ORLANDO HEALTH®

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

Title:	***Protocol Deviations/Violations/ Non-compliance***	Policy #:	**0330-1001**
		Replaces #:	ORMC IRB# 6000-307 MDA IRB# 1000-0001-S
Page:	1 of 3	Developed By:	Orlando Health Institutional Review Board (IRB)
Issue Date:	**1/22/08**	Approved By:	Philip Giordano, MD Institutional Official
Revision Dates:	5/10/11, 9/10/12, 8/29/16, 1/16/17, 1/19/18, 1/19/21, 1/16/24, 07/15/25		**SIGNATURE ON FILE**

I. PURPOSE:

The purpose of this policy is to provide reporting requirements for protocol deviations and/or non-compliance and a procedure for reviewing these reports for the Orlando Health Institutional Review Boards (IRB).

II. DEFINITIONS:

Please refer to the IRB Definition Policy

III. POLICY:

It is the policy of the IRB that any serious Protocol Deviation/Violation or any serious or continuing non-compliance involved in the conduct of human subjects'(participants') research be reported promptly and accurately. The report must be detailed for it will be reviewed by the Board and/or IRB Chair/Vice Chair/IRB Designee. The IRB will issue an appropriate action relative to its level of severity. The Corporate Office of Research Operations (CORO) is responsible for handling suspicions allegations or detected non-compliance within the research community at Orlando Health. When non-compliance is alleged, further information will be obtained by the CORO to determine whether the allegation is true.

IV. PROCEDURE:

A. Minor Protocol Deviation reporting requirements

1. A Minor Protocol Deviation is a protocol deviation that meets **all** of the following criteria:
   a. Does not have the potential to place the subject's (participants, or others) rights, safety, or well-being at a greater risk of harm,
   b. Does not violate ethical principles,
   c. Does not have a major impact on the integrity of study data or the scientific design of the study, and
   d. Does not result from willful or knowing misconduct on the part of the Investigator(s) or their study team.
2. Minor Protocol Deviations shall be reported at the time of Continuing Review (refer to the Continuing Review Application for further guidance).

B. Major Protocol Deviation/Violation reporting requirements:

1. If the protocol deviation/violation meets **any** of the following criteria, it may be considered an unanticipated problem:
   a. Potentially places the subject (participants, or others) at a greater risk of harm (rights, well-being and/or welfare),
   b. Potentially violates ethical principles
   c. Potentially has a major impact on the integrity of study data or the scientific design of the study,
   d. Resulted from willful or knowing misconduct on the part of the Investigator(s) or their study team
2. A Major Protocol Violation/Deviation Form must be submitted to the IRB within **5 working days** from the time any study team member (including the Investigator) becomes aware of the deviation.

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3. An explanation from the Principal Investigator describing corrective actions to prevent future occurrences is also required.

C. Regulatory Non-compliance reporting requirements:
1. 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.
2. For instances involving expired studies (i.e., studies that have lapsed in IRB approval), the procedures outlined in the *Continuing Review Process* IRB Policy shall be followed.
3. For instances involving studies which do not have an expiration date (i.e., require continuing review) and have passed its annual check-in date, the procedures outlined in the *Continuing Review Process* IRB Policy shall be followed.

D. When the non-compliance is alleged in a clinical trial within the research community at Orlando Health, further information must be obtained to determine whether the allegation is true.
1. An investigative team will be convened by the CORO.
   a. Individuals alleging non-compliance may be in sensitive positions relative to colleagues and superiors and must be protected from possible retaliation.
   b. Investigations will be confidential and whistleblower protections, as well as researcher integrity, will be respected.
2. When a confirmed report of non-compliance is received, an initial inquiry should be made promptly to determine whether the non-compliance is serious or continuing.
3. The CORO Director or designee will immediately notify the IRB Chair (or designee about the report).

E. Reviewing reports of Major Protocol Deviations/Violations and/or Regulatory Non-compliance:
1. When a report of a Protocol Deviation or Non-Compliance is received, the Principal Investigator or other parties may be asked to provide additional information in order to ensure the report is complete.
2. The report will be reviewed by the IRB Office, IRB Chair or designee. If needed, the IRB Office and/or IRB Chair will investigate the incident with any combination of the following individuals: the CORO, Principal Investigator, Director of Research, and/or the institutional human subjects (participants) protection signatory official.
3. If needed, the IRB Chair will determine if an immediate, temporary suspension of participant enrollment is required for the project in question as well as for other projects with the same Principal Investigator in an effort to ensure the welfare of research subjects (participants) and to ensure compliance with applicable regulatory requirements. This initial decision will be based on preliminary information and the seriousness of the situation.
4. Final IRB determination:
   a. If the IRB Chair determines the non-compliance to be non-serious and/or non-continuing:

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1) The IRB will provide a written acknowledgement letter to the Principal Investigator in response to the report.
2) If one exists, the temporary suspension of patient enrollment will be lifted.

b. Otherwise, the IRB Chair or designee may decide to consult with the Board at a convened meeting for a determination.
1) If this is the case, the IRB office will distribute the report at the next available Board meeting.
2) In order to determine serious or continuing non-compliance, it may be necessary to require an audit of study records at which time the Principal Investigator will be required to produce all signed consent forms and all data related to the study project at the time of the audit.
3) If, at a convened meeting, the IRB determines the incident to indicate serious and/or continuing non-compliance, then the procedures outlined in the IRB Policy #0330-1019 "Study Closure, Termination, or Suspension of Research" will be followed.

5. The Principal Investigator will be informed in writing of the required actions and/or results of the IRB's review.
6. The IRB Office shall maintain documentation for all IRB decisions and audits.

V. DOCUMENTATION:

A. Major Protocol Violation/Deviation Form
B. Continuing Review Application for Human Research Minor Protocol Deviation Log Sheet

VI. REFERENCES:

A. IRB Policy #0330-1007: *Continuing Review Process*
B. IRB Policy #0330-1019: *Study Closure, Termination, or Suspension of Research*
C. Code of Federal Regulations – 21 CFR 56.108 (b) and 45 CFR 46.108 (4)
D. Guidance for Industry- E6 Good Clinical Practice (4.5)
E. IRB Forms and Templates

VII. ATTACHMENTS:

A. Major Protocol Deviations/Violations & Regulatory Non-Compliance Examples