

I. Policy

It is the policy of the Department of Health (DOH) Institutional Review Board (IRB) that all human subjects research activities under its jurisdiction be reviewed to determine whether the research meets one or more of the expedited categories described in the Federal regulations.

II. Authority

- A. Chapter 381.86, Florida Statutes, Institutional Review Board

III. Supportive Data

- A. 45 CFR 46
- B. 21 CFR 50, 56, 312, and 600
- C. DOH IRB Policy, "IRB Member Conflicts of Interest"

IV. Definitions

- A. **Children:** According to Federal regulations children are "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." According to Florida State law, the legal age of consent is 18 years of age.
- B. **Minimal Risk:** 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.
- C. **Minor Amendment:** A proposed change in research related activities that does not materially affect an assessment of the risks and benefits of the study and does not substantially change the specific aims or design of the study.

V. Procedures

- A. **Expedited Eligibility**
 - 1. Federal regulations (45 CFR 46.110, 21 CFR 56.110 and 38 CFR 16.110) allow the IRB to review certain applications on an expedited basis if they meet specified criteria. All expedited protocols are reviewed by the IRB at least once per year. Additionally, the standard requirements for informed consent (or its waiver, alteration, or exception) apply to all IRB approvals regardless of the type of review - expedited or full Committee - utilized by the IRB.

2. An expedited review consists of a review of research involving human subjects by the appropriate IRB Committee Chairperson or his/her designee. In reviewing the research, the reviewer may exercise all of the authorities of the full Committee except that the reviewer may not disapprove the research. Disapproval is only determined by the full IRB Committee. Additionally, the reviewer may refer the application to the full Committee for a standard review as warranted.
3. General Restrictions on Expedited Review
 - a. Expedited review procedures may not be used for research involving prisoners.
 - b. Expedited review procedures may not be used for classified research.
 - c. Expedited review procedures 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.
4. Appropriate Use of Expedited Review Procedures for Initial Review of Research

The IRB may use an expedited procedure to conduct initial review of research provided all research activities do not fall under any of the general restrictions, present no more than minimal risk to human subjects, and involve procedures listed in one or more of the following categories only:

- a. 45 CFR 46.110(F)(1)/21 CFR 56.110(F)(1): Clinical studies of drugs and medical devices only when condition (1) or (2) below is met.
 - (1) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. NOTE: Research on marketed drugs that significantly increase the risks or decrease the acceptability of the risks associated with the use of the product is not eligible for expedited review.
 - (2) Research on medical devices for which;
 - (a) An investigational device exemption application (21 CFR Part 812) is not required; or

- (b) The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- b. 45 CFR 46.110(F)(2)/21 CFR 56.110(F)(2): Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
- (1) 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
 - (2) From other adults and children, when 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 are considered. For these participants, 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 federal 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" (See 45 CFR 46.402(a)).
- c. 45 CFR 46.110(F)(3)/21 CFR 56.110(F)(3): Prospective collection of biological specimens for research purposes by noninvasive means. For example:
- (1) Hair and nail clippings in a non-disfiguring manner;
 - (2) Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
 - (3) Permanent teeth if routine patient care indicates a need for extraction;
 - (4) Excreta and external secretions (including sweat);
 - (5) 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;
 - (6) Placenta removed at delivery;
 - (7) Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

- (8) 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;
 - (9) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; and/or
 - (10) Sputum collected after saline mist nebulization.
- d. 45 CFR 46.110(F)(4)/21 CFR 56.110(F)(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 include:
- (1) 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;
 - (2) Weighing or testing sensory acuity;
 - (3) Magnetic resonance imaging;
 - (4) Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
 - (5) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual;
 - (6) 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 requirement that it obtain IRB approval (See IRB Policy concerning Exempt Research; this listing refers only to research that is not exempt);

- (7) Collection of data from voice, video, digital, or image recordings made for research purposes; and/or
 - (8) Research on individual or 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 requirement that it obtain IRB approval (See IRB Policy concerning Exempt Research; this listing refers only to research that is not exempt.).
- e. 45 CFR 46.110(F)(5)/21 CFR 56.110(F)(5): Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). NOTE: Some research in this category may meet exemption under 45 CFR 46.101(b)(4); this listing refers only to research that is not exempt (See IRB Policy concerning Exempt Research).
 - f. 45 CFR 46.110(F)(6)/21 CFR 56.110(F)(6): Collection of data from voice, video, digital, or image recordings made for research purposes.
 - g. 45 CFR 46.110(F)(7)/21 CFR 56.110(F)(7): Research on individual or 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 meet exemption under 45 CFR 46.101(b)(2); this listing refers only to research that is not exempt (See IRB Policy concerning Exempt Research).
5. Appropriate Use of Expedited Review Procedures for Continuing Review of Research: The IRB may use an expedited procedure to conduct continuing review of research provided all research activities do not fall under any of the general restrictions, present no more than minimal risk to human subjects, and involve procedures listed in one or more of the following categories:
- a. Research procedures that meet the criteria for initial review of research by an expedited procedure.

