



October 25, 2011

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

**RE: Request for Public Comment on Proposed Changes to Human Participant Research Regulations, HHS-OPHS-2011-0005**

Dear Dr. Menikoff:

The National Business Group on Health appreciates the opportunity to comment on the advance notice of proposed rulemaking (ANPRM) to revise the current regulations protecting human subjects participating in research. The National Business Group on Health strongly urges you to modernize these regulations and exempt from human subject investigational review board (IRB) review studies that only involve the collection of information on routine operations (including clinical effectiveness assessments and quality improvement activities) and carry no more than minimal risk to patients. HHS needs to exempt operational clinical effectiveness and quality improvement assessments (involving accepted therapies) from IRB reviews to establish a continuous learning health care system and avoid harming patients by delaying the introduction of quality improvements that work into clinical care. The very lives of patients are at risk if hospitals are unable to continuously improve their processes to increase the safety of patients.

The National Business Group on Health represents over 330 companies, including many of America's largest employers (68 of the Fortune 100) who voluntarily provide health benefits and other health programs to over 55 million American employees, retirees, and their families.

The Institute of Medicine's (IOM) Roundtable on Value & Science-Driven Health Care has addressed incorporating continuous improvement in all aspects of health and health care delivery to create a continuous *learning health care system*. In a learning health care system organizations use evidence-based approaches for prevention, diagnosis, and treatment, and also learn from care delivered to develop new evidence. These processes incorporate elements traditionally considered quality improvement activities and others classified as evaluation of clinical effectiveness.

A major focus of IRB reviews is the need for patients to have full informed consent in human subject research. Yet, studies have found that the IRB's often time consuming and expensive bureaucratic burdens do not fully inform patients of the risks involved in taking part in studies and may contribute to the abandonment of important initiatives to improve the effective delivery of care. IRB reviews and/or the requirement for an obtrusive informed consent process should not hold up routine, risk-free interventions intended to enhance adherence to accepted clinical practices.

Attached, please find the Roundtable's responses to the APRM's questions to modernize the rules protecting human subjects participating in research. The responses distinguish between the quality and clinical effectiveness assessments for continuous improvement and research from activities that differ from accepted practice or pose more than minimal risk to patients' privacy and confidentiality that still require formal oversight by IRB reviews. Members of the Roundtable also addressed these issues in a recent IOM discussion paper *Stewarding Continuous Improvement in Healthcare: A Learning Health System Perspective*. (See separate document). The discussion paper emphasizes how best to reshape the regulations and create a continuously improving health care system that meets the needs of patients, clinicians, and institutions involved in this work.

Examples of activities the discussion paper cites as routine operations that HHS should exempt from IRB reviews when conducted on behalf of health care organizations/providers to assess quality or effectiveness initiatives, include:

- Use of routinely collected health care information for purposes other than direct care of individual patients;
- Analysis of administrative databases;
- Surveys related to quality and effectiveness of care;
- Systematic variation of care within a health care system or patient population, provided that all patients receive care that is in general use, is consistent with the guidance of regulatory and standard-setting bodies, and carries no more than minimal risk;
- Dissemination of learning from tests of change through publication or other means; and
- Coordination of any of these activities among multiple providers or organizations. For example, a hospital or individual practice may only learn which patients are readmitted to other hospitals by obtaining this information from the patients' health plans or insurers.

We look forward to continuing to work with you to implement a risk-based framework that exempts from IRB review studies limited to the collection of routine information or with minimal risk. Modernizing the existing regulations protecting human subjects participating in research will establish a continuous learning system to successfully introduce quality improvements into clinical care in a timely manner. Please contact me or Steven Wojcik, the National Business Group on Health's Vice President of Public Policy, at (202) 558-3012, if you would like to discuss our comments in more detail.

Sincerely,

A handwritten signature in black ink that reads "Helen Darling". The signature is written in a cursive, flowing style.

Helen Darling  
President and CEO

**ANPRM Questions Addressed in the IOM Discussion Paper  
Stewarding Continuous Improvement in Healthcare: A Learning Health System  
Perspective**

