SUSPENSION OR TERMINATION

INITIATED OUTSIDE OF THE CONVENED IRB

<Date>

*<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>, <(<IRB Chair or Executive Director of the HRPP> or <Instutitional Official> > <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, obtaining consent, interventions, interactions, and collection or analysis of private identifiable information. Advertisements currently running in the media must be pulled.
* All recruitment, screening, enrollment, obtaining consent, interventions, and interactions must stop. Collection and analysis of private identifiable information may continue.
* All recruitment, screening, enrollment, and obtaining consent must stop. Interventions, interactions, and collection and analysis of private identifiable information may continue.
* *<Other: Describe requirements>*

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

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 immediately take or initiate the following actions to protect participants:*<examples>*

* *Transfer subjects to another investigator.*
* *Make arrangements for clinical care outside the research.*
* *Allow continuation of some research activities <list which activities> under the supervision of an independent monitor.*
* *Require or permit follow-up of subjects for safety reasons.*
* *Require adverse events or outcomes to be reported to the IRB and the sponsor.*
* *Notify current Human Subjects.*
* *Notify former Human Subjects.*

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

* 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 in writing.

Your response, if any, will be evaluated by an IRB member, in consultation with others as necessary, and a decision made as to whether there is an over-riding safety concern or ethical issue involved such that itis in the best interest of subjects to continue. Any granted continuation will be communicated to you in writing in a timely manner.

If you have questions or concerns prior to the scheduled review of this matter by the IRB, please feel free to contact me directly at < contact info>.

Sincerely,

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

cc: *<Protocol Contact>*

*<Institutional Official>*

*<Sponsored Projects Administration>*

*<Research Compliance Office>*

*<Research Partners (e.g. Fairview or Gillette)*

*<Department leadership of the Principal Investigator>*

*<Others as deemed appropriate by the Institutional Official.>*

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

*<The Privacy Officer of an organization, if the report involves unauthorized use, loss, or disclosure of the organization’s individually identifiable information>*