Template: IRB Letter Information item		
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HRP-519-R02	11/27/19	1 of 3

Version	Date	Revisions
R00	3/25/14	Original issue
R01	9/11/17	Change to Click template
R02	11/27/19	Changes to formatting and updated logo
R02	12/16/2020	Annual review, no changes
R02	1/12/2021	Annual review, no changes
R02	1/14/2022	Annual review, no changes
R02	11/17/2022	Annual review, no changes

Review of New Information Report

June 26, 2012

Dear <*Hailing of Principal Investigator*>:

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

- <*New information Summary*>

This information is in regard to:

Type of Review:	<*Indicate Initial, Continuing, or Modification*>
Title:	
Submitted by:	[Submitter First Name]
Responsible Party:	*[Principal Investigator First Last Name]*
IRB ID	
Related Submission:	

This IRB determined that this information is:

- [Determination]

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 describe above:

  o Prepare a written list of subjects who will be harmed.

  o Identify the research procedures that need to continue.

  o Describe the reasons that these procedures need to continue.

  o 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 at 716-888-4888 or ub-irb@buffalo.edu. Please include the project title and number in all correspondence with the UBIRB.