

Revised Common Rule & Other Regulatory Changes

Special Series

October 30, 2018

Issue 3



Coming January 21, 2019!

What to expect and how to prepare.

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Overview

In addition to the new consent elements discussed in last week's newsletter, the revised Common Rule (i.e., 2018 Requirements) includes several more changes involving informed consent. Like the new consent elements, some of these other changes are substantial. Overall these changes are intended to make the informed consent process and form more focused and understandable. Note: Subjects/participants are used interchangeably.

Be sure to check out the **Resources** section which includes videos and other educational materials on these topics.

Making Consent Understandable

Like the new elements of consent, other changes require an emphasis on facilitating understanding and comprehension. Informed consent must be clearer and more focused in

organization, content and language. The requirements below apply to both the overall consent process and the consent document.

Sufficient Opportunity to Discuss and Consider

The 2018 Requirements state in multiple sections that

- An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity **to discuss and** consider whether or not to participate and that minimize the possibility of coercion or undue influence.¹
- 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.**²

What this means:

The revised Common Rule makes explicit the expectation that investigators are to provide potential participants with sufficient time and opportunities to both consider **and discuss** their participation. These changes also emphasize the expectation that the consent process must be thorough and ongoing to facilitate participant understanding and comprehension.

Notice the requirement **does not specify with whom participants should have the “opportunity to discuss.”** An opportunity to discuss whether or not to participate should apply to anyone a prospective participant might choose (family, friends, physician, etc.).

Reasonable Person Standard

As noted above, the 2018 Requirements introduce the reasonable person standard stating that subjects must be provided with **information that a reasonable person would want** to have in order to make a decision about their participation.

What this means:

This new language states explicitly what had been previously implied in the regulations. It places emphasis on ensuring the information provided, and how it is provided, is appropriate to the participant population. This is another change emphasizing that participant consent must facilitate understanding and comprehension.

Key Information

The 2018 Requirement states that 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

¹ 45 CFR 46.116 (a)(2) (Revised)

² 45 CFR 46.116 (a)(4) (Revised)

authorized representative in understanding the reasons why one might or might not want to participate in the research.³

What this means:

The revised Common Rule does not identify what specific information constitutes key information. What constitutes key information depends primarily on the nature of the study, the participant population and what other information is provided.

There is some discussion in the preamble to the revised Common Rule that suggests DHHS considers such information would include a statement that the project is research, participation is voluntary, a summary of the purpose, duration, procedures, risks, discomforts, benefits, appropriate alternatives, costs and payment. It is important to reiterate that the information included in this section should be based on the specifics of the research in question.

Organization and Presentation of Information

Informed consent must be organized and presented in a way that facilitates participant understanding of the reasons why one might or might not want to participate. This requirement applies to the overall consent form as well as the consent process.⁴

What this means:

This requirement seeks to move the consent process/document away from merely providing lists of facts and towards establishing a means of communication that promotes participant understanding and comprehension.

What to Expect:

- **New consent templates have been created and are now available on our website for your use.** These templates contain all the required elements of consent, tips and instructions, sample language (written at the 8th grade reading level or lower), and utilize a number of strategies shown to enhance readability. When followed properly, use of these templates and sample language should minimize the number of revisions needed to consent materials.
- Informed consent guidance including sample language for various types of research, study procedures, populations, etc. is being created and will be posted.
- The IRB application is being revised to collect information about how researchers will ensure that individuals will have sufficient time to consider and discuss their participation before enrollment in the research. What is considered to be sufficient time will vary depending on the complexity and/or nature of the research.

We do not anticipate significant changes to the procedures that researchers currently use to make sure individuals have sufficient time to make a decision about their participation. The most substantial change is that researchers will need to specifically

³ 45 CFR 46.116 (a)(5)(i) (Revised)

⁴ 45 CFR 46.116 (a)(5)(ii) (Revised)

address this issue in the IRB application. Below are some examples of these procedures and how they may vary based on study type.

