

Response to Advance notice of proposed rulemaking (ANPRM), “Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators.”

**Submitted by the Committee on Professional Ethics, Rights, and Freedoms
American Political Science Association**

October 26, 2011

The American Political Science Association’s Committee on Professional Ethics, Rights, and Freedoms welcomes the initiative in the Advance Notice and agrees with most of its aims. In particular, we support, and see as quite complementary, the goals of focusing effort on protecting human subjects where that protection really is necessary, on one hand, and reducing unnecessary restrictions and ambiguity for researchers, on the other. But we are concerned that ambiguity remains about the boundaries of risks for subjects and are especially worried that the proposals to reduce informational risk will seriously hamper secondary research.

The APSA Committee on Professional Ethics, Rights, and Freedoms

Founded in 1903, the American Political Science Association is the leading professional organization for the study of political science and serves more than 15,000 members in over 80 countries. With a range of programs and services for individuals, departments and institutions, APSA brings together political scientists from all fields of inquiry, regions, and occupational endeavors within and outside academe to expand awareness and understanding of politics.

The Association’s Committee on Professional Ethics, Rights, and Freedoms is a standing committee of the Association and advises the APSA Council and the political science community on ethical guidelines for research and professional practice. In September 2011, the APSA Council requested that the Committee coordinate comments from the Association in response to the ANPRM and to lead the Association in continuing deliberation, formulation and dissemination about good practice in human subjects protection and scholarship.

Key Concerns

1. Where the protection of human subjects is at issue in social, behavioral, and historical sciences, we are concerned that research risks not be exaggerated. The physical risks in our research are essentially non-existent. Where risks do exist, it goes without saying that consent issues are compelling. Psychological risk is more plausible, but is also usually modest to nil. Here too, regulation should match risk, not presuppose it.
2. For a number of our colleagues, the human subject in question is a political or bureaucratic actor. If there is a power differential in this situation, it favors the

subject. In common with historians and other humanists, many of our colleagues work with archival material whose authors or subjects are deceased. We are anxious that such work be clearly insulated from human subjects regulations and IRB oversight. We worry that the shift in language from “exempt” to “excused” will blur the boundary rather than sharpen it.

3. Although we welcome the initiative to remove informational risk from the purview of IRBs, we fear that the alternative of statutory regulation is too blunt. The distinction between data collected for research purposes and that collected for other purposes does not seem compelling. The requirement that consent from the original subjects be required for further use of research-oriented data,¹ is unduly onerous. It would also impose costs on both the research community and the population of potential subjects; if data cannot be repurposed, waste of valuable effort and money seems inevitable. And some research projects are designed specifically for the general purposes of a research community, and are funded on precisely that basis. Finally, restrictions along these lines run squarely counter to transparency and replicability, ethical values of critical importance to the political science community.

¹ As we read the proposal de-identified data would be not be exempt from this requirement