ORLANDO HEALTH®

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 Membership and Structure***	Policy #:	**0330-1013**
		Replaces #:	ORMC IRB # 6000-101 MDACCO IRB # 1000-0001F
Page 1 of 5		Developed 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, 10/15/12, 8/14/14, 10/13/16, 1/21/19, 4/5/21, 9/14/22, 7/12/23,1/16/24, 7/15/25, 11/12/25		

I. PURPOSE:

The Orlando Health Institutional Review Board (IRB) is a fully functioning, standing committee, which is independent of any other committee at Orlando Health, Inc. The Orlando Health IRB shall review human subject (participant) research studies that are conducted by Orlando Health, Inc. employees, or studies in which Orlando Health is engaged in research, as well as research conducted elsewhere by Orlando Health, Inc. personnel in connection with their institutional responsibilities.

II. DEFINITIONS:

Please refer to the IRB Definition Policy.

III. POLICY:

A. **IRB Membership**: IRB members and their alternates on the IRB shall include experienced researchers, with expertise and professional training in a variety of disciplines, as well as representatives from nonscientific areas and the community at large. The IRB may invite individuals with competence in special areas to assist in the review of issues, which require expertise beyond that found among the IRB membership. These individuals may not vote with the IRB.

1. **Primary and Alternate Members:** Membership shall include both sexes and may not consist entirely of members of one profession. At least one member shall have a scientific background and at least one a primary concern in nonscientific areas. At least one member shall have no otherwise affiliation with Orlando Health, Inc. nor have an immediate family member who is affiliated with Orlando Health, Inc. Persons knowledgeable about groups of subjects (participants) that is vulnerable to coercion or undue influence (children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons) shall be members of the Board or consulted when such groups are to be primary subjects (participants) of the research. A list of IRB members with earned degrees, representative capacity, experience and any employment or other relationship between the member and Orlando Health, Inc. shall be maintained. New primary and alternate members shall receive an orientation, and IRB member training through CITI and the IRB Member and Alternate Member Responsibilities form to educate them of their responsibilities. The Responsibilities Form will be signed by each member and their alternate at the beginning of their term. There shall be a minimum of 5 primary members and 5 alternate members appointed every 2 years by the Corporate Office for Research Operations where staggering and overlapping terms shall be used.
2. **IRB Chairperson**- the Chairperson of the IRB is appointed in the same manner as the members, but every 5 years. The Chairperson will sign the IRB Chairperson form at the beginning of their term.

IV. PROCEDURE:

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A. Quorum: In order for the meeting to be held, Quorum consists of no fewer than 5 voting members and no more than 9 voting members. One of these members must be primarily concerned with nonscientific areas. If a quorum is not available, or if a quorum is lost during the deliberations of the IRB, the IRB meeting will be terminated. Action taken may include disapproval, request for modification, or approval. Approval of any action, other than expedited review, requires approval of a majority of those members present at the meeting**.** When necessary, primary reviewers can be assigned by the IRB Chairperson. The primary reviewer is a limited number of IRB members, usually two or three, are assigned as special reviewers for each protocol to be reviewed at the full committee meeting. Findings will be reported at the convened IRB meeting. All other members will receive complete documents, or a summary of the material where full documents are available at the IRB office.

B. Voting: Only primary members and their alternates have voting rights. Votes can be cast by being present at the meeting or via a teleconferenced IRB meeting. A voting record will be maintained in the IRB minutes.

1. For most human subjects (participants) research **not** subject to limited IRB review, IRB approval is based on when the following criteria has been met:
   a. Risks to subjects (participants) are minimized:
      1) by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects (participants) to risk, and
      2) whenever appropriate, by using procedures already being performed on the subjects (participants) for diagnostic or treatment purposes.
   b. Risks are reasonable in relation to anticipated benefits, if any, to subjects (participants), and the importance of the knowledge that may be reasonably expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects (participants) would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
   c. Selection of subjects (participants) is equitable. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects (participants) who are vulnerable to coercion or undue influence.
   d. Informed consent will be sought from each prospective subject (participant) or their legally authorized representative with all appropriate elements expressed in understandable terms and documented.

