PRE-REVIEW OF USE OF AN UNAPPROVED TEST ARTICLE – CRITERIA MET

June 10, 2012

*<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>*:

The IRB reviewed your proposed use of an unapproved *[drug/biologic/device]*:

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

The IRB determined that as proposed the use complies with regulatory requirements.

By close of business *<five-day deadline date>* you are to submit to the IRB written notification of the emergency use of a test article in a life-threatening situation with a copy of the signed consent document used or certification by you and a physician that the criteria for the exception from informed consent were met.

By close of business on *<30-day deadline>* submit to the IRB a standing protocol for any future uses. If a protocol is not received by this date, the IRB’s policy is to not approve any subsequent research you submit for initial review until this protocol is submitted.

Sincerely,

IRB Manager

cc: *<Protocol Contact>*

*<Chairman or Supervisor of the Principal Investigator>*