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

Title:	***Informed Consent Process***	Policy #:	**0330-1002**
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I. PURPOSE:

To maintain ethical and legal standards when administering and reviewing the informed consent process for all research studies (for example, but not limited to: expedited, exempt and greater than minimal risk studies) throughout the research subject's 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 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 Authorized Representative (LAR): Legally Authorized Representative means an individual or judicial or other body authorized under applicable 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 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.

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

J. 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.

K. 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.

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 or research specific test (e.g., screening).

B. A prospective subject for a research study shall be given the information (both verbal and written) that a reasonable person would want to have in order to make a voluntary, informed decision, without coercion or undue influence, 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:

Only the Investigator and/or sub-Investigator (as approved on Form FDA 1572 or the IRB Application where there is no Form FDA 1572) 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 as investigators to consent prospective subjects. These staff members must be deemed by the board to have the knowledge and expertise to support this decision as long as the project is within their scope of practice and/or license. 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. When written informed consent is required, 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 (NOTE: ICF(s) used in the electronic informed consent process will have an IRB approval stamp on the first and signature page; the approval letter will document approval of the ICF(s)) . 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 Consent forms must comply with current requirements of Florida and Federal Law and Orlando Health, Inc. policies and procedures.

D. 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 prospective subject, parent of a minor, and/or LAR. The prospective subject, parent of a minor, and/or 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 prospective subject, parent of a minor, and/or LAR giving consent, the name of the study, the name of the person obtaining consent, the time, and the date.

E. The Informed Consent process involves:

1. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
2. Informed consent as a whole must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.
3. Giving a subject adequate information about the research.
4. The person obtaining consent will discuss details about the study in a clear and non-technical manner.
5. The discussion must include:

a. Purpose of the study
b. Procedures to be followed
c. Aspects of the research that are experimental
d. Subject responsibilities
e. Risks and discomforts
f. Alternative treatments
g. Potential benefits
h. Cost and compensation
i. Issues related to confidentiality
j. Voluntary participation and withdrawal at any time

6. 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 include:
   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?"
7. The person obtaining consent will answer questions related to the study.
8. Providing adequate time and opportunity 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.
9. Obtaining the prospective subject's voluntary agreement to participate. 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.
10. Providing the prospective subject with a copy of the signed ICF
11. Continuing to provide information as the subject or situation requires.

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. Completion of the Informed Consent Form:
1. All blanks must be completed in blue or black ink, unless the electronic consent method is utilized.
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.

H. 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 that 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

13. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
    a. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
    b. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

I. Additional Elements of Informed Consent:
1. 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
2. Anticipated circumstances under which the subject's participation may be terminated by the Investigator without regard to the subject's consent
3. Any additional costs to the subject that may result from participation in the research
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
5. 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
6. The approximate number of subjects involved in the study
7. If applicable, a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit
8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions
9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)

J. Alternative required elements for consent for the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens:
1. A description of the following:
    a. any reasonably foreseeable risks or discomforts to the subject,
    b. any benefits to the subject or to others that may reasonably be expected from the research
    c. the extent, if any, to which confidentiality of records identifying the subject will be maintained,

d. 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

e. the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit

f. whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen);

2. A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted

3. A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens

4. A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);

5. Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;

6. Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and

7. An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

K. HIPAA Authorization for Research

1. The Orlando Health IRBs do not review and approve stand-alone HIPAA Authorization for Research documents.

2. 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.

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

M. Use of "Short Forms"

1. In general, the IRB does not encourage 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.
2. 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.
3. 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 or a family member of the subject) 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.

N. Use of electronic informed consent process

1. The use of an electronic informed consent process is permitted as long as there is an option to provide a paper version of the ICF too. For greater than minimal risk studies, it is required for the investigator obtaining consent be present (in person or via video/ teleconference), unless otherwise determined by the IRB.
2. Transferring IRB approved consent forms to Epic do not require prior Orlando Health IRB review and approval. Since this is an electronic representation of the IRB approved consent form, the Orlando Health IRB recognizes that the IRB approval stamp will only show on the first page and

signature page, and page numbers will not be displayed on the electronic representation because it is not possible in Epic.

3. The informed consent form used in the electronic informed consent process should be consistent with the IRB approved consent template; however, this will be decided on a case by case basis (i.e., investigator-initiated study vs. sponsored study).
4. When utilizing an electronic consent process, the following additional items need to be included in the submission to the respective Orlando Health IRB:
   a. The consent and/or assent form in an editable format (e.g., Word document) AND in electronic format used in the electronic consent process.
   b. All eIC informational materials, including any videos or web-based presentation, which will be viewed by the potential subject/LAR.
   c. If hyperlinks are included within the electronic consent process, then the information from these hyperlinks should be included in the same format the study team plans to present it to the subject/LAR.
   d. All eIC materials must include a version date for version control. Screenshots should reference this information.
   e. An affidavit from the electronic system vendor ensuring Part 11 compliance.
   f. A description of how to provide a copy of the signed and dated consent form to the subject/LAR, unless the research is requesting a waiver of the documentation of consent in which only a copy of the consent form is provided.
5. IRB responsibilities associated with the use of an electronic informed consent process:
   a. Review all electronic informed consent materials, including associated hyperlinks used to convey study-related information.
   b. Review the usability of the electronic informed consent process to ensure it is easy to navigate with special considerations given to subjects who lack the familiarity with electronic systems, poor eyesight, impaired motor skills, etc. The use of an electronic informed consent process should not impede the capability of obtaining consent and/or assent.
   c. The IRB letter approving the submission will serve as the IRB approval for the electronic consent process (NOTE: the electronic ICF will have an IRB approval stamp on the first page and signature page).

O. Waiver of Informed Consent

1. 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.

2. The IRB must find and document 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 requested waiver or alteration
   d. The research could not practicably be conducted without access to and use of the PHI
   e. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format
   f. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
   g. There is an adequate plan to protect the identifiers from improper use or disclosure
   h. 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
   i. 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.

c. 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.

d. If an individual was asked to provide consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens under the alternative required consent elements listed above, and refused to consent, the IRB cannot waive consent for these individuals.

e. 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.

P. 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:

1. 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.
2. Obtaining Informed Consent is not feasible.
3. Participation in the research holds out the prospect of direct benefit to the subjects.
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 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.

6. 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.
7. Additional protections of the rights and welfare of the subjects will be provided.

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

1. 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.
2. 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)].

R. Documentation of Informed Consent:

1. Guidance for the investigator:
   a. 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.
   b. A copy shall be given to the person signing the form.
   c. Notation that Informed Consent was obtained, and a copy of the consent form must also be placed in the patient's chart/medical record.

d. 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.

2. For all regulated studies, the IRB may waive the requirements for a signed consent form for some or all subjects if it finds either:
   a. 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
   b. 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. 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
   c. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

V. 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. OHRP/FDA Information sheet, December 2016: Use of Electronic Informed Consent - Questions and Answers: Guidance for Institutional Review Boards, Investigators, and Sponsors
H. IRBNet Template Library

VI. Attachments:

A. None