- b. 45 CFR 46.110(F)(8)/21 CFR 56.110(F)(8): Continuing review of research previously approved by a full IRB Committee as follows:
 - (1) Where the research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; or
 - (2) Where no subjects have ever been enrolled (at any site, if multi-center trial) and no additional risks have been identified; or
 - (3) Where the remaining research activities are limited to data analysis
- c. 45 CFR 46.110(F)(9) and 21 CFR 56.110(F)(9): Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories (4)(b) through (4)(g) above do not apply but the IRB has determined and documented at a convened full IRB Committee meeting that the research involves no greater than minimal risk and no additional risks have been identified.

6. **Appropriate Use of Expedited Review Procedures for Review of Modifications to Previously Approved Research:** The IRB may use an expedited procedure to conduct review of modifications to previously approved research provided the changes represent a minor amendment.

B. Required Review

- 1. The IRB Chair or one or more experienced Reviewers designated by the Chair is required to review and approve research meeting expedited criteria. An experienced IRB member means a voting member or alternate voting member who has served on an IRB for at least one year, has received training relative to the expedited review categories, and possesses the scientific expertise needed to review the proposed research. However, the Reviewer may request a second reviewer or refer the research to the full IRB Committee for further determination.
- 2. The Reviewer may also request that IRB staff identify additional expertise for issues which require expertise beyond, or in addition to, that available on the Committee.
- 3. Research materials submitted include sufficient detail for the Reviewer to determine the study meets criteria 45 CFR 46.111, 21 CFR 56.111 and 38 CFR 16.111, if applicable for approval:
 - a. Risks to subjects are minimized by using procedures which are

consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;

- b. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the Reviewer should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The Reviewer should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility;
- c. Selection of subjects is equitable considering the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations and the potential need for additional protections, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons;
- d. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by the Federal and State regulations and Institutional policies and procedures including the IRB;
- e. Informed Consent will be appropriately documented, in accordance with, and to the extent required by the Federal regulations and Institutional policies and procedures including the IRB;
- f. When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects;
- g. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data; and
- h. There are adequate provisions to protect the rights and welfare of vulnerable populations from coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. The Reviewer must determine that additional safeguards have been included in the study to protect the rights and welfare of these subjects.

4. Materials to be Reviewed. The following materials are provided to the reviewer and the Chair for expedited review applications:
 - a. A completed IRB application with a signature page and conflict of interest statement;
 - b. Full investigator's or sponsor's protocol;
 - c. Proposed informed consent document(s) and/or script as appropriate;
 - d. Copies of surveys, questionnaires, or videotapes;
 - e. Copies of letters of assurance or cooperation with research sites;
 - f. Relevant grant applications;
 - g. Investigator's brochure (if one exists);
 - h. Advertising intended to be seen or heard by potential subjects, including email solicitations.
5. The Reviewer determines a review interval for the research as appropriate to the degree of risk, but not greater than one year from the last date of IRB approval (See IRB Policy "Continuing Review"). The regulations make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval. Therefore, continuing review and re-approval of the research occurs on or before the date when IRB approval expires. OHRP recognizes the logistical advantages of keeping the IRB approval period constant from year to year throughout the life of each project. When continuing review occurs annually and the IRB performs continuing review within 30 days before the IRB approval period expires, the IRB may retain the anniversary date as the date by which the continuing review must occur.
6. Standard requirements for informed consent or its waiver or alteration apply to all studies meeting criteria for approval under the expedited criteria.
7. Information obtained during the review of an amendment, adverse event, sponsor notification, or other pertinent information may possibly disqualify the study from being approved under an expedited status. The study is forwarded to the full IRB Committee for determination.
8. The full Committee is advised of research proposals/activities that have been approved under the expedited review procedure. As a means of notifying the Committee and allowing for comments regarding a review conducted utilizing expedited review procedures, a summary of the application is documented in the agenda provided to the full Committee


for the next possible convened meeting. This documentation includes a citation to the specific permissible category or categories justifying the expedited review.

9. All research activities approved by expedited review are conducted in accordance with all applicable institutional policies and procedures.
10. Research cannot be disapproved by the Chair or his/her designee; it is forwarded to the full Committee for review.
11. See IRB Policy on Waiver of Informed Consent.

VI. History Notes

This is a new policy. The Office of Statewide Research, Ethics and Human Research Protections Program are responsible for this policy.

VII. Signature Block with Effective Date



John O. Agwunobi, M.D., M.B.A., M.P.H.
Secretary, Department of Health

06/29/05
Date