HUMAN RESEARCH PROTECTION PROGRAM | NEWSLETTER

Revised Common Rule & Other Regulatory Changes

Special Series
October 23, 2018
Issue 2

Coming January 21, 2019!

What to expect and how to prepare.

In this issue: New Elements of Informed Consent

Overview

The revised Common Rule (also referred to as the 2018 Requirements) makes a number of changes to informed consent requirements. Most of these changes, including the addition of new consent elements, focus on facilitating participants' understanding of the proposed research and about how their data and biospecimens may be used. As you review these new elements, please note the circumstances in which they are required to determine whether they apply to your research.

New Elements of Informed Consent

Secondary Use

What it is:

One of the following statements must be included in the informed consent document.

- 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

- 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.

When it is required:

Any research involving the collection of identifiable private Information or identifiable private biospecimens.

Commercial Profit

What it is:

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.

When it is required:

This additional element is required when there is any possibility of this use. For example, if there is a possibility of future research involving this type of use. If there is no possibility of this usage, the language is not needed.

Clinically Relevant Results

What it is:

A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

When it is required:

This additional element is required only if there is a possibility that clinically relevant results will be returned to subjects. This includes any tests conducted for screening purposes.

Whole Genome Sequencing

What it is:

A statement must be included in the informed consent document about whether the research will or might include whole genome sequencing.

Whole genome sequencing is defined by the Common Rule as sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.

When it is required:

Any research involving the collection of biospecimens.

What to Expect

Now

The **Elements of Consent** document posted on our website's Forms page has been revised to include these new elements.

New **consent templates** have been created to include the new consent elements and meet other new requirements in the revised Common Rule (see our upcoming October 30th issue). On Monday, October 30th, three new templates, listed below, will be posted on our website's Forms page.

- Standard Informed Consent Template
- Anonymous Survey Consent Template
- Federally Sponsored Research Consent Template

These templates include tips and guidance on what information to include and suggested language. Additionally, the language in these new templates is simplified to align with the best practice of writing consent documents at the 8th grade reading level or lower promoting participant understanding of the proposed research.

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.

We will soon post an informed consent guidance document with expanded sample language for various types of research, study procedures, populations, etc.

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 research.

Ongoing Studies

Previously-approved research which 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 submission of an amendment that changes the consent document.

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.

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 • ClinicalTrials.gov • CGP Training
	12.25.2018	No Newsletter – Winter Break
11	1.8.2019	Grant Application Review
12	1.15.2018	Single IRB Review