FEDERAL AGENCIES PROPOSE TO FURTHER DELAY IMPLEMENTATION OF SWEEPING REVISIONS TO THE "COMMON RULE"—BUT OFFER INCENTIVES FOR INSTITUTIONS WILLING TO TRANSITION EXISTING RESEARCH PROJECTS

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U.S. Health Care Alert

On April 20, 2018, as anticipated, 17 federal departments and agencies (the "Agencies") [1] issued a notice of proposed rulemaking ("2018 NPRM") in which the Agencies propose a six-month delay to the general compliance date for the updated Federal Policy for the Protection of Human Subjects (the "Common Rule"), from July 19, 2018 until January 21, 2019. [2]

The Common Rule is designed to protect human subjects in connection with research conducted or supported by one of the Agencies. The Common Rule requirements are codified at various places, including, for example, 45 C.F.R. Part 46. The Common Rule applies only to:

Human subject research; and

Research either conducted or supported by the federal government or otherwise covered by a U.S. Department of Health and Human Services Office for Human Research Protection-approved federal-wide assurance.

The Agencies also propose that institutions may elect to voluntarily transition existing research projects to the new Common Rule requirements once those requirements go into effect on January 21, 2019. Under the proposal, institutions that make this election could, during the six-month interim period from July 19, 2018 to January 21, 2019, adopt three burden-reducing provisions, discussed in more detail below, that are lifted from the provisions that are otherwise being delayed. Alternatively, an institution can choose to forego the three burden-reducing provisions and continue to have existing research projects be subject to current Common Rule requirements (i.e., even past January 21, 2019).

BACKGROUND

The Agencies made sweeping revisions to the Common Rule in a final rule published on January 19, 2017 (the "2018 Requirements"). [3] The 2018 Requirements defined new categories of research as exempt from Institutional Review Board ("IRB") review, altered patient consent requirements, imposed a new provision for broad consent for future research, and made multiple additional changes to IRB requirements. For a more detailed discussion of the 2018 Requirements, see our January 22, 2018 alert, "Federal Agencies Delay Implementation of Common Rule Requirements." [4]

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The 2018 Requirements were to take effect on January 19, 2018 (with the exception of the revisions to the cooperative research provision.) However, on January 17, 2018, the Agencies published an interim final rule delaying the effective date and general compliance date for the 2018 Requirements for six months, from January 19, 2018 until July 19, 2018. The interim final rule also stated that the Agencies anticipated issuing additional rulemaking to further extend the compliance date, which has now come to fruition with the 2018 NPRM to delay the general compliance date for the 2018 Requirements for an additional six months, from July 19, 2018 until January 21, 2019.

2018 NPRM BURDEN-REDUCING PROVISIONS AND DELAY OF IMPLEMENTATION

Recognizing the complexity involved with implementing the revised Common Rule, the Agencies propose in the 2018 NPRM to provide additional time for regulated entities to prepare for the implementation of the 2018 Requirements.

The 2018 NPRM, if finalized, would require regulated entities to continue to comply with the requirements of the current Common Rule (hereafter, the "pre-2018 Requirements") until January 21, 2019. Research initiated (i.e., initially approved by an IRB, or for which IRB review was waived pursuant to § 46.101(i), or determined to be exempt) on or after January 21, 2019, would need to be conducted entirely in compliance with the 2018 Requirements. However, research initiated before January 21, 2019, would, by default, continue to be subject to the pre-2018 Requirements for the duration of the research.

Significantly, however, the 2018 NPRM proposes to allow institutions to elect to take advantage of three burden-reducing provisions in the 2018 Requirements for existing research projects if they document that election between July 19, 2018 and January 21, 2019, and agree, after January 21, 2019, to transition those projects to the 2018 Requirements. (Note that, except for the three burden-reducing 2018 Requirements, institutions that choose the option between July 19, 2018 and January 21, 2019, will still be required to comply with the pre-2018 Requirements until January 21, 2019.)

