THE NEW *COMMON RULE* CORRECTS AN OLD MISUNDERSTANDING: JOURNALISTIC INVESTIGATION, BIOGRAPHICAL INTERVIEWING, LEGAL RESEARCH, AND CREATIVE AND HISTORICAL WRITING FOCUSING ON SPECIFIC PEOPLE ARE NOT "RESEARCH" "INVOLVING HUMAN SUBJECTS" REQUIRING IRB APPROVAL

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Over the last two decades, university Institutional Review Boards ("IRBs") have increasingly policed the scholarly and creative activities of faculty engaged in journalism, documentary filmmaking, creative and biographical writing, oral history, and legal research.[1] Notwithstanding federal regulations and court decisions to the contrary, IRBs have required faculty to submit projects for approval or risk sanctions,[2] the loss of resources,[3] or the blacklisting of their work.[4] Not surprisingly, most faculty

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[2] ROBERT L. KLITZMAN, THE ETHICS POLICE?: THE STRUGGLE TO MAKE HUMAN RESEARCH SAFE 294–95 (Oxford University Press 2015); CARL E. SCHNEIDER, THE CENSOR'S HAND: THE MISREGULATION OF HUMAN-SUBJECT RESEARCH 61, 198–99 (2015 MIT Press) (chronicling formal charges against faculty). In one frequently cited case, a university accused a creative literature professor of "bad research practices," because he had not obtained IRB approval for a story-writing exercise used in class and later discussed in an article on pedagogy. The exercise required students to use creative writing techniques to write stories about themselves. Hamburger, *supra* note 1, at 293; Wright, *supra* note 1, at 204–05.

[3] ZACHARY M. SCHRAG, ETHICAL IMPERIALISM, INSTITUTIONAL REVIEW BOARDS AND THE SOCIAL SCIENCES, 1965–2009 127, 137–38 (2010); SCHNEIDER, *supra* note 2, at 174 (listing institutions that withdrew support).

[4] Jaschik 2018, *supra* note 1; KLITZMAN *supra* note 2, at 278–79 (noting common

submit for approval.[5]

IRBs maintain that they are simply carrying out their duties to review "all research"[6] under the Federal Regulations for the Protection of Human Subjects (45 C.F.R. § 46), better known as the Common Rule. The Common Rule regulates and sets ethical guidelines for certain types of "research involving human subjects:"[7] before faculty can commence "research," as defined by the Common Rule,[8] an IRB must review[9] and approve it.[10] Many IRBs construe "research" expansively to encompass all methods and notions of academic inquiry, evidence-based scholarship, or expository creative activity. Accordingly, if such activities collect information about or focus on people, IRBs and faculty often think they are deemed "human subjects research" requiring approval.[11]

Although faculty generally do not dispute that journalism, non-fiction filmmaking and writing, and legal and historical investigation involve some form of research,[12] they complain that *as applied to* these activities, the Regulations are inapt, unnecessary, and improperly restrictive.[13] More specifically, they argue that: (a) because the Common Rule's substantive requirements[14] were designed for the biomedical and behavioral sciences**,** they do not translate[15] or necessitate Rube-Goldberg-like workarounds to

problems of publishing unapproved research); SCHNEIDER, *supra* note 2, at 59–60, 198–99.

[5] SCHRAG, *supra* note 3, at 5, 143–50; Bledsoe, *supra* note 1, at 595–96; *see also* SCHNEIDER, *supra* note 2, at 199–200 (explaining that scholars submit and comply out of ignorance about Regulations). Because IRB submission forms are designed for biomedical and behavioral science protocols, their informed consent requirements, and the equitable distribution of subject populations, faculty in other disciplines may need to change aspects of a project to fit it into and comply fully with an IRB submission form. This may also require faculty to replace legally enforceable contracts, consent forms, and waivers (crafted by counsel or held valid by courts) with those drafted by lay IRBs.

[6] 45 C.F.R. § 46.101 (2018).

[7] 45 C.F.R. § 46.102 (e)(1).

[8] 45 C.F.R. § 46.102 (l).

[9] 45 C.F.R. § 46.109.

[10] 45 C.F.R. § 46.111 (articulating criteria for approval).

[11] *See generally* KLITZMAN, *supra* note 2, at 74–76, 99–105.

[12] *See infra* notes 85-91 and accompanying text.

[13] CENTER, *supra* note 1, at 3–5; Hamburger, *supra* note 1, at 274 (complaining that IRB rules abridge academic freedom); Jaschik 2018, *supra* note 1; Frank LoMonte, *New Federal Rule Would Protect College Journalists from IRB Demands to Review Their "Research,"* STUDENT PRESS L. CTR. (Dec. 27, 2015), http://www.splc.org/blog/splc/2015/12/hhs-considers-rule-protecting-journalism-irb; Moss, *supra* note 1, at 801– 02; Bledsoe, *supra* note 1, at 595–96.

[14] This includes informed consent, disclosure of participant risks, pre-approved questions, weighing the likely harm posed by the research against its benefits, ensuring an equitable selection of research subjects.

[15] AAUP Report, *supra* note 1; CENTER, *supra* note 1, at 3–6 (complaining that "research" and "human subject" are ambiguous when applied outside of biomedical and behavioral science and applying the Common Rule to humanistic, creative, and journalistic

implement;[16] (b) applying the Regulations outside of the fields for which they were written leads to "inappropriate regulation and restriction;"[17] (c) some provisions, such as those that limit human interactions to pre-approved topics and questions, demand the destruction of original notes and recordings, and prohibit the disclosure of people's names,[18] are inconsistent with the fundamental nature and purposes of journalism, oral history, biographical writing, and nonfiction filmmaking;[19] (d) existing disciplinary and professional codes better address the ethical concerns in these fields;[20] and (e) the comparatively low risk of harm posed by these activities warrants exemption from or some less intrusive method of review.[21]

I. ARTICLE OVERVIEW

This article explores whether the noted academic and creative activities require IRB approval and why. In doing so, it draws on the new

inquiry leads to "inappropriate regulation and restriction"); Hamburger, *supra* note 1, at 294; Jaschik 2008, *supra* note 1; Kerr, *supra* note 1, at 403–07; Moss, *supra* note 1, at 802.

[16] SCHNEIDER, *supra* note 2, at 53–54, 63 (detailing how one scholar was required to interview herself about her notes, and another needed to grant consent to herself in order to reference her own past, present, and future writings and artifacts of her life).

[17] CENTER *supra* note 1, at 3–5; Jaschik 2018, *supra* note 1 ("IRBs have become censors. . . [who] decide what questions researchers can ask, how to ask them"); Kerr, *supra* note 1, at 403–07 (complaining that IRBs prohibit "questions that any other person can ask freely"); LoMonte, *supra* note 13; Moss, *supra* note 1, at 801–02.

[18] Hamburger, *supra* note 1, at 294, 335; Kerr, *supra* note 1, at 403–07 (prohibiting "questions that any other person can ask freely"); LoMonte, *supra* note 13 (requiring pre-approved questions in journalistic interviews); Moss, *supra* note 1, at 801–02; SCHNEIDER, *supra* note 1, at 53–54 (treating all research like biomedical research and, therefore, imposing those protocols and protections), 147–48 (requiring destruction of interviews and oral history recordings).

[19] Citing the possible emotional stress to interviewees, IRBs have prevented oral historians from talking to people about their experiences during the Holocaust and "civil disobedience during social protest movements." CENTER, *supra* note 1, at 4; Jaschik 2008, *supra* note 1. Several IRBs have expressed concerns that asking people about traumatic events will harm them. Elana Newman & Danny G. Kaloupek, *The Risks and Benefits of participating in Trauma-Focused Research Studies*, 17 J. TRAUMATIC STRESS 383, 390 (2004).

[20] CENTER, *supra* note 1, at 4; Naomi Palosaari, *Intellectual Property Rights and Informed Consent In American Indian Communities: Legal and Ethical Issues*, 41 AM. INDIAN L. REV. 125, 148 (2016) ("Researchers in oral history, anthropology, linguistics, and folklore hold themselves to [their own disciplinary] standards for ethical research conduct"). For details regarding those standards, *see id*., at 148–151.

[21] SCHRAG, *supra* note 3, at 143–160, 153–59 (providing an overview of Shopes's and historians' quest for express inclusion, then expedited review, then exemption), at 144–158 (anthropologists, historians, sociologists, social folklorists, political scientists). In describing the focus on obtaining "exempt" status, it appears that authors (or at least the people they describe) mistake research that is exempt from some of the Code's standard provisions for activity that is not research or is *excluded* from the Code.

2018 Common Rule, agency guidance, federal legislation, and court decisions. More broadly, this article aims to correct the pervasive misunderstandings regarding "human subjects' research" that underlie this dispute.[22]

To accomplish these goals in the most straightforward way possible, this article begins, somewhat unconventionally, by explaining a critical misunderstanding at the heart of the confusion, how it impacts IRB submission and review, and why it persists. This is necessary not only to raze the existing foundation of erroneous information and contextualize the issue, but also to establish a sound framework for analysis.

A. A Foundation of Misunderstanding

The conflict regarding IRB oversight can be traced to a widely held, flawed premise.[23] For the most part, IRB members and faculty have presumed that the aforementioned work and works are some form of research, and thus interpret the issue as whether these should be subjected to IRB review, given the Code's science-valanced provisions and concerns. This, however, reflects a profound misunderstanding of the type of "research" "involving human subjects" that the Common Rule covers.[24]

Fundamentally, whether activities must be IRB approved depends on whether they fall within the Common Rule and meet its definition of "research." If those activities do, they must be approved; if they do not, an IRB has no discretion to review them.[25] As this article explains, the Common Rule does not cover all types of research, but only a particular species of it.[26] As detailed below, scores of agency publications, court and administrative opinions, and past and present regulations, journalistic, biographical, historical, humanistic, and similar scholarly activities that focus on specific individuals do *not* constitute "research" under the

[22] The answer will not be especially insightful to people who have read and understood the Code or supplemented their knowledge with OHRP Guidance documents, Opinion Letters, or court decisions. Nonetheless, this article recognizes that a majority of the impacted constituencies have not.

[23] *See, e.g.*, SCHRAG, *supra* note 3, at ix–xi.

