

 [On the new IRB regulations by Richard Nisbett](#) by Louise S. [2017, Mar 19]

Hi Folks,

Please see attached article in Chronicle of Higher Education. The Office for Human Research Protections has freed researchers from the necessity to get IRB approval for benign behavioral research of the sort that accounts for at least 95 percent of what psychologists do. But there is sure to be pushback from many IRBs and university administrators. This is going to put a lot of people's jobs in jeopardy if the new regulations are put into practice. Make sure your university follows the spirit and the letter of these regulations and doesn't decide to keep any of the IRB functions that the regs no longer require.

PLEASE TREAT THIS AS A CHAIN LETTER: send to at least two colleagues. If Harvard keeps to the old regs it will be harder for Yale to adopt the new ones.

Best wishes,
Dick

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 [Shweder.Nisbett IRB Chronicle of HE](#)

 [Comment by Dr. Gayle Morse](#) by Louise S. [2017, Mar 19]

After reading this article I thought Low risk and no risk are not the same.

Gayle

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 [Comment by Richard A. Shweder](#) by Louise S. [2017, Mar 19]

Hi Louise,

Below is a link to a talk I gave in October at a New School conference on "The Future of Scholarly Knowledge." It is titled "The End of the Modern Academy: At the University of Chicago, For Example." I suspect it will be of interest to the IP community. Let me know what you think. The discussion of viewpoint diversity and identity politics on campus might spark a good debate. Other threats to the modern academy are discussed as well.

<https://humdev.uchicago.edu/sites/humdev.uchicago.edu/files/uploads/shweder/NewSchoolScholarlyKnowledgeEssay.pdf>

As ever,

Rick

P.S. Zachary Schrag (author of an important book on the history of the IRB and the social sciences titled "Ethical Imperialism") just brought the following to my attention.

On January 26, 1981 the Office of the Secretary of HHS issued an announcement of the revised 45 CFR 46 regulations which included this statement:

"HHS has carefully considered its proposed policy regarding the regulation of non HHS-funded research in light of the comments received and the statutory basis for the more expansive interpretation. The public comment, including that of the President's Commission, revealed a broad based and significant amount of objection to the extension. Further, the HHS General Counsel has advised that there is no clear statutory mandate in the National Research Act to support a requirement for IRB review of other than Public Health Service-funded research. Therefore, the Secretary of HHS, after considering a number of possible options, has decided not to extend the requirements for prior IRB review and approval to non HHS-funded research." (46 FR 8369, <https://archive.hhs.gov/ohrp/documents/19810126.pdf>)

It appears to be one of the best kept secrets in the academy.

 [Comment by Joseph P. Gone](#) by Louise S. [2017, Mar 19]

Hi, folks. This is already quite interesting!

I have a few thoughts about this that may run in a slightly different direction.

First, it is important to remember that the absence of IRB review does NOT relieve researchers of acting ethically in their professional roles. Moreover, it is important to acknowledge that IRB review is, at best, an imperfect and unreliable means to ensure ethical conduct by researchers.

Second, the proposed changes to the IRB regulations concern *psychosocial* research. Biomedical research (e.g., involving sick people, invasive interventions, and so forth) will remain subject to full IRB scrutiny. Thus, the question at hand is the degree to which *psychosocial research* poses risks or dangers to participants that would merit regulation in this regard.

Third, while I am sympathetic to the idea of protecting vulnerable populations, I am also aware of longstanding patterns of interaction with some of our communities by powerful outsiders ("elites") that are presumptuous, paternalistic, and patronizing. It is an exercise of power to vet psychosocial research proposals whether it is in the name of "protecting" vulnerable populations or, alternately, construed as deciding for community members whether they should be allowed to participate in a given research project. Allow me to suggest that the risk of harm should be high before we decide to exercise this power in the name of others who have not openly and explicitly authorized us to do so (for example, many tribes now run their own research review boards and look after their own interests).

Fourth, we should at least consider that those of us from historically marginalized pops may obtain subconscious reinforcement for acting protectively because exercising our expertise as researchers "on behalf of our communities" offers us a validating professional role and recognition of our social identities. For example, I feel that some American Indian psychologists are themselves psychologically conflicted about (a) not having especially strong ties to their own communities, or (b) representing the few from their communities to have "made it" professionally. While I don't want to make too much of this, I do think that such conflict can occasionally play out in compensatory activities that involve routine bids to wield influence in the name of representing and protecting Indian interests.

