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 it complied with regulatory requirements.

By close of business on *<30-day deadline>* you are to 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>*