

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

**SUBMIT COMPLETED FORM TO *IRB@LAWRENCE.EDU***

**Answers must be typed**

**ANSWER ALL QUESTIONS (if not applicable, type “NA”)**

**For questions about this form, contact** **irb@lawrence.edu**

**See** [***Lawrence University IRB website***](https://www.lawrence.edu/academics/research/irb/) **for links to Federal regulations for the protection of human participants**

**SECTION 1: RESEARCH PROJECT**

**Project Title:**

**Anticipated Start Date: Anticipated End Date:**

**If project has grant funding, indicate grant title, award number, and source (clarify if internal or external to LU):**

**SECTION 2: INVESTIGATORS/SPONSORS**

**List ALL Investigator(s) and identify Principal Investigator (the main contact person):**

**PRINCIPAL INVESTIGATOR**

Name Email Phone LU Faculty/Staff/Student/Other?

**ADDITIONAL INVESTIGATORS (list ALL – expand this section if you need to for additional investigators)**

Name Email Phone LU Faculty/Staff/Student/Other?

Name Email Phone LU Faculty/Staff/Student/Other?

Name Email Phone LU/Faculty/Staff/Student/Other?

Name Email Phone LU Faculty/Staff/Student/Other?

**FACULTY/STAFF SPONSOR(S) (*Required for ALL student projects*)**

Name Email Phone LU Department

**SECTION 3: RESEARCH PURPOSE/DESIGN, PARTICIPANTS/ RECRUITMENT, PROCEDURES**

1. **Briefly but clearly summarize your research aims. What are you investigating? What specific question(s) do you hope to answer? What hypotheses will you be testing (if hypothesis-driven)?**
2. **Briefly but clearly summarize your research type or design (e.g., ethnography, experiment, questionnaire):**
3. **How many sessions will each participant typically take part in and approximately how long will each last?**
4. **How many participants will be recruited? How and where will participants be recruited? Provide an EXACT RECRUITMENT SCRIPT as participants will see or hear it. Describe any restrictions or “inclusion criteria” that will determine who will participate. If certain people will be excluded, explain why:**
5. **Will participants receive any compensation for participating (e.g., course credit, raffle ticket, payment)? If so, will participants who decide not to complete the study or who do not meet inclusion criteria be offered alternative ways to earn extra class credit (if offered)?**
6. **Check all *VULNERABLE PARTICIPANTS* (as defined by Federal regulations) involved in the study.**

*\_\_\_* CHILDREN (ANYONE UNDER 18 YEARS OLD)

\_\_\_ PRISONERS

\_\_\_ PREGNANT WOMEN

\_\_\_ HUMAN FETUSES/NEONATES

\_\_\_ PERSONS AT RISK FOR SUICIDE

\_\_\_ PERSONS WITH IMPAIRED DECISION-MAKING CAPABILITY

\_\_\_ OTHER VULNERABLE GROUPS, SPECIFY:

1. **Detail your procedures and methods: what will participants typically do, be told, experience? Be as exact as possible. Provide complete and FINAL versions of questionnaires or measures, descriptions of experimental “manipulations,” protocols for medical or other invasive procedures, and all other materials that will be encountered by subjects as part of the research. Explicitly note any deceptions or misleading information participants may encounter. (For longer materials, such as a questionnaire, you may attach a file):**

**SECTION 4: PARTICIPANT RISKS AND BENEFITS**

1. **Indicate whether the project is Minimal Risk or Greater than Minimal Risk (CHECK ONE OF THE TWO BELOW):**

\_\_\_\_**MINIMAL RISK:** The probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

\_\_\_\_**GREATER THAN MINIMAL RISK:** The probability and magnitude of harm or discomfort anticipated in the proposed research are greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

1. Briefly explain both the ***risks*** and ***benefits*** (e.g., compensation, receiving information about the topic being studied) to participants. Benefits may also include wider societal benefits.

***\*\*\*IF YOU CHECKED “MINIMAL RISK” THEN SKIP THE REMAINDER OF THIS SECTION, GO TO SECTION 5\*\*\****

1. **If you checked “Greater than Minimal Risk” above, which risks listed below apply (CHECK ALL THAT APPLY):**

\_\_\_PHYSICAL (E.G., FATIGUE, PAIN, INJURY)

\_\_\_PSYCHOLOGICAL (E.G., DISTRESS, ANXIETY, DEPRESSION, NEGATIVE MOOD)

\_\_\_SOCIAL (E.G., STIGMA)

\_\_\_LEGAL (E.G., DISCLOSURE OF DRUG USE)

\_\_\_ECONOMIC (E.G., LOSS OF JOB OR ADVANCEMENT, LOSS OF INSURANCE)

\_\_\_OTHER (SPECIFY)

**Complete the following table for all of the risk categories checked above:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Risk Category***(Physical, Psychological, Social, Legal, Economic, or Other)* | **Specific Risk** (e.g., Anxiety) | **Protection(s)***(e.g., Allow family or friend to stay with participant during procedures. Provide list of available mental health resources.)* | **Magnitude***(i.e., mild, moderate, severe)* |
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1. **Explain why each risk you checked cannot be avoided to accomplish your research goals:**

**SECTION 5: INFORMED CONSENT**

Informed consent means telling a participant about everything a ***REASONABLE PERSON would want to know BEFORE agreeing to participate***, (e.g., procedures, risks). This does NOT require revealing exact hypotheses. Rather, consider informed consent from the participant’s perspective: What exactly will I be asked to do? What will I experience? How long will it take? Are there any risks or discomfort?

