Informed Consent Guidelines

Ethical Principles of Informed Consent

The principle of respect for persons requires that people be given the opportunity to choose what will or will not happen to them. 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.

This policy provides guidance for conducting a proper informed consent process and ensuring adequate documentation in the research record, in compliance with institutional policy, 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).

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:

1. Subject recruitment materials;
2. Verbal instructions;
3. Written materials;
4. Question and answer sessions;
5. Agreement documented by signature.

I. WHO MAY ENROLL SUBJECTS

The Principal Investigator is required to submit to the IRB for each protocol the names of the individuals authorized to obtain informed consent from the subjects in the study. All of these individuals must be knowledgeable about the study and must have completed the training program required by Einstein and Montefiore. The PI must obtain the IRB’s approval prior to adding additional individuals to the authorized list. The PI remains responsible for ensuring that adequate informed consent is obtained from each subject enrolled in the study protocol.

The prospective participants or their representatives must be given sufficient information to make an informed decision whether or not they want to participate and have the opportunity to have their questions answered. Consent must be informative, interactive, understandable, voluntary, and free of coercion or undue influence.

II. DOCUMENTATION REQUIREMENTS

FDA regulations (312.62(b) state “The case history of each individual shall document that informed consent was obtained prior to participation in the study” for studies
utilizing either an experimental drug or device or an approved drug in an unapproved fashion. Institutional policy extends this requirement to all research that is more than minimal risk or that involves patients

1. who are in significant pain,
2. who have an altered mental status,
3. who may not be capable of giving informed consent,
4. who are in labor.

A. Minimal Risk Research

For behavioral studies, observational studies, and clinical studies, the presence of the properly executed informed consent document in the study file is adequate.

B. All Other Research

The following should be documented in the research file by the person designated to conduct the consent process:

1. The title of the study
2. That the inclusion/exclusion criteria for enrollment in the study have been met
3. That the purpose, procedures, risks, benefits (if any), voluntariness, and alternatives were discussed, understood, and accepted.
4. That the participant was given a copy of the informed consent.
5. The date and time that the consent was obtained.

For studies that involve PHI, the IRB expects signed documentation of the consent and HIPAA Authorization except in the following situations:

1. Full waiver of consent and HIPAA Authorization (e.g. chart reviews)
2. Phone or internet based research.
3. Other minimal risk studies in which the researcher has demonstrated the impracticability of obtaining signed documentation (e.g. cultural resistance to signing forms).

For studies that do not involve PHI, the IRB expects signed documentation except in the following situations:

1. Full waiver of consent (e.g. record reviews)
2. The only study procedures are procedures for which written consent is not normally required outside of research context.
3. Research in which the principal risk is breach of confidentiality and the consent document is the only link between the participant and the study.

II. THE CONSENT DOCUMENT

For studies in which signed documentation of consent is required, the IRB requires that subjects sign 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 in iRIS).

III. THE CONSENT PROCESS

The consent process contains four main components:

1. **Information:** “The reasonable person” standard should be used. This means that enough information is given to enable the person to decide whether or not to participate in the research. The person should clearly understand the range of risk, the potential benefits, if any, and the voluntary nature of participating in the study. Although each research study involving human subjects has unique elements, federal regulations and institutional policy require that all consent documents contain the following information elements:

   1. Introduction (with clear statement that this is research).
   2. Confidentiality of records statement (the mechanism for maintenance of confidentiality and who will have access to the research records and medical records).
   3. Compensation for injury statement (for greater than minimal risk studies).
   4. 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.
   5. Purpose of study.
   6. Description of study procedures (identifying any that are experimental), including use of randomization and placebo controls, if applicable.
   7. For studies of investigational articles, a statement that the purpose of the study includes evaluation of the safety and/or effectiveness of the test article.
   8. Duration of the subject’s participation.
   9. Potential risks, discomforts, and inconveniences of participation, especially for tests that carry significant risk of morbidity/mortality.
   10. Potential benefits of participation, clearly presented and not overstated.
   11. Alternatives (medical treatment or other courses of action, if any). If none, a statement such as, “You may choose not to participate in this study.”
12. Statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may withdraw from the study at any time without penalty or loss of benefits to which the subject is otherwise entitled.

13. If applicable, the following information should be included in the consent form:

   a. Reasons for involuntary termination of participation.
   b. A statement that the particular treatment or procedure may involve risks to the subject (or to the fetus, if the subject is or may become pregnant) that are currently unforeseeable.
   c. Potential costs to participants.
   d. Consequences of withdrawal (adverse health/welfare effects.
   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. Number of subjects (if it may have an impact on the decision to participate).
   g. Payments (incentives and/or expense reimbursements)

2. **Comprehension**: The manner and context in which the information is conveyed is as important as the information itself. The individual’s ability to understand is based upon that person’s level of intelligence, rationality, maturity, and language. The presentation of the information must be adapted to each person’s capabilities.

3. **Voluntariness**: Subjects must be told that they have the right to decline participation and to withdraw from the study at any time after it has begun.

4. **Signatures**: Signatures should be dated.

