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.”

“The prospective subject or the 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.” 46.116(a)(4)

This new language requires that investigators provide information that a "reasonable person" would want when considering participation. Investigators continue have the responsibility to provide sufficient time and opportunity to discuss the research, answer questions, and to provide additional information when requested.

“Informed consent as a whole must present information in sufficient detail ... and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates...understanding of why one might or might not want to participate. 46.116(a)(5)(ii)

This new regulatory language serves to remind investigators of their responsibility to present information in sufficient detail and organize it in a meaningful manner.

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:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The fact that consent is being sought for research and that participation is voluntary</td>
</tr>
<tr>
<td>2</td>
<td>The purposes of the research, expected duration of the prospective subject's participation, and the procedures to be followed in the research</td>
</tr>
<tr>
<td>3</td>
<td>The reasonably foreseeable risks or discomforts to the prospective subject</td>
</tr>
<tr>
<td>4</td>
<td>The benefits to the prospective subject or others that may reasonably be expected from the research</td>
</tr>
<tr>
<td>5</td>
<td>Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.</td>
</tr>
</tbody>
</table>

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):

<table>
<thead>
<tr>
<th>Statements</th>
</tr>
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<tbody>
<tr>
<td>Information about you, including your biospecimens, will <em>only</em> be used by the research team for the project described in this document.</td>
</tr>
<tr>
<td>OR</td>
</tr>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

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.

- **46.116(c)(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)(8)**: A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

- **46.116(c)(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).

Iowa State IRB’s informed consent templates are updated with suggested language meeting these requirements.
Informed Consent Process

Changes to waiver process for use of identifiable private information

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.

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):

"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)

To waive informed consent for use of identifiable private information or bio-specimens, researchers must justify why the research could not be done without using identifiable information.

New provision for assessing eligibility of prospective subjects without prior consent

Allowance of electronic signatures to document consent

New consent posting requirement for federally-funded clinical trials

Summary of 2018 Common Rule Changes to Informed Consent
01.21.2019
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 information 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 publicly 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

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.