**Investigators usually obtain WRITTEN consent – see the “Informed Consent Template” to develop a form for your project (**[**http://www.lawrence.edu/academics/research/irb/forms**](http://www.lawrence.edu/academics/research/irb/forms)**). For studies conducted online, it is permissible for participants to indicate consent by clicking that they have read and agree to a consent statement.**

1. **Paste your consent form or statement below (or state “see attachment”). Provide an EXACT CONSENT FORM as participants will receive it. If you do NOT intend to obtain written consent, describe how/whether you will obtain consent, justifying this choice by referring to Office of Human Research Protections (OHRP) guidelines on informed consent waivers**. (See <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/>)
2. **Signed consent forms must be retained at least 3 years and then may be shredded. Certify that consent forms will be secured for at least 3 years by initialing the statement below (may be typed):**

 The PI or faculty sponsor will keep signed consent forms for at least 3 years in a secure location; if consent forms

 \_\_\_\_\_\_ are later discarded, they will be shredded.

1. **FOR RESEARCH USING MINORS: Anyone under the age of 18 must have a parent or legal guardian provide consent. Additionally, the minor must *assent* to participation. If minors will participate, initial below to affirm that you will obtain consent from a parent or guardian (may be typed):**

 \_\_\_\_ I will obtain signed informed consent from a parent or legal guardian for all minors who participate.

 \_\_\_\_ I will obtain assent from any minor participants using age appropriate descriptions of research procedures.

 **Describe below how you will obtain children’s assent:**

**SECTION 6: CONFIDENTIALITY**

Participants’ responses must be kept confidential. Investigators should take all possible steps to ensure confidentiality (e.g., when possible: not recording participants’ names on questionnaires, using secure files only investigators can access, and reporting only group data – averaged across participants in any presentations or papers). In addition to names, “identifiers” such as age, gender, ethnicity, and so on can potentially reveal identities and must also be kept confidential (e.g., by securing the data and reporting only group averages not individual data in any papers, presentations. or reports).

1. **Below are some typical steps to ensure confidentiality; check ALL you will take:**

 **\_\_\_ ANONYMOUS RESPONSES: Will NOT record names OR any identifiers (e.g. gender)**

 **\_\_\_ IDENTITY OBSCURED: No names, but broad identifiers (e.g., gender) will be recorded**

 **\_\_\_ CODING TO MINIMIZE IDENTIFIABILITY (e.g., codes replace names in recorded data)**

 **\_\_\_ SECURE FILES: password protected computer files, hard copies locked away**

 **\_\_\_ WILL REPORT ONLY GROUP AVERAGES in any presentations/reports on study**

1. **Explain in detail the steps you will take to ensure confidentiality (as noted above identifiers such as age, gender, and ethnicity can potentially reveal identities and must also be kept confidential):**
2. **If recording participants on audio or video, detail steps you will take to maintain confidentiality of these materials, how they will be kept, and how and when they will be destroyed or erased when no longer needed.**

**SECTION 7: DECEPTION AND DEBRIEFING**

Deception includes any untruthful or misleading statements made to participants and should be avoided whenever possible. Deceptions may be mild and consistent with Minimal Risk research (e.g., telling participants in different conditions that the same musical piece was played by a man versus a woman). Deceptions are NOT mild if they prevent participants from knowing details that would potentially alter a reasonable person’s willingness to participate (e.g., failing to warn participants that they may experience physical pain constitutes a severe deception).

Researchers should try to avoid deception. For example, rather than a misleading cover story to avoid participants guessing the hypothesis, simply provide a broad, true, but general description of purpose. For example, for a study on whether people rate physically attractive others more favorably, you might tell participants you are studying “how we perceive others” – a true but general characterization that is NOT deceptive, but does not reveal your hypothesis.

