Before the U.S. Department of Health and Human Services
"Federal Policy for the Protection of Human Subjects"
Comments of the Student Press Law Center
RIN #0937-AA02

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A. Introduction and Summary

The Student Press Law Center ("SPLC") respectfully submits the following comments to Unified Agenda #0937-AA02, which concerns protection for the human subjects of research under the auspices of the Department of Health and Human Services ("HHS"). The SPLC is a nonprofit source of legal research and advocacy in support of those producing journalism in the educational setting. The SPLC assists thousands of student journalists and educators every year in navigating legal and ethical questions, including those regarding the protocols for interviewing sources.

The SPLC's comments are directed to subsection II(A)(2)(a)(ii), titled "Oral History, Journalism, Biography, and Historical Scholarship Activities" (NPRM at § __.101(b)(1)(ii)), which proposes a categorical exclusion from the definition of "research" that is subject to the Common Rule, encompassing "oral history, journalism, biography and historical scholarship activities that focus directly on the specific individuals about whom the information is collected." The SPLC encourages the adoption of this exclusion as proposed.

The SPLC legal hotline receives calls several times a year from college journalists and journalism educators whose campuses have attempted to restrict student newsgathering under the misapprehension that journalistic activity is "behavioral research" requiring the approval of an Institutional Review Board ("IRB"). As explained below, the IRB review process is simply incompatible with, and unnecessary for, the effective practice of journalism.

College student journalists regularly produce work indistinguishable in quality from that of paid professionals, and increasingly are filling the void left by the eroding ranks of full-time salaried professional journalists. A 2014 student by the Pew Research Center found that students constitute 14 percent of all journalists assigned to cover state Capitols, and in several states, the majority of the reporters covering the Capitol are students.[1] Campus-based news organizations such as News21 in Phoenix, Georgia News Lab in Atlanta and the New England Center for Investigative Reporting in Boston are harnessing the talent of college students to create in-depth reporting that is published and broadcast far beyond the campus in *The Washington Post*, *The Atlanta Journal-Constitution* and other major metropolitan media outlets. The general public is more dependent than at any time in America's history on students to fulfill essential information needs, and consequently, the federal government

[1] *See* Jodi Enda *et al.*, "America's Shifting Statehouse Press," PEW RESEARCH CENTER, July 10, 2014, *available at* http://www.journalism.org/2014/07/10/americas-shifting-statehouse-press/.

should make every effort to remove regulatory impediments that unnecessarily burden students' ability to gather and publish news.

B. Discussion and Recommendations

1. Journalism does not qualify as federally regulated research on human subjects.

As a threshold matter, newsgathering simply does not fit the jurisdictional and definitional prerequisites to be regulated as "human subject research."

The jurisdiction of Health and Human Services to set policy for the conduct of university research is confined to activity that is "conducted, supported or otherwise subject to regulation by any federal department or agency(.)" 45 C.F.R. § 46.101(a). Newsgathering is none of these things. No federal department or agency regulates the way journalists gather news, and doing so would raise insurmountable First Amendment concerns. HHS regulations go on to define "research subject to regulation" as research "for which a federal department or agency has specific responsibility for regulating as a research activity" such as the production of pharmaceuticals. 45 C.F.R. § 46.102(e). Obviously, there is no "U.S. Department of Journalistic Standards" and no history of, or legal authority for, the regulation of journalistic practices by a federal agency.

"Research" is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." 45 C.F.R. § 46.102(d). The process of preparing a news story does not fit this description. News stories are not "developed, tested and evaluated" in a laboratory setting. Their "evaluation" is a matter of audience response, much like the "evaluation" of a work of art, music or literature, none of which would qualify as IRB-regulated "research" even if they involved human subjects.

Because journalism does not meet the threshold to qualify as federally regulated research, it is appropriate for HHS rules to clarify that journalistic activity is categorically excluded from IRB purview.

2. IRB review is legally and structurally incompatible with the practice of journalism.

The "Common Rule" that is codified in HHS research protocols and enforced by IRB reviewers has the foundational purpose of requiring "informed consent" of participants in human-subject research, to ensure that subjects have been briefed on any foreseeable health risks and voluntarily accepted those risks. The principle of "informed consent" as understood and implemented in federal law is neither necessary for, nor suited to, the practice of journalism. Indeed, the Common Rule imperative to protect the privacy of research subjects has little-to-no relevance to journalism, since ordinarily the *entire point* of the journalist's work will be to bring the individual's story to widespread public attention. While on occasion journalistic sources are granted anonymity on a carefully considered case-by-case basis, such is not the prevailing practice. It would undermine effective storytelling if institutions could direct students to routinely conceal the identities of the subjects of news stories.[2]

[2] Prof. Leon Dash elaborates on this point in his authoritative article, *Journalism and Institutional Review Boards*, QUALITATIVE INQUIRY, Vol. 13, No. 6 (Sept. 2007), *available at* http://users.polisci.wisc.edu/schatzberg/ps816/Dash2007.pdf, which supports the Agency's conclusion that journalism and related activities such as oral history should be categorically excluded from IRB purview.

