.578.8692
F: 225.578.5983
irb@lsu.edu | lsu.edu/research

-- Applicant, please fill out the application in its entirety and include parts B-F, listed below. Once the application is completed, please submit to the IRB Office by e-mail (irb@lsu.edu) for review and allow ample time for the application to be reviewed. Expedited reviews usually take one month. Carefully completed applications should be submitted three weeks before a meeting to ensure a prompt decision.

-- 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: (http://phrp.nihtraining.com/users/login.php)
(F) Signed copy of the IRB Security of Data Agreement: (https://sites01.lsu.edu/wp/ored/files/2013/07/IRB-Security-of-Data.pdf)

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

*PI **must be** an LSU Faculty Member

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.

3) Project Title: _____

4) Proposed Start Date: _____ **5) Proposed Duration Months:** _____

6) Number of Subjects Requested: _____ **7) LSU Proposal #:** _____

8) Funding Sought From: _____

9) Is your project regulated by the FDA? Y/N____; If unsure, click here for a checklist.

10) Does your study include participants (counting MTurk) in the 28 member states of the EU or the three additional countries?
(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) ☐ **Yes** ☐ **No**

ASSURANCE OF PRINCIPAL INVESTIGATOR named above
I accept personal responsibility for the conduct of this study (including ensuring compliance of co-investigators/co-workers) in accordance with the documents submitted herewith and the following guidelines for human subject protection: The Belmont Report, LSU's Assurance (FWA00003892) with OHRP and 45 CFR 46 (available from http://www.lsu.edu/irb). I also understand that copies of all consent forms **must be maintained at LSU for three years after the completion of the project**. If I leave LSU before that time, the consent forms should be preserved in the Departmental Office.

Signature of PI _____ Date _____

ASSURANCE OF STUDENT/PROJECT COORDINATOR named above. If multiple Co-Investigators, please create a "signature page" for all Co-Investigators to sign. Attach the "signature page" to the application.

I agree to adhere to the terms of this document and am familiar with the documents referenced above.

Signature of Co-PI (s) _____ Date _____

Continue on the next page

Part 1: A. Is a HIPAA Agreement Needed?

Are you obtaining any health information **from a health care provider or participant** 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, admission date, discharge date, or date of death
    ii. 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 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. Identification card numbers
R. Cookie Id
S. Race or origin
T. Sexual life or orientation
U. Political opinions, religious, or philosophical beliefs
V. 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** Your study falls under the HIPAA (Health Information Privacy and Accountability Act) and you must obtain either a limited data set use agreement or a HIPAA authorization agreement from the health care provider. This agreement must be submitted with your IRB protocol.

☐ **NO** You do not need a HIPAA agreement.

B. Are pregnant women specifically excluded from participation on the consent form?

☐ **YES** Skip to Part C.

☐ **NO** You need to document the following:

☐ 1. Is the purpose of the activity to meet the health needs of the mother and

☐ a. Fetus will be placed at risk only to minimum to meet mother's needs.

☐ b. Fetus risk is minimal.

☐ 2. Have mother and father given informed consent including potential affects on the fetus?

☐ 3. Father's consent to be omitted when:

☐ a. Purpose of activity is to meet health needs of the mother

☐ b. His identity cannot be ascertained

☐ c. He is not reasonably available

☐ d. Pregnancy is from rape

Continue on the next page

C. Are any of your participants incarcerated?

☐ **YES** - You must document the following information:

- ☐ 1. Is the study minimal risk? (it must be)
- ☐ 2. Research fits one of the allowed categories below
  - ☐ Causes or effects of incarceration
  - ☐ Study of prisons or prisoners
  - ☐ Conditions affecting prisoners as a class
  - ☐ Practices that may improve health or well-being of subjects
- ☐ 3. Are the risks commensurate with risks accepted by non-prisoners?
  - ☐ Selection of subjects is fair - controls random
  - ☐ Language is understandable
  - ☐ Study does not affect parole
  - ☐ If necessary, follow up care will be provided

☐ **NO**

D. Are children involved?

☐ **YES** - You need both parental consent form and a child assent form

- ☐ If the study has greater than minimal risk and no direct benefits, then you must show that the risk is only a minor increase above minimal, and it involves experiences that are commensurate with ordinary medical, psychological, social or educational situations

☐ **NO**

Part 2: Project Abstract - Provide a brief abstract of the project

☐ I have attached a project abstract to this application

Part 3: Research Protocol

A. Describe study procedures

Describe study procedures with emphasis on those procedures affecting subjects and safety measures. Also, provide script for telephone surveys.

☐ I have attached a description of my study procedures to this application

B. Answer each of the following questions

1. Specify sites of data collection

Continue on the next page

2. If surgical or invasive procedures are used, give name, address, and telephone number of supervising physician and the qualifications of the person(s) performing the procedures. Comparable information when qualified participation is required or appropriate.

3. Provide the names, dosage, and actions of any drugs or other materials administered to the subjects and the qualifications of the person(s) administering the drugs.

4. Detail all the physical, psychological, and social risks to which the subjects may be exposed.

5. What steps will be taken to minimize risks to subjects?

Continue on the next page

6. Describe the recruitment pool (community, institution, group) and the criteria used to select and exclude subjects.

7. List any vulnerable population whose members are included in this project (e.g., children under the age of 18; mentally impaired persons; pregnant women; prisoners; the aged.

8. Describe the process through which informed consent will be obtained. (Informed consent usually requires an oral explanation, discussion, and opportunity for questions before seeking consent form signature.)

9. (A) Is this study anonymous or confidential? (Anonymous means that the identity of the subjects is never linked to the data, directly or indirectly through a code system.)

(B) If a confidential study, detail how the privacy of subjects and security of their data will be protected

Continue on the next page

Part 4: Consent Form (including assent form and parental permission form if minors are involved)

- **Please note:** 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
- For example consent forms and a complete checklist of required items, please refer to our website, www.lsu.edu/irb. Remember, **IRB contact information must be included on the consent form!**
- To waive signed consent. **IRB must be provided with the consent script** that will present the informed consent information to human subjects regarding the study/research. Also, note that waiving signed consent requires full IRB approval, which may delay approval of your study.

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.

Expedited reviews usually take one month. See our website for information about meeting dates. Carefully completed applications should be submitted three weeks before a meeting to ensure a prompt decision.

Institutional Review Board
Dr. Dennis Landin, Chair
130 David Boyd Hall
Baton Rouge, LA 70803
P: 225.578.8692
F: 225.578.5983
irb@lsu.edu |
lsu.edu/research