The Society for the Psychological Study of Social Issues

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Dear Dr. Menikoff and colleagues:

We write on behalf of members of the Society for the Psychological Study of Social Issues (SPSSI) regarding the NPRM for revisions to the Common Rule for the protection of human subjects in research. As a body of social scientists who conduct research to inform policy about social issues, especially related to human rights and social justice, SPSSI is well-positioned to comment on the proposed changes and their impacts.

As scientists, we share the desire to reduce delay or burdens associated with research administration to facilitate promising research that offers considerable benefits for society at large. As professionals who conduct research on issues of human rights and social justice, we share concerns to provide better protection of human subjects.

Protection of Human Subjects

The paramount concern for SPSSI members is the protection of human subjects, especially from populations who are vulnerable to exploitation. The goals of the NPRM in this regard are

> ***to increase human subjects' ability and opportunity to make informed decisions; [and] reduce potential for harm and increase justice by increasing the uniformity of human subject protections in areas such as information disclosure risk, coverage of clinical trials.***

Of the proposed changes listed in the OHRM summary document,[1] the primary rationale for half of the changes—including items 1 (improved informed consent), 2 (consent requirement for stored biospecimens), 5 (rarity of waiver for consent for biospecimen research), and 8 (extended scope of policy)—is this shared concern. The protection of human subjects is the primary concern of Issues 1, 2, 3, 5, and 14 in the OHRP document with a table comparing proposed changes.[2]

[1] http://www.hhs.gov/ohrp/humansubjects/regulations/nprm2015summary.html
[2] http://www.hhs.gov/ohrp/humansubjects/anprmchangetable.html

Many of the proposed changes to facilitate research and relieve administrative burdens are dependent on Issue 1 (data security protections). We agree that the pursuit of uniform data security standards is a worthwhile endeavor. We propose that OHRP should consider whether local institutions should have the privilege to impose additional security protections, based on local conditions or special concerns.

We remain concerned about the security of de-identified data sets. Skilled researchers who analyze "big data" are developing strong tools to cross-reference datasets; this can allow re-identification of participants from ostensibly de-identified data (e.g., de Montjoye, Hidalgo, Verleysen, & Blondel, 2013; de Montjoye, Radaelli, & Singh, 2015; Narayanan & Shmatikov, 2008; Sweeney, 2013; see also Narayanan & Felten, 2014, for an overview of why de-identification efforts of many datasets are unsuccessful). Because of the strong pressure developing throughout the human sciences for more open science with widespread publication and public sharing of datasets, the issue of identifiability becomes even more critical. The appropriate regulatory bodies need clear and specific guidance about how to set standards for data security to protect human research participants.

We must have confidence in data security to support several other proposed changes. For example, six categories of currently exempt studies will become subject to new data security provisions (Issue #14). This proposed change would increase protection of human subjects only if *required* data security standards are high.

We strongly support the increased protection that comes from requiring written consent for research use of biospecimens (Issue #2). SPSSI seeks clarification of what constitutes a "biospecimen." What sorts of data will require the blanket consent form for unspecified future use? Would non-invasive samples (e.g., neurologic tests) and low-tech procedures (e.g., saliva samples) constitute biospecimens for regulatory purposes? For example, will researchers who use behavioral or self-report data be required to use the blanket consent form, knowing that future publication is likely to entail the promise to share data with other qualified scientists?

The blanket consent form for biospecimen research will be stronger if it includes language explicitly permitting the use of biospecimens for the purposes of education and training. This would more accurately inform participants about the potential uses of their data in cases (e.g., teaching hospitals) where investigators use biospecimens for purposes other than published research.

We ask the committee to consider whether the blanket consent form could more fully inform participants about the possible uses of their biospecimens. In some cases, there are risks of collective identifiability (and harm) that some vulnerable groups (e.g., indigenous populations in the United States and Canada) may experience in certain types of research studies.[3] Because participants are not expert in the uses of research data, the proposed change to the Common Rule places a burden on the participant to imagine and foresee all

[3] See http://genetics.ncai.org/case-study/havasupai-Tribe.cfm

potential uses and the resultant impacts not just to themselves as individuals, but also to their communities.

Extending the Common Rule to all research conducted with human participants regardless of funding source (Issue #3) clearly reduces the "potential for harm and increase[s] justice by increasing the uniformity of human subject protections." Having common standards will allow local IRBs to streamline the review process, facilitating timely conduct of research. SPSSI endorses this change.

SPSSI supports the move toward a uniform consent document that focuses on information to participants (Issue #5). One concern is that the standard form and consent process remain sufficiently flexible to accommodate local considerations: for example, research in communities who consider formal consent improper and potentially offensive, research among populations (e.g., victims of violent crime) for whom a signature poses a real or perceived threat, and collaborative research with investigators (e.g., outside the U.S.) whose research and consent process follows different standards. In these circumstances, a signed consent form may not be the best way of treating participants with consideration for their privacy as well as their values.