The principal HHS rule governing informed consent is set forth at 45 C.F.R. § 46.116 and provides in pertinent part:

> [N]o investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

These requirements cannot be accommodated practically to the demands of journalism, for obvious reasons. Just to cite one example, the prohibition against "exculpatory language" is inconsistent with the commonplace journalistic practice of obtaining a privacy waiver for the broadcast of information of a personal nature gleaned through interviewing.

That these regulations were never designed or intended to apply to journalism is readily apparent by the description in Section 46.116 of the types of warnings and disclaimers required before a researcher may experiment on human subjects, including "disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous" and "description of any reasonably foreseeable risks or discomforts to the subject," which by their terms simply make no sense when applied to oral history, journalism or comparable activities. One need only envision the rather ridiculous spectacle of a television reporter standing outside of a polling place on Election Day interviewing voters and explaining before each interview, "Here is the purpose of my research, the expected duration of your participation, the known risks and alternatives, who to contact in the event of a research-related injury…" and so forth, to see that these protocols are unnecessary and unworkable in the newsgathering setting.

More to the point, there may occasionally be times when it is essential for effective journalism for interviewees <u>not</u> to be given full advance warning of the subject matter. Consider, for example, the work of investigative reporters who reexamine "cold" criminal cases for the possibility of wrongful convictions. It could literally place the interviewer's safety in peril if, while interviewing a dangerous criminal, she was forced to explain, "Mr. Jones, I am interviewing you for the purpose of determining whether you, and not Inmate Smith, are the real murderer, and the known potential consequences from your participation in my research could include implicating yourself in a homicide."

As a practical matter, the IRB process is structurally unsuited to the deadline-sensitive world of news reporting. Even getting an IRB to verify that a student's research is exempt typically imposes a delay of two to three weeks. While two weeks may represent a minimal inconvenience for an academic researcher working with a calendar that is measured in semesters, a journalist's deadlines are measured in hours, not weeks. Placing a weeks-long hold on interviewing pending institutional approval would be, in many instances, tantamount to killing a news story entirely.

Delay exacts an especially significant toll on newsgathering because the subjects of newsgathering are unique and irreplaceable individuals. A behavioral-science experiment might be successfully carried out with any pool of volunteers, one as good as the next. But journalism relies on eyewitness accounts from individuals with unique subject-matter knowledge. A behavioral scientist can conduct research about public attitudes toward fraternity hazing by obtaining a cross-section of participants from the desired demographic pool, but a journalist attempting to document a particular hazing crime will need access to a limited universe of specific individual witnesses. With the passage of weeks, individuals may become unavailable, their memories may fade, or they may experience pressure to withdraw from cooperating.

College journalists at public institutions enjoy significant First Amendment protections comparable to those afforded to professional practitioners. At the college level, student journalistic publications operate as "public forums" for the expression of student views, entitled to the highest degree of constitutional insulation against government content control.[3] The notion that a government regulatory body could impose and enforce protocols on the way that journalists conduct their interviews and what they choose to publish cannot be reconciled with the constitutional guarantees of a free and independent press.[4] Indeed, the mere fact that a journalist might be forced to submit her proposed course of inquiry to pre-approval by the very same agency she might be investigating would impose an impermissible "chill" on journalists' willingness to pursue difficult subjects.

IRB review is further incompatible with journalism because newsgathering relies heavily on whistleblowers who disclose information only under the assurance of confidentiality. An IRB is empowered, for example, to require documentation that each subject has provided informed consent. A directive from university authorities to disclose information shared by a confidential informant, or information leading to the unmasking of a confidential informant, would be in tension with the widely recognized constitutional, statutory and common-law rights to protect the identity of journalists' sources, and could place the journalist in a position of being asked to breach a contractually enforceable assurance of confidentiality. *See Cohen v. Cowles Media Co.*, 501 U.S. 663, 111 S.Ct. 2513 (1991) (journalists can be sued for breach of promise of confidentiality that injures betrayed source).

As the Department has recognized, journalists are answerable to their own professional codes of ethics that cover quite a bit of the same ground as the Common Rule (for example, the ethics code of the Society of Professional Journalists counsels that journalists should "[b]e cautious when making promises, but keep the promises they make"). These ethical guidelines have been crafted by the most knowledgeable practitioners in the profession, and the IRB process should neither duplicate nor contradict their authoritative guidance.

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[3] *See Kincaid v. Gibson*, 236 F.3d 342, 349 (6th Cir. 2001) (*en banc*).

[4] As Prof. Philip Hamburger explains, the First Amendment disfavors all content-based restrictions on speech but most strictly disfavors pre-publication restraints that require approval of the subject matter before speaking, as contemplated by the IRB protocol. *See* Philip Hamburger, *The New Censorship: Institutional Review Boards*, 2004 SUP. CT. REV. 271, 280 (2004) ("The First Amendment centrally and unequivocally forbids laws requiring that one get permission for verbal speech or the press").

C. Conclusion

For the foregoing reasons, the Department should enact as proposed a categorical exclusion from the definition of "research" covering "oral history, journalism, biography and historical scholarship activities that focus directly on the specific individuals about whom the information is collected."

Respectfully Submitted,

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