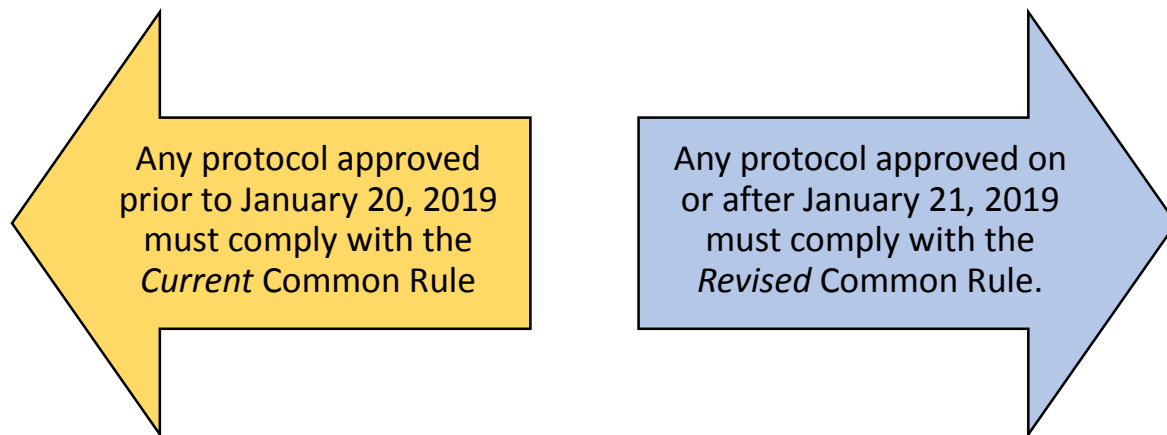


University of Kentucky Office of Research Integrity (ORI) Revised Common Rule Changes Summary

The Federal Policy for the Protection of Human Subjects (commonly referred to as “*the Common Rule*”), provides ethically based regulations for the review and conduct of human research studies. The Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) issued changes to modernize, strengthen, and streamline the rule in January 2017. However, the rule was amended to delay the effective and compliance dates. Most changes will go into effect on January 21, 2019.

This document provides plans for transitioning to the revised rule, as well as an overview of the 2019 primary changes. We will update this document with additional information and answers to frequently asked questions (FAQ) as OHRP provides federal guidance on interpretation and practical application of the new rule.



Existing Studies Approved under the Current Common Rule

Existing IRB approved studies may continue through completion under the Current Common Rule. Studies approved by the IRB prior to January 21, 2019 will continue to operate under the current rule, and as such, will not be expected to comply with all of the changes generated by the Revised Rule.

However, if a research investigator wishes to transition an existing study to the Revised Common Rule, contact ORI to discuss options. Note: The new application must comply with all applicable revised common rule requirements.

Studies Approved Under the Revised Common Rule

While much of the revised regulations apply to IRB review and management, investigators will see a number of changes. This document provides an overview of key changes. The University of Kentucky E-IRB system, standard operating procedures, policies, guidance, and website are undergoing provisional changes based on the revised regulations. However, there are pending lists and guidance documents that HHS has yet to issue. Should OHRP release guidance that alters the interpretation and application of the Revised Rule, we will update materials accordingly.

Studies Subject to Food and Drug Administration (FDA) Regulations

The revised rule has created differences between HHS and FDA human subject regulations. The FDA has not yet revised their regulations. They issued guidance in October 2018 indicating intent to harmonize, to the extent possible, with the Revised Common Rule. Until that time, ORI and Research Information Services (RIS) have included instructions or programming logic to apply provisions that do not conflict with FDA regulations.

KEY REGULATORY CHANGES UNDER THE REVISED COMMON RULE

Activities Deemed not to be research that do not require IRB review:

There has been no change in the process for determining what activities meet the federal of research and human subject and require IRB review. Investigators are encouraged to consult [ORI guidance and contact ORI for questions or a “Not Human Subject Determination”](#). The revised rule has provided determinations on select activities that are considered “not human research and do not require IRB review” if done purely as described below. These include:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance.
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

See the “What Research Activities Need Institutional Review Board (IRB) Review?” Fast Pass Video [[YouTube Video](#)] or [What Needs IRB Review](#) website for additional information.

Informed Consent Documentation & Process:

The revised rule shifts the focus of informed consent to the potential subject with:

- Information that a “Reasonable Person” would want in order to make an informed decision;
- Changes to facilitate subject’s understanding of the key reasons he/she would or would not choose to participate in research; and
- Requirements that Key Information essential to that decision be presented first in the document and discussion.

In preparation for the change, the UK ORI implemented revised informed consent templates a year in advance of the Revised Rule compliance date. The changes focus on a reasonable person standard and encourages creating consent documents that facilitate understanding. This involves formatting to fit the context of the study and the study population’s needs, rather than prescriptive reliance on template language. The [UK Consent Form Template FAQ](#) provides guidelines for improving the consent documents and process.

The rule includes a new required element for studies that collect identifiable information or identifiable specimens. The element informs subjects regarding intent to conduct future research with the identifiable information or specimens collected as part of the initial research. Specifically, whether or not identifiers will be removed and material used or shared with others for future research, without the subject's additional consent. There are also three additional elements, which the investigator must include when applicable. The three elements inform subjects regarding potential commercial profit, whole genome sequencing, and return of research results. To ensure your consent documents include all required elements, use the [UK Federally Required Elements of Informed Consent](#) Checklist.

