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Lead

Improving the Informed Consent Process

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Regulatory Counsel

March 13, 2013
Secretary's Advisory Committee on Human Research Protection (SACHRP)

Association of American Medical Colleges

Association of American Medical Colleges

The AAMC serves and leads the academic medicine community to improve the health of all.

- Founded in 1876
- Not-for-profit association representing:
  - 141 accredited U.S. and 17 accredited Canadian medical schools
  - Nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers
  - 90 academic and scientific societies

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AAMC Informed Consent Simplification Project

- July 2009 AAMC convened a group of 13 experts to review three existing IRB approved protocols with long, complicated consent forms

- Approach:
  - Reviewed literature about the consent process and usefulness of consent forms
  - Discussed and created model templates that are readable, brief, and included all the required regulatory elements
- The charge was to simplify not to simply shorten the actual consent document and then to field test the new templates

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AAMC Informed Consent Simplification Project

- Each group created a series of drafts and considered options
  - a form plus an appendix
  - a form plus a handbook
  - a summary plus a form
- Two groups created a stand alone form and one group created a 3 part form (basic information, the consent and instructions to researchers)
- Developed documents were shared with FDA and OHRP for review and comment

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AAMC Informed Consent Simplification Project

"What a fascinating and enlightening exercise - even though I've read the required and additional elements of informed consent a hundred times, I learned that I have a pretty skewed view of what is "required" for valid informed consent. (Maybe it's because I've read sponsors' drafts even more!) I used the regulatory elements (instead of the investigator's draft) as my primary source for deciding where to draw the line for these documents, and found I could eliminate far more than I'd expected."

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The Full Spectrum of Research

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Enhancing Capacity for Clinical Effectiveness and Implementation Science

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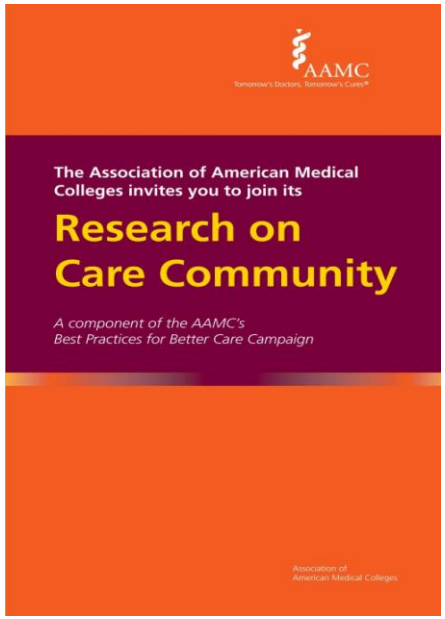
INSTITUTE OF MEDICINE

BUILDING EFFECTIVENESS & IMPLEMENTATION RESEARCH INTO CLINICAL PRACTICE

February 13, 2012



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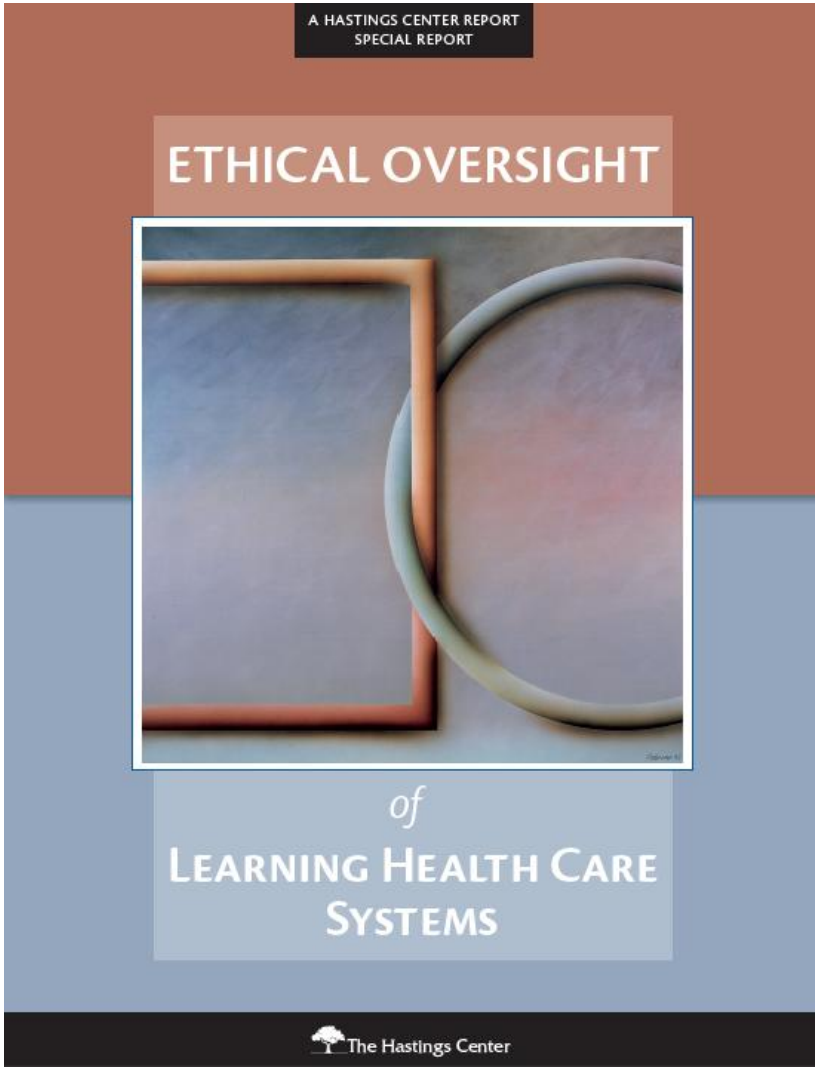
A HASTINGS CENTER REPORT
SPECIAL REPORT
ETHICAL OVERSIGHT
of
LEARNING HEALTH CARE SYSTEMS
The Hastings Center

