

**PROTOCOL APPLICATION**

**FOR IRB REVIEW OF RESEARCH INVOLVING HUMAN SUBJECTS**

Please complete this application as thoroughly as possible.

**Form must be typed—HANDWRITTEN DOCUMENTS will not be accepted.**

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| **1. Research Project** | | | | | |
| Project Title: | | | | | |
| Project start date: | | | Project end date: | | |
| Unfunded project | | |  | | |
| Internally funded project | | | Source: | | |
| Externally funded project *(provide grant title and award # below)* | | | Sponsor/Agency: | | |
| Grant Title: | | | Grant Award #: | | |
| **2. Principal Investigator (PI) [Complete 2a OR 2b]** | | | | | |
|  | | | | | |
| **2a. Student PI \*** | | | | | |
| Name: | Telephone: xxx-xxx-xxxx | | | | Email: |
| Course # and Name\*\*: | | | | | |
| *\*\*Use “Independent Student Research” for course name if research project is not for a specific course.* | | | | | |
| Supervisory Faculty: | | Supervisory Faculty Email: | | | |
| ***\*ALL student investigators must have a supervisory faculty member for their project. Supervisory faculty members need to review and approve the protocol before it is submitted, and indicate their approval by signing and submitting a Supervisory Faculty Assurance Form, which can be found on the*** [*Lawrence University IRB we*bsite](http://www.lawrence.edu/dept/ora/irb/) ***under “Forms and Templates”.***  ***The form must be submitted to*** [***irb@lawrence.edu***](mailto:irb@lawrence.edu)***.*** | | | | | |
| **2b. Faculty/Staff PI (Do not complete this section if you are a student.)** | | | | | |
| Name:  Email: | | | Department:  Phone: | | |
| Status (Faculty, Lawrence Fellow, Staff, Visiting, or Other): | | | | | |
| **3. Co-Investigators** | | | | | |
| Name:  Email:  Faculty  Student  Staff Other (specify) | | | | Institution *(if not Lawrence)*: | |
| Name:  Email:  Faculty  Student  Staff Other (specify) | | | | Institution *(if not Lawrence)*: | |
| Name:  Email:  Faculty  Student  Staff Other (specify) | | | | Institution *(if not Lawrence)*: | |
| Name:  Email:  Faculty  Student  Staff Other (specify) | | | | Institution *(if not Lawrence)*: | |
| Name:  Email:  Faculty  Student  Staff Other (specify) | | | | Institution *(if not Lawrence)*: | |
| Name:  Email:  Faculty  Student  Staff Other (specify) | | | | Institution *(if not Lawrence)*: | |
| **4. Cooperating Institutions** | | | | | |
| **4 (a)** Will the research be conducted on the Lawrence campus?  Yes  No (*If “Yes”, skip to section 5)*  If “No”, please indicate the location(s): | | | | | |
| **4 (b)** Have you obtained permission to conduct the research at the off-campus location?  Yes  No  ***\*\*If “Yes”, please provide a copy of the documentation of permission if it was provided with this application to*** [***irb@lawrence.edu***](mailto:irb@lawrence.edu)***.\*\**** | | | | | |
| **4 (c)** Have you received IRB approval for this study from an IRB at another institution?  Yes  No  ***\*\*If “Yes”, please provide a copy of the IRB approval with this application to*** [***irb@lawrence.edu***](mailto:irb@lawrence.edu)***.\*\**** | | | | | |
| **5. Research Methods** | | | | | |
| ***\*\*A copy of all tests, questionnaires, interview questions, surveys, scripts, etc. must be submitted with this application to*** [***irb@lawrence.edu***](mailto:irb@lawrence.edu)***.\*\**** | | | | | |
| **5 (a)** Which of the following will be used to collect information about participants? *(Check all that apply.)*  Tests (e.g., educational tests including cognitive, diagnostic, aptitude, achievement)  *Type of test:  published/standardized or  researcher-created*  Questionnaire/Survey  *Type of survey:*  *paper  telephone  online*  Interviews  *Type of interview:  face-to-face  telephone  e-mail/chat room*  Recordings made of participants  *Type:  audio or  video*  Focus Groups  Observation  Existing Data  Experiment without Deception  Experiment with Deception  Other (*please specify)* | | | | | |
| **5 (b)** Please describe the content, format, or use of all data collection instruments, which includes questionnaires, tests, interviews, or recording devices used to gather information from or about participants. *(maximum of 500 words)* | | | | | |
| **6. Procedures** | | | | | |
| **6 (a)** Please provide a brief statement on the purpose of the research and a brief description of the research procedures that will be followed, including any experimental procedures and use of placebos. | | | | | |
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| **6 (b)** Please describe what you will ask participants to do and what will be done to them. | | | | | |
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| **6 (c)** How long are participants expected to participate in the project? | | | | | |
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| **6 (d)** Please identify any alternative procedures, if any, for those who choose not to participate. | | | | | |
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| **7. Participants** | | | | | |
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| **7a. Participant Population** | | | | | |
| **7a(1)** What is the TOTAL # of participants expected to be enrolled? | | | | | |
| **7a(2)** Will any of the following classes of vulnerable participants be involved in the proposed study?  Yes  No  *(If “No”, skip to 7(a)4)* | | | | | |
| **7a(3)** *Class of vulnerable subjects (check all that apply):* | | | | | *Estimated age range of participants for each class* |
| Children/Minors | | | | |  |
| Prisoners or parolees | | | | |  |
| Pregnant women | | | | |  |
| Human fetuses or neonates | | | | |  |
| Mentally disabled persons | | | | |  |
| Economically or educationally disadvantaged persons | | | | |  |
| Other *(please describe)* | | | | |  |
| **7a(4)** What do you estimate the ratio of males to females to be? | | | | | |
| **7a(5)** Please list inclusion and exclusion criteria: | | | | | |
| **7b. Participant Recruitment** | | | | | |
