CITI PROGRAM
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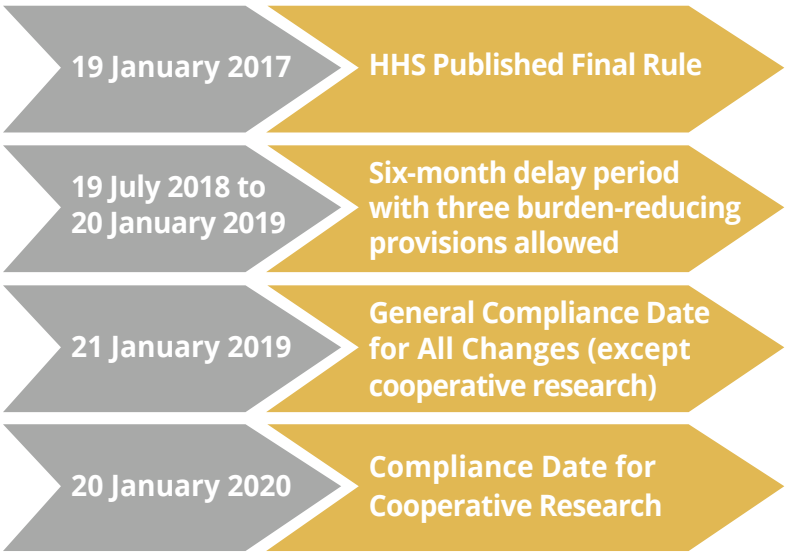
Overview of Important Changes to the Common Rule

What are the Transition Dates and Provisions?



Final Rule Delay

On 19 June 2018, HHS and 16 other agencies published a Final Rule ("2018 Final Rule") to delay the general compliance date until 21 January 2019, but allow for three provisions from the revised Common Rule (2018 requirements) to be available in the delay period (HHS 2018).

Research Study Initiation Date	Standards
Research initially approved by an IRB, waived pursuant to [former subsection] 101(i), or determined to be exempt [under former subsection 101(b)] **before** 21 January 2019 (Grandfathered research)	These studies are by default subject to the pre-2018 rule (the Common Rule as published in the 2016 edition of the CFR). However, an organization engaged in such research may choose to comply with the Final Rule (2018 requirements) for such a study (the grandfathered research) if the organization applies the Final Rule to the study and an IRB documents this determination. Further guidance is pending to determine if the IRB must document this per study even if the institution issues an institutional policy applying the Final Rule to all research.
Research initially approved by an IRB, waived pursuant to [former subsection] 101(i), or determined to be exempt on or **after** 21 January 2019	These studies are subject to the Final Rule (2018 requirements).

What Are the Major Changes?

Updates to Definitions – New and Revised Terms

New Terms Added:

Clinical Trial,
Public Health Authority,
Written or In Writing

Revised Exisiting Terms:

Vulnerable
Human Subject, Research,
Legally Authorized Representative

Updates to Informed Consent Process and Document

1

Changes meant to facilitate subjects' understanding of the reasons to participate (or not) in the research.

2

Requires that key information essential to decision making receive priority by:

- *Being presented first in the consent discussion;*
- *Appearing at the beginning of the consent document*

3

Prospective subject (or LAR) must be provided with the information that a reasonable person would want to have to make an informed decision about whether to participate, and be given an opportunity to discuss that information.

4

Broad consent may be obtained in lieu of informed consent obtained only for storage, maintenance, and secondary research uses of private information and identifiable biospecimens.

Updates to Exempt Categories, Addition of Limited IRB Review, and Use of Broad Consent

New Exempt Categories and Limited IRB Review

The Final Rule establishes new exempt categories of research. Under some of the new categories, exempt research would be required to undergo limited IRB review. Limited IRB review is needed in four of the eight exempt categories.

In two of the categories, limited IRB review is required to ensure there are adequate confidentiality and privacy safeguards. In the other two categories, limited IRB review is required for broad consent in studies involving identifiable private information or identifiable biospecimens.

Updates to Subparts and Exemptions

Can Research Regulated by the Subparts Be Exempt?

Section 46.104(b) specifically states the applicability of the exemption categories to 45 CFR 46, Subparts B, C, and D, and changes the current policy to allow the exemptions at this section to apply to Subpart C.

Subpart B - Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research	Yes, all exemption categories.
Subpart C - Additional Protections Pertaining to Biomedical & Behavioral Research Involving Prisoners as Subjects	Only for research aimed at involving a broader subject population that only incidentally includes prisoners.
Subpart D - Additional Protections for Children Involved as Subjects in Research	Yes, for exemptions at paragraphs 46.104 (d)(1), (4), (5) (6), (7), and (8).
	Only for research involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed for paragraphs (d)(2)(i) and (ii).
	No, for exemption at paragraph 46.104 (d)(2)(iii) of this section.

Updates to Expedited Review Process

Elimination of Continuing Review for Some Research

The Final Rule removes the requirement to conduct continuing review of ongoing research for studies that undergo expedited review and for studies that have completed study interventions and are merely analyzing study data or involve only observational follow up in conjunction with standard clinical care.

Limited IRB review has no continuing review requirement.

Does an IRB have to make a "minimal risk" determination for expedited review?	*Not under the Final Rule; however, all human subject research that is greater than minimal risk must be reviewed at a convened meeting.*
Which studies can be reviewed via expedited review?	*Research that fits into one or more of the broad categories in the Secretary's list and does not pose greater than minimal risk.*

Multi-Site Research Using Cooperative Review and Single IRB (sIRB) Review

Choosing a sIRB of Record

The reviewing sIRB will be specified by the federal department or agency supporting or conducting the research; the "lead institution" may propose the reviewing IRB, but final approval will be required.

Additional Requirements

Documentation specifying the responsibilities of each entity when research takes place at an institution in which IRB oversight is outsourced.

When does Cooperative Research become effective?

This is the only part of the regulations that will go into effect after three years from publication of the Final Rule (on 20 January 2020).

Single IRB

The Final Rule creates a new requirement for U.S. institutions engaged in multi-site (more than one) cooperative research to use a sIRB for that portion of the research that takes place within the U.S., with certain exceptions.

This requirement becomes effective three years after publication (20 January 2020).

Note: For studies that must comply with the National Institutes of Health (NIH) policy on sIRB review, the effective date was 25 January 2018 (with certain exceptions).