

ABRAMSON CENTER FOR JEWISH LIFE

INFORMED CONSENT GUIDELINES

Informed consent is more than just a signature on a form; it is 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. Institutional Review Boards (IRBs) and investigators share responsibility for ensuring that the informed consent process is adequate. Thus, rather than an endpoint, the consent document should be the basis for a meaningful exchange between the investigator and the subject.

The consent form has two purposes: (1) to provide adequate information to potential research subjects to allow them to make an informed choice as to their participation in a study, and (2) to document their decision to participate.

The investigator is responsible for ensuring that informed consent is obtained from each research subject before that subject participates in the research study. The investigator is not required to personally conduct the consent interview, but remains ultimately responsible, even when delegating the task of obtaining informed consent to another individual knowledgeable about the research.

In addition to signing the consent, the subject/representative should enter the date of signature on the consent document, to permit verification that consent was actually obtained before the subject began participation in the study. If consent is obtained the same day that the subject's involvement in the study begins, the subject's case report form should document that consent was obtained prior to participation in the research. A copy of the consent document must be provided to the subject and the original signed consent document should be retained in the study records.

The IRB should be aware of who will conduct the consent interview. The IRB should also be informed of such matters as the timing of obtaining informed consent and of any waiting period (between informing the subject and obtaining the consent) that will be observed.

The consent process begins when a potential research subject is initially contacted. Although an investigator may not recruit subjects to participate in a research study before the IRB reviews and approves the study, an investigator may query potential subjects to determine if an adequate number of potentially eligible subjects is available.

The consent form may be either of the following:

1. A **written consent** document that embodies the elements of informed consent required by 45 CFR 46.116 (**Attached at end of document**).
 - This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator should give either the subject or the representative adequate opportunity to read it before it is signed.
2. A **short form written consent** document, stating that the elements of informed consent required by 45 CFR 46.116 have been presented **orally** to the subject or the subject's legally authorized representative.
 - When this method is used, there shall be a **witness** to the oral presentation. Also, the IRB shall approve a **written summary** of what is to be said to the subject or the representative.
 - Only the short form itself is to be signed by the subject or the representative.
 - 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 representative, in addition to a copy of the short form.

CONSENT FORM FORMATTING AND OTHER REQUIREMENTS

- 1) The title of the study shall be consistent on all documents (consent form, application, protocol, etc.).
- 2) There must be one inch of blank space from the top edge of the paper to the header and one inch of blank space on the bottom edge of the paper to the footer.
- 3) The title of the study shall be typed at the top of each page of the consent form. You may use a header if you wish.
- 4) Consent forms should be typed in large (preferably 14-point), bold print, labeled at the top "Consent Form". Consent forms from outside organizations doing research at the Center should label it "Consent Form" at the top and state the name of the institution in the heading.
- 5) Each page of the consent form should have pagination listed, preferably at the bottom of each page, as follows: Page 1 of 2, Page 2 of 2.
- 6) A current revision date must be entered in the footer of each page of the consent form. When submitting **revisions or continuation reviews**, the revision date needs to be updated each time it is submitted for approval.
- 7) At the top of the first page where the principal investigator's name is listed, use degrees (e.g., Ph.D., Ed.D., etc.). The first time an individual's name is listed in the consent form, use the degree rather than generic "Dr."
- 8) The page of the consent form that contains the signature blocks must contain some content.
- 9) Bolded questions or headings are required (**See Consent Form Checklist for required and optional elements**).
- 10) The reading level of the consent form must be at a level understandable by the subject population for whom the study is planned.
- 11) Do not include statements in the text of the consent form that state "I understand" as this makes an assumption that will not be tested and implies legal responsibility.
- 12) The consent form may not contain any exculpatory language, language that implies or asks subjects to forego any rights.
- 13) Only a consent form which contains a current revision date and IRB stamp may be used for consenting.
- 14) The individual obtaining consent should sign the consent form at the time the subject is signing rather than beforehand.
- 15) When a subject cannot read due to literacy issues or blindness, there must be a witness to the consent process who attests to the fact that the information read to or provided to the prospective subject was an accurate and complete representation of the information in the written consent form.
- 16) When there are multiple consent forms, it is strongly recommended to use the footer of the form to indicate the target population (e.g., participant consent, LAR consent, etc)
- 17) Passive "consent" is not permitted (return this form if you do not want to participate).
- 18) You must provide a copy of the consent form for the subject to retain.

CONSENT AND COGNITIVELY IMPAIRED INDIVIDUALS

Investigators are expected to put extra protections into place to ensure risks to cognitively impaired populations are minimized. Such risks include physical, psychological, and emotional risks. For example, investigators should revisit ability to provide informed consent multiple times over the course of a longitudinal study, should ask subjects to express their understanding of what they have consented to, and assess their understanding of the risks and benefits of the study. At the same time, such protections should not unnecessarily impede the opportunity for this population to participate in research activities. So, for example, a subject may be given several opportunities to assent to participate in a research study, provided that the requests do not upset or agitate the subject. Provisions should be made to train project staff in how to interact with subjects who may be displaying agitation or other negative affect.

In determining whether an individual can provide informed consent, the investigator shall develop procedures that rely on clinical judgment and, if deemed appropriate, supplemental clinical tests. Investigators shall also develop procedures that recognize that the ability to provide informed consent may change over time. That is, during the course of a longitudinal study, investigators may choose to assess the subjects' ability to provide and obtain from them informed consent multiple times.

