**HUMAN RESEARCH PROTOCOL CONTINUING REVIEW (CR) SUBMISSION FORM**

This form is required to be submitted with current continuing review (CR) forms to the Gonzaga IRB.

1. **PROTOCOL TITLE:**

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1. **PRINCIPAL INVESTIGATOR(S) AT GU:**

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

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1. **FORMS NEEDED FOR CONTINUING REVIEW (CR) APPROVAL**

       Copy of current protocol.

       Current consent form (if applicable).

        Summary of amendment/changes being requested with this renewal (if applicable).

       Recruitment materials (if applicable).

       Study tools, such as data collection forms (if applicable).

1. **Have any of the following study-related events occurred during the continuing review period and have not been reported to the Gonzaga IRB?**

**Answer Y or N**

                 Major modifications to the research protocol and any modifications that could *potentially increase risk to subjects*.

Note: Gonzaga IRB defines a substantive modification as: A change in Principal Investigator, change or addition of an institution, elimination or alteration of the consent process, change to the study population that has regulatory consequences (i.e. adding children), significant change in study design, or a change that could potentially increase risks to subjects. (If you are unsure, ask the IRB: IRB@gonzaga.edu)

                Suspensions or terminations of the research by your advisor, institution (Gonzaga or other), etc.

                 Unanticipated problems involving risks to subjects or others (UPIRTSO). If so, provide a description of the event(s).

**Per the HHS, UPIRTSOs are defined as problems/events that are:**

* Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
* Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
* Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

1. **RESEARCH RESULTS TO DATE**

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| *(Total number of subjects enrolled in the study; summary of study findings so far, etc.)* |

1. **ANY ISSUES SINCE ORIGINAL IRB APPROVAL**

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| *(Please explain any unexpected delays, problems with recruitment or retention, etc.)* |

**INVESTIGATOR ASSURANCE:** I certify that the information supplied in this form is complete and correct.

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Principal Investigator Date

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Faculty Sponsor (if PI is a student) Date