INFORMATICS PROFESSIONALS. LEADING THE WAY.

June 9, 2017

The Honorable Thomas Price, M.D.
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable John M. Mulvaney
Director
The Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Re: Final Revisions to the Federal Policy for the Protection of Human Subjects

Dear Secretary Price and Director Mulvaney:

The American Medical Informatics Association (AMIA) wishes to call your attention to the Federal Policy for the Protection of Human Subjects (49 CFR Part 11), which was amended and finalized in the January 19, 2017 edition of the *Federal Register*.[1] While we appreciate the purview of your offices to review this rule as part of the Regulatory Freeze Memorandum, **AMIA strongly encourages you to keep the updated rule's original effective date of January 19, 2018, and we request you express this intent to stakeholders as soon as possible. Additionally, we request you set the rule's compliance date as June 19, 2018 to give regulated industry time to harmonize old and new provisions.**

Such actions will provide much-needed certainty to stakeholders that important policies involving research will proceed, and it will allow for timely implementation of new processes and procedures needed to harmonize the old and new rules. The absence of such actions will leave in place a legacy rule that neither serves research participants, nor the research community.

AMIA is the professional home for more than 5,400 informatics professionals, representing frontline clinicians, researchers, public health experts, and educators who bring meaning to data, manage information

[1] Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. 12 (January 19, 2017). Federal Register: The Daily Journal of the United States. https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01058.pdf

and generate new knowledge across the research and healthcare enterprise. Our members include the nation's most prestigious universities and most advanced health systems seeking to improve care delivery and clinical discovery through the collection, analysis, and application of data.

It has been over a decade since 45 CFR Part 46, known as the Common Rule, has been updated. Numerous stakeholders, including patients, researchers, manufacturers, healthcare providers, and the government itself, acknowledged in the final rule that substantial updates were needed to keep pace with innovation. In the last several years, a paradigm shift has occurred in the nature, scope and frequency of research involving human subjects, their biospecimens, and their data. Combined with rapid adoption of electronic health records (EHRs) by care providers and dramatic improvements in computing technology, we believe the final revisions to the Common Rule are necessary to improve discovery of new health insights and advance healthcare transformation.

Bipartisan legislation, known as the 21st Century Cures Act of 2016 (PL-114-255), requires HHS to update and harmonize the Common Rule in order to achieve the Act's central purpose to deliver better cures to patients faster. Furthermore, the success of the All of Us Research program and Beau Biden Cancer Moonshot initiative is dependent on many of the Common Rule updates.

Similarly, the Medicare Access and CHIP Reauthorization Act (PL-114-10) has dramatically shifted the focus of clinical stakeholders toward critical analyses of quality, cost and outcomes as part of the move to value-based payment models. To be successful under MACRA, providers will need to leverage clinical data and align research efforts to improve patient-centered care. Various provisions in the updated Common Rule provide for better access to EHR data for such purposes and lower administrative barriers to conduct more meaningful research in hospitals and physician offices.

Concurrent with these developments is the rapid adoption of EHRs in both ambulatory and inpatient settings, including a proliferation of health information technology, and related informatics applications that enable systematic collection, evaluation and application of data. The merging of research and care through large-scale human genome sequencing and proteomics projects has also provided new insights into population health, disease management and cures. AMIA firmly believes the revised Common Rule will result in quicker translation of these discoveries into patient-centered care.

American Medical Informatics Association | AMIA
4720 Montgomery Lane, Suite 500 | Bethesda, Maryland 20814

June 9, 2017

These tectonic shifts are resulting in the development of a learning health system where science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience. However, these improvements cannot move forward quickly without the updated Common Rule.

The final rule contained many provisions 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;[2]
- 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;[3]
- Enables more secondary research of EHR data by exempting certain low-risk studies conducted by HIPAA covered entities.[4] Such research could include observational studies meant to find patterns in patient records to improve how joint replacements are performed.
- 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;[5]
- Eliminates the need for continuing review for many studies, reducing administrative burden;[6] 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.[7]

The final revisions to the Common Rule reflect the kind of transparent, deliberate, and constructive process we all seek in government regulation. This process, which began more than five years ago and is meant to advance clinical research in the United States for years to come, must be carried through to completion.

A public statement, indicating that (1) the effective date of January 19, 2018 and (2) the rule's compliance dates will be extended by six months, will greatly ease concerns of this rule's status. The additional time will allow for concerted implementation, and it will ensure the continued leadership of our national research enterprise. The absence of such a signal will delay the

[2] §___.116(a), .116(b) & .116(c) discussion beginning 82 Fed. Reg. 12, page 7210
[3] §___.116(d) discussion beginning 82 Fed. Reg. 12, page 7216
[4] §___.104(d)(4) discussion beginning 82 Fed. Reg. 12, page 7191
[5] §___.102(l)(2) discussion beginning 82 Fed. Reg. 12, page 7175
[6] §___.109(f) discussion beginning 82 Fed. Reg. 12, page 7205
[7] §___.116(g) discussion beginning 82 Fed. Reg. 12, page 7227

American Medical Informatics Association | AMIA
4720 Montgomery Lane, Suite 500 | Bethesda, Maryland 20814

revised Common Rule's new benefits, and leave in place a legacy rule that neither serves research participants, nor the research community.

We appreciate your attention to this pressing need. 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).

Sincerely,

Douglas B. Fridsma, MD, PhD, FACP, FACMI
President and CEO
AMIA

Thomas H. Payne, MD, FACP, FACMI
AMIA Board Chair
Medical Director, IT Services, UW Medicine
University of Washington

American Medical Informatics Association | AMIA
4720 Montgomery Lane, Suite 500 | Bethesda, Maryland 20814