This form must be completed for each protocol deviation or violation on an IRB-approved research protocol.

For purposes of this form: A **protocol deviation** is any change, divergence, or departure from the study design or procedures of a research protocol that is under the investigator's control and that has not been approved by the IRB.

A **protocol violation** is a deviation from the IRB approved protocol that may affect the subject's rights, safety, or well-being and/or the completeness, accuracy and reliability of the study data. Upon discovery, the Principal Investigator is responsible for reporting protocol deviations and/or protocol violations to the IRB. For more detailed information, visit: <https://orra.rutgers.edu/reportable-events>):

**Investigators** **must notify the IRB according to the following timeline**:

* Protocol Deviation(s)/Protocol Violation(s): **5 business days - from date of discovery;**

|  |
| --- |
| **[\_] Initial Report** [\_] **Follow-up Report**, Report # |
| **Rutgers Protocol #**: |
| **Principal Investigator** **Name:** |
| **For Student Investigators, list your Faculty Advisor:** |
| **Protocol Title:** |

**Please complete the following:**

|  |  |  |
| --- | --- | --- |
| 1. **Date of protocol deviation or protocol violation:** | | |
|  |  |  |
| 1. **Date the deviation and/or the violation was discovered by the Principal Investigator:** | | |
|  |  |  |
| 1. **Describe the nature of the deviation(s)/violation(s), including date(s): (e.g., wrong informed consent used, wrong recruitment letters mailed etc):** | | |
|  |  |  |
| 1. **Did the deviation(s) and/or the violation(s) affect subject safety?** | | |
|  |  | [\_] Yes\* [\_] No \*Please explain below. |
|  |  |  |
| 1. **Please explain below why the deviation and/or violation occurred. Describe any known outcomes.** | | |
|  |  |  |
| 1. **Did the deviation affect the risk/benefit ratio of this study?** | | |
|  |  | [\_] Yes\* [\_] No \*Please explain below**.** |
|  |  |  |
| 1. **Does the violation affect the integrity of the study data? (e.g. enrollment of an ineligible subject)?** | | |
|  |  | [\_] Yes\* [\_] No \*Please explain below**.** |
|  |  |  |
| 1. **Did the violation impact the rights of research participants? (e.g. subject enrolled without proper documentation of informed consent)** | | |
|  |  | [\_] Yes\* [\_] No \*Please explain below**.** |
|  |  |  |
| 1. **The protocol deviation or protocol violation will also be reported to (*check all that apply*):** | | |
|  | [\_] | Sponsor/Attach Copy of Sponsor’s Response |
|  | [\_] | Collaborating investigators |
|  | [\_] | Privacy Officer (if involving protected health information) |
|  | [\_] | No other reporting or unknown |
|  | [\_] | Other – specify: |

|  |  |  |
| --- | --- | --- |
| CORRECTIVE ACTIONS TO BE TAKEN: | | |
| **As a result of the deviation and/or the violation, indicate your corrective action plan (*check all that apply*):** | | |
|  |  | The protocol or study procedures will be modified. |
|  |  | The consent process and/or research instruments will be modified. |
|  |  | Additional information and/or follow-up will be provided to current and/or past participants. |
|  |  | Current participants will be asked to re-consent to participation. |
|  |  | The Investigator will education and re-train project staff on IRB-approved protocol procedures. |
|  |  | The Investigator has voluntarily placed the research on hold, pending more information or resolution of problem. ***(This requires immediate reporting).*** |
|  |  | The Rutgers research project (portion) is being stopped. ***(This requires immediate reporting).*** |
|  |  | Other Action (***Provide explanation***): |
|  |  | No action is planned. ***Provide explanation*** |

[**For any document to be modified, please submit two copies. On one copy, underline and use boldface type to indicate revisions and use strikeout for deletions. And include one copy using only plain font (or clean version**)].

|  |
| --- |
| Attach a full description of the protocol deviation and/or protocol violation being reported, any actions taken. Attach additional documents as necessary. Do not include (and remove where necessary) any participants’ personally identifiable information from submitted material. Indicate if follow up reports will be submitted. |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature of Principal Investigator** **Date**

**NOTE:**

Please submit your completed form (electronic signature is acceptable) along with all RELEVANT MATERIALS to [irb-admin@ored.rutgers.edu](mailto:irb-admin@ored.rutgers.edu).

Questions about whether an event constitutes an adverse/unexpected event or questions about completing this form should be directed to the Institutional Review Board (IRB) in the Office of Research and Regulatory Affairs: <https://orra.rutgers.edu/irb-contact-us>