#	Question	How issue is addressed in paper
23	<p><i>Under what circumstances should it be permissible to waive consent for research involving the collection and study of existing data and biospecimens as described in Section 3(a)(3) above [section describes use of data or specimens previously collected for use other than research]? Should the rules for waiving consent be different if the information or biospecimens were originally collected for research or non-research purposes? Should a request to waive informed consent trigger a requirement for IRB review?</i></p>	<ul style="list-style-type: none"> <li>- Consent should not be needed for operational assessments of low (info-only, minimal) risk.</li> </ul>
24	<p><i>We seek comment on whether and, if so, how, the Common Rule should be changed to clarify whether or not oversight of quality improvement, program evaluation studies, or public health activities are covered.</i></p> <p><i>a. Are there specific types of these studies for which the existing rules (even after the changes proposed in this Notice) are inappropriate?</i></p> <p style="padding-left: 20px;"><i>i. If so, should this problem be addressed through modifications to the exemption (Excused) categories, or by changing the definition of “research” used in the Common Rule to exclude some of these studies, or a combination of both?</i></p> <p style="padding-left: 40px;"><i>a. And if the definition of research were to be changed, how should the activities to be excluded be defined (e.g., “quality improvement” or “program evaluation”)?</i></p> <p><i>b. Are there some such activities that should not be excluded from being subject to the Common Rule because the protections provided by that rule are appropriate and no similar protections are provided by other regulations?</i></p> <p><i>c. With regard to quality improvement activities, might it be useful to adopt the distinction</i></p>	<ul style="list-style-type: none"> <li>- Assessments that health care institutions formally classify as being in support of operations, are a responsibility of the institution and should not be subject to IRB oversight unless they impose greater than minimal risk.</li> <li>- Determination of oversight should not be based on what assessments are called (research, QI etc) but whether or not they are part of an institution’s operations and their level of risk.</li> <li>- We suggest that the distinction between operations and research made in HIPAA is a useful basis by which to distinguish assessments.</li> <li>- Intent to produce generalizable results should not be a criterion for assessment categorization; assessments in support of operations may be generalizable.</li> </ul>

	<p><i>made by the HIPAA Privacy Rule (45 CFR 164.501(1)), which distinguishes between “health care operations” and “research” activities, defining “health care operations” to include “conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities”?</i></p>	
30	<p><i>What are the advantages and disadvantages of mandating, as opposed to simply encouraging, one IRB of record for domestic multi-site research studies?</i></p>	<ul style="list-style-type: none"> <li>- Using a single IRB for domestic, multi-site studies is desirable, since this will decrease administrative burden and minimize inconsistencies across IRBs</li> </ul>
33	<p><i>How significant are the inefficiencies created by local IRB review of multi-site studies?</i></p>	<ul style="list-style-type: none"> <li>- They are substantial and often constitute a serious impediment.</li> </ul>
45	<p><i>Under what circumstances should future research of data initially collected for non-research purposes require informed consent? Should consent requirements vary based on the likelihood of identifying a research subject? Are there other circumstances in which it should not be necessary to obtain additional consent for the research of currently available data that were collected for a purpose other than the currently proposed research?</i></p>	<ul style="list-style-type: none"> <li>- Use of routinely collected health care information should not be subject to consent requirements if it is necessary to study a generalizable population. Fair information practices should apply. .</li> </ul>
46	<p><i>Under what circumstances should unanticipated future analysis of data that were collected for a different research purpose be permitted without consent? Should consent requirements vary based on the likelihood of identifying a research subject?</i></p>	<ul style="list-style-type: none"> <li>- Use of routinely collected health care information should not be subject to consent requirements if it is necessary to study a generalizable population. Fair information practices should apply. .</li> </ul>
53	<p><i>In cases in which consent for future research use is not obtained at the time of collection, should there be presumption that obtaining consent for secondary analysis of existing biospecimens or identifiable data would be deemed impracticable, such as when more than a specified threshold number of individuals are involved? (SACHRP provided the Secretary with recommendations on this issue.\81\) If so, what threshold number should constitute impracticability? Is the number of potential human subjects the only measure of impracticability?</i></p>	<ul style="list-style-type: none"> <li>- Use of routinely collected health care information for purposes other than the direct care of individual patients should be considered routine operations, not subject to consent requirements.</li> </ul>

54	<i>Will use of the HIPAA Privacy Rule's standards for identifiable and de-identified information, and limited data sets, facilitate the implementation of the data security and information protection provisions being considered? Are the HIPAA standards, which were designed for dealing with health information, appropriate for use in all types of research studies, including social and behavioral research? If the HIPAA standards are not appropriate for all studies, what standards would be more appropriate?</i>	<ul style="list-style-type: none"> <li>- Application of HIPAA standards should depend on whether an assessment is operational in nature or not, as well as the level of risk. Assessments that are operational and of low (info-only, minimal) risk should be held to HIPAA standards for operations.</li> <li>- All assessments should be held to fair information practices.</li> </ul>
61	<i>Are there additional data security and information protection standards that should be considered? Should such mandatory standards be modeled on those used by the Federal government (for instance, the National Institute of Standards and Technology recently issued a "Guide to Protecting the Confidentiality of Personally Identifiable Information.")?</i>	<ul style="list-style-type: none"> <li>- All assessments should be held to fair information practices.</li> </ul>