ORLANDO HEALTH®

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Type of Policy:	***PROTECTION OF HUMAN RESEARCH PARTICIPANTS***	Category:	**Institutional Review Board (IRB)**

Title:	***Informed Consent Process***	Policy #:	**0330-1002**
		Replaced #:	ORMC IRB# 6000-304 MDACCO IRB# 1000-0005
Page 1 of 10		Issued By:	Orlando Health Institutional Review Board (IRB)
Issue Date:	**7/19/95**	Approved By:	Mildred Beam, Esq. Institutional Official **SIGNATURE ON FILE**
Revision Dates:	1/1/01, 3/20/02, 11/12/07, 2/25/08, 6/18/12, 9/26/13, 8/14/14 4/14/15, 6/1/15, 5/16/16, 8/16/17		

I. PURPOSE:

To maintain ethical and legal standards when administering and reviewing the informed consent process throughout their participation in the research.

II. DEFINITIONS:

When used in this policy these terms have the following meanings:

A. Informed Consent: A process of information exchange that may include, in addition to reading and signing the informed consent document, subject recruitment materials, verbal instructions, question/answer sessions and measures of subject understanding.

B. Informed Consent Document or Form (ICF): A written summary of the information that is provided to the prospective subject. The prospective subject's signature with date and time provides documentation of agreement to participate in research, but is only one part of the consent process.

C. Assent: A child's affirmative agreement to participate in research.

D. Family Member: Means any one of the following legally competent persons: Spouse, parents, children (including adopted children), brothers, sisters, and spouses of brothers and sisters; and any individual related by blood or affinity whose close association with the subject is the equivalent of a family relationship.

E. 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.

F. Legally Acceptable Representative (LAR): Legally Acceptable Representative means an individual or judicial or other body authorized under Florida law to consent on behalf of a prospective subject to the subject's participation in the research.

G. Impartial Witness: A person, who is independent of the research, who cannot be unfairly influenced by people involved with the research, who attends the entire informed consent process if the subject or the subject's Legally Acceptable Representative (LAR) cannot read, and who reads the informed consent form and any other written information supplied to the subject. This person may be a family member or a friend, but not someone on the study staff.

H. Witness for a secure electronically transmitted consent form: A person on the investigator's team who is witnessing the consent process remotely and is not affirming or confirming the prospective subject's knowledge of the procedure/treatment.

I. Emergency Research: is defined as a human subject in a life threatening situation, when available treatment is unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-control investigations, is necessary to determine the safety and effectiveness of particular intervention.

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III. POLICY:

Informed Consent is a fundamental and thoughtful process to ensure respect for human subjects and to ensure that their initial and continuing participation in studies is an informed, voluntary act. With few exceptions:

A. No study may involve a human participant unless the human participant is fully informed of the basic elements of the study and the Investigator has obtained the legally effective, informed voluntary consent of the subject or the subject's LAR PRIOR to the subject's participation.

B. A prospective subject for a research study shall be given the information (both verbal and written) to allow him/her to make a voluntary, informed decision, without coercion, to participate in the research study.

C. The prospective subject must confirm that his/her questions have been answered about the purpose and requirements of the study, record the date, and sign the ICF before participating in the research study.

D. Research subjects are required to be re-consented at the discretion of the IRB.

IV. PROCEDURE:

Prior to any research related test (screening)

Only the Investigator and/or sub-Investigator (as approved on the Form FDA 1572 or IRB Application or where there is no Form FDA 1572 on the IRB approved form) may obtain consent. Consent/Assent shall be obtained only under circumstances that provide the prospective subject or the LAR sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. It is critical that the person obtaining consent has a discussion with the prospective subject and then confirm in his/her own mind that the prospective subject understands. The Orlando Health IRBs comply with Florida statute 766.103 that delegating duty (Informed Consent) to those not qualified by training, experience, or professional licensure to perform them are grounds for disciplinary action. In certain situations, on a case by case basis, other study staff may be approved by the IRB chair to consent prospective subjects. These staff members must be deemed to have the knowledge and expertise to support this decision. The consent is the agreement between the researcher and the subject.