FDA clarified in the [2018 Guidance](#), that the Revised Common Rule provisions related to content, organization, and presentation of the consent form and process are not inconsistent with FDA's current policies. The clarification is in effort to avoid the need for sponsors or investigators to develop, and IRBs to review, two separate informed consent forms.

General Waiver of Informed Consent:

The IRB may waive the requirement or approve alteration of elements of informed consent if it finds and documents that the research meets certain conditions. In addition to the current criteria for waiving or altering consent, the rule adds consideration of a fifth condition. This new requirement is that the research could not practicably be carried out without accessing or using information or biospecimens in an identifiable format. See the Waiver of Informed Consent/Assent Process and Documentation Video for additional information. [[YouTube Video](#)]

Waiver of Documentation of Informed Consent:

The IRB may waive the requirement to obtain a signed consent document for some or all of the subjects if certain conditions are met. In addition to the current conditions for waiving documentation, a waiver may be granted for international research where the signature on the informed consent form is not culturally appropriate. See the Waiver of Informed Consent/Assent Process and Documentation Video for additional information. [[YouTube Video](#)]

Screening or Determining Eligibility:

An IRB may approve a research proposal in which an investigator will review information or results from previously collected biospecimens for the purpose of screening or determining the eligibility of prospective subjects without obtaining informed consent if either of the following conditions are met:

- 1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or,
- 2) The investigator will use identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

The UK IRB is awaiting federal guidance on specific application of this exception in terms of recruitment. The UK IRB policies and guidance on recruitment have not

changed (see [A Principal Investigator's Guide to Identification and Recruitment of Human Subjects for Research](#)).

Exempt Review (Non-FDA-Regulated New Exemption Categories):

The Final Rule establishes new exempt categories of research. The new categories will appear in E-IRB after the revised rule effective date.

Certain research that required Expedited IRB review, will be eligible for Exempt IRB review under the revised rule. For instance, a record review qualifying for the new Exemption Category 4, will allow both prospective and retrospective review of records, whereas in the past, only retrospective reviews qualified for Exempt review. See the [UK ORI Exemption Categories Tool](#) for the six categories available at UK, and associated conditions, allowances and limitations.

In addition to making the exempt certification determination, the IRB reviewers are required to conduct a limited review for select exempt categories, in order to ensure there are adequate provisions to protect the privacy of subjects and maintain confidentiality of data.

Investigators are encouraged to review [the exempt review categories](#) before submitting an application in E-IRB. Since the E-IRB system does not allow switching review types (i.e., expedited to exempt) once the application is created, changing review type would require creating a new application.

Expedited Review (Non-FDA-Regulated):

- The expedited categories have not been updated by OHRP as of yet.
- Select Social Behavioral Education research that required initial Expedited Review will be eligible for Exempt review (see above) under the revised rule.
- Non-FDA Regulated Expedited research will undergo an abbreviated administrative review (consisting of four questions), instead of a continuing review.

Continuing Review:

Continuing review provides the IRB with an opportunity to determine whether there is new information that represents a significant new finding and whether the finding warrants communicating to subjects who have already enrolled in the research.

Comprehensive Continuing Review is no longer required in select minimal risk research (see Expedited Review section above).

Investigators with Full review or FDA-regulated protocols will complete a continuing review application to allow for substantive IRB review.

Non-FDA regulated, Expedited review protocols will undergo with an abbreviated annual review. The abbreviated review maintains open lines of communication between the investigator and the IRB, while streamlining reporting appropriate to minimal risk research.

Clinical Trials Definition:

In order to harmonize with other agencies' definition of a clinical trial, the revised rule definition is, "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".

Principal Investigator Posting of Clinical Trial Consent Form:

There is a new requirement for clinical trials conducted or supported by a Common Rule department or agency (e.g., National Institutes of Health) for posting the consent form on a publicly available federal website. The consent form must:

- have been used in enrolling participants;
- be posted on the Federal website after the clinical trial is closed to recruitment; and
- be posted no later than 60 days after the last study visit by any subject, as required by the protocol.

At this time, two publicly available federal websites will satisfy the consent form posting requirement:

- ClinicalTrials.gov; and
- a docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021).

HHS and other Common Rule agencies are developing guidance about [this posting requirement](#) that will shape the University of Kentucky's Policies and Procedures.

Staying Informed:

Information contained in this document will be updated as additional information is available, and if/when OHRP issues guidance or announcements regarding the revised Common Rule. Information will be posted on the [ORI website](#), [ORI News & Announcements webpage](#), and via the [IRB listserv](#) and [education sessions/materials](#).

Email general questions to IRBsubmission@uky.edu or contact the ORI main line at 859-257-9428.

For protocol specific questions, contact the ORI main line at 859-257-9428, with the protocol number to connect with the ORI Professional Associate managing your protocol.

The Office of Research Integrity will strive to facilitate the conduct of ethical human subject research during this transition. We appreciate the service of the Institutional Review Board members and the cooperation of the research community.