**Proposal Number:**

**The University of Louisiana Lafayette Institutional Review Board**

**Application Instructions and checklist**

**Application Instructions:**

All applications for IRB review are to be completed electronically using this form. **FILES MUST BE CONVERTED TO A SINGLE PDF WITH A TABLE OF CONTENTS ON THE FIRST PAGE** prior to submission. ELECTRONIC files should be emailed to the IRB Chair at irb@louisiana.edu. NOTE: GRADUATE STUDENTS must have their professor’s signature prior to forwarding to the IRB chair and copy the email to their professor.

**Name of Investigator:**

**Name of Graduate Student (if applicable):**

**Title of Proposal:**

**Date of Application:**

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**Investigators Checklist**

|  |  |  |
| --- | --- | --- |
| **Completed** | **Not Applicable** |  |
| [ ]  | [ ]  | **Application Form:** Answer questions 1 through 9 in the provided gray text box and check boxes. **Do not reference pages in the proposal for requested information.**  Be sure to “**sign” and date** the first page |
| [ ]  | [ ]  | **Attach Research Proposal (optional)**: Graduate students may use the "Methods" section of their thesis/dissertation (if available) in lieu of a research proposal. A proposal is a document explaining the purpose and procedures to be used in the study. **It should be attached if the questions on the application do not allow for a full understanding of the research project.** |
| [ ]  | [ ]  | **Attach Consent Forms:** Examples of consent forms are available at <http://vpresearch.louisiana.edu/node/432>They **must** include… [ ]  1) Researchers’ names and UL Lafayette emails and telephone numbers [ ]  2) IRB contact information should be irb@louisiana.edu or 337-482-5811. [ ]  3) A statement indicating that questions concerning protection of human participants in research can be addressed to the UL Lafayette IRB. |
| [ ]  | [ ]  | **Attach Testing Instruments**: questionnaires, tests, interview questions, other data collection instruments or a detailed description of data collection procedures. If a data collection tool exists only as a computer program, videotape, audio tape etc., a full and complete description of the tool is needed. |
| [ ]  | [ ]  | **Attach a written copy** of any communication, oral or written, to be used to recruit participants**. e.g.** scripts, announcements, posters or advertisements**.** |
| [ ]  | [ ]  | **Human Subject Training**: No new applications will be accepted without the required completion of CITI Basic Human Subjects Research training. The NIH training and the CITI Social and Behavioral Basic/Refresher are no longer accepted. All researchers must take the updated training via CITI to be in compliance with the Revised Common Rule. Certificates do NOT need to be attached. |
| [ ]  | [ ]  | **Students:** Attach a signed letter from your major professor or committee chair stating that he/she has reviewed and approves the proposed project. |
| [ ]  | [ ]  | **Graduate Students applying for approval of a thesis or dissertation project:** the application must be signed by your professor and emailed to the IRB chair. |

**Proposal Number:**

**The University of Louisiana at Lafayette Institutional Review Board**

**APPLICATION FOR REVIEW OF RESEARCH INVOLVING HUMAN PARTICIPANTS**

1. **PERSONNEL**

|  |  |  |
| --- | --- | --- |
|  | **RESPONSIBLE FACULTY OR STAFF** **SUPERVISOR / INVESTIGATOR** | **STATUS OF THIS INVESTIGATOR:** |
| **Name &** **credentials** |       | [ ]  Faculty | [ ]  Full time |
| [ ]  Part time |
| [ ]  Adjunct |
| [ ]  Visiting |
| **Department** |       | [ ]  Staff | [ ]  Full time |
| [ ]  Part time |
| **Campus Address** |       |  |
| **Phone** |       |  |
| **Email** |       |  |

|  |  |  |
| --- | --- | --- |
|  | **STUDENT RESEARCHER** | **STATUS OF STUDENT INVESTIGATOR:** |
| **Name**  |       | [ ]  Graduate Student |
| **Department** |       | [ ]  Undergraduate Student |
| **Campus Address** |       |  |
| **Phone** |       |  |
| **Email** |       |  |

**Students, be sure to include the required letter from your supervising professor--see checklist.**

**For additional investigators or research staff, list their names, departments and dates of CITI program Basic Human Subjects Research training completion (one line per investigator). NOTE – the IRB may assign additional modules as necessary, dependent on research topic and participant pool.**

**Name Department Training and date of completion**

Enter names, dept., CITI training dates

**This Application is for a:**

|  |  |
| --- | --- |
| [ ]  **Graduate Student** **Thesis** | [ ]  **Graduate Student** **Dissertation** |
| [ ]  DNP Synthesis Project | [ ]  **Graduate Student Capstone Project** |
| [ ]  **Undergraduate Student Research Project** | [ ]  **Research Project** |
|  | [ ]  **Other Project Type**       |

1. **STATUS OF PROJECT**

 [ ]  New Project

[ ]  Renewal

 [ ]  Change in Procedure for a Continuing Project

 **Project/Proposal Title:**

1. **Collaboration.** **Will this project be an inter-institutional collaboration?**

**If yes, complete the following:**

1. **List the collaborators and provide evidence of their Human Subject Protection training**.

