**Notification of Protocol Deviation/Violation**

Western Carolina University

Please complete and send the form with any attachments to IRB@wcu.edu

1. **ADMINISTRATIVE INFORMATION**

**Principal Investigator:**

**Department:**

**WCU IRB #:**

**Study Title:**

1. **REPORTING CRITERIA**

This deviation/violation adversely affects: (check all that apply)

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| Rights/Welfare of Subjects |  |  |
| Safety of Subjects |  |  |
| Integrity of Research Data |  |  |
| Subject’s willingness to continue study participation |  |  |

*(note: if you have checked “no” to all of the above, please do not proceed with this report. This is not a reportable deviation.* ***However,*** *if the IRB has specifically requested that you submit this report because of a lapse in approval or late submission, all sections of this form must be completed)*

1. **CHARACTERIZATION**

The deviation/violation involves:

[ ] Enrollment process (*inclusion/exclusion criteria, ascertainment/recruitment, etc.)*

[ ] Consent Process *(oral or written)*

[ ] Drug/Device Administration *(dosage, schedule, route of administration, formulation, etc.)*

[ ] Other Protocol Activities *(research activities, data analysis, reporting, etc.)*

[ ] Compliant from Research Subject

[ ] Audit Finding that requires corrective action

[ ] Other:

1. **DESCRIPTION**
2. Date(s) of the deviation/violation

*Note: if more than 10 business days prior to the date of submission to the IRB (or more than 24 hours for an unanticipated study-related death), please explain the delay in reporting*

1. Describe in detail the specific deviation/violations:
2. If the purpose of this deviation report is a lapse in IRB approval, please describe all study activities, including enrollment, interventions, data analysis, that have occurred during the lapse.
3. Explain how/why the deviation/violation occurred:
4. Describe how the deviation/violation affected the:
	1. Risk/benefit ratio for the subject(s)
	2. Integrity of the research data
	3. Subjects willingness to continue study participation

1. Does this protocol deviation/violation require revision of the protocol and/or consent form?

[ ] Yes *(if yes, please submit a completed amendment form and revised documents)*

[ ] No

1. Describe:
	1. Corrective actions, if applicable, for the deviations/violations
	2. A plan for preventing the recurrence of the deviation/violation

*By submitting this request, the Principal Investigator (and responsible faculty member if the PI is a student) I declare that I have reviewed this report which provides a complete and accurate description of the deviation/violation and that upon receipt of the IRB’s review, I will fully and immediately implement any corrective actions required by the IRB.*

*The parties (the IRB, the Principal Investigator, and responsible faculty member if the PI is a student) have agreed to conduct this application process by electronic means, and this application is signed electronically by the Principal Investigator and by the responsible faculty member if a student is the PI.*

*My name and email address together constitute the symbol and/or process I have adopted with the intent to sign this application, and my name and email address, set out below, thus constitute my electronic signature to this application.*

Date

PI Name PI Email Address

Responsible Faculty Name if PI is a Student Responsible Faculty Email Address if PI is a Student