



Linguistic Society of America
Archibald A Hill Suite
1325 18th Street, NW #211
Washington, DC 20036-6501

Phone: 202.835.1714
Fax: 202.835.1717
Email: lsa@lsadc.org
Web: www.lsadc.org

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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

Dear Dr. Menikoff:

On behalf of the Linguistic Society of America (LSA), I am writing this letter to offer comments on the proposed changes to the Common Rule as described in the Advance Notice of Proposed Rulemaking (ANPRM), *Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators*. The LSA is the major professional society in the United States that is exclusively dedicated to the advancement of the scientific study of language.

Linguists employ a wide variety of research methods involving human subjects, ranging from MRI techniques, used to examine which parts of the brain are stimulated by speech, to psychological experiments, conducted to test hypotheses about language processing, to interviews and participant observation with speakers of undescribed languages in order to gather information on their language's vocabulary and grammar. As a result, the field as a whole is aware of a wide range of issues relating to research on human subjects, including concerns emanating from both biomedical and social science research methods. Moreover, linguistic research making use of social science research methods is itself quite heterogenous, in some cases involving highly-constrained investigation in controlled settings and in others involving relatively open-ended humanistic techniques—as well as many things in between.

The main areas of comment about the ANPRM from the LSA membership have come from linguists employing research methods generally associated with the social sciences, in particular methods involving the use of structured and unstructured interviews or participant observation to gather information about a particular language or speakers of a language. We highlight two specific issues that have been raised by the Society's members in this regard here:

1. HIPAA Privacy Rules are inappropriate for many kinds of linguistic data

The comments below are relevant to ANPRM questions 39, 54, 58, 59, all concerning the potential application of HIPAA Rules to human subjects research.

While the adoption of HIPAA Privacy Rules for linguistic research employing biomedical methods may often be reasonable, there are many cases where they are not only inappropriate but may even be contrary to basic ethical principles of linguistic research. For instance, linguists frequently gather information from linguistic consultants about the vocabulary and grammar of the consultants' native languages. This language information, far from being considered private, is collected both to further linguistic research and to assist with a community's efforts to maintain or revitalize its language. If HIPAA Privacy Rules are adopted as the norm, then a linguist could, for example, be placed in the clearly bizarre situation of having to obtain a special exemption to allow a community to have access to data on its own language in case its members are not in a position to ensure its "security", even when the relevant language data has been explicitly categorized as not needing to be secure by the individual providing it.

We provide this one example here to clarify how HIPAA privacy rules do not always align well with accepted ethical practice in linguistics but should emphasize that this is an issue of broad concern to many linguists who conduct minimal-risk studies collecting data that has never been considered to need strong security protections—quite the contrary, the data is often collected specifically in order to allow information about a language to become more widely available.

We are also concerned that many departments and universities lack the computational resources and funding to implement HIPAA security measures for all projects, including short-term student research projects. For very low-risk projects, such as psycholinguistic studies of how a particular sound is perceived, this level of data protection is again unnecessary, and it will hinder research without any obvious benefits to human subjects.

2. Evaluation of diverse research practices requires application of local knowledge

The comments below are relevant at least to ANPRM questions 1, 5, 6, 7, 9, and 12 (covering determination of risks, categories of research eligible for expedited review, and documents required for review), 21 (regarding recommendations for application of retrospective audits), 35–37 (regarding content and length of consent forms), and 41–44 (regarding waivers of informed consent).

On the whole, the creation of a new *Excused* category for research is welcomed by the linguistics community. However, we would like to stress that due to the varied nature of linguistic research, and in particular the fact that much of it is conducted internationally and in culturally diverse environments, it is often important for a researcher's local IRB to have sufficient autonomy to be able to adjust the requirements for the protection of human subjects in ways that are responsive to the specific human subjects issues raised by a given research project. In short, we are advocating for more local control in research evaluation. In particular, we believe local control will ensure that the best decisions are made regarding when requirements for informed consent can be waived or modified and, relating to our first comment above, what sorts of security requirements are required for a given collection of data.

In advocating for more local control, it is important to make clear that this should not be understood as advocating for varying local interpretations regarding the details of implementation of a highly prescriptive regulatory framework. As documented in Bower's (2010) survey of the experiences of linguists conducting field work with IRBs (published in *Language* 86:897-905), a common concern has been inconsistencies in the application of federal

requirements that have been framed with a biomedical research model in mind and which linguistic field research rarely conforms to. Rather, we are supporting increased local autonomy in assessing fundamental questions, such as what the level of risk is for human subjects in a given research project or which kinds of data collected by a project contain potentially sensitive information.

We note in particular that local IRBs are in a position to build long-term relationships with researchers, giving them insight into the diverse research projects conducted at their institution. Such insight allows IRBs to focus their attention on those aspects of any project most likely to pose risk to human subjects, to the benefit of all involved. The development of these relationships is especially valuable in the context of work adopting humanistic methods of investigation where key research questions often emerge over time, rather than being known from the outset, and where human subject concerns cannot be cleanly encapsulated by pre-determined lists of points to consider.

Again, the LSA would like to thank you for the opportunity to review and comment on the ANPRM. Please do not hesitate to contact me if you would like clarification on any of the points made here.

Sincerely,

A handwritten signature in black ink, appearing to read 'Sandra Chung', written in a cursive style.

Sandra Chung

President