Modifications required: Draft

DATE: [CURRENT DATE]

TO: [PI NAME]

FROM: SUNY University at Buffalo Institutional Review Board

PROJECT TITLE: [IRBNET ID AND PROJECT TITLE]

SUBMISSION TYPE: [SUBMISSION TYPE]

ACTION: MODIFICATIONS REQUIRED

Dear PI NAME, DEGREE

The University at Buffalo Institutional Review Board by [REVIEW LEVEL] has considered the [SUBMISSION TYPE] submission for the project referenced above on [EFFECTIVE DATE].

The following is a list of the documents reviewed in this package:

[List of study documents in this package]

Requested revisions/clarifications are indicated below. Please make the necessary revisions to all appropriate documents, or provide written justification for not doing so. In addition, please provide a cover letter with a point by point response to all requested items.

Modifications Requested: [MINUTES SECTION]

## **SUBMIT CHANGES AS FOLLOWS:**

- Create a new package in IRBNet
- Upload any requested new forms or documents
- Revise relevant, previously submitted documents (e.g. protocol, consent documents, etc.) using the tracked change feature in MS Word
- Use the Pencil Icon in IRBNet to upload all revised documents, as follows:
  - Go to the Designer Page in IRBNet.
  - Find the newest version of the document in the list of documents from previous packages.
  - o Select the pencil icon to the right of the document title.
  - This will prompt you to upload a new document.
  - Upload the tracked change version of the revised document

Research activities in accordance with this submission may not begin until this committee has received a response to these conditions and issued final approval. Research activities (including screening, new recruitment, follow-up, and continued participation of enrolled participants) that have been previously approved may not be conducted beyond the expiration date unless a continuation/renewal is requested and approved by the IRB.

If you have any questions, please contact the UBIRB. Please include your project title and IRBNet Project Number in all correspondence with the IRB.

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This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within [YOUR ORGANIZATION NAME]'s records.