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Revised Common Rule

The U.S. Department of Health and Human Services and fifteen other Federal Departments and Agencies have issued final revisions to the Federal Policy for the Protection of Human Subjects (the Common Rule). A final rule was published in the *Federal Register* (FR) on January 19, 2017, and was amended to delay the effective and compliance dates on January 22, 2018 and June 19, 2018.

The revised Common Rule is effective July 19, 2018; note that from July 19, 2018 through January 20, 2019 institutions are not permitted to implement the entirety of the revised Common Rule. This is explained in the transition provision (45 CFR 46.101(l), as amended June 19, 2018).

In order to understand the regulatory text of the revised Common Rule, OHRP recommends reviewing the preamble and regulatory text from:

- The final rule to revise the Common Rule - PDF
<<https://www.govinfo.gov/content/pkg/fr-2017-01-19/pdf/2017-01058.pdf>>  (published January 19, 2017)
- The interim final rule to delay the effective date and general compliance date of the revised Common Rule to July 19, 2018 - PDF
<<https://www.govinfo.gov/content/pkg/fr-2018-01-22/pdf/2018-00997.pdf>>  (published January 22, 2018), and

- The final rule to further delay the general compliance date of the 2018 Requirements to January 21, 2019, while permitting the use of three burden-reducing provisions of the 2018 Requirements during the delay period - PDF <<https://www.govinfo.gov/content/pkg/fr-2018-06-19/pdf/2018-13187.pdf>> ⓘ (published June 19, 2018)

All other documents related to the revised Common Rule rulemaking process are listed in chronological order below:

2011

July 26, 2011--Advance notice of proposed rulemaking (ANPRM) seeking comments on potential revisions to the Common Rule

Summary : Before making changes to the federal policy for the protection of human subjects (which have been in place since 1991 and are often referred to as the Common Rule), the government sought the public's input on an array of issues related to the ethics, safety, and oversight of human research in a July 26, 2011 ANPRM.

- July 26, 2011 FR Notice (HTML version)
<<https://www.federalregister.gov/documents/2011/07/26/2011-18792/human-subjects-research-protections-enhancing-protections-for-research-subjects-and-reducing-burden>> ⓘ
- July 26, 2011 PDF FR Notice - PDF <<https://www.govinfo.gov/content/pkg/fr-2011-07-26/pdf/2011-18792.pdf>> ⓘ
- View the OHRP page listing all HHS documents relevant to this ANPRM
<<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/anprm-for-revision-to-common-rule/index.html>> ⓘ

2015

September 8, 2015--Notice of Proposed Rulemaking (NPRM) seeking comments on proposals to comprehensively revise the Common Rule

Summary : This NPRM proposed revisions to modernize, strengthen, and make more effective the Federal Policy for the Protection of Human Subjects that was promulgated as a Common Rule in 1991. This NPRM sought comment on proposals to better protect human subjects involved in research, while facilitating

valuable research and reducing burden, delay, and ambiguity for investigators. This proposed rule was an effort to modernize, simplify, and enhance the current system of oversight

- September 8, 2015 FR notice (HTML version)
<<https://www.federalregister.gov/documents/2015/09/08/2015-21756/federal-policy-for-the-protection-of-human-subjects>> ⓘ
- September 8, 2015 PDF FR notice - PDF <<https://www.govinfo.gov/content/pkg/fr-2015-09-08/pdf/2015-21756.pdf>> ⓘ
- View the OHRP page listing all HHS documents relevant to this NPRM
<<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/nprm-home/index.html>> ⓘ

2017

January 19, 2017--Final rule implementing major revisions to the Common Rule

Summary : This final rule strengthens protections for people who volunteer to participate in research, while ensuring that the oversight system does not add inappropriate administrative burdens, particularly to low-risk research. It also allows more flexibility in keeping with today's dynamic research environment. The final rule will now generally expect consent forms to include a concise explanation – at the beginning of the document – of the key information that would be most important to individuals contemplating participation in a particular study, including the purpose of the research, the risks and benefits, and appropriate alternative treatments that might be beneficial to the prospective subject.

- January 19, 2017 FR notice (HTML version)
<<https://www.federalregister.gov/documents/2017/01/19/2017-01058/federal-policy-for-the-protection-of-human-subjects>> ⓘ
- January 19, 2017 PDF FR notice - PDF <<https://www.govinfo.gov/content/pkg/fr-2017-01-19/pdf/2017-01058.pdf>> ⓘ

2018

January 22, 2018--Interim final rule delaying the effective date and general compliance date of the revised Common Rule to July 19, 2018

Summary : This interim final rule delayed the effective and compliance dates of the revised Common Rule from January 19, 2018 to July 19, 2018. This interim final rule did not delay the compliance date of the revised Common Rule's cooperative research provision (___114), which remains January 20, 2020.

