Conference on College Composition and Communication (CCCC)
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U.S. Department of Health and Human Services (HHS)
Office for Human Research Protections (OHRP)
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Dear colleagues,

We write on behalf of the Conference on College Composition and Communication (CCCC), a division of the National Council of Teachers of English (NCTE). We are a group of teachers and scholars deeply invested in empirical research on writing. Our work concerns not only writing in education, but in everyday life: we study writers and writing from diverse contexts, and we seek to build and share knowledge about writing best practices, writing processes, and the relationships between writing and other profound human activities. Our teaching, informed by research, seeks to provide students with skills, experience, and knowledge appropriate for their particular writing lives, meaning that it is as diverse and varied as our research. In classrooms and beyond, we rely on research methods derived from both the humanities and social sciences, some long-standing, some cutting-edge, and most directly engaged with writers and their writing. Our research has illuminated, for example, articles in the natural sciences (Bazerman 1988), connections young people make between literacy and identity (Kinloch 2009), writing with social media in distributed work (Pigg, 2014), college students' writing for school and other purposes (Sternglass, 1997), relations between writing for school, at workplaces, or in community organizations (Cox et al., 2009), writing and communication in medicine (Dautermann, 1997) — and much, much more.

For these and other reasons, research ethics are deeply important to us, and the proposed changes to the Common Rule have broad implications for our work, our students, and the institutions in which we study and teach. This comment is organized in three sections: (A) proposed changes we support; (B) concerns we have; (C) concerns about implementation of proposed tools and processes. References are attached.

In 2011, the CCCC commented (80f5ccf2) on the Advance Notice of Public Rulemaking published at that time (HHS-OPHS-2011-0005-0001). Many of the changes proposed at that time are repeated in the current NPRM. We repeat our support for them below. While some of our 2011 concerns were addressed in the current NPRM, many remain. For these reasons, we note that portions of this comment are repeated directly from the 2011 comment made by the CCCC.

A) Support for proposed changes

1. Elimination of continuing review requirements for some research

We support elimination (§46.109(f)) of continuing review requirements for research approved by expedited review, and for research which has reached data analysis.

2. Making informed consent "more meaningful and transparent"

As above, research in our field has also acknowledged that informed consent processes can become complex and counterproductive, especially for internet-based research (McKee & Porter, 2008) or research with participants who might struggle to understand traditional consent forms and language (Wright 2012). We support efforts (§46.116) to improve the consent process while maintaining its integrity, especially specific reforms such as waiver of signature requirement and/or alternative means for obtaining consent when appropriate.

B) Concerns about research methods common in writing research

1. "Not research" language may undermine credibility and funding for writing research

We are generally in favor of the proposed exclusion of certain types of research such as history, journalism, and biography from research regulated by the Common Rule, in §46.101(b). Writing research engages these methods in both writing assessment and other forms of research which focus on individual writers. However, we are concerned that the language "not research" will lead to the perception that these forms of inquiry do not contribute to generalizable knowledge, as "research" regulated by the Common Rule does. We fear this exclusion, coarsely applied, could further limit the already thin funding opportunities for writing research as grantmakers would be less likely to see this work as legitimate scholarly inquiry.

We ask that HHS avoid the potentially misleading language "not research," and explicitly emphasize that the term "exclusion" is limited to exclusion from regulation under Common Rule, not a determination these important activities are not research. Public comment questions #12 and #21 address the differences between "exemptions" and "exclusions;" we note the difference between these two forms of research is one possible confusion of the term "exclusion."

2. New exclusions may lead to proliferation of external standards or regulations

Here we consider not only the research methods mentioned in §46.101(b)(1), but the exclusion of "low risk" human subjects research and educational tests in §46.101(b)(2).

As above, we support this exclusion given the nature of these research activities and the minimal risks to participants. However, we expect that some institutions will seek to regulate this research in some manner given that risks are still present. Institutions may develop rules which seek to maintain oversight of this type of research activity.

One possibility is that common best practices may become adopted by institutions who seek to regulate excluded research, perhaps because they lack the resources or staff to ensure oversight, but are not comfortable with the prospect of unsupervised research. For example, in supporting exclusions in §46.101(b)(1), the American History Association (AHA) refers to the best practices and ethical codes they have developed over time, suggesting these aggregated experiences work well for the specific methods they have developed. We agree, and indeed, writing researchers have our own similar documents, such as the "Conference on College Composition and Communication Guidelines for the Ethical Conduct of Research in Composition Studies" (2015). However, we also note the AHA writes in a public comment on the

NPRM, “Individuals *in any discipline* who plan to do oral history interviews should follow the practices and ethical codes developed by the Oral History Association” (our emphasis). We feel this type of disciplinary creep is not appropriate and, ironically, threatens to reproduce the conditions the AHA and other professional organizations have long objected to, when regulations designed for research in one discipline are applied wholesale to another.

