

I. Policy

It is the policy of the Department of Health (DOH) Institutional Review Board (IRB) to have sole authority to determine whether an activity meets the definition of "Human Subject Research". When activities are conducted that might represent "Human Subject Research," the activities must be submitted to the IRB for a determination.

II. Authority

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

III. Supportive Data

- A. 45 CFR 46
- B. 21 CFR 50 and 56
- C. OHRP Guidance on Research Involving Coded Private Information or Biological Specimens, August 10, 2004

IV. Definitions

- A. **Clinical Investigation:** Any experiment that involves a test article and one or more human subjects and that is subject to the Food and Drug Administration (FDA) regulations.
1. **Test article:** Any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to FDA regulation.
- B. **Coded Information:** For the purposes of this policy, identifying information that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.
- C. **Human Subject:** A living individual about whom an Investigator (whether professional or student) conducting research obtains either data (of any kind) through intervention or interaction with the individual or identifiable private information (of any kind) even in the absence of intervention or interaction or an individual who is or becomes a participant in research, either as a recipient of the test article or as a control.
1. **Intervention:** Includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subjects' environment that are performed for research purposes.

2. Interaction: Includes communication or interpersonal contact between an Investigator or his/her research staff and the research participant or their private identifiable information.
 3. Private Information: Includes information about behavior that occurs in a setting in which an individual can reasonably expect that no observation or recording is taking place. It includes information, which has been provided for specific purposes by an individual, and the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable in order to be considered information to constitute research involving human participants. This may include identifiable private information obtained from a primary participant about a third party.
- D. Research: Any systematic investigation (including research development, testing and evaluation) designed to develop or contribute to generalizable knowledge.
- E. Human Subject Research: Any research that involves humans and any clinical investigation.
- F. Non-Human Subject Research: Any activity determined by the IRB to not represent "Human Subject Research."

V. Procedures

- A. "Human Subject Research"/"Non-Human Subject Research" determinations
1. The IRB has sole authority to determine whether an activity represents "Human Subject Research."
 2. Investigators do not have the authority to make an independent determination and must submit a "Request for Determination of Non-Human Subject Research" to the IRB.
 3. An Investigator may request a determination that an activity is "Non-Human Subject Research," but the final determination will be made by the Assistant Director, Office of Statewide Research, or the IRB Administrator.
 4. The IRB will make a determination whether an activity is "Human Subject Research" by considering whether the activity either:
 - a. Meets the regulatory definitions of "research" that involves "humans subjects," or
 - b. Meets the regulatory definition of "clinical investigation."
- B. Non-Research

1. Activities are not research if they do not involve a systematic approach involving a predetermined method for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory.
 - a. Examples of systematic investigations include, but are not limited to:
 - (1) Observational studies;
 - (2) Interviews (including those that are open-ended) or survey studies;
 - (3) Group comparison studies;
 - (4) Test development; or
 - (5) Program evaluation.
 - b. Examples of activities that would not normally be considered systematic investigations include, but are not limited to:
 - (1) Training activities (e.g., human subjects being trained to perform a certain technique or therapy such as art therapy, psychoanalysis, oral history techniques); and
 - (2) Classroom exercises involving human participants or human participant data where the objective of the activity is to teach proficiency in performing certain tasks or using specific tools or methods.
 - (3) Surveillance specified in state or federal statute or regulation
2. Activities are not research if they do not contribute to generalizable knowledge or if the results (or conclusions) of an activity are not intended to be extended beyond a single individual or an internal program (e.g., publications or presentations).
 - a. Examples of activities that are typically not generalizable include:
 - (1) Biographies and service or program evaluations, unless they can be generalized to other individuals;
 - (2) Services, program evaluations or concepts where it is not the intention to share them beyond the Department of Health;

- (3) Classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices; and
 - (4) Quality Assurance activities designed to continuously improve the quality or performance of a division, bureau, office, county health department or program where it is not the intention to share them beyond the Department of Health.
3. Thesis or dissertation projects conducted to meet the requirements of a graduate degree are usually considered generalizable and therefore, require IRB review and approval.

C. Non-Human Subject

- 1. Activities do not involve humans as participants if they do not involve the process of obtaining specimens or data through intervention or interaction with individual participants or identifiable private information.
- 2. Information is considered "not identifiable" if it includes none of the following:
 - (a) Name;
 - (b) Any geographic subdivisions smaller than a state, including street address, city, country, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of a ZIP code;
 - (c) All elements of dates (except year) directly related to an individual (e.g., date of birth, admission);
 - (d) Telephone numbers;
 - (f) Fax numbers;
 - (g) Electronic mail addresses;
 - (h) Social security numbers;
 - (i) Medical record numbers;
 - (j) Health plan beneficiary numbers;
 - (k) Account numbers;
 - (l) Certificate/license numbers;

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- (m) Vehicle identifiers and serial numbers, including license plate numbers;
 - (n) Device identifiers and serial numbers;
 - (n) Web Universal Resource Locators (URLs);
 - (o) Internet Protocol (IP) address numbers;
 - (p) Biometric identifiers, including finger and voiceprints;
 - (q) Full-face photographic images and any comparable images; and
 - (r) Any other unique identifying number, characteristic, or code.
3. Specimens/data that are received by the Investigator as de-identified stripped of all HIPAA identifiers as noted above.
4. When the Investigator receives the private information or specimens with no code or link that would allow an Investigator to establish identity, this would not involve human subjects. For example, a publicly available, unidentifiable, non-linked cell line qualifies as not involving human subjects.
5. The Investigator may receive coded private information or specimens and qualify for non-human subject if the following conditions are met:
- a. The code is not derived or related to the HIPAA identifiers that must be stripped from private health information (e.g. patient medical record number and the last 4 digits of individual's Social Security Number);
 - b. The private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and
 - c. The Investigator cannot readily ascertain the identity of the individuals to whom the coded private information or specimens pertain, because:
 - (1) The key to decipher the code is destroyed before the research begins;
 - (2) The Investigator and the holder of the key enter into an agreement prohibiting the release of the key to the Investigator under any circumstances, until the individuals are deceased;

- (3) The private information is received from an IRB-approved repository or data management center that includes written operating procedures that prohibit the release of the key to the Investigator under any circumstances, until the individuals are deceased; or
- (4) There are other legal requirements prohibiting the release of the key to the Investigator until the individuals are deceased.

D. Amendments

Any change that might disqualify the activity from a "Non-Human Subject" or "Non-Research" status must be reported to the IRB for review and verification prior to implementation.

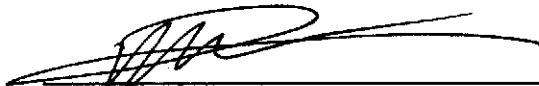
E. Additional Requirements

All "Non-Human Subject Research" is subject to all applicable institutional and IRB policies and procedures.

VI. History Notes

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

VI. Signature Block with Effective Date



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

06/29/05

Date