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Hastings Center/AAMC Report on Ethical Oversight of Learning Health Care Systems

"A moral framework for a learning health care system will depart in important respects from contemporary conceptions of clinical and research ethics. The dominant paradigm in research ethics and in federal regulations has relied on a sharp distinction between research and practice… The learning health care system, by contrast, proposes that it is acceptable and indeed essential to integrate research and practice."

- Faden et al.

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AAMC Workshop: Facilitating IRB Review of CBPR

University of Alabama at Birmingham

Medical College of Wisconsin

Vanderbilt University

Case studies of successful strategies based on the experiences of six institutions, including approaches to informed consent

Morehouse School of Medicine

University of Michigan Medical School

Virginia Commonwealth University

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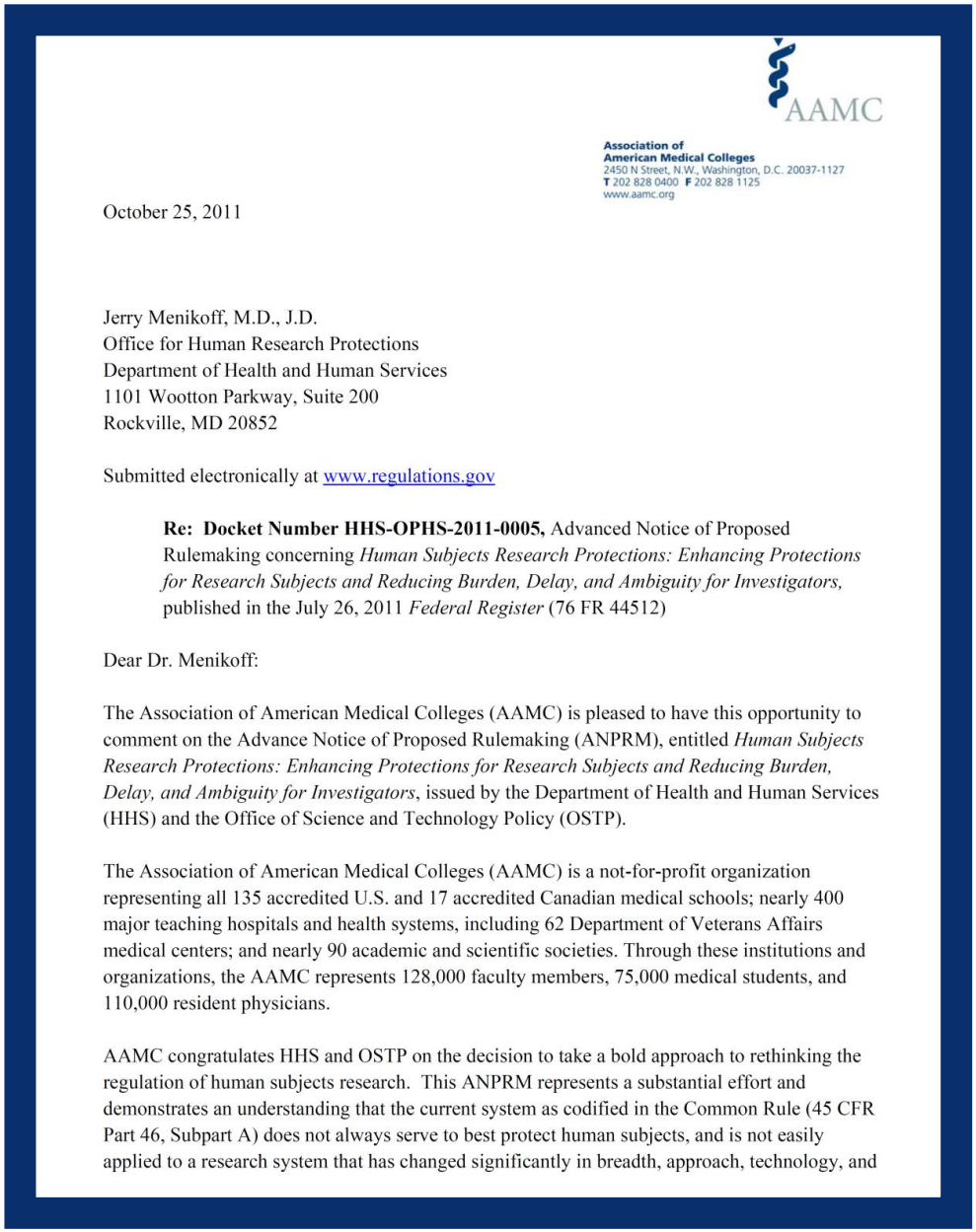