The first-available burden-reducing provision is the use of the 2018 Requirements' definition of "research," which deems certain activities not to be research subject to IRB review and approval. Specifically, the 2018 Requirements exclude four categories of endeavor from the definition of research:

Scholarly and journalistic activities, including the collection and use of information that focuses directly on the specific individuals about whom the information is collected; [5]

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; [6]

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; [7] an

Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions. [8]

The second-available burden-reducing provision is the relaxation of the need for annual continuing review of the following categories of research, unless an IRB determines otherwise:

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Research eligible for expedited review (in accord with 45 C.F.R. § 46.110);

Research given limited IRB review (as described in 45 C.F.R. § 46.104(d)(2)(iii)); and

Research that is part of an IRB-approved study and has progressed to the point that it involves only one or both of the following:

data analysis, including analysis of identifiable private information or identifiable biospecimens; or

assessing follow-up clinical data from procedures that subjects would undergo as part of standard care for their medical condition.

The third-available burden-reducing provision is the elimination of the requirement that IRBs review grant applications, as they do with funded research grants.

Institutions can elect to take advantage of the burden-reducing provisions for ongoing studies, as well as for studies newly initiated after July 19, 2018, at any time between July 19, 2018 and January 21, 2019. An institution may elect to implement the three burden-reducing provisions on a protocol-by-protocol basis, for a class of protocols (e.g., all minimal risk research), or for the institution's entire research portfolio. An institution could also elect as a matter of institutional policy to adopt a more stringent standard in the interim period (provided pre-2018 Requirements continue to be met).

The 2018 NPRM does require that where an institution opts for the three burden-reducing provisions, it must follow the 2018 Requirements effective January 21, 2019. Thus, as the commentary in the 2018 NPRM notes, an institution's decision on whether to transition a study to the 2018 Requirements to take advantage of the three burden-reducing provisions may vary depending on the "nature and progress" of the study, including whether study activity that would be affected by the 2018 Requirements is expected to extend beyond January 21, 2019. For example, ongoing studies planning to recruit additional subjects on or after January 21, 2019, will be subject to the 2018 Requirements for obtaining informed consent if the institution elects to transition to the 2018 Requirements, which may caution against electing to transition.

In summary, the proposed rule would create three options, available beginning July 19, 2018, that institutions may choose to follow for research studies initiated before January 21, 2019. The first option, and the default one, is to continue to follow all of the pre-2018 Requirements for the duration of a research study. The second option is to choose to follow the pre-2018 Requirements, except for the three burden-reducing 2018 Requirements, until January 21, 2019, when all of 2018 Requirements would become applicable. The third option would be to follow the pre-2018 Requirements beyond January 21, 2019, but at some point thereafter choose to follow all of the 2018 Requirements for the duration of a research study.

SOLICITATION OF ADDITIONAL COMMENTS

Additionally, the 2018 NPRM solicits comments on the following topics:

- The advisability of the alternative of delaying the effective date and general compliance date until January 21, 2019, but without the option to implement certain 2018 Requirements during that delay period;
- The desirability of the alternative of delaying the effective date and general compliance date beyond January 21, 2019; and

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- The advisability of not making the changes proposed in the 2018 NPRM (i.e., allowing the effective date and general compliance date to remain as July 19, 2018).

Comments to the Agencies on the 2018 NPRM are due on or before May 21, 2018, to be ensured consideration. Given the Agencies' past activity and prior statements that they would seek further delays, the likelihood of the Agencies adhering to the July 19, 2018 effective date seems low, and indeed, it is quite possible that further refinements or delays of the 2018 Requirements could be implemented between now and January 21, 2019.

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[1] The Agencies include the Department of Homeland Security; Department of Agriculture; Department of Energy; National Aeronautics and Space Administration; Department of Commerce; Consumer Product Safety Commission; Social Security Administration; Agency for International Development; Department of Housing and Urban Development; Department of Labor; Department of Defense; Department of Education; Department of Veterans Affairs; Environmental Protection Agency; Department of Health and Human Services; National Science Foundation; and Department of Transportation.

[2] 83 Fed. Reg. 17595 (April 20, 2018), 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.

[3] 82 Fed. Reg. 7149 (Jan. 19, 2017), https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01058.pdf.

[4] http://www.klgateshub.com/details/?pub=Federal-Agencies-Delay-Implementation-of-Common-Rule-Revisions-01-22-2018.

[5] 45 C.F.R. § 46.102(l)(1) (effective January 21, 2019).

[6] 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 (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters). 45 C.F.R. § 46.102(l)(2) (effective January 21, 2019).

[7] *Id*. at (l)(3) (effective January 21, 2019).

[8] *Id*. at (l)(4) (effective January 21, 2019).

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