

### Institutional Review Board Request

### For

**Protocol Revision or Modification**

This form is to be completed when requesting a modification to an approved or exempt study. Please submit this coversheet, as well as *tracked* and *clean* copies of the revised protocol and/or any revised supporting documents.

Proposed changes to the protocol or study documents may **NOT** be implemented until after the IRB has approved the modification

**CONTACT INFORMATION**

|  |  |
| --- | --- |
| **Principal Investigator (PI):** | Click or tap here to enter text. |
| **IRB #:** | Click or tap here to enter text. |
| **Study Title:**  | Click or tap here to enter text. |

**OVERVIEW OF CHANGE**

|  |
| --- |
| **Specify whether changes are made to the following:** |
| [ ]  Protocol Title – New Protocol Title:Click or tap here to enter text. |
| [ ]  Funding Source - Explain:Click or tap here to enter text. |
| [ ]  Study Population/Eligibility Criteria |
| [ ]  Study Sample Size |
| [ ]  Research Sites or Locations |
| [ ]  Recruitment Methods or Materials |
| [ ]  Consent/Assent Forms or Process |
| [ ]  Data Management/Confidentiality |
| [ ]  Modification to Instruments or Measures (e.g. Interview protocols, surveys) |
| [ ]  Others, please explain:Click or tap here to enter text. |

**SUMMARY OF CHANGES**

|  |
| --- |
| **Provide a brief summary of *each* change:** |
| Click or tap here to enter text. |
| **Provide a rationale for *each* change:** |
| Click or tap here to enter text. |

**RECONSENTING OF PARTICIPANTS**

|  |
| --- |
| **Could the requested change affect a participant’s willingness to continue taking part in this research study?** |
| [ ]  No[ ]  If YES, please provide the plan for re-consenting already enrolled participants: Click or tap here to enter text. |

**RISK/BENEFIT RATIO**

|  |
| --- |
| **Provide an assessment of how the modification alters, or does not alter, the risks and benefits of the study. This assessment should explain whether the proposed modification increases, decreases, or does not change the level of risk to participants:** |
| Click or tap here to enter text. |

|  |  |
| --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Signature of Principal Investigator** | **Date** |