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Johanna Phelps-Hillen

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Updates to the “Common Rule”: Implications for International Service-Learning and Community Engagement Research

Johanna Phelps-Hillen
Washington State University-Vancouver

This article provides an overview of recent changes to 45 C.F.R. § 46, the policy that undergirds human-subjects protections in research and that is manifested in institutional review board (IRB) review of research. Originally published in 1991, this policy was updated on January 19, 2017, with the changes set to be implemented in early 2018. This article discusses the unique process of engaging with local IRBs and addresses how updates to federal policy regarding international research may impact service-learning and community-engaged scholarship. Specifically, researchers should be familiar with regulations outside of the United States and engage thoughtfully with the study design process such that IRB submission and review are most effective and expedient. These goals are fortified by considering the updated regulatory framework as justice-oriented.

Keywords: *institutional review board, federal policy, service-learning, community engagement, participatory research, international research*

The relationships among service-learning, community-based research, and institutional review board (IRB) review have been addressed in the service-learning literature, but IRBs are typically mentioned only in passing, occasionally analyzed, and sometimes even disparaged. References to IRBs are oftentimes brief and related to IRB approval or exemption. However, some of the service-learning and community engagement literature has focused on the functions and impacts of IRBs. For instance, Wendler (2012) used the ethical principles upon which IRBs rely to propose actionable methods of engaging ethically with service-learning. Alternatively, others (Stewart-Sicking et al. 2013; Stoeker, 2008; Tyron et al., 2008) have articulated the problematic application of the federal policy known as the “Common Rule” (45 C.F.R. § 46), namely in relation to community-based and service-learning activities. The 1991 Common Rule outlines all federally required protections for human subjects who are enrolled in research studies—particularly research conducted with support of federal monies.¹ For instance, requirements for informed consent, the composition of IRBs, and the identification of designated vulnerable populations are all included in this policy. In early 2018, however, the Common Rule will be updated. In line with the anecdotes, narratives, and scholarship regarding IRBs in the community engagement literature, this article provides an overview of the upcoming policy updates that are likely to impact service-learning scholars and community-engaged researchers.

While IRBs across the United States work toward the compliance date in early 2018, researchers can minimize the impact of this policy change on their research and their partners. This article explicates the updated policies and explores their implications, providing researchers with methods for accounting for this new policy in their research design. Researchers across the field can expect diverse reactions by their local IRBs to a number of the policy updates; however, this article focuses specifically on the

¹ Please refer to the later explanation of organizations’ Federalwide Assurance and the application of the policy to all research.

updates to the policy regarding international research. To mitigate the impact of local IRB precedents and federal policy updates on the field’s work, I offer three suggestions, to be discussed in detail in later sections. First, researchers should be familiar with the policy changes related to human-subject protections. Second, researchers should understand the impact of this overarching federal policy on local IRBs. Finally, researchers should engage with the review process, now and in the future, as a justice-oriented activity for improving research design and outcomes.

At most U.S. institutions of higher education, IRB review is necessary for researchers who conduct research with humans and who aim to produce generalizable knowledge. While the definition of *generalizable knowledge* is vague in the Common Rule, it is traditionally interpreted as the production of knowledge about one group of individuals (e.g., a specific population of students or community members) to make claims about a broader population (e.g., students at a particular type of institution enrolled in a specific course or community members seeking a particular kind of support from certain organizations).

Though, traditionally, the term *generalizable* encompasses studies with large sample sizes, IRBs increasingly believe the term is applicable to those with small samples. Taking any amount of data from any methodological design and generalizing those data to make claims about any population is research and therefore can produce generalizable knowledge. Broadly, most institutions interpret this to mean sharing material outside the institution, in publication, presentations, or graduate-level theses and dissertations (e.g., Utah State University [USU], 2015).

The processes and outcomes of pursuing IRB approval differ based on a number of variables, including the target population, area of study, location of study, and methodology. For research conducted outside the United States by or with U.S. researchers, IRB review can be time-intensive and even frustrating. However, I argue that the language shifts and updates to the Common Rule are indicative of an increasingly justice-oriented policymaking process. In turn, I recommend adopting an asset-based approach that considers the review process as an opportunity to educate and advocate.