To the extent that research oversight may come to mean the imposition of best practices, ethical codes, or similar rules in contexts where they are a poor fit, we suggest that the HHS clarify the purpose and nature of these exclusions from regulation by Common Rule.

3. Definition of “benign interventions” is broad

Section 46.104(d)(3) establishes a specific category of exempt “benign interventions” which involve “the collection of data from an adult subject through verbal or written responses.” As written, this definition seems very broad: for example, risky or embarrassing subject matter is rightfully explicitly excluded, but how is that line drawn? We recommend the HHS seek to clarify the definition.

4. Diverse research methods should be better represented in OHRP decision-making

Writing research often draws on non-experimental qualitative methods such as interviews, case studies and ethnography (Brice Heath et al., 2008). The human subject protection efforts of the Office for Human Research Protections (OHRP) focus on experimental medical research, and with good reason, given its legal mandate. However, we note that few of the materials prepared by OHRP staff in support of the NPRM address the methods writing researchers frequently engage. We are concerned that development of the NPRM, and its upcoming implementation, will exclude perspectives unique to qualitative research. For example, we note that the October 20 town hall, questions about ethnographic research were largely deflected.

We recommend that the OHRP seek to address non-experimental and qualitative research methods more vigorously, consider the impacts of proposed changes for broad types of research, and consult with and/or include a broad diversity of researchers in decision-making processes. Please see below (C3 and C4) for specific suggestions.

5. Student research is not explicitly addressed

The public comment made by the CCCC in 2011 noted the ANPR did not address student-conducted research (§II.4). Since 2011, student research has become ever more important, as more students, educators, and institutions have recognized its value (Kuh, 2008). Unfortunately, the length of time necessary for IRB review can make it impossible to complete in courses. For this reason, we echo the CCCC’s 2011 request for development of IRB review provisions which minimize the time necessary for review of faculty-supervised student research integrated into courses.

C) Implementation: concerns and suggestions

1. Implementation of decision tools and other centralized support systems is not described

We welcome the proposed development of centralized tools intended to make research oversight more efficient, such as the decision tool to aid in determining which research qualifies as exempt (§46.104(c)), and the proposed repository of informed consent materials (§46.116.(h)). We agree that these resources will help institutional staff and researchers alike better understand and follow the intent of the Common Rule. However, the lack of discussion of implementation of these and other tools raises questions about the design of these tools and the manner of their operation. For us, questions for public comment #27–33 reflect the considerable variation possible. Given that much writing research qualifies as exempt, that tool, in particular, will be important for us.

We suggest the HHS publish more information about plans to develop and implement these decision tools and resources. We request that writing researchers be included, especially for the exempt research decision tool, given our expertise in technical communication. We also request that development include a public beta testing period and request for public comment.

2. Implementation of streamlining IRB review of multi-site studies is not described

Research in our field has noted the labor intensity, complexity, and chilling effects of obtaining multiple IRB approvals for inter-institutional research (Lunsford & Lunsford, 2008). The shift to a single IRB could provide adequate oversight far more efficiently, and we generally support this change. However, we note that public comment questions #74–78, and many NPRM comments already submitted, raise concerns about implementation which we share. As above, given the considerable room for variation here, we request the HHS further clarify its vision for single IRB approvals with a request for public comment.

3. Provide funding opportunities to initiate changes and to track their impact

We quote at length from the 2011 comment by the CCCC:

> *Many of the proposed reforms will require substantial reorganization for local IRBs and for disciplinary societies. We request that the OHRP provide grants to support the development of more streamlined review processes, informed consent forms, and ethics guidelines among academic societies; as well as for the re-education of IRB members. We also request that the OHRP provide grants to allow research communities to track the impact of the proposed changes.*

Given continued declines in state support for higher education, we find the establishment of these funding opportunities even more important today.

4. Convene a panel with diverse constituencies, including writing researchers, to review the impact of the changes in three years

Again, we quote the CCCC comment from 2011, emphasizing the need for inclusion of writing researchers given the issues we observe in section B, above:

> *As with any large-scale endeavor, the proposed reforms will likely have unintended consequences. We ask that, three years after the reforms are implemented, the OHRP should convene a panel with diverse constituencies to review their impact. We ask that a member from the CCCC be included on the panel.*

We thank the OHRP for the opportunity to comment on the NPRM. Please contact us if you have any questions.

Respectfully submitted,

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