SUSPENSION OR TERMINATION

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 *<Date> <I/the convened IRB> <suspended/terminated>* the following protocol(s):

|  |  |
| --- | --- |
| 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: |  |

As part of this action the following research activities must stop:

*<select one>*

* All research activities must stop. This includes recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection or analysis of private identifiable information. Advertisements currently running in the media must be pulled.
* All recruitment, screening, enrollment, and consent must stop. Interventions, interactions, and collection and analysis of private identifiable information may continue.
* *<Other: Describe requirements>*

The rationale for this actionis as follows:

|  |
| --- |
| Reasons |
|  |

This action will be reviewed by the convened IRB at its meeting on *<Date and Time of Meeting>*.

Please take the following actions to protect participants:*<examples>*

* *Transferring subjects to another investigator.*
* *Making arrangements for clinical care outside the research.*
* *Allowing continuation of some research activities under the supervision of an independent monitor.*
* *Requiring or permitting follow-up of subjects for safety reasons.*
* *Requiring adverse events or outcomes to be reported to the IRB and the sponsor.*
* *Notification to current Human Subjects.*
* *Notification to former Human Subjects.*

Continuation of research activities without prior IRB review and approval is a violation of federal regulations.

If you believe that current subjects are at risk of harm by stopping research procedures described above:

* Prepare a written list of subjects who will be harmed.
* Identify the research procedures that need to continue.
* Describe the reasons that these procedures need to continue.
* Immediately provide the IRB Office with this information.

An IRB member (if needed, in consultation with others) will decide whether there is an over-riding safety concern or ethical issue involved such that it is in the best interest of individual subjects.

Sincerely,

*<Name and title of person who ordered the suspension or termination>*

cc: *<Protocol Contact>*

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

*<Chairman or Supervisor of the Principal Investigator>*

*<Organizational Official of designee of the Organizational Official>*