1. **List the collaborating institutions and their Federal Wide Assurance numbers. Indicate which will be the IRB of record**.

1. **Is the collaborating institution’s IRB reviewing the project?**

**If yes, what is the (expected) approval date? Attach a copy of any existing approvals.**

1. **Will a Memorandum of Understanding or reliance/authorization agreement be required?**

 b**. Funding:**

[ ]  Externally Funded **Funding Agency:**

[ ]  Internally Funded **Funding Source:**

[ ]  No internal funds or external funds are proposed.

c. **Financial conflict of interest disclosure**:

**[ ]  No members of the research team have any financial conflict of interest.**

**[ ]  Some members of the research team have a financial conflict of interest. Describe.**

d. **Anticipated start date** **to begin data collection:**

1. **Type of Review (**see the Guidelines, pgs. 10-12 for more information)**:**

 **[ ]  Exempt**

 **[ ]  Exempt requiring limited review, because identifying information is collected or recordings are made**

**[ ]  Expedited**

**[ ]  Full – Meeting attendance is required for at least one research team member listed on the application.**

**[ ]  Uncertain**

 **[ ]  Under review by Collaborating Institution’s IRB, which will be the IRB of record (this option may not be available if all data collection is to occur at UL Lafayette. Consult with the Chair). Only items 1-3, 4. a. and 4. g. must be completed. All documentation requested above and this form must be turned into the IRB Chair.**

**Rationale for choosing this review type** (See Guidelines, pgs. 4, 9 -11):

1. **PROJECT DESCRIPTION:**
2. **Provide the purpose of the research**:

1. **Describe briefly how this study/project will contribute to the existing knowledge in the field.**

1. **Provide a step-by-step description of the activities that participants will be asked to perform in each phase of the study/project.**

1. **Provide an estimated time commitment for each participant during each phase of the study/project.**

1. **List the testing instruments, surveys, or questionnaires that will be used (attach all of these documents or send as email attachments).**

1. **Describe all interventions or treatments that will be used**.

1. **Provide the location where the research will take place.**

5. **PARTICIPANT POPULATION: Please check all of the following, either "yes" or "no".**

* 1. **Will any of the following be primary participants (participants selected specifically for their status indicated below):**

 **VULNERABLE POPULATIONS ACCORDING TO 45 CFR 46**

**Yes** **No**

**[ ]  [ ]  Children under 18 (45 CFR 46 Subpart D)**

**[ ]  [ ]  Prisoners (45 CFR 46 Subpart C)**

**[ ]  [ ]  Individuals who have Impaired Decision-making Abilities**

**[ ]  [ ]  Economically or Educationally Disadvantaged Persons**

**POPULATIONS DESERVING SPECIAL CONSIDERATIONS**

**Yes** **No**

**[ ]  [ ]  Pregnant Women, Fetuses, or Neonates (45 CFR 46 Subpart B)**

**[ ]  [ ]  UL Lafayette Students**

**[ ]  [ ]  Minorities**

**[ ]  [ ]  Individuals who cannot read/speak English**

**[ ]  [ ]  Individuals who are Institutionalized in non-prison settings**

**[ ]  [ ]  Hospitalized individuals or individuals with severe illnesses (e.g., terminal illnesses)**

**[ ]  [ ]  Individuals living outside of the U.S**

**[ ]  [ ]  Women of Childbearing Age**

**[ ]  [ ]  Individuals who are Physically Disabled**

* 1. **Number of participants, including controls:**
	2. **What is the age range of your intended participant population?**
	3. **Are you associated with the participants (e.g., your students, employees, subordinates, or patients)?**

[ ]  **Yes** [ ]  **No**

 **IF YES, explain the nature of the association.**

1. **Who will be contacting the potential research participants?**

1. **How will participants be contacted/recruited? (Check all that apply)**

**[ ]  Phone Calls**

**[ ]  United States Postal Service**

**[ ]  Email**

**[ ]  Internet social media or other online sites**

**[ ]  Posted Flyers**

**[ ]  TV, radio, print advertisements**

**[ ]  UL Lafayette research participant pool**

**[ ]  Face to face with individuals/public**

**[ ]  Presentation at meetings**

**[ ]  Other:** Click here and describe.

**If contacting specific people directly via any form of communication above, explain how this contact information will be obtained.**

