INFORMED CONSENT

Adapted from the Code of Federal Regulations - 45 CFR 46.116

4.1 A process - not a form

Since subjects retain the right to withdraw from a study, consent is an ongoing process. It starts

- Explain the purposes of the research;
- Report the expected duration of the subject's participation;
- Describe the procedures to be followed;
- Identify any procedures or products that are experimental;
- Explain why the subject is eligible to participate;
- Describe any foreseeable risks or discomforts that the subject will bear;
- Describe any benefits to the subject or to others that can reasonably be expected;
- Disclose appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- Explain the confidentiality of any records that identify the subject;
- Explain, for research that involves physical contact or physical activity, whether compensation or medical treatment will be available if the subject is injured and where to get further information about this;
- Identify people who can answer questions about the research, including the principal investigator and a neutral third party who can explain the rights of research subjects and who should be contacted if the subject suffers injury related to the research (the "out-of-

- Identify pilot or feasibility studies. Some subjects are willing to participate in a study that has a track record but are not willing to participate in a pilot phase. Participants need to be told if they are among the first people to receive the treatment or intervention.

- Inform women of child-bearing age whenever a pregnancy test is part of the research protocol. They must also be told whether such tests will be repeated during the course of a research project and whether they must use contraceptives to participate in a clinical trial. Men, too, need to be told if contraception is recommended for them.

- Make clear whether the procedures or drugs used in a study are standard, standard but used in a non-standard manner, or experimental.

If the study involves experimental drugs or devices, inform the subject that the research and medical records may be reviewed by the Food and Drug Administration (FDA) and by the company sponsoring the research.

Avoid stating that drugs or devices have been approved for human use by the FDA if any part of the study is outside the licensed and approved indications of those items. Patients interpret such a claim to mean that the FDA has licensed and approved this use of the item, not that the FDA has merely granted permission to investigate the use of the item.

Distinguish between consent to a study and consent to a treatment. In "treatment studies" (in which a patient who is undergoing a treatment is given a choice between undergoing it as part of a study or undergoing it in a standard health care context), the study and the treatment involve different benefits, risks, and alternatives.

If consent to the research and consent to the treatment can be confused, they should be presented in separate consent forms.

In discussing risks, the subject should be informed that there might not be any benefit to being treated "on study" instead of "off study."

In discussing risks, the subject should be informed whether the risks of being treated "on study" are different from the risks of being treated "off study."

In discussing alternatives, the subject should be told whether the study treatment (drug or device) is or is not available outside of the study context.

4.4 What must be said about the conduct of the research

Confidentiality

The researcher should describe the level of confidentiality of the research data and the measures that will be taken to ensure that confidentiality is maintained.

The phrase "only aggregate data will be presented" is appropriate only when it is true. Strictly understood, it means that the researcher will not describe a patient individually, even if the patient has a unique event. What is more common, however, and what the subject should be told, is that the subject's identity will not be disclosed.

Finder's fees

Companies sometimes offer researchers incentives for recruiting subjects or conducting research on an investigational drug or device manufactured by the company. The incentive may be either a monetary fee or a donation of equipment or materials. Researchers should report these incentives to the IRB, which may require that this information be disclosed to prospective subjects.

Payments to research subjects

If researchers plan to compensate subjects for participating in a study, the consent form must describe the terms of payment and the conditions under which subjects would receive partial payment or no payment (for example, if they withdraw from the study before their participation is completed).

In contrast, examples of closed-ended and far less useful questions are:

"Do you understand?"

"Do you have any questions?"

"Do you see that there are some risks to taking this drug?"

Instead of furthering the discussion, closed-ended questions tend to bring it to a stop and so should be avoided.

4.6 Documenting the subject's consent with a consent form

Once a subject understands a study and has expressed a willingness to participate, researchers must document the subject's consent with a c

- Print the IRB code number assigned to the study on the consent form.

- Include a consent form version date. This date should be updated each time a new version of the consent form is approved by the IRB.

- Write in the second person ("you") rather than the first person ("I"), and avoid shifting from one to other.

- Avoid strike-out formats (such as "You/Your spouse/Your child"), since they depersonalize the form and often make it difficult to read.

- Keep the description of the study as brief as possible, even if the study is complex. The details can be placed in an appendix.

- List only the major risks associated with an experimental drug or procedure. Some effective consent forms simply state, "The risk of being on this study is that the treatment may not turn out to be as successful as we hope, and may even be less effective than our previous standard treatment. In addition to this risk of being on the study, the drugs used in the treatment have their own risks and side effects. The most important ones are: ..." Again, the details go in an appendix.

