****

**PROTOCOL CLOSURE FORM**

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

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

Complete this form when an approved human subject research project is **concluded** or **cancelled**. Projects that involve long-term follow-up of participants must remain open, even if enrollment of new participants has ended. Send the completed and signed Protocol Closure Form to **irb@lawrence.edu**. **Please include a final summary of the project with this form. Attach any results, articles, and reports to support the closure.**

|  |
| --- |
| **1. Protocol Information** |
| IRB Protocol Number:       |
| Project Title:       |
| Type of Approval: [ ]  Full Review [ ]  Expedited [ ]  Exempt |
| Was this a pilot study? [ ]  Yes [ ]  No If “Yes”, will the data be used for a larger scale study and has that protocol been submitted to IRB? [ ]  Yes [ ]  No  |
| Project start date: Click here to enter a date. | Project end date: Click here to enter a date. |
| **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:       |
|  **2b. Faculty/Staff PI (Do not complete this section if you are a student.)** |
| Name:      Email:       | Department:      Phone:       |
| **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)*:       |
| **4. Participants**  |
| **4 (a)** What is the TOTAL # of participants enrolled?       |
| **4 (b)** Has all contact with subjects been terminated? [ ]  Yes [ ]  No |
| **4 (c)** Are there any results to report? [ ]  Yes [ ]  NoIf “Yes”, will results have either direct benefit of any impact to the participants? [ ]  Yes [ ]  No |
| **5. Adverse Events, Unanticipated Problems, and Protocol Violations**  |
| **5 (a)** Have you encountered and reported any adverse events?[ ]  Yes [ ]  No If “Yes,” how many?       |
| **5 (b)** Have you encountered and reported any unanticipated problems?[ ]  Yes [ ]  No If “Yes,” how many?       |
| **5 (c)** Have you encountered and reported any protocol violations?[ ]  Yes [ ]  No If “Yes,” how many?       |
| **6. Reason for Protocol Closure** |
| **6 (a)** What is the reason work has ended on this project? *(check all that apply)**[ ]*  All research investigation activities completed including data analysis and reporting. *[ ]*  Human subject accrual/involvement and data collection is complete. No follow-up planned with participants. Data are de-identified (no longer contains identifiers or codes that can link them to individuals). Only remaining activity is data analysis. [ ]  Project no longer funded.[ ]  PI never initiated project.[ ]  PI no longer at Lawrence University.[ ]  PI intends to leave Lawrence University and continue research at another institution. (Specify institution)      [ ]  Project cancelled for other reason. Please describe:       |
|  |
| **7. Document Retention**  |
| **Federal guidelines mandate consent forms must be retained for at least** **three years** **following completion of the research.** **7 (a)** Please indicate the location of where consent forms will be kept.       |
| **7 (b)** Please indicate where and how the data are filed and stored?       |
| **7 (c)** How will confidentiality and data access will be secured?        |
| **8. Signatures**  |
|       Click here to enter a date. |
| Signature of Principal Investigator\*\* Date |
|       Click here to enter a date. |
| Signature of Supervisory Faculty Member\*\* 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******.***

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