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Joseph Jeyaraj, *New York City College of Technology (CUNY)*

Choice Reflection: Distinguishing Research from Human Subjects Research

Michael Salvo

Purdue University

Abstract: IRBs have suffered mission creep, moving from assessing dangers presented to participants in research (human subjects) to becoming de facto assessors of research. This brief essay traces engagement with the IRB, documenting understanding of human subjects research review through interactions with the committee over two decades and through numerous configurations and reconfigurations of the committee, its members, its focus, and its understanding of its role in the research process.

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After 20 years of modest activist engagement with the Institutional Research Review Board (IRB), recently I have been questioning whether the cost of engagement has outweighed the benefits. IRBs have suffered mission creep, moving from assessing dangers presented to participants in research (human subjects) to becoming de facto assessors of research (Nichols, 2015). This brief essay traces my engagement with the IRB as I moved through tenure-track, tenured, and senior research faculty positions. I reflect on my understanding of human subjects research review through my interactions with the committee over two decades and through numerous configurations and reconfigurations of the committee, its members, its focus, and its understanding of its role in the research process. As a senior research professional, I reflect on my original impulse to participate in institutional review of research and what has happened in the two decades since.

I engaged meaningfully with the institution's understanding of qualitative, quantitative, and naturalistic methods and articulated ethical concerns about research. As a research-focused faculty member, I enjoyed a few dozen interactions with different instantiations of the review committee as primary investigator, one of many academic responsibilities. Early on, I took a modest

activist position asserting that my work was research at the start of the process of recognizing inclusive, user-engaged, and participatory methods like usability. Generally, I accepted that I was not performing human subjects research, yet I sought institutional recognition that the observations and descriptions—methods for creating knowledge—constituted a research program and there was value in having the IRB review the research plan as a tacit acknowledgement of its status as research.

In the 1990s, emergent technologies like the world-wide web and graphical browsers invited discussion of whether usability research was human subjects research because we involved participants. Participatory design goes further as participants contribute in the research project, going so far as to co-create, comment, and redirect, the flow of expert observation. In 2024, this language is not novel or particularly noteworthy except to assert its historical significance and value. One of the first mentions of usability as research is Sullivan's 1989 "Beyond a Narrow Conception of Usability Testing" which argued, in a prescient volume on user research, for placing Usability in the category of research rather than marketing. Through experience, while user-based research does not meet the demands of scientific research, it is undeniably recognized as research, yielding important insights. But that recognition has a history; its status today as an accepted research paradigm—as mundane practice—is not natural or a given, but the outcome of continued engagement by numerous researcher-scholars.

So, over the course of twenty years, I submitted my studies to IRB, and with little fanfare, review committees (usually) quickly offered exempt status while each submission would be institutionally marked as research. It bears repeating: although tangential to the IRB review process, the institution acknowledged the work as research, which was the whole point of the modest activist position I was taking as a novice researcher. I saw the engagement with IRB as a facet of "Institutional Critique" (Porter, Sullivan, et al, 2000), and sought change in the recognition of my work as, formally *research* and not merely inquiry or literature.

Fast forward 20 years and routinization of submission to the IRB is normalized (even that phrase reminds of the power differential between committee and researcher). While I would not assert engagement has been a mistake, mission creep is evident in the scope of the IRB's authority (in broad, general terms). Now, IRB reviews *everything*. Before submission for publication, journals want IRB case numbers. Internal and external grant-making organizations require IRB review before funding requests can be submitted. Publishers want book proposals to have IRB approvals. Locally, annual activity reports now even require IRB memo reference numbers! Let me slow down just a moment and I'll talk about the latest project I had reviewed.

In early 2023, I submitted a research proposal: the project described a series of interviews with working professionals incorporating new technologies into their work. And IRB sent back recommended corrections and changes so the interview protocol would protect human subjects and be exempt from further review. Five or six rounds of minor changes over three weeks of submission and return yielded

the golden ticket: an official exemption from further review. On the one hand, this was a positive response in a functional process because comments were returned 24 to 36 hours after submission, and I would take six to 12 hours to make changes (depending when the responses hit my email and what my schedule looked like on any given day). That part—the quick turn-around and in-depth response—was constructive. That quick back-and-forth represented huge improvement from previous processes where two or three weeks would pass before receiving response. (At one point years ago, the IRB became dysfunctional and it would take four to six weeks to get a reply! I remember one classroom-based project where ten weeks of a sixteen-week semester ticked away before IRB was back with meaningful response. The current IRB is much better.)

