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: Acknowledgment of Reportable New Information

Dear PI NAME, DEGREE:

Please accept this letter as acknowledgement that the SUNY University at Buffalo Institutional Review Board (UBIRB) has received the letter in this package, dated [ ] regarding [---].

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

[List of study documents in this package]

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>
  o 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.
  o All recruitment, screening, enrollment, and consent must stop. Interventions, interactions, and collection and analysis of private identifiable information may continue.
  o <Other: Describe requirements>

- If you believe that current subjects are at risk of harm by stopping research procedures described above:
  o Prepare a written list of subjects who will be harmed.
  o 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.

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

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