NOT HUMAN RESEARCH DETERMINATION

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 the proposed activity is not research involving human subjects as defined by DHHS and FDA regulations.

*<or>*

The IRB determined that the proposed activity is research involving human subjects as defined by *<DHHS/FDA/both DHHS and FDA>* regulations but that this organization is not engaged in the research.

IRB review and approval by this organization is not required. This determination applies only to the activities described in the IRB submission and does not apply should any changes be made. If changes are made and there are questions about whether these activities are research involving human in which the organization is engaged, please submit a new request to the IRB for a determination.

Sincerely,

IRB Manager

cc: *<Protocol Contact>*