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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** **within 14 working days** of the occurrence.

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| --- |
| **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**  |
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|  |  |  |
| --- | --- | --- |
| 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:       |

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| **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 [ ]  NoIf “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***.

***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**