ORLANDO HEALTH®

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

Title:	***Use of External IRB of Record***	Policy #:	**0330-1025**
		Replaces #:	
Page:	1 of 2	Developed By:	Orlando Health Institutional Review Board (IRB)
Issue Date:	**09/25/2024**	Approved By:	Philip Giordano, MD
Revision Dates:			Institutional Official
			SIGNATURE ON FILE

I. PURPOSE:

This Orlando Health policy and procedure sets forth Orlando Health requirements for compliance with this policy and may also provide a guidance structure for the use of external IRBs and summarizes IRB processes for local review requirements.

II. DEFINITIONS:

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

A. OH: Orlando Health
B. OH IRB: Orlando Health Institutional Review Board
C. IRBNet: Electronic IRB submission system used at Orlando Health
D. COI: Conflict of Interest: Occurs when an individual's personal interests – family, friendships, financial, or social factors – could compromise his or her judgment, decisions, or actions in the workplace.
E. ICOI: Institutional Conflict of Interest: an institution's own financial interests or those of its senior officials pose risks of undue influence on decisions involving the institution's primary interests.
F. Boilerplate language: Required informed consent form language to include HIPAA language, compensation, and subject injury language.
G. External IRB: any non-OH IRB (For Example: NCI CIRB, WCG, Advarra, etc.)
H. Cede Review: The act of transferring IRB review and oversight.
I. Reliance Agreement: a written agreement between Orlando Health and a non-OH institution that is used to document IRB review responsibilities.
J. Reviewing IRB - the IRB of record performing review on behalf of Orlando Health, also referred to as the external IRB.
K. Relying Institution – when Orlando Health agrees to rely upon the reviewing IRB.

III. POLICY:

A. It is the policy of OH IRB, as the local institution, to ensure the safe and appropriate conduct of the research at OH.
   1. The IRB will confirm relevant experience and required CITI training to conduct research for the Principal Investigator.
   2. Confirm the inclusion of the Institutional Letter providing approval of waiver of oversight from the Corporate Office of Research Oversight in the initial submission.
   3. Review initial and any subsequent changes in conflict of interest (COI) or financial disclosures or interests for participating Investigators.
   4. Review initial and any subsequent changes in institutional conflict of interest (ICOI).
   5. Changes in Principal Investigator.
   6. Confirm the insertion of Orlando Health required boilerplate language in the Informed Consent Forms prior to ceded review.
   7. The IRB will annually monitor protocol compliance as part of its quality assurance program.

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B. Upon ceded review, the oversight of the research project will be under the reviewing institution. The Orlando Health IRB will no longer have oversight of the research approval process. Research staff will continue to maintain regulatory documents and will notify the relying institution of any required changes as per the External IRB Workflows document located in IRBNet and this policy.

IV. PROCEDURE:

Procedures for multi-site studies (when Orlando Health relies on an external IRB) are published separately by the Corporate Office of Research Oversight and/or the Orlando Health IRBs.

V. DOCUMENTATION:

A. Local Context for Multi-site Research Registration Form
B. External IRB Workflows

VI. REFERENCES:

A. U.S. Department of Health and Human Services (https://www.hhs.gov/ohrp)

VII. ATTACHMENTS:

A. None.