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

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| Title: | ***IRB Definition Policy*** | Policy #: | **0330-1026** |
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| Page: | 1 of 10 | Developed By: | Orlando Health Institutional Review Board (IRB) |
| Issue Date: | **07/15/2025** | Approved By: | Philip Giordano, MD<br>Institutional Official<br>**SIGNATURE ON FILE** |
| Revision Dates: | | | |

## I. PURPOSE:

This policy contains the definitions used by the Orlando Health Institutional Review Board (IRB)

## II. DEFINITIONS:

A. 2018 Requirements: The Federal Policy for the Protection of Human Subjects requirements contained in 45 CFR 46 Subparts A, effective January 19, 2018, as well as Subpart B, C, and D, exclusive of requirements for reporting to, certification by, or review by a federal department of agency head.

B. Adverse event: Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally (the time between the study intervention and the adverse event) associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

C. An unapproved medical device - a device that is used for a purpose or condition for which the device requires, but does not have, an approved application for pre-market approval under section 515 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C 360(e)].

D. Assent: A minor's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

E. Basic Principles of Research:

1) **Respect for Persons:** Individuals should be treated as autonomous agents and those persons with diminished autonomy should be entitled to protection. This principle is applied by obtaining informed consent with due consideration of privacy, confidentiality, and additional protections for **vulnerable populations.**

2) **Beneficence:** Individuals should be treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. This principle is applied by appropriately weighing risks and benefits.

3) **Justice:** All individuals should equally share the burdens and benefits of research. This principle is applied by the equitable selection of research subjects. Benign Behavioral Intervention: An intervention that is brief in duration, harmless, painless, not physically invasive, such as playing an online game, solving puzzles under various noise conditions, etc.

F. Boilerplate language: Required informed consent form language to include HIPAA language, compensation, and subject injury language.

G. Broad Consent: A consent that allows the institution to collect, store, maintain and use subjects' identifiable data and/or identifiable biospecimens for unspecified, future secondary research.

H. Ceded Review: The act of transferring IRB review and oversight.

I. Conflict of Interest (COI): Occurs when an individual's personal interests – family, friendships, financial, or social factors – could compromise his or her judgment, decisions, or actions in the workplace.

J. Continuing non-compliance - A pattern of non-compliance that indicates an inability or unwillingness to comply with the requirements of an applicable law, regulation, or institutional policy pertaining to the protection of human subjects and/or with the requirements or determinations of an IRB.

K. Cooperative research: Non-exempt Human Subjects Research that involve more than one institution and is supported and/or funded by the HHS.

L. CORO: Corporate Office for Research Oversight (Orlando Health)

M. Dead fetus: a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

N. Delivery: complete separation of the fetus from the persons by expulsion or extraction or any other means.

O. Direct Advertisement: an advertisement that is intended to be seen or heard by prospective subjects to solicit their participation in a research study. Direct Advertisements includes, but are not limited to, newspaper, radio, TV, bulletin boards, posters and flyers.

1) Direct Advertisements do not include the following:
   a) "Dear Doctor" letters (written communication from the Principal Investigator to other clinicians requesting for the referral of potentially eligible patients),
   b) Subject retention materials,
   c) News stories or advertising that is publicly intended for other audiences such as financial pages directed toward investors.

P. Emancipated minor: An individual less than 18 years of age who is married, widowed or divorced, is in the military, is pregnant (as related to the pregnancy), has a child (as related to the child), or whose minor status has been approved by a court of law.

Q. Emergency Research: is defined as a human subject in a life-threatening situation, unable to provide consent, 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.

R. Emergency use - the use of a test article on a human subject (patient) in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval for the use of the trial article.

S. Emergency/urgent conditions: When adult/minor is in danger of loss of life or permanent loss of bodily functions.

T. Engaged in Research (See OHRP guidance document "Guidance on Engagement of Institutions in Human Subjects Research" issued October 16, 2008): In general, an institution is considered engaged in a particular non-exempt human subject's research project when its employees or agents for the purposes of the research project obtain:

1) data about the subjects of the research through intervention or interaction with them;
2) identifiable private information about the subjects of the research; or
3) the informed consent of human subjects for the research.

U. Epic: Electronic health record system utilized in the Orlando Health hospital system which is 21 CFR 11 compliant.

V. Exempt Review: Exempt research projects present risks so benign to the human subjects who participate in them, that the federal regulations say such projects are exempt from review. The majority of research studies

that qualify for exempt review involve the use of anonymous existing data or specimens. Anonymous means the study information can never be linked to identifiers by anyone.

W. Expedited Review Procedure: consists of a review of research involving human subjects by the IRB Chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 21 CFR 56.110 and 45 CFR 46.110.

