

 Institutional Review Board

 Research Project Modification Form

Directions to Investigators: This form is needed any time you plan to change any specific item listed below or other substantive details about your previously approved research. After selecting the appropriate category under which your request falls, please attach any revised documents that relate to the change.

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| --- | --- |
| Title of Research Proposal and Log Number      | Principal Investigator      |
| Phone      | Email      |

**Minor Modification Request (Check all that apply)**

[ ]  Change of protocol title.

[ ]  Change in principal or co-investigators.

[ ]  Change of research site.

[ ]  Change in participant enrollment or recruitment of participants.

[ ]  Addition of procedures that do not significantly increase risk to subjects, considering the original purpose and study design of the approved study.

[ ]  Removal of research procedures that would thereby reduce the risk to subjects.

[ ]  Addition of non-sensitive questions to survey or interview procedures.

[ ]  Addition of or revisions to recruitment materials or strategies.

[ ]  Administrative changes to the approved documents (e.g., correction of spelling, grammatical or typographical errors).

[ ]  Other Click here to enter text.

Document all checked modifications in an attachment.

**Major Modification Request (Check all that apply)**

[ ]  Change of informed consent.

[ ]  Change to instruments used.

[ ]  Addition of a new and/or separate subject population (e.g., control group, additional cohort, vulnerable population, etc.)

[ ]  Addition of research procedures that involve greater than minimal risk to subjects.

[ ]  Addition of surveys/questionnaires/interview procedures that could have adverse psychological consequences for subjects or damage their financial standing, employability, insurability, or reputation.

[ ]  Removal of follow-up visits that appear necessary for monitoring subject safety and welfare.

[ ]  Change in the purpose of the original project or study or use of the data, from that initially provided to subjects and to the IRB.

[ ]  Other Click here to enter text.

Document all checked modifications in an attachment.

|  |  |
| --- | --- |
| Principal Investigator Signature | Date |

**Routing Instructions**

 1) IRB Chair, A242