AJRR American Joint Replacement Registry
Improving Orthopaedic Care Through Data

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January 6, 2016

Jerry Menikoff, M.D., J.D.
Office of Human Research Protections (OHRP)
Department of Health and Human Services
Attention: HHS-OPHS-2015-0008
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Subject: HHS-OPHS-2015-0008 Federal Policy for the Protection of Human Subjects: Notice of Proposed Rule Making on the Common Rule

Dear Dr. Menikoff:

The American Joint Replacement Registry (AJRR) appreciates the opportunity to review and comment on the Office of Human Research Protection (OHRP) *Federal Policy for the Protection of Human Subjects: Notice of Proposed Rule Making on the Common Rule,* published in the Federal Register on September 8, 2015.

AJRR is the only national hip and knee arthroplasty registry collecting data in all 50 states, and is the largest orthopaedic registry with over 400,000 procedures, 612 hospitals, and 4,300 surgeons. AJRR collects Level I (patient, hospital, surgeon, and procedure info), some Level II (patient risk factors, co-morbidities, post-operative complications, and surgical approaches) data on patients, surgeons, medical devices, and revision complications reported under the procedural codes for primary hip and knee arthroplasty, and Level III (patient-reported outcome measures). AJRR also has a mechanism in place for orthopaedic professionals to submit their Physician Quality Reporting System (PQRS) data to CMS through our Qualified Clinical Data Registry (QCDR). AJRR initially was designated a QCDR in FY 2014, and was successfully re-designated in 2015.

Proposed Exclusion for Quality Assurance/Improvement Activities

AJRR agrees with the proposal to create an exclusion for quality assurance/improvement activities that are designed to alter the use of an accepted practice and collect identifiable patient data to evaluate the effects of the practice on utilization. However, AJRR urges OHRP to expand the exclusion to cover quality improvement activities that allow providers to compare their outcomes to generalized statistics on the outcomes of a group of providers. Clinical data registries engage in benchmarking that involves the aggregation of data collected from participating providers and reporting statistics of that data to physician and hospital participants. AJRR uses benchmarking to provide participants with general statistics that allow

providers to compare their performance with their peers. This benchmarking is a type of quality improvement and statistical comparison that is not considered as research. Therefore, these quality improvement activities should be part of the exclusion of quality assurance/improvement activities.

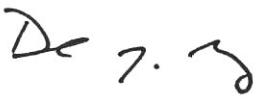
Proposal for Harmonization of Agency Guidance

AJRR supports the provision that states that the final guidance on the Common Rule shall only be issued after consultation among the Common Rule agencies for the purpose of harmonization of guidance, to the extent appropriate, before Federal guidance on the Common Rule is issued, unless such consultation is not feasible. We respectfully request that this proposal be modified to also require harmonization between the Common Rule and HIPAA Rules since these rules overlap in many ways.

AJRR appreciates the response from OHRP in posting the OHRP correspondence with Dr. Anthony Asher on the OHRP website, in which you responded to issues pertaining to clinical data registries. However, AJRR respectfully requests that OHRP issue a guidance in respect to the application of subpart A of part 46 of title 45, Code of Federal Regulations, governing the protection of human subjects in research, to activities, including quality improvement activities, involving clinical data registries, including entities that are qualified clinical data registries pursuant to section 1848(m)(3)(E) of the Social Security Act (42 U.S.C. 1395w-4(m)(3)(E)). We suggest that OHRP consider creating a time table of events with dates so that organizations can plan accordingly.

The AJRR appreciates this opportunity to provide comments on the *Federal Policy for the Protection of Human Subjects: Notice of Proposed Rule Making on the Common Rule*. We look forward to continuing to work with OHRP to provide guidance and input on issues related to the clinical data registries. If you have questions regarding our comments, please do not hesitate to contact our Executive Director, Jeffrey P. Knezovich, CAE at (847) 430-5036 or at knezovich@ajrr.net.

Sincerely,



Daniel J. Berry, MD
Chair
American Joint Replacement Registry

cc: Jeffrey P. Knezovich, CAE, Executive Director
David G. Lewallen, MD, Medical Director