Long-Sought Research Deregulation Is Upon Us. Don’t Squander the Moment.

By Richard A. Shweder and Richard E. Nisbett

It has been a 40-year labor: Regulatory systems are not easy to undo. Nevertheless, in January the federal government opened the door for universities to deregulate vast portions of research in the social sciences, law, and the humanities. This long-sought and welcome reform of the regulations requiring administrative oversight of federally funded human-subject research on college campuses limits the scope of institutional review board, or IRB, management by exempting low-risk research with human subjects from the board's review.

The new regulations state: "We acknowledge that guidance may be useful for interpreting some of the terms in this exemption, and that some cases will be debatable. However, we also believe that a substantial number of research activities will plainly fit this exemption, and should be allowed to proceed without IRB review."

The exempted research activities include surveys, interviews, and other forms of free communication between researchers and human adults, aptitude testing, the observation and recording of verbal and nonverbal behavior in schools and public places (for example, courtrooms), benign behavioral interventions (including ordinary psychology experiments), secondary-data analysis, and other low-risk projects and research procedures.
The decision as to whether a project should be exempt is left to the researcher, presumably using a plainly defined, self-administered exemption tool. The overhauled policy — which holds that exempted research activities should be excused from board review with no requirement of IRB approval of the exemption — aligns with a longstanding recommendation for reform proposed by a special committee of the American Association of University Professors and is consistent with the recommendations of a special panel of the National Research Council. That’s the good news.

The bad news is that the new regulations don’t take effect until next January. University research administrators have 10 months to decide how to interpret and put them in place, via the local institutional review boards, which are made up of faculty members and nonacademic professionals. Will they do the right thing and walk through the door? Will the delivery of a new and improved review-board system prove to have been worth the wait?

The reform is long overdue. In 1974, Congress created a federal regulatory system for institutional-review-board oversight of federally funded research projects involving interactions with humans. Risk-averse university administrators throughout the country, advised by cautious general counsels, decided to run an extra regulatory mile. Although there was no federal requirement that they do so, they enabled mission creep by requiring IRB approval of all research with humans regardless of the funding source (public, private, or personal).

This was a shock to many academic researchers. Socrates himself would probably roll over in his grave if he knew about the hoops his academic heirs in the humanities, law, and the social sciences have been jumping through in recent decades to even gain permission to ask questions, including the requirement for vetting of questions by a review board before they get asked.

When the regulatory system was first launched in the 1970s many scholars fought the good fight, but they lost the battle to protect low-risk social-science research activities from bureaucratic surveillance, project licensing, and the power of prior restraint granted to IRB committees. Over the decades their defeat has been costly for everyone.
The considerable burden of unnecessary reviewing placed on review-board staffs results in delays of weeks and months before research permission is granted at many places.

Applications seeking permission to do low-risk research are routinely returned time and again with requests from the IRB for more information of no importance. One of our favorites: "What consonant strings will you have subjects memorize?" There are many examples where arbitrary limits have been placed on free inquiry and scientific discovery, none of which are subject to appeal.

In general, far too much effort has been expended protecting human subjects from the nonexistent risks of being asked questions or from participating in verbal learning experiments. All this has had a chilling and damaging effect on the creativity (and careers) of scholars and scientists, especially those just beginning their careers.

Happily, we are now in a position to fix the system. University research administrators are at liberty to exempt all low-risk research (including government-supported projects) from IRB review. The ball is in their court.

University faculty members in the humanities and the social sciences should make sure it is in their court, as well. We hope our colleagues across the country will invite their academic administrators to acknowledge their newfound capacity to deregulate low-risk research with human subjects and find out what they are planning to do over the next 10 months, or not do.

They should urge administrators to generously interpret and fully support the opportunity for exemptions. Those who have become accustomed to licensing research may not want to give up institutional review board control, or may be inclined to interpret the new regulations as narrowly as possible.

Faculty members, then, must beware of overly defensive (nothing ventured, nothing lost) legal strategies that encourage mission creep and be skeptical of proposed additions to the new rules, such as a requirement for formal IRB review before any research project is exempted. Research administrators and IRB heads should be asked to report their intentions at faculty meetings, where they can be discussed and debated.
This is a moment of truth for academe. American universities know how to talk the talk of academic freedom. Yet after so many years of overregulation do we still have the will, and the courage, to actually walk the walk?

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