Consent procedures for qualitative research, participant observations, oral history: how are they different?

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Criteria for the Approval of Research

Main Criteria
(45 CFR §46.111/ 21 CFR §56.111)
(a)(1) – Minimization of risks
(a)(2) – Risk-benefit relationship
(a)(3) – Equitable selection
(a)(4) – Consent process
(a)(5) – Consent documentation
(a)(6) – Data monitoring
(a)(7) – Privacy/confidentiality

The IRB must determine that criteria delineated in all three boxes are met.

Consent Process
(45 CFR §46.116, 21 CFR §50.20, §50.25)
Intro – Consent process
(a)– Required disclosures
(b)– Additional disclosures
(c)– Waiver #1
(d)– Waiver #2

Consent Documentation
(45 CFR §46.117, 21 CFR §50.27, §56.109)
(a) – General
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Slide courtesy of Jeffrey Cooper, MD, MMM
Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

(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:
Required disclosures
45 CFR 46.116 (a)

(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;
45 CFR 46.116(a)

(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;
45 CFR 46.116(a)

(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;
45 CFR 46.116(a)

(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
45 CFR 46.116(a)

(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:
45 CFR 46.116(b)

(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.
Informed consent is a prerequisite for research participation

- Regulations allow IRBs to waive the requirement for consent, if the IRB finds that certain conditions are met

- Unless waived by the IRB, consent is required
Documentation of Consent
Criteria for the Approval of Research

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Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.
(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.
Short Form continued...

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.
Either may be appropriate, under the right circumstances
IRB should review and approve proposed use in advance
Short form should not be used as “an easy way out”
- There are additional provisions (e.g. witness) to compensate for absence of long form in language the subject can understand
- May be appropriate for unexpected, incidental enrollment of subject who is
  - illiterate?
  - does not read English?
  - does not read language into which the long form has been translated?
- Some IRBs provide template of the language to be used in short form
Regulatory differences

- DHHS requires consent documents to be signed
- FDA requires consent documents to be signed and dated
- DHHS and FDA require participants be provided copies of consent documents, which do not have to be signed and dated
- VA and ICH–GCP require participants be provided signed and dated copies of consent documents
DHHS and FDA differences

- DHHS requires a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
- FDA requires a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.
Regulatory Options for Waivers
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# Mechanisms for Waiver of Consent

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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.
prac·ti·ca·ble  [prak-ti-kuh-buhl] adjective
   1. capable of being done, effected, or put into practice, with the available means; feasible: a practicable solution.
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:

- 45 CFR 46.116(d), but not FDA
Research involves no more than minimal risk to the subjects;

Waiver or alteration will not adversely affect the rights and welfare of the subjects;

Research could not practicably be carried out without the waiver or alteration; and

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

45 CFR 46.116(d), but not FDA
Waiver or Alteration of Informed Consent

- Third criterion refers to practicability of research
  - Question is whether the research could be conducted without the waiver, and **not whether it is practicable or possible to obtain consent**

- Fourth criterion might apply to circumstances where...
  - some information is withheld at the outset to allow unbiased responses and valid conclusions
    - e.g., debriefing procedure for “deception research”
  - information of clinical relevance is obtained under waiver
    - e.g., follow up after retrospective medical records review
Waiver or Alteration of Informed Consent Process

- IRB must both *find and document* that criteria are met
- May apply to some or all elements of consent
- May be considered for some types of research where it is not relevant or meaningful to include all elements
- May be necessary in order to obtain valid results in some research designs
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(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.
The Regulations are flexible

- IRBs are not always flexible—reluctant to grant waivers
- Researchers may not know of these regulatory options
- Subjects/Participants may be suspicious of written documentation requirements
- Consider a default to a justification for written consent in minimal risk research