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Review of Research Involving Human Participants –
Research Continuation Request and/or Proposed Modifications to Protocol

Project Title	Click here to enter text.
Principal Investigators	Click here to enter text.
Contact Address	Click here to enter text.
Telephone	Click here to enter text.
Email (Regis Email)	Click here to enter text.
Research Advisor (student projects)	Click here to enter text.
Project Start Date	Click here to enter a date.
Estimated Project End Date	Click here to enter a date.

Please check the box corresponding to the appropriate portion of the form to be used.

**** NOTE: If you are making significant changes to your research study, such as adding or removing a vulnerable population, you should contact IRB@regis.edu for guidance. Please check to ensure you are using the correct form. ****

☐**Part A: Research Continuation Request**

Complete Part A if you need to request that your previously approved research be continued past the initial approval date.

☐**Part B: Research with Proposed Modifications**

Complete Part B if you need to modify your previously approved research, but do not need to extend the expiration date of the project.

☐**Part C: Research Continuation Request and Research with Proposed Modifications**

Complete both Parts A & B to continue your previously approved research and modify it.

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Part A: Research Continuation Request

Federal guidelines (45CFR46.109e) require that Institutional Review Boards (IRB) "conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year." In conducting the continuation review, the IRB will review, at a minimum, a protocol summary and informed consent/assent forms, as well as a status report on the progress of the research. **Complete Part A if you need to request that your research be continued past the initial approval date.**

1. Approximate total number of participants who will be enrolled: Click here to enter text.
   Number of participants actually enrolled as of this date: Click here to enter text.
   Number of participants who have dropped out: Click here to enter text.
   Number of participants who have been lost to follow-up: Click here to enter text.
   Number of participants who have formally withdrawn: Click here to enter text.
   Please summarize reason(s) for withdrawal.
   Click here to enter text.

2. Since the last IRB review, have any unanticipated problems involving risks to participants or others occurred? Yes☐ No ☐ If yes, please describe:
   Click here to enter text.

3. Since the last IRB review, have any injuries or adverse events occurred? If yes, please describe:
   Click here to enter text.

4. Since the last IRB review, have any complaints about the research been received? Yes☐ No ☐ If yes, please describe:
   Click here to enter text.

5. Are there any changes in the protocol requested? Yes☐ No ☐ If yes, please describe proposed changes to the protocol and attach a protocol summary. Include amendments or modifications to the research since the last review.

Click here to enter text.

6. Are there any changes to the informed consent/assent form(s)? Yes☐ No ☐ If yes, please describe changes and attach new consent/assent form(s) with changes highlighted as a Word document.

Click here to enter text.

7. Are there any additions and/or changes in sites where data are being collected? Yes☐ No ☐ If yes, list additional sites or changes.

Click here to enter text.

8. Are there changes in key personnel assisting in the research project? Yes☐ No ☐ If yes, list the changes (i.e., who is being added, who has left project). Include for new personnel, name, rank/degree, affiliation, and responsibility in project.

Click here to enter text.

9. Summarize any relevant recent literature and interim findings.

Click here to enter text.

10. If this is a multi-center trial, summarize any relevant trial reports.

Click here to enter text.

11. Will any portion of your research project be conducted in person or present a risk of COVID to either the participants or researchers?
☐ Yes ☐ No ******If yes, please complete the COVID mitigation form that is available in IRBNet by clicking on the "Forms and Templates" button.**

Investigator Assurance

I certify that the information provided for this project is correct and that no other procedures will be used in this protocol. I agree to conduct this research as described in the attached supporting documents. I will request approval from the IRB for changes to the study's protocol and/or consent forms and will not implement the changes until I receive IRB approval for these changes. I will comply with the IRB policy for the conduct of ethical research. I will promptly report significant or adverse effects to the IRB in writing within 5 days of occurrence. I will be responsible for ensuring that the work of others involved with this project complies with this protocol. I will complete, on request by the IRB, the Continuation Request or Completion of Research Activities Forms.

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_____ Click here to enter a date.

Principal Investigator's Signature Date

Faculty or PSS Assurance (required when a student or person external to Regis University is the PI)

This is to certify that I have reviewed this proposed continuation request and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct the project. I assure that the investigator(s) is knowledgeable about the regulations and policies governing research with human subjects. I agree to meet with the investigator on a regular basis to monitor study progress and compliance with IRB policy for the conduct of ethical research.

_____ Click here to enter a date.

Faculty or Sponsor's Signature Date

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Part B: Research with Proposed Modifications

Complete Part B if you need to modify your previously approved research, but do not need to extend the expiration date of the project.

1. Describe proposed changes to the protocol and submit protocol with revisions incorporated.

   Click here to enter text.

2. Describe (if any) proposed changes to the informed consent/assent form(s) with changes highlighted.

   Click here to enter text.

3. Are there any additions and/or changes in sites where data are being collected? Yes☐ No ☐ If yes, list additional sites or changes.

   Click here to enter text.

4. Are there changes in key personnel assisting in the research project? Yes☐ No ☐ If yes, list the changes (i.e., who is being added, who has left project). Include for new personnel, name, rank/degree, affiliation, and responsibility in project.

   Click here to enter text.

5. Describe any proposed changes, not listed above.

   Click here to enter text.

6. Will any portion of your research project be conducted in person or present a risk of COVID to either the participants or researchers?
☐ Yes ☐ No ****If yes, please complete the COVID mitigation form that is available in IRBNet by clicking on the "Forms and Templates" button.**

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