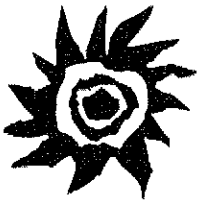

Special Task Force
Conference on College Composition and Communication (CCCC)

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Department of Health and Human Services
1101 Wootton Parkway, Suite 200
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Re: Public Commentary on HHS 45 CFR Parts 46, 160, and 164; FDA 21 CFR Parts 50 and 56; Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators.

Docket ID number HHS–OPHS–2011–0005

We write on behalf of approximately 6,000 teachers and researchers who specialize in the study of writers, writing, and writing contexts. As a discipline, we seek to understand both the products and processes of writing. Our research often combines methods from the humanities (textual analysis, rhetoric, hermeneutics) and from the social/behavioral sciences (qualitative and quantitative methods; classroom research). We conduct studies on how knowledge is created and communicated within different contexts; how writers of all ages learn strategies specific to these contexts; and how institutions, personal and social histories, technologies, and media continually reshape expectations for writing. As a result, human subjects protections and IRB practices directly impact our research, and the proposed changes have profound implications for the future of our discipline. We thank you for your well-written and well-considered work on this initiative, and we respectfully submit these comments on the proposed changes for your consideration.

Throughout this document, we refer to the section / page numbers for the Advance Notice of Proposed Rulemaking, as published in the *Federal Register,* vol. 76, no. 143, July 26, 2011.

I. REFORMS WE SUPPORT

1). Eliminating Continuing Review of Expedited Studies (Section iii.b, p. 44517)

We support the recommendations in this section.

2). Changing the Term "Exempt" to "Registered" (p. 44520, Question 20)

We believe that the term "Registered" better emphasizes that no human subjects research is excused or exempt from following the principles of the Belmont Report.

3). Streamlining IRB Review of Multi-Site Studies (Section III, pp. 44521-44522)

We enthusiastically support the proposal to streamline IRB review of multi-site studies. Researchers in our discipline often solicit participants from more than one research site: for example, to do comparative studies of writing processes in different locations; to locate a sufficient number of interviewees who work within a certain profession; to collect nationwide samples of documents; and so on.

In response to Question 33, researchers in our discipline have reported considerable delays (i.e., several months) in acquiring approvals for studies because of local IRB assumptions that all sites must review and

approve of the research--even for studies that some IRBs consider exempt. These delays typically have not been because of concerns about risks to participants, but because of inefficiencies in submitting documentation to and hearing back from different review boards.

For this reason, in response to Question 30, we feel that this reform should be mandated. If it is not mandated, but only encouraged, then we anticipate that very little will change.

In response to Question 31, regarding local knowledge: Currently, IRB boards vary in their willingness to consult with researchers from other institutions about local knowledge or expectations. A request for consultation may be met with a demand that the study be submitted for review first -- and some IRBs are inclined to insist upon a full review for any study submitted by a researcher from another institution. We recommend that IRBs separate the consulting role from the jurisdictional role, particularly for minimal-risk studies. It is possible for researchers to take into account local mores without being subject to local jurisdiction.

In response to Question 34, regarding how the central IRB of record should be selected: We recommend the home institution of the lead PI.

4). Requiring Appeal Mechanisms (Section iii.d, p. 44521, Question 28)

We support the requirement that institutions develop appropriate appeal mechanisms for IRB decisions that fundamentally alter or shut down a proposed study. The appeal mechanisms also should be available when an IRB applies inappropriate lenses for a review; for example, when an IRB censors research about student writing or classroom practice because of fears that it will "make the university look bad." Researchers in our field suggest that censorship problems such as these arise because our discipline's research methods and aims often are unfamiliar to faculty who serve on IRB boards, and there are reports of studies being dismissed because another discipline's expectations have been applied to them. Therefore, we recommend that as part of the appeal process, the local IRB be encouraged to consider external resources about the discipline's research ethics (e.g., published codes of ethics), and possibly to consult with external researchers in the field in question.

5). Improving Informed Consent (Section IV, p. 44523, Part A)

We support the reduction of institutional "boilerplate" language on consent forms so as to simplify them and to draw attention to the language that is genuinely informative about the research. If standardized consent form templates are to be developed, then we recommend that researchers from a broad range of disciplines/constituencies be consulted.