- January 22, 2018 FR notice (HTML version)
<<https://www.federalregister.gov/documents/2018/01/22/2018-00997/federal-policy-for-the-protection-of-human-subjects-delay-of-the-revisions-to-the-federal-policy-for>> ⓘ
- January 22, 2018 PDF FR Notice - PDF <<https://www.govinfo.gov/content/pkg/fr-2018-01-22/pdf/2018-00997.pdf>> ⓘ
- HHS announcement about the January 22, 2018 interim final rule
<<https://www.hhs.gov/ohrp/ifr-delays-revisions-common-rule-published-fr.html-1>> ⓘ

April 20, 2018--NPRM seeking comments on a proposal to delay the general compliance date of the revised Common Rule while permitting the use of three burden-reducing provisions of the 2018 Requirements during the delay period

Summary : As per the interim final rule published January 22, 2018, the effective date of the 2018 Requirements is now July 19, 2018. This NPRM proposed delaying the general compliance date for the 2018 Requirements for an additional six months, for the time period of July 19, 2018 until January 21, 2019. This proposed rule was intended to provide additional time to regulated entities for the preparations necessary to implement the 2018 Requirements. This proposed rule, if finalized, would require regulated entities to continue to comply with the requirements of the current Federal Policy for the Protection of Human Subjects (hereafter the “pre-2018 Requirements”) until January 21, 2019. This proposal also sought comment on whether to permit institutions to implement, for certain research studies, three burden-reducing provisions of the 2018 Requirements during the period from July 19, 2018, through January 20, 2019 (i.e., the proposed additional delay in the general compliance date for most provisions of the 2018 Requirements). This NPRM did not propose delaying the compliance date for the cooperative research provision (sec. 114), which would remain January 20, 2020.

- April 20, 2018 FR notice (HTML version)
<<https://www.federalregister.gov/documents/2018/04/20/2018-08231/federal-policy-for-the-protection-of-human-subjects-proposed-six-month-delay-of-the-general>> ⓘ
- April 20, 2018 PDF FR notice - PDF <<https://www.govinfo.gov/content/pkg/fr-2018-04-20/pdf/2018-08231.pdf>> ⓘ

- HHS announcement about the April 20, 2018 NPRM

<<https://www.hhs.gov/ohrp/nprm-proposing-additional-6-months-delay.html>> ⓘ

June 19, 2018--Final rule to delay the general compliance date of the revised Common Rule, while permitting the use of three burden-reducing provisions of the 2018 Requirements during the delay period

Summary : This final rule adopts the April 20, 2018 NPRM proposals, with minor changes made to the regulatory text for clarification and accuracy. This rule delays the general compliance date for the 2018 Requirements for an additional 6-month period, until January 21, 2019. As a result of this delay, regulated entities will be required, with an exception, to continue to comply with the requirements of the pre-2018 version of the Federal Policy for the Protection of Human Subjects (the “pre-2018 Requirements”) until January 21, 2019. The one exception to this general rule is that institutions will be permitted (but not required) to implement, for certain research, three burden-reducing provisions of the 2018 Requirements during the delay period (July 19, 2018, through January 20, 2019).

- June 19, 2018 FR notice (HTML version)

<<https://www.federalregister.gov/documents/2018/06/19/2018-13187/federal-policy-for-the-protection-of-human-subjects-six-month-delay-of-the-general-compliance-date>> ⓘ

- June 19, 2018 PDF FR notice - PDF <<https://www.govinfo.gov/content/pkg/fr-2018-06-19/pdf/2018-13187.pdf>> ⓘ

- HHS announcement about the June 19, 2018 final rule

<<https://www.hhs.gov/ohrp/final-rule-delays-compliance-published-federal-register.html>> ⓘ

Related Information

- **The Common Rule, Updated**

By Jerry Menikoff, Julie Kaneshiro, and Ivor Pritchard

New England Journal of Medicine , January 19, 2017 (Vol. 376 No. 3)

View this article online ⓘ <<http://www.nejm.org/doi/pdf/10.1056/nejmp1700736>> ⓘ

(Requires NEJM subscription or article purchase)

Content created by Office for Human Research Protections (OHRP)
Content last reviewed January 19, 2017