INFORMATION ITEM

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 *<Review Date>* the IRB reviewed the following information item(s):

* *<briefly describe items>*

This information is in regard to:

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

This IRB determined that this information <is/is not any of the following>: *<delete all that do not apply>*

* An unanticipated problem involving risks to subjects or others
* Serious or continuing non-compliance with the regulations or the requirements or determinations of the IRB
* A suspension or termination of IRB approval

The IRB requests the following additional information:

* *<Insert description. Delete this section if no information is required.>*

The IRB requests that you take the following actions:

*<Delete this section if no information is required>*

* *<Describe actions and the reasons for those actions. For example: Revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, or increase monitoring of subjects.>*

*<If research is suspended or terminated, add:>*

* *As part of this <suspension/termination> 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>*
* *If you believe that current subjects are at risk of harm by stopping research procedures describe 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.*

Should you wish to respond, please submit a written response to the IRB within 10 business days.

Please let us know if you need additional information.

Sincerely,

IRB Manager

cc: *<Convened IRB by inclusion in the agenda materials as an information item>*

*<Protocol Contact>*

*<Principal Investigator>*

***<Also copy the following individuals when the information item was determined to be an unanticipated problem involving risks to subjects or others, suspension or termination of IRB approval, or serious or continuing non-compliance.>***

*<Organizational Official>*

*<Grants and Contracts Office>*

*<Sponsor. Delete if none.>*

*<Contract Research Organization. Delete if none>*

*<Chairman or Supervisor of the Principal Investigator>*

*<Legal Counsel>*

*<Risk Management>*

*<Others as deemed appropriate by the Organizational 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>*

*<The Information Security Officer of an organization, if the report involves violations of the organization’s information security requirements.>*