**Harvard Pilgrim Health Care, Inc.**
**Harvard Pilgrim Health Care Institute, LLC**
***Office of Sponsored Programs***

**Policy and Procedure**

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**TITLE:** Informed Consent

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**PURPOSE:**

To describe the policies and procedures for:

- investigators obtaining, documenting, or securing a waiver of informed consent/assent for non-exempt human subjects research; and
- Institutional Review Board (IRB) evaluation of the informed consent process.

**PERSONS AFFECTED:**

This policy & procedure (P/P) applies to all Harvard Pilgrim Health Care, Inc. (HPHC) and Harvard Pilgrim Health Care Institute, LLC (HPHCI) (collectively, HPHC/I) personnel engaged in research, teaching or research administration activities in support of the charitable and educational mission of HPHC.

**POLICY:**

General Requirements - General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in this policy. (Note: Notwithstanding language in this P/P to the contrary, HPHC shall defer implementation of Broad Consent until promulgation of regulatory guidance.) Broad consent may be obtained in lieu of informed consent obtained in accordance with this P/P only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens. Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials is in this P/P as is general waiver or alteration of informed consent. Except as provided elsewhere in this P/P:

(1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative (LAR).
(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the LAR sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
(3) The information that is given to the subject or the LAR shall be in language understandable to the subject or the LAR.
(4) The prospective subject or the LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
(5) Except for broad consent obtained in accordance this P&P:
    (i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR 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.
    (ii) 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 LAR's understanding of the reasons why one might or might not want to participate.
(6) No informed consent 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.

The IRB's evaluation of these criteria cannot be accomplished solely by evaluating a written consent document since:

- The consent process is a discussion that should be culturally and linguistically appropriate to the study population and not simply a consent document. To determine whether the criteria for approval of research are met, the IRB should know the nature and circumstances of the consent process, such as:
    - who will conduct the consent interview;
    - the timing of obtaining consent, and
    - any waiting period between informing the subject and obtaining consent.
- The consent document does not reflect all the information communicated to the subject during the consent process. To determine whether the investigators have informed subjects of all the required disclosures, the IRB should evaluate the information that will be communicated to the subject during the consent process and determine which information will be disclosed.

The IRB shall determine whether the consent process shall be documented using a consent document.

In limited circumstances, when the criteria for waivers or alterations are met, the IRB may waive the requirement to obtain informed consent or allow alteration of the informed consent process or informed consent documentation.

**DEFINITIONS:**

*Assent*
A positive indication of willingness to participate in a study and/or a child's affirmative agreement to participate in research. Mere failure to object may not, absent affirmative agreement, be construed as assent. (45 CFR §46.402(b); 21 CFR §50.3(n)).

*Children*
Persons who have not attained the legal age for consent to treatments or procedures involved in research, under the applicable law of the jurisdiction in which the research will be conducted. (45 CFR 46.402(a)).

*Guardian*
An individual who is authorized under applicable state or local law to consent on behalf of a person to general medical care. 45 CFR 46.402(e)).

*Legally Authorized Representative (LAR)*
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 procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research. (45 CFR §46.102(i)); 21 CFR §50.3(l)). Depending on the circumstances, this may include, but is not limited to, a parent, guardian, or health care agent.

*Parent*
A child's biological or adoptive parent.

*Permission*
The agreement of the LAR to the participation of the subject in research.

**PROCEDURE:**

*Note:* Investigators may refer to the *Consent Authorization Checklist and Guidance* to ensure the general regulatory requirements are met prior to submitting informed consent documents for IRB review.

The IRB also offers a *Consent and Authorization Template* including language for genetic studies. Both are available in 'Forms and Templates' in the HPHC Documents for Researchers section in IRBNet. If vulnerable populations (such as minors, prisoners, or adults with diminished capacity) or other vulnerable groups are subjects in the research study, the

investigator should contact the Senior Compliance Manager (SCM) at (617) 867-4587 with questions. Please see the *Policy and Procedure on Additional Protections of Vulnerable Subjects.*

1. Information required to be provided for IRB analysis of the consent process.

Prior to IRB review, the IRB staff shall screen the application form to ensure that the investigator has included all the required information necessary for IRB analysis of the consent process, including:

a. the name of the investigator who will conduct the consent interview;
b. the name of the subject or LAR who will provide consent or assent;
c. any waiting period between informing the prospective subject and obtaining consent;
d. steps taken to minimize the possibility of coercion or undue influence;
e. the language used by those obtaining consent;
f. the language understood by the prospective subject or LAR; and
g. the information to be communicated to the prospective subject or LAR.

