****

**CONTINUATION REVIEW AND/OR MODIFICATION REQUEST 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.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **1. Research Project** | | | | |
| IRB Protocol Number: | | | | |
| Project Title: | | | | |
| This request is for:  Re-approval  Modification  **If checked,** does the request increase risk to participants?  Yes  No  If “Yes”, what was your original review?  Exempt  Expedited  Full Review  Both (project is soon to expire and changes are requested) | | | | |
| Do you need IRB approval to continue past the end date of your current approval period?  Yes  No  NA  If “Yes”, what is the estimated project end date: Click here to enter a date. | | | | |
| Has the project title changed from the original submission?  Yes  No  NA  If “Yes”, what is the new title? | | | | |
| **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 application 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): | | | | |
| **2c. Personnel Changes** | | | | |
| **2c(1)** Has there been a change (addition or removal of) to Student Researchers in your project since the last IRB approval?  Yes  No  NA  If “Yes”, please specify changes below.   |  |  | | --- | --- | | Names: | Add or Remove: | |  | Add  Remove | |  | Add  Remove | |  | Add  Remove | |  | Add  Remove | |  | Add  Remove | | | | | |
| **2c(2)** Has there been a change (addition or removal of) to the Supervisory Faculty member in your project since the last IRB approval?  Yes  No  NA  If “Yes”, please specify changes below.   |  |  | | --- | --- | | Names: | Add or Remove: | |  | Add  Remove | |  | Add  Remove | | | | | |
| **2c(3)** Has there been a change to co-investigators in your project since the last IRB approval?  Yes  No  NA  If “Yes”, please specify changes below.   |  |  | | --- | --- | | Names: | Add or Remove: | |  | Add  Remove | |  | Add  Remove | |  | Add  Remove | |  | Add  Remove | |  | Add  Remove | | | | | |
| **2c(4)** Have all new personnel completed a mandatory human subjects research training program?  Yes  No  NA  If “No”, please complete required training. See [Lawrence University IRB website](http://www.lawrence.edu/dept/ora/irb)under “Training and Certification”. | | | | |
| **2c(5)** 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: | |  | NIH  CITI | |  | NIH  CITI | |  | NIH  CITI | |  | NIH  CITI | |  | NIH  CITI | | | | | |
| **3. Cooperating Institutions** | | | | |
| **3 (a)** Has there been a change with regards to cooperating institutions since the last IRB approval?  Yes  No  NA (*If “No” or “NA”, skip to section 4)* | | | | |
| **3 (b)** Has there been a change with regards to the location where the research will be conducted since the last IRB approval?  Yes  No (*If “No”, skip to section 4)*  If “Yes”, please indicate the location(s): | | | | |
| **3 (c)** Have you obtained permission to conduct the research at the new 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)***.\*\**** | | | | |
| **3 (d)** Do you have current IRB approval for this study from an IRB at another institution?  Yes  No  ***\*\*If “Yes”, please provide a copy of the current IRB approval with this application to*** [***irb@lawrence.edu***](mailto:irb@lawrence.edu)***.\*\**** | | | | |
| **4. Status of Project** | | | | |
| *Check all that apply:*  The project is currently closed to enrollment of new participants.  All participants have completed all research-related interventions.  The project remains active for long-term follow-up of subjects.  Data are being collected from additional subjects.  Data analysis is the only remaining activity for this project.  *Type of data:*  *identified (either directly or through codes/links to the data)*  *de-identified (no participant identifying codes/links to the data so researcher or research team cannot identify*  *participants)*  All project activities are complete. IRB approval can be inactivated.\*\*  **\*\**If checked, you must submit the Protocol Closure Form to*** [***irb@lawrence.edu***](mailto:irb@lawrence.edu) ***with this application.\*\****  *The Protocol Closure Form can be found on the* [*Lawrence University IRB web site*](http://www.lawrence.edu/dept/ora/irb/) *under “Forms and Templates”.* | | | | |
| **5. Funding/Sponsor Information** | | | | |
| **5 (a)** Has there been a change in funding or sponsors?  Yes  No  NA (*If “No” or “NA”, skip to section 6)*  If “Yes”,please list the name of the original funder/sponsor and related information.   |  |  | | --- | --- | | Current Funding: | Change to : | | Unfunded project | Unfunded project | | Internally funded project | Internally funded project | | Externally funded project *(provide grant title and award # below)* | Externally funded project *(provide grant title and award # below)* | | Grant Title: | Grant Title: | | Grant Award #: | Grant Award #: | | Budget Amount $: | Budget Amount $: | | Other (*please specify)* | Other (*please specify)* | | | | | |
| **5 (b)** Was additional funding received?  Yes  No  If “Yes”, specify dollar amount:  ***\*\*A copy of the current award letter(s) must be submitted with this application to*** [***irb@lawrence.edu***](mailto:irb@lawrence.edu)***.\*\**** | | | | |
| **6. Current Research Methods** | | | | |
