Albert Einstein College of Medicine

Informed Consent Guidelines

I. Purpose

These guidelines are to ensure that all researchers at the Albert Einstein College of Medicine ("Einstein") and Montefiore Medical Center ("MMC") that are authorized to obtain informed consent, are in compliance with research ethical principles, Department of Health and Human Services (HHS) regulations for the Protection of Human Research Subjects (45 CFR 46) and FDA regulations (21 CFR 50 & 56).

II. Scope

These guidelines apply to all research where ethical and legal regulations require authorized individuals to obtain/document written, oral, and/or a waiver of an IRB approved informed consent process with research subjects or their legally authorized representative.

III. Guidelines

Ethical Principles of Informed Consent

Freely given informed consent must be obtained from every decisionally capable, potential adult subject before any research procedures begin, unless the IRB has waived some or all of the consent requirements.

Informed consent is not just a form or a signature, but a process of information exchange that takes place between the prospective subject and the investigator before, during, and sometimes after the study, which includes subject recruitment materials, verbal instructions, written materials, question and answer sessions, and agreement documented by signature.

Who May Enroll Subjects

Individuals who will obtain informed consent from the subjects in the study must be listed as Key Personnel in the approved IRB protocol file. All of these individuals must be knowledgeable about the study and must have completed the CITI training program required by Einstein and MMC. The PI remains responsible for ensuring that adequate informed consent is obtained from each subject enrolled in the study protocol.

Informed Consent General Requirements, per 45 CFR 46.116

1) General requirements for informed consent, whether oral or written:

a) Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative, unless the requirement for informed consent has been waived by the IRB.
b) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
c) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.
d) The prospective subject or the legally authorized representative 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.
e) 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.
f) 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.
g) No informed consent may include any exculpatory language through which the subject or the legally authorized representative 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.

2) *Basic Elements of Informed Consent*
a) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and 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 that 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 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 subjects' rights, and whom to contact in the event of a research-related injury to the subject;

h) 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;
i) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
    i) 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
    ii) 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

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 legally authorized representative'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).

Documentation of Consent

For studies in which signed documentation of consent is required, the IRB requires that subjects sign and date the current IRB-approved and stamped consent document. The current version is the most recently IRB-approved version of the consent (with valid dates) received by the research team (or available electronically in the protocol submission system). A copy must be given to the person signing the form.

For research involving MMC patients, consent must be documented in accordance with MMC policy JC10.1, “Consents, Informed Consent and Refusal.”

Waiver of Consent and Waiver of Documentation of Consent

1) Waiver of Consent

a) Per 45 CFR 46.116, in order for an IRB to waive or alter consent, the IRB must find and document:
   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;
   v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

2) Waiver of Consent for Screening, Recruitment, or Determining Eligibility
   a) The IRB may waive the requirement consent specifically for the purposes of screening, recruiting, or determining eligibility. An investigator may obtain information or biospecimens for such purposes without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:
      i) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
      ii) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

3) Waiver of Documentation of Consent (e.g. oral consent)
   a) The IRB may waive the requirement for the investigator to obtained a signed inform consent form if it finds any of the following:
      i) 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 legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
      ii) 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
      iii) 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.

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

Consent Forms for Non-English Speaking Research Subjects

Unless written consent has been waived as a requirement for the study, the subjects who do not speak English must be provided with:

- A written consent document in a language understandable to them, and
- An interpreter fluent in both English and the subject's spoken language to aid in the consent process (Note: The interpreter should sign and date the consent form. For greater than minimal risks studies, the time should be included as well.)

Depending upon the research, the written consent document can be either a translation of the entire English version of the IRB approved consent document, or a "short form" consent document stating that the elements of consent have been fully presented orally. For more information on the short form process related to non-English speaking subjects, please refer to the document "Short Form Procedure for Non-English Speaking Subjects."

A fully translated consent form is required for studies that anticipate enrolling more than 5 subjects speaking the same non-English language. A fully translated consent form is also required once 5 subjects speaking the same non-English language have been enrolled via the short form procedure.

If a study has the potential for direct benefit to subjects, it should not exclude non-English speaking subjects. If you will exclude non-English speaking subjects, you must provide justification in the IRB application.

Examples of situations that require a translated consent form:

- The investigator is targeting a non-English speaking group
- Research will be done in a foreign country
- The investigator anticipates that more than 5 subjects who speak the same non-English language will want to enroll in the study

Translations can be obtained through a translation service of the investigator's choice. An "Affidavit of Accuracy" is required. Alternatively, the translation can be prepared "in house." This method requires that one individual translate the document into the appropriate language and another individual convert the translated document back into English. The two English documents can then be compared side by side for accuracy and completeness. For the "in house" translation, both the translated and back-translated consent forms must be submitted to the IRB, along with the names and qualifications of the individuals involved in the process.

Since any changes made by the Einstein IRB to the submitted English version of the informed consent document must be included in the translation of the informed consent document, investigators are advised to have the translation completed after Einstein IRB approval of the English version of the informed consent document.

Posting Clinical Trial Consent Forms to a Federal Website

For each clinical trial conducted or supported by a Federal department or agency that received initial IRB approval on or after January 21, 2019, one IRB-approved informed consent form used to enroll subjects must be posted on either ClinicalTrials.gov or Regulations.gov.

The informed consent form must be posted 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.

Additional Requirements for FDA-Regulated Research

When a subject withdraws from a study, the data collected on the subject to the point of withdrawal remains part of the study database and may not be removed. The consent document cannot give the subject the option of having data removed.

An investigator may ask a subject who is withdrawing whether the participant 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 distinguishes between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through non-invasive 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). The IRB must approve the consent document.

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 must 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.

IV. Effective Date

Effective as of: March 23, 2020

Revised as of: January 5, 2024

V. Document Management and Responsibilities

Einstein's Office of Human Research Affairs is the Responsible Office under this document. Einstein's Executive Dean is the Responsible Executive for this document. The OHRA Director is the Responsible Officer for the management of this document.