Informed Consent

Informed Consent Documents

Updates to the regulatory language represent an effort to improve and clarify informed consent. Specifically, the aim is to ensure that consent documents provide essential information that a reasonable person would want to know to make an informed decision about participation, in sufficient detail, and in a manner that facilitates understanding. Updated informed consent document templates designed to assist investigators in meeting these new requirements are available on the IRB website.

New requirements for the informed consent document:

New focus on how information is presented to facilitate understanding

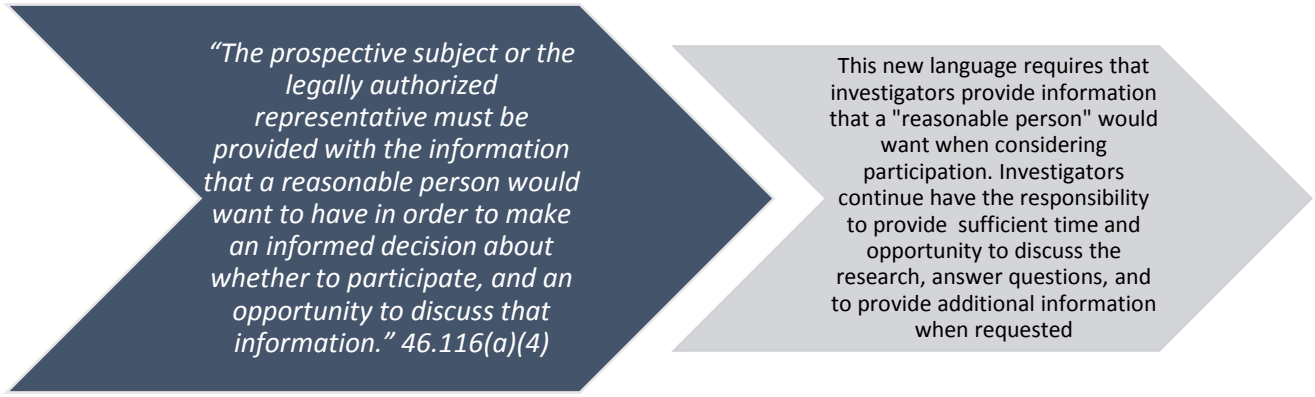
New Concise and Focused Key Information section required for longer consent forms

New required consent element related to use of data/biospecimens beyond current study

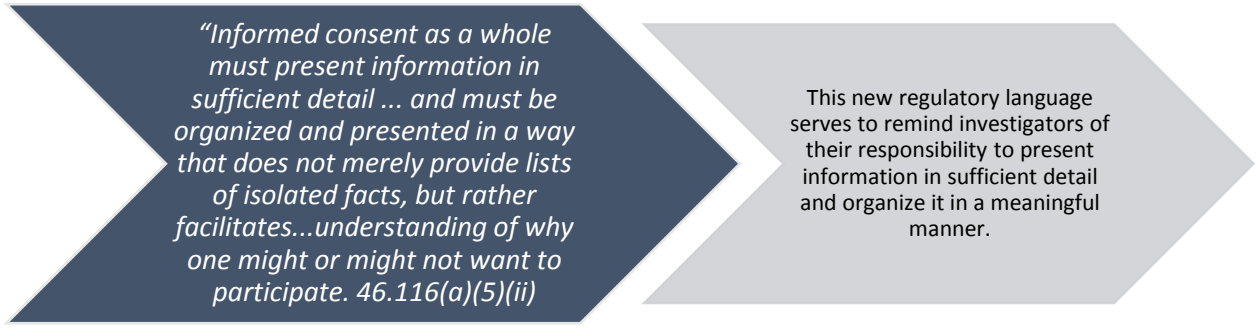
3 new Additional Elements of Consent
(when applicable)

Updated: General Consent Requirements

In general, requirements of this section of the regulations remain the same. However, the 2018 updates represent an increased regulatory focus on presenting information in a manner that facilitates prospective participants' understanding. While this has always been the goal of informed consent, the revisions include a new explicit requirement for providing 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."*



and



Researchers should work to craft informed consent documents to meet these requirements. Iowa State IRB's informed consent templates (link) are updated, however, researchers must carefully consider the needs of the participants included in a given study when drafting meaningful consent documents.

New: Concise and Focused Key Information Section

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 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.

There is currently no federal guidance on interpreting this new requirement. Iowa State's IRB considers, in general, consent forms that are already concise (i.e. 4 or few pages) do not need to include the new concise and focused summary of key information.

The preamble to the 2018 Common Rule includes a reference to five factors expected as part of a concise explanation:

1	The fact that consent is being sought for research and that participation is vountary
2	The purposes of the research, expected duration of the prospective subject's participation, and the procedures to be followed in the research
3	The reasonably foreseeable risks or discomforts to the prospective subject
4	The benefits to the prospective subject or others that may reasonably be expected from the research
5	Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.

