



March 19, 2018

Dr. Jerry Menikoff, M.D., J.D.  
Director, Office for Human Research Protections  
US Department of Health and Human Services  
1101 Wootton Parkway, Suite 200  
Rockville, MD 20852

Submitted electronically at <http://www.regulations.gov>

RE: Federal Policy for the Protection of Human Subjects (Docket ID: HHS-OPHS-2017-0001)

Dear Director Menikoff:

The American Medical Informatics Association (AMIA) appreciates the opportunity to comment on the U.S. Department of Health and Human Services' Office for Human Research Protections (OHRP) delay of the Revisions to the Federal Policy for the Protection of Human Subjects, also known as the Common Rule.

AMIA is the professional home for more than 5,500 informatics professionals, representing frontline clinicians, researchers, public health experts, and educators who bring meaning to data, manage information, and generate new knowledge across the research and healthcare enterprise. As the voice of the nation's biomedical and health informatics professionals, AMIA plays a leading role in advancing health and wellness by moving basic research findings from bench to bedside, and evaluating interventions, innovations, and public policy across settings and patient populations.

In comments submitted to your office in 2016, AMIA expressed support for numerous provisions in the Final Rule meant to improve the availability of data for secondary research, while strengthening protections for research participants. The final rule also opted not to move forward with several provisions that would have incurred undue burden to those involved with conducting research. Specifically, the final rule:

- Makes important changes to consent by requiring the most important information regarding a study to be explained clearly and concisely, and in a way that a "reasonable person" could understand;<sup>1</sup>
- Permits researchers to seek broad consent, which will greatly improve the availability of biospecimens and patient-reported data (including real-time data from mobile applications and devices) for secondary research;<sup>2</sup>
- Enables more secondary research of EHR data by exempting certain low-risk studies conducted by HIPAA covered entities.<sup>3</sup> Such research could include observational studies meant to find patterns in patient records to improve how joint replacements are performed.

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<sup>1</sup> § \_\_\_\_.116(a), .116(b) & .116(c) discussion beginning 82 Fed. Reg. 12, page 7210

<sup>2</sup> § \_\_\_\_.116(d) discussion beginning 82 Fed. Reg. 12, page 7216

<sup>3</sup> § \_\_\_\_.104(d)(4) discussion beginning 82 Fed. Reg. 12, page 7191

- Clarifies that certain public health surveillance activities are explicitly outside the scope of the Common Rule, so that the spread of disease can be more easily monitored;<sup>4</sup>
- Eliminates the need for continuing review for many studies, reducing administrative burden;<sup>5</sup> and
- Provides a new option meant to help screening of potential participants, so patients who qualify for new treatments are more likely to learn about them.<sup>6</sup>

In a letter to HHS and OMB leadership in June 2017, we strongly encouraged your office to keep the updated rule's original effective date of January 19, 2018, and we requested that the rule's compliance date be delayed until June 19, 2018.<sup>7</sup> At the time, this recommendation was intended to (1) give stakeholders confidence that the rule would be enforced as intended and (2) that there was a clear timeline for implementation that would enable stakeholders to harmonize old and new provisions.

Given the history of the Common Rule 2018 Requirements, **AMIA recommends that OHRP proceed with an effective date of July 19, 2018 and a compliance date of January 19, 2019 for the 2018 Requirements.** Based on feedback from AMIA members, there exists a range of readiness among institutions subject to the Common Rule. An effective date of July 19, 2018 would give those more prepared researchers and Institutional Review Boards an opportunity to proceed with the 2018 Requirements, thus enabling implementation of provisions important to data-driven discovery and stronger protections for research participants. A compliance date of January 19, 2019 would signal to stakeholders this administration's intention to proceed in a timely fashion with implementation of the 2018 Requirements, thus ensuring that the aforementioned benefits can accrue. The absence of such a signal will delay the revised Common Rule's new benefits, and leave in place a legacy rule that neither serves research participants, nor the research community.

We appreciate the opportunity to share our recommendations. Should you have any questions or require additional information, please contact Jeffery Smith, M.P.P., Vice President of Public Policy, AMIA ([jsmith@amia.org](mailto:jsmith@amia.org)).

Sincerely,



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<sup>4</sup> § \_\_.102(l)(2) discussion beginning 82 Fed. Reg. 12, page 7175

<sup>5</sup> § \_\_.109(f) discussion beginning 82 Fed. Reg. 12, page 7205

<sup>6</sup> § \_\_.116(g) discussion beginning 82 Fed. Reg. 12, page 7227

<sup>7</sup> AMIA letter to HHS Secretary Price and OMB Director Mulvey Re: Common Rule Revisions. Available at <https://www.amia.org/sites/default/files/AMIA%20Letter%20Regarding%20the%20Common%20Rule.pdf>