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**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**](mailto: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  No  If “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***](mailto: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.***