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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 7		Issued By:	Orlando Health Institutional Review Board (IRB)
Issue Date:	**7/19/95**	Approved By:	Philip Giordano, MD Institutional Official **SIGNATURE ON FILE**
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I. PURPOSE:

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

II. DEFINITIONS:

A. IRB Approval: IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by Orlando Health's IRB and other institutional or federal guidelines.

B. Investigator: An individual who actually conducts a clinical investigation (i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject). In the event of an investigation conducted by a team of individuals, the Principal Investigator is the responsible leader of that team.

C. Investigational Drug or Device: An investigational drug or device is a drug or device permitted by the Food and Drug Administration to be tested in humans, but not yet determined to be safe and effective for a particular use in the general population. An investigational drug or device may be a new drug or device not yet approved for marketing, or may be an approved drug or device being tested for the purpose of supporting a new labeling indication. (See FDA Information Sheet "Off Label and Investigational Use of Marketed Drugs, Biologics and Medical Devices")

D. Sponsor: The sponsor is the person or entity that initiates the clinical trial. The sponsor is typically the manufacturer or research institute that developed the drug or device. In this case, the sponsor does not actually conduct the clinical trial but rather distributes the investigational drug or device to a clinical investigator who directs the conduct of the trial. A clinical investigator may, however, serve as both the sponsor and investigator (called "investigator-sponsor") of a clinical trial. The sponsor assumes responsibility for the studies involving the investigational drug or device, including responsibility for compliance with applicable laws and regulations. The sponsor is responsible for obtaining FDA approval to conduct a trial and for reporting the results of the trial to the FDA.

E. Engaged in Research (See OHRP guidance document "Guidance on Engagement of Institutions in Human Subjects Research" issued October 16, 2008): In general, an institution is considered engaged in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain:

1. data about the subjects of the research through intervention or interaction with them;
2. identifiable private information about the subjects of the research; or
3. the informed consent of human subjects for the research.

F. Identifiable private information: Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

G. Identifiable biospecimen: A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

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H. IRB Oversight: Oversight means that the IRB has reviewed the project and has determined it to be either Human Subjects Research (HSR) or Not Human Subjects Research (NHSR)

IIa. <u>Definition of Human Subject Research</u>

A. The Orlando Health IRBs define an activity as human subject research if it meets either the HHS or FDA definition.

B. <u>HHS Definition of Human Subject Research</u>: Activities are human subject research subject to HHS regulations when they meet the HHS definition of "research" and involve one or more "human subjects" as defined in HHS regulations.

1. Research (as defined by HHS regulations in 45 CFR 46.102(l)): a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
2. Human subjects (as defined by HHS Regulations in 45 CFR 46.102(e)): a living individual about whom an investigator conducting research:
    a. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
    b. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
3. Intervention: includes both the physical procedures by which data are gathered (e.g., venipunctures) and manipulations of the subject or the subject's environment that are performed for research purposes.
4. Interaction: communication or interpersonal contact (e.g., questionnaires, interviews) between the investigator and the subject for research purposes.
5. Private information: information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.
6. Clinical Trial (as defined by HHS regulations in 45 CFR 46.102(b)): a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

C. <u>FDA Definition of Human Subject Research</u>: Activities are human subject research subject to FDA regulations when they meet the FDA definition of "research" and involve one or more "human subjects" as defined in FDA regulations.

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1. Clinical Investigation (as defined by FDA Regulations (21 CFR 56.102): any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA under section 505(i), or 520(g) of the Federal Food, Drug and Cosmetic Act ("the Act"), or need not meet the requirements for prior submission to the FDA under these sections of the Act, but the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. The term "clinical investigation" does not include experiments that must meet the provisions of part 58, regarding non-clinical laboratory studies.
   a. The terms *research, clinical research, clinical study, study,* and *clinical investigation* are deemed to be synonymous for purposes of this part.
   b. Research is subject to 21 CFR 50 (Protection of Human Subjects) and 56 (Institutional Review Boards) when it involves:
      1) The use of any drug other than the use of an approved drug in the course of medical practice, or
      2) The use of any medical device other than the use of an approved medical device in the course of medical practice. Clinical investigators agree to conditions regarding the conduct of the clinical investigation outlined by FDA regulations, or
      3) Clinical investigations regulated by the FDA under Sections 505(i) and 520(g) of the Act including investigations of foods, dietary supplements that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products.
   c. Clinical investigators may be required to agree to these conditions by signing an FDA form (Form FDA 1572) that certifies that the investigator has obtained IRB review and approval prior to conducting the study.
2. Human subject (as defined by FDA regulations in 21 CFR 56.102(e)): an individual who is or becomes a participant in research either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. If the research involves a medical device, human subjects are individuals when they participate in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control (21 CFR 812.3(p)).

III. POLICY:

A. IRB Authority over Human Subjects Research:
   1. Orlando Health, Inc. has given authority to the Orlando Health IRBs to protect human subject rights and welfare in human subjects research.

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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. In accordance with FDA regulations, the IRB has the authority to approve, disapprove or modify human subjects research activities covered by regulations; conduct continuing reviews of research involving human subjects (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 research. Research involving human subjects can be disapproved by other officials or committees.
3. Additionally, the IRB has the authority to suspend or terminate approval of human subjects 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.

B. Exceptions from Orlando Health IRB approval:
1. Research involving human subjects 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 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 (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.

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.

IV. PROCEDURE:

A. IRB Approval Authority:

1. With the exception of research delegated to external IRBs that have been authorized by Orlando Health, the Orlando Health IRBs have the responsibility of reviewing and approving all human subject 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 #1 (Adult IRB).

b. Submit research involving children and/or involve primarily pregnant women to Orlando Health IRB #2 (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.

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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.
4. Research which is approved by the Orlando Health IRBs 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 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.
4. the research involves the use or collection of Orlando Health, Inc. private (non-public) information including to identify or contact human research subjects or prospective subjects.
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 IRBs 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 IRBs 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 research. Therefore, no further action from the IRB is needed unless there are

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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

VI ATTACHMENTS:

A. None