IRBs in the Service-Learning and Community Engagement Literature

In a search of articles published since 2000 in the *International Journal on Research in Service-Learning and Community Engagement*, the *Michigan Journal of Community Service Learning*, the *Journal of Higher Education Outreach and Engagement*, and the *Journal of Public Scholarship in Higher Education* containing the keywords *IRB* or *institutional review board*, the majority of the instances are functional in nature. By this, I mean that the references are used to provide the reader with assurance that the author’s or authors’ IRB was consulted. However, three articles were set apart from those that discussed either the importance of IRBs or merely referenced IRB review/approval.

First, Wendler (2012) discussed the correlations and divergences of the Belmont Report (1978) principles in relation to service-learning activities (not exclusively research activities). In aligning best practices in service-learning with the foundational principles of the Belmont Report—beneficence, justice, and respect for persons—Wendler recognized the assets of a human-subjects/participants protection agenda for service-learning scholars.

Second, Stoeker (2008) noted that the rigor demanded by many IRBs might seem, at best, problematic in terms of research delays, especially for projects situated in methodologies identified as feminist, participatory, and/or community-based/engaged. At worst, IRBs may be unable to comprehend the needs and legacies of such methodologies. If IRBs are unable to include reviewers familiar with or practiced in these methodologies, researchers can be frustrated by the review process (Schrag, 2010). However, the increasing demand for data that support the efficacy of service-learning and community-engaged projects relies on the notion of generalizability. These sorts of data allow researchers to make claims regarding the legitimacy of such methods of teaching and serving. It is at this intersection of broadening the field and making data-substantiated claims about the efficacy of service-learning practice that IRB review emerges as an obvious concern for researchers.

Furco (2013) held that “external limitations on researchers, due to districts’ institutional review board requirements and other human-subject protection requirements (e.g., securing active parent

consent), pose other challenges that limit researchers' capacities to conduct research that can produce evidence" (p. 16). Despite these limitations, he maintained, such research should be embraced and these sorts of challenges overcome in order to prove the efficacy of service-learning. Together, these voices provide encouragement for researchers as they navigate the IRB review process; moreover, they represent a justice-oriented, asset-based approach to IRB review.

Variable IRB Representations in the Service-Learning Literature

Like the adage "the only constant is change," one could easily say about IRBs that "the only assurance is variability." Local IRB variability can significantly influence the outcome of any review and the implementation of any research. Processes and implications differ among researchers working with K-12 students (or individuals who have not yet reached the age of majority), researchers working with healthy adults, researchers investigating in international settings, or researchers seeking to utilize unique or novel methodological frameworks. All of these variations, combined with the IRB reviewer(s) as an additional human variable, result in what Stark (2012) referred to as "local precedents."

Because federal policy provides a broad framework within which thousands of IRBs navigate, interpret, and apply that policy, the outcome of an individual researchers' IRB review may vary from that of a fellow researcher seeking approval from a different IRB. Yet, some community engagement literature has perpetuated misconceptions about the role of IRBs in relation to service-learning evaluation and community-engaged research. I provide the following brief literature review to illustrate the variance between local governance and interpretation of federal policy. In the articles discussed, the behavior of a single IRB is treated as an expected commonplace for all researchers. After each discussion, I identify the ways in which the representation may not apply for all researchers. These examples are provided to contextualize the updates to federal policy discussed later, and to offer context for the recommendations I offer to researchers in the latter half of this article.

Tryon et al. (2008) suggested that "service-learning is a higher education intervention like any experimental research. Ironically, however, there is no institutional review board or informed consent process required for service-learning activities" (p. 24). Rather, while certain types of program evaluation are not subject to IRB review or oversight, IRBs do review work that contributes to generalizable knowledge and falls under the category of "research," which the regulations define as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (45 CFR 46.102 [d]). Thus, occasionally program evaluation may indeed require IRB review if findings are shared with outside audiences to improve the processes of engaging in, for instance, pedagogy. Tryon et al.'s statement suggests that all service-learning is only subject to program evaluation oversight (which is often not reviewed by IRBs, per the federal definition of research), but this is certainly not the case.