A. The Investigator is responsible for obtaining Informed Consent from each prospective subject before that person participates in the research.

B. The Investigator and/or designee may discuss the availability of research studies and the possibility of entry into a study with a prospective subject at the request of that person or treating physician.

C. The Informed Consent process consists of two components: verbal explanation and written document. The written document must be the most current version with the IRB approval stamp. The information must be presented to the subject or LAR in a language understandable to the subject or representative. No Informed Consent, whether oral or written, may include any exculpatory language through which the subject or the LAR is made to waive or appear to waive

any of the subject's legal rights, or releases or appears to release the Investigator, the sponsor, the institution or its agents from liability for negligence. All Informed Consents must comply with current requirements of Florida and Federal Law and Orlando Health, Inc. policies and procedures. Under certain circumstances where Federal Law and the IRB allow for waiver of Informed Consent, all data collected must be de-identified as defined in the HIPAA Guidelines and in Orlando Health, Inc. Policy #8462.

A. Telephone and Secure Electronic Consent Process:
   1. In non-emergency situations, the consent form can be sent by a secure electronic device (for example, fax) to the LAR. The LAR will sign and date the consent form and return the signed consent form to the person obtaining consent by a secure electronic device.
   2. The person obtaining consent will obtain the signatures of two licensed witnesses for all telephone consents (i.e., two RNs, or, RN and physician). Document the name of the LAR giving consent, the name of the study, the name of the person obtaining consent, the time and the date.

B. The Informed Consent process involves:
   1. Giving a subject adequate information about the research.
   2. Asking open-ended questions to determine if the subject can verbalize what the research is for and what is required of him/her in the study. Open ended-questions allow the prospective subject to give full answers rather than yes or no. Examples of open-ended questions:
      a. "Describe in your own words what you think this study (trial) involves."
      b. "What are the possible benefits and risks to you?"
      c. "What are the alternatives to participating in this study?"
   3. Providing adequate opportunity for the prospective subject to consider all options.
   4. Obtaining the prospective subject's voluntary agreement to participate.
   5. Continuing to provide information as the subject or situation requires.

C. The person obtaining consent will discuss details about the study in a clear and non-technical manner.

D. The discussion must include:
   1. Purpose of the study
   2. Procedures to be followed
   3. Aspects of the research that are experimental
   4. Subject responsibilities
   5. Risks and discomforts
   6. Alternative treatments
   7. Potential benefits
   8. Cost and compensation

9. Issues related to confidentiality
10. Voluntary participation and withdrawal at any time

E. The person obtaining consent will answer questions related to the study and provide the prospective subject with a copy of the signed ICF.

F. Unless otherwise approved by the IRB, the full ICF must be consistent with the IRB approved consent template. An exception is given for the short form and its accompanying written summary. See section on "Use of Short Forms".

G. The person obtaining consent must provide adequate time for the prospective subject to review the ICF, consider all options, discuss the study with significant others, ask questions, and make an informed decision.
Adequate time must reflect the complexity and risk involved in the study.

H. If the prospective subject voluntarily agrees to participate in the research study, the ICF must be signed and dated by the subject and/or LAR, the person obtaining consent, and one impartial witness (if required), unless otherwise approved by the IRB.

I. Completion of the Informed Consent Form:
1. All blanks must be completed in blue or black ink.
2. The prospective subject or LAR must personally sign and date,
3. Unless otherwise approved by the IRB, the person obtaining consent must personally sign and date the ICF in the designated Signature section on the same day the prospective subject signs it.
4. If an error is made in signing the ICF, the person making the error must mark through the error with a single line, provide their initials, date the error, and then write the correct information beside the error.
5. For research studies involving medical procedures, if the ICF is signed on the same day that the subject's participation in the study begins, the person obtaining consent will document clearly in the subject's record that the consent was obtained prior to participation in the research.
6. English speaking individuals who cannot read or individuals with disabilities (that prevent the personal reading of the document) may have the document read to them and "make their mark." However, these individuals are considered vulnerable to coercion and undue influence. The person obtaining consent may contact the local IRB chairman or manager for guidance in conducting an appropriate informed consent process. An impartial witness should witness the entire consent process and sign the ICF. Witnessing of consents is witnessing the consent process and signature and is an attestation by the witness of the subject's apparent understanding.