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October 25, 2011

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

Submitted electronically at www.regulations.gov

Re: Docket Number HHS-OPHS-2011-0005, Advanced Notice of Proposed Rulemaking concerning *Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators,* published in the July 26, 2011 *Federal Register* (76 FR 44512)

Dear Dr. Menikoff:

The Association of American Medical Colleges (AAMC) is pleased to have this opportunity to comment on the Advance Notice of Proposed Rulemaking (ANPRM), entitled *Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators*, issued by the Department of Health and Human Services (HHS) and the Office of Science and Technology Policy (OSTP).

The Association of American Medical Colleges (AAMC) is a not-for-profit organization representing all 135 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 62 Department of Veterans Affairs medical centers; and nearly 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 128,000 faculty members, 75,000 medical students, and 110,000 resident physicians.

AAMC congratulates HHS and OSTP on the decision to take a bold approach to rethinking the regulation of human subjects research. This ANPRM represents a substantial effort and demonstrates an understanding that the current system as codified in the Common Rule (45 CFR Part 46, Subpart A) does not always serve to best protect human subjects, and is not easily applied to a research system that has changed significantly in breadth, approach, technology, and

The AAMC comment letter generally supports the proposals to streamline the initial and continuing review of research and to improve the informed consent requirements to make the process more meaningful to research subjects.

Comment letter online at https://www.aamc.org/initiatives/research/257508/humansubjectprotections.html

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AAMC Response to the ANPRM

- Informed consent has become a documentation process that serves many purposes, perhaps at the expense of the fundamental goals:
  - to provide individuals with the relevant information, time, and opportunities to formulate questions about the research
  - to ensure that the subject has given voluntary, informed consent

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AAMC Response to the ANPRM

- **Flexibility is Key**
  - "While we support the shortening and simplification of informed consent forms and have been involved in efforts to further this goal, we do not believe that imposing specific page limits or other proscriptive formatting requirements is appropriate."
  - "Instead, we suggest that the regulations and accompanying guidance stress the flexibility that IRBs have to approve documents that provide all meaningful and relevant information to individuals, including easy access to more information as needed."

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AAMC Response to the ANPRM

- **Focus on the process, not the document**
  - The Common Rule and the ANPRM maintains regulatory focus on the *document*
  - Ideally, the consent "form" only serves as written documentation that such a process has occurred.
  - "The regulations should dictate required elements of the process but not the precise manner in which the information is provided. Novel document formats… should be allowed and encouraged by the regulations."

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U.S. Food and Drug Administration

Protecting and Promoting *Your* Health

A Guide to Informed Consent - Information Sheet

Guidance for Institutional Review Boards and Clinical Investigators

Contents

The Consent Process

Informed consent is more than just a signature on a form, it is a process of information exchange that may include, in addition to reading and signing the informed consent document, subject recruitment materials, verbal instructions, question/answer sessions and measures of subject understanding. Institutional Review Boards (IRBs), clinical investigators, and research sponsors all share responsibility for ensuring that the informed consent process is adequate. Thus, rather than an endpoint, the consent document should be the basis for a meaningful exchange between the investigator and the subject.

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