Stewart-Sicking et al. (2013) stated that "according to [their university's] institutional review board, normal class assignments are exempt from signed informed consent" (p. 49). However, this is not the case at many institutions, where classroom materials comprise FERPA-protected data and are therefore considered to be under expedited review at some institutions and governed by complex and rigorous consent processes at others.² Increasingly, universities are aware of protecting students' data as federally restricted material and also recognize that students are, by definition, subject to coercion if they are asked to participate in research as part of their classroom learning. Stewart-Sicking et al.'s experience, therefore, is likely quite rare.

Goertzen and Greenleaf (2016) suggested that their study was granted an exemption because it posed minimal risk to participants. However, both exemptions and expedited approvals are granted to minimal-risk studies, a conflation that is common and appears across discipline-specific literatures (e.g.,

² See, for instance, Metropolitan State University of Denver's policy (<http://www.msudenver.edu/irb/guidance/studentsasresearchsubjects/>) or Utah State University's policy (<http://rgs.usu.edu/irb/wp-content/uploads/sites/12/2017/03/Students-as-Research-Participants-Guidance.pdf>)

Hassel, 2014). However, it confuses the levels of oversight and review by IRBs, which can prove problematic for researchers searching for language with which to engage their local IRB.

These generalized representations are, in large part, the result of researchers interpreting overarching federal policy based on their experiences with their local IRBs. Yet, while IRBs are accountable to federal policy, their practices vary drastically. A common saying among IRB professionals is that “the regulations are the floor, not the ceiling.” The implication, of course, is that many IRBs seek greater rigor in review and accountability from researchers than mandated by federal policy.

This additional rigor is evident in institutions opting to “check the box” on their Federalwide Assurance. This document codifies an institution’s commitment to comply with federal regulations regarding human participants. When institution’s “check the box,” they apply the federal regulations not only to research funded by federal monies, but also to all human-subjects research conducted at the institution (U.S. Department of Health and Human Services [HHS], 2016). Some institutions opt not to apply the same standards across the board and only apply the standards to federally funded projects. Additionally, some IRBs seek accreditation from organizations such as the Association for Accreditation of Human Research Protections Programs (AAHRPP) (2009). In many cases, accreditation by such an organization requires higher standards of review; for instance, while federal policy allows for researchers to make their own determination about whether their research is exempt (45 CFR 46.101 [b]),³ AAHRPP-accredited IRBs are required to have this determination made by someone other than the researcher.⁴ These variations, therefore, represent a significant challenge not only for researchers as they seek to understand the IRB review process, but also for those who engage with relatively novel or unique methodologies.

Rather than suggesting firm heuristics, expectations, or template language for researchers to employ as they work with IRBs to navigate policy updates, this article seeks to inform researchers of the updates themselves. It also outlines some implications these updates may have on individual researchers’ experiences with their local IRBs.

Policy

Publications like those discussed earlier suggest that service-learning and community engagement researchers are aware of their respective local institutional review board’s oversight. Researchers attempting to determine and share what the regulatory language calls “generalizable knowledge” about their area of study are familiar with their local IRBs’ processes and expectations. Some universities have online IRB systems; others still work via hardcopy documents. Some institutions outline procedural processes for researchers (e.g. USU, 2015); others rely loosely on the widely interpreted federal regulation alone. Fundamentally, the existence of these many processes, and IRBs themselves, relies on the Common Rule. Considering that this policy was originally published and implemented in 1991,⁵ local governing bodies have had over two decades to determine their method of approaching and adhering to federal policy.

Recently, however, this policy was updated after several proposals and federally required review processes governed by the Administrative Procedures Act. The precursors to the finalized policy included an “Advanced Notice of Proposed Rulemaking” (ANPRM) (Federal Register, 2011) and a “Notice of Proposed Rulemaking” (NPRM) (Federal Register, 2015). The finalized policy underwent nearly six years of review, commentary, and revision before the final regulation was published on January 19,

³ Though the Office of Human Research Protections recommends against this, the organization notes that it is not necessary (<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/exempt-research-determination>). This has been the subject of embarrassing confusion for a number of researchers unfamiliar with IRBs, such as Scheweder and Nesbitt (2017), who suggested that all researchers can make their own determinations; this is blatantly false, and they have misrepresented the literature in stating so.

⁴ See Standard II.2.a.in

https://admin.share.aahrpp.org/Website%20Documents/AAHRPP_Accreditation_Standards.PDF.

⁵ While regulations and policies existed prior to this date, the CFR as it exists today was updated in 1991.