Investigators with projects necessitating longer consent documents (greater than 4 pages) should include a concise and focused key information summary that covers the five points noted above. Researchers must carefully consider the informational needs of the targeted subject population when creating this summary. The key information summary should be included at the beginning of the informed consent document.

New: Required Element of Informed Consent

The updated regulations include no changes to the previously required eight basic elements of consent, but add a **new required element**. The aim of the new consent element is to inform participants of the possible future use or distribution of their data/biospecimens beyond the current study.

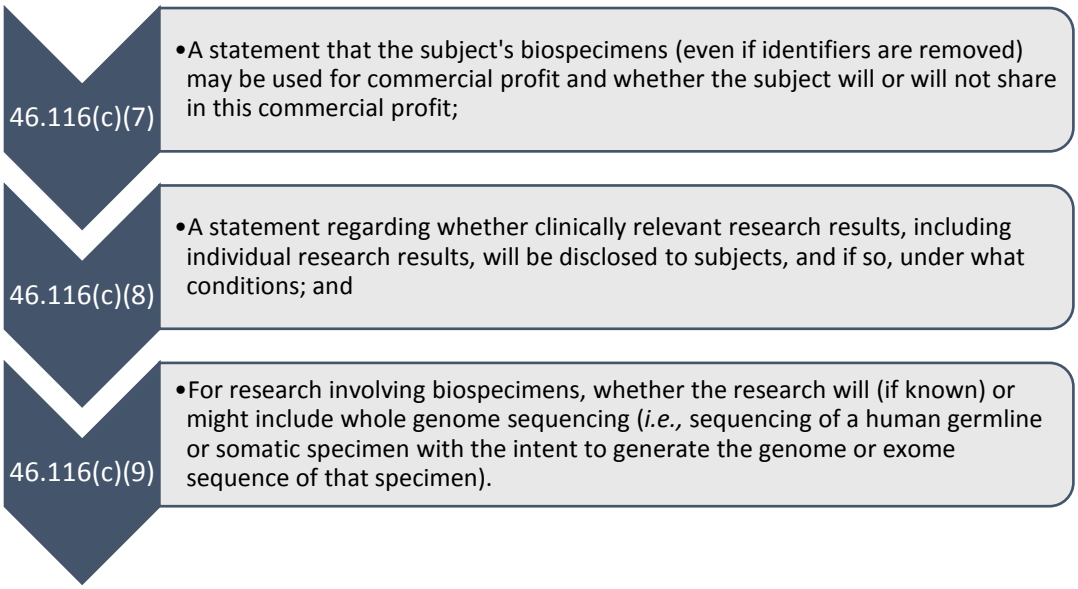
Iowa State IRB's informed consent templates are updated with suggested language meeting this requirement.

Investigators should include one of the following statements to describe plans for future use of the data (reference to biospecimens may be removed, if not applicable to the study):

> Information about you, including your biospecimens, will *only* be used by the research team for the project described in this document.
>
> **OR**
>
> Information about you, including your biospecimens, collected for this study may be shared with other researchers. It may also be used for other research studies. Any personal information (or details) that could identify you will be removed or changed before information is shared with other researchers. We will not ask you for additional permission before sharing the information.

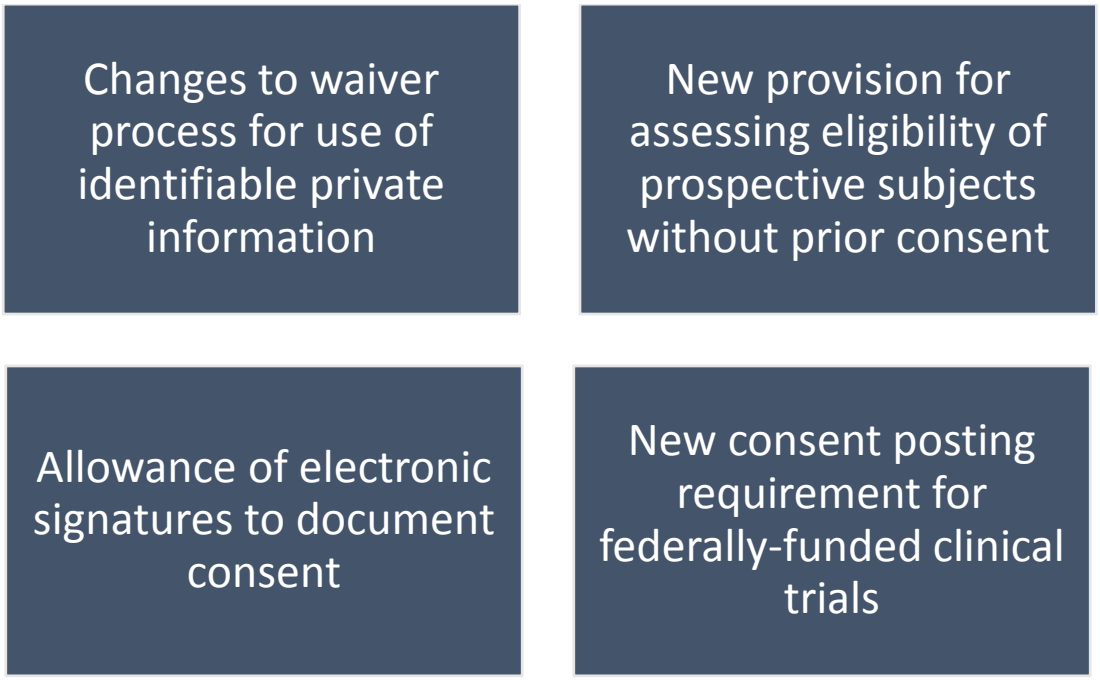
New: Additional Elements of Informed Consent

