**MODIFICATION FORM**

***Instructions:***North Memorial Health (NMH) investigators use this form to request NMH Research Office administrative approval of changes to previously approved research. Modifications must be submitted to the NMH Research Office for the following: the addition or removal of any NMH study personnel, change in sponsor or the addition of funding, change in study title, protocol revisions *only* if they require review by an NMH ancillary committee/program (e.g., updates to the Investigator’s Brochure, changes to research procedures requiring radiation), or sponsor-requested changes to the subject injury or HIPAA authorization language in the informed consent document. Modification requests should be submitted to and approved by the NMH Research Office *prior to* submission of a modification to the reviewing IRB. Email the form to Research.Office@northmemorial.com.

**Section A: Investigator Information**

|  |  |
| --- | --- |
| Name of NMH Principal Investigator |  |
| Email address of NMH PI  |  |
| Phone number of NMH PI  |  |
| List any additional contact persons (e.g., study coordinator), including their name and contact information  |  |

**Section B: Study Information**

|  |  |
| --- | --- |
| Study Title |  |
| NMH Protocol Number |  |
| Name of Reviewing IRB |  |
| Date Form Completed |  |

**Section C: Modification Type**

|  |
| --- |
| **Type of Modification *(check all that apply)*** |
| [ ]  Update study personnel – if this is the *only* change being submitted, please only check this box, skip to the Personnel Change in Section D below and continue completing the form. [ ] Change in sponsor or addition of funding[ ]  Change in study title[ ]  Protocol revisions that require additional NMH ancillary review – Please specify ancillary review required (e.g., Investigational Pharmacy, Radiation Safety):       |

**Section D: Personnel Change**

|  |
| --- |
| **Type of Personnel Change *(check all that apply)*** |
| [ ]  Removal of Study Personnel[ ]  Change in Principal Investigator[ ]  Addition of New Study Personnel  |

If removing Study Personnel, please provide the name(s) of the individual(s) being removed:

If changing the PI or adding new Study Personnel, complete the table below. Note that each new study personnel added must have current human subjects protections training and a current COI disclosure on file with the NMH Research Office.

|  |  |  |  |
| --- | --- | --- | --- |
| **New study personnel name** | **Role in the research (e.g., PI, study coordinator, co-investigator)** | **Current human subjects training? Y/N** | **Does the new personnel have a conflict of interest related to this research? Y/N** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Section E: Modification Summary**

If changes other than personnel changes are being made, provide a description of the proposed change in the text box below. If funding is being added or the study title is being changed, provide corresponding documentation from the sponsor/funding source. If protocol revisions or updates to the Investigator’s Brochure require NMH ancillary review, please specify what ancillary review needs to occur and provide corresponding updated materials.

|  |
| --- |
|  |

**Signature of PI:**

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

Signature Date