X. External adverse event: From the perspective of one particular institution engaged in a multicenter clinical trial, external adverse events are those adverse events experienced by subjects enrolled by investigators at other institutions engaged in the clinical trial. An IND safety report is an example of an external adverse event.

Y. External IRB: any non-OH IRB (For Example: NCI CIRB, WCG, Advarra, etc.)

Z. 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.

AA. Fetus: the product of conception from implantation until delivery

BB. Food and Drug Administration (FDA) Definition of Human Subject Research: Activities are human subject research subject to FDA regulations when they meet the FDA definition of "research" and involve one or more "human subjects" as defined in FDA regulations.

2) Clinical Investigation (as defined by FDA Regulations (21 CFR 56.102): any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA under section 505(i), or 520(g) of the Federal Food, Drug and Cosmetic Act ("the Act"), or need not meet the requirements for prior submission to the FDA under these sections of the Act, but the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. The term "clinical investigation" does not include experiments that must meet the provisions of part 58, regarding non-clinical laboratory studies.
    a) The terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous for purposes of this part.
    b) Research is subject to 21 CFR 50 (Protection of Human Subjects) and 56 (Institutional Review Boards) when it involves:
        i) The use of any drug other than the use of an approved drug in the course of medical practice, or
        ii) The use of any medical device other than the use of an approved medical device in the course of medical practice. Clinical investigators agree to conditions regarding the conduct of the clinical investigation outlined by FDA regulations, or
    c) Clinical investigations regulated by the FDA under Sections 505(i) and 520(g) of the Act including investigations of foods, dietary supplements that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products.

i) Clinical investigators may be required to agree to these conditions by signing an FDA form (Form FDA 1572) that certifies that the investigator has obtained IRB review and approval prior to conducting the study.

CC. Guardian Advocate: is a person appointed by a court to make decisions regarding mental health treatment on behalf of a patient who has been found incompetent to consent to treatment.

DD. Health and Human Services (HHS) Definition of Human Subject Research: Activities are human subject research subject to HHS regulations when they meet the HHS definition of "research" and involve one or more "human subjects" as defined in HHS regulations.

1) Research (as defined by HHS regulations in 45 CFR 46.102(l)): a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
2) Human subjects (as defined by HHS Regulations in 45 CFR 46.102(e)): a living individual about whom an investigator conducting research:
3) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
4) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
5) Intervention: includes both the physical procedures by which data are gathered (e.g., venipunctures) and manipulations of the subject or the subject's environment that are performed for research purposes.
6) Interaction: communication or interpersonal contact (e.g., questionnaires, interviews) between the investigator and the subject for research purposes.
7) Private information: information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.
8) Clinical Trial (as defined by HHS regulations in 45 CFR 46.102(b)): a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

EE. Human subject (as defined by FDA regulations in 21 CFR 56.102(e)): an individual who is or becomes a participant in research either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. If the research involves a medical device, human subjects are individuals when they participate in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control (21 CFR 812.3(p)).

FF. Human subjects: Human subjects are defined by HHS Regulations at 45 CFR 46.102(f) as "a living individual about whom an investigator conducting research

1) obtains information or biospecimens through intervention or interaction with the individual, and uses studies, or analyzes the information or biospecimens; or
2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

GG. ”Humanitarian Device Exemption (HDE) is an application that is similar to a premarket approval (PMA) application, but exempt from the effectiveness requirements of a PMA. An approved HDE authorizes marketing of a Humanitarian Use Device (HUD).

HH. Humanitarian Use Device (HUD) – a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects no more than 8,000 individuals in the United States per year.

II. Identifiable biospecimen: A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

JJ. Identifiable private information: Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

KK. 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 Authorized 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.

LL. Informed consent: A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject’s decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form.

MM. 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 provides documentation of agreement to participate in research but is only one part of the consent process.

NN. Institutional Conflict of Interest (ICOI): an institution’s own financial interests or those of its senior officials pose risks of undue influence on decisions involving the institution’s primary interests.

OO. Internal (local) adverse event: With regards to a multicenter clinical trial, internal adverse events are those adverse events experienced by subjects enrolled by the investigator(s) at Orlando Health (OH) or any OH-affiliated site. In the context of a single-center clinical trial, all adverse events would be considered internal adverse events.

PP. Investigational Drug or Device: An investigational drug or device is a drug or device permitted by the Food and Drug Administration to be tested in humans, but not yet determined to be safe and effective for a particular use in the general population. An investigational drug or device may be a new drug or device not yet approved for marketing or may be an approved drug or device being tested for the purpose of supporting a new labeling indication. (See FDA Information Sheet “Off Label and Investigational Use of Marketed Drugs, Biologics and Medical Devices”)

QQ. Investigator: An individual who actually conducts a clinical investigation (i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject). In the event of an

investigation conducted by a team of individuals, the Principal Investigator is the responsible leader of that team.

