Date

Name

Title

Company

Subject: Response to

Protocol: Title

IRB#: #

Dear,

In response to your letter, an internal investigation was conducted. The root cause(s) of the issue were identified, and a Corrective and Preventative Action (CAPA) plan generated (Attachment 1).

I would like to highlight that some of the activities were immediately implemented once we were made aware of the issue and actions, including revisions to policies and procedures, are planned to ensure this event does not reoccur in the future. I believe this issue did not put the subjects at an increased risk of harm.

As Principal Investigator, I will have oversight of the implementation of the CAPA and remain fully committed to the responsible conduct of research and following Good Clinical Practices.

I welcome the opportunity to discuss the actions outlined in the attached CAPA.

Sincerely,

PI name, credentials

Title

Department

Address

Contact Information