III. NON ENGLISH-SPEAKING RESEARCH PARTICIPANTS

1. The informed consent document must be “in language understandable to the subject” (45 CFR 46.116 and 117, and 21 CFR 50.20). Subjects who do not speak English should be presented with a fully translated consent document written in a language that is understandable to them.

   a. The Einstein IRB generally requires Spanish translations of consent documents for studies that plan to enroll 5 or more subjects with a potential for direct benefit to the participants.

      A. The use of a Spanish short form (see below) is permitted with IRB approval for studies that plan to enroll fewer than 5 subjects over the
lifetime of the study, provided that the subjects are given a Spanish schematic of the trial.

B. Studies providing an adequate scientific justification precluding Spanish translation may have the requirement waived.

b. Translations can be obtained through a translation service of your choice (see Appendix). An ‘Affidavit of Accuracy’ is required. Alternatively, the translation can be prepared “in house”. This 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, submit to the IRB the translated and back translated consents together with the names and qualifications of the individuals involved in the process.

c. The interpreter should sign and date the consent form. (For greater than minimal risks studies, the time should be included as well.)
   A. When a telephonic interpreter is used, the name and/or ID number should be recorded by the person obtaining consent along with the date (and time, for greater than minimal risks studies). “Telephonic Interpreter” should be noted in place of a signature.

2. If a non-English speaking subject is unexpectedly encountered, the investigator must rely on oral translation. The oral presentation of informed consent information is permitted, in conjunction with a short form written consent document in the language understandable to the subject (stating that the elements of consent have been presented orally) and a written summary of what is presented orally.

   a. If the person obtaining consent is not fluent in both English and the language of the subject, an interpreter (fluent in both English and the language of the subject) is required.
      A. This should be a professional member of the staff (e.g. physician, nurse, social worker, psychologist, study coordinator, etc.), or the hospital’s telephonic translation service may be used. The identity of the interpreter must be documented as described in III.1.c.
      B. If a subject refuses the use of an institutional interpreter, s/he may designate a family member or friend to interpret. The researcher must document in the record the subject’s refusal to use an institutional interpreter and the name and relationship of the person designated by the subject to interpret. Whenever a non-professional interpreter is designated by a subject, the researchers must consider issues of competence, appropriateness, conflicts of interest, and confidentiality.
b. A witness to the oral presentation is required. The witness should be fluent in both English and the language of the subject (if available), and must be physically present during the oral presentation and translation.
   A. When a professional staff member has served as interpreter, s/he also may serve as the witness.
   B. If the telephonic service is used, an employee, family member or friend accompanying the subject may serve as witness.
c. The subject must be given copies of the short form document and the summary. At the time of consent,
   A. the short form document must be signed by the subject (or the subject’s legally authorized representative);
   B. the summary (i.e. the English language informed consent document) must be signed by the person obtaining consent; and
   C. the short form document and the summary must be signed by the witness.
d. The IRB must receive all foreign language versions of the short form document (and study schematic as applicable) as a condition of approval under the provisions of 46.117(b)(2). Expedited review of these versions is acceptable if the protocol, the full English language informed consent document, and the English version of the short form document have already been approved by the convened IRB.

3. It is the responsibility of the IRB to determine which of the procedures at 46.117(b) is appropriate for documenting informed consent in protocols that it reviews.¹

IV. ILLITERATE ENGLISH-SPEAKING PARTICIPANTS AND THOSE WITH PHYSICAL DISABILITIES

“A person who can understand and comprehend spoken English, but is physically unable to talk or write, can be entered into a study if they are competent and able to indicate approval or disapproval by other means. If (1) the person retains the ability to understand the concepts of the study and evaluate the risk and benefit of being in the study when it is explained verbally and (2) is able to indicate approval or disapproval to study entry, they may be entered into the study. The consent form should document the method used for communication with the prospective subject and the specific means by which the prospective subject communicated agreement to participate in the study. An impartial third party should witness the entire consent process and sign the consent document. A video tape recording of the consent interview is recommended.” (FDA Information Sheet, 9/98)

¹ The IRB may approve use of the short form consent process for greater than minimal risk studies with no direct benefit on a case-by-case basis.
V. INCLUSION OF MINORS

See IRB policy for Enrollment of Minors in Research

VI. WAIVER OF INFORMED CONSENT, ALTERNATIVE CONSENT MECHANISM, WAIVER OF DOCUMENTATION OF INFORMED CONSENT

A waiver of informed consent, alternative consent mechanism, or waiver of the documentation of informed consent is permitted under the regulations. A CONSENT WAIVER FORM is included in the IRB Research Application. All waivers require IRB review and approval.

VII. INFORMED CONSENT TEMPLATES

Consent templates are available on the Einstein IRB website.
Appendix

The Einstein IRB will generally accept any certified translation by a professional translator. The following list is provided for your convenience but does not represent a specific endorsement by the IRB:

- Einstein offers an English-to-Spanish translation service. Investigators without external funding may request a fee reduction or waiver. The primary translator, Ms. Yovana Coupey, received her translation certification from the NYU School of Professional and Continuing Studies and also currently serves as Course Leader of the Medical Spanish Program. To request translation services, visit the Community Engagement Portal at: http://www.einstein.yu.edu/centers/ictr/.
- Inlingua Language Centers, 609-921-2080