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:	***Exempt Review***	Policy #:	**0330-1004**
		Replaced #:	ORMC IRB# 6000-202 MDACCO IRB# 1000-0001H
Page 1 of 3		Issued By:	Orlando Health Institutional Review Board (IRB)
Issue Date:	**7/19/95**	Approved By:	Steve Harr Orlando Health, Inc. Executive Vice President
Revision Dates:	1/1/01, 3/20/02, 11/9/07, 8/27/12, 6/1/15		

I. PURPOSE:

To maintain ethical and legal standards when determining a submission qualifies for exempt review.

II. POLICY:

A study may be recommended to the IRB as exempt from IRB review, and it may be approved by the IRB chair or chair-designee as exempt if it involves very little if any risk to human subjects and if it fits within an exempt category listed under 45 CFR 46.101(b)(1)-(6). The categories for exempt review do not apply to research involving prisoners.

III. DEFINITIONS:

A. Exempt: Exempt research projects present risks so benign to the human subjects who participate in them, that the federal regulations say such projects are exempt from review. The majority of research studies that qualify for exempt review involve the use of anonymous existing data or specimens. Anonymous means the study information can never be linked to identifiers by anyone.

B. PHI: Protected Health Information is individually identifiable health information. This includes any direct or indirect subject identifiers that can be connected to the subject, including codes that can be used to identify subjects.

C. Retrospective: A term used in research to describe material or data that is existent prior to the initiation of the study.

D. Human Subjects Research: A living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information through a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

IV. PROCEDURE:

A. Research activities that involve the following will be exempt as defined in policy # from review:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
   a. research on regular and special education instructional strategies, or
   b. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

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:	***Exempt Review***	Policy #:	**0330-1004**
		Replaced #:	ORMC IRB# 6000-202 MDACCO IRB# 1000-0001H
Page 2 of 3		Issued By:	Orlando Health Institutional Review Board (IRB)
Issue Date:	**7/19/95**	Approved By:	Steve Harr Orlando Health, Inc. Executive Vice President
Revision Dates:	1/1/01, 3/20/02, 11/9/07, 8/27/12, 6/1/15		

2. Research involving the use of educational tests, survey procedures, interview procedures or observation of public behavior, unless:
   a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
   b. any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

   NOTE: The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

3. Research involving the use of educational tests, survey or interview procedures or the observations of public behavior that is not exempt under section 2 of this policy:
   a. the human subjects are elected or appointed public officials or candidates for public office
   b. federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Collection or study of existing (retrospective) data, documents, records, pathological or diagnostic specimens, if these items are publicly available or the information is recorded by the investigator in such a manner that the subjects can not be identified.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are assigned to study, evaluate, or otherwise examine;
   a. Public benefit or service programs;
   b. procedures for obtaining benefits or services under those programs;
   c. those programs or procedures; or
   d. possible changes in methods or levels of payment for benefits or services under those programs

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:	***Exempt Review***	Policy #:	**0330-1004**
		Replaced #:	ORMC IRB# 6000-202 MDACCO IRB# 1000-0001H
Page 3 of 3		Issued By:	Orlando Health Institutional Review Board (IRB)
Issue Date:	**7/19/95**	Approved By:	Steve Harr Orlando Health, Inc. Executive Vice President
Revision Dates:	1/1/01, 3/20/02, 11/9/07, 8/27/12, 6/1/15		

6. Taste and food quality evaluation and consumer acceptance studies
   a. if wholesome foods without additives are consumed
   b. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture

B. Documentation of Exempt Review:
   1. All IRB project records are stored in IRBNet.
   2. It is the responsibility of that investigator to maintain the research files in a secure environment.

IV. REFERENCES:

A. Institutional Review Board Management and Function,, Robert Amdur, M. D., and Elizabeth Bankert, MA, Jones and Bartlett Publishers, 2006.
B. Code of Federal Regulations: 21 CFR 56.104.
C. Code of Federal Regulations: 45 CFR 46.101.
D. https://www.irbnet.org/ - Orlando Health On-line Application
E. IRBNet Template Library

V. Attachments:

A. None.