Modification Request Form with Exceptions

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

1. **PRINCIPAL INVESTIGATOR & STUDY INFORMATION**
2. **Principal Investigator**

|  |  |
| --- | --- |
| **PI Name** | **Date** |
| Study Title/Study Number | |

|  |  |
| --- | --- |
| Faculty  Fellow  Other: | Department/Division: |
| Address: | |
| Email: | Phone Number: |

1. **Faculty Advisor** *(if appropriate)* NA

**NOTE*:*** *A Faculty Advisor is required if the PI is a student, resident or fellow and the Faculty Advisor MUST sign this submission.*

|  |  |
| --- | --- |
| Name: | Department/Division: |
| 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** - circumstances in which the specific procedures called for in a protocol are not in the best interests of a specific subject or group of subjects (examples: a subject is allergic to one of the medications provided as supportive care; a subject is not eligible in a direct benefit study). Usually an Exception is a change that is planned and has prior agreement from the sponsor. (**Note**: *Protocol deviations are unplanned and are reported on an “Event Reporting Form.”)*

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

1. **PROTOCOL MODIFICATION**  NA – 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 expedited review would not be considered a minor change. Examples 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. Adding procedures that are not eligible for expedited review would not be considered a minor change.

1. **Describe the modification:** Describe the requested change(s) and clearly reference materials 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?  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?  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 if applicable:**

Revised Initial Submission Form

Revised protocol (tracked and clean versions)

Revised consent form(s) (tracked and clean versions)

Revised recruitment materials

Revised research materials (surveys, questionnaires, instruments)

Conflict of Interest Declaration for new study personnel

Other:

1. **Protocol Exception**  NA – 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. **Sponsor Approval**

If there is an external sponsor, has the sponsor approved the Protocol Exception?

Yes  No

If yes, attach documentation of sponsor approval

1. **SIGNATURES**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator Signature Date

**IF THE INVESTIGATOR IS A FELLOW, A FACULTY ADVISOR MUST SIGN BELOW**  NA

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Faculty Advisor Signature Date