At the end of a month of submission and revision, the project received an official exemption and I have the official IRB memo exempting my study as revised from further review. Along the way, two dozen little changes were made to the project and procedure: what the protocol now allows. But it is no longer the project originally proposed. At the end of a month-long process of review, revision, and resubmission, I realized I was no longer doing the research that I had set out to do. And that upset me.

After I gave myself a few days to slow down and let my initial emotional response pass, I looked at my original proposal. I realized two things:

- First, the IRB consultant had worked diligently to help articulate the project among a menu of human subjects research methods. That, for formative and descriptive research, is a problem: research practices emerge through engagement. It emerges once research has commenced. The research, if it continued to develop in this way, would need thorough review with IRB committee members who valued and understood formative recursive research and iterative design practice, or who at least tolerated descriptive, naturalistic research.
- Second: while this particular project was clearly not human subjects research, it also did not seem to be research at all but a kind of descriptive site survey where my purpose was not to intervene in any way but simply to understand what was happening at emergent, exemplary workplaces.

“I don’t think this is actually reviewable,” I said to myself. From my perspective, it is not human subjects research, but I accept that there is institutional value created in the process of review and getting another uninvolved team to take a look. I wondered why I was concerned. Was it because I felt ensnared in a trap of my own making? I knew the project I had undertaken was valuable research, but again, I knew it would fall outside the parameters of human subjects researchers, unintelligible to colleagues taking tissue samples or interviewing workplace whistleblowers. The research would be *illegible*, possibly invisible, to reviewers accustomed to research involving disempowered research subjects and the scientific practices of research. Where these reviewers have routinized the inherent dangers of physical extraction of tissues that necessitated layers of

anonymization, how would a simple workplace interview study be comprehended? On the other hand, I understood the importance of obscuring and anonymizing whistleblowers revealing sensitive information about failed industrial projects and the vulnerabilities such charged projects bring with them—long-term vulnerabilities that leave research subjects exposed to repercussions long after research projects have ended. So, I recognize and respect the role of IRB—I have recognized and respected it all along. But my proposed project would do nothing more than describe breakthrough best practices. The investigation was not even likely to violate non-disclosure agreements or reveal sensitive proprietary processes. I simply set out to describe the practices that made innovative organizations unique. My intent was to learn, to learn by talking to professionals working in the field about the high-technology work that they were currently undertaking and asking them to describe their everyday work and goals. I did not intend my results to change the process or to change the activities or to change the workplaces or the practices I was told about or witnessed. I just wanted to learn what people were doing on a daily basis: I wanted to observe.

And I wasn't interested in changing and participating or in any way intervening in what was going on in these workplaces. For me, that is not human subjects research. I thought I remembered having seen something new on the original login screen at the IRB submission portal.

I logged in to the IRB and there was the new choice: a new radio button. I was concerned that perhaps I had invented it in an optimistic delusion. Lo and behold, there it was: a new choice:

“I need to know if my project is considered “Human Subjects Research.”

I resubmitted my original proposal for research, ticking that radio button. Interestingly, the review took longer—four days as opposed to the 24 to 36 hours to reply to the original exemption request. But after four days, I received a memo that said that the review board agrees that this is not human subjects research. I was free to commence the research project *as I originally imagined it*. There was no indication whether or not it was research, but clearly stated the project was not considered *human subjects research*. While it represented a relief for me, more importantly, it represents a noteworthy innovation and important change to the way the IRB defines its mission and clarifies its authority. Such clarification curtails IRB mission creep.

