SITE 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 site submission:

|  |  |
| --- | --- |
| Site Information | |
| Type of Review: |  |
| Site Name: |  |
| Submission ID: |  |
| Site Investigator: | *<Indicate pSite PI>* |
| Additional Site Funding: | *<Indicate “None” if there is none.>* |
| Site Grant Title: | *<Indicate “None” if there is none.>* |
| Site Grant ID: | *<Indicate “None” if there is none.>* |
| Site Documents Reviewed: |  |
|  | |
| Study Information | |
| Study Title: |  |
| Study ID: |  |
| Study Funding: | *<Indicate “None” if there is none.>* |
| Study Grant Title: | *<Indicate “None” if there is none.>* |
| Study Grant ID: | *<Indicate “None” if there is none.>* |
| IND, IDE or HDE: | *<Indicate “None” if there is none.>* |

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

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

Please submit:

* A point-by-point response to the above changes indicating whether you agree or do not agree with each requested change.
* A “clean” copy of all revised and requested additional documents and edit the study in the IRB system as needed.
* Submit the changes back to the IRB, attaching your point-by-point response letter in the Submit Response form.

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>