

Submit Comments at: <https://www.federalregister.gov/articles/2015/09/08/2015-21756/federal-policy-for-the-protection-of-human-subjects#open-comment>

Comments of the Association of Academic Health Sciences Libraries (AAHSL) and Medical Library Association (MLA)

In Response to the Proposed Rule, *Federal Policy for the Protection of Human Subjects*, ID Number HHS-OPHS-2015-0008.

As health sciences librarians who fulfill requests for information from researchers, clinicians, and patients, we enthusiastically support efforts to modernize, strengthen, and make more effective the 1991 Federal Policy for the Protection of Human Subjects. We agree that updating the Common Rule for the protection of human participants in research is very much needed. Our comments focus on the informed consent provisions outlined in the proposed policy.

The Medical Library Association (MLA) and Association of Academic Health Sciences Libraries (AAHSL) maintain that study participants must have a clear understanding of what they are agreeing to before signing up for a study. They should be provided with information written in plain language that describes the study's scope, its risks and benefits, and alternatives to participating in the study.

Because the proposed rule would apply to all clinical trials, we recommend that ClinicalTrials.gov be used as the repository where the informed consent forms are stored. Using ClinicalTrials.gov ensures that all of the information related to a specific trial is found in one place by the more than 61,000 researchers, clinicians, and public who use the database daily.

The proposed rule complements the goals of the recently released *Draft NIH Policy on Dissemination of NIH-Funded Clinical Trial Information, Clinical Trials Registration and Results Submission* to expand and clarify regulations for clinical trials registration and results submission. Adding a copy of the final version of the consent form into the ClinicalTrials.gov record would offer researchers, clinicians, and the public a one-stop trustworthy database where they could access comprehensive and transparent information. The benefits would provide a current and complete picture of the results of clinical trials, protect the safety of clinical trials' participants, enable human subjects and their health care providers to make more informed decisions about participating in a trial, and broaden the evidence base for systematic reviewers and others. Another benefit is the cost savings that will be achieved by adding functionality and value to the current ClinicalTrials database while avoiding the costs associated with creating a new website.

Thank you for the opportunity to share our recommendations on the proposed changes to the Common Rule for the Protection of Human Subjects in Research. On behalf of the health sciences library community, please let us know if we can provide additional information.

Organizational Bios

The Medical Library Association (MLA) is a nonprofit, educational organization with 3,500 health sciences information professional members worldwide. Founded in 1898, MLA provides lifelong educational opportunities, supports a knowledgebase of health information research, and works with a global network of partners to promote the importance of quality information for improved health to the health care community and the public.

The Association of Academic Health Sciences Libraries (AAHSL) supports academic health sciences libraries and directors in advancing the patient care, research, education and community service missions of academic health centers through visionary executive leadership and expertise in health information, scholarly communication, and knowledge management.

Print your comment

Print

Federal Policy for the Protection of Human Subjects

A Proposed Rule by the Department of Labor

Document URL

<https://www.federalregister.gov/a/2015-21756>

Published On

2015-09-08

Comment Tracking Number

1jz-8lsh-koaw

Comment Submission Date

2015-10-20

First Name

Mary

Last Name

Langman

Mailing Address

Medical Library Association

Mailing Address 2

65 E. Wacker Place, Suite 1900

City

Chicago

Country

United States

State or Province

Illinois

ZIP/Postal Code

60601-7246

Email Address

langman@mail.mlahq.org

Phone Number

312/419-9094, ext. 27

Organization Name

Medical Library Association & Association of Academic Health Sciences Libraries

Comment

Comments of the Association of Academic Health Sciences Libraries (AAHSL) and Medical Library Association (MLA)

In Response to the Proposed Rule, Federal Policy for the Protection of Human Subjects, ID Number HHS-OPHS-2015-0008.

As health sciences librarians who fulfill requests for information from researchers, clinicians, and patients, we enthusiastically support efforts to modernize, strengthen, and make more effective the 1991 Federal Policy for the Protection of Human Subjects. We agree that updating the Common Rule for the protection of human participants in research is very much needed. Our comments focus on the informed consent provisions outlined in the proposed policy.

The Medical Library Association (MLA) and Association of Academic Health Sciences Libraries (AAHSL) maintain that study participants must have a clear understanding of what they are agreeing to before signing up for a study. They should be provided with information written in plain language that describes the study's scope, its risks and benefits, and alternatives to participating in the study.

Because the proposed rule would apply to all clinical trials, we recommend that ClinicalTrials.gov be used as the repository where the informed consent forms are stored. Using ClinicalTrials.gov

ensures that all of the information related to a specific trial is found in one place by the more than 61,000 researchers, clinicians, and public who use the database daily.

The proposed rule complements the goals of the recently released Draft NIH Policy on Dissemination of NIH-Funded Clinical Trial Information, Clinical Trials Registration and Results Submission to expand and clarify regulations for clinical trials registration and results submission. Adding a copy of the final version of the consent form into the ClinicalTrials.gov record would offer researchers, clinicians, and the public a one-stop trustworthy database where they could access comprehensive and transparent information. The benefits would provide a current and complete picture of the results of clinical trials, protect the safety of clinical trials' participants, enable human subjects and their health care providers to make more informed decisions about participating in a trial, and broaden the evidence base for systematic reviewers and others. Another benefit is the cost savings that will be achieved by adding functionality and value to the current ClinicalTrials database while avoiding the costs associated with creating a new website.

Thank you for the opportunity to share our recommendations on the proposed changes to the Common Rule for the Protection of Human Subjects in Research. On behalf of the health sciences library community, please let us know if we can provide additional information.

Organizational Bios

The Medical Library Association (MLA) is a nonprofit, educational organization with 3,500 health sciences information professional members worldwide. Founded in 1898, MLA provides lifelong educational opportunities, supports a knowledgebase of health information research, and works with a global network of partners to promote the importance of quality information for improved health to the health care community and the public.

The Association of Academic Health Sciences Libraries (AAHSL) supports academic health sciences libraries and directors in advancing the patient care, research, education and community service missions of academic health centers through visionary executive leadership and expertise in health information, scholarly communication, and knowledge management.