ORLANDO HEALTH®

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

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

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.

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V. DOCUMENTATION:

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