| Describe how participant recruitment will be performed. Include your exact recruitment script or text here, which must address (a) how the purpose of the study will be described to potential participants, (b) what potential participants will be told about what they will do in the study, and (c) how long participants will be told the study will take. If vulnerable participants are being recruited, please describe the additional safeguards in place to protect against coercion and undue influence. | | | | | |
| ***\*\*Please send a copy of any recruiting materials and/or the text of email or web-based solicitations you will use with this application to*** [***irb@lawrence.edu***](mailto:irb@lawrence.edu)***.\*\**** | | | | | |
| **7c. Participant Compensation** | | | | | |
| **7c(1)** Will participants be offered compensation?  Yes  No *If “Yes”, please describe.* | | | | | |
| **7c(2)** Will participants who are students be offered class credit?  Yes  No  N/A | | | | | |
| **7c(3)** If you plan to offer course credit for participation, please describe what alternative assignment(s) students may complete to get an equal amount of credit should they choose not to participate in the study. | | | | | |
| **7d. Participant Risks and Benefits** | | | | | |
| **7d(1)** List any reasons people should not participate in this study. | | | | | |
| **7d(2)** Is deception involved in this research?  Yes  No | | | | | |
| If “Yes”, please answer the following questions: Why is deception necessary and does it pose a risk to participants? What significant prospective scientific, educational, or applied value justifies the use of deception? What is the likelihood that a person would decline participating in the study if deception was disclosed before the study began? Please explain. | | | | | |
| **\*\**If the study involves deception, you must submit the Debriefing Form to*** [***irb@lawrence.edu***](mailto:irb@lawrence.edu) ***with this application.\*\****  *The Debriefing Form can be found on the* [*Lawrence University IRB web site*](http://www.lawrence.edu/dept/ora/irb/) *under “Forms and Templates”.* | | | | | |
| **7d(3)** Indicate the degree of risk (physical, psychological, social, legal, economic, or other) you believe the research poses to human subjects *(check* ***the one*** *which applies).* | | | | | |
| MINIMAL RISK: A risk is minimal where 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. - ***Proceed to Section 7(d)6*** | | | | | |
| GREATER THAN MINIMAL RISK: Greater than minimal risk is greater where 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. | | | | | |
| **7d(4)** If you checked GREATER THAN MINIMAL RISK in the previous question, in which of the following categories is there risk of harm? *(check all that apply)*  Physical (i.e., fatigue, pain, injury)  Psychological (i.e., distress, anxiety, depression)  Social (i.e., stigma)  Legal (i.e., disclosure of illegal drug use)  Economic (i.e., loss of job or advancement, loss of insurance)  Other (please describe) | | | | | |
| **7d(5)** Please 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)* | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | | | | | | |
| **7d(6)** What are the benefits to participants in this study? | | | | | |
| **7d(7)** Describe how the benefits outweigh the risks. | | | | | |
| **8. Confidentiality, Anonymity and Data Security** | | | | | |
| **8 (a)** Will personal identifiers be collected?  Yes  No Will identifiers be translated to a code?  Yes  No | | | | | |
| **8 (b)** Describe the procedures to assure confidentiality of the participants and their responses. | | | | | |
| **8 (c)** Describe how you will assure anonymity of participants, if appropriate. | | | | | |
| **8 (d)** Please explain how identifying information will be handled, how/where data will be stored, and how it will be protected. | | | | | |
| **8 (e)** Who will have access to data (surveys, questionnaires, recordings, interview records, etc.)? | | | | | |
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| **9. Consent** | | | | | |
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| **9a. Informed Consent** | | | | | |
| **9a(1)** Which type of informed consent do you plan to use?  Written  Oral  Implied  Passive/Opt Out  Waiver  **If “Written or Oral”**, please develop an informed consent form according to the Office for Human Research Protections (OHRP) checklist or using the Lawrence University Informed Consent Form templates.  *The checklist and templates can be found on the* [*Lawrence University IRB web*site](http://www.lawrence.edu/dept/ora/irb/) *under “Forms and Templates”.*  **If “Implied or Passive/Opt Out”**, please describe how this will be accomplished.  **If “Waiver”**, you must complete Section 9b below on waiver of written informed consent.  ***\*\*Please send a copy of any consent and/or assent forms you will use with this application to*** [***irb@lawrence.edu.\*\****](mailto:irb@lawrence.edu.**) | | | | | |
| **9a(2)** Are minor children being recruited?  Yes  No  If “Yes”, Child Assent and Informed Parental Consent forms are required. *Forms can be found on the* [*Lawrence University IRB website*](http://www.lawrence.edu/dept/ora/irb/) *under “Forms and Templates”.* | | | | | |
| **9b. Waiver of Written Informed Consent** | | | | | |
| Are you requesting a waiver of written documentation (signed) of informed consent?  Yes  No  If “Yes,” please answer the following questions: | | | | | |
| **9b(1)** Will the only record linking the participant and the research be the consent document and the principal risk to the participant would be from breach of confidentiality?  Yes  No | | | | | |
| **9b(2)** Do you consider this a minimal risk study that involves no procedures for which written consent is normally required outside of research?  Yes  No | | | | | |
| **9b(3)** Explain how you plan to obtain consent. | | | | | |
| ***\*\*Please note IRB may require you to provide participants a written statement regarding the research.\*\**** | | | | | |
| **9c. Retention of Signed Consent Forms** | | | | | |
