ORLANDO HEALTH®

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

Title:	***Use of a single IRB of record***	Policy #:	**0330-1023**
		Replaces #:	
Page:	1 of 2	Developed By:	Orlando Health Institutional Review Board (IRB)
Issue Date:	1/19/18	Approved By:	Philip Giordano, MD Institutional Official
Revision Dates:	1/19/21, 09/14/22		**SIGNATURE ON FILE**

I. **PURPOSE:** All domestic sites participating in cooperative research, supported and/or funded by the Department of Health and Human Services (HHS), are required to use a single Institutional Review Board (sIRB) to conduct the ethical review required for the protection of human subjects. This policy applies to applications for National Institutes of Health (NIH) funded multi-site research with due dates on or after January 25, 2018, and contract solicitations published on or after January 25, 2018, and, as of January 20, 2020, all other multi-site HHS-sponsored cooperative research subject to the revised Common Rule (45 CFR 46, Subpart A) where each site within the United States will conduct the same protocol involving non-exempt Human Subjects Research. This Orlando Health IRB Policy and Procedure sets forth the Orlando Health requirements for compliance with this policy and may also provide a guidance structure for other research utilizing a sIRB for a multi-site study.

II. **DEFINITIONS:**

A. Cooperative research: Non-exempt Human Subjects Research that involve more than one institution and is supported and/or funded by the HHS.
B. sIRB: Single Institutional Review Board, designated as the IRB of record for all sites in a multi-site study.
C. Relied-upon IRB/Institution: The sIRB or site designated as the IRB of record.
D. Relying IRB/Institution: Any of the sites in a multi-site study which relies on the sIRB to be the IRB of record.
E. OH IRB: Orlando Health Institutional Review Board
F. CORO: Corporate Office for Research Operations (Orlando Health)
G. IRBNet: Electronic IRB submission system used at Orlando Health
H. Relying Site Application Form – an application with information on how the study will be conducted at the relying site, including Principal Investigator (PI), team members, relying site consent process, data protection, etc.
I. Smart IRB – a platform developed by the National Center for Advancing Translational Sciences (NCATS) to facilitate IRB authorization agreements (reliance agreements) among institutions engaged in cooperative research.
J. Boilerplate language – required informed consent form language specific to a single participating institution.

III. **POLICY:**

A. For studies utilizing an Orlando Health IRB as the sIRB in a multi-site study, the Orlando Health research team and all participating sites must comply with the multi-site procedures published separately by the CORO and/or the OH IRBs. These procedures will ensure that the local PI is adequately managing and overseeing all sites.
B. For studies that require an Orlando Health research team to rely on another IRB as the sIRB in a multi-site study, the Orlando Health team and the sIRB must comply with the multi-site procedures published separately by the CORO and/or the OH IRBs These procedures will ensure that Orlando Health's participation in sIRB multi-site studies is consistent with local resources, and with local policies and procedures.

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C. Exceptions to the Single IRB mandate and this IRB policy:
   a. Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context; or
   b. Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or
   c. Cooperative research conducted or supported by HHS agencies other than the NIH, if an IRB approved the research before January 20, 2020; or
   d. Cooperative research conducted or supported by NIH if either:
      i. The NIH single IRB policy does not apply, and the research was initially approved by an IRB before January 20, 2020, or
      ii. The NIH excepted the research from its single IRB policy before January 20, 2020.

IV. PROCEDURES:

Procedures for multi-site studies (when Orlando Health is the sIRB for the study or when Orlando Health relies on an external IRB as the sIRB) are published separately by the CORO and/or the Orlando Health IRBs.

V. DOCUMENTATION:

Orlando Health Procedures for Multi-Site Studies.

VI. REFERENCES:

A. Code of Federal Regulations: 45 CFR 46.114
B. Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research
C. OHRP Guidance Documents
D. “Guidance on Exceptions to the NIH Single IRB Policy" released October 11, 2017
E. Resources for Smart IRB (web page - https://smartirb.org/resources/)

VII. ATTACHMENTS:

A. None.