2. Basic Elements of Informed Consent - required to be provided to the subject and LAR.

The IRB shall confirm that the investigator provides the following basic elements of informed consent to each subject or LAR when seeking informed consent:

a. A statement that the study involves research, including:
   (1) an explanation of the purposes of the research;
   (2) the expected duration of the subject's participation;
   (3) a description of the procedures to be followed; and
   (4) identification of any procedures that are experimental.
b. A description of any reasonably foreseeable risks or discomforts to the subject;
c. A description of any benefits to the subject or to others which may reasonably be expected from the research;
d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
e. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
f. For research involving more than minimal risk, an explanation as to whether there is 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;
g. An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject;
h. A statement that participation is voluntary, including that:
   i. refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled; and
   ii. the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
i. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

1. 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 LAR, if this might be a possibility; or
2. 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.

3. Additional Elements of Informed Consent – Office of Human Research Programs (OHRP).
Except under the circumstances when broad consent, waiver or alteration of consent involving public benefits or waiver or alteration generally applies, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the LAR in the informed consent form:

a. 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) that are currently unforeseeable;
b. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the LAR's consent;
c. Any additional costs to the subject that may result from participation in the research;
d. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
e. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
f. The approximate number of subjects involved in the study;
g. 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;
h. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
i. 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).

4. Elements of Informed Consent - U.S. Food and Drug Administration (FDA).
When following FDA requirements, the IRB must determine that the required and appropriate additional elements of disclosure are included in the consent process, including a statement noting the possibility that the FDA may inspect the records that will be provided to each subject, and a statement that a description of the clinical trial will be available on http://www.clinicaltrials.gov as required by U.S. law.

5. Elements of Broad Consent - for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.

*[This section intentionally left blank pending promulgation of regulatory guidance. 45 CFR 46.116(d).]*

6. Additional Informed Consent Information for Subjects.

The IRB may require that additional information be given to the subjects when in the IRB's judgement the information would meaningfully add to the protection of the rights and welfare of subjects.

7. Waiver or Alteration of Consent in Research involving Public Benefit and Service Programs Conducted by or Subject to the Approval of State or Local Officials.

a. Waiver. An IRB may waive the requirement to obtain informed consent for research provided the IRB satisfies the ***Requirements for Waiver and Alteration*** below. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

b. Alteration. An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent provided the IRB satisfies the requirements for waiver and alteration set forth in the next section. An IRB may not omit or alter any of the requirements described in the previous waiver section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required for broad consent.

c. Requirements for Waiver and Alteration. In order for an IRB to waive or alter consent, the IRB must find and document that:

    i. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
        1. Public benefit or service programs;
        2. Procedures for obtaining benefits or services under those programs;
        3. Possible changes in or alternatives to those programs or procedures; or
        4. Possible changes in methods or levels of payment for benefits or services under those programs; and

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

8. General waiver or Alteration of Consent:

a. Waiver. An IRB may waive the requirement to obtain informed consent for research provided the IRB satisfies the Requirements for Waiver and Alteration, below. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in

accordance with broad consent requirements (above), and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

b. Alteration. An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent (Basic Elements of Informed Consent and Additional Elements of Informed Consent) provided the IRB satisfies the requirements of Requirements for Waiver and Alteration (below). An IRB may not omit or alter any of the requirements described in General (above). If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under Elements of Broad Consent (above).

c. Requirements for Waiver and Alteration. In order for an IRB to waive or alter consent, the IRB must find and document that:

   i. The research involves no more than minimal risk to the subjects;
   ii. The research could not practicably be carried out without the requested waiver or alteration;
   iii. 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;
   iv. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
   v. Whenever appropriate, the subjects or LAR will be provided with additional pertinent information after participation.

9. Screening, Recruiting, or Determining Eligibility.

An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's LAR, if either of the following conditions are met:

a. The investigator will obtain information through oral or written communication with the prospective subject or LAR, or
b. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

10. Posting of Clinical Trial Consent Form.

a. For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal web site that will be established as a repository for such informed consent forms.
b. If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal web site (e.g. confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.
c. The informed consent form must be posted on the Federal web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

11. Preemption. The informed consent requirements of the P/P are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in or for informed consent to be legally effective.

12. Emergency medical care. Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, state, or local law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).

13. Documentation of informed consent.
Informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's LAR. A written copy shall be given to the person signing the informed consent form. Unless the IRB waives the requirements for the investigator to obtain a signed informed consent form, the informed consent form may be either of the following:

a. a written informed consent form that meets the requirements of the General Requirements for Informed Consent (45 CFR 46.116). The investigator shall give either the subject or the subject's LAR adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's LAR; or
b. a short form written informed consent form stating that the Elements of Informed Consent required by 45 CFR 116 have been presented orally to the subject or the subject's LAR, and that the key information required by 45 CFR 46.116(a)(5)(i) (Informed consent must begin with a concise and focused presentation of the key that is most likely assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research and is organized and presented in a way that facilitates comprehension) was presented first to the subject, before other information if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the LAR. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's LAR. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject's LAR, in addition to a copy of the short form.

