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**Protocol Amendment Form**

**INSTITUTIONAL ETHICS COMMITTEE (IEC)**

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| **All modifications to a previously approved protocol for human subjects’ research must be reviewed and approved by the IEC prior to implementation.**  **Refer below for the definitions of minor and major modifications.**  **Minor modifications** Minor modifications to previously approved protocol include those that do not alter the risk–benefit assessment for the research. Examples include changes in study period, changes in the investigators; 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. Minor modifications may also include changes to other parameters, whereby the investigator provides the subjects with more accurate information as a result of additional experience with the protocol.  **Major modifications** Major modifications include significant protocol 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 assessment for the research. For example, adding a new subject population, adding new measures that significantly differ from those currently approved, changing inclusion or exclusion criteria, changing the informed consent process, and changing procedures affecting subject confidentiality are all potentially major modifications. |

**1.** **PROTOCOL DETAILS**

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| --- | --- | --- | --- | --- | --- |
| **Principal Investigator:** | |  | | **Date:** |  |
|  | | | | | |
| **IEC Ref. No**: |  | |  | | |
|  | | | | | |
| **Protocol Title\*** |  | | | | |
| \* *As stated in your original approval letter.* | | | | |

**2. MAJOR OR MINOR MODIFICATION?** In the principal investigator’s judgment, which category of modification is this? *(check whichever is applicable)*

Minor  Major  Uncertain

For revisions to currently approved procedures (including discontinuation of previously approved procedures, measures, etc.), or to add new procedures that were not previously approved, please resubmit the New Protocol Application Form.

**3. DESCRIBE CHANGES TO THE APPROVED PROTOCOL.** Explain in detail in the space below the reasons for requesting these changes and which part(s) of the approved document will be amended. Please highlight changes in the amended document.

**4. DESCRIBE CHANGES TO THE PATIENT INFORMATION SHEET (PIS) & CONSENT FORM (CF), RECRUITMENT ADVERTISEMENT, ETC.**  Explain which sections of these items are being changed. Please highlight changes in the amended document

*If additional information to item 3 and 4 is attached, check here:*

**5. I CERTIFY** that the information supplied in this form, with attachments, is complete and correct, that the modified protocol has not yet been used with any human subject, and that it will not be implemented until IEC approval has been obtained.

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| Principal Investigator [name and signature] | Date |

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| Sign below only if there are changes to the list of co-investigators(s). *Please submit copy of their CVs.* | | |
|  |  |  |
| New Co-Investigator(s): [name and signature] | Date |
|  |  |
|
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| New Co-Investigator(s): [name and signature] | Date |

*(Please attach separate sheet, if required.)*