Monmouth University

Human Research Protection Program/Institutional Review Board Office

**Modifications Request Form**

**NOTE: NO CHANGES IN THE RESEARCH MAY BE IMPLEMENTED WITHOUT PRIOR IRB APPROVAL.**

1. **PRINCIPAL INVESTIGATOR**
2. **Principal Investigator**

|  |  |
| --- | --- |
| **PI Name** | **Date** |
| IRB #: | |
| Title | |

|  |  |
| --- | --- |
| Faculty  Other: | Department/Unit: |
| Address: | |
| Email: | Phone Number: |

1. **TYPE OF MODIFICATION**

Indicate the type of modification:

**Protocol Modification** – change of the protocol for all remaining subjects.

**Protocol Exception** – a request to modify some aspect of the IRB-approved study for a specific subject or group of subjects (e.g., changing the scheduling of completion of multiple surveys completion due to subject illness etc.). An Exception is a change that is planned and, when the study is funded, has prior agreement from the study sponsor/funding agency. (**Note**: *Protocol deviations are unplanned and are reported on the “Event Reporting Form.”)*

For Protocol Modification, answer the following questions. For Protocol Exceptions, skip to Section IV.

1. **PROTOCOL MODIFICATION**  N/A – Skip to section IV.
2. **Extent of the modification**

Minor modification\*

Major modification

*\*A minor modification is one which makes no substantial alteration in (i) the level of risks to subjects or the balance of risks to benefits; (ii) the research design or methodology; (iii) the number of subjects enrolled in the research (e.g., no greater than 10% of the total requested); (iv) the qualifications of the research team; or (v) the facilities available to support safe conduct of the research. Adding procedures that are not eligible for exemption (for exempt studies) or expedited review (for nonexempt studies) would not be considered a minor change. Examples of minor changes include changes in the research team; minor wording changes in the consent form(s), recruiting materials, or measures; minor changes in subject payment, time of participation, or subject recruitment; or the use of a new site that is not materially different from a previously approved site.*

1. **Describe the modification:** Describe the requested change(s) and clearly reference materials that have been added/revised and which are submitted with this form.

1. **Rationale:** Provide a clear rationale for the proposed change(s)

1. **Effects of the Modification**
   1. Will the modification affect the risks or benefits to subjects?  Yes  No

If yes, please provide a rationale for the modification:

* 1. Will the modification require a change in the consent process or form?

Yes  No

If yes, please explain the nature of the change:

* 1. Will the modification affect the recruitment process?  Yes  No

If yes, please describe:

* 1. Will the modification require a revised data safety plan?  N/A (study is exempt or expedited)  Yes  No

If yes, please describe:

* 1. Will the modification affect the privacy or confidentiality of subjects?  Yes  No

If yes, please describe:

* 1. Will the modification affect the protection of vulnerable subjects?  N/A-there are no vulnerable subjects (e.g., children etc.) in this study  Yes  No

If yes, please describe:

1. **Informing Current Subjects**

Will current/former subjects be notified about the modification?  Yes  No

If yes, how will current/former subjects be informed?

Re-Consent will occur at the subjects next scheduled visit

Subject will be called at home

A letter will be mailed to the subject’s home (a copy of the letter must be included with this submission)

Other:

1. **Attachments**

**Please attach the following:**

Revised IRB Application Form indicating the changes (required for all amendments)

Revised consent form(s), if applicable

Revised recruitment materials, if applicable

Revised research materials (surveys, questionnaires, instruments, debriefing), if applicable

1. **Protocol Exception**  N/A – Skip to section V
2. **Subject Information**

**This Protocol Exception pertains to:**

A single study subject.

More than one study subject: number of subjects

1. **Describe the Protocol Exception.** Include an explanation of what protocol procedures are being changed.

1. **Provide a rationale for the Protocol Exception.**

1. **Describe the net effect on risk/benefit.**

1. **SIGNATURES**

**By submitting this Modifications/Exception Request Form and required attachments via my Monmouth University password-protected e-mail account, I acknowledge and agree that I am submitting an electronic signature indicating that I certify that the information provided in this Form is complete and correct. I further acknowledge and agree that submitting this Form shall constitute my signature hereto and shall be valid and have the full force and effect as an original signature.  I understand and agree that it is recommended that I print a copy of this Form and required attachments for my file.  If I do not wish to submit an electronic signature, I may request that a paper copy be provided to me for my signature.**

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Investigator Signature Date