- Use paragraph headings and illustrations. Use flow charts or calendar-like tables to

dysplasia a- abnormal cells
edema - increased fluid
efficacy - effectiveness
extravasate - to leak outside of a blood vessel
hematoma - a bruise, a black and blue mark
heparin - lock needle placed in the arm with blood thinner to keep the blood from clotting
monitor - check on, keep track of, watch carefully
morbidity - undesired result or complication
mortality - death or death rate
necrosis - death of tissue
oncology - the study of tumors or cancer
percutaneous - through the skin
placebo - a substance of no medical value, an inactive substance
PRN - as needed
protocol - plan of study
random - by chance, like the flip of a coin
relapse - the return of a disease
retrospective - looking back over past experience

4.7 When to submit the form to the IRB

Researchers must submit consent forms when they first apply for IRB review and approval, and when they apply for continuing review. Since the standards for consent forms change over time, in part due to changes in regulatory mandates and community styles and expectations, the IRB reviews the form at renewal to ensure that it is up to date.

In addition, the IRB may ask researchers to modify consent forms at other times, when circumstances warrant. Any revisions made to a previously approved consent form must be submitted to the IRB for approval before use.

4.8 When the consent requirement can be waived

On rare occasions, the federal regulations for human subjects research allow a waiver of the requirement for informed consent. For example, a waiver is possible if a study investigates certain aspects of public benefit or service programs. Also, either a waiver or a consent process that omits or modifies the essential elements of informed consent is possible if the IRB finds that:

- The research involves no greater than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;

- The research would be impracticable without the waiver or alteration; and
- The subjects will be informed of the study when it is over (if at all possible).

Only the IRB can waive or modify the consent process. Researchers are not authorized to make this decision.

4.9 The Certificate of Confidentiality - an additional protection

A "Certificate of Confidentiality" protects subjects' anonymity by protecting research records from subpoena. The assistant secretary for health in the Department of Health and Human Services issues the certificate under two conditions: the research is on a sensitive topic, and the protection is necessary to achieve the research objectives. The certificates are granted sparingly. The study's funding source is not relevant to the decision.

The certificate goes beyond the consent form in ensuring confidentiality and anonymity. Without the certificate, researchers can be required by a court-ordered subpoena to disclose research results (usually as part of a criminal investigation of the subjects).

Research can be considered "sensitive" if it involves the collection of:

- Information about sexual attitudes, preferences, practices;
- Information about the use of alcohol, drugs, or other addictive products;
- Information about illegal conduct;
- Information that could damage an individual's financial standing, employability, or reputation within the community;
- Information in a subject's medical record that could lead to social stigmao73 Tw.4 0 TDty;

second signature is not reasonably available. A single signature is sufficient if only one parent has legal responsibility for the care and custody of the child or if one parent is deceased, unknown, or incompetent. Parental permission is documented in a form similar to an adult subject consent form, tailored to invite "your child" to participate rather than "you".

On rare occasions, the IRB can grant a "waiver of parental consent," but only if the research will yield great benefit to the population being studied and if obtaining parental consent would pose a considerable risk to the potential subjects.

Once parental permission has been obtained, the agreement of the child is required. Parental permission overrules a child's decision not to participate in therapeutic settings.

The child's agreement is documented with an "assent form," a child-friendly document that outlines the essential information about the research. All children 8 years through 17 years old should be given an opportunity to assent, since most children 8 years old have the cognitive and emotional maturity to understand a research project and to decide whether they want to participate in it.

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In instances where critical therapeutic research is involved, parental permission overrules a child's decision to participate. In such cases, a child's dissent would not be honored; therefore an "information sheet" rather than an assent form should be used. The information sheet should include the same info found in an assent form except:

- It should not indicate that the decision to participate is up to the child nor that it is okay to say no.

- It should not include signatures.

Subpart D of 45 CFR 46.401-409, "Additional Protections for Children Involved as Subjects in Research," outlines the conditions of participation for minor subjects.

4.11 Consent and language barriers

When planning research which will include non-English speaking subjects, researchers should prepare both English-language and translated consent forms for proposals involving non-English-speaking subjects. An explanation of the translations and the expertise of the translator should be provided for IRB review. The IRB may consult with language experts or require a "back-translation" into English.

As an alternative to translated consent forms, an oral presentation of informed consent information in conjunction with a short form written consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally can be approved by the IRB. A witness to the oral presentation is required, and the subject must be given copies of the short form document and the summary.

When this procedure is used with subjects who do not speak English:

- The oral presentation and the short form written document (see sample attached) should be in a language understandable to the subject;

- The IRB-approved English language informed consent document may serve as the summary; and

- The witness should be fluent in both English and the language of the subject.

At the time of consent, the following signatures should be obtained:

- The short form document should be signed by the subject (or the subject's legally authorized representative);

- The summary (i.e., the English language informed consent document) should be signed by the person obtaining consent as authorized under the protocol; and

- The short form document and the summary should be signed by the witness. When the person obtaining consent is assisted by a translator, the translator may serve as the witness.

The IRB must receive all foreign language versions of the short form document as a condition of approval (see 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.

Download short forms in different language (languages available: Arabic, Cambodian, Croatian, French, Hmong, Lao, Oromo, Russian, Somali, Spanish, Vietnamese)

Sometimes a subject understands English but does not read or write English. An impartial witness should document that the subject understands the study and the consent process and consented to participate.

4.12 Cross Cultural Consent Issues