No changes were made to the six additional elements of informed consent included in the Pre-2018 regulations. The 2018 Common Rule adds three additional elements of consent that, when appropriate, are required as part of informed consent. These elements are only necessary when applicable to the study.



Iowa State IRB's informed consent templates are updated with suggested language meeting these requirements.

Informed Consent Process

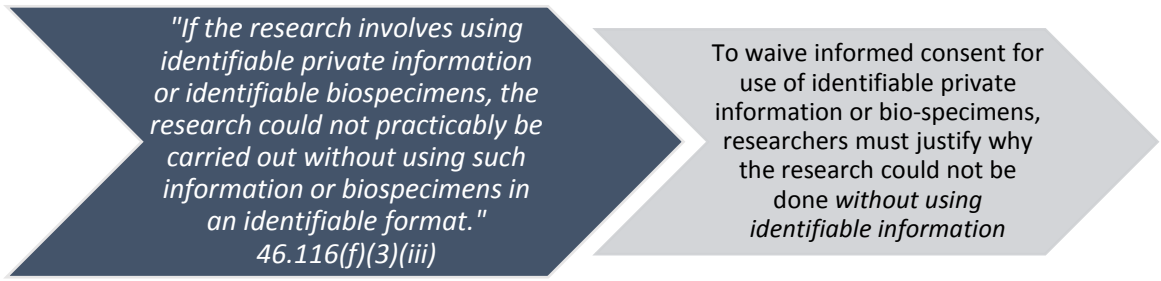


Updated: Waivers or alterations of informed consent

Consent Waivers for Identifiable Private Information
As with the Pre-2018 Common Rule, the IRB may approve a consent procedure that alters or omits some or all of the elements of consent.

In order for the IRB to waive or alter the informed consent requirement for research involving *identifiable private information* or *identifiable biospecimens*, the updated regulations now require justification that the research *could not be carried out using de-identified* information or biospecimens be documented.

This requirement is in addition to those already required as part of the Pre-2018 Common Rule. This additional determination is added to the regulations at 46.116(f)(3):



New: Consent *Exception* for Screening, Recruiting, or Determining Eligibility

The IRB may approve an investigator obtaining information or biospecimens for use in screening or assessing eligibility without prior informed consent when procedures are limited to obtaining formation through communication (e.g., initial screening interviews or surveys), or by assessing data from existing records or stored biospecimens. This is not a waiver of informed consent requirements, rather a limited "exception" to the requirement of informed consent for a limited aspect of the study procedure.

Note:

This *exception* must be granted by the IRB as part of the approval process. In other words, investigators are still required to have IRB approval in place ***prior*** to conducting any screening or recruitment activities.

New: Allowance of electronic signatures to document informed consent

The 2018 Common Rule includes a definition for *"written or in writing"* meaning *"writing on a tangible medium (e.g., paper) or in an electronic format"* (46.102(m)) to clarify that the terms include electronic formats, which are increasingly used to fulfill many documentation requirements.

New: Posting of Consent Documents for Federally Funded Clinical Trials

For federally-funded clinical trials, one IRB-approved informed consent document used to enroll subjects must be posted on a publically available Federal repository website. Posting must occur after the clinical trial is closed to recruitment but no later than 60 days after the last study visit is completed. In some cases, redactions to information posted may be allowed.

The Office for Human Research Protections has identified two websites that will satisfy the posting requirement:

1. ClinicalTrials.gov
2. A docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021)

Additional federal websites may be identified in the future. Currently, no instructions regarding posting procedures have been issued.

New: Definition of Clinical Trial (for purposes of posting informed consent)

Clinical trial means 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. (46 CFR 102(b))

When social and behavioral research meets the definition of a clinical trial, the posting requirement applies.

Document History

Created: 01.21.2019