[24] *See generally*, KLITZMAN, *supra* note 2, at 74–76, 99–105 (stating that IRBs mis-define and misinterpret Code's terms); SCHNEIDER, *supra* note 2, at 152–56 (describing ways that IRBs misunderstand and misapply Code's terms and substitute personal opinion), 199–200 (lacking knowledge of Code). In turn, IRBs misconstrue what must be IRB-approved.

[25] Federal Policy for the Protection of Human Subjects, 83 Fed. Reg. No. 14 (Jan. 22, 2018); OHRP, *Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements*, www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-scholarly-and-journalistic-activities-deemed-not-to-be-research/index.html [Hereinafter OHRP 2018].

[26] OHRP 2018, *supra* note 25; 45 C.F.R. §§ 46.108–09, 112.

Common Rule.[27] As such, they do not need approval.

Faculty and IRB members, however, have overlooked this authority in favor of their own idiosyncratic interpretations of "research,"[28] which encompass more than what is covered by the Common Rule.[29] As a result, IRBs wrongly review uncovered activities, but faculty do not assert the correct arguments to stop it.[30] Instead, they raise previously rejected objections,[31] or plead that their work warrants different treatment under the Code.[32] Furthermore, because this argument is largely untethered to the source documents, more debate has not generated more clarity, but, instead, creates something of a centrifugal force taking people farther from the answer.[33]

B. An Opportunity for Understanding

Although previous United States Department of Human and Health Services ("HHS"), Office of Human Research Protections ("OHRP"), and judicial pronouncements have done little to correct these pervasive misunderstandings, we are at an inflection point. First, in 2018, the Human

[27] Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements, https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/scholarly-and-journalistic-activities-deemed-not-to-be-research-guidance/index.html (last visited 2018). OHRP recently declared that IRB authority extends only to the types of research covered by the Common Rule. OHRP 2018, *supra* note 25. Therefore, while it is true that IRBs must approve all research covered by the Code even if doing so impedes it or is inferior to some other means, most of these activities do not qualify as "research," let alone "human subjects' research."

[28] *See generally* KLITZMAN, *supra* note 2, at 175–76 (failure to follow Code and OHRP/ HHS Guidance documents), 152–56 (misunderstand Code's terms and substitute personal opinion and perceptions).

[29] *See* KLITZMAN, *supra* note 2, at 99–104, 173–76, (mis-defining "research" and "general knowledge" and not following Regulations or Guidance documents defining these terms); SCHNEIDER, *supra* note 2, at 78–79. (IRBs misconstrue and reinterpret "research").

[30] SCHNEIDER, *supra* note 1, at 199 (stating faculty do not know enough about the Code to fight IRB overreach).

[31] Additionally, corresponding to complaints unsuccessfully raised by researchers in the bio-medical and behavioral sciences, faculty also complain that IRBs impede research, elevate non-experts to arbiters of "good" research, require prior review of interview questions and topics, demand illogical changes to projects, and produce inconsistent results. Although these symptomatic concerns present differently in the context of journalism, biographical interviewing and writing, oral history collection, and documentation, they, too, were rejected or taken as an indication that projects of humanities and arts faculty needed to be closely monitored and scrutinized. *See* KLITZMAN, *supra* note 2, at 9.

[32] SCHRAG, *supra* note 3, at 143–160; *Cf. Clarification of OHRP's Position on Oral History Information* (2015), https://research.utexas.edu/wp-content/uploads/sites/3/2015/10/michael_carome_updated.pdf.

[33] Those documents include: OHRP Opinion Letters, the regulation's definition of "research," statutes, court decisions, Guidance documents and Decision Charts from HHS (the agency that has regulated "human subjects" "research" since the 1970s).

Subject Research Regulations were amended, and, consistent with their implementation, institutions are presently revising their IRB policies and practices. Second, in hopes of ending long-standing confusion about IRB review,[34] the 2018 Common Rule added to the definition of "research" a subparagraph that states what *does not* constitute research (which HHS supplemented with a concurrent publication).[35] Because faculty and IRBs are now focused on this issue and the answer is now beyond dispute, this article is uniquely important at this juncture.

II. FEDERAL REGULATION OF RESEARCH

This article does not dispute the justifications for or substantive regulations governing "human subjects' research," but, rather, considers whether certain scholarly, creative, and journalistic activities are covered by those regulations.[36] Understanding the legislative history and architecture of the Regulations, however, assists in understanding what activity is regulated (and, in turn, what is subject to IRB review). Indeed, the titles and language that help illuminate their scope are obscured by the time they are implemented at the institutional level as the nondescriptly titled "Common Rule."

A. A Brief History of Federal Regulation

In the 1970s, the U.S. government began devising principles and policies for conducting biomedical and behavioral research involving humans.[37] In the summer of 1974, Congress passed the National Research Act: Protection of Human Subjects of Biomedical and Behavioral Research.[38] The National Research Act established: (1) the Office for the

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[34] OHRP 2018, *supra* note 25.

[35] This is not a substantive change, but it does render the answer indisputable. Additionally, concurrent with the publication of the 2018 Common Rule, OHRP published a guidance reiterating that these are not "research," explaining why they are not, and declaring that they are not subject to IRB review or any of the Code's prophylactic provisions.

[36] As such, it does not include the standard narrative of the scandals prompting regulation. Such a detour risks mis-framing the issue. For a comprehensive history of the events underlying regulation, *see* Center, *supra* note 1; Kerr, *supra* note 1, at 412; JAMES H. JONES, BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT (Free Press 1993).

[37] This was prompted by the exposure of (yet another round of) a number of abuses of human research subjects. *See* Klitzman, *supra* note 2, at 11–13; Schneider, *supra* note 1, at 109–110.

Some authors aver that the common invocation that scandals necessitated expanding IRB review was unfounded, and actually reflected moral panics about research rather than a plethora of actual instances of harmful research. *See* Schneider, *supra* note 1, at 191–94; Will C. van den Hoonaard, *Is Research-Ethics Review a Moral Panic?*, 38 CAN. REV. OF SOC. ANTHROPOLOGY 19, 25 (2001).

[38] National Research Act: Protection of Human Subjects of Biomedical and Behavioral Research, Pub. L. No. 93-348 (1974).

Protection of Research Risks[39] (now the Office for Human Research Protection, Department of Health and Human Services[40]) to oversee and regulate biomedical and behavioral research on human subjects; and (2) the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, a temporary body, to study problems associated with biomedical and behavioral research and propose guidelines for it.[41]

In 1978, the National Commission authored *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, better known as *The Belmont Report*.[42] *The Belmont Report* articulated three ethical principles: respect for people, beneficence, and justice,[43] to guide biomedical and behavioral research.[44] Although heavy on principles, *The Belmont Report* was light on operational rules for conducting research.[45] Instead, the task of translating *The Belmont Report*'s principles into concrete regulations was assigned to its successor, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research.[46]

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[39] 42 U.S.C.S. §300v-1–3 (providing for the establishment, duties, administration, funding, and termination of the President's Commission, terminated Dec. 31, 1982).

[40] In 1979, the Department Health, Education, and Welfare was divided into the Department of Health and Human Services and the Department of Education. *See* 20 U.S.C. § 3508 (2019).

[41] 42 U.S.C. 6A §§ 289–300v-1 (Westlaw through Pub. L. No 10-43) (1993). The National Commission met from 1974–1978. Much of its work is recounted in DHEW, Institutional Review Boards: Report and Recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 43 Fed. Reg. 54081, 56186 (Nov. 20, 1978).

[42] DEPT. OF HEALTH, EDUCATION, AND WELFARE, THE BELMONT REPORT (1979); 44 Fed. Reg. 23192, 23193 (Apr. 17, 1979), http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html (last visited Jan. 13, 2020).

[43] To quote from the Report, these principles were: "(1) to avoid harm whenever possible, or at least to minimize harm; (2) to provide for fair treatment by avoiding discrimination between classes or among members of the same class; and (3) to respect the integrity of human subjects by requiring informed consent." The *Belmont Report* did not define (or clearly define) these principles, but in some ways treated them as conceptual labels. *See* Schneider, *supra* note 1, at 110–17. And the "interim" principles were formulated in the context of research on fetuses, further underscoring the intended application of the provisions and their limitations. THE NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, REPORT AND RECOMMENDATIONS: RESEARCH ON THE FETUS, 76–127 (1975).

[44] DEPT. OF HEALTH, EDUCATION, AND WELFARE, *supra* note 42, at Part B.

[45] *See* Finbarr W. O'Connor, *The Ethical Demands of the Belmont Report*, in DEVIANCE AND DECENCY: THE ETHICS OF RESEARCH WITH HUMAN SUBJECTS (Carl B. Klockars & Finbarr W. O'Connor, eds.,1979) (opining on the application of ethical pronouncements to social science and humanistic research); SCHRAG, *supra* note 3, at 79–90 (describing attempts to translate Belmont's broader ethical suggestions into regulations).

[46] The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research was established on November 9, 1978. Its authority is articulated in 42 U.S.C. §300v and 42 U.S.C. §300v-1.

Perhaps the most enduring action regulating the conduct of human subject research was at the agency level. In 1974, while Congress debated what would become the National Research Act, the Department of Health, Education, and Welfare ("HEW") (now HHS) preemptively enacted its own policy,[47] thereafter codified as 45 C.F.R. § 46.[48] In light of the impending legislation, it may have seemed pointless for Congress to create agency policy but, ultimately, it was what enabled HEW and HHS to establish and implement a template for regulating research, and allowed Commissions to spend several years studying the issue.[49]

In fact, a few years later, when the President's Commission[50] began drafting its rules for Biomedical and Behavioral Research, it drew upon the HHS/OHRP policy already implemented. Ultimately, in 1981, the President's Commission's regulations were integrated into[51] and codified under 45 C.F.R. § 46.[52]

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[47] It was established May 30, 1974 (HRSA Internal Memo (1974)). The internal HRSA memo calling for rules was entitled *Biomedical Research and the Need for Public Policy. Id.* at 8; *see also* Beno v. Shalala, 853 F. Supp. 1195, 1210–11 (E.D. Cal. 1993) (citing 120 Cong. Rec. 31,596-97 (1974) (the Act "simply establishes in law and somewhat broadens the protection of human subjects of research and experimentation and similar activities which is already a part of HEW regulations . . . to include activities carried out by HEW itself") (statement of Sen. Buckley)).