- Participants in **studies that are more complex** (multiple visits, multiple procedures, etc.) **or that pose greater than minimal risk** may need a waiting period and be encouraged to discuss their possible participation with family members, close friends or trusted advisers.
- Participants in studies that are more straight-forward, shorter in duration and pose no greater than minimal risk may only require a verbal explanation of the research and/or review of the consent form plus an opportunity to ask the researcher questions.
- Only federally sponsored research (unless otherwise requested by the IRB) will be required to begin informed consent with a concise and focused presentation of the key information most likely to assist a prospective subject in deciding to participate in the research. A template is available specifically for federally sponsored research.

Waivers of Consent

Change to Waiver of Consent

For some non-exempt research, the IRB may (1) a waive the requirement to obtain informed consent, or (2) approve an alteration to omit or change specific elements of consent. Waivers of this sort are typically requested for research involving secondary data analysis or deception.

A waiver or alteration of consent or (for research involving children) parental permission may only be granted when the research meets specific criteria. The revised Common Rule adds another condition that must be meet to be eligible for a waiver. Beginning January 21, 2019, IRBs must determine that research meets all the following criteria.

- The research involves no more than minimal risk to the subjects;
- The research could not practicably be carried out without the requested waiver or alteration;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation; and
- **NEW** – 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.⁵

Exception to Consent for Eligibility Screening

Some non-exempt research under the pre-2018 Common Rule, a waiver of consent was required to access records or stored identifiable biospecimens for the purpose of screening,

⁵ 45 CFR 46.116 (f)(3)(iii) (Revised)

recruiting, or determining the eligibility of prospective subjects by interaction or by access to records or stored identifiable biospecimens.

NEW – Under the 2018 Requirements, **a waiver of consent for this purpose is no longer required if the following conditions are met:**

- information will be obtained through oral or written communication with the prospective participant, or
- identifiable private information or identifiable biospecimens will be obtained by accessing records or stored identifiable biospecimens.⁶

Prospective participants will still need to consent prior to having any procedures performed to determine eligibility (e.g. measuring height or weight, urine test, etc).

Note: Although consent will no longer be required for the eligible activities listed above, if HIPAA applies to the research, then either HIPAA authorization or a waiver of HIPAA authorization will still be required. If HIPAA authorization is required, a stand-alone HIPAA authorization should be used.

Change to Waiver of Consent Documentation

For research conducted under the Common Rule, obtaining signed informed consent or parental permission (for research involving children) is the standard. Under limited circumstances, the IRB may waive the requirement to obtain signed consent/parental permission. In these cases, the researcher must obtain consent following the same requirements as written consent but the participant/parent does not sign a consent document. Verbal consent, electronic consent or implied consent refer to consent processes often used in lieu of signed consent. These alternatives typically involve the use of a consent statement/information sheet (i.e., consent form without the signature line).

Under the pre-2018 Common Rule, research may qualify for this waiver if the IRB determines:

- 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
- 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;

NEW – The 2018 Requirements add a new option under which this waiver may be granted:

- 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 mechanism for documenting that informed consent was obtained.⁷

⁶ 45 CFR 46.116 (g) (Revised)

⁷ 45 CFR 46.117 (c)(1) (Revised)

What to Expect:

- The IRB application is being revised to include the changes described above. The revised application will require researchers to justify how their research meets these new requirements when requesting the waivers and exceptions described above.
- Guidance is being developed and will be posted on our website.

Posting of Consent Documents

If you will conduct a clinical trial funded by a **Common Rule agency** will be required to post an IRB-approved consent form used to enroll participants “on a publicly available Federal Web site that will be established as a repository for such informed consent forms,”⁸ after recruitment is closed.

The unsigned consent document can be posted to a designated website any time after the clinical trial closes to recruitment but no later than 60 days after the last study visit by any research participant as required by the approved study protocol. Currently, there are two publicly available websites that may be used: **ClinicalTrials.gov**, or **Regulations.gov** (Docket folder **HHS-OPHS-2018-0021**).

