DISAPPROVAL

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 disapproved the protocol. The reasons for the IRB’s decision and recommendations, if any, are as follows:

|  |  |
| --- | --- |
| Reason | Recommendation |
|  |  |

You may respond with a revised application. Please include a point-by-point response to the above reasons. For each modified document please include a copy in “Tracked Changes” format or similarly notated to indicate what changes were made.

Sincerely,

IRB Manager

cc: *<Protocol Contact>*

*<For international or collaborative research, the local research ethics committee or equivalent, as applicable>*

*<If the disapproved involved a request for a waiver of the consent process for planned emergency research that is FDA-regulated, send to the sponsor>*

*<If the research is conducted or funded by the Department of Defense (DOD), attach associated minutes and send to:>*

Director, Defense Research and Engineering

ddre@dtic.mil

*<If the research is conducted or funded by the Department of the Navy (DOD), attach associated minutes and send to:>*

Under Secretary of the Navy

1000 Navy Pentagon

Washington, D.C. 20350-1000

*<If the research is conducted or funded by the Environmental Protection Agency (EPA): the Environmental Protection Agency (EPA) Human Subjects Research Review official.>*