[48] *See* HHS, Health Resources and Services Administration Program, *Protection of Human Subjects Participating in Research Programs Conducted or Supported by HRSA Policy*, HRSA Circular 03, V, available at www.hrsa.gov/humansubjects/policy/html; Office for the Protection of Research Risks (NIH), *Summary of Basic Protections for Human Subjects* (Dec. 23, 1997).

[49] Although one author has cited this as evidence of a "power grab" or turf war, HEW had already been reviewing and regulating certain types of research. *See* Schneider, *supra* note 1, at 191–92; Will C. Van den Hoonaard, SEDUCTION OF ETHICS: TRANSFORMING THE SOCIAL SCIENCES, 137 (University of Toronto Press, 2011).

[50] The Commission was directed to review of the adequacy and uniformity: (1) of the rules, policies, guidelines, and regulations of all Federal Departments and Agencies regarding the protection of human subjects of biomedical or behavioral research which such Departments and Agencies conduct or support, and (2) of the implementation of such rules, policies, guidelines, and regulations by such Departments and Agencies, including recommendations for legislation and administrative action. Thereafter, it was to report on the protection of human subjects of biomedical and behavioral research, biennially to the President, Congress, and appropriate federal Departments and Agencies. *See* 45 C.F.R. § 46.

[51] *See* 44 Fed. Reg. 47692 (Aug. 14, 1979).

[52] In accordance with the Commission's recommendation, the Model Federal Policy is based on subpart A of the HHS Regulations for The Protection of Human Research Subjects, 45 C.F.R. § 46; *see* HRSA, *Circular*, *supra* note 47, at 03, V.

B. The Federal Policy for the Protection of Human Subjects: The Common Rule

In 1991, more than a dozen other federal agencies and departments adopted 45 C.F.R. § 46,[53] which became "The Federal Policy for the Protection of Human Subjects."[54] Because the policy is common among them, it is known as The Common Rule, but it is also referred to as the "Code," "Policy," and "Regulations."[55] The Department of Health and Human Services, along with the Office of Human Research Protection, which is under its charge, fulfils its statutory duty to regulate "biomedical or behavioral research involving human subjects"[56] by administering these regulations.[57]

Institutions and universities engaged in "research covered by th[e] policy"[58] "and institutional review boards (IRBs) reviewing research subject to th[e] policy must comply with [the Common Rule]."[59]

III. THE COMMON RULE AT THE UNIVERSITY LEVEL

A. Institutional Review Boards

Because it is not feasible for OHRP to directly oversee all of the nation's institutions and researchers, the Common Rule requires[60] that

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[53] As of 2018, the following agencies have adopted the Common Rule: Department of Homeland Security, Department of Agriculture, Department of Energy, National Aeronautics and Space Administration, Department of Commerce, Social Security Administration, Agency for International Development, Department of Housing and Urban Development, Department of Justice, Department of Labor, Department of Education, Department of Veteran Affairs, Environmental Protection Agency, Department of Health and Human Services, National Science Foundation, Department of Transportation, Office of the Director of National Intelligence, Central Intelligence Agency, and Consumer Product Safety Commission. *See* U.S. DEPT. OF HEALTH & HUMAN SERVICES, *Federal Policy for Protection of Human Subjects*, https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html (last visited Jan. 14, 2020).

[54] 45 C.F.R. § 46. Research on humans is regulated through *two* rules: 45 C.F.R. § 46 (Health & Human Services), the focus here, and 21 C.F.R. § 50 of the FDA Code, which is applicable to research on experimental drugs and medical devices subject to FDA approval.

[55] Because this article analyzes whether certain activities fall within the Common Rule, rather than its substantive rules for ethical research, those provisions are not detailed here.

[56] 42 U.S.C. § 289 (2019).

[57] Regulations are typically effectuated as law. *See* United States v. Mead Corp., 533 U.S. 218, 226–27 (2001); Georgia v. United States, 411 U.S. 526, (1973).

[58] 45 C.F.R. § 46.103(a) (2020).

[59] *Id*. ("conducted, supported, or otherwise subject to regulation by any Federal department or agency").

[60] 42 U.S.C. § 289(a) (2019). The National Research Act provides for the creation of Institutional Review Boards "to review biomedical and behavioral research involving human subjects . . . ."

universities establish "local" IRBs[61] to review "all research activities covered by the policy,"[62] and ensure they satisfy its provisions.[63] Researchers desiring to conduct covered "research" must first obtain IRB approval[64] and implement any modifications the IRB decrees.[65] If the IRB denies approval, the research cannot proceed.[66]

Despite being a lynchpin of the federal regulatory apparatus, most faculty were unaware of IRBs until the late 1990s to mid-2000s.[67] After a number of high-profile lawsuits[68] and federal enforcement actions,[69] universities became more vigilant about Common Rule compliance, and IRBs proliferated across campuses.[70]

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[61] KLITZMAN, *supra* note 2, at 212–13 (describing the local nature and relationship with the university). The federal structure of "local" IRB review is modeled after the NIH Clinical Center's "Clinical Research Committees" (which existed before federal government began regulating research conduct); LAURA STARK, BEHIND CLOSED DOORS: IRBS AND THE MAKING OF ETHICAL RESEARCH (Univ. of Chicago Press 2012).

[62] 45 C.F.R. § 46.103(a) (2020).

[63] 45 C.F.R. § 46.111 (2020) (listing requirements that IRB "shall determine . . . are satisfied"). This includes minimizing and weighing risks of the research to subjects against its benefits, ensuring the subject's privacy, requiring informed consent, and ensuring the research design is sound. 45 C.F.R. § 46.111(a)(1)(i) (2020); 45 C.F.R. § 46.111(a)(2) (2020). These prescriptions are extrapolated from the Belmont Report's central principles of beneficence, justice, and autonomy of human subjects. DEPT. OF HEALTH, EDUCATION, AND WELFARE, *supra* note 42.

[64] 45 C.F.R. § 46.109. The federal review process then obligates IRBs and/ or their institutions to file with OHRP an "Assurance of Compliance" or Federal-Wide Assurance. § 46.103.

[65] 45 C.F.R. § 46.108(a)(3)(iii).

[66] 45 C.F.R. § 46.109. By one estimate, only 20% of proposals are approved as submitted. *See* J. Nichols, *The Canadian Model: A Potential Solution to Institutional Review Board Overreach*, 6 AAUP J. ACAD. FREEDOM, no. 1, 2015, at 1, 3.

[67] *See generally* SCHRAG, *supra* note 3 at 126.

[68] Klitzman, *supra* note 2, at 15–18. Holly Fernandez Lynch, *Opening Closed Doors: Promoting IRB Transparency*, 46 J. L. MED. & ETHICS 145, 154 n.78 (2018) (noting early 2000's increase in litigation, including that against IRBs and individual board members). *See, e.g.*, Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807 (Md. 2001) (regarding infamous lead paint study in Baltimore City, dismissed by stipulation); *see also* M. M. Mello, D. M. Studdert, and T. A. Brennan, *The Rise of Litigation in Human Subjects Research*, 139 ANNALS OF INTERNAL MEDICINE 40, 40 (2003) (expressing concern that similar litigation would increase). In reality, litigation by research subjects is relatively infrequent. Lynch, *supra* note 68, at 154.

[69] *See* Caroline H. Bledsoe, et al., *Regulating Creativity; Research and Survival in the IRB Iron Cage*, 101 NW. U. L. REV., No. 2, 593, 601–03 (2007) (discussing the withholding of federal funds as an alternative means of regulating IRBs); KLITZMAN, *supra* note 2, at 178–79 (detailing federal actions shuttering research at some universities in 1999-2000 and the resulting fear it caused); Eliot Marshall, *Shutdown of Research at Duke Sends a Message*, 284 SCIENCE 1246 (May 21, 1999); SCHRAG, *supra* note 3, at 141 (regarding a sudden stream of "compliance oversight determination letters"); *see also* OHRP, *OHRP Compliance Oversight Activities: Significant Findings and Concerns of Noncompliance*, Oct., 12, 2005, www.hhs.gov/ohrp/compliance/findings.pdf (report on compliance actions).

[70] Jack Katz, *Toward a Natural History of Ethical Censorship*, 41 LAW & SOC'Y REV.

B. Local IRB Decision-making

If not for outsourcing to local IRBs, research review would require a distended bureaucracy,[71] millions in resources, and longer review periods. The tradeoff for ease and expediency, however, is that, because the system relies on unsupervised lay people applying administrative regulations,[72] mistakes occur.[73] Additionally, decisions issued by IRBs are widely divergent and inconsistent,[74] and because IRBs operate as closed systems without external appeal, there is no mechanism for identifying and correcting mistakes.[75] This permits misunderstandings to thrive and become de facto policy.[76]

Among the more troubling revelations salient here, research shows that university IRB members often misinterpret or misapply the Code's provisions,[77] substitute their own interpretations for the Common Rule's definitions,[78] and unknowingly stray beyond their authority.[79] This is the case with research involving human subjects.

C. What May IRBs Review?

The Common Rule requires that any "covered" "research"[80] be reviewed and approved by an IRB.[81] Conversely, IRBs are obligated to

797, 799 (2007); Marshall, *supra* note 69.

[71] *See* KLITZMAN, *supra* note 2, at 337–38 (describing perceived benefits of local oversight and problems with centralized systems).

[72] SCHNEIDER, *supra* note 1, at 68–69, 154–56 (discussing the intensification of currently existing judicial due process issues when lay people, as opposed to expert judges, attempt to discern and apply federal regulations in IRBs).

[73] KLITZMAN, *supra* note 2, at 63 (relating that IRBs at prominent institutions have misinterpreted the Regulations.); *see also* SCHNEIDER, *supra* note 2, at 78–97 (noting survey of IRBs that showed IRBs correctly answered only 55% of questions regarding content covered in OHRP/ HHS Guidance Documents).

[74] *See* SCHNEIDER, *supra* note 2, at 71–74, 78–97; KLITZMAN, *supra* note 2, at 7–8, 60; SCHRAG, *supra* note 3, at 168–69.

