AMENDMENT APPLICATION

Submission Date: **Recent IRB Approval Date:**

Research Protocol Title:

Principal Investigator: **Institution:**

Research Study Contact: **Email:**

Phone:

❖ **AMENDMENT/S TO RESEARCH STUDY (Select all that apply)**

1. ☐ **Research Plan.** Describe and provide justification for change. Attach research plan with changes evident as track change mark ups.

2. ☐ **Recruitment materials or process.** Describe and provide justification for change. Attach research plan with changes evident as track change mark ups.

3. ☐ **Consent Process and/or Document/s.** Describe and provide justification for change. Attach research plan with changes evident as track change mark ups.

4. ☐ **Research Instruments**. Describe and provide justification for change. Attach research plan with changes evident as track change mark ups.

5. ☐ **Other.** Describe and provide justification for change. Attach research plan with changes evident as track change mark ups.

❖ **RISK/BENEFIT ASSESSMENT**

1. Will the changes affect the risk/benefit ratio of the project? ☐Yes ☐No

If 'Yes', please describe.

❖ **RECONSENT**

1. Consent form or Consent process changes? ☐Yes ☐No

2. Will participants need to be re-consented? ☐Yes ☐No

If 'yes', describe the plans for re-consent (e.g. within 30 days, at next visit)

❖ **AMENDMENT TO KEY RESEARCH PERSONNEL** ☐N/A

1. ☐ **Change of Principal Investigator (PI)**

Explain the reason for the change. Also explain if the current PI will remain on the research project in another capacity. If applicable, provide an overview of their new role. Include a brief bio indicating the relevant expertise of the individual replacing the current principal investigator. Also attach the new PI's CV and certificate of human subjects' protections training.

2. ☐ **Other Key Personnel Additions:**

Attach a document listing the individuals added to the research team in alphabetical order by surname. In a separate file, attach all of the human subjects' protections

training certificates for new additions. Include the following information for each individual added to the research team:

- Full Name
- Date of Completion for Human Subjects Training
- Organizational Affiliation
- Role in the Research Study (e.g., recruitment, informed consent, intervention, data collection, data analysis, project management, project coordination, research oversight)

3. ☐ Other Key Personnel Removals:

Attach a document listing the full names of the individuals being removed in alphabetical order by surname.

I certify that the information provided in this application, including attachments, is true.

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Principal Investigator Signature Date