| **9c(1)** How and where will the written, signed consent forms be stored and protected? | | | | | |
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| **9c(2)** For how long will the consent forms be retained? (**Federal guidelines mandate consent forms must be retained for at least** **three years** **following completion of the research.)** | | | | | |
|  | | | | | |
| **9c(3)** If these forms will later be destroyed, specify how and when? | | | | | |
| **10. International Research** | | | | | |
| **10 (a)** Is the research being conducted internationally?  Yes  No *(if “No”, skip to section 11)* | | | | | |
| **10 (b)** In what language will the research documents (i.e., consent forms, surveys, interview questions) be written?  English only  Both English and other language(s) *(please specify)*  Language(s) other than English *(please specify)* | | | | | |
| **10 (c)** If the research documents will be in a language other than English, please describe in which language each document will be written: | | | | | |
| **10 (d)** Did the research documents go through the translation/back-translation procedure to assure the correct information is being communicated?  Yes  No | | | | | |
| **10 (e)** Describe to what extent the researchers are aware of cultural norms and sensitivities where research will be conducted? | | | | | |
| **10 (f)** Are you familiar with the “International Compilation of Human Research Protections” compiled by the Office for Human Research Protections (OHRP) for the country in which you are conducting research? *This can be found on the* [*Lawrence University IRB web*site](http://www.lawrence.edu/dept/ora/irb/) *under “International Research” or at* [*www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html*](http://www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html)*.*  Yes  No | | | | | |
| **10 (g)** Have you completed the CITI International Research Modules? *(recommended)*  Yes  No | | | | | |
| **11. IRB Training** | | | | | |
| **11 (a)** Have you as the Principal Researcher/Investigator completed a mandatory human subjects research training program?  Yes  No  If “No”, please complete required training. See [Lawrence University IRB website](http://www.lawrence.edu/dept/ora/irb)under “Training and Certification”. | | | | | |
| **11 (b)** Have all members of your research team completed the mandatory human subjects research training program?  Yes  No  Not applicable  If “No”, please complete required training. See [Lawrence University IRB website](http://www.lawrence.edu/dept/ora/irb)under “Training and Certification”. | | | | | |
| **11 (c)** Please list the name(s) of researcher(s) who completed training below.  Training choices include the National Institutes of Health (NIH) and/or Collaborative Institutional Training Initiative (CITI).  *(NIH training is required; CITI is recommended)* \*\****Send the proof of completion for each researcher to*** [***irb@lawrence.edu***](mailto:irb@lawrence.edu)**.\*\*** | | | | | |
| Names: | | | | Completed: | |
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| **SUBMISSION CHECKLIST (This section must be FULLY completed.):** |
| **For submission to be complete, all applicable documents must be sent as attachments to** [***irb@lawrence.edu***](mailto:irb@lawrence.edu). **Incomplete protocol submissions will not be sent out for review and will be returned to the investigator.** |
| **My submission contains the following documents (IF APPLICABLE, DOCUMENTS MUST BE ATTACHED TO THE SAME E-MAIL USED TO SUBMIT THIS PROTOCOL APPLICATION):** |
| **Attached N/A** |
| This protocol application form, fully completed and signed by researcher. |
| (#4b) Documentation of permission to conduct research in a location other than Lawrence  University. |
| (#4c) IRB approval documentation from another institution. |
| (#5a) Tests, questionnaires, interview questions, surveys, scripts, etc. |
| (#7b) Recruiting materials, text of email or web-based solicitation. |
| (#7d2) Debriefing form. |
| (#9a1/9a2) Consent and/or assent form(s). |
| (#9a1) **If using** **oral consent,** comply with theCode of Federal Regulations as follows:   * short form written consent document * states participant or participant's legally authorized representative have been presented the eight basic required elements of informed consent orally (*see Office for Human Research Protections (OHRP) checklist found on the* [*Lawrence University IRB website*](http://www.lawrence.edu/dept/ora/irb) *under “Forms and Templates”).* * a witness to the oral presentation * signed by the participant or participant's legally authorized representative AND witness * copy of short form given to participant or participant's legally authorized representative * a written summary of the oral presentation/content * contains what is to be said to participant or participant's legally authorized representative embodying the basic and appropriate elements of disclosure * LU IRB reviews and approves or disapproves written summary * copy signed by the witness AND person obtaining consent * copy of summary given to participant or participant's legally authorized representative |
| (#11c) Certificate of training completion for researcher(s). |
| **ADDITIONAL SUBMISSION REQUIREMENT FOR ALL STUDENT PRINCIPAL INVESTIGATORS (including independent research projects):** |
| Application and all other related documentation reviewed by supervisory faculty member. |
| Supervisory Faculty Assurance Formcompleted by student and forwarded to supervisory faculty member for their signature and submission to IRB.  **STUDENT PI protocol submissions will be sent out for review after the following requirements are met:**   1. **Protocol application and supporting documentation has been reviewed and approved by the supervisory faculty member designated in 2(a) and then submitted to** [***irb@lawrence.edu***](mailto:irb@lawrence.edu)**.** 2. **The LU IRB has received a completed Supervisory Faculty Assurance Form sent from the supervisory faculty member.** |