AUDIO/VIDEO/PHOTOGRAPHIC RECORDING OF HUMAN SUBJECTS

If a research protocol involves the recording of research subjects, the Principal Investigator must include the following elements for consideration, in his/her protocol and informed consent form for submission to and review by the IRB:

Elements for consideration:

- Type of recording that will be utilized;
- Specific identifiers that will be recorded, e.g., partial facial features, full facial features, subject's name;
- People who will have access to the recording(s);
- Mechanisms in place to protect the confidentiality of the person(s) being recorded;
- Clear indication of when the recording(s) will be destroyed or that recording(s) will be kept indefinitely;
- Use(s) of the recording(s), including educational or commercial purposes, analysis by the research team; or future unspecified use;
- Compensation, if any, to subjects for allowing themselves to be taped.

If the taping is an integral part of the research and not an optional procedure, a separate informed consent document is not required. However, documentation of the considerations listed above must be included within the body of the informed consent document for the overall study. It is important that this information be clearly stated, preferably preceded by a heading, so that it is clear to the subject that a recording will be made.

If the recording is not required as part of the research procedures, then the consent document must include a specific statement indicating that participation in the research study is not contingent upon agreeing to be recorded. A separate consent signature for permission to record will be necessary. If a separate signature line is used, the considerations listed above must be included within the body of the informed consent document.

§46.116- Informed Consent Checklist - Basic and Additional Elements

Reference: <http://www.hhs.gov/ohrp/policy/consentckls.html>

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| | A statement that the study involves research |
| | An explanation of the purposes of the research |
| | The expected duration of the subject's participation |
| | A description of the procedures to be followed |
| | Identification of any procedures which are experimental |
| | A description of any reasonably foreseeable risks or discomforts to the subject |
| | A description of any benefits to the subject or to others which may reasonably be expected from the research |
| | A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject |
| | A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained |
| | 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 |
| () Research Qs | 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 |
| () Rights Qs | |
| () Injury Qs | |
| | 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 |
| Additional elements, as appropriate | |
| | 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 |
| | Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent |
| | Any additional costs to the subject that may result from participation in the research |
| | The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject |

Additional elements, as appropriate (cont.)

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| | 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 |
| | The approximate number of subjects involved in the study |

§46.117 Documentation of Informed Consent Checklist

a. Except as provided in paragraph "c" of this section, informed consent shall be documented by the use of a written consent form approved by the IRB, and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

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| WRITTEN | <p>The consent form may be either of the following:</p> <p>1. A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator should give either the subject or the representative adequate opportunity to read it before it is signed.</p> |
| DONE ORALLY | <p>2. A short form written consent document, stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. 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 representative, in addition to a copy of the short form.</p> |
| WAIVER of req't for signed form | <p>c. An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, if it finds either:</p> <p>1. That 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 the subject's wishes will govern; or</p> <p>2. 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.</p> <p>In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.</p> |

IRB Latitude to Approve a Consent Procedure that Alters or Waives some or all of the Elements of Consent

§ 46.116 - An IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

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| | C: 1. 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: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and |
| | C: 2. The research could not practicably be carried out without the waiver or alteration. |
| | D: 1. The research involves no more than minimal risk to the subjects; |
| | D: 2. The waiver or alteration will not adversely affect the rights and welfare of the subjects; |
| | D: 3. The research could not practicably be carried out without the waiver or alteration; and |
| | D: 4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation. |

CONSENT FORM – Do's and Don't's

1. Use the current IRB-approved version

- ✓ **DO** update your consent form, when you change study procedures and/or identify new risks to participants.
- ✓ **DO** obtain IRB approval before using a revised consent form.
- ✓ **DO** keep all original signed consent forms with research study records.

Don't use expired consent forms.

Don't alter approved consent forms.

- ✓ **DO** verify that each participant is given a signed *and* dated copy of the consent form at the time of initial consent.

2. Ensure all items are completed

- ✓ **DO** verify that participant answers all questions on the consent form.
- ✓ **DO** verify that participant follows consent form instructions - or consider modification of the consent form, if appropriate.

Don't confuse initials with checkmarks.

Don't include consent instructions that you do not follow; it may be considered noncompliant.

CONSENT FORM – Do’s and Don’t’s (cont.)

3. Get all necessary signatures and dates

- ✓ **DO** verify that person obtaining consent (POC) has signed, when applicable.
- ✓ **DO** verify that signers complete **all applicable lines** on consent form.

Don’t leave representative’s authority to act undocumented.

✓ **TIP**

Use sticky tabs to indicate all pages that need signatures and/or other responses from signer, so POC can quickly check the consent form for completeness, before giving the signer a copy.

- ✓ **DO** verify **participant enters date of signing** at the time of consent. This is “Best Practice”.

Don’t enter dates for participants – they must write it themselves

- ✓ **DO** verify signature **dates** are complete, formatted as consistent with your study SOPs, and legible.

Don’t ignore ambiguous dates (Ju = June or July?). Explain them, if needed.

4. Using PHI? Ensure HIPAA Authorization is signed & dated

- ✓ **DO** verify that participant signs and dates **HIPAA Authorization**, if applicable, before using protected health information.

Don’t use data, if signed HIPAA Authorization is not obtained, as required.

Code of Federal Regulations

TITLE 45 PUBLIC WELFARE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 46 PROTECTION OF HUMAN SUBJECTS

§46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the 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.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) 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 which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) 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;

(7) 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; and

(8) 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.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(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; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) 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: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) 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.

(Approved by the Office of Management and Budget under Control Number 0990-0260.)

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. 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 representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That 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 the subject's wishes will govern; or

(2) 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.

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

(Approved by the Office of Management and Budget under Control Number 0990-0260.)

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

**ABRAMSON CENTER FOR JEWISH LIFE
INFORMED CONSENT GUIDELINES**

By signing below, I acknowledge that I have received a copy and read the Informed Consent Guidelines, and I agree to follow to the rules and guidelines.

Signature

Date

Printed Name

PLEASE SIGN AND RETURN TO THE ABRAMSON CENTER IRB ADMINISTRATOR