ORLANDO HEALTH®

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

Title:	***Ethical Principles***	Policy #:	**0330-1017**
		Replaces #:	ORMC 6000-100; MDACCO 1000-0001
Page 1 of 2		Developed By:	Orlando Health Institutional Review Board (IRB)
Issue Date:	**7/19/95**	Approved By:	**SIGNATURE ON FILE** Philip Giordano, MD Institutional Official
Revision Dates:	1/1/01, 3/20/02, 11/7/07, 8/14/14, 5/16/16, 3/4/19, 04/12/22, 1/18/23, 7/15/25		

I. PURPOSE:

To establish an administrative body which protects the rights and welfare of human research subjects (participants) recruited to participate in research activities conducted under the auspices of Orlando Health, Inc.

II. DEFINITIONS:

Please refer to the IRB Definition Policy.

III. POLICY:

The Orlando Health Institutional Review Boards' (IRB) primary responsibility is to ensure that human subjects (participants) enrolled in research studies conducted under the auspices of Orlando Health, Inc. are afforded maximum protection of their rights and welfare, while ensuring that the research being performed is in the best interest of the study subjects (participants) and Orlando Health, Inc. The IRB shall at all times be guided by the basic ethical principles expressed in the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report and will report to the Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Department of Health and Human Services (DHHS) and National Institute of Health (NIH). In addition, the state and federal laws for the protection of human research subjects (participants) shall be followed; applicable state law if more stringent will take precedence. In particular, 45 CFR 46, 21 CFR 50 and 56 will provide the legal structure within which the IRB shall operate. If at any time an investigator is out of compliance with these regulations a letter will be sent to the Investigator and the FDA, OHRP, NIH, and/or other interested parties (e.g. Sponsor).

An important aspect of respect for persons is that individuals should be treated as being autonomous. Potential study participants should be given information about a study without undue influence or coercion, so that they can make a reasoned decision on their own. However, there are certain individuals who are particularly subject to influences that may limit their ability to make decisions freely (e.g., children and prisoners). They are considered to be vulnerable and are entitled to additional protections. Respect for persons is particularly relevant to the consent process.
In striving for beneficence, harm should be minimized and benefits maximized. Investigators should attempt to seek alternative ways of investigating hypotheses that would lead to a more favorable risk-benefit ratio.

Beneficence is understood in a stronger sense, as an obligation from the researcher to the human subject (participant) population. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms. For example, when considering a research design, the principle of beneficence should raise a question if there is another way in which the same knowledge can be obtained but with lower risks to participants.

Justice involves the equitable treatment of human subjects (participants). Thus, care should be taken to avoid performing studies that might cause excessive risks or benefits for one group over another group. In other words, to

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the extent possible, risks and benefits should be equally distributed. Justice is highly relevant to the selection of research subjects (participants) for a study.

IV. PROCEDURE:

In accordance with the above ethical principles, in reviewing research protocols, the Orlando Health IRBs must consider all of the following:

A. The rights and welfare of the individual or group involved
B. The minimization of risks to human subjects (participants) by using procedures consistent with sound research design
C. The appropriateness of the procedures and methods employed to the aims, underlying hypotheses and goals of the research
D. The adequacy and appropriateness of the consent form and the process by which consent would be obtained
E. The medical, social or psychological risks to the subject (participant) and the reasonableness of these risks in relation to the anticipated medical and/or psychosocial benefits of the investigation, if any, to the subjects (participants) and the importance of the knowledge that may reasonably be expected to result
F. The fairness and equitability of the inclusion of individuals according to race, ethnicity, gender, and age

V. REFERENCES:

A. Nuremberg Code
B. The Declaration of Helsinki
C. The Belmont Report

VI. ATTACHMENTS:

None