Fifth, what are the specific and particular grounds for suggesting that people need to be protected from *psychosocial* research? In Indian Country, we have a very developed critique of research that routinely asserts that communities have been harmed. There are some examples--often pretty dated--that appear to justify this claim, but I am mostly struck by how few and far between these are. Here are the most egregious examples I know for Indian communities: (1) In the early 20th century, anthropologist Alfred Kroeber sent the brain of his deceased "informant" Ishi to the Smithsonian for preservation without anyone's permission; (2) not long thereafter, an Alaska Native man who died while visiting the Smithsonian was cremated with his child as witness, only the cremation was staged and his body was kept by the Smithsonian for its collections; (3) In the 1950s, the US Air Force administered radioactive iodine to

Alaska Natives to study acclimation to cold weather; (4) In the 1970s, Foulks reported on high alcoholism rates for an Alaska Native community that was picked up by the national news and resulted in a downgrading of the community's bond rating; (5) In the 1990s, the James Bay Crees in Canada decided to kick out 5/6 psychology researchers and end research participation in their community; and (6) In the "oughts," Havasupai tribal members provided genetic material that was subsequently analyzed for purposes for which that participants had not consented. If we step back and consider these breaches collectively, a few things become clear. The early "specimen" collecting has now been remedied by NAGPRA (and by shifts in anthropological practice and common human decency). The iodine and genetic materials would still be regulated as biomedical research. The James Bay situation is a perfect example of communities defending their own interests. The Barrow alcohol study resulted in an unpredictable sequence of adverse events that were not entirely the researcher's fault, and which now would be governed by tribal IRBs. So, it does not seem to me that IRB regulation of psychosocial research today is necessary to prevent these kinds of breaches. Melanie, you mentioned Spanish translation as an issue that you helped to regulate. This is intriguing. Was this for psychosocial research? What were the stakes? And do we really believe that the average IRB can manage such issues? What other examples can we offer from different vulnerable pops that would offer a better rationale for maintaining strict review of psychosocial protocols.

Sixth, what is the evidence that IRB review of psychosocial research has actually remedied the problem of unethical or exploitative research for our (or any) communities?

Finally, the other side of the coin for IRB regulation of psychosocial research is the (seemingly abandoned and much maligned) respect for academic freedom. Should IRBs really be in the business of ensuring that research is smart, sound, sensitive, and significant (all involving judgments that lie well beyond the mandate to protect research participants from harm)? It seems to me that surrendering these judgments to a bureaucratic university entity is folly, especially in the times we now live in which academic freedom has become absolutely crucial to both exercise and defend. In contrast, then, to concerns about "imperialist" research, should we not also be concerned about imperialist ethics?

In sum, I think this debate is complex, and that the evidence is not clear. What we need is a substantive list of compelling examples that shows in nuanced terms how unethical psychosocial research has been/will be stopped by continuing the practices of IRB review of this specific category of research (given that biomedical research will continue to be regulated).

My \$.02,

Joe

☐  [Comment by Joseph P. Gone](#) by Louise S. [2017, Mar 19]

Hi, Louise.

I sent the email below (slightly revised here) to a couple listserves, but perhaps it's too far afield for the IP group?

I'll leave it to you to decide.

Trusting all is well,

Joe

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☐  [Comment by Judith Gibbons](#) by Louise S. [2017, Mar 20]

Hi - just a brief comment with respect to Spanish translation and oversight by the IRB. I had prepared a research protocol for research in Guatemala, done in collaboration with native Spanish speakers in Guatemala. The IRB had our translation checked by a Spaniard, who declared it completely inadequate. It took several rounds of resubmissions to have our argument that Spanish is not Spanish accepted by the IRB.

In other words, IRB members can be uninformed about what is appropriate.

Judith Gibbons

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Judith L. Gibbons, Ph.D.

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 [Comment by Richard A. Shweder](#) by Louise S. [2017, May 14]

Hi Louise,

I thought you might be interested in this follow up Commentary on IRB reform, which Richard Nisbett and I published this morning in the Chronicle of Higher Education. Please feel free to circulate it far and wide.

http://www.chronicle.com/article/Don-t-Let-Your/239823?cid=at&utm_source=at&utm_medium=en&elqTrackId=efe72a1de677467eb251a96db3376779&elq=1c0d5147ef0c46de97d79f919feab22c&elqaid=13555&elqat=1&elqCampaignId=5630

Warm regards, as ever,

Rick