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:	Philip Giordano, MD 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, 6/19/19, 11/17/22		

I. PURPOSE:

To maintain ethical and legal standards when reviewing changes to approved research.

II. DEFINITIONS:

When used in this policy these terms have the following meanings:

A. Serious non-compliance – any non-compliance that increases risk of harm to subjects; adversely affects the rights, safety, or welfare of subjects; or adversely affects the integrity of the data and research.

B. Unanticipated Problem - any incident (including deviations and/or non-compliance), experience, or outcome that meets **all** of the following criteria:

1. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
2. Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

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, but not limited to, changes to the approved protocol or approved informed consent documents or process, changes to approved advertisements, change in the number of subjects to be enrolled, questionnaires or any other change to the approved application) must be submitted to the IRB for approval using the appropriate form from IRBNet's Forms and Templates.

B. In accordance with federal regulations, the IRB may use expedited review procedures to review minor changes (See Attachment 1) in ongoing previously-approved research during the period for which approval is authorized.

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C. 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.

D. 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). **Refer to Policy 0330-1002 Informed Consent Process for further guidance**

E. 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.

F. 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 by completing a Major Protocol Deviation/Violation report. 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. In this case, the Investigator and/or sponsor should strongly consider revising the protocol. **Refer to Policy 0330-1001 Protocol Deviations/Violations/Non-Compliance for further guidance**

G. Once an activity has been determined to be Regulatory Non-compliance that could most likely be serious or continuing non-compliance, the Major Protocol Violation/Deviation form should be used and submitted to the IRB via IRBNet within 5 working days. At the IRB's discretion, an explanation from the Principal Investigator describing corrective actions may also be required. **Refer to Policy 0330-1001 Protocol Deviations/Violations/Non-Compliance for further guidance.**

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
D. Informed Consent Process Policy #0330-1002
E. Protocol Deviations/Violations/Non-Compliance Policy #0330-1001

VII. ATTACHMENTS:

A. Amendment/Revision Guidance for Researchers