RR. Investigator-Initiated Suspension of study activities: Investigator-initiated suspension of study activities refers to a determination made by the Principal Investigator to temporarily suspend some or all activities of a currently approved research study.

SS. Investigator-Initiated Termination of study activities: Investigator-initiated termination of study activities refers to a determination made by the Principal Investigator to permanently terminate some or all activities of a currently approved research study.

TT. IRB Approval: IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by Orlando Health's IRB and other institutional or federal guidelines.

UU. IRB Oversight: Oversight means that the IRB has reviewed the project and has determined it to be either Human Subjects Research (HSR) or Not Human Subjects Research (NHSR) Definition of Human Subject Research:

1) The Orlando Health IRB defines an activity as human subject research if it meets either the HHS or FDA definition.

VV. IRB-Initiated Suspension of Approval: IRB-initiated suspension of approval refers to a determination made by the Orlando Health IRB to temporarily withdraw IRB approval for some or all activities of a currently approved research study.

WW. IRB-Initiated Termination of Approval: IRB-initiated termination of approval refers to a determination made by the Orlando Health IRB to permanently withdraw IRB approval for some or all activities of a currently approved research study.

XX. IRBNet is the electronic system used by Orlando Health IRBs for submission, review, and document storage of all research reviewed by Orlando Health IRBs. It can be accessed at www.IRBNet.org. IRB staff can provide training materials and in-person training for using the IRBNet web site.

YY. Legal representative: A person who, under applicable law, has the authority to act on behalf of an individual. A legal representative includes a healthcare surrogate, proxy, guardian, or parent or other person acting in place of a parent (in loco parentis) for a non-emancipated minor, or an executor or administrator of an estate.

1) Minor: Any person under the age of 18.

ZZ. Life-threatening, for the purposes of 21 Code of Federal Regulations (CFR) 56.102(d): includes the scope of both “life-threatening” and “severely debilitating”, as defined below:

1) Life-threatening: diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the endpoint of clinical trial analysis is survival. The criteria for life-threatening do not require the condition to be immediately life-threatening or to immediately result in death. Rather, the subjects (patients) must be in a life-threatening situation requiring intervention before review at a convened meeting of the IRB is feasible.

2) Severely debilitating: diseases or conditions that cause major irreversible morbidity. Examples of severely debilitating conditions include blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis, or stroke.

AAA. Limited IRB Review: Some exempt research projects subject to 2018 requirements require limited IRB review by the IRB Chair/designee. The limited IRB review process consists of the IRB Chair/designee ensuring that adequate privacy safeguards for identifiable private information and/or identifiable biospecimens are in place.

BBB. Major Protocol Deviation/Violation - A protocol deviation which meets any of the following criteria:
1) Potentially places the subject (or others) at a greater risk of harm (rights, well-being and/or welfare),
2) Potentially violates ethical principles,
3) Potentially has a major impact on the integrity of study data or the scientific design of the study,
4) Resulted from willful or knowing misconduct on the part of the Investigator(s) or their study team (See Attachment A – Major Protocol Deviations/Violations & Regulatory Non-Compliance Examples)

CCC. 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.

DDD. "Minimal Risk" as it pertains to research involving prisoners: The probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons (i.e., healthy individuals who are not prisoners).

EEE. Minor Protocol Deviation - A protocol deviation that does not fit the Major Protocol Deviation definition.

FFF. Neonate: a newborn, from time of birth to thirty days.

GGG. Non-Significant Risk (NSR): An NSR device study is one that does not meet the definition for an SR device study

HHH. Non-viable neonate: a neonate after delivery that, although living, is not viable.

III. OH: Orlando Health

JJJ. OH IRB: Orlando Health Institutional Review Board

KKK. PHI: Protected Health Information is individually identifiable health information. This includes any direct or indirect subject identifiers that can be connected to the subject, including codes that can be used to identify subjects.

LLL. Possibly related to the research: There is a reasonable possibility that the adverse event, incident, experience or outcome may have been caused by the procedures involved in the research

MMM. Pre-2018 Requirements: The Federal Policy for the Protection of Human Subjects requirements contained in 45 CFR 46 Subparts A as published in the 2016 edition of the Code of Federal Regulations, as well as Subpart B, C, and D, exclusive of requirements for reporting to, certification by, or review by a federal department of agency head.

