Attachment A: Approved by SACHRP July 20, 2011

Guidance on Applying the Regulatory Requirements for Research Consent Forms: What Should and Should Not be Included?

Consent forms must convey basic elements of information as required by federal regulations. It is essential that consent disclosures be tailored to the research at hand and focus on the information that prospective participants need to make an informed decision. Conversely, standard disclaimers or statements without meaningful content may not help subjects and should be discouraged. To assist in focusing and simplifying consent forms, we offer the following clarifications concerning what federal regulations do and do not require. In cases where a required element is not relevant or applicable, IRBs do not need to document a waiver of the element in their minutes. It is the responsibility of the person seeking consent to ensure that the process includes sufficient detail to enable each potential subject to make an informed and voluntary decision.

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§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

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1. **What has to be included? Consent forms for research should identify and describe procedures that are experimental or that are performed solely for research purposes.**

    a. Consent forms for biomedical research should focus on *things that would happen because the person participates in research* that otherwise would <u>not</u> happen as part of his or her clinical care.

        Examples:

        - Having treatment randomly selected rather than determined by medical practice
        - Undergoing an experimental intervention (e.g., drug, device, procedure)
        - Taking *extra* blood or tissue during a procedure needed for clinical care
        - As part of the clinical trial, the researcher will access and use specimens/data that were originally collected for clinical purposes

    A special example of something that would happen because the person takes part in research that otherwise would not happen is when research participation places *constraints* on the person's clinical care.

        - Example: In a trial of a new chemotherapy agent, the research protocol prescribes the dose and schedule for adjuvant radiation therapy that must be followed. Even though this prescription reflects "standard of care," research participation constrains adjustments to the radiation dose or schedule that the participant's physician might otherwise recommend.

Such constraints should be described in consent forms (including the risks) as a consequence of research participation.

b. Similarly, consent forms for non-biomedical research (e.g., social/behavioral studies) should identify and describe procedures that are experimental or that are performed solely for research purposes. In other words, consent forms should focus on *activities that would happen because the person participates in research.*

- Example: Survey of risk-taking behaviors by adolescents who are already enrolled in a drivers education program. In this case, the consent form would describe the purpose and procedures of the survey research rather than details of the educational program.

2. What does *not* have to be included?

a. Activities that would occur if he or she were not participating in research do not need to be described in consent forms.

- Removing this kind of information represents a potential opportunity to shorten/simplify consent forms.
- Consent forms may refer to an appendix or educational materials that contain this information, or state "your doctor will tell you more about the procedures needed for your clinical care."

b. While there may be circumstances where it may be relevant or appropriate to note that here are no experimental procedures, a statement to that effect is not required by the regulations and consequently no requirement to document that in the minutes of the IRB meeting.

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§46.116(a)(2) A description of any reasonably foreseeable risks or discomforts to the subject

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1. What has to be included?

a. Consent forms should identify reasonably foreseeable risks, not all possible risks.

- Consent forms should address risks arising from research participation (not from things that would happen anyway).

b. IRBs and investigators have a responsibility to review information regarding potential risks and to assess relatedness, severity, and likelihood. Risk statements in consent forms should be simplified such that the information included is understandable and relevant to the subject population. Detailed descriptions of all potential risks are counterproductive if they do not provide potential subjects with useful information and may inadvertently distract subjects from relevant data.

- Example: In a previous study, a single subject experienced a tonic clonic seizure. First the IRB must determine whether this is a reasonably foreseeable risk about

which potential subjects should be aware. If so, the consent form might simply state "There is a small risk of seizures" rather than providing a long description of the circumstances of the single subject.

The investigator may choose to provide additional information placing this risk in context during discussions with prospective participants.

2. What does *not* have to be included?

a. When there are no reasonably foreseeable risks and to participants, consent forms may include statements to this effect but such statements are not required by the regulations.

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

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1. What has to be included?

a. Consent forms should identify reasonably expected benefits, not all theoretical benefits.

- Consent forms should address benefits arising from research participation (not from things that would happen anyway).

b. When research participation involves greater than minimal risk but no reasonably foreseeable benefits, consent forms should alert prospective participants that there is no anticipated benefit to them. Including this statement may help minimize the presumption of benefit or therapeutic misconception.

2. What does *not* have to be included?

- When there are no reasonably expected benefits to participants, consent forms may include statements to this effect but such statements are not required by the regulations.
- A statement that individuals "may or may not benefit from participation" confers no useful information and may in fact be misleading in some circumstances. Investigators and IRBs should strive to describe as accurately as possible the nature and likelihood of any anticipated benefits.

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

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1. What has to be included?

- Consent forms should identify appropriate alternatives to the research intervention. For example, in research on pain management following tooth extraction, the consent form

might provide information about standard analgesics available outside of any research study.

2. What does *not* have to be included?

- When the only alternative to research participation is not to participate, it is not necessary to include a statement to this effect. "Not participating" is already fully addressed in sections of the form emphasizing that participation is voluntary; see §46.116(a)(8).

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

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1. What has to be included?

- When appropriate, consent forms should explain that research records will be kept confidential. General descriptions of the measures that will be taken to protect confidentiality can be described when it helps inform the prospective participant's decision.

- Absolute confidentiality should not be guaranteed. Participants should be informed of limits to confidentiality, including circumstances under which confidentiality will not be maintained (e.g., legal requirements, mandated reporting).

2. What does *not* have to be included?

- Detailed technical descriptions of the measures in place to maintain confidentiality (e.g. encrypted FTP sites, locked file cabinets) are not likely helpful to subjects, under most circumstances.

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§46.116(a)(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

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1. What has to be included?

- For research involving *more than minimal risk*, consent forms should provide explanations about the availability of compensation and medical treatment, consistent with sponsor and institutional policies.

2. What does *not* have to be included?

- For research involving *no more than minimal risk*, these explanations are not required and may be unnecessarily alarming, particularly when the risks do not involve physical injury. IRBs are not required to document in their minutes that this statement is not required.

§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

- Providing contact information for each of these circumstances is appropriate for all study types where informed consent is required unless the IRB approves and documents a waiver of that element.

§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

- Including these statements is appropriate for all study types where informed consent is required unless the IRB approves and documents a waiver of that element.

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

- **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**
- **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**

1. What has to be included?

a. It is up to the IRB to determine in a particular instance whether some or all of the above additional elements must be included in the consent form for a particular study. The IRB should make this determination based on the nature of the research and its knowledge of the local research context (from "Informed Consent-FAQs" http://answers.hhs.gov/ohrp/categories/1566)

b. In general:

- Several of these elements may be most appropriate for clinical trials and may be less applicable to other kinds of studies.
- When determining whether to include any particular element, a key consideration is the likely relevance of the information to prospective participants' decision**s** about whether to take part.

2. What does *not* have to be included?

- These additional elements are particularly susceptible to automatic inclusion of boilerplate language in every consent form. Removing information that is not applicable to a particular study represents an important opportunity to shorten and/or simplify consent forms.