It's such an interesting case to consider in hindsight upon reflection on early experiences in the late 1990s, early 2000s, and into the oughts and 20s. Then, I was very concerned with having the work of usability recognized as research. But through that co-creation of authority, mine as researcher, IRB as institutional arbiter of research practices, IRB has suffered expansion and creep of its mission as it gained institutional authority.

This latest IRB interaction in 2023 allowed me to reflect about how my relationship to the IRB was changing. And how my own sense of what my work was, what the

research was, had been redefined by IRB's intervention. The process and focus of the research had, however inadvertently, changed. I saw it as the institution meddling in my research. I don't want to upset or irritate my colleagues who serve on IRB boards, and I value their time and service, but my sense is that IRB had grown beyond what it was designed to accomplish. The original rationale for IRB is hugely important, using the threat of loss of research funds to curtail misuses and abuses of research subjects human research subjects, so that the Tuskegee Syphilis experiments, that another Henrietta Lax, Nazi medical experiments, and all the instances of abuse and neglect never happen again. A strong IRB helps avoid the abuses that made the Belmont Report necessary, while emphasizing that the process of research review is essential in the research university. See Childress' *Belmont Revisited* (2005) for the life and afterlife of the report for more.

For all the problems with review I had experienced, that misuse of human beings—whether race-based or otherwise—would not be tolerated nor would it really be possible under today's review regimes. I believe in those limits placed particularly on scientific studies of human beings. Where the outcomes are not clear, where researchers often do not see the forest for the trees, protections increase their value. While there is an existential sense that researchers do not see their participants as human beings, it is perhaps more important that researchers literally don't see the human beings who participate in the research. These pieces of human research participants are reduced to mere information. Researchers often do not even see words, or understand the experiences of participants, and further, existentially, they don't see human beings. They analyze numbers. As grants and support monies become increasingly scarce and competitive and lab costs rise, robust and powerful oversight is increasingly important.

Tissue samples transformed into statistics and analyzed for significance are not the same thing as a researcher discerning the current state of work in the field. If I overstep my bounds, those professionals will not tolerate it, nor will they work with me again. These professionals have agency, and, housed as I am in a humanities department in a technology- and engineering-centered institution, there are very clear consequences if I overstep what my participants are comfortable discussing. That is a different relationship to research participants. IRB in its paternalistic protection of human subjects has no conception of an inverted power dynamic between researcher and researched: as a protector of research subjects, IRB assumes the observed is unaware of the establishment of a research protocol.

My reflection revealed that I encountered a rhetorical problem. Perhaps I should have discerned that earlier. IRB representatives are tasked, in the techno-mediated process of review, with determining whether a human research project could be dangerous to participants, require further review, or be considered exempt from review. Any response assumes the project is human subjects research, impacting the reviewer response. The committee now asks a preliminary scene-setting question: "I need to know if my research is considered human subjects research," sidestepping potential category confusion. The option represents a rare example of clear, concise, institutional boundary-setting.

Choice Reflection

Boundary-drawing is a huge innovation for IRB. There was no further review: IRB made firm demarcation between human subjects research and, well, everything else. The question shows that the researcher is performing due diligence by working with the committee and inviting outside expertise to decide whether this project falls under the committee's remit. It brings the researcher and review committee closer to shared governance.

In the twenty years since my first tentative engagements with IRB, almost everything has improved. Overall functioning of the office has improved, and while these observations may be specific to my local committee, recognition of user-participation in research and inclusive methods have developed and matured in broader context, recognized as part of social science knowledge-making. I do not regret two decades of engagement and applaud the inclusion of a seemingly simple radio button that represents positive change. The innovation reflects redrawn boundaries for IRB's institutional authority and avoids unnecessary misunderstanding and draws clear boundaries between what is and is not the purview of the review committee.

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Author Information

Michael Salvo is Professor of Professional Writing in the English Department at Purdue University, where he directed the Professional Writing Program from 2009-2019. Routledge published *Writing Postindustrial Places: Technoculture amid the Cornfields*, exploring globally competitive firms in the American Midwest (2018). He also edited *Rhetoric and Experience Architecture* with Liza Potts (Parlor Press, 2017). He is writing a book on Artificial Intelligence with John T. Sherrill.