J. Basic Elements of Informed Consent:
1. A statement that the study involves research

2. An explanation of the purposes of the research
3. The expected duration of the subject's participation
4. A description of the procedures to be followed
5. Identification of any procedures which are experimental
6. A description of any reasonably foreseeable risks or discomforts to the subject
7. A description of any benefits to the subject or to others which may reasonably be expected from the research
8. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
9. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
10. For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
11. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
12. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled

B. Additional Elements of Informed Consent:

2. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
3. Anticipated circumstances under which the subject's participation may be terminated by the Investigator without regard to the subject's consent
4. Any additional costs to the subject that may result from participation in the research
5. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
6. A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
7. The approximate number of subjects involved in the study

C. HIPAA Authorization for Research

2. The Orlando Health IRBs do not review and approve stand-alone HIPAA Authorization for Research documents.
3. However, when the HIPAA Authorization for Research has been combined with an informed consent form, it is known as a compound authorization. The Orlando Health IRBs are required to review compound authorizations because IRBs are required to review and approve informed consent documents in accordance with federal regulations. The HIPAA Authorization for Research language must be consistent with Orlando Health's Compliance & Ethics standards.

D. Requirements for permission by parents or guardians and for assent by children can be found in "Children in Research including Unmarried Pregnant Minors, Unmarried Minor Mothers, Married Minors, and Emancipated Minors" Policy #0330-1011.

E. Use of "Short Forms"

2. In general, the IRB does not approve the use of the short form for subjects who do not speak English because the IRB feels that it is imperative for subjects to have a written consent that explains the research and what subjects have agreed to in a language they understand.
3. However, in the situation where translation of the ICF is not provided by the Investigator then the IRB may approve the following:
   a. A short form written consent document stating the required elements of Informed Consent have been presented orally to the subject or their LAR(s).
   b. A written summary of what is to be said to the subject or their LAR(s) is provided and approved by the IRB.
4. When the use of the short form is used, the following is required:
   a. There needs to be an impartial witness (i.e., Orlando Health certified translator) to the oral presentation.
   b. The short form is signed and dated by the subject or the representative(s), the person obtaining consent and by the impartial witness.
   c. The written summary is signed and dated by the person obtaining consent and by the impartial witness.
   d. A copy of the translated short form must be given to each subject or LAR.

F. Waiver of Informed Consent

2. In order for the IRB to approve the request to waive Informed Consent, the waiver of the need for authorization for the use of, or disclosure of Protected Health Information (PHI) must also be met. The IRB must find that:
   a. The research and the use or disclosure of PHI involves no more than minimal risk to the subjects;

b. The alteration or waiver will not adversely affect the privacy, rights and the welfare of the subjects;

c. The research could not practicably be conducted without the waiver or alteration;

d. The research could not practicably be conducted without access to and use of the PHI;

e. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

f. There is an adequate plan to protect the identifiers from improper use or disclosure;

g. There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

h. There are adequate written assurances the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project or for other research for which the use or disclosure of PHI would be permitted by this subpart.

3. IRB Responsibilities Associated With Waiver of Consent:

a. The IRB is responsible for ensuring that procedures are in place to inform, at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, a LAR of the subject, or if such a representative is not reasonably available, a family member of the subject, of the subject's inclusion in the clinical investigation, the details of the investigation and other information contained in the informed consent document. The IRB shall also ensure that there is a procedure to inform the subject, or if the subject remains incapacitated, a LAR of the subject, or if such a representative is not reasonably available, a family member, that he or she may discontinue the subject's participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. If a LAR 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. If a subject is entered into a clinical investigation with waived consent and the subject dies before a LAR or family member can be contacted; information about the clinical investigation is to be provided to the subject's LAR or family member, if feasible.