2017. This date is notable, since the policy was published the day before the inauguration of the 45th president of the United States. Barring any act of Congress to backtrack President Obama's late-term policy updates, the "final rule" is effective for all IRBs and their researchers on January 19, 2018.⁶ While the revisions to the 1991 Common Rule are substantial, I focus here only on policy language regarding international human-subjects research—in fact, I focus on a single sentence that was removed from the original 1991 policy. Originally, the Common Rule included the following language:

When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issue either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized. In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy.

The updated policy, however, removes the sentence, "An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issue either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized." While the revised policy remains effectively similar to the original, there is no longer a standardized external metric in the policy for IRBs to use in their evaluation criteria.

In the Federal Register (2017), policymakers summarized the original 1991 policy and then articulated a justification for the changes proposed in the NPRM. They also shared a synthesis of the public comments (solicited and received in late 2015-early 2016) on the NPRM. Finally, each section concluded with a statement about whether or not the change was adopted and provided responses to the public comments in the context of the final updates. For brevity, I provide a summary of the narrative from the Federal Register regarding this update to the policy on international research; readers interested in reading the complete text can refer to the narrative beginning on page 7159 of the Federal Register.

The narrative states that between 1991 and 2018, "when research covered by [the Common Rule] takes place in foreign countries, procedures normally followed in those countries to protect human subjects may differ from those set forth in this policy" and cited

[the] Declaration of Helsinki, as amended in 1989, as an example of internationally recognized ethical standards that a foreign country might use as its ethical standard. The rule provided that if a department or agency head determined that procedures prescribed by the institution in the foreign country afforded protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy.

The NPRM proposed to remove a specific reference to a non-U.S. policy, suggesting that, like the Federal Register, these documents were subject to change and could eventually contradict what is found in U.S. policies.

Public comments on this topic, though few, were decisively split. Over 2,000 comments were received on the full Notice of Proposed Rulemaking; however, not all comments addressed all facets of the proposed updates. In fact, many addressed specific components of the proposed rule. Because of its complex nature, comments rarely addressed each component of the proposed updates. Regarding the seemingly minor change to the 1991 policy regarding international research, comments were balanced; some were in favor of removing the language referencing the Declaration of Helsinki, and some were opposed.

⁶ Except for one component: "Single IRB review." IRBs have three years to comply with this update.

The Federal Register recorded policymakers’ responses to the public’s comments; despite objections, the reference to the Declaration of Helsinki was removed:

Although the pre-2018 requirements cited the Declaration of Helsinki as an example of internationally recognized ethical standards that a foreign country might use as its ethical base, we note that providing a specific example of an internationally recognized ethical document is concerning because such a document is subject to change independent of Common Rule department or agency policies, and therefore might be modified in ways that create standards that are inconsistent with U.S. laws and regulations.

Despite concerns expressed in public comments, policymakers’ claims did not shift between their discussion of the Common Rule deficits and the finalization of the updated policy.

There are many ways to interpret this update; I’ll address two, which rest on either end of a vast spectrum influenced by local IRB processes and forthcoming federal guidance on the interpretation of the updated policy. One interpretation considers the update restrictive and contradictory to healthy methodological planning in community engagement and service-learning research. Policy updates that eliminate references to the Declaration of Helsinki suggest that the United States no longer recognizes the unique affordances and assets of diverse research settings and requires its standards to be met regardless of where research is conducted. Removing the flexibility for researchers to call upon external recommendations and regulations, and requiring adherence to domestic perspectives and policies in addition to international policies (where applicable) creates a more complex process. Additionally, prioritizing U.S. standards could contradict or jeopardize international partners’ positions and needs. This appears at its surface tremendously problematic, particularly for researchers working with communities in the global south. Additionally, for researchers based in nations that have domestic policies that attend to local concerns, having to collaborate with a U.S.-based researcher bound by these policies may inhibit or prevent productive research on service-learning and community engagement. Arguably, the policymakers behind the 2017 revision have undone important legislation that opened up locations and populations to researchers. Perhaps the 1991 policy, more than this updated version, recognized the burgeoning necessity of both domestic policy and appropriate affiliation with international policy on human-subjects research. This approach, however, is deficit-based; it suggests loss, greater control, and close-mindedness rather than gain or neutral change, as intimated in the policy updates.