14. Waiver of Documentation of Informed Consent Form.
The IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

a. that the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject or LAR will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

b. that 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.; or
c. if the subjects or LARs 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.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or LARs with a written statement regarding the research.

15. Submission of written informed consent document to IRB.
Prior to obtaining informed consent from subjects, the investigator must submit a written informed consent form to the IRB for review and approval. This form may be submitted at the time of initial submission or through an amendment and must be approved by the IRB prior to the start of the informed consent process with the subjects.

16. The most current informed consent form must be used.
Only the most recently IRB approved informed consent form may be used by the investigator to obtain informed consent for a study. All informed consent forms approved by the IRB are marked with a version date on the document footer and stored in IRBNet. At the time of continuing review, IRB staff screens the Continuing Review application form against the IRBNet version to ensure that the most current version is used. The IRB has the authority to observe or have a third party observe the informed consent process.

17. Requirements for informed consent/assent involving children.
a. Additional safeguards apply for the protection of children involved in research activities. Studies involving children require LAR consent and the subject's assent (unless waived). The investigator must follow the requirements of the state/country in which the research occurs. The investigator is responsible for identifying which individuals qualify as an LAR and the statutory definition of "child" in that location and submitting this information to the IRB. The IRB shall review the investigator's determination prior to approval and consult subject matter or legal experts, as needed.
b. If there is any person other than the biological or adoptive parent who claims to be the child's LAR, the investigator must verify documentation that the individual has the legal authority to make research decisions on behalf of the child. If the IRB finds that no greater than minimal risk to children is presented, approval may be given only if adequate provisions are made for soliciting the assent of the children and the permission of at the LAR.
c. The IRB must determine that adequate provisions have been made for soliciting the assent of all, some, or none of the children, when in the judgment of the IRB the children are capable of providing assent. Investigators must obtain the consent of the LAR and the assent of the child if he/she is seven (7) years or older. The IRB has the authority to waive the assent requirement and may determine that assent is not a necessary condition for proceeding with the research if:

(1) the aptitude of some or all of the children is so limited that they cannot reasonably be assented (determinations of capacity to assent will be assessed by age, maturity, and psychological state, and may be made for one, some, or all children in the research).
(2) the intervention or procedure involved holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of research; or
(3) the research meets the required criteria for waiver of consent described above in this document.

d. When assent is required, the investigator and the child will sign the assent form to document that the subject has been given an explanation of the proposed research, in language appropriate to the child's age and intellectual capacity.
e. In addition to the child's assent, the investigator is required to solicit consent of the LAR. The IRB may specify additional criteria for such consent. The LAR's is sufficient for research that is minimal risk or greater than minimal risk with the prospect of direct benefit to the subject. For clinical investigations involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subjects' disorder or condition, consent is required from both parents unless:
   a. one parent is deceased, unknown, incompetent, or not reasonably available; or
   b. when only one parent has legal responsibility for the care and custody of the child.
f. LAR consent must be documented.
g. The IRB may waive the requirement for obtaining consent from a LAR by determining that the criteria for waivers and alterations are met if the IRB determines that the research is designed for conditions or a population for which the LAR is not a reasonable requirement to protect the subjects (examples: homeless, neglected, abused children) or when the waiver is consistent with federal, state, or local law, and the research is not subject to FDA regulations. However, in such cases the IRB will substitute an appropriate mechanism for protecting the children who will participate. The determination for an appropriate mechanism would depend upon the nature and purpose of the research, risks, benefits, age, maturity, and psychological condition of the subjects.
h. Children who are wards of the state or any other agency, institution, or entity can be included in research only if such research is:
   (1) related to their status as wards; or
   (2) conducted in school, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

   If the research meets the criteria above, the IRB requires the appointment of a subject advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or legally authorized LAR. One individual may serve as an advocate for more than one child. The advocate must have necessary expertise and experience, and agree to act in the best interest of the child. Only those individuals without any conflicts of interest can be appointed as advocates.

18. Non-English-speaking subjects.

Subjects whose primary language is other than English will be presented with an informed consent document written in the language understandable to them. The investigator shall submit the foreign language consent form (along with a translated copy if available) to the IRB after approval of the English consent form. The IRB encourages investigators to include non-English speaking subjects in their research studies whenever appropriate. Investigators should consider this population at the time of grant submissions to allow for adequate budget planning so that appropriate interpreter and translation resources may be designated at the outset.