| ***\*\*A copy of all current tests, questionnaires, interview questions, surveys, scripts, etc. must be submitted with this application to*** [***irb@lawrence.edu***](mailto:irb@lawrence.edu)***.\*\**** | | | | |
| **6 (a)** Has there been a change in research methods from the last IRB approval? Yes  No (*If “No”, skip to section 7)* | | | | |
| **6 (b)** Please describe the **current** types of research methods that are being used for the project. *(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  *Type:  audio or  video*  Focus Groups  Observation  Existing Data  Experiment without Deception  Experiment with Deception \*\*  Other (*please specify)*  ***\*\*A copy of the current Debriefing Form must be submitted with this application to*** [***irb@lawrence.edu***](mailto:irb@lawrence.edu)***.\*\****  *The Debriefing Form can be found on the* [*Lawrence University IRB web site*](http://www.lawrence.edu/dept/ora/irb/) *under “Forms and Templates”.* | | | | |
| **7. Current Participants** | | | | |
|  | | | | |
| **7a. Current Participant Population** | | | | |
| **7a(1)** Is your project closed to the enrollment of new participants?  Yes  No | | | | |
| **7a(2)** What is the cumulative number of participants enrolled to date? | | | | |
| **7a(3)** **Is enrollment consistent with the planned number of participants described in the IRB-approved protocol?**  Yes  No  If “No”, please explain how the difference between the actual and expected number of participants will impact your project. | | | | |
| **7a(4)** Will you be increasing or decreasing the number of participants?  Increasing  Decreasing  Both I  Neither  If checked “Increasing”, “Decreasing”, or “Both”, (specify number to be added or removed)   |  |  | | --- | --- | | Population: | Add or Remove (specify quantity): | | Adults | Add        Remove | | Children/Minors | Add        Remove | | | | | |
| **7a(5)** How many participants do you estimate you will have at completion of the project? | | | | |
| **7a(6)** Will any of the following classes of vulnerable participants be involved ?  Yes  No *(If “No”, skip to 7(a)8)* | | | | |
| **7a(7)** *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(8)** Has the ratio of males to females changed since the last IRB approval?  Yes  No  If “Yes”,describe the current ratio. | | | | |
| **7a(9)** Have the inclusion and exclusion criteria changed since the last IRB approval?  Yes  No  If “Yes”, describe the changes. | | | | |
| **7b. Participant Recruitment** | | | | |
| **7b(1)** Have there been any changes to participant recruitment since the last IRB approval?  Yes  No  If “Yes”, describe the changes including how vulnerable participants are recruited, if applicable. | | | | |
| ***\*\*Please send a current 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)** Have there been any changes to participant compensation since the last IRB approval?  Yes  No  N/A  If “Yes”,please describe. | | | | |
| **7d. Participant Consent** | | | | |
| **7d(1)** Was consent obtained for all subjects? Yes  No  N/A *(If “NA”, skip to section 8)* | | | | |
| **7d(2)** Did all participants receive a copy of the signed consent form? Yes  No | | | | |
| **7d(3)** Where are the signed consent forms stored (building and room number)? | | | | |
| **7d(4)** Did you encounter any problems in obtaining consent?  Yes  No  If “Yes”, please describe. | | | | |
| **8. Progress to Date** | | | | |
| **8 (a)** Please report the number of participants accrued to date. | | | | |
| **8 (b)** Please provide a summary of your progress to date, including accomplishments and barriers. Please include a summary of any unanticipated problems and/or adverse events. | | | | |
| **8 (c)** Please provide a brief summary of any amendments or modifications to the research project since the initial review or last continuation review. | | | | |
| **8 (d)** Describe the changes in risks or benefits to participants since the last IRB approval. | | | | |
| **9. Proposed Modifications (Complete only if applicable)** | | | | |
|  | | | | |
| **9a. Participant Type and Number** | | | | |
| **9a(1)** Is participant enrollment being re-opened via this modification request?  Yes  No | | | | |
| **9a(2)** Are you proposing to increase or decrease the number of participants?  Yes  No | | | | |
| **9a(3)** Does the modification affect the risk(s) to participants?  Yes  No  If “Yes”, explain how: | | | | |
| **9a(4)** Does the modification affect the benefit(s) to participants?  Yes  No  If “Yes”, explain how: | | | | |
| **9a(5)** Does the modification affect currently enrolled participants’ willingness to continue in the study (i.e., revised study procedures, changes in compensation, etc.)?  Yes  No  If “Yes”, explain how: | | | | |
| **9b. Informed Consent/Assent** | | | | |
| **9b(1)** How will the currently enrolled participants be informed about the changes requested in this modification?  Participants will complete a new informed consent/assent form  Participants will complete an addendum informed consent/assent form | | | | |
| **9b(1)** Will you be adding or revising any currently approved consent/assent forms?  Yes  No  ***\*\*Please send a copy of any current and proposed modifications to the consent and/or assent forms you will use with this application to*** [***irb@lawrence.edu***](mailto:irb@lawrence.edu)***.\*\**** | | | | |
| **9c. Instrumentation** | | | | |