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| **Principal Investigator’s\* Assurance Statement for Using Human Subjects in Research** | |
| I certify that the information provided in this IRB application is complete and accurate.  I understand that as Principal Investigator, I have ultimate responsibility 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. | |
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| Principal Investigator Name and Signature\*\* | Date |

***\*\* A handwritten signature is not needed if this form is emailed from a Lawrence University email account. Please type in name and date and submit to*** [***irb@lawrence.edu***](mailto:irb@lawrence.edu).

***A handwritten signature is required if this form is not emailed from a Lawrence University email account. Please mail this application including the handwritten signature to Lawrence University, Office of Research Administration, 711 E. Boldt Way, Appleton, WI, 54911.***

Questions? Please contact Dr. William Skinner, IRB Chair ([*william.f.skinner@lawrence.edu*](mailto:william.f.skinner@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*](http://www.lawrence.edu/dept/ora/irb).]

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| *For internal use only:*  **Application:**  LU IRB Protocol #:  Full Review  Expedited Review  Exempt Review  Application Received:  Date Faculty Assurance Form Received:        N/A  Distribution Date:  Reviewer Comments due:  Reviewer Initials: |
| **Decision:**  Approve  Approve with suggested changes/recommendations\* (specify)  Request required modification \* (specify)  Defer approval until (specify terms/conditions)  Withhold approval |
| **Expiration date:** |
| **Continuation Review due:** |
| **Comments:** |