[75] *See* SCHNEIDER, *supra* note 2, at xxix (contending that IRBs make poor decisions because they are unaccountable).

[76] SCHNEIDER, *supra* note 2, at xxix.

[77] *See* notes 72–74, *supra*, notes 83, 84, *infra.*

[78] Klitzman, *supra* note 2, at 63, 74–76; SCHNEIDER, *supra* note 2, at 78–79 (relating that studies reveal that IRBs misunderstand the Code's definition of "research"), 93–95 (IRB members often lack familiarity with Code).

[79] Zywicki, *supra* note 1, at 881. Indeed, federal agencies have been surprised by how IRBs have attempted to expand both their and the Regulation's scope. KLITZMAN, *supra* note 2, at 183–84.

[80] 45 C.F.R. § 46.109(a).

[81] *See supra* note 63 and accompanying text. 45 C.F.R. §46.111 (listing requirements that IRB "shall determine . . . are satisfied"). IRB review includes minimizing and weighing risks of the research to subjects against its benefits, §46.111(a)(2), ensuring the subjects' privacy, § 46.111(a)(7), requiring informed consent, § 46.111(a)(4), and ensuring the

review and approve any research covered by the Common Rule. Disputes regarding what is subject to IRB approval[82] stem from confusion about, or more accurately, a failure to comprehend, what qualifies as "research" under the Common Rule.[83] Because faculty and IRBs misconstrue which "research" is covered,[84] they misconstrue which activities must be approved.

Ironically, this occurs *not* because the word "research" is alien, but because it is familiar. The familiarity of the word does not signal, and faculty and IRBs do not realize, the term possesses a unique meaning in the context of the Common Rule.[85] Accordingly, IRB members overlook the Common Rule's definition, and interpret it colloquially or as a reflection of whatever methods, practices, and products their disciplines deem "research."[86] This is not surprising considering faculty and IRB members are not legal scholars versed in administrative law and statutory construction.[87] These interpretations, however, transmogrify "research" into something different than what is covered by the Common Rule. Indeed, it has led IRBs to assert authority over a wide variety of academic undertakings and modes of inquiry including: journalistic investigation,

research design is sound, § 46.111(a)(1)(i).These prescriptions are extrapolated from the Belmont Report's central principles of beneficence, justice, and autonomy of human subjects. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Belmont Report), DHEW Publication OS78-0012, Washington, D.C., September 30, 1978.

[82] *See, e.g.*, SCHRAG, *supra* note 3, at ix-xi.

[83] OHRP 2018 ("*Scholarly and Journalistic Activities Deemed Not to be Research")* OHRP, 83 Federal Register 28497; *see* KLITZMAN, supra note 2, 173–76 (IRBs do not follow OHRP/ HHS Guidance, and are confused about what constitutes research and exempt research.).

[84] KLITZMAN, *supra* note 2, at 99–104 (discussing common confusion of "research" and "general knowledge" as terms of art); SCHNEIDER, *supra* note 1, at 78–79 (enumerating evidence that IRBs misconstrue definition of "research" or believe it is subject to IRB interpretation).

[85] KLITZMAN, *supra* note 2, at 74–76 (detailing IRB members' lack of understanding of and failure to apply Code's terms). Schneider, *supra* note 1, at 68, 97–105 (same). Counterintuitively, a fabricated term (such as SINCOGENK, standing for "systematic investigation designed to contribute to generalizable knowledge", the Code's definition of research) might have prevented misunderstandings, because it would signal its inimitability and force people to read the Common Rule's definition.

[86] OHRP 2018 ("*Scholarly and Journalistic Activities Deemed Not to be Research*"*)* OHRP 2018, *supra* note 25; *see* Katz, *supra* note 1*,* at [86]; see KLITZMAN, *supra* note 2, at 74–76, 99–102 (stating that IRB members substitute opinion for the Code's definitions and fail to follow OHRP/ HHS Guidance documents); SCHNEIDER, *supra* note 2, at 152 (stating IRBs rely on personal experience and intuition to define terms).

[87] SCHNEIDER, *supra* note 2, at 97–105. It is nonetheless dispiriting that scholars do not read the source material or HHS/ OHRP Guidance documents.

oral history collection and documentation,[88] non-fiction filmmaking and biographical writing, creative and reconstructive non-fiction writing,[89] oral history collection and documentation,[90] and legal research.[91] Furthermore, when an IRB wrongly asserts authority over a scholarly, journalistic, or creative activity, it reinforces that authority. Every submission becomes proof that such projects must be submitted and becomes precedent that IRBs have the authority to review them.

IV. "RESEARCH" COVERED BY THE COMMON RULE

Whether an activity requires IRB approval hinges on whether it constitutes "research" under the Common Rule. Fundamentally, it is critical to understand that the Common Rule does not cover every investigational, scholarly, or research-oriented undertaking involving people. Instead, it applies only to a particular type of research "involving human subjects."[92]

A. "Research" Defined

As is often the case with legal language, the Code defines "research" in a specific way:

> *Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for

[88] *See, e.g.*, CENTER, supra note 1; Robert L. Kerr, supra note 1, at 403–07; SCHRAG, *supra* note 3, at 137–38.

Appearing to extend their historical rivalry to IRB review, both Duke University and the University of North Carolina at Chapel Hill implemented policies requiring IRB review of student journalism projects. Hamburger, *supra* note 1, at 293–94. And UNC Chapel Hill threatened to withhold a degree from a journalism student who had requested printed material, by phone, for a project. Jack Katz, *Ethical Escape Routes for Underground Ethnographers*, 33 American Ethnologist 501 (Nov. 2006); *AAUP, Protecting Human Beings*, Academe: Bulletin of the AAUP, May-June 2001, at 55, 59.

[89] Hamburger, *supra* note 1, 293–94; Katz, *supra* note 1, at 799 ("creative writing and the visual arts"); Wright, *supra* note 1, at 204 (creative and biographical writing). Narrative research/Narrative studies typically involve biographical study of an individual or collecting several people's accounts of a specific event or time period. Shaun B. Spencer, *Using Empirical Methods to Study Legal Writing*, 20 Legal Writing 141, 172 (2015).

[90] AAUP Report, *supra* note 1; Center, *supra* note 1, at 4; Katz, *supra* note 1, at 799; OHRP 2018, *supra* note 25.

Citing possible emotional stress to interviewees, IRBs have prohibited oral historians and documentarians from talking with Holocaust survivors or protestors engaged in "civil disobedience." Center, *supra* note 1, at 4; Jaschik 2015, *supra* note 1.

[91] *Cf.* OHRP 2018, *supra* note 25 (noting that questions about whether legal research is "research").

[92] 45 C.F.R. § 46.101(a).

> purposes of this policy. . . . [93]

The 2005, 1992, and 1981 Common Rules share this definition.[94]

In 2018, to rectify the longstanding misunderstandings discussed in this article, the Code[95] added to this definition a paragraph explicitly stating that:[96]

> For purposes of this part, the following activities are deemed *not to be* research:
>
> (1) Scholarly and journalistic activities (*e.g.,* oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information that focus directly on the specific individuals about whom the information is collected . . . .[97]

Subparagraph (1) is not a substantive change in policy, but a clarification.[98] In 2011, as part of the inter-agency reassessment of the Common Rule, HHS sought public comment.[99] Several organizations asked that "research" be clarified or that the Code exclude certain activities.[100] As a result, the 2018 Code added subparagraph (1), hoping that people would finally understand what constituted "research" under the Code.[101]

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93 45 C.F.R. § 46.102(I).

94 The 1981, 1992, and 2005 Common Rules also define research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." 45 C.F.R. § 46.102(l).

95 The new 2018 Common Rule became effective July 2018. Federal Policy for the Protection of Human Subjects: Six Month Delay of the General Compliance Date of Revisions While Allowing the Use of Three Burden-Reducing Provisions during the Delay Period. 83 Fed. Reg. 28497, 28499 (Jun. 19, 2018).

96 Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. 7149, 7261 (Jan. 19, 2017).

97 45 C.F.R. § 46.102(l)(1).

98 OHRP, 83 Fed. Reg. 28497.

99 *Id.*

100 *Id.*; *see also* CENTER, *supra* note 1, at 3–5 (complaining that "research" and "human subject" are ambiguous); SCHRAG, *supra* note 3, at 143–61 (recounting confusion among anthropologists, historians, sociologists, social folklorists, political scientists, and entreaties to clarify). For decades, IRBs and faculty ignored existing HHS/OHRP Guidance Documents, Opinion Letters, and court decisions explaining the limited nature of "Common Rule" "research."

101 On September 8, 2015, HHS and 15 other federal departments and agencies published a Notice of Proposed Rulemaking which presented the proposed revisions. 80 Fed. Reg. 53931 (Sept. 8, 2015). On January 19, 2017, HHS/OHRP published the final revised Federal Policy for the Protection of Human Subjects, with implementation to begin (and a general compliance mandate for most provisions) July 19, 2018. 82 Fed. Reg. 7149 (July 19, 2018).

B. Characteristics of "Research"

There are two components to Common Rule research. First, the investigation is designed to systematically collect data or information (be it quantitative or qualitative) or test a hypothesis.[102] Although this is typified by an experimental protocol,[103] it also includes methodologies such as participant observation and ethnographic study.[104]

Second, the primary objective is to develop or contribute to "generalizable knowledge."[105] This does not mean that the undertaking or its end-product contributes to others' knowing things or collects "factual information" of general interest. Instead, "generalizable knowledge" is that which can be applied to other situations beyond the parameters of the specific undertaking, extended to other groups, or used to draw broader generalizations about phenomena or populations.[106] Hence, its purpose is to discover or obtain information and extend this information to other people and situations.[107]

By contrast, activities "that focus directly on the specific individuals about whom information is collected and used, without extending that information to draw generalizations about other individuals or groups," are not "research."[108] For example, documentaries, biographical or reconstructive nonfiction books, journalistic investigations, oral history collections, literary criticisms, and legal research and case studies do not—

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[102] OHRP 2018, *supra* note 25; Letter from Michael Carome, Associate Director for Regulatory Affairs, OHRP, to Linda Shopes and Donald Ritchie (Sep. 22, 2003), available at http://grants.nih.gov/grants/policy/hs/Oral_History.doc; updated Clarification of OHRP's Position on Oral History Information (2015), https://research.utexas.edu/wpcontent/uploads/sites/3/2015/10/michael_carome_updated.pdf .

