**Protocol Modification Form**

**Principal Investigator (PI) Information:**

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| Name of PI:        | School/Department:       |
| Email Address:       | Phone Number:       |
| PI Status: [ ]  Faculty [ ]  Adjunct Faculty [ ]  Graduate Student [ ]  Undergraduate Student [ ]  Staff [ ]  Other (Specify:      ) |

**For Sponsored Projects (required when the PI is a student):**

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| Supervising Faculty:        | School/Department:       |
| Email Address:       | Phone Number:       |

**Project Information:**

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| Project Title:       |
| Type of Review for Original Application: [ ]  Exempt [ ]  Expedited [ ]  Full  |
| Protocol Approval Date:       Protocol Expiration Date:       |

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| **Type of Modifications Proposed:** **[ ]** Minor [ ]  Major[ ]  COVID-related |
| **Minor modifications** Minor modifications are defined as changes that do not alter the risk–benefit ratio for the research. Examples: personnel changes; 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.  |
| **Major modifications** Major modifications are defined as 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 ratio for the research. Examples: changes to subject population, including changing of inclusion/exclusion criteria, new measures that differ significantly from approved measures, changes to the informed consent process, and procedures affecting subject confidentiality. |
| **COVID-related modifications** COVID-related modifications are defined as changes that are being proposed as a result of the COVID-19 pandemic and the resulting public safety recommendations issued by the Centers for Disease Control, the State of NJ, and Caldwell University. |

**Major or Minor Modifications that not COVID-related**

**Describe any data collection or recruitment thus far (e.g., number of participants, advertisement, etc.):**

**Describe the requested changes:**

**Explain the rationale for the proposed changes:**

**Describe how the proposed changes might affect the risk-benefit ratio for participants (if at all):**

**For COVID-related Modifications**

**Describe any data collection or recruitment thus far (e.g., number of participants, advertisement, etc.):**

**Can this research be conducted remotely?**

[ ]  Yes

[ ]  No If no, explain:

**Please check all that apply:**

[ ]  Research sessions will be conducted remotely.

**[ ]** Research sessions will be conducted outdoors.

[ ]  Research sessions will be conducted indoors.

[ ]  Investigator and participants will be separated by a physical barrier.

[ ]  Investigator and participants will remain at least 6” apart at all times.

[ ]  Investigator and participants will remain at least 6” apart when possible.

**[ ]** Investigator and participants will wear masks for the entirety of in-person research sessions.

**[ ]** Investigator and participants will use hand sanitizer at the beginning and end of all sessions.

**[ ]** Participants will receive their own research materials (not to be used by others).

[ ]  Investigator will sanitize all shared research materials with disinfectant wipes after each use.

[ ]  Other - Describe:

**Explain clearly how benefits outlined in the original application are outweighed by the risks OR explain how participation in this study will not present any additional risk to participants above the risks participants face in their daily lives:**

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| **For revisions to currently approved procedures or to add new procedures resubmit the original approved application. Ensure that all new and revised documents are attached with this amendment.** **For each revised document submit one copy highlighting changes (i.e., track changes, highlighting, etc.) and one clean copy for stamping.** |

**List the revised documents submitted with this modification form:**

**List new documents submitted with this modification form:**

**Indicate that you have attached one copy highlighting changes and one clean copy for each revised document:** **[ ]** Revisions Indicated

**Assurances:**

I, the investigator (and if applicable, the faculty sponsor), certify that Ihave reviewed the contents of this form, with attachments, and that the information provided is complete and accurate to the best of my knowledge. I agree that any changes to the project will be submitted to the Institutional Review Board before they are implemented unless necessary to protect subjects, and that any adverse events will be reported in a timely manner. I also recognize that the Institutional Review Board is only responsible for ensuring the safety and integrity of human participants. I recognize that I am responsible for ensuring this research complies with the mission statement of the University.

The PI’s signature (and that of the faculty sponsor, if applicable) is required before this application can be processed (electronic signatures are acceptable). Send this application and all supporting documents to irb@caldwell.edu. Please note that this document and any others requiring IRB stamps must be in doc/docx format so that the electronic stamp may be applied. Any other formats will be returned.

 **Principal Investigator** **Date**

 **Faculty Sponsor Date**

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| **This Section is for IRB Use Only**Protocol Modifications Approved [ ]  Yes [ ]  NoNotes:      Reviewed by:      Stamp:   |