The second interpretation rests on the other end of the spectrum. The United States is often deemed to have some of the most rigorous and comprehensive human-subjects protections for participants in research. This is due in large part to the country’s history of harming and/or further disenfranchising marginalized populations by enrolling them—even without their consent—in research.⁷ While the original policy was justice-oriented, the updated policy walks back much positivist and paternalistic language present in the 1991 Common Rule. For instance, references to pregnant women as “vulnerable” were removed; while pregnant women’s participation is still governed by specific regulatory guidelines, women, by nature of their being pregnant, are no longer “vulnerable.” The commentary on the updates recognizes the paternalistic nature of the original rule:

We agree with comments that said that the list of example vulnerable populations listed in the pre-2018 rule is out of date. In agreement with the majority of comments, the final rule no longer includes pregnant women or “handicapped” or physically disabled individuals as examples of populations that are potentially vulnerable to coercion or undue influence. (p. 7204)

This update is but one example of how policymakers sought to update what was generally seen as a heavy-handed and monolithic interpretation of participants and the research enterprise.

In many ways, this reorientation is a reaction to scholarship published across disciplines (Klitzman, 2015; Schneider, 2006; Schrag, 2010; Stark, 2012), but it is also informed largely by public commentary on the NPRM. This explicit acknowledgement of avoiding paternalistic and patronizing

⁷ For instance, in the Tuskegee study, Black men with syphilis were left untreated so that researchers could examine the progress of the disease, including spreading it to sexual partners and children, despite treatment being available.

language in the updated policy suggests an overarching methodological frame of reorienting the policy to its justice-oriented roots.

Considering this justice-oriented mindset, one centering on improved outcomes for both individual participants and society at large, the updated policy regarding international human-subjects research should be interpreted as one intended to protect participants, rather than hinder research. Especially for researchers working in international contexts, this may seem counterintuitive, and the default mindset would be to disengage from the IRB review process when it dictates strict adherence to U.S. standards with seemingly little flexibility. However, in the following section, I discuss the implications of engaging with the updated policy from an asset-based orientation. While the transition period between use of the 1991 policy and the promulgation of the new policy may prove to be somewhat rocky, these implications will hopefully help researchers as they envision, plan, and implement international research on service-learning and community engagement.

Implications

Researchers based in the United States, and their collaborators in other nations, should expect longer review times in the months following the implementation of the new updates—and perhaps well beyond. As long and tedious as processes may seem now, IRBs have been working with the same policy since 1991; however, effective January 19, 2018, all IRBs will be working to maintain compliance with the updated federal standards. This will comprise a significant effort for IRBs, which are often staffed and maintain membership just enough to complete the review workloads with which they are familiar. In addition to acclimating to and implementing the new policy, IRBs will also be required to update internal documents, policies, protocol materials, and database requirements.

International researchers in the United States with a well-developed understanding of human-subjects protections in their partnering country or countries may experience shorter review times and greater accommodations from their IRBs. If a U.S. researcher makes it clear that he or she is attending not only to U.S. policy but also to local policy at his or her research site, the review may be more expedient because the researcher can more readily advocate for the study site, articulate policy, and provide references for his or her IRB.

Non-U.S. Researchers Working with U.S.-Based Co-Investigators

For researchers not based in the United States but who are working with U.S. co-investigators, it is perhaps most important to be familiar with one's own human-subjects protections policies. Should non-U.S. researchers work with U.S.-based co-investigators, or conduct research in the United States, they should be able to explicate or share resources with colleagues that can be provided to the relevant local IRB. While a working understanding of U.S. policy is not necessary, an awareness of the timeframe for review may be useful for project planning purposes; thus, it is worth asking colleagues about expected timelines and processes if it becomes clear that a U.S. IRB review will be necessary.

There is also an important discussion to be had about resources, authorship, and data usage. For instance, if a U.S. researcher does not plan to publish or utilize data from a shared project, but is willing to provide institutional resources, it is still important that he or she consults with the appropriate institutional representatives to ensure that the project does not get hamstrung or halted at any point due to lack of IRB review.