1. **Does the project involve deception**? \_\_\_\_ YES \_\_\_\_NO **(IF “NO,” SKIP TO SECTION 8)**
2. **Is the deception consistent with Minimal Risk (defined in Section 4)**? : \_\_\_\_ YES \_\_\_\_NO
3. **Explain the deception and how/why it fits into Minimal Risk or Greater than Minimal Risk.**
4. **Deceptions must revealed in a debriefing during which researchers try to mitigate any harm or negative feelings the deception or revealing it may cause. Debriefing must include an *explanation as to why you chose to use deception*. Provide an EXACT version of the debriefing statement and procedure (below or in an attachment).**

**SECTION 8: OFF-CAMPUS PROJECTS AND INTERNATIONAL RESEARCH**

**\*\*\*FOR RESEARCH CONDUCTED ON THE LU CAMPUS OR ON-LINE SKIP TO SECTION 9\*\*\***

1. **Where will the research be conducted? Explain what permissions you have obtained and from whom to conduct research at this/these site(s):**
2. **Have you obtained or will you seek IRB approval from cooperating institutions? Explain below***:*
3. **If the research will be conducted in a language other than English, you must translate and back-translate all materials (e.g., consent form) for accuracy. Please affirm that you have or will do so by initialing below (may be typed):**

 \_\_\_\_ Before collecting data, all materials will be back-translated to ensure accuracy.

1. **If you are conducting research in a language other than English OR you are conducting international research you must complete the CITI training course for “International and Multilingual Research” in addition to the basic “Human Subjects Research” course (see below).**
2. **If you are conducting international research you must also ensure that you adhere to human subjects research requirements in the country where you are collecting data. These requirements can be found at:**

[**https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html**](https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html)

**SECTION 9: HUMAN SUBJECTS RESEARCH TRAINING CERTIFICATION**

**ALL investigators must complete ethics training for research with human participants via the Collaborative Institutional Training Initiative (CITI). ALL investigators must certify having completed the “Human Subjects Research” (HSR) course. Investigators working in multilingual or international contexts must also complete the “International and Multilingual Research” course**

**If possible, attach a copy of the completion notification or certificate. Otherwise you can email it separately.**

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| --- | --- |
| **Investigator Names (add rows if needed):** | **CITI Training completed:** |
|       | [ ]  HSR [ ]  International and Multilingual |
|       | [ ]  HSR [ ]  International and Multilingual |
|       | [ ]  HSR [ ]  International and Multilingual |
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**SECTION 10: ASSURANCE STATEMENTS**

**PRINCIPAL INVESTIGATOR ASSURANCE STATEMENT**

**I certify that the information provided in this IRB application is complete and accurate.**

**As Principal Investigator, I understand I am responsible for the conduct of IRB approved studies, the ethical performance of protocols, the protection of the rights and welfare of human participants, and strict adherence to the study’s protocol and any stipulations imposed by the Lawrence University Institutional Review Board.**

**If applicable, I understand that it is my responsibility to ensure that the human participants’ involvement as described in the funding proposal(s) is consistent in principle, to that contained in the IRB application. I will submit modifications and/or changes to the IRB as necessary.**

**I agree to comply with all Lawrence University policies and procedures, as well as with all applicable federal, state, and local laws, regarding the protection of human participants in research.**

 **PI Name and Signature (may be typed) Date**

**FACULTY SPONSOR ASSURANCE STATEMENT (required for all student projects)**

**I am the faculty member for the student submitting this protocol. I have reviewed the protocol and attachments, and approve them. I confirm that all items required by the IRB checklist (below) are submitted with this proposal and that the proposed consent procedure is appropriate for this research**.

**Faculty Signature (may be typed) Date**

|  |
| --- |
| **SUBMISSION CHECKLIST (This section must be FULLY completed.):** |
| **ALL applicable documents must be sent as attachments to** ***irb@lawrence.edu*** **in the same email as this form.** **Incomplete submissions will not be reviewed and will be returned to the investigator.** |
| **My submission contains the following (ATTACHMENTS MUST BE SENT IN SAME EMAIL WITH THIS FORM):** |
| **Included/ N/A****Attached** |
|  [ ]  This application form, fully completed, signed by researcher & (if applicable) faculty sponsor. |
|  [ ]  [ ]  Documented permission to conduct research in a location other than Lawrence University |
|  [ ]  [ ]  IRB approval documentation from another institution. |
|  [ ]  [ ]  All research materials (e.g., tests, questionnaires, interview questions, surveys, scripts, etc.) |
|  [ ]  [ ]  Recruiting materials (e.g., text of email or web-based solicitation). |
|  [ ]  [ ]  Debriefing form (if deception involved). |
|  [ ]  [ ]  Informed Consent and/or assent form(s) or justification for consent wavier |
|  [ ]  [ ]  Certificate(s) of training completion for researcher(s). |

**For questions about this form or IRB concerns, email:** **irb@lawrence.edu**

**Links to the policies and Federal regulations for the protection of human research subjects including the Code of Federal Regulations are available on the** [***Lawrence University IRB website*.**](https://www.lawrence.edu/academics/research/irb/regulations_ethical_guidelines)

**FOR IRB USE ONLY:**

Protocol identification/date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Type of review: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reviewer(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Action taken: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Expiration date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_