ORLANDO HEALTH®

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

Title:	***New/Initial Protocol Submission/Full Board Review***	Policy #:	**0330-1014**
		Replaced #:	ORMC Policy # 6000-305 MDACCO Policy # 1000-0001H
Page 1 of 3		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, 10/29/12, 8/11/14, 8/16/17, 4/21/20, 7/16/24		

I. PURPOSE:

This policy outlines the process for review, by the Orlando Health IRBs, of Human Subjects Research that is more than minimal risk.

II. DEFINITION:

A. IRBNet is the electronic system used by Orlando Health IRBs for submission, review, and document storage of all research reviewed by Orlando Health IRBs. It can be accessed at www.IRBNet.org. IRB staff can provide training materials and in-person training for using the IRBNet web site.

B. Significant Risk (SR): Under 21 CFR 812.3(m), an SR device means an investigational device that:

- Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
- Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

C. Non-Significant Risk (NSR): An NSR device study is one that does not meet the definition for an SR device study

III. POLICY:

Full Board Review: Human Subjects Research submissions that do not meet the criteria for Expedited Review or Exempt Review must be reviewed by the convened IRB (Full Committee Review).

IV. PROCEDURE:

The necessary forms required for IRB review of new protocol submissions are provided on the IRBNet website. Such documents and forms shall be submitted by the Principal Investigator and/or their research team to the IRB, via IRBNet submission, by the deadline for new/initial submissions. All new submissions must have electronic signature provided by the Principal Investigator and, if applicable, Co-Investigators via IRBNet tools.

A. New Protocol submission:

1. All submissions for approval must be accompanied by, but not limited to, an Orlando Health - IRB Application (online document in IRBNet), Informed Consent form (or waiver of informed consent form), Investigator's Brochure (as appropriate), Protocol, and a copy of the signed Form FDA 1572 (when appropriate).
2. For funded protocols, a completed Financial Disclosure form is required for all investigators.

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3. Researchers submitting protocols for the first time should ensure their current curriculum vitae/resume and the appropriate CITI Completion Reports (showing modules completed) are uploaded into their own IRBNet User Profiles in order for these documents to be kept on record in IRBNet. This requirement applies to all members of the study team.
4. Completed submissions for new protocols to be reviewed by the Full Board must be submitted to the Institutional Review Board via IRBNet by the posted deadline. Any studies that are greater than minimal risk are reviewed by the Pre-Review committee, unless otherwise specified by the IRB. The Chair and/or Pre-Review committee members will determine if a study moves forward to a Full Board Review.

B. The Principal Investigator shall be in attendance at the Full Board meeting to present the information and answer any questions that may arise during discussion. If the Principal Investigator is unable to attend, he/she may appoint another member of the study personnel who is knowledgeable to present the facts. If no representative is in attendance at the meeting, the protocol will be tabled until the next meeting, unless otherwise specified by the IRB.

C. The IRB shall review and have authority to approve, require modification(s) to, place restrictions on, or disapprove all research activities covered by this policy.

D. No research activities may begin until all completed forms have been reviewed and approved by the IRB. The IRB shall notify investigators and the institution of its decisions via IRBNet. If the IRB disapproves a research proposal, a statement of the reasons for its decision shall be included in its notification. The Principal Investigator will have an opportunity to respond to the Board in person or via IRBNet correspondence. **Reversal of IRB disapproval is only authorized by a majority vote upon the investigator's response to the issues of disapproval. Any additional information must be posted on IRBNet in the appropriate submission package for the protocol.**

1. **The Full Board IRB approval letter will have the following statement regarding signature of the board approval.** This statement is to certify that the information contained in this letter is in accordance with all applicable regulations, and a copy is retained within Orlando Health IRB records. The IRB certifies compliance with Good Clinical Practice, FDA 21CFR Part 11, the U.S. Department of Health and Human Services (HHS) and International Conference of Harmonisation (ICH) guidelines.

E. The IRB has the authority to observe, or have a third party observe, the consent process and the research at any time, with or without prior notification to the investigator.

F. The IRB is responsible for the initial risk determination. This determination will be made at the Full Board meeting.

V. REFERENCES

A. Expedited Review Policy # 0330-1003

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B. Exempt Review Policy # 0330-1004
C. IRB Authority and Jurisdiction Policy # 0330-1005

VI. ATTACHMENTS

None.