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**PROTOCOL VIOLATION FORM**

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

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

Complete this form when there is a protocol violation to an approved human subject research project. The IRB defines and categorizes protocol violations in two categories: Protocol Exceptions and Protocol Deviations. Send the completed and signed Protocol Violation Form to [**irb@lawrence.edu**](mailto:irb@lawrence.edu) **within 14 working days** of the occurrence.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **1. Protocol Information** | | | | | |
| IRB Protocol Number: | | | | | |
| Project Title: | | | | | |
| Type of Approval:  Full Review  Expedited  Exempt | | | | | |
| Project start date: Click here to enter a date. | | | Project end date: Click here to enter a 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: | | | |
| **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. Violation Report** | | | | | |
| |  |  |  |  | | --- | --- | --- | --- | | Reporter Name: | Telephone: xxx-xxx-xxxx | | Email: | | Date Violation Occurred: Click here to enter a date. | | Date Violation Reported: Click here to enter a date. | | | Location of Violation: | | | | | | | | | |
| **4 (a)** Indicate the nature of the protocol violation (check **the one** which applies).  Protocol Exception (defined as the enrollment of a research subject in a protocol that fails to meet protocol inclusion criteria or a person who should **not** have been enrolled based on protocol exclusion criteria)  Protocol Deviation (defined as a departure from the protocol for a research subject once that subject has actually been satisfactorily enrolled) | | | | | |
| **5. Description, Actions, and Outcome of Violation** | | | | | |
| **5 (a)** Provide a description (include dates and details) of the violation: | | | | | |
| **5 (b)** Has this kind of violation happened before in connection with this study?  Yes  No  If “Yes”, please explain in detail. | | | | | |
| **5 (c)** Provide a description of how the violation was managed. | | | | | |
| **5 (d)** Provide a description of the corrective actions taken to ensure this type of violation does not occur again in the future. | | | | | |
| **6. Signatures** | | | | | |
| Click here to enter a date. | | | | | |
| Signature of Reporter\*\* Date | | | | | |
| 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.***

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*FOR IRB USE ONLY\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

**The violation(s) does not constitute an unanticipated problem(s) involving risk(s) to subjects or others.**

**Justification for determination** *(required)***:**

**Report reviewed/no further action requested**

**Revisions and/or additional information required**

**Protocol requires full review**

**Comments:**

**Committee Reviewer Signature**

Click here to enter a date.

**Date**