II. AREAS OF CONCERN & RECOMMENDATIONS

1). Defining Types of Research Studies that Qualify for the Excused/Registered Category (pp. 44518-44520, Questions 14-17)

We are somewhat skeptical of conflating risk-assessment with the type of method employed (interview, survey, etc.), as risks also depend on the research focus and the context(s) in which a method is used. However, we agree that, typically, research in our field involving competent adult participants offers minimal risks. We therefore support an expansion of the categories of research studies that qualify for the excused/registered designation with these provisos:

a) Regulators should consult with a broad range of diverse constituencies when compiling the final list of categories of research. It is essential that the list be expansive and fully representative of research done across the disciplines, so that research that should be considered excused/registered does not end up going through a full board review simply because "it is not on the list."

b) The regulations should emphasize that the categories of exempt/registered methods refer to non-charged topics (Question 16). To determine what counts as non-charged topics, researchers and IRBs should consult the ethics guidelines that relate to the specific field of study.

c) The OHRP should carefully monitor the impact of these proposed changes, starting within one year of implementation.

2). HIPAA Security Requirements for All Research (Section V, pp. 44524-44527)

We agree that all researchers should have data security procedures to safeguard the confidentiality of data and appropriate levels of privacy for participants. However, we are concerned that the proposed changes to make uniform the application of HIPAA data security requirements do not serve to "calibrat[e] the review process to the risk of research" (p. 44513). Instead, as currently proposed, they are calibrated to "the level of identifiability of the information, which would be based on the standards of identifiability under the HIPAA Privacy Rule" (p. 44516). The HIPAA Privacy Rule includes the comprehensive category of "Any Other Unique Identifying Number, Characteristic, or Code," which means that any document-based or interview-based research may fall under HIPAA Privacy and Security requirements. For writing researchers, the consequence is that many studies would be inappropriately held to HIPAA standards.

The proposed change is framed as a way of eliminating inequality of treatment, but it is instead a reification of inequality. Instead of enabling IRBs to better judge research risks, the proposed change requires all researchers' data to be treated as equally risky if made public. For some types of research in our field, this assumption is problematic. For example, as one researcher commented, "My first category of data, work that students produce for class, involves work that students have already chosen to make public on the class website, in class workshops and discussions, in class presentations, and often to extra-curricular audiences (via letters to the editor, e.g.). Being required to hold that data in some kind of super-protected manner would hold me to a higher privacy standard of the data than the original authors had for it."

In addition, for much research in our field--such as participatory action research, research involving professional and published documents, and research involving multimedia--anonymity and/or pseudonymity may not be desired by participants. For instance, when some participants are interviewed about their documents, they may wish to be identified so as to gain further recognition for their work. Insisting that these participants hide their authorship may actually be causing them harm rather than protecting them from harm. Even though, as Question 59 notes, "HIPAA Rules would allow subjects to authorize researchers to disclose the subjects' identities" (p. 44526), researchers in our field frequently report that their IRBs are extremely reluctant to allow voluntary disclosures. We anticipate that this HIPAA provision for disclosure would be, at best, not uniformly interpreted and, at worst, entirely ignored.

Therefore, we recommend that not all studies be subject to standards modeled on the HIPAA Security Rule (Question 59). We recommend that IRBs consider the level of study risk, not just data identification, when determining what data security levels to apply and whether to require anonymity and/or pseudonymity. Currently, studies such as the examples we mentioned typically undergo an expedited review because they involve minimal risk. An unintended consequence of the proposed change is that these studies might be considered high risk simply because they collect identifiable data. If one of the goals for the proposed reforms is to ensure that IRBs can more effectively direct limited resources to the highest-risk studies, then the proposed change, as written, will not accomplish this goal.

3). Regulations Regarding the Re-Use of Data / Archived Material (Section IV.C, p. 44523)

This section appears to focus on biomedical data and biospecimens; however, we are concerned that the principles and procedures articulated here will be misapplied to research in our discipline. Throughout this section, the term "data" is vague. In some cases, it appears to be confined to biomedical data; in other cases, it appears to refer to all research data. We anticipate that this slippage in meaning will cause problems when local IRBs interpret the new regulations. As researchers in our discipline have frequently reported, IRB boards tend to impose regulations originally intended for medical studies on our research. For example, researchers have reported that IRBs have required them to destroy data -- such as documents and interviews -- that the researchers and participants would have preferred to have been made available for further study. We recommend that an obvious and clear distinction be made between regulations meant for biospecimens and related HIPAA-protected data, and other kinds of archival work.

