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## Proposed Rule would Delay Common Rule General Compliance Date Until January 21, 2019 While Permitting Earlier Implementation of Three “Burden-Reducing” Provisions

In January 2017, the federal departments and agencies that follow the Federal Policy for the Protection of Human Subjects, which is typically referred to as the “Common Rule,” issued a Final Rule substantially revising the Common Rule. The Final Rule set the effective and general compliance dates of the Common Rule revisions as January 19, 2018, but as we reported in an earlier [Alert](#), those dates were delayed until July 19, 2018 through an interim final rule published in January 2018 (the “January 2018 Interim Final Rule”). 83 Fed. Reg. 2,885 (Jan. 22, 2018). The January 2018 Interim Final Rule stated that the general compliance date may be subject to additional delay through further rulemaking.

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On April 20, 2018, that further rulemaking arrived, through publication in the *Federal Register* of a Notice of Proposed Rulemaking (the “April 2018 NPRM”) proposing a further six month delay in the general compliance date of the Common Rule revisions until January 21, 2019, while permitting institutions voluntarily to implement as of July 19, 2018 three “burden-reducing” provisions contained in the revised rule. [83 Fed. Reg. 17,595 \(Apr. 20, 2018\)](#). The April 2018 NPRM leaves unchanged the January 19, 2020 compliance date of the cooperative research provision contained in the revised Common Rule.

The April 2018 NPRM lists the following as the three “burden-reducing” provisions of the revised Common Rule that institutions can choose to implement as of July 19, 2018:

- Implementing the revised definition of “research” found at §\_\_.102(l) of the revised Common Rule, which deems certain activities **not** to be research for purposes of the Common Rule, including:
  - i. scholarly and journalistic activities that focus directly on the specific individuals about whom the information is collected,
  - ii. public health surveillance activities conducted, supported, requested, ordered, required or authorized by a public health authority (as defined at §\_\_.102(k) of the revised Common Rule),
  - iii. 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, and
  - iv. authorized operational activities in support of intelligence, homeland security, defense, or other national security measures.
- Eliminating the requirement that IRBs review grant applications or proposals, found at §\_\_.103(f) of the current Common Rule.

- Allowing institutions not to conduct annual continuing review of certain categories of research, as specified at §\_\_.109(f)(1)(i) and (iii) of the Common Rule revisions. These revisions eliminate the requirement of annual continuing review for (i) research eligible for expedited review under §\_\_.110 (which, for purposes of the April 2018 NPRM refers to this section as it appears in the current and not the revised Common Rule), and (ii) research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study: (a) data analysis, including analysis of identifiable private information or identifiable biospecimens, or (b) accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

Notably, the April 2018 NPRM would not permit institutions to implement any other provisions of the revised Common Rule, such as the revised exemption categories, before the proposed general compliance date of January 21, 2019. The Common Rule Agencies explained that allowing institutions voluntarily to implement other provisions before the general compliance date “could result in confusion regarding implementation of the revised Common Rule that could be minimized by issuance of guidance from the Common Rule departments and agencies,” 83 Fed. Reg. at 17,598, thereby suggesting that the Common Rule Agencies anticipate issuing guidance regarding the Common Rule revisions in the coming months.

The April 2018 NPRM solicits public comment through May 21, 2018 on (i) the advisability of an alternative approach of delaying the effective date and general compliance date until January 21, 2019 without the option to implement the three “burden-reducing” provisions in July 2018, (ii) delaying the effective date and the general compliance date beyond January 21, 2019, and (iii) not making the changes proposed in the April 2018 NPRM. It does not propose or solicit comment on any substantive changes to the content of the Common Rule revisions.

We will continue to monitor further developments regarding the revisions to the Common Rule. Please contact [David Peloquin](#), [Leslie Thornton](#), [Abram Barth](#) or [Mark Barnes](#) if you wish to discuss these revisions in more detail.