[103] G.J. Annas, *Questing for Grails: Duplicity, Betrayal and Self-deception in Postmodern Medical Research,* 12 J. CONTEMPORARY HEALTH L. & POL'Y 297, 315 (1996).

[104] OHRP 2018, *supra* note 25.

[105] 45 C.F.R. § 46.102(l); OHRP 2018, *supra* note 25; *cf*. Mayfield v. Dalton*,* 901 F. Supp. 300 (D. Hawaii *1995).*

[106] OHRP 2018, *supra* note 25; Sims v. Central Intelligence Agency, 479 F. Supp. 84 (D.D.C 1979). The phrase was added to distinguish hypothesis-testing and experimentation, which *are* research, from humanistic inquiry, creation, professional practice, and therapeutic treatment which are not. OHRP Clarification (2015), *supra* note 102; *see* Vodopest v. MacGregor, 913 P.2d 779 (Sup. Ct. Wa. 1996).

[107] Amy L. Fairchild, *Population-Based Surveillance and Research: Dealing With Humpty Dumpty: Research, Practice, and the Ethics of Public Health Surveillance*, 31 J. L. MED. & ETHICS 615 (2003) (Robert Levine, who drafted the definition for the National Commission, required the activity be "done with the intent" of generating new knowledge); *see also* ROBERT J. LEVINE, ETHICS AND REGULATION OF CLINICAL RESEARCH 3 (2d ed. 1988) (explaining that research refers to categories of activities designed to contribute to generalizable knowledge, which consists of theories, principles, or relationships, and can be corroborated by accepted scientific observation).

[108] OHRP 2018, *supra* note 25.

and are not primarily intended to—develop generalizable knowledge.[109] Accordingly, these activities are not "research."[110] This is true even if they "collect and present factual information to support their presentation of the [person's] character," provide "evidence-based portrayal[s] of the individuals involved," or are motivated to better understand people and events.[111] Indeed, as far back as 2003, an OHRP Opinion Letter stated that, even though open-ended biographical, journalistic, and "oral history interviewing"[112] seek to better understand people and events, they are not primarily intended to produce or contribute to generalizable knowledge, and are not, therefore, "research."[113] OHRP subsequently republished this in 2015 and expounded on it in a publication coinciding with the roll out of the 2018 Common Rule. It is also reflected in subparagraph (1) of the 2018 Code.

Because the undertaking's *primary* motivation must be to contribute to generalizable knowledge, courts have held that something may be "research" in one instance, but not in another.[114] For example, if a doctor uses a non-standard "experimental" medical intervention to collect

[109] OHRP 2018, *supra* note 25. *Compare* Freeman v. NBC, 80 F.3d 78 (2nd Cir. 1996) (describing broadcast news-writing as "inventive and imaginative"), *with* Silkwood v. Kerr-McGee Corp., 563 F.2d 433 (10th Cir. 1977) (stating films are artistic works that entertain), *and* Candelaria v. Spurlock, 2008 U.S. Dist. LEXIS 51595 (E.D.N.Y. July 3, 2008) (noting documentary films educate the public), *and* Huckabee v. Time Warner Entertainment Group, 19 S.W.3d 413 (Sup. Ct. Tx. 2000) (illustrating that documentary film uses information to tell a story).

[110] Gathering information about a few people, such as participant observation or ethnographic study, with the purpose of revealing or discerning something about the beliefs or customs of the community or group to which those people belong (rather than to just obtain information about or collect evidence to expose the specific people) would meet the definition of "research." OHRP 2018, *supra* note 25.

[111] OHRP 2018, *supra* note 25; OHRP Clarification (2015), *supra* note 102.

[112] This was in response to queries from Oral History Association and the American Historical Association. Historian Michael Carhart was one of the few in the discipline who correctly stated that history is not a science, is not predictive, and does not seek to produce "generalizable knowledge," so does not meet the definition of "research," hence is excluded. SCHRAG, *supra* note 3, at 154–55.

[113] OHRP Clarification (2015), *supra* note 102; Carome Letter, 2003, *supra* note 102. OHRP added that these activities are not systematic in the way of "research" contemplated by the Code. OHRP Opinion Letter.

[114] As applied to the types of creative activity here, filming a dozen people on an island for a television reality competition show, one's video travelogue, as footage for a documentary film about a few (or all) of those people, or as evidence of what portends to become "Lord of the Flies" anarchy is not primarily motivated to collect information to be applied to or generalized to other people or populations; It is to make a TV show, travelogue, film, or evidence for future litigation and blackmail. Moreover, it is specific to *those* people, so is not "research." Filming those same people on the same island in order to document group dynamics with the intention of learning about group dynamics generally or to see how members of different genders expressed leadership, in order to use this evidence to espouse a theory of gender and leadership applicable to others, is research.

information about its efficacy or treatment effects in an effort to apply what is learned to pharmaceutical development or broader patient populations, it is "research."[115] If a physician uses that same experimental—i.e., non-standard, intervention[116]—to treat a patient, it is not.[117] For example, in *Mayfield v. Dalton*, the Department of Defense ("DOD") collected, tested, and catalogued DNA of military personnel. The court held that this was not "research" because the DNA was collected in case the DOD needed to identify someone's remains, rather than to develop "generalizable knowledge about DNA, the traits of service personnel, or anything else."[118]

C. Activities that are Not "Research"

It is clear that many things colloquially called "research"—finding and reading journal articles, interviewing people, querying library databases, "Googling," obtaining archival footage, and comparing hotel prices on Trivago—are not the species of "research" covered by the Common Rule.[119] These activities, as opposed to "research," are not intended to discover information or explanations to be generalized to *other* situations or populations.

Furthermore, the activities on which this article focuses also do not meet the Code's definition of "research." Underscoring this, in 2018, the Office of Human Research Protections published supplementary materials in conjunction with the implementation of the Revised Common Rule. OHRP explained that, because the main purpose of oral history, journalism,

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[115] Jane L. v. Bangerter, 61 F.3d 1493 (10th Cir. 1995), *rev'd on other grounds*, 518 U.S. 137 (1996) (noting that consent is needed in experimentation); Margaret S. v. Edwards, 794 F.2d 994 (5th Cir. 1986) (same); *cf.* Sims v. Central Intelligence Agency, 479 F. Supp. 84, 84, 91 (D.D.C. 1979) (explaining that CIA's MK-ULTRA research program failed to obtain consent from subjects).

[116] In this context, "experimental" does not designate a research "experiment," but something that is not a standard treatment. Indeed, health insurers distinguish between "experimental" and "standard" treatments. Dale L. Moore, *An IRB Member's Perspective on Access to Innovative Therapy*, 67 ALB. L. REV. 560, 561–62 (1994).

[117] Whitlock v. Duke University, 637 F. Supp. 1463, 1467–68 (M.D.N.C. 1998) (noting the goal of nontherapeutic experimentation is to discover and collect data); *see also* Jay Katz, *Human Experimentation and Human Rights*, 38 ST. LOUIS U. L.J. 7, 14–15 (1993) (comparing ethical duties of doctors towards patients with those of clinical researchers toward subjects and patient-subjects).

[118] Mayfield v. Dalton, 901 F. Supp. 300, 305 (D. Haw. 1995); *see also* State v. Jensen, 373 N.W.2d 902 (N.D. 1985) (detailing that a urinalysis program implemented by a prison to deter drug use and trafficking was not "research" because its main purpose was not to produce generalizable knowledge).

[119] There is a universe of scholarly and creative activities and works that faculty, academic and professional organizations, Promotion and Tenure Guidelines, funders, conferences, and publishers call "research," and then there is the much smaller category of what qualifies as Common Rule "research." The latter is covered by the Common Rule and IRB review; the former is not.

biography, literary criticism, and legal research "is to focus on specific individuals" (and "not to extend the activity's findings to other individuals or groups"), they are not "research."[120] Moreover, these activities fall within new subparagraph (1) which explicitly states they are not Common Rule "research." Consequently, they do not require IRB approval.[121]

V. OTHER MISUNDERSTANDINGS CONTRIBUTING TO CONFUSION AND IRB OVERREACH

Misunderstandings about "research" are supported and compounded by misreading other sections of the Code. Because this article aims to correct misconceptions about what activities that require IRB approval, these misunderstandings require attention.

A. "Exempt Research"

Section 46.104(d) enumerates certain activities that are "human subjects' "research," but have been designated as exempt from a full standard IRB review.[122] Instead, these receive "limited review."[123] A researcher claiming an exemption submits the project to the IRB,[124] which then confirms that the research falls within the exemption and signs-off.[125]

Importantly, § 46.104 is not an exhaustive listing of everything that is not "research" or covered by the Common Rule—after all, activities that are not "research" are not covered by the Code, so they do not need to be exempted from it.[126]

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[120] OHRP 2018, *supra* note 25; OHRP Clarification (2015), *supra* note 102; Carome Letter *(2003), supra note 102.*

[121] Aside from what qualifies as "research," The Common Rule applies only to "research" regulated by a federal department or agency. 45 C.F.R. § 46.101(a). Therefore, even if an activity qualifies as "research," it may not be subject to IRB approval, unless Congress has specially given an agency the responsibility for regulating it as "research." Documentary filmmaking, journalistic, biographical writing, and other artistic, creative, and scholarly activities addressed in this article are not specifically regulated by a federal agency, let alone by one empowered to regulate them as "research activity." In fact, as explained below, attempts to do so would likely run afoul of the First Amendment. Accordingly, even activity within these spheres that might qualify as "research" is not *"research"* that a federal agency regulates as research activity; in turn it would not fall within the Common Rule.

[122] 45 C.F.R. § 46.104(d).

[123] 45 C.F.R. § 46.104(d).

[124] Hence, a researcher claiming an exemption is acknowledging that the activity is "research."

[125] 45 C.F.R. § 46.104(d)(2)(iii), (d)(3)(i)(C), (d)(7), d(8) (stating exemptions, process, and that exemption is conditioned on limited review).

