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| **STUDY TITLE** |  |
| **PI NAME** |  |

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| **Type of Change Request (check all that apply)** | | | |
|  | Protocol goals/design/methodology |  | Informed consent process and/or forms |
|  | Data Collection tools and/or procedures |  | Funding Source (include a copy of the grant) |
|  | Inclusion/Exclusion criteria |  | Subject recruitment methods |
|  | Number of participants |  |  |

Be sure to submit copies of any **NEW** documents.

For any **REVISED** documents, submit:

* One copy with the change(s) underlined, highlighted, or shaded (“tracked”) including updating the version dates and numbers on all applicable documents. (See G-03 Tracking Changes in a Word Document if you need assistance.)

AND

* One copy with the change(s) incorporated (“clean”) including updating the version dates and numbers on all applicable documents. (All changes made with no underlining, highlighting, or shading.)

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| Provide a brief description of changes and rationale. |

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| **1.** | Will there be any change in the risk(s) to subjects?  **If yes,** explain: | Yes  No |
|  | | |
| **2.** | Will there be any change in the benefit(s) to subjects? NOTE: Compensation is not to be considered a benefit.  **If yes,** explain: | Yes  No |
|  | | |
| **3.** | Could the proposed change(s) affect currently enrolled subjects’ willingness to continue to take part in the research?  **If yes,** how will information be communicated to currently enrolled subjects (e.g., revised consent form, letter to participants, etc.)? | Yes  No |