

AAHRPP

Association for the Accreditation of
Human Research Protection Programs, Inc.®

September 28, 2004

Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Notice of proposed rulemaking – Institutional Review Boards:
Registration Requirements, Docket No. 2004N-0242

FOUNDERS:

ASSOCIATION OF
AMERICAN MEDICAL
COLLEGES

ASSOCIATION
OF AMERICAN
UNIVERSITIES

CONSORTIUM OF
SOCIAL SCIENCE
ASSOCIATIONS

FEDERATION OF
AMERICAN SOCIETIES
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BIOLOGY

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ASSOCIATION OF
STATE UNIVERSITIES
AND LAND-GRANT
COLLEGES

NATIONAL HEALTH
COUNCIL

PUBLIC
RESPONSIBILITY
IN MEDICINE AND
RESEARCH

The Association for the Accreditation of Human Research Protection Programs (AAHRPP) is an accrediting body. AAHRPP accredits organizations that conduct or review research involving human participants, and evaluation of the institutional review board function is one of five domains in our accreditation standards. AAHRPP strongly supports the intentions of the Food and Drug Administration and the Department of Health and Human Services and to register IRBs. Numerous governmental reports and Congressional hearings have highlighted the need for basic, essential information about human research, including information about IRBs. The proposed registration would provide important information about IRBs with little, if any, increased burden on organizations that would be required to report under this rule.

AAHRPP offers the following comments about the notice of proposed rule making:

1. Under the rule, an institution or IRB organization would be required to report the number of protocols it reviews using a range system of small, medium, or large. Small would be defined as 1 - 25, medium as 26 - 499, and large as 500 or more. Based on our experience, we would encourage you to consider redefining the ranges as small 1 - 99, medium 100 - 499, large 500 - 1,999, and very large as 2,000 or more. There is a substantial number of organizations that oversee thousands of protocols and they operate quite differently from those with protocols in the 500 range. Further, at the lower end, there appears to be a small number of organizations with fewer than 25 protocols. Organizations with very few protocols often rely upon another IRB rather than form their own.
2. The notice of proposed rule making refers to IRB accreditation. AAHRPP does not accredit IRBs, per se; rather, it accredits an organization's human research protection program. Even when AAHRPP accredits an independent IRB, it is evaluated based on the standards for a comprehensive human research protection

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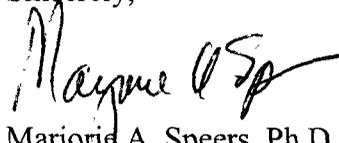
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program. Our accreditation program, and this point in particular, is based on the recommendations of the Institute of Medicine's reports, "Preserving Public Trust" and "Responsible Research," which were commissioned by the Department of Health and Human Services. We recommend that you refer to accreditation of human research protection programs rather than IRBs.

3. You propose to collect information about the date of accreditation and the name of the accrediting body. This information is wholly appropriate. In addition, we recommend capturing information about the name of the accredited organization under which the IRB functions. It is not clear to us in the notice of proposed rule making whether you will be collecting information about accreditation at the institutional or IRB level.
4. You may wish to consider collecting information about accreditation type or level. For example, AAHRPP has two accredited categories – Full AAHRPP Accreditation and Qualified AAHRPP Accreditation. To achieve either category, an organization must meet federal regulatory requirements. The difference between them relates to minor administrative issues that could be improved upon in the qualified category. Accreditation in either category is valid for three years. Another accrediting body, for example, has two categories of accreditation but the time period for accreditation differs; it is either one or three years.

We applaud the Food and Drug Administration and the Department of Health and Human Services' efforts to better understand the IRB landscape and to collect important information that will help to improve the public's confidence in the oversight of human research.

Sincerely,



Marjorie A. Speers, Ph.D.
Executive Director