[126] To illustrate, every state has laws or regulations requiring that cars be registered. *See, e.g.*, S.C. Code § 56-3-110 (vehicles to be registered). These typically exempt from registration certain categories of vehicles or owners. *See, e.g.*, S.C. Code, § 56-3-120 (Exemptions from registration), § 56-3-140 (Exemption of certain professional racing cars).

Many do not realize that the Common Rule applies only to a certain type of "research," and others read the term "exempt" out of context. As a result, these individuals often think the "exempt" section enumerates everything that is not "research" or that does not require IRB review (rather than stating which "research" is exempt from the standard review process). In turn, they mistakenly conclude that activities *not* listed, *must* be reviewed (and are research).

In fact, The American Historical Association ("AHA") and its sister organizations have long been mired in this misunderstanding. In 2007, attempting to protect its methods of inquiry from unnecessary IRB intrusion,[127] the AHA lobbied OHRP to add oral history activities to the "expedited review" category.[128] This category enumerates certain "low risk" "research" that does not require a full board meeting for review, thereby expediting its review. Nonetheless, expedited review applies only to "research." Therefore, by asking to include activities in the "expedited" category, the AHA self-designated them "research."

After succeeding, the AHA asked that these be moved into the "exempt" category.[129] Although preferable to expedited review, this reveals the same misunderstanding; by advocating that these activities be in the "exempt" category, these organizations incorrectly designated them "research." Oral history activities, however, generally do not qualify as "research," and, therefore, do not need to be reviewed or approved.[130]

Although they would not be found in any of these registration exemptions, a two-inch Matchbox car, Bumblebee Transformer that turns into a VW bug, and D battery-operated plastic car for a Barbie doll do not need to be registered. This is because, as a threshold matter, they do not meet the definition of "car." In turn, because they are not covered by the registration laws, they do not need to be exempted from them.

127 Kerr, *supra* note 1*,* at 406–07.

128 45 C.F.R. § 46.110. Presaging this, in March 1998, the then-president of the Oral History Association requested on behalf of the Oral History Association, the American Historical Association, the Organization of American Historians, and the American Studies Association, that oral history interviewers using informed consent procedures and forms eligible for expedited review, and, that oral history interviewers *not* using these procedures and forms be subjected to full IRB review. American Association of University Professors, *Institutional Review Boards and Social Science Research* (2000), https://www.aaup.org/report/institutional-review-boards-and-social-science-research. In November 1998, OHRP added oral history to the list of activities eligible for expedited review, HHS, "*Protection of Human Subjects: Categories of Research That May be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure*," 63 Fed. Reg. 60364-60367 (9 Nov. 1998).

129 Jaschik 2008, *supra* note 1.

130 "Oral history refers both to a method of recording and preserving oral testimony and to the product of that process. It begins with an audio or video recording of a first-person account made by an interviewer with an interviewee (also referred to as narrator), both of whom have the conscious intention of creating a permanent record to contribute to an understanding of the past. A verbal document, the oral history, results from this process and is preserved and made available in different forms to other users, researchers, and the

Therefore, this was either a mystifyingly bad strategy to keep IRBs at bay or an indication of a profound misunderstanding of what "exempt" and "research" mean.[131] Additionally, the desire to include oral history in the Code may have been a misguided attempt to obtain official recognition that it was on par with research activities in the sciences.[132] Indeed, the main advocate for these changes feared that if historians and related disciplines said they did *not* conduct Common Rule "research" (or if their activities were expressly excluded from the definition of "research"), then funding agencies would be hesitant to award them research grants.[133] While the constraints of this article prevent a full accounting of the ways this is intellectually flawed, that an activity is not the kind of research covered by the Common Rule, or does not meet its definition of "research," does not mean it is not research for some other purpose or context. Conversely, referring to it as research does not make it so.

B. The Scope of IRB Authority and Review of Uncovered Activity

IRBs may also review uncovered activities because they misconstrue the scope of their regulatory authority and the nature of their duty to protect human research subjects and institutions.[134]

Some IRBs simply think it prudent to review the ethical dimensions of creative processes and professional practices.[135] They reason that the Common Rule's mandate to review "research" does not preclude them from *also* reviewing activities that are not "research," or note that the Code allows IRBs to impose enhanced protections on "research."[136] This

public." The Oral History Association, *Principles and Best Practices for Oral History* (2009), http://www.oralhistory.org/about/principles-and-practices.

131 Independent of this, the ethics of sacrificing some uncovered faculty activity to advantage other uncovered faculty activity (*see* note 126)—in the pursuit of upholding research ethics—is ironic. More likely, this was the result of a profound lack of understanding.

132 At some level, this may have reflected debate within the discipline about oral history's methods and their status as "creditable" scholarship. During this period, the discipline was debating the practice of oral history. Historians favoring traditional methods were skeptical of oral history: They criticized its methodologies as too dependent on memory and subject to revision, and asserted it was not research. Jennifer *Howard, Oral History Under Review*, *Chronicle of Higher Education* (Nov. 10, 2006) https://www.chronicle.com/article/Oral-History-Under-Review/6566. Oral historians argued that their methods were legitimate, and their work constituted research, comparable to traditional scholarly activity. The insistence that oral history was research (as understood by the discipline) may have manifested as broader movement to ensure that everyone, including OHRP, deem it research.

133 SCHRAG, *supra* note 3, at 155 (citing comments by Shopes).

134 *See* KLITZMAN, *supra* note 2, at 323 (demonstrating that some IRBs are overly cautious or believe their duty is to protect the university).

135 KLITZMAN, *supra* note 2, at 8; SCHRAG, *supra* note 3, at 167.

136 KLITZMAN, *supra* note 2, at 174.

misreads the Code and overlooks its limitations on IRB authority.

Although situated within their respective universities, IRBs derive their authority from the Code.[137] Their authority is also constrained by federal law and code.[138] IRBs are authorized to review *only* the category of research covered by the Common Rule.[139] Activities "not included in the [Common Rule's] definition of 'research' . . . do not fall within the scope of the regulations" or IRB purview.[140] Hence, IRBs have no discretion to review "non-Common Rule" undertakings, even if academics or funders refer to them as research.[141]

Furthermore, while an IRB can impose enhanced safeguards on certain types of *covered* "research," it cannot use a desire for increased safety as a justification to control activities that are *not* covered "research."[142] IRBs implement federal agency regulations, and are bound by the agency's interpretation of them, unless clearly contradicted by statute or constitutional provision.[143] Of relevant here, HHS states that "human subjects research under . . . the Common Rule," does *not include* journalistic investigation and interviewing, legal research and case studies, literary criticism and creative writing, biographical filmmaking and writing, and historical scholarship.[144] As this is perfectly consistent with the underlying statutory authority, IRBs and universities cannot go beyond this.

Moreover, regulations cannot exceed their underlying statutory authority.[145] If Congress' intent is clear, "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."[146] Here, the underlying statutes speak of and authorize regulation of *only* biomedical and behavioral research, to wit: The National Research Act: Protection of Human Subjects *of Biomedical*

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137 KLITZMAN, *supra* note 2*,* at 212–13 (describing local nature and relationship with university).

138 42 U.S.C. Ch. 6A; 45 CFR §46.112.

139 OHRP, Fed. Reg. (July 2018).

140 *Id*.

141 *Id.* Furthermore, regulations cannot exceed their underlying statutory authority. *See* Roberts v. United States, 44 Ct. Cl. 411 (Fed. Cl. 1909).

142 SCHNEIDER, *supra* note 2, at 2.

143 Smith v. United States, 170 U.S. 372 (1890); *cf*. NY Dept. of Soc. Servs. v. Dublino, 413 U.S. 405, 421 (1973).

144 OHRP 2018, *supra* note 25.

Further clarifying its domain, HHS states that its duty is to oversee and "protect human subjects in *biomedical and behavioral research.*" OHRP, *History*, https://www.hhs.gov/ohrp/about-ohrp/history/index.html.

145 Roberts v. United States, 44 Ct. Cl. 411 (Fed. Cl. 1909).

146 *Chevron v. Natural Res. Def. Council, 467 U.S. 837, 842–43 (1984).*

and Behavioral Research[147] imposes on HHS/OHRP the duty to regulate entities engaged in "*biomedical and behavioral research* involving human subjects"[148] and provides guidance regarding "*biomedical or behavioral research* involving human subjects."[149] Section 289(a) provides for '"Institutional Review Board[s] to review *biomedical and behavioral research* involving human subjects."[150] Further, 42 U.S.C. § 300v-v-1 created the National Commission for the Protection of *Human Subjects of Biomedical and Behavioral Research,*[151] and directed the Presidential Commission for the Study of Ethical Problems in *Medicine and Biomedical and Behavioral Research*[152] to investigate "medicine or *biomedical or behavioral research*"[153] and report on "the protection of *human subjects of biomedical or behavioral research*."[154] The scope is clear. Therefore, even if OHRP preferred a more expansive concept of "research" or to regulate more forms of scholarship and academic inquiry, it would not have the legal authority to do so.

Some IRBs believe that since the Common Rule obligates them to minimize risks to human research subjects, IRBs can review any activity that could harm a person who is the "subject" of a journalistic, historical, or other creative work.[155] This includes the emotional or reputational harm from revealing unflattering or embarrassing personal information or asking about traumatic events.[156] This is incorrect.[157] Not only does it invert the protections that the Code imposes *on* covered "research" into a test *for* "research," but it also disregards the definitions of "human subject," "research," and "private information."

147 42 U.S.C. §§ 201-205.

148 42 U.S.C. § 289(a).

149 42 U.S.C. § 289(b)(1).

150 42 U.S.C. § 289(a).

151 Report by National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, on Institutional Review Boards, September 1, 1978.

152 42 U.S.C. § 300v-1 *et seq.*

153 42 U.S.C. § 300v-1(a)(2).

154 42 U.S.C. § 300v-1(c), § 300v-1 (a)(1) (E)(i); (a)(2)).

155 *See* research cited at notes 15–21.