19. Genetic testing, tissue repositories, DNA banking, etc. involved in the research.

The investigator is encouraged to contact the IRB for guidance on the particular requirements of consent prior to review when the research involves genetic testing, tissue repositories, DNA banking and similar studies.

20. Data retention when the subject withdraws from clinical research.

a. In cases when the subjects withdraw from clinical research, the IRB will ensure that the consent form provides that: the data collected on the subject to the point of withdrawal remains part of the study database and may not be removed.
b. The investigator may ask a subject who is withdrawing whether the subject wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the subject must distinguish between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through noninvasive chart review, and address the maintenance of privacy and confidentiality of the subject's information. The investigator must obtain the subject's consent for this limited participation in the study (assuming such a situation was not described in the original consent document), and the IRB must approve the consent document.
c. If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator will not access for purposes related to the study the subject's medical record or other confidential records requiring the subject's consent. However, an investigator may review study data related to the subject collected prior to the subject's withdrawal from the study, and may consult public records, such as those establishing survival status.

21. *Electronic Informed Consent (eIC).*

eIC may be used to provide information usually contained within the written informed consent document, evaluate the subject's comprehension of the information presented, and document the consent of the subject or the subject's LAR. To assist the subject in understanding the material, the eIC may use interactive electronic-based technology, which may include diagrams, images, graphics, videos, and narration. The eIC should be appropriate for the intended audience, taking into consideration the subject's age, language, and comprehension level. Electronic records, electronic signatures, and handwritten signatures executed to electronic records must be trustworthy, reliable, and generally equivalent to a handwritten signature executed on paper. The

electronic system must also capture and record the date that the subject or subject's LAR provides consent.

The regulations permit a wide variety of methods to create electronic signatures, including using computer-readable ID cards, biometrics, digital signatures, and user name and password combinations. The IRB must consider how the electronic signature is created and whether the informed consent or permission document can be produced in hard copy for review by the subject upon request. The IRB and investigators may rely on a statement from the vendor of the electronic system used for obtaining the electronic signature that describes how the signature is created and that the system meets the relevant requirements. The investigator must verify the identity of an individual before accepting an individual's electronic signature or any element of such electronic signature.

When approving an eIC assent process, the IRB must consider whether the capability of a child to assent may be affected by the method used to obtain and/or document assent. For example, if assent would otherwise be required, the method used to obtain eIC assent should not impede the child's capability to provide assent. The language and presentation of information must be understandable to the child. In addition, when the IRB determines that assent is required, it must also determine whether and how assent must be documented. It may be reasonable for the LAR to initially document the child's assent, which can then be verified when the investigator first sees the child.

U.S. Department of Health & Human Services (HHS) and FDA regulations require that the person signing the informed consent be given a copy of the written informed consent form, unless the requirement for documentation of informed consent has been waived. Although FDA regulations do not require that the subject's copy include a signature, FDA recommends that a copy of the signed informed consent form that includes the date when the eIC was signed be provided to the subject.

**REVISION HISTORY:**

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| **Department:** OSP - Research Integrity & Compliance | **Title**: Informed Consent |
| **Effective Date**: 01/21/19 | **Owner:** Senior Compliance Manager |
| **Replaces P/P Dated**: IRB SOP (02/08/17); P/P (07/10/18) | |
| **Related Documents:** Initial Application; Reviewer Sheet-Initial Review; Consent Authorization Template; Consent/Authorization Checklist and Guidance | |
| **References**: 45 CFR 46.116; 45 CFR 46.117; 45 CFR 46.402; 45 CFR 46.102(i). HHS and FDA Guidance for Institutional Review Boards, Investigators, and Sponsors, (Dec 2016): Use of Electronic Informed Consent; 21 CFR 50.20; 21 CFR 50.3(n); 21 CFR 56.109(b); 21 CFR 56.109(f); 21 CFR 56.111(a)(4); 21 CFR 50.25(a); 21 CFR 50.25(b); 21 CFR 50.27(a); 21 CFR 50.27(b); 21 CFR 56.111(a)(5); 28 CFR 512.16; ICH-GCP: 2.9, 3.1.5, 3.1.9, 4.3.4, 4.8.1-4.8.9, 4.8.11; MGL 94C (105 CMR 700.009(D)); MA Executive Office of Health and Human Services (EOHHS): Conduct of Human Subjects Research, revised April 15, 2013; M.G.L. | |

ch.190B § 5-101; AAHRPP Tip Sheets: 1, 11, 19, 20; AAHRPP Elements II.3.F, II.3.G, II.4.B, and III.1.F