e. When Informed consent is not required the IRB may approve a request to waive of some or all of the required elements of informed consent under specific circumstance in accordance with 45 CFR 46.117. **Refer to Policy 0330-1011 for further guidance regarding Waiver of Informed Consent.**

f. Studies Involving Children: The IRB will determine the requirements for permission by parent or guardians for assent by children are met in accordance with 45 CFR 46.408; 21 CF 50.55) **Refer to Policy 0330-1011 for further guidance regarding assent.**

g. Privacy and confidentiality of subjects (participants) will be protected, when appropriate.

h. The investigator is qualified to conduct the research

i. There are adequate provisions for monitoring the data collected to ensure subject (participant) safety, when appropriate.

j. Vulnerable categories of subjects (participants) have appropriate additional safeguards included in the study to protect the rights and welfare of these subjects (participants), when appropriate.

2. For purposes of conducting the limited IRB review process required for the storage or maintenance of identifiable information and/or identifiable biospecimens for any secondary research for which broad consent is required, the IRB must determine the following:

a. Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements for alternative required elements of broad consent as defined per 45 CFR 46.116(a)(1)-(4), (a)(6), and (d);

b. Broad consent is appropriately documented, or the waiver of documentation is appropriate in accordance with 45 CFR 46.117; and

c. If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects (participants) and to maintain the confidentiality of data.

C. IRB Relationships: Minutes of the IRB will be reported to the Corporate Office for Research Operations.

1. Research Investigator: Any Orlando Health, Inc. employee or Medical Staff member who desires to do human subject Research, may contact the IRB office for assistance.

2. Other Institutions: All projects that fall under Orlando Health IRB jurisdiction may require review by an Orlando Health IRB even if they have IRB approval at other institutions depending on the IRB Authorization Agreement with the other institution. If a patient receives treatment at OH facilities, is a research subject (participant) of a research protocol at another institution, and does not involve Orlando Health, Inc. medical staff or employees as part of the research team, then the protocol does not fall under OH IRB Jurisdiction.

3. Orlando Health Board Member Relationships: IRB Members shall not participate in final board discussion and voting when at least one of the following circumstances apply:
   a. when they have a financial/personal interest in a company whose proposal is being presented
   b. when the member has a professional conflict of interest, except to provide the IRB with requested information
   c. when they have a personal conflict of interest.

D. The IRB will be provided with, at the minimum, the following: staff to conduct IRB responsibilities, space, equipment, phone, fax, Xerox, computer, printer, internet access, and dietary support.

E. IRB Member Education: All new IRB members and alternates shall receive an orientation and complete the IRB required training as mentioned above. As funds are available, board members will be encouraged to participate in continuing education opportunities to increase their knowledge of their responsibilities including the protection of human subjects in accordance with 45 CFR 46, 21 CFR parts 50 and 56.

F. IRB Processes: Unless specifically authorized by the IRB Chairperson, all materials for the IRB meeting shall be provided to members at least one week prior to the meeting via IRBNet. **Refer to the appropriate policy and checklist for IRB review type (i.e., Exempt (0330-1004), Expedited (0330-1003), New/Initial Protocol Submission/Full Board Review (0330-1014), etc).**

G. IRB Record Retention: Records of IRB business shall be retained for at least 15 years, and records relating to research which is conducted shall be retained for at least 15 years after completion of the research. All records shall be accessible for inspection and copying by authorized agents at reasonable times and in a reasonable manner. The following documents shall be retained:
   a. copies of all research proposals reviewed, scientific evaluation, if any, that accompany the proposal, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects (participants)
   b. minutes of IRB meetings which show attendance at the meetings, actions taken, the number of members voting for, against, and abstaining, the basis for requiring changes in or disapproving research, a written summary of the discussion of controversial issues and their resolution, and documentation of all continuing education
   c. records of continuing review activities
   d. copies of all correspondence between the IRB and the investigators
   e. a list of IRB primary members and alternates
   f. written policies and procedures
   g. statements of significant new findings provided to subjects (participants)

V. REFERENCES:

A. Code of Federal Regulations - 45 CFR 46, 45 CFR 46.107

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B. Code of Federal Regulations - 21 CFR parts 50 and 56
C. OHRP document “Guidance on Engagement of Institutions in Human Subjects Research” dated October 16, 2008