REVIEW OF USE OF AN UNAPPROVED TEST ARTICLE – CRITERIA NOT 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 this use was non-compliant with federal regulations for the following reasons:

* *<insert reasons>*

This matter will be handled under the IRB’s policies and procedures regarding non-compliance.

Sincerely,

IRB Manager

cc: *<Protocol Contact>*

*<Chairman or Supervisor of the Principal Investigator>*