IRB Amendment Form

to make changes to a previously approved human subjects research study\*

**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 revisions 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 studies include those that DO NOT alter the risk-benefit assessment for the research.**  Examples of minor modifications 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 subject(s) 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. |

**Please Answer The Following:**

1. **PROTOCOL CODE # OF STUDY/PROJECT YOU ARE AMENDING:**

Click or tap here to enter text.

1. **TITLE OF STUDY/PROJECT:** Click or tap here to enter text.
2. **RESPONSIBLE PRINCIPLE INVESTIGATOR(S) AND/OR STUDENT INVESTIGATOR(S) AT GONZAGA:**

Responsible PI: Click or tap here to enter text.

Student Investigator: Click or tap here to enter text.

1. **DATE THIS STUDY/PROJECT WAS APPROVED:** Click or tap to enter a date.
2. **EXPECTED DATE THIS PROJECT WILL BE CLOSED:** Click or tap to enter a date.
3. **IS THIS STUDY/PROJECT FUNDED?**

NO

YES

1. **IF STUDY/PROJECT IS FUNDED:**

Internal funding

External funding

1. **WHAT IS THE FUNDING STATUS?**

Proposal is in preparation

Pending agency decision

Funded

1. **FUNDING AGENCY (if applicable):**

Click or tap here to enter text.

1. **GRANT/CONTRACT Number:**

Click or tap here to enter text.

**11. DESCRIBE THE REQUESTED CHANGE(S) AND CLEARLY REFERENCE THE 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 THE AMENDMENT:** Click or tap here to enter text.

**IMPORTANT:** All Amendments **MUST** be signed and submitted in SharePoint along with all the accompanying study materials.

**12. INVESTIGATOR ASSURANCES**

All signatures are required before this form can be processed. All co-investigators are 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.*

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**Principal Investigator (PI) Date**

***or* Student Investigator (SI)**

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**Responsible Principal Investigator (Faculty Date**

**Advisor if Investigator is a Student)**

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**Department Chair or Supervisor (If no Chair) Date**

**SUBMIT THE FOLLOWING** **MATERIALS** **WITH YOUR SIGNED AMENDMENT FORM VIA SHAREPOINT:**

* Your original IRB application forms with **HIGHLIGHTS** indicating the revisions you plan to make.
* Include details if you’re **discontinuing** any previously approved procedures, measures, etc.
* Include details if you’re **adding** new procedures that were not previously approved.
* Include any modifications of consent forms, assent forms, flyers, recruitment posters, measures, interview or survey questions, and any other relevant attachments that will change as a result of the Amendment.

**You may find Submission information on the IRB webpage:** [**www.gonzaga.edu/irb**](http://www.gonzaga.edu/irb)**.**