**ATTACH A WRITTEN COPY of any communication, oral or written, to be used to recruit participants. See 7.e. in the IRB Guidelines for requirements of recruitment materials.**

1. **Describe the inclusion and exclusion criteria for the participants, applicable to this study/project.**

1. **Are you offering incentives, such as SONA credit, extra credit, gift card, or chance to win a prize, for participation in this research project?**[ ]  **No, move onto Section 6.**[ ]  **Yes, please answer question i.**
2. **Are you giving….**

[ ]  **Neither SONA nor extra credit, move on to question j.**

[ ]  **Psychology Department SONA credit, if yes, move on to question j.**

[ ]  **Extra class credit**

[ ]  **I will offer class extra credit for participants from classes I teach**

**If you offer extra credit (after answering the following 3 questions, move to question j),**

**How much extra credit is offered?** enter description

**To assist the IRB in determining the level of influence this will have on participants, please provide the percentage of the total class points the extra credit will represent.** enter description

**How will students in the class not participating in the research earn extra credit?** enter description

[ ]  **Faculty/colleagues may assist in recruiting participants by offering class extra credit. The manner in which they offer extra class credit is at the instructor’s discretion.**

 **Please answer question j.**

1. **Are you giving gift cards or cash to all participants?**

[ ]  **No, move onto question k**

[ ]  **Yes, please answer the following questions:**

**If yes, will the gift cards or cash be disbursed from….**

[ ]  **personal funds**

[ ]  **University/grant funds**

**NOTE – When University/grant funds are used, departments are required to track the distribution for tax purposes. Please ensure that your department has a policy approved by the purchasing department and a mechanism for tracking distributions to participants.**

**To assist the IRB in determining the level of influence the cash/gift card will have on participants, please provide the value of cash/gift cards that will be provided.** enter description

**When and how will the cash/gift cards be disbursed?** enter description

 **Please answer question k.**

1. **Are you offering an opportunity to enter a drawing for a prize? NOTE- University employees and students ARE eligible to enter a drawing to win a prize. There is n need to track this for tax purposes. Individuals must file on their personal taxes.**

[ ]  **No, move onto question l.**

[ ]  **Yes**

**If yes, to assist the IRB in determining the level of influence, please provide a description and the value of the prize:** enter description

 **Please answer question l.**

1. **Are you offering an incentive that is not described above?**

[ ]  **No, move onto Section 6.**

[ ]  **Yes**

**If yes, to assist the IRB in determining the level of influence, please describe the incentive that will be provided.** enter description

**6. CONFIDENTIALITY AND PRIVACY**

1. **Describe your procedures for safeguarding and insuring confidentiality or privacy of the research participants. (See IRB Guidelines, pgs. 5 and 6) Include:**
	* + **How private information will be collected. e.g. private interview, paper and pen**
		+ **How documents or specimens with identifiers will be transported from the research site to storage.**
		+ **How personally identifiable data or biospecimens be protected from loss or theft.**
		+ **NOTE - UL Lafayette provides access to OneDrive for secure storage of electronic files that can be accessed from Home or Office by the owner of the file and anyone that person shares the file or folder with. This should be used to protect data instead of storing files on flash drives or portable hard drives.**

1. **Will the PI or any member of the research team collect or have access to any of the following personal identifiers: Select all that apply:**

**[ ]  Name**

**[ ]  DOB**

**[ ]  Mailing or email address**

**[ ]  Phone or fax numbers**

**[ ]  Social security numbers**

**[ ]  Medical record**

**[ ]  License, certificate or vehicle ID**

**[ ]  IP address**

**[ ]  Biometric identifiers**

**[ ]  Photos/images**

**[ ]  Audio recording**

**[ ]  Video recording**

**[ ]  Signatures, handwriting samples**

**[ ]  Any unique identifier not mentioned above. Describe:**

[ ]  **No member of the research team will have access to any personal identifiers – this option is valid only if none of the other options are selected**

1. **How will data be reported in publications?**

1. **How long will data be held?**

**[ ]  De-identified data will be held indefinitely in a database/biospecimen bank.**

**[ ]  Identified data will be held indefinitely in a database/biospecimen bank.**

**[ ]  De-identified data will be held for a short time in a database/biospecimen bank. Provide length of time**

**[ ]  Identified data will be held for a short time in a database/biospecimen bank. Provide length of time**

**Explain the reason for the statement chosen above**.

1. **INFORMED CONSENT and VOLUNTARY PARTICIPATION:**
	1. **Chose at least one of the following. (Guidelines, pgs. 6-8)**