156 SCHRAG, *supra* note 3*,* at 164; Kathryn A. Becker-Blease & Jennifer J. Freyd, *Research Participants Telling the Truth About Their Lives: The Ethics of Asking and Not Asking About Abuse,* 61 AM. PSYCHOLOGIST 218, 221–23 (2006). Studies dispute the notion that asking questions about trauma re-traumatizes people; Rather, it is the event itself that traumatizes. One study reported that "no participants reported adverse reactions" to questions, even when subjects reported some discomfort, they found talking about the event and taking control of their narrative helpful.

157 *See* OHRP, Fed. Reg. (July 2018).

As OHRP recently explained, if an activity is not Common Rule "research," it is not covered by the Common Rule, and its protections do not apply.[158] In turn, limiting perceived harm from that uncovered activity is not relevant. Nonetheless, courts have repeatedly held that the First Amendment rights of creators, writers, and journalists prevail over an individual's claim of emotional distress or embarrassment from being portrayed unflatteringly in such works.[159]

This also misconstrues what a "human subject" is. "Human subject" does not mean that a person is the subject matter of scholarship, journalism, a case study, or creative work. Instead, it means "a living individual about whom *an investigator conduct[s] research*"[160] and obtains "private information" as enumerated in the Code.[161] Quite simply, if there is no Common Rule research, there can be no "human subjects." Similarly, "private information" is not a synonym for "personal information,"[162] but is "information about behavior that occurs in a context in which an individual can *reasonably expect that no observation or recording is taking place*, and . . . can *reasonably expect will not be made public*."[163] A person disclosing information in an interview or in the presence of others reasonably understands it might be shown or disclosed. Therefore, by definition, it is not private information.[164] In fact, it is generally

158 *Id.* Consequently, that an activity could diminish "individuals' reputations, and deliberately expose the individuals to public scrutiny or even possible harm, such as losing their positions or employment," does not bring it within the purview of an IRB. *Id.* OHRP, Fed. Reg. (July 2018).

159 Candelaria v. Spurlock, 2008 U.S. Dist. LEXIS 51595 (E.D.N.Y. July 3, 2008); Aronson v. Dog Eat Dog Films, 738 F. Supp. 2d 1104 (W.D. Wash. 2010); Hamburger, *supra* note 1, at 134 (providing no legal claims countenanced for mere embarrassment); *see also* (government may not censor speech based on belief that it is "too harmful," U.S. v. Stevens, 559 U.S. 460 (2010); R.A.V. v. St. Paul, 505 U.S. 377, 382–83 (1992), or emotionally-distressing, Reed v. Town of Gilbert 135 S. Ct. 2218 (2015), to its targets and those who hear it.

160 45 CFR § 46.102(e)(1).

161 45 CFR § 46.102(e)(4)–(5).

162 *See generally* Patricia Sanchez Abril, *Recasting Privacy Torts in a Spaceless World*, 21 HARV. J. L, & TECH. 1, 17–18 (2007) (explaining that current privacy doctrine protects actions in a private spaces).

163 45 CFR § 46.102(e)(1)(ii)(4). This tracks comparable state-based privacy protections. States that protect similar privacy rights require the plaintiff to be secluded or in a place where they reasonably believe they cannot be seen or heard. *See* Ruth Gavison, *Privacy and the Limits of Law,* 89 YALE L. J, 421, 428–29 (1980) (explaining that privacy requires solitude, anonymity, and secrecy); *see, e.g.,* Johnson v. Allen*,* 613 S.E.2d 657 (Ga. Ct. App 2005) (video surveillance in restroom); Sabrina W. v. Willman*,* 540 N.W.2d 364 (Neb. Ct. App. 1995 (intrusion into tanning booth); Placement of secret audio transmitter and camera in doctor's home. Dietemann v. Time, Inc., 449 F.2d 245, 249 (1971).

164 Peruto v. ROC Nation, 386 F. Supp. 3d 471 (E.D. Pa. 2019) (holding that plaintiff speaking to interviewer and being video-recorded for television documentary series, could not reasonably believe he was not being recorded and that conversation would not be used);

permissible to record individuals in public—wherever they reasonably expect to be seen or heard—without their consent,[165] and even when embarrassing.[166]

Absent these limitations, when it comes to the activities, individual rights, and potential legal liabilities discussed here, the notion that review by lay people is superior to that of experts in the profession and courts is spurious at best.[167] First, IRB members have no expertise in law,[168] and often misconstrue it.[169] Second, they lack the collective background necessary to evaluate or appropriately modify these undertakings.[170] This can also be damaging. When an institutional authority deems itself the arbiter of non-Common Rule activities, IRB "approval" implies that the undertaking has been vetted and is, in some broad sense, permissible. If not, then what did the IRB approve? Such approval, however, confers no such protection, but, instead, a misplaced sense of security. In fact, when an IRB changes legally sound consent forms and waivers into IRB-approved Informed Consent,[171] a faculty, who may have been operating safely within the bounds of law, has now unknowingly sacrificed protection from tort liability.[172]

Mayhall v. Dennis Stuff, Inc., 31 MLR 1567 (2002) (stating that flashing breasts at a concert, at a privately-owned venue, is a public act, and a photo or video taken of the flashed bare breasts does not reveal private information).

165 Candelaria v. Spurlock, 2008 U.S. Dist. LEXIS 51595 (E.D.N.Y. July 3, 2008); Wilkins v. NBC, 84 Cal. Rptr. 2d 329 (CA. Ct. App. 1999); Mayhall, 31 MLR 1567.

166 Schulman v. Group W Productions, Inc., 18 Cal.4th 200, 231–32 (CA. Sup. Ct. 1998); Wehling v. CBS, 721 F.2d 506, 509 (5th Cir. 1983); *see also* Boddie v. Am. Broad. Co., 694 F. Supp. 1304 (N.D. Oh. 1989) (stating that Congress did not intend wiretap statutes and similar state laws to be used against journalists surreptitiously recording conversations that result in news stories that embarrass speaker).

167 *See* SCHNEIDER, *supra* note 2 at 67–69.

168 *See* SCHNEIDER, *supra* note 2 at 67–69.

169 *See* SCHNEIDER, *supra* note 2 at 67–69.

170 45 C.F.R. § 46.107 requires IRB members to possess expertise and competencies in the biological/ biomedical and social sciences.

171 IRBs sometimes make changes to informed consent forms that render them substantively incorrect and non-compliant. KLITZMAN, *supra* note 2, at 134–41; Schneider, *supra* note 1, at 74, 88–90 (recounting studies that found multiple errors in IRB-revised informed consent forms); SCHRAG, *supra* note 3, at 162–63 (reporting instances where IRBs changes to informed consent and waiver forms rendered them less accurate, more difficult to comprehend or read, omitted required sections, or potentially violated the privacy rights of the mentally-disabled).

172 Although the law permits liability waivers, the Regulations' Informed Consent provisions do not permit a researcher or institution to require a "human subject" of "research" to waive claims of liability. Hence, any IRB-approved Informed Consent form would need to excise such waivers.

VI. RAMIFICATIONS OF IMPROPER REVIEW

Whether due to misunderstanding, negligence, or a misguided sense of duty, the failure of IRBs to abide by the Common Rule has consequences for not only the faculty and scholarly pursuits wrongly regulated, but also for the universities and individual board members that improperly regulate them. This section provides a general overview of potential liabilities in order to rebuff the notion that reviewing more activity than is covered by the Regulations provides more protection.

A. First Amendment Concerns

When an IRB overreaches into speech, creative activity, and expression (documentary filmmaking, historical interviewing, journalism, etc.), it implicates the First Amendment.[173] Public universities, and by extension their IRBs, are government actors, who must abide by the First Amendment.[174] The First Amendment prohibits the government from "restrict[ing] expression because of its messages, ideas, its subject matter, or its content."[175] Among the limitations found unconstitutional are: requiring a permit or license to speak,[176] punishing speakers afterwards,[177] disfavoring certain subjects,[178] or censoring content because it is deemed "too harmful"[179] or emotionally-distressing.[180] These restrictions "operate

[173] The Common Rule covers the *conduct* of research on people, albeit where questions may be a mechanism of that research, but it does not cover "non-research" speech. James Weinstein, *Symposium: Censorship and Institutional Review Board: Institutional Review Boards and the Constitution*, 101 NW. U. L. REV. 493, 494, 505–06 (2007) (clarifying that the Regulations are triggered *not* by asking humans questions, but by using human subjects in research). Therefore, whereas regulating the use of humans in biomedical, behavioral, and social science research does not implicate the First Amendment. Barry McDonald, *Government Regulation and Other "Abridgements" of Scientific Research: The Proper Scope of Judicial Review Under the First Amendment*, 54 EMORY L. J. 979, 1018–19 (2005); Weinstein, *supra* note 173, at 522–23, suggests that limiting traditional interviewing and journalistic techniques does, and is, therefore, constitutionally suspect.

[174] As this article focuses on whether certain activities are "research" requiring IRB review, a detailed analysis of the First Amendment implications of improper review is beyond its scope. This section is meant only to underscore the ramifications of improper review.

[175] Ashcroft v. ACLU, 535 U.S. 564, 573 (2002).

[176] Watchtower Bible and Tract Soc'y of NY v. Village of Stratton, 536 U.S. 150, 165–66 (2002).

[177] New York Times Co. v. Sullivan, 376 U.S. 254, 267 (1964); Brandenburg v. Ohio, 395 U.S. 444, 448–49 (1969).

[178] Matal v. Tam, 137 S. Ct. 1744, 1763 (2017); U.S. v. Playboy, 529 U.S. 803, 813 (2000).

[179] U.S. v. Stevens, 559 U.S. 460, 460 (2010); R.A.V. v. St. Paul, 505 U.S. 377, 382–83 (1992).

