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

Title:	***Expedited Review***	Policy #:	**0330-1003**
		Replaced #:	ORMC IRB #6000-203 MDACCO IRB #1000-0001L
Page 1 of 4		Issued By:	Orlando Health Institutional Review Board (IRB)
Issue Date:	**7/19/95**	Approved By:	Philip Giordano, MD Institutional Official SIGNATURE ON FILE
Revision Dates:	1/1/01, 3/20/02, 11/12/07, 9/10/12, 8/29/16, 6/3/19, 04/12/22		

I. PURPOSE:

To maintain compliance with ethical and legal standards when reviewing submissions through an Expedited Review Procedure.

II. DEFINITIONS:

When used in this policy these terms have the following meanings

A. Expedited Review Procedure: consists of a review of research involving human subjects by the IRB Chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 21 CFR 56.110 and 45 CFR 46.110.

B. Minimal Risk: minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

III. POLICY:

Any study that provides minimal risk for research subjects must be approved by the IRB prior to the start of any research activity.

IV. PROCEDURE:

A. Applicability:

1. Expedited Review Procedures may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. It can only be disapproved after review at a convened meeting with a quorum present.
2. Research activities may be reviewed by the IRB through an Expedited Review Procedure if the research activities:
   a. present no more than minimal risk to human subjects, and
   b. involve only procedures listed in one or more of the following categories may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on the following list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
   c. involve minor changes which do not increase risk to study participants in previously approved research that has active IRB approval.
3. The convened board will be notified of all expedited review approval actions at the next Full Board meeting.
4. The Research Categories listed below apply regardless of the age of subjects, except as noted.
5. An Expedited Review Procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the

subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

6. An Expedited Review Procedure may not be used for classified research involving human subjects.
7. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.

B. Research Categories (categories (1) through (7) pertain to both initial and continuing IRB review):

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   b. Research on medical devices for which:
      i. (21 CFR Part 812) is not required, or
      ii. the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   a. from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   b. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week. Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted" 45 CFR 46.402(a).
3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:
   a. hair and nail clippings in a non-disfiguring manner;
   b. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
   c. permanent teeth if routine care indicates a need for extraction;
   d. excreta and external secretions (including sweat);
   e. uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
   f. placenta removed at delivery;
   g. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
   h. supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;

i. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
j. sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:
   a. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
   b. weighing or testing sensory acuity;
   c. magnetic resonance imaging;
   d. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroetinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
   e. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
8. Continuing review of research previously approved by the convened IRB is as follows:
   a. Where:
      i. the research is permanently closed to the enrollment of new subjects,
      ii. all subjects have completed all research-related interventions; and
      iii. the research remains active only for long-term follow-up of subjects; or
   b. Where no subjects have been enrolled and no additional risks have been identified; or
   c. Where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories (2) through (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

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V. REFERENCES:

A. Institutional Review Board Management and Function,, Robert Amdur, M. D., and Elizabeth Bankert, MA, Jones and Bartlett Publishers, 2006.
A. Code of Federal Regulations: 21 CFR 56.110.
B. Code of Federal Regulations: 45 CFR 46.110.
C. https://www.irbnet.org/ - Orlando Health IRB On-line Application

VI. Attachments:

A. None.