

**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 exemption categories described in the Federal regulations and complies with the Department of Health's ethical standards.

**II. Authority**

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

**III. Supportive Data**

- A. 45 CFR 46.101(b)
- B. 45 CFR 46.401(b)
- C. IRB Policy, "Non-Human Subject/Non-Research Determination"
- D. OHRP Compliance Activities: Common Findings and Guidance -7/10/2002 Item #30
- E. OHRP Guidance: Coded Private Information - 8/10/2004

**IV. Definitions**

- A. Children: 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 for 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.

**V. Procedures**

- A. Exempt Eligibility
  - 1. Research activities involving human subjects that are exempt from the requirement that they receive IRB full or expedited review are identified in 45 CFR 46.101(b)(1)-(6), 45 CFR 406.301(a), 45 CFR 46.401(b) and 21 CFR 6.104(d). The IRB may not create new categories of this exempt research. Only the Department of Health may determine which activities qualify for an exempt review. Investigators do not have the authority to make an independent determination that research involving human subjects is exempt and must contact the DOH Ethics and Human Protections Program concerning the status of proposed research or changes in ongoing research.

2. An Investigator may request a particular category of exemption, but the final determination of applicability will be made by the DOH. A final determination for exemption may be made by the Assistant Director, Ethics and Human Research Protections or the IRB Administrator, in consultation with the IRB Chair or Co-Chair.
3. Research may be granted exempt status by the IRB if all research activities involve procedures listed in one or more of the specific categories under 45 CFR 46.101(b). NOTE: These categories do not apply to research involving prisoners, fetuses, pregnant women, human in vitro fertilization, or to research involving deception. Also, categories 1-5 do not apply to FDA regulated research. Categories at 45 CFR 46.101(b) permitting exemption are:
  - a. 45 CFR 46.101(b)(1): Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
    - (1) Research on regular and special education instructional strategies; or
    - (2) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
  - b. 45 CFR 46.101(b)(2): Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
    - (1) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
    - (2) Any disclosure of the human subjects' responses outside of 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.
    - (3) If the research involves children as participants, the research must be limited to educational tests (cognitive, diagnostic, aptitude, achievement), and observation of public behavior when the investigator(s) do not participate in the activities being observed. Research that uses survey procedures, interview procedures, or observation of public behavior when the investigator(s) participate in the activities being observed cannot be granted an exemption.

- c. 45 CFR 46.101(b)(3): Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under 45 CFR 46.101(b)(2) if:
- (1) The human subjects are elected or appointed public officials or candidates for public office; or
  - (2) Federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- d. 45 CFR 46.101(b)(4): Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or the information is recorded by the Investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. To qualify for this exemption, normally data, documents, records, or specimens must have been collected before the research project begins. However, OHRP Guidance (08/10/05) specifies limited conditions whereby a PI may de-identify data prior to the initiation of research that would qualify for exempt review.
- (1) Example: Investigator A wishes to screen blood samples at a rural hospital for incidence of HIV infection. She does not want to draw specimens specifically for this purpose; rather she proposes to use specimens that were drawn for some other purpose but which remain in the hospital laboratory. If Investigator A proposes to use specimens that had been drawn prior to the initiation of her research and are, for some reason, "on the shelf," the protocol may qualify as exempt, assuming the other requirements are met (i.e., the sources are either publicly available or the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects).
  - (2) Under this exemption, an investigator (with proper institutional authorization) may inspect private, identifiable records, but may only record information in a non-identifiable manner. The data must be permanently and completely de-linked at the time of extraction. A code may be used to organize data as it is collected. However, the code may not be a means of re-linking the data set to the original data source.
  - (3) Example: Investigator B wishes to examine court records of involuntary commitments to psychological institutions. If

he uses court records that were on file before the initiation of his research, the protocol may qualify as exempt.

- e. 45 CFR 46.101(b)(5): Research and demonstration projects, which are conducted by or subject to the approval of Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
- (1) Public benefit or service programs; this exemption is for Federally supported projects and is most appropriately invoked with authorization or concurrence by the funding agency. The following criteria must be satisfied to invoke the exemption for research and demonstration projects examining "public benefit or service programs:"
    - (a) The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services under the Older Americans Act);
    - (b) The research or demonstration project must be conducted pursuant to specific Federal statutory authority;
    - (c) There must be no statutory requirements that the project be reviewed by an IRB; or
    - (e) The project must not involve significant physical invasions or intrusions upon the privacy of participants.
  - (2) Procedures for obtaining benefits or services under those programs;
  - (3) Possible changes in or alternatives to those programs or procedures; or
  - (4) Possible changes in methods or levels of payment for benefits or services under those programs.
  - (5) This exemption is for projects conducted by or subject to approval of Federal agencies and requires authorization or concurrence by the funding agency.
- f. 45 CFR 46.101(b)(6) and 21 CFR 56.104(d): Taste and food quality evaluation and consumer acceptance studies;
- (1) If wholesome foods without additives are consumed; or

- (2) 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. Amendments**

1. Any proposed changes to an exempt study within the first year of approval must be submitted to the IRB for review and approval prior to implementation.
2. Any proposed changes to an exempt study occurring after the first year of IRB approval must be submitted to the IRB as a new "Claim of Exemption."
3. Certain changes may disqualify the research from exempt status; therefore, all changes in the research plan must be reported to the IRB for review and approval, prior to implementation.

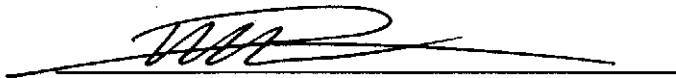
**C. Other Considerations Concerning Exempt Research**

1. All research conducted under exempt review is subject to all applicable DOH institutional and IRB policies and procedures.
2. Exempt research activities are subject to the same subject protections and ethical standards as outlined in *The Belmont Report*.

**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