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1414 Kuhl Ave.
Orlando, Florida 32806
321.843.7000

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

Title:	***IRB Authority and Jurisdiction***	Policy #:	**0330-1005**
		Replaced #:	ORMC IRB #6000-102 MDACCO IRB #1000-0001-D
Page 1 of 5		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, 11/7/07, 7/1/13, 8/11/14, 8/3/15, 8/1/18, 1/21/19, 6/19/19 4/5/21, 9/14/22, 1/14/25, 07/15/25		

I. PURPOSE:

This policy outlines the authority and jurisdiction of the Orlando Health IRB.

II. DEFINITIONS:

Please refer to the IRB Definition Policy

III. POLICY:

A. IRB Authority over Human Subjects (Participants) Research:

1. Orlando Health, Inc. has given authority to the Orlando Health IRB to protect human subject (participant) rights and welfare in human subjects (participants) research.
2. Under FDA regulations, an IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research and social behavior involving human subjects (participants). In accordance with FDA regulations, the IRB has the authority to approve, disapprove or modify human subjects (participants) research activities covered by regulations; conduct continuing reviews of research involving human subjects (participants) (when appropriate); observe the conduct of the study (i.e., consent processes and other research processes) and verify changes. Only the IRB can approve human subjects (participants) research. Research involving human subjects (participants) can be disapproved by other officials or committees.
3. Additionally, the IRB has the authority to suspend or terminate approval of human subjects (participants) research that is not being conducted in accordance with the Orlando Health IRBs' requirements or that has been associated with unexpected serious harm to human subjects (participants).

B. Exceptions from Orlando Health IRB approval:

1. Research involving human subjects (participants) may be under the oversight of an external, non-Orlando Health IRB.
2. An IRB Authorization Agreement (or equivalent) with the non-Orlando Health (external) IRB must be executed and approved by the Institutional Official.

C. Not Human Subjects Research:

1. The following activities are deemed not to be human subjects (participants) research and do not require IRB oversight if the project or its elements do not change. Staff can join or leave without IRB review. However, changes to intent, methodology, or participants can change the project to HSR (Human Subjects Research) and require further IRB review for oversight:

a. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

b. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

c. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

d. Authorized operational activities (as determined by each appropriate federal agency) in support of intelligence, homeland security, defense, or other national security missions.

2. Certain studies submitted for exempt review, and other projects conducted at Orlando Health may be determined as “Not Human Subjects Research” because the activity meets neither the HHS definition nor the FDA definition of human subject research as referenced above. For example, some projects may not meet the HHS definition of “research” if they are not designed to develop or contribute to generalizable knowledge (45 CFR 46.102) and some projects do not meet the FDA definition of research if they do not involve the administration of drugs or devices (21 CFR 56.102). Innovative or newly introduced procedures or therapies do not require IRB review and approval except when they meet either the HHS or FDA definition of "research".

3. As determined by the IRB Chair or designee, studies that are research, but do not involve human subjects (participants) (according to the regulations) might include those in which:

a. the investigator conducting research neither interacts nor intervenes with an individual to obtain data (including identifiable specimens) about that person or

b. the investigator does not obtain identifiable private information or identifiable biospecimens.

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4. NOTE: Studies that involve identifiable private information and/or identifiable biospecimens must be reviewed by the IRB chair or designee for determination that the project is "Not Human Subjects Research", and/or if the project does not involve human subjects (participants).

IV. PROCEDURE:

A. IRB Approval Authority:

1. With the exception of research delegated to external IRB that have been authorized by Orlando Health, the Orlando Health IRB have the responsibility of reviewing and approving all human subject (participants) research, conducting periodic reviews on established projects when appropriate and ensuring compliance with the above laws and ethical principles.
   a. Submit research that does NOT involve minors or pregnant women to Orlando Health IRB (Adult IRB).
   b. Submit research involving children and/or involve primarily pregnant women to Orlando Health IRB (Pediatric and Pregnant Women IRB).
2. Once received, the IRB Office staff will review all submissions for completeness and may, at their discretion, withdraw submissions they have determined to be incomplete.
3. Upon review by the respective Orlando Health IRB, the IRB has the authority to forward research submissions from one Orlando Health IRB to another, if deemed necessary and appropriate to provide adequate protection of human subjects (participants).
4. Research which is approved by the Orlando Health IRB will be conducted only within:
   a. Orlando Health, Inc. facilities; OR
   b. other facilities which are clearly identified in the originally approved research proposal; OR
   c. other facilities which have subsequently been identified in an amendment and approved by the IRB.

B. If Orlando Health is engaged in research, approval must be obtained from an Orlando Health-authorized IRB prior to the start of any research activity that involves human subjects (participants) and:

1. the research is sponsored by Orlando Health, Inc.
2. the research is conducted by or under the direction of any employee or agent or affiliated student of Orlando Health, Inc. in connection with his/her institutional responsibilities.
3. the research is conducted by or under the direction of any employee or agent of Orlando Health, Inc.

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4. the research involves the use or collection of Orlando Health, Inc. private (non-public) information including to identify or contact human research subjects (participants) or prospective subjects (participants).
5. for research conducted at other non-affiliated institutions, clinics, lab or offices may be reviewed by the IRB if at least one investigator is affiliated with Orlando Health, Inc. or if an Individual Investigator Agreement is in place. The Orlando Health IRB will make a determination whether to review this type of research on a case-by-case basis.
6. for research studies involving the use of, but not limited to, investigational drugs, biologics, antibiotics, vaccines, human behavior devices, surgical applications, teaching devices or Humanitarian Use Devices (HUD).

C. Not Human Subjects Research submissions:

1. The Orlando Health IRB can provide a Not Research determination letter at the request of the individual responsible for an applicable project.
2. The requesting individual should submit the Not Human Subjects Research submission form with any supporting documents via IRBNet to the appropriate Orlando Health IRB.
3. The IRB chair and/or designee will review the submission and notify the investigator whether or not the project is "Human Subjects Research."
   a. If the project meets the criteria for Human Subjects Research, the IRB Office will advise the investigator on the appropriate submission materials and processes for submitting the project to the IRB for review.
   b. If the project does not meet the definition of "Human Subjects Research", the IRB designee will issue a letter verifying that the project has been reviewed by the IRB and is not human subjects (participants) research. Therefore, no further action from the IRB is needed unless there are changes to the project. The IRB designee may designate submissions sent via IRBNet as "Not Human Subjects Research".

V. REFERENCES:

A. FDA Information Sheet "Off Label and Investigational Use of Marketed Drugs, Biologics and Medical Devices"
B. OHRP guidance document issued October 16, 2008 "Guidance on Engagement of Institutions in Human Subjects Research"
C. Code of Federal Regulations - 45 CFR 46.102, 45 CFR 46.104, 21 CFR 50.3, 21 CFR 56.102
D. IRBNet Template Library

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VI ATTACHMENTS:

A. None