MODIFICATIONS REQUIRED TO SECURE APPROVAL

July 1, 2019

*<Name of Principal Investigator>*

*<Address of Principal Investigator>*

*<Phone Number of Principal Investigator>*

*<Fax Number of Principal Investigator>*

*<Email Address of Principal Investigator>*

Dear *<Hailing of Principal Investigator>*:

On <Review Date> the IRB reviewed the following protocol:

|  |  |
| --- | --- |
| Type of Review: | *<Indicate Initial, Continuing, or Modification>* |
| Title: |  |
| Investigator: |  |
| IRB ID: |  |
| Funding: | *<Indicate “None” if there is none.>* |
| Grant Title: | *<Indicate “None” if there is none.>* |
| Grant ID: | *<Indicate “None” if there is none.>* |
| IND, IDE or HDE: | *<Indicate “None” if there is none.>* |
| Documents Reviewed: |  |

The IRB determined that modifications are required to approve the protocol. The modifications required and their reasons are listed here:

|  |  |
| --- | --- |
| Required Change | Reason for Change |
|  |  |

Please submit:

* A letter with a point-by-point response to the above changes indicating whether you agree or do not agree with each requested change.
* A copy of all revised documents in “Tracked Changes” format or similarly notated to indicate what changes were made.
* A “clean” copy of all revised and requested additional documents.

If a response is not received by close of business on *<Response Deadline Date>*, the IRB will withdraw this offer.

Should you disagree with these requested changes, your response will be reviewed by the convened IRB. At your request, you can respond in person to the IRB.

Sincerely,

IRB Manager

cc: *<Protocol Contact>*