b. FDA regulated protocols involving 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 such protocols as protocols that may include subjects who are unable to consent. The submission of those protocols in a separate IND/IDE is required even if an IND for the same drug product or an IDE for the same device already exists.

a. If the IRB determines that a waiver cannot be approved because the waiver does not meet the regulatory criteria of this policy or because of other relevant ethical concerns, the IRB must document its findings and provide these findings promptly in writing to the clinical Investigator and to the sponsor of the clinical investigation.

b. The IRB cannot provide an informed consent waiver for HHS-funded research involving newborn dried blood spots.

c. The IRB determinations required of this policy and the documentation are to be retained by the IRB in accordance with local, state, and FDA guidelines after completion of the clinical investigation, and the records shall be accessible for inspection and copying by FDA.

B. Exception from Informed Consent for **Emergency Research (21 CFR 50.24):** This waiver is explicitly excluded when the research involves certain protected research populations: Prisoners, fetuses, pregnant women and human in vitro fertilization. If the Orlando Health IRB can proceed under this exception the Orlando Health IRB is responsible for the review, approval, and continuing review of clinical investigations without requiring that informed consent of all research subjects be obtained if the IRB finds and documents each of the following:

2. The human subjects are 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.
3. Obtaining Informed Consent is not feasible.
4. Participation in the research holds out the prospect of direct benefit to the subjects.
5. The clinical investigation could not practicably be carried out without the waiver.
6. The proposed investigational plan defines the length of the potential therapeutic window based on scientific evidence, and the Investigator has committed to attempt to contact a LAR for each subject within that window of time and, if feasible, to ask the LAR contacted for consent within that window rather than proceed without consent. The Investigator will summarize efforts made to contact LARs and make this information available to the IRB at the time of continuing review.
7. The IRB has reviewed and approved informed consent procedures and an Informed Consent document. These procedures and the Informed Consent document are to be used

with subjects or their LARs in situations where use of such procedures and information is feasible. IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a subject's participation in the clinical investigation.

2. Additional protections of the rights and welfare of the subjects will be provided.

B. Exception from Informed Consent for **Emergency Use**

2. Even for an emergency use, the Investigator is required to obtain Informed Consent of the subject's LAR unless both the Investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following [21 CFR 50.23(a)]:
   a. The subject for an emergency use is confronted by a life-threatening situation necessitating the use of the test article.
   b. Informed Consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject.
   c. Time is not sufficient to obtain consent from the subject's LAR.
   d. No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life.
3. If, in the Investigator's opinion, immediate use of the test article is required to preserve the subject's life, and if time is not sufficient to obtain independent physician's determination that the four conditions above apply, the clinical Investigator should make the determination and, within 5 working days after the use of the article, have the determination reviewed and evaluated in writing by a physician who is not participating in the clinical investigation. The Investigator must notify the IRB within 5 working days after the use of the test article [21 CFR 50.23 (c)].

C. Documentation of Informed Consent: Informed Consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's LAR. A copy shall be given to the person signing the form. Notation that Informed Consent was obtained and a copy of the consent form must also be placed in the patient's chart/medical record. The approved form may be read to the subject or the LAR, but the Investigator shall give the signer adequate opportunity to read it before it is signed. For all regulated studies, the IRB may waive the requirements for a signed consent form for some or all subjects if it finds either:

2. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research and their wishes shall be followed; or
3. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

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In cases in which documentation of Informed Consent is waived, the IRB may require the Investigator to provide subjects with a written statement regarding the research.

XVI. REFERENCES:

A. Code of Federal Regulations - 21 CFR 50.20, 21 CFR 50.27, 21 CFR 56.109, 45 CFR 46.109, 45 CFR 46.116, 45 CFR 46.117
B. FDA Guidance, July 2017, titled "IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects"
C. Florida State Statute 766.103C.
D. Patient Care Policy and Procedure #8462, *Uses and Disclosures of Protected Health Information for Research Purposes*
E. International Conference on Harmonization Good Clinical Practice 4.8.6
F. FDA Information sheet: *A Guide to Informed Consent*
G. IRBNet Template Library

XVII. Attachments:

A. None