HUMAN RESEARCH PROTECTION PROGRAM | NEWSLETTER

Revised Common Rule
& Other Regulatory Changes

Special Series
October 17, 2018
Issue 1

Coming January 21, 2019!

What to expect and how to prepare.

In this issue: Revised Common Rule Basics

Purpose

This special series of our HRPP Newsletter will provide timely information about the revised Common Rule and its impact on human subjects research at UT as well as other regulatory changes.

The **revised Common Rule is scheduled to go into effect on January 21, 2019**. Until that time, we will publish a new issue of this special series newsletter each week (except Winter Break). Each newsletter will also be posted on our website.

Each issue will focus on a regulatory change including:

- What the change involves;
- How the change will affect your research;
- Impact on IRB review processes, forms, templates, etc.; and
- How you can plan for these changes.

What is the Common Rule?

On January 18, 2017, the U.S. Department of Health and Human Services (HHS) and 15 other federal departments and agencies issued a **final rule** revising the federal regulations that safeguard individuals who participate in research. After two delays, most of these revised regulations are scheduled to go into effect on **January 21, 2019**.

In 1981, the first regulations protecting human research subjects were issued based on the Belmont Report. It was only after their revision and subsequent adoption by more than a dozen **federal departments and agencies** in 1991 that these regulations become known as the "**Common Rule**" signifying the widespread application of one basic regulatory framework. The main elements of the Common Rule include:

- requirements for assuring compliance by research institutions;
- requirements for Institutional Review Board (IRB) membership, function, operations, review of research, and record keeping;
- requirements for researchers obtaining and documenting informed consent; and
- additional protections for certain vulnerable research subjects-- pregnant women, prisoners, and children

These regulations are applied to all research conducted under the auspices of the University of Tennessee, Knoxville regardless of funding.

Why was the Common Rule revised?

These revisions are the first systematic changes made to these regulations since 1991. Since that time the human research enterprise has changed dramatically growing in scale and diversity. In response, the Office for Human Research Protections (OHRP) in the Department of Health and Human Services (DHHS) began the revision process in 2011.

Although some of the revisions are to clarify how to interpret and apply existing regulatory requirements, the most significant revisions intend to "modernize, strengthen, and make more effective" the current system of oversight. The revised regulations purport to:

- Improve the oversight system to enhance protections for research participants.
- Facilitate the conduct of minimal risk research.
- Reduce unnecessary regulatory burden, particularly for low-risk studies.
- Better manage and more thoroughly address broader types of research issues such as behavioral and social science research, evolving technology including the scale and nature of information collected in research activities, multi-site research studies, etc.
- Harmonize human subjects research policies across federal departments and agencies.

What to Expect

Below is our schedule of topics. A new issue will be published each Tuesday. As is our current practice, we will distribute these newsletters through the iMedRIS users distribution list.

Also, we are asking the Associate Deans for Research to distribute it to their respective colleges/units.

We encourage members of our research community to contact us with any questions about the revised Common Rule, other regulatory revisions or plans for their implementation. 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**.

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