Guide 608: Informed Consent Requirements

Based on the revised Common Rule 45 CFR 46.116; compliance date: January 21, 2019

Summary of Key Revisions

- Changes to the PROCESS of obtaining informed consent, including providing information that a "reasonable person" would want to have about the study, as well "key information" to facilitate a prospective participant's decision about whether to participate in the research
- New requirements for the BASIC and ADDITIONAL elements of consent
- Electronic consent is allowed, but a written copy must be provided to the participant
- Changes to the waiver and alteration criteria for consent
- New provision that allows investigators to obtain information or biospecimens for the purpose of Screening, Recruiting, or Determining Eligibility, without the informed consent of prospective participant under certain conditions
- New requirement for clinical trials to post a copy of the IRB-approved consent form to a federal website

Reasonable Person Standard: 46.116 (a)(4)

*A prospective subject (or the subject's legally authorized representative) must be provided with the information that a **reasonable person** would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.*

- "Reasonable person" remains undefined
- Allow sufficient time to discuss the research and answer questions
- Provide more information when requested

NEW

Key Information: 46.116(a)(5)(i) *Informed consent must begin with a concise and focused presentation of the **key information** that is most likely to assist a prospective subject (or the subject's legally authorized representative) in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.*

NEW

- The fact that consent is being sought for research and that participation is voluntary
- The purpose of the research, expected duration of the subject's participation, and procedures to be followed in the research
- The reasonably forseeable risks or discomforts to the prospective subject
- The benefits to the prospective subject or others that may reasonably be expected
- Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject

Source: preamble to the Final Rule briefly describes the five factors at beginning of an informed consent form that would encompass the key information.

Basic Elements of Informed Consent: 46.116(b)

There are no changes to the eight (8) previous basic elements of informed consent, however, a new requirement was added (#9 below).

	Basic Elements	**Citation**	
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	46.116(b)(1)	
2	A description of any reasonably foreseeable risks or discomforts to the subject	46.116(b)(2)	
3	A description of any benefits to the subject or to others which may reasonably be expected from the research	46.116(b)(3)	
4	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject	46.116(b)(4)	
5	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained	46.116(b)(5)	
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	46.116(b)(6)	
7	An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject	46.116(b)(7)	
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	46.116(b)(8)	
9	One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens: i. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or ii. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.	46.116(b)(9)	**NEW**

Additional Elements of Informed Consent: 46.116(c)

There are no changes to the six (6) previous additional elements of informed consent, however, three new requirements were added (#7-9 below).

	Additional Elements, to be used as appropriate	Citation	
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) that are currently unforeseeable	46.116(c)(1)	
2	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the subject's legally authorized representative's consent	46.116(c)(2)	
3	Any additional costs to the subject that may result from participation in the research	46.116(c)(3)	
4	The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject	46.116(c)(4)	
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	46.116(c)(5)	
6	The approximate number of subjects involved in the study	46.116(c)(6)	
7	A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit	46.116(c)(7)	**NEW**
8	A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions	46.116(c)(8)	**NEW**
9	For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)	46.116(c)(9)	**NEW**

General Waiver or Alteration of Consent: 46.116(f)(3)

There are no changes to the four (4) existing waiver conditions, however, an additional criterion was added. In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

	Waiver or Alteration Criterion	Citation	
1.	The research involves no more than minimal risk to the subjects	46.116(f)(3)(i)	
2.	The research could not practicably be carried out without the requested waiver or alteration	46.116(f)(3)(ii)	
3.	If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;	46.116(f)(3)(iii)	**NEW**

4.	The waiver or alteration will not adversely affect the rights and welfare of the subjects; and	46.116(f)(3)(iv)	
5.	Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.	46.116(f)(3)(v)	

Screening, Recruiting, or Determining Eligibility: 46.116(g) NEW

An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

	Screening, Recruiting, or Eligibility Determination Criterion	Citation	
1.	The information will be obtained by communicating with the prospective subject or the subject's legally authorized representative; or	46.116(g)(1)	**NEW**
2.	The information will be obtained by accessing records or stored biospecimens.	46.116(g)(2)	**NEW**

Posting of Clinical Trial Consent Form: 46.116(h) NEW

The revised Common Rule requires that the consent form for any clinical trial conducted or supported by a Common Rule department or agency must be posted on a publicly available federal website. The informed consent form must be posted after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol (46.116(h)(3).

At this time, two publicly available federal websites that will satisfy the consent form posting requirement, as required by the revised Common Rule, have been identified: ClinicalTrials.gov and a docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021). HHS and other Common Rule departments and agencies are developing instructions and other materials providing more information to the regulated community about this posting requirement.

Clinical Trial definition: 46.102(b)

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes

- This definition is new under the revised Common rule
- Mirrors the more broad NIH definition

Documentation of Informed Consent: 46.117

*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 **(including in an electronic format)** by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form.*

The consent form may be either of the following:

Written 46.117(b)(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.

Oral Presentation 46.117(b)(2)

- A short form written informed consent form 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, and that the key information required by 46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's legally authorized 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 subject's legally authorized representative, in addition to a copy of the short form.

Waiver 46.117(c)(1)

- An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all of the subjects if it finds any of the following:
  - 1. That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) 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; or
  - 3. If the subjects or legally authorized representatives are members of a **distinct cultural group or community in which signing forms is not the norm,** that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanisim for documenting that informed consent was obtained. **NEW**
- In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

UH HSP Note: "Broad Consent" requirements under the revised Common Rule are not referenced in this guidance document because UH has opted not to utilize broad consent at this time.