NNN. Pregnancy: encompasses the period of time from implantation until delivery. A persons shall be assumed to be pregnant if they exhibit any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

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OOO. Prisoner: Any individual involuntarily confined or detained in a penal institution (for example, jail, prison, juvenile offender facility, and alcohol and drug treatment facility). The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. This definition applies to minors as well as to adults

PPP. Protected health information (PHI): Individually identifiable health information, held or maintained by an Orlando Health or its business associates acting, that is transmitted or maintained in any form or medium (including the individually identifiable health information of non-U.S. citizens). This includes identifiable and other information relating to the past, present or future physical or mental health or condition of an individual, the provision of healthcare to an individual, or the past, or future payment for the provision of healthcare to an individual.

QQQ. Protocol Deviation - A protocol deviation is any change, divergence, or departure from a research protocol that is under the investigator's control and that has not been previously approved by the IRB.

RRR. Regulatory Non-compliance - In some cases, problems from the conduct of the study may not be considered protocol deviations/violations but are still required to be reported to the IRB. Failure to comply with any of the federal and/or state regulations or institutional policies governing human subjects research that, in the judgment of the Orlando Health IRB, may potentially compromise human subjects protection or the integrity of the Orlando Health IRB's human subjects protection program results in Regulatory Non-compliance.

SSS. Reliance Agreement: a written agreement between Orlando Health and a non-OH institution that is used to document IRB review responsibilities.

TTT. Relying Institution – when Orlando Health agrees to rely upon the reviewing IRB.

UUU. Relying Site Application Form – an application with information on how the study will be conducted at the relying site, including Principal Investigator (PI), team members, relying site consent process, data protection, etc.

VVV. Retrospective: A term used in research to describe material or data that is existent prior to the initiation of the study.

WWW. Reviewing IRB - the IRB of record performing review on behalf of Orlando Health, also referred to as the external IRB.

XXX. Serious adverse event: Any adverse event temporally associated with the subject's participation in research that meets any of the following criteria:

1) results in death;
2) is life-threatening (places the subject at immediate risk of death from the event as it occurred);
3) requires inpatient hospitalization or prolongation of existing hospitalization;
4) results in a persistent or significant disability/incapacity;
5) results in a congenital anomaly/birth defect; or
6) any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in

the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

YYY. Serious non-compliance - Non-compliance that adversely affects the rights or welfare of research participants or adversely affects the integrity of the data and research.

ZZZ. Significant Risk (SR): Under 21 CFR 812.3(m), an SR device means an investigational device that:

1) Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
2) Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
3) Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
4) Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

AAAA. sIRB: Single Institutional Review Board, designated as the IRB of record for all sites in a multi-site study.

BBBB. Smart IRB – a platform developed by the National Center for Advancing Translational Sciences (NCATS) to facilitate IRB authorization agreements (reliance agreements) among institutions engaged in cooperative research.

CCCC. Sponsor: The sponsor is the person or entity that initiates the clinical trial. The sponsor is typically the manufacturer or research institute that developed the drug or device. In this case, the sponsor does not actually conduct the clinical trial but rather distributes the investigational drug or device to a clinical investigator who directs the conduct of the trial. A clinical investigator may, however, serve as both the sponsor and investigator (called "investigator-sponsor") of a clinical trial. The sponsor assumes responsibility for the studies involving the investigational drug or device, including responsibility for compliance with applicable laws and regulations. The sponsor is responsible for obtaining FDA approval to conduct a trial and for reporting the results of the trial to the FDA.

DDDD. Sponsor-Initiated Suspension of study activities: Sponsor-initiated termination of study activities refers to a determination made by the sponsor to temporarily suspend some or all activities of a currently approved research study.

EEEE. Sponsor-Initiated Termination of study activities: Sponsor-initiated termination of study activities refers to a determination made by the sponsor to permanently terminate some or all activities of a currently approved research study.

FFFF. Test article: an investigational drug, device or biologic for human use that is not approved by the FDA.

GGGG. Unanticipated Problem (i.e., unanticipated problem involving risks to subjects or others): any incident, experience, or outcome that meets all of the following criteria:

1) unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

2) related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
3) suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

HHHH. Unapproved medical device: a device that is utilized for a purpose, condition, or use for which the device requires, but does not have, an approved application for premarket approval under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) or an approved IDE under section 520(g) of 21 U.S.C. 360j(g).

IIII. Unexpected adverse event: Any adverse event occurring in one or more subjects in a research protocol, the nature, severity, or frequency of which is:
1) Not consistent with the known, or foreseeable risk, of adverse events associated with the research procedures as described in protocol-related documents, such as the IRB-approved research protocol, the current IRB-approved informed consent document, and any other relevant sources of information (i.e., product labeling, investigator brochures, package inserts, etc.); or
2) Not consistent with the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

JJJJ. Viable neonate: a neonate that is able, after delivery, to survive (given the benefit of medical therapy) to the point of independently maintaining heartbeat and respiration.

KKKK. Ward: a person for whom a guardian has been appointed and is a child whose welfare is the responsibility of the State or any other agency, institution, or entity

LLLL. 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.