**Research Amendment Form**

**For Submitting Changes to Previously Approved Human Subjects Research\***

All modifications to human subjects research must be reviewed and approved prior to implementation.

*\* Amendments for Quality Improvement/Quality Assurance (QI/QA) Projects do not need to be submitted unless the changes involve changes in a data use agreement, changes in use of HIPAA protected data, or changes in risk to the subjects.*

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| **Minor Modifications** | Minor modifications to previously approved projects include those that do not alter the risk-benefit assessment for the research. Examples include changes in the investigators; minor changes in the consent form(s), recruiting materials, measures, or procedures; minor changes in compensation, time of participation, or subject recruitment; or the use of a new site that is not materially different from a previously approved site. Minor modifications may also include changes to other parameters, whereby the investigator provides the subjects with more accurate information as a result of additional experiences with the protocol. |
| **Major Modifications** | Major modifications include significant protocol changes that would cause subjects to engage in activities not previously approved; or that involve an increased level of risk to the physical, emotional, or psychological well-being of participants (including the loss of confidentiality); or that involve a decreased benefit; or that otherwise result in alteration of the risk-benefit assessment for the research. For example, adding a new subject population, adding new measure that significantly differ from those currently approved, changing inclusion or exclusion criteria, changing the informed consent process, and changing procedures affecting subject confidentiality are all potentially major modifications. |

(Type the following directly in this application)

1. **TITLE OF PROJECT:**

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1. **RESPONSIBLE PROJECT INVESTIGATOR(S) AT GU:**

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1. **DATE THIS PROJECT WAS APPROVED:**

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**4. DATE THIS PROJECT WILL BE TERMINATED:**

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**5. FUNDING: Non-funded – Internal funding – External funding**

**FUNDING Status: Proposal in preparation – Pending agency decision – Funded**

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| (*Please explain*) |

**6. FUNDING Agency (if applicable): GRANT/CONTRACT Number:**

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**7. REVISED MATERIALS**: For revisions to currently approved procedures (including discontinuation of previously approved procedures, measures, etc.) or to add new procedures that were not previously approved, please resubmit the Original IRB Application or Application for Exemption incorporating the revisions as appropriate throughout the form. Amendments often require modification of consent forms, assent forms, measures and other relevant attachments.

* **PLEASE SUPPLY THE FOLLOWING** with this Research Amendment:
	+ A marked up version of the Original IRB Application or Application for Exemption and any modified attachments or consent documents, using track changes on Microsoft Word.
	+ Revised consent documents and other relevant attachments that have changed as a result of the amendment

**8. DESCRIBE THE AMENDMENT**. Describe the requested change(s) and clearly reference materials submitted with this form. Provide a clear rationale for the proposed change(s). Explain whether the risk-benefit assessment for the research is likely to change as a result of the proposed amendment(s). Justify changes that will affect risks, benefits, informed consent, inclusion or exclusion criteria, the subject population(s), research sites, or the confidentiality of private, identifiable subject information. Describe in the space provided:

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**9. INVESTIGATOR ASSURANCES** The original, inked signature of the Responsible Project Investigator is required before this form can be processed. Other investigators are also responsible for these assurances and are encouraged to sign.

I certify that the information supplied in this form, with attachment, is complete and correct, that the modified protocol has not yet been used with any human subject, and that it will not be implemented until IRB approval has been obtained.

NOTE: The signature of the PI must be submitted before IRB Review (scanned and emailed signatures are acceptable)

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Principal Investigator (PI) Date

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Faculty Sponsor (if PI is a student) Date

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Department Chair Date