# Protocol Deviation or Noncompliance Report

**IRB2**

*Investigators are required to report deviations from the approved research protocol to the Institutional Review Board when discovered during the course of research. Please complete the following information and submit to the IRB2 coordinator.*

IRB Protocol Number:

Protocol Title:

Principal Investigator:

Phone Number:

Date of Event:

|  |
| --- |
| 1. Briefly describe the purpose of the study:
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| 1. Date of *discovery* of the event:
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| 1. Category of deviation:

[ ]  Recruitment was over number of currently approved subjects.[ ]  Procedures were performed that were not described in currently approved protocol.[ ]  Procedures were not preformed as described in currently approved protocol.[ ]  Conducted research activities without IRB approval.[ ]  Other, specify:       |
| 4. Describe the specific deviation:        |
| 1. Has this protocol deviation (or similar deviations) previously occurred in this study?
 | [ ]  Yes[ ]  No |
| If Yes, describe the event(s) and when the event(s) occurred:       |
| 1. In the opinion of the PI, does this deviation affect the safety of the subjects?
 | [ ]  Yes[ ]  No |
| 1. In the opinion of the PI, does this deviation affect the integrity

(i.e., validity and ethics) of the research? | [ ]  Yes[ ]  No |
| 1. Describe your preventive/corrective action plan to avoid this occurrence in the future:

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| 1. Is the research federally funded?
 | [ ]  Yes[ ]  No |
| If Yes, give the name of the agency:       |