SPSSI strongly encourages OHRP to adopt a participatory process for designing the standard consent form. This process should include stakeholders or representatives from a variety of research participant populations. It also should draw upon the expertise of researchers who investigate consent form intelligibility.

We are encouraged that OHRP will publish guidance about the new consent form. Because some of our members are from institutions and non-affiliated programs with no consistent exchange between the IRB and the Federal Register, we anticipate education and communication will be necessary to help all institutions adopt changes that increase protection of participants. (This is true for all Common Rule changes, but seems particularly salient for this one.)

Facilitation of Promising Research and Easing Administrative Burden

SPSSI shares the desire to ease burdens of research administration to facilitate research. This is consistent with our mission to promote understanding of societal problems (including human rights and social justice). The goals of the NPRM in this regard are

> ***to facilitate current and evolving types of research that offer promising approaches to treating and preventing medical and societal problems through reduced ambiguity in interpretation of the regulations, increased efficiencies in the performance of the review system, and reduced burdens on researchers that do not appear to provide commensurate protections to human subjects.***

The primary rationale for half of the changes—including items 3 (broader exclusions from Common Rule), 4 (expanded categories of exempt research), 6 (reliance on a single IRB for collaborative research), and 7 (elimination of the continuing review requirement for some

research)—is this facilitation. This is also true of Issues 6-13 and 15-19 in the OHRP comparison of proposed changes.

Determination of Review Category

The NPRM includes some changes designed to reduce ambiguity (Issue #15) and administrative burden (Issue #16) regarding determination of the exempt category. The creation of a web-based decision tool for investigators to determine whether the investigation is exempt from review will facilitate research, by freeing investigators to proceed without further review, and by freeing IRBs to concentrate on proposals requiring higher levels of scrutiny.

SPSSI supports these initiatives to facilitate research, but we also recommend that any decision tool contain clear and specific questions. Otherwise, ambiguous questions increase the non-trivial possibility that researchers might, knowingly or inadvertently, seek to reduce administrative burden and interpret vague questions in a way to ensure exemption from review. SPSSI urges post-policy evaluation to ensure that the use of the tool does not have the undesired consequence of exempting investigations that place participants at risk.

Broadened Eligibility for Expedited and Exempt Research

The NPRM includes other changes designed to broaden eligibility for the expedited (Issues # 10 and 12) and exempt (Issues # 16-19) categories of research. These changes promise to facilitate research by reducing ambiguity and administrative burdens, eliminating inefficiencies, and removing restrictions on investigations with minimal or no risk.

SPSSI recommends careful supervision of procedures for initial and ongoing modification of the list of expedited research categories (Issue #10). Particular areas for care include questions about what constitutes "appropriate data" for modification of the list, the process for selection of people who administer the procedures, the training and qualifications of these administrators, and whether the OHRP will include stakeholders or representatives from a variety of research participant populations.

There is some concern of circularity underlying the assumption of minimal risk (Issue #12) (i.e., *the study is expedited because it is minimal risk, and the study is minimal risk because it is expedited*). Will circular reasoning simply lead reviewers to believe that studies using procedures on the list of expedited-*eligible* categories are exempt from full review? SPSSI recommends making explicit the standards for making such judgments.

SPSSI supports in principle the proposal to broaden the exempt category by eliminating restrictions based on concerns about identifiability and risk (Issue #17). However, concerns about data security protections qualify our support. Because researchers cannot foresee potential consequences at the outset of a project, they cannot adequately inform reviewers and participants about potential risks of participation. This is particularly true of

at-risk populations, some students, indigenous peoples, and people who might inadvertently open themselves to criminal liability.

SPSSI requests further consideration of the proposed rule to include more guidance about FERPA-protected information. While the proposed rule change mentions both HIPAA and FERPA, discussion focuses on HIPAA-covered data and makes no mention of the process for guidelines regarding treatment and protection of FERPA-covered data (e.g., research using data collected about students at application, admission, and enrollment to institutions of higher learning).

To facilitate promising research, SPSSI favors changes that expand eligibility for the exempt category to a broad range of studies using common social and behavioral science methodologies (Issue #18). SPSSI requests clarifications of language; the meaning and implications of this exemption are unclear. Would such research be excluded from the review process altogether?

The common methodologies of the social and behavioral scientists who constitute SPSSI generally include omission of information (and sometimes include deception) about hypotheses, design, or procedures. SPSSI urges that any extension of exempt status come with clarification about what constitutes deception under the proposed rule change. This clarification is especially necessary if researchers use a decision tool to determine for themselves whether their investigation is exempt from review. As one solution, new rules might (a) define *deception* as active misinformation about features of the investigation and (b) state explicitly that *omission* of information about hypotheses or minimal risk design features does not constitute deception.