U.S. Researchers Working with Non-U.S.-Based Co-Investigators

Researchers in the United States working with non-U.S.-based co-investigators or in non-U.S. settings should consider the implications of engaging with the U.S. IRB process, any processes required by the co-investigator's institution, and, if the research team is working in or with a third nation, the implications of engaging with that nation's ethics review process for human-subjects research. For U.S.-based researchers, all of these implications should be addressed and, ideally, an internal research team policy established before engaging with one's local IRB.

Additionally, collaboration with one’s local IRB to determine timelines for approval, especially as they begin to revise their processes to incorporate the updated policy, is important. Awareness of an IRB’s timeframe for review and approval will help co-investigators to establish realistic timelines for interventions and investigations.

Participant populations, research site(s), data collection methods, and analysis processes are only some of the components that influence the ways in which IRBs make determinations, and like the United States, many nations have unique processes for evaluating the ethical components of human-subjects protections. A U.S.-based researcher working with a co-investigator from another nation—sharing experiences and policies early and often regarding human-subjects protections—will ensure that as the U.S.-based counterpart engages with the IRB review process all needs are accounted for, especially if the co-investigator’s nation has particular concerns. For instance, European Union nations’ concerns rarely align holistically with U.S. standards, but their concerns about privacy and the “where” of data storage, since the passage of the U.S. Patriot Act, are significant. This to say that some nations focus on specific components of participant protections where the U.S. policy is more lenient.

Ethical Engagement

As Wendler (2012) suggested, human-subjects protections frameworks can serve a useful function in orienting and shaping ethical research agendas. While this may be a challenge for researchers engaging with methodologies that are not traditionally encountered by IRBs, particularly for researchers at institutions with medical schools or high biomedical research activity, the IRB review process requires attendance to ethical research design early and often. The expectations across methodological frameworks are standardized by federal policy and unique for local implementation by IRBs. However, the regulatory framework, when justice-oriented in its design, serves as a useful tool for researchers beginning to consider the outcomes of their research. It also presents researchers an opportunity to weigh the risks and benefits to participants and to determine the benefits to society and/or scholarship. Reflecting on how U.S.-based researchers can and do enact reciprocity with both populations outside the United States, despite shifting policies and bureaucratic experiences, can enhance research and the work associated with it.

Conclusion

In the coming years, as new policies are implemented and new projects are conceptualized and carried about by researchers in service-learning and community engagement, the following recommendations may prove useful:

- Expect longer than average review times.
- Be familiar with U.S. and international policies on human-subjects protections.
- Be aware of any corollary policies like the Common Rule at international research sites.
- Be prepared to explain and advocate methodologies; consider any discussion or revision requests as opportunities to educate IRB reviewers.
- Researchers outside the United States should be aware of the updated policy and implications for any of their U.S.-based collaborators.
- Researchers outside the United States should note that U.S. policy is not stringent about all aspects of the research process and should be ready to articulate their needs (e.g., tighter privacy protections).

When possible, U.S. researchers should engage with institutional opportunities to provide input on any processes their local IRBs may revise in accordance with updated federal policies. These may or may not extend to international settings, but representation of researchers examining community engagement and service-learning can shape the accessibility of the IRB review process for colleagues engaging in methodological or site-specific work. Representation on committees and in focus groups, or simple email feedback, can heighten an IRB’s focus on international, community-engaged, and service-learning research.

While the updates to federal policy will take several years to solidify at the institutional level and shape local precedents, it is useful to engage with the updates as a manifestation of a justice-oriented shift in federal policy. Also, while the elimination of the Declaration of Helsinki as common ground for researchers around the world may seem concerning, this update can instead be viewed as new space for engaging in an asset-based and justice-oriented reflection. While I hesitate to provide firm language or concrete heuristics because of the reality of local precedent for IRBs, the implications provided would hopefully ease the processes of determining whether a U.S.-based IRB review is necessary, how to plan for such a review, and how to engage with the review process.

Author Note

Johanna Phelps-Hillen, Professional Writing, Washington State University Vancouver.

Correspondence regarding this article should be addressed to Johanna Phelps-Hillen, Assistant Professor, Director of Technical and Professional Writing, Washington State University-Vancouver, Multimedia (VMMC) Room 102R, 14204 NE Salmon Creek Avenue, Vancouver, WA, 98686. Phone: (360) 546-9729. E-mail: j.hillen@wsu.edu

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