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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:	Mildred Beam, Esq. Institutional Official
Revision Dates:	1/1/01, 3/20/02, 11/7/07, 8/14/14, 5/16/16		

I. PURPOSE:

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

II. DEFINITIONS:

When used in this policy these terms have the following meanings:

A. Respect for Persons: Individuals should be treated as autonomous agents and those persons with diminished autonomy should be entitled to protection. This principle is applied by obtaining informed consent with due consideration of privacy, confidentiality, and additional protections for vulnerable populations.

B. Beneficence: Individuals should be treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. This principle is applied by appropriately weighing risks and benefits.

C. Justice: All individuals should equally share the burdens and benefits of research. This principle is applied by the equitable selection of research subjects.

III. POLICY:

The Orlando Health Institutional Review Board's (IRB's) primary responsibility is to ensure that human subjects 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 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 shall be followed; Florida state law 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 and/or NIH.

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.

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Justice involves the equitable treatment of human subjects. 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 the extent possible, risks and benefits should be equally distributed. Justice is highly relevant to the selection of research subjects for a study.

IV. PROCEDURE:

In accordance with the above ethical principles, in reviewing research protocols, the Orlando Health IRB 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 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 and the reasonableness of these risks in relation to the anticipated medical and/or psychosocial benefits of the investigation, if any, to the subjects 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