[180] Reed v. Town of Gilbert, 576 U.S. 2218, 2226 (2015).

at different points in the speech process."[181]

As applied to IRB review of uncovered expressive activity, the IRB approval process is quite literally the government licensing speech.[182] Faculty may not commence "research" unless and until the IRB issues an approval or has had a chance to censor it. The First Amendment forbids such "speech approval" procedures and presumes them unconstitutional.[183] Additionally, an official restriction of speech prior to publication is a prior restraint, long recognized to be the least tolerable infringement on First Amendment rights and presumed unconstitutional.[184] Thus, when an IRB restricts speech, either by limiting the questions posed and topics broached in interviews or by censoring or prohibiting the publication of the resulting article, film, or video, it constitutes a prior restraint.[185]

Regarding the content of the speech itself, the First Amendment forbids the government from prohibiting speech simply because it finds the underlying or expressed ideas offensive or disagreeable.[186] When an IRB prohibits or punishes speech, or the resulting speech products and creative works, due to the subject matter, it is exactly this type of content-based restriction. Indeed, the First Amendment "underwrites the freedom . . . to create [film] in the realm of thought and speech."[187]

These restrictions also implicate academic freedom,[188] which is a "transcendent value" and special concern of the First Amendment.[189] Although courts have interpreted academic freedom somewhat differently[190]—whether it is understood as a right possessed by

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[181] Citizens United v. FEC*,* 558 U.S. 310, 336 (2010).

[182] Hamburger, *supra* note 1*,* at 311–12; Schneider, *supra* note 1*,* at 200.

[183] Watchtower Bible v. Village of Stratton, 536 U.S. 150, 167 (2002).

[184] Patterson v. Colorado, 205 U.S. 454 (1907); Near v. Minnesota, 283 U.S. 697, 733 (1931); Hamburger , *supra* note 1, at 312–13.

[185] McDonald, *supra* note 173, at 993; James Weinstein, *Symposium: Censorship and Institutional Review Board: Institutional Review Boards and the Constitution*, 101 NW. U. L. Rev. 493, 494, 505–06 (2007).

[186] Texas v. Johnson, 491 U.S. 397, 414 (1989); Tinker v. Des Moines, 393 U.S. 503, 514 (1969).

[187] Citizens United v. FEC*,* 558 U.S. 310, at slip op. 57.

[188] Although Justice Douglas first articulated academic freedom in a dissent, Adler v. BOE City of New York, 342 U.S. 485, 508 (1952), he later spoke of it as a settled first amendment shield against the state's control of public education, Whitehill v. Elkins, 389 U.S. 54, 62 (1967).

[189] Regents of the Univ. of California v. Bakke*,* 438 U.S. 265, 312 (1978); Keyishian v. Bd. of Regents, 385 U.S. 589, 603 (1967). The Court has sometimes discussed academic freedom as a variant of the First Amendment. *See* Sweezy v. New Hampshire, 354 U.S. 234, 250 (1957) (distinguishing "academic freedom" from general first amendment right of political expression.).

[190] William W. Van Alstyne, *Academic Freedom and the First Amendment in the Supreme Court of the United States*, 52 L. & CONTEMPORARY PROB., 79 (1990).

institutions,[191] or extending to faculty vis-à-vis their universities[192]—improper IRB limitation and censorship directly impacts academic inquiry and creation.

B. Private Universities as Government Actors

Although the First Amendment applies to government restrictions on speech, it can sometimes extend to private actors.[193] When a private entity exercises powers on behalf of or that are "traditionally the exclusive prerogative of the State,"[194] or demonstrates "a sufficiently close nexus between the State and the challenged action [of a private entity] . . . , the action of the [private entity] may be fairly treated as that of the State itself."[195] In such instances, the private entity effectively is engaged in governmental action.[196] For example, the Second Circuit held that a private organization's review committee operating pursuant to, and following a decision-making process governed largely by federal guidelines, constitutes state action.[197]

IRBs at private universities are mandated by, operated pursuant to, and duty-bound to the Federal Code. More than that, they are part of the federal government's regulatory system for human subject research oversight. Thus, when an IRB at a private university decides under the Common Rule, it becomes a government official, and its decisions are functionally those of the government. Consequently, an IRB at a private

191 Regents of Univ. of California v. Bakke, 438 U.S. at 311–12.

192 Sweezy, 354 U.S. 234; Grutter v. Bollinger, 539 U.S. 306, 329 (2003).

193 Jackson v. Metro. Edison Co., 419 U.S. 345, 351-53; *see* Ponce v. Basketball Fed'n, 760 F.2d 375, 377 (1st Cir. 1985); Tynecki v. Tufts Univ. Sch. of Dental Med., 875 F. Supp. 26, 31 (D. Mass. 1994); Kraemer v. Heckler, 737 F.2d 214, 220 (2d Cir. 1984).

194 Jackson, 419 U.S. at 353.

195 *Id.* at 351; *see also* Blum v. Yaretsky, 457 U.S. 991, 1004, 1005 (1982) (identifying key components courts must consider in assessing the action).

196 Jackson, 419 U.S. at 353; Ponce, 760 F.2d at 377; Tynecki., 875 F. Supp. at 31 (holding that the decision of a utilization review committee may be state action where the "decision-making process itself appears to be governed largely" by federal guidelines). In such instances, private entities can become liable for First Amendment infringements. Kraemer, 737 F.2d at 220; Catanzano v. Dowling, 60 F.3d 113, 117 (2d Cir. 1995) (finding state action where private home care providers were required to make certain decisions under the statutory and regulatory scheme).

197 Kraemer, 737 F.2d at 220; *see also* Catanzano, 60 F.3d at 117 (finding state action where private home care providers were required to make certain decisions under the statutory and regulatory scheme). To determine whether a private actor may be found to be a state actor, courts must examine: (1) whether there is a sufficient nexus between the state and the private actor which compels the private actor to act as it did; (2) whether the private actor assumes a traditionally public function; or (3) whether there is a sufficient "symbiotic relationship" between the state and the private actor so that the state might be recognized as a joint participant in the challenged activity. Ponce, 760 F.2d at 377; Tynecki, 875 F. Supp. at 31.

university engages in state action and the First Amendment applies.[198]

C. Board Member Liability

Because states and state entities, such as universities, enjoy sovereign immunity under the Eleventh Amendment,[199] they can be sued only where law expressly permits it.[200] Typically, this immunity extends to agents legitimately acting on behalf of the state, such as when state employees make or implement policies and decisions.[201] In practice, this means that as long as those individuals are acting within the scope of their authority "as the state," they are personally immune from lawsuit for the formulation of "plans, policies, or designs."[202]

This protection, however, is not absolute. While the exact boundaries differ somewhat depending on state law (that is, a state's law abrogating immunity and permitting suit), individuals are typically not immune when acting "beyond [their] authority, or under a mistaken interpretation of the law," or "willfully, maliciously, fraudulently, [or] in bad faith."[203] When IRBs review, prohibit, or punish activity not covered by the Common Rule, they are not only violating the Code, but also acting beyond their authority. In turn, those actions are beyond the scope of any immunity they otherwise enjoy. Accordingly, they may be held individually liable.[204]

D. Compromising Federal-Wide Assurance Systems

Finally, an IRB's failure to follow the Code and overreach into "non-research" jeopardizes an institution's Common Rule compliance, as well as the validity of the formal assurances it must file with the federal agency.[205] The federal-wide assurance system ("FWA") is constructed on and requires each institution to file a written "Assurance of Compliance"[206] with the

198 Chung-Lin Chen, *Constitutional Analysis of Research Ethics Review Laws: The United States and Beyond*, 16 COLUM. SCI. & TECH. L. REV. 248, 250 (2015) ("Where the ethics review requirement is compelled by law, the constitutional concern of free research arises.").

199 U.S. Const. amend. XI.

200 Ex parte Young, 209 U.S. 123 (1908) (acknowledging sovereign immunity but holding that state can be sued for constitutional violations); 1946 Federal Tort Claims Act, 28 U.S.C. § 2674 (waiving immunity under certain circumstances).

201 Ex parte Cranman, 792 So. 2d 392, 405 (Ala. 2000).

202 *Id*.

203 *Id*. In other words, if a state agent acts contrary to or outside of the bounds of the state-based authority, they are no longer acting as the state, and are not covered by the state's protection.

204 *See* Lynch, *supra* note 68, at 145–46, 154 (noting that some human subjects research litigation has named IRBs and individual board members as defendants).

205 45 C.F.R. §§ 46.102–103.

206 Institutions must file with Office of Human Research Protections an "Assurance of

Department of Health and Human Services confirming that it complies with the Common Rule and its covered "research" is conducted consistent with a statement of ethical principles.[207] This is not a mere formality, but also means to hold universities accountable.

By definition, an IRB reviewing activities that are not "research" is not following the Code, at least some of the time. Consequently, any FWAs or Assurances of Common Rule compliance an IRB issues are not credible or objectively false, at least some of the time. Independent of this, when the IRB responsible for ensuring compliance either refuses to follow or is so ignorant of the Common Rule's terms that it cannot discern to what it applies, substantively that IRB's decisions lack validity. Such procedural and substantive issues may render the resulting FWAs invalid, and the university noncompliant.

VII. CONCLUSION

Misunderstandings about the Common Rule and what qualifies as "research involving human subjects" have long permitted IRBs to improperly restrict a variety of scholarly, professional, and creative activities. The 2018 Code and HHS publications now make clear that undertakings such as journalistic and legal investigation, non-fiction filmmaking and writing, and biographical and oral history interviewing, typically are not "research," and, therefore, do not require IRB approval. Indeed, IRBs have no legal authority to review these undertakings, and doing so can threaten a university's federal research compliance and funding, and even expose it and its IRB to legal liability.

Nonetheless, these recent amendments and publications cannot be expected to automatically enlighten faculty, especially considering that they have long been ignored or misread. Rather, IRBs must implement these changes through their policies and submission practices, and faculty must stop submitting, both literally and figuratively, to IRBs. In the past, faculty may have found it easier to yield to an IRB's misguided claim of authority, but this neither bestowed protection upon faculty nor universities, instead only perpetuating the problem. To the extent that faculty and academic organizations felt ill-equipped to challenge IRB overreach, this article hopes to be a resource. It lays out the central misunderstanding about "research," explains what is and is not "human subject" "research" requiring approval and supports its notions with annotations and citations to relevant Code provisions, HHS/OHRP publications, and court opinions. The article also anticipates and dispenses

Compliance," 45 C.F.R. §46.103(a), (f), or a Federal-Wide Assurance, 45 C.F.R.§46.103(a).

[207] 45 C.F.R. § 46.109, §46.111.

with alternative justifications for IRB review, and warns of the liabilities universities and IRB members face should they refuse to abide by the Common Rule.