



Social Science History Association

October 25, 2011

Dr. Jerry Menikoff
OHRP
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Dear Dr. Menikoff:

The Social Science History Association welcomes this opportunity to comment on the proposals for revisions to the Common Rule. SSHA supports the goals of the ANPRM to focus the IRB system on the protection of human subjects and to reduce unnecessary burdens on investigators and on IRB committees. SSHA members have noted with alarm the tendency of some IRBs to expand their scrutiny to research with little or no risk to subjects and to inappropriately apply bio-medical analogies to social science research.

The Social Science History Association is an interdisciplinary group of scholars that shares interests in social life and theory, historiography, and historical and social-scientific methodologies. SSHA brings together a range of scholarly communities with interests ranging from everyday life in the medieval world – and sometimes earlier – to contemporary global politics. We are united in our historicized approach to understanding human events, explaining social processes, and developing innovative theory.

- SSHA strongly supports the proposal to create new, simpler procedures for minimal risk research, which would reduce IRB requirements for most investigators in the social sciences.
- We support proposals to simplify informed consent and to broaden the use of oral consent.
- Investigators who do not interact with subjects or use identifiable (or re-identifiable) confidential information should not be required to report to IRBs
- We are concerned that data security measures designed for confidential health data will be applied to other domains with very different research models. For example, the standard practice in Oral History is to inform interviewees that they will be identified by name. Since the subject has no expectation of confidentiality, cumbersome data security procedures should be unnecessary.

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Question 19

No. The onus should be on the IRB to act quickly.

Question 25

We see no benefits in extending the IRB oversight to fields that were not intended to be covered under the Common Rule. Historians studying public records of long-dead subjects are clearly outside the scope of the Common Rule. Researchers should not need to register with an IRB for research that does not involve (living) human subjects or is based entirely on publicly available sources. HHS should also recognize codes of ethical conduct that assure minimal risks to subjects, and investigators who commit to abiding by those codes should be “Excused” from further IRB review.

Question 28

A mechanism for appealing IRB decisions would be welcome.

Question 29

If IRBs engage in activities outside their mandate, they should be required to explain their actions.

Question 54

HIPAA standards are not appropriate for most social science research. The HIPAA approach to de-identification is not applicable to many types of qualitative data, where rich descriptions make re-identification possible.

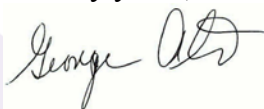
Question 59

We oppose extending stringent data security measures to all data without a mechanism for evaluating informational risks. Many data sets used in social science research are currently provided to other researchers as public-use data without data protection requirements. An across the board approach to data security will impose unnecessary burdens on a large number of researchers using data that could be considered public use.

Question 63

We support a prohibition on re-identification of subjects in de-identified data that was obtained under an expectation of confidentiality.

Sincerely yours,

A handwritten signature in black ink, appearing to read "George Alter", is placed over a light yellow rectangular background.

George Alter
Professor of History
University of Michigan
SSHA President, 2011