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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 5		Issued By:	Orlando Health Institutional Review Board (IRB)
Issue Date:	**7/19/95**	Approved By:	Philip Giordano, MD Institutional Official
Revision Dates:	1/1/01, 3/20/02, 11/9/07, 8/27/12, 6/1/15, 3/26/18, 1/21/19 2/25/19, 04/12/2022		SIGNATURE ON FILE

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, but it may only be determined 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 46.104. The categories for exempt review do not apply to research involving prisoners except for exempt research aimed at involving a broader subject population that only incidentally includes prisoners.

III. DEFINITIONS:

A. 2018 Requirements: The Federal Policy for the Protection of Human Subjects requirements contained in 45 CFR 46 Subparts A, effective January 19, 2018, as well as Subpart B, C, and D, exclusive of requirements for reporting to, certification by, or review by a federal department of agency head.

B. Pre-2018 Requirements: The Federal Policy for the Protection of Human Subjects requirements contained in 45 CFR 46 Subparts A as published in the 2016 edition of the Code of Federal Regulations, as well as Subpart B, C, and D, exclusive of requirements for reporting to, certification by, or review by a federal department of agency head.

C. Exempt Review: 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.

D. 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.

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

F. Human Subjects Research: Activities are human subject research subject to HHS regulations when they meet the definition of "research" and involve one or more "human subjects" as defined in IRB Policy #0330-1005 IRB Authority and Jurisdiction.

G. Identifiable private information: Refer to IRB Policy 0330-1005 "IRB Authority and Jurisdiction" for definition.

H. Identifiable Biospecimen: Refer to IRB Policy 0330-1005 "IRB Authority and Jurisdiction" for definition.

I. Benign Behavioral Intervention: An intervention that is brief in duration, harmless, painless, not physically invasive, such as playing an online game, solving puzzles under various noise conditions, etc.

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J. Limited IRB Review: Some exempt research projects subject to 2018 requirements require limited IRB review by the IRB Chair/designee. The limited IRB review process consists of the IRB Chair/designee ensuring that adequate privacy safeguards for identifiable private information and/or identifiable biospecimens are in place.

K. Broad Consent: Refer to IRB Policy #0330-1002 "Informed Consent Process" for definition.

IV. PROCEDURE:

A. The following research activities may qualify for exempt review:

1. Research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes:
   i. most research on regular and special education instructional strategies, and
   ii. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least ONE of the following criteria is met*:
   i. the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
   ii. any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation; or
   iii. the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to ensure that safeguards are in place to protect subjects' privacy and to maintain the confidentiality of data, when appropriate, as required by 45 CFR 46.111(a)(7).

   *NOTE: Only research with children (Subpart D) involving educational tests or the observation of public behavior when the investigator(s) does not participate in the activities being observed can be exempt.

3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least ONE of the following criteria is met

i. information obtained is recorded by the investigator in such a manner that the identity of human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
ii. any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation; or
iii. information obtained is recorded by the investigator in such a manner that the identity of human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited review to ensure that safeguards are in place to protect subjects' privacy and to maintain the confidentiality of data, when appropriate, as required by 45 CFR 46.111(a)(7).

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least ONE of the following criteria is met:
   i. The identifiable private information or identifiable biospecimens are publically available;
   ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; the investigator does not contact the subjects; and the investigator will not re-identify subjects;
   iii. The research involves only data collection and analysis involving the investigator's use of identifiable information when that use is regulated under 45 CFR parts 160 and 164 (HIPAA); or
   iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information recorded for non-research activities; if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with various federal privacy laws.

   NOTE: The information or biospecimens don't have to exist at the time of the exemption determination; they can be collected into the future.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, improve, or otherwise examine public benefit or service programs including:
   i. procedures for obtaining benefits or services under those programs;
   ii. possible changes in or alternatives to those programs or procedures; or
   iii. possible changes in methods or levels of payment for benefits or services under those programs

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NOTE: Each agency must maintain a public list of these projects, to be published prior to conducting the research.

6. Taste and food quality evaluation and consumer acceptance studies
    i. if wholesome foods without additives are consumed
    ii. 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

7. Storage and maintenance for secondary research:
    i. Storage or maintenance for secondary research for which broad consent is required.
    ii. Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary use if an IRB conducts a limited IRB review and makes the determinations required by 45 CFR 46.111(a)(8).

8. Use of information or biospecimens in secondary research:
    i. Secondary research for which broad consent is required
    ii. Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if ALL of the following criteria are met:
        1. Broad consent for the storage, maintenance, and secondary research use was obtained in accordance with the requirements of the alternative required elements for broad consent as defined per 45 CFR 46.116(a)(1) through (4), (a)(6), and (d);
        2. Consent documented or has waiver of documentation per 45 CFR 46.117;
        3. IRB conducts a limited IRB review under 45 CFR 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent;
        4. The investigator does not include returning individual research results to subjects as part of the study plan.

B. The following categories of clinical investigations subject to FDA regulations and oversight are exempt from the requirements for IRB review:
    1. Any investigation which commenced before July 27, 1981 and was subject to requirements for IRB review under FDA regulations before that date, provided that the investigation remains subject to review of an IRB which meets the FDA requirements in effect before July 27, 1981.
    2. Any investigation commenced before July 27, 1981 and was not otherwise subject to requirements for IRB review under Food and Drug Administration regulations before that date.

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3. Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review.
4. Taste and food quality evaluations and consumer acceptance studies, if wholesome foods without additives are consumed or 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.

C. 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 46.104.
D. https://www.irbnet.org/ - Orlando Health On-line Application
E. IRBNet Template Library

V. Attachments:

A. None.