[ ]  **CONSENT FORM(S) WILL BE USED and are attached (See the IRB Guidelines for assistance with consent form content. Any identified risks must be stated).**

**When will consent be obtained?**

**Where will consent be obtained?**

**Who will obtain consent?**

**Explain the consent process.**

[ ]  **CONSENT FORM WILL NOT BE USED.**

**Explain why a consent form will not be used.**

**When will consent be obtained?**

**Where will consent be obtained?**

**Who will obtain consent?**

**Explain the consent process.**

[ ]  **Assent will be obtained from children.**

**When will assent be obtained?**

**Where will assent be obtained?**

**Who will obtain assent?**

**Explain the assent process.**

[ ]  **Assent will NOT be obtained from children.**

**Explain why assent will not be obtained (If children are not part of the study, enter N/A)?**

* 1. **REGARDING DECEPTION, chose one of the following:**

**[ ]  Information will NOT be withheld from participants, during consent.**

**[ ]  Information will be withheld from participants, during consent.**

**Explain what information will be withheld and why it is necessary to withhold this information.**

**Will you explain in the consent form that some information will be withheld or that deception is part of the research? (Providing this explanation can allow some research to be exempt from the policy – 45 CFR 46.104(d)(3)(iii))**

**Describe your debriefing plan and attach your debriefing document.**

* 1. **Describe your method or procedures for assuring that participation is voluntary.**

8. **RISK: Please indicate the level of risk for the participants in this research (See Guidelines, pgs 8, 9 and 12)**

[ ]  Minimal Risk

[ ]  More than Minimal Risk

**[ ]** Uncertain

**RISK/BENEFIT RATIO:** **Assess any potential risks (physical, psychological, social, legal, economic or other) and assess the likelihood and seriousness of such risks. The concept of "risk" includes risks to the participant's dignity and self-respect.**

**Select all of the potential risks that are involved in your study/project**

**[ ]  Use of deceptive techniques**

**[ ]  Psychological: boredom, anxiety, embarrassment, depression, or exacerbation of psychological condition**

**[ ]  Psychological: Manipulation of psychological or social state such as sensory deprivation, social isolation, psychological stress**

**[ ]  Psychological: Emergence of mental health issues such as suicidal ideation or psychosis**

**[ ]  Psychological: Presentation and/or discussion of material which some participants may consider sensitive or offensive, threatening or degrading**

**[ ]  Limited Access to Privacy: such as persons living in prisons, nursing homes or assisted living facilities**

**[ ]  Loss of Privacy: Gathering personal or sensitive information in surveys or interviews, use of private records**

**[ ]  Loss of Privacy: Possible invasion of privacy of participant or participant’s family**

**[ ]  Social: stigmatization, harm to reputation, harm to relationships**

**[ ]  Economic: lost time at work, transportation costs, medical bills, legal fines**

**[ ]  Legal: Identification of abuse or illegal activity**

**[ ]  Physical: Risk of injury or bodily harm, high blood pressure, sexual dysfunction, death, exacerbation of a physical condition**

**[ ]  Other risks (please specify)**

**Describe in detail your procedures for protecting against or minimizing potential risks and an assessment of the likely effectiveness of these procedures. Note – All risks must be disclosed in the consent form.**

**Assess the potential benefits to be gained by the individual participants, as well as benefits which may accrue to society in general as a result of the planned work.**

**Describe any benefits that participants may reasonably expect. If there are none, state ‘None’**

**Describe the anticipated benefits of this study to society, academic knowledge or both.**

1. **ASSURANCES**

[ ]  I certify that I have read and understood the guidelines and procedures developed by The University of Louisiana at Lafayette for the protection of human participants and that I will comply with both the letter and the spirit of the university's policies.

[ ]  I further acknowledge my responsibility to report any significant changes in the protocol involving human participants and to obtain written approval from the Institutional Review Board for these changes prior to making these changes.

[ ]  I understand that IRB approval extends for one year, and if the project continues beyond the date of approval, then I will notify the IRB and request a renewal.

[ ]  By checking this box, I, type researcher/student name, am hereby signing my name.
Date:

**Faculty Advisor Certification for Student Projects**

[ ]  I certify, as faculty advisor, I have read and approve of the research described in this application and will provide guidance and support to the student as needed.

[ ]  By checking this box, I, type faculty sponsor name, am hereby signing my name.
Date:

**Remember to include all items on the check list (pg 1).**

Form Revised 10/27/2000 EMW:

Approved U.L.Lafayette IRB 10/27/00

Revised EMW 2004

Approved U.L. Lafayette I.R.B. 2004

Revised EMW I.R.B. 2008

Approved U.L. I.R.B. 2008

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