



1414 Kuhl Ave.
Orlando, FL 32806
321.843.7000
orlandohealth.com

NOTE TO FILE

to: IRB Policies and Procedures
from: Orlando Health IRB Office
date: October 20, 2016
subject: Policy #0330-1008: Amendment Review Process, version date 10/13/2016 (effective on 10/19/2016)

The purpose of this memo is to clarify Section IV. (B) and Section IV. (G) of Policy #0330-1008: Amendment Review Process, version date 10/13/2016, which went into effect on 10/19/2016.

Section IV. B reads:

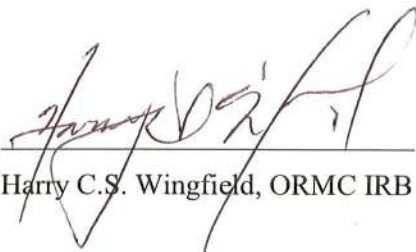
The IRB should review the change following its implementation and the IRB should review the change to determine that it is consistent with ensuring the subjects' continued welfare.

Section IV. G reads:

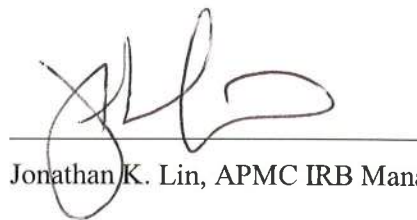
If the change to approved research was necessary to eliminate apparent immediate hazards to the human subjects, the IRB should be notified promptly via IRBNet.

As stated within this policy, "The Investigator or study team must report to the IRB in a timely manner all changes in research activity and will not make any changes in the research without IRB approval. The only exception is where the change is necessary to eliminate apparent immediate hazards to the human subjects. In this case, the IRB should be promptly informed of the change following its implementation."

Note that these 2 sections are only to be applied towards an exceptional case where a change to the approved research is necessary to eliminate apparent immediate hazards to the human subjects. These 2 sections will be clarified in the next revision of this policy.



Harry C.S. Wingfield, ORMC IRB Manager



Jonathan K. Lin, APMC IRB Manager



1414 Kuhl Ave.
Orlando, Florida 32806
321.843.7000

Type of Policy:	PROTECTION OF HUMAN RESEARCH PARTICIPANTS	Category:	Orlando Health Institutional Review Board (IRB)
-----------------	--	-----------	--

Title:	<i>Amendment Review Process</i>	Policy #:	0330-1008
Page 1 of 2		Replaced #:	ORMC IRB# 6000-0010
Issue Date:	7/19/95	Issued By:	Orlando Health Institutional Review Board (IRB)
Revision Dates:	1/1/01, 3/20/02, 11/12/07, 9/23/13, 8/14/14, 10/13/16	Approved By:	Mildred Beam, Esq. Institutional Official
			<i>Mildred Beam</i>

- I. **PURPOSE:**
To maintain ethical and legal standards when reviewing changes to approved research.

- II. **DEFINITIONS:**
None.

- III. **POLICY:**
The Investigator or study team must report to the IRB in a timely manner all changes in research activity and will not make any changes in the research without IRB approval. The only exception is where the change is necessary to eliminate apparent immediate hazards to the human subjects. In this case, the IRB should be promptly informed of the change following its implementation.


- IV. **PROCEDURE:**
 - A. ALL study modifications including changes in the protocol or informed consent documents or process, changes in advertisements, number of subjects to be enrolled, questionnaires or any other change in the approved application must be submitted to the IRB for approval using the appropriate form from the IRBNet library.
 - B. The IRB should review the change following its implementation and the IRB should review the change to determine that it is consistent with ensuring the subjects' continued welfare.
 - C. In accordance with federal regulations, the IRB may use expedited review procedures to review minor changes in ongoing previously-approved research during the period for which approval is authorized.
 - D. When a proposed change in a research study is not minor (e.g., procedures involving increased risk or discomfort are added), then the IRB must review and approve the proposed changes at a convened meeting before the change can be implemented.
 - E. When applicable, the IRB will make a decision as to inform subjects currently enrolled on the study of the new information (for example, re-consenting).
 - F. If a change to the protocol or consent form is requested or if a request is made by the IRB to re-consent or inform patients of added risk, these requests will be communicated in a letter by the IRB to the Investigator and study team. Letters will be sent promptly after the conclusion of the Board meeting.
 - G. If the change to approved research was necessary to eliminate apparent immediate hazards to the human subjects, the IRB should be notified promptly via IRBNet.

- V. **DOCUMENTATION:**



1414 Kuhl Ave.
Orlando, Florida 32806
321.843.7000

Type of Policy:	PROTECTION OF HUMAN RESEARCH PARTICIPANTS	Category:	Orlando Health Institutional Review Board (IRB)
-----------------	--	-----------	--

Title:	<i>Amendment Review Process</i>	Policy #:	0330-1008
Page 2 of 2		Replaced #:	ORMC IRB# 6000-0010
Issue Date:	7/19/95	Issued By:	Orlando Health Institutional Review Board (IRB)
Revision Dates:	1/1/01, 3/20/02, 11/12/07, 9/23/13, 8/14/14, 10/13/16	Approved By:	Mildred Beam, Esq. Institutional Official
			

- A. IRBNet Forms and Template Library

VI. REFERENCES:

- A. Code of Federal Regulations: 45 CFR 46.103(b)(4), 21 CFR 56.110, and 21 CFR 56.108
- B. Code of Federal Regulations: 21 CFR 312.53(c)(iv)
- C. IRBNet Template Library

VII. ATTACHMENTS:

- A. None