In response to Question 49, concerning a standardized consent form for the re-use of data: We suggest that a universal consent form would be difficult, as other regulatory mechanisms [such as "deed of gift" processes for submitting materials to university library archives] would also need to be taken into account for different studies. In response to Questions 52 and 53, we suggest that, for our discipline, it is not desirable to control secondary use of pre-existing data if it has been published, or if it exists in a formal public archive, especially if the data pose no more than minimal risk; nor should the reformed rules impose such restrictions on pre-existing data prospectively or retrospectively. If the data exist in an informal archive (such as an individual researcher's archive), then we agree that an IRB review may be necessary, but should be done in accordance with a discipline's code of ethics.

In particular, we oppose the universal application of HIPAA Privacy and Data Security standards to archived research materials, as these standards are inappropriate. Researchers in our discipline may employ archives of materials that were gathered by previous agencies, and they may actively collect documents and other, related artifacts that enable the study of writing, writers, and writing contexts. For historical study (for example, writing instruction in rural East Texas in the 1890s), researchers might rely upon artifacts likely collected for purposes other than writing research. For institutional or program studies, researchers may examine student papers and portfolios gathered over long periods of time. For studies of digital media, researchers may access large archives (such as the Internet Archive) of stored websites or preserved video/audio recordings that likely are not anonymous. For large areas of writing research--especially disciplinary histories dependent on particular writers, instructors, institutions, and rhetorical situations--the proposed data security protections would seriously jeopardize the potential for sound research.

4). How Regulations Should Apply to Student Researchers

The ANPR does not address the issue of student researchers -- that is, when undergraduates and graduate students are the researchers themselves. In our discipline, students may conduct research studies of writers and writing as part of their coursework. Most of this research is conducted only for the course and thus meets current exempt criteria. Increasingly, however, with the rise of venues for publishing undergraduate and graduate research, students are electing to publish or present papers at conferences based on their research. For this reason, faculty mentor students through the processes of obtaining IRB approval for their studies. But this is where problems occur. Too many IRBs take too long to review applications from student researchers who are taking a class requiring research, and because quarters and semesters are short, any delay in the process is problematic. Because the proposed changes explore a number of processes for streamlining review, we urge the inclusion of "fast-track" or "rapid review" provisions for research conducted by students who are enrolled in a course.

5). Safeguards Against Mission Creep

The ANPR mentions the issue of IRB "mission creep," but more can and should be said explicitly in the proposed reform. It is tempting for institutions to treat the human subjects review as "one-stop shopping" for all institutional concerns. In particular, because of mandates to track potential conflicts of interest in research, IRBs have begun to take intellectual property issues into account. These issues include copyright laws. However, although we agree that participants should be informed of the sources of funding for research (Question 40), we believe that intellectual property / copyright issues form another set of concerns that should not be conflated with human subjects protections.

III. RECOMMENDATIONS FOR FUTURE PROCESSES

1). Provide Funding Opportunities To Initiate Changes and To Track Their Impact

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.

2). Convene Panel With Diverse Constituencies, Including the CCCC, To Review the Impact of the Changes in 3 Years

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.

IV. ADDITIONAL RESOURCES

We attach an appendix of literature in our field that addresses human subjects regulations, as well as a listing of more general resources.

V. TASK FORCE RATIONALE & PROCEDURES

The CCCC is a constituent group associated with the National Council of Teachers of English (NCTE).

This Special Task Force was appointed by CCCC Chair Gwendolyn Pough. We are experienced researchers in writing studies and, in one case, an experienced member of a human subjects review board. Two members are liaisons with the main research committees in the organization, and one is the liaison with the CCCC leadership.

The Task Force solicited commentary on the ANPR from CCCC members via the major listservs in the discipline. A version of this document was posted openly for review by CCCC members, and it was also reviewed by the CCCC research committees. Before submission to the OHRP, this document received approvals from the research committees and from the CCCC Officers.

Task Force members are available for further consultation on these issues, and we would be pleased to work with you.

Respectfully submitted by the deadline of the 26th day of October 2011,
Conference on College Composition and Communication

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