So long as omission or deception is about features that pose no more than minimal risks for participation, the primary ethical concern about omission or active deception is that they compromise the informed consent process (how can a participant give informed consent when she lacks information about the study?). To address this concern (and enhance protection of human subjects), SPSSI proposes that the extension of exempt status to studies involving deception should presume that researchers will include a post-investigation debriefing procedure that both (a) fully informs the participant about deceptive information regarding design and procedures; and (b) provides the opportunity for the participant to revoke consent and withdraw their responses in light of this information. In this manner, the proposed rules can extend exempt status to common methodologies that routinely include either omission or deception—a change that serves the goal of facilitating promising research—while simultaneously enhancing ethical treatment of human subjects.

As with other proposals to broaden the exempt category, SPSSI offers support for the proposal to extend the exempt category to include use of identified (or identifiable) data, documents, and biospecimens. The prior condition for this support is the understanding that effective data security provisions must be in place.

Continuing Review

SPSSI supports the changes that eliminate the requirement for continuing review of research in the expedited category (Issue #11) or after completion of interventions (Issue #9); this facilitates research. We suggest that protections will be stronger if the proposed rules provide specific guidelines about when continuing review is necessary, and we recommend policy evaluation to ensure that they do not compromise protection to human subjects.

Coordination across Research Sites and Agencies

SPSSI endorses the change toward uniformity across agencies in regulations for research with human subjects (Issue # 7). The elimination of gaps in standards between Common Rule agencies and the FDA should provide better, more uniform protection of human subjects and eliminate ambiguity, inefficiencies, and administrative burden in the review process.

Finally, the NPRM includes a requirement for multi-site studies to maintain a single IRB of record for all U.S. research sites (Issue #6). This change promises to eliminate ambiguity, inefficiencies, and administrative burden in the review process. The proposed change may even offer greater protection of human subjects by eliminating diffusion of responsibility for oversight among multiple research sites.

SPSSI advises the OHRP to ensure that this change does not enable a race to the bottom. The proliferation of IRBs in non-residential, for-profit, and other advanced degree programs will produce variation in interpretation of standards. Investigators in multi-site research might select as the IRB of record the one that offers the path of least resistance.

The greatest risk may be in cases of multi-site research among institutions that span geographic regions or cultural communities. The proposed rule change might deprive local IRBs of authority to protect their constituents when off-site IRBs grant approval for off-site investigators to conduct research without local knowledge or approval. When researchers work with institutions distant from their home institution, the home IRB may lack expertise to assess risks and ensure protection for some participants. These concerns are particularly applicable to research where the open-ended nature of the procedure affords investigators considerable latitude for discretion.

Human subjects from vulnerable populations in marginalized or disempowered communities are most likely to put at risk by this proposed rule change. Institutions serving such vulnerable populations are likely to be the less powerful or "junior" partners in multi-site research. In such cases, the proposed change could strip responsibility for protection of human subjects from local IRBs who may be best situated to understand and to protect the interests of vulnerable communities and participants. Distant institutions may lack local knowledge to perform their oversight function adequately.

Given the potential to reduce protection for human subjects, especially from vulnerable populations in disempowered communities, SPSSI opposes the proposed

rule change, at least in its current form. We remain open to some version of the rule change that would permit partners in multi-site research to agree that one of them serve as IRB of record. This would reduce administrative burden and eliminate the problem of diffusion of responsibility while doing much to address the concerns that we noted above.

Summary

SPSSI endorses without reservation proposed changes to the Common Rule on Issues 3, 7, 13, 14, 15, and 16 in the OHRP comparison table. SPSSI also supports changes to the Common Rule on Issues 2, 5, 9, 10, 11, 12, 17, 18, and 19 in the table, but for these issues we seek clarification or more specific language.

SPSSI's most broad-ranging concern about the proposed changes is ensuring data security and participant privacy (Issue #1). We encourage the development of strong language to ensure participant protections.

SPSSI identifies a concern about the proposed elimination of multi-site review (Issue #6). A workable solution, we feel, must address the issues of protection of human subjects from vulnerable populations and institutions, who may be at greater risk and may require more attention to protection.

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Respectfully Submitted,
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The Society for the Psychological Study of Social Issues (SPSSI) is an interdisciplinary association of social scientists dedicated to the proposition that sound public policy should be based on sound behavioral science. Since SPSSI's founding in 1936, we have drawn on the expertise of 3000 members worldwide whose empirical research spans a broad range of social issues, and we help policy makers apply that research to formulate effective social policy at local, state, federal, and international levels.

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