

I. Policy

It is the policy of the Department of Health (DOH) Institutional Review Board (IRB) to grant a waiver from informed consent for research or an exception from informed consent for qualifying emergency research in congruence with the Federal regulations and IRB policies and procedures.

II. Authority

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

III. Supportive Data

- A. 45 CFR 46
- B. 45 CFR 46.116
- C. 21 CFR 50 and 56
- D. 21 CFR 50.24
- E. OHRP Guidance Document; Emergency Research Informed Consent Requirements (OPRR 96-01)
- F. 45 CFR 46 Waiver Of Informed Consent Requirements in Certain Emergency Research (Federal Register, Vol. 61, No. 192, pp. 51531-51533, October 2, 1996)
- G. FDA Guidance for Institutional Review Boards and Clinical Investigators, 1998 Update.
- H. DOH IRB Policy, "Legally Effective and Prospectively Obtained Informed Consent"
- I. DOH IRB Policy, "Emergency Use of FDA Regulated Products"

IV. Definitions

- A. **Legally Authorized Representative:** A court appointed guardian or conservator, a Durable Power of Attorney for Health Care (DPAHC) or a Health Care Decision Maker.
- 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. An example of minimal risk is the risk of drawing a small amount of blood from a healthy individual for research purposes (because the risk of doing so is no greater than the risk of doing so as part of a routine physical examination).

- C. Short Form Consent: A written informed consent document that summarizes the required elements of informed consent to be presented orally to the participant or his or her legally authorized representative.

VI. Procedures

A. Presumption Against Waivers of Informed Consent

Generally, the IRB must assure that provisions are made to obtain legally effective informed consent prospectively from each research participant or the participant's legally authorized representative. There are only four circumstances under which the regulations give the IRB authority to waive the required informed consent.

B. Option One: Waiver for Research Activities Designed to Study Certain Aspects of Public Benefit or Service Programs

1. The IRB may approve a consent procedure, which does not include, or which alters, some or all of the required elements of informed consent (See IRB Policy, "Legally Effective and Prospectively Obtained Informed Consent"), or waive the requirement to obtain informed consent entirely provided the research is not subject to the FDA regulations and the IRB finds and documents that:

- a. The research or demonstration project is to be conducted by or subject to the approval of State or local government officials and is designed to study, evaluate, or otherwise examine:

- (1) Public benefit or service programs;
- (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; and

- b. The research could not practicably be carried out without the waiver or alteration.

C. Option Two: Waiver for Minimal Risk Studies

Additionally, the IRB may approve a consent procedure, which does not include, or which alters, some or all of the required elements of informed consent (See IRB Policy, "Legally Effective and Prospectively Obtained Informed Consent"), or waive the requirements to obtain informed consent entirely provided the research is not subject to the FDA regulations and the IRB finds and documents that:

1. The research involves no more than minimal risk to the participant; and
2. The waiver or alteration will not adversely affect the rights and welfare of the participants; and
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the participants will be provided with additional pertinent information after participation.
5. Or, the IRB may waive the documentation of consent for some or all of the participants if the research involves no more than minimal risk and written consent would normally not be required outside of the research context.

D. Option Three: Exception from Informed Consent Requirements for Emergency Research Subject to FDA Regulation

NOTE: Do NOT confuse with Emergency Use of FDA Regulated Products – See IRB Policy, “Emergency Use of FDA Regulated Products.”

The IRB may review and approve a clinical investigation without requiring informed consent of all research subjects be obtained if the IRB (with the concurrence of a licensed physician who is a member of or consultant to the IRB and who is not otherwise participating in the clinical investigation) finds and documents each of the following:

1. The target population for the research is in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.
2. Obtaining informed consent is not feasible because:
 - a. The subjects will not be able to give their informed consent as a result of their medical condition;
 - b. The intervention under investigation must be administered before consent from the subjects' legally authorized representatives is feasible; and
 - c. There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.
3. Participation in the research holds out the prospect of direct benefit to the subjects because:

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- a. The subjects are facing a life-threatening situation that necessitates intervention;
 - b. Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects; and
 - c. The risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of the proposed intervention or activity.
4. The clinical investigation could not practicably be carried out without the waiver.
 5. The proposed investigational plan defines the length of the potential therapeutic window based on scientific evidence, and the Investigator has committed to attempting to contact a legally authorized representative for each subject within that window of time and, if feasible, to asking the legally authorized representative contacted for consent within that window rather than proceeding without consent. The Investigator must agree to summarize efforts made to contact legally authorized representatives and make this information available to the IRB at the time of continuing review.
 6. The IRB has reviewed and approved informed consent procedures and an informed consent document consistent with Federal regulations and IRB policies and procedures. The informed consent procedures and the informed consent document are to be used with subjects or their legally authorized representatives in situations where use of such procedures and documents is feasible.
 7. Additional protections of the rights and welfare of the subjects will be provided, including, at least:
 - a. Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn;
 - b. Prior to the initiation of the clinical investigation, public disclosure to the communities in which the clinical investigation will be conducted and from which the subjects will be drawn of plans for the investigation and its risks and expected benefits;
 - c. At the completion of the clinical investigation there are plans for Public disclosure of sufficient information to apprise the community and researchers of the study. The information must

- include the demographic characteristics of the research population and results of the clinical investigation.
- d. Establishment of an independent data and safety monitoring committee to exercise oversight of the clinical investigation; and
 - e. If obtaining informed consent is not feasible and a legally authorized representative is not reasonably available, the Investigator must commit to attempting to contact within the therapeutic window, the subject's family member who is not a legally authorized representative, and asking whether he/she objects to the subject's participation in the clinical investigation. The Investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.
8. Procedures must be in place to inform, at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, of the subject's inclusion in the clinical investigation, the details of the investigation and other information contained in the informed consent document, specifically that the he/she may discontinue the subject's participation at any time without penalty or loss of benefits of which the subject is otherwise entitled.
 9. If a legally authorized representative or family member is told about the clinical investigation and the subject's condition improves, the subject is also to be informed as soon as feasible.
 10. If a subject is entered into a clinical investigation with waived consent and the subject dies before a legally authorized representative or family member can be contacted, information about the clinical investigation is to be provided to the subject's legally authorized representative or family member, if feasible.
 11. All clinical investigation records, including regulatory files, must be maintained for at least three years after the completion of the clinical investigation and will be accessible for inspection and copying by the regulatory authorities, as applicable.
 12. Clinical investigations that are granted an exception to the informed consent requirement under this section must be performed under a separate investigational new drug application (IND) or investigational device exemption (IDE) that clearly identifies that the clinical investigation may include subjects who are unable to consent. The submission of these clinical investigations to the FDA for a separate IND/IDE is required even if an IND for the same drug product or an IDE for the same device already exists. Applications for this IND/IDE may not be submitted as an amendment to the existing IND/IDE.

13. If the IRB determines it cannot approve a request for exception from informed consent requirements in emergency research because the clinical investigation does not meet the criteria according to Federal regulations, IRB policies and procedures, or other relevant ethical concerns, the IRB must document its findings and provide these findings promptly in writing to the clinical investigator who will forward to the sponsor of the clinical investigation.

E. Option Four: Emergency Research Not-Subject to FDA Regulation

The IRB Committee review finds:

1. The research does not meet FDA regulations in 21 CFR 50; and
2. Items D 1-7 as stated in option three above are met.

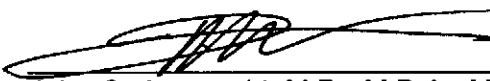
F. No Deferred Consent or Un-Approved Waivers of Informed Consent

Informed consent procedures, which provide for other than legally authorized and prospectively obtained consent, fail to constitute informed consent under Federal regulations for the protection of human subjects in research. Therefore, waiving informed consent using a method other than those described in this policy is a violation of IRB policy and Federal regulations and is subject to reporting to the appropriate Federal, State, and Institutional officials.

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