| **9c(1)** Are you adding or removing any instruments from your currently approved protocol?  Yes  No | | | | |
| If “Yes”, please describe and list the title of the instrument(s) added or removed below and attach all additional instruments.   |  |  | | --- | --- | | Instrument(s): | Add or Remove: | |  | Add  Remove | |  | Add  Remove | |  | Add  Remove | |  | Add  Remove | |  | Add  Remove | | | | | |
| **9c(2)** How many instruments will you be using in total?  ***\*\*Please send a copy of the current instruments you will use with this application to*** [***irb@lawrence.edu***](mailto:irb@lawrence.edu)***.\*\**** | | | | |
| **9d. Other** | | | | |
| **9d(1)**  Please describe any other proposed modifications in detail with regards to the following: *(check and describe all that apply)*  Scope *(specify)*  Research Methods *(specify)*  Risks and Benefits *(specify)*  Location *(specify)*  Other *(specify)* | | | | |
| **10. Reportable Events** | | | | |
| **10 (a)** Have any participants withdrawn or dropped out from your project since the last IRB review?  Yes  No  *(If “No”, skip to 10e)* | | | | |
| **10 (b)** What is the cumulative number of participants that have withdrawn or dropped out? | | | | |
| **10 (c)** What are the reasons for withdrawal? (*check all that apply)*  Withdrawn at direction of PI  Serious adverse events  Unanticipated problems  Protocol violations  Conflict with investigators  Transportation issues  Other *(specify)* | | | | |
| **10(d)** What is the cumulative number of participants that have dropped out because of unanticipated problems?  **\*\*Note this number should match the number previously submitted on the *Adverse Events/Unanticipated Problems Reporting Form.\*\**** | | | | |
| **10 (e)** Have there been any complaints to your knowledge from participants or others about your research project?  Yes  No  If “Yes”, please provide a summary. | | | | |
| **10 (f)** Have there been any adverse events or unanticipated problems with your project?  Yes  No  **\*\**If “Yes”, you must submit the Adverse Events/Unanticipated Problems Reporting Form to*** [***irb@lawrence.edu***](mailto:irb@lawrence.edu) ***with this application.\*\**** | | | | |
| **10 (g)** Have there been any protocol violations with your project?  Yes  No  **\*\**If “Yes”, you must submit the Protocol Violation Form to*** [***irb@lawrence.edu***](mailto:irb@lawrence.edu) ***with this application.\*\**** | | | | |
| **10(h)** Were the events listed above promptly reported to the IRB?  Yes  No  If “No”, please explain. | | | | |
| **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 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 CONTINUATION/MODIFICATION APPLICATION):** | | | | |
| **Attached N/A** | | | | |
| This continuation/modification application form, fully completed and signed by researcher. | | | | |
| Latest version of IRB-approved protocol (proposal and approval letter) | | | | |
| (#2c5) Certificate of training completion for researcher(s). | | | | |
| (#3c) Documentation of permission to conduct research in a location other than Lawrence  University. | | | | |
| (#3d) IRB approval documentation from another institution. | | | | |
| (#4) Protocol closure form. | | | | |
| (#5) Current and new award letter(s) for funding. | | | | |
| (#6) Current and newly proposed tests, questionnaires, interview questions, surveys, scripts, etc. | | | | |
| (#6b) Debriefing form. | | | | |
| (#7b1) Current and newly proposed recruiting materials, text of email or web-based solicitation. | | | | |
| (#9b1) Current and newly proposed consent and/or assent form(s). | | | | |
| (#9c2) Current and newly proposed instruments. | | | | |
| (#10f) Adverse events and unanticipated problems reporting form. | | | | |
| (#10g) Protocol violation form. | | | | |
| **ADDITIONAL SUBMISSION REQUIREMENT FOR ALL STUDENT PRINCIPAL INVESTIGATORS (including independent research projects):** | | | | |
| This 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 continuation review and/or modification request submissions will be sent out for review after the following requirements are met:**   1. **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.** | | | | |

|  |  |
| --- | --- |
| **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 certify that the information provided is consistent with the research proposal previously approved by the IRB.  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 further 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. | |
|  | |
|  | Click here to enter a date. |
| 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).]

|  |
| --- |
| *For internal use only:*  **Application:**  LU IRB Protocol #:  Continuation Review  Modification Review  Both  Full Review  Expedited Review  Exempt Review  Application Received: Click here to enter a date.  Distribution Date: Click here to enter a date.  Reviewer Comments due: Click here to enter a date.  Reviewer Initials: |
| **Decision:** Click here to enter a date.  Approve  Approve with suggested changes/recommendations\* (specify)  Request required modification \* (specify)  Defer approval until (specify terms/conditions)  Withhold approval |
| **Expiration date:** Click here to enter a date. |
| **Continuation Review due:** Click here to enter a date. |
| **Comments:** |