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

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Faculty Advisor Signature Date