What to Expect:

- The IRB application is being revised to identify research that meets this requirement.
- Guidance is being developed and will be posted on our website.

Broad Consent

The revised Common Rule introduces “broad consent.” Broad consent⁹ is an alternative consent process that **may only be used** for the storage, maintenance, and secondary use of identifiable private information or identifiable biospecimens for future, yet-to-be-specified research.

To utilize “Broad Consent,” the research team and/or organization responsible for the storage of the identifiable data/biospecimens are required to:

- identify the types of research that may be conducted with the data/biospecimens,
- record and track who has agreed to or refused consent, and
- to track the terms of consent to determine whether proposed future secondary research use falls within the scope of the identified types of research.

⁸ 45 CFR 46.116 (h) (Revised)

⁹ 45 CFR 46.116 (d) (Revised)

What to Expect:

Currently, UT does not plan to offer this option. The requirements for broad consent are significant. Should regulators issue guidance clarifying aspects of this consent option, this decision may be revisited.

Transition Plans

Now

New consent templates have been created to include the new consent elements and improve readability for participants. These templates are organized to present information in a manner that facilitates participant understanding and include sample language written at the 8th grade reading level or lower.

We strongly recommend that researchers begin using these new consent templates.

These templates do not conflict with current regulatory requirements and, although not required until January 21, 2019, when followed properly, the use of these templates and suggested language should minimize the number of revisions needed to the consent documents.

Beginning January 21, 2019

New Studies

All new applications must include consent documents that meet the revised Common Rule requirements as is applicable to the proposed research.

The IRB application will include the new criteria for consent waivers and exceptions to informed consent. It will also require researchers to identify studies that are required to post consent forms for clinical trials.

Ongoing Studies

Previously-approved research that is open to enrollment will be required to update to the new informed consent template, or add the additional consent elements and other requirements, at time of renewal or amendment submission that changes the consent document, whichever occurs first.

Resources

To learn more, check out these resources.

Watch UT IRB Video: The Revised Common Rule: Revised Regulations on Human Subjects Research January 21, 2019.

In this video UT IRB Chair, Colleen Gilrane, explains expected changes related to the revised regulations and their impact on the UT research Community. To access the video you will be prompted to enter your UT NetID.

Watch OHRP Video: What's New in Informed Consent: Revisions to the Common Rule [July 12, 2018]

In this video, OHRP Director, Jerry Menikoff, explains the changes and requirements for informed consent in the revised Common Rule.

Federal Policy on the Protection Human Subjects (the Common Rule), January 19, 2017
Revised Common Rule Educational Materials, Office for Human Research Protections
CITI Program Final Rule Resources

Questions

We encourage members of our research community to contact us with any questions about the revised Common Rule, plans for their implementation or other regulatory revisions. We will do our best to answer your questions in future issues of this newsletter series. Submit your questions to utkirb@utk.edu and use the subject line **revised Common Rule question**.

Schedule of Topics

Below is our schedule of topics. New issues will be distributed through the iMedRIS users distribution list and posted on the [Newsletter Archive](#) page of our website.

Issue	Date	Topic
1	10.17.2018	Revised Common Rule – Background and Basics
2	10.23.2018	Informed Consent – New Elements
3	10.30.2018	Informed Consent – Facilitating Understanding & Comprehension, Waivers, etc.
4	11.6.2018	Exempt Research – New Category 3: Benign Behavioral Interventions
5	11.13.2018	Exempt Research – Revised Category 4: Secondary Research
6	11.20.2018	Exempt Research – Other Changes
7	11.27.2018	Continuing Review
8	12.4.2018	Transition to revised Common Rule – Existing Studies
9	12.11.2018	Definitions
10	12.18.2018	NIH Policy Changes <ul style="list-style-type: none">• ClinicalTrials.gov• CGP Training
	12.25.2018	No Newsletter – Winter Break

Issue	Date	Topic
11	1.8.2019	Grant Application Review
12	1.15.2018	Single IRB Review