

The Nanny State Meets the Inner Lawyer: Overregulating While Underprotecting Human Participants in Research

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Without any systematic data or evidence of a problem, or even a thoughtful analysis of costs and benefits, the application of the human participant review system within universities is overreaching at the same time that some risky experimentation on humans outside of universities is unregulated. This article questions the purpose, feasibility, and effectiveness of current IRB approaches to most "2 people talking" situations and proposes scaling back the regulatory system to increase respect accorded it by researchers and its ability to protect human participants of research from real versus imagined harms. In too many cases, the focus is on form over ethical substance: counting what can be counted, rather than focusing instead on what counts. Some disciplines—oral history and journalism, for example—simply do not belong within the scope of institutional review board jurisdiction. Others, such as survey research, informational interviews, and informal interactions, call for a shift from centralized review to more departmentally based (i.e., rooted in disciplinary ethics) oversight, and clearer guidelines on what requires advance review as opposed to provision of *post hoc* complaint systems.

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Why did our system, designed to protect and respect human participants of research *experiments*, come to regulate human *interactions*, including interviews

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that one of the parties might later write about? Why are we choosing to spend resources—including our own credibility—on very low-risk activities when we face serious and mounting problems in appropriately protecting human participants in activities we know are much higher risk endeavors? We know that the sheer number and complexity of multicenter clinical trials are increasing (Burman, Reeves, Cohn, & Schooley, 2001), that we have more inexperienced project coordinators and higher turnover rates among principal investigators than ever (Getz, 2004), and that we face significant institutional review board (IRB) morale and resource constraints (Levine, 2001). With this as context, and in the absence of any data indicating a need, the time has come to consider whether we should be reversing current trends to regulate more and more low-risk activities so we can concentrate our resources on areas of greatest need and greatest potential harm. With reports variously identifying IRBs as a system in jeopardy, needing reform, or facing a crisis in confidence, pulling ever more activities into the regulatory sphere seems counterproductive. Instead, we need to find ways to increase effective regulatory coverage in the areas of greatest risk for harm and withdraw gracefully from the mission creep that has caused IRBs to increasingly require review and approval for extremely low-risk areas of human interactions.

Because the federal human participant regulations apply only to recipients of federal funding (Federal Policy for the Protection of Human Subjects, 2001), the primary effect of regulatory mission creep is seen in universities, which receive the bulk of federal funding for research. Activities outside universities that pose much greater risks to human participants are neither scrutinized nor regulated in a manner that provides recourse for damages suffered. Examples range from doctors experimenting (and publishing their findings) with surgical approaches or novel applications of approved drugs (e.g., various formulations for children of short stature or Viagra for female sexual response), to development within biotechnology companies of genetic tests in advance of any efforts to apply for Food and Drug Administration (FDA) approval, to corporate programs on team management and fright response (Gunsalus, 1998). However, inside universities, both the scope and intensity of scrutiny continues to expand. Over time, with regulatory prodding and the desire to be and to seem ethical, universities have surpassed the requirements to apply the standards of the federal regulations to *all* scholarly activities within the institution regardless of funding; and in many cases, they have gone even further and have voluntarily given jurisdiction to the federal regulators over all activities involving human participants conducted under institutional auspices, again regardless of the source of funding. For the purposes of illustration, this means that an activity in a university involving human participants that receives no external funding and otherwise would not fall under federal regulations, say students in a class on investigative journalism, could have come to require an institution's IRB approval and could also be audited by federal regulators at a university that had filed an assurance (the paperwork) extending federal jurisdiction.

Therefore, we now see IRBs reviewing and restricting activities that were never originally intended to be covered, that arguably are *not* covered by existing federal regulation, and that endure an added burden of IRB review (for both the reviewed and the reviewers) disproportionate to the negligible value added for the protection of human participants. Consider whether one of the barriers to the improvement of our system of protections for human participants is the very mission creep that plagues IRBs and their standing within certain disciplines. To create greater uniformity in degree of regulation between academia and other research venues by extending protection to all participants of research is not feasible for now: Our current interpretation of the federal regulations, primarily in terms of what is *covered research*, is too broad and would encompass too many activities for which review and regulation would be burdensome and strenuously resisted. As currently interpreted, large sectors of industry, from pollsters and market researchers to most of the media in our country, would be swept into the regulatory scope. Perhaps we would be making better progress at expanding the protection of people on whom others are experimenting outside the umbrella of federal funding if we concentrate our regulatory review and oversight on activities about which a general consensus that protection is truly needed (i.e., research that poses more than *de minimus* risk of harm to its participants) can be easily achieved. Most such research now is in the biomedical realm.

THINKING ABOUT TWO (OR MORE) PEOPLE TALKING

The Illinois White Paper¹ (in press) advocated that we “rebalance” our IRB resources so that we “increase the likelihood that the cases *most likely* to have *serious* consequences will be *most likely* to receive the *most thorough* level of review.” That work examines the fallacy of extending, without serious examination, the biomedical model to scholarly activities in the social sciences and humanities. It proposes a

shift in orientation from trying to anticipate, or hypothesize, every conceivable harm, to accepting that despite best efforts occasional harms *will* occur, and that in those cases, alternative mechanisms for redress should be established (through *post-hoc* complaint procedures, campus hearings, lawsuits, etc.).

This article builds on the work of the Illinois White Paper by targeting one kind of interaction: an informational interview in nonbiomedical and nonbehavioral research involving decisionally capable adults being interviewed or surveyed by in-

¹I am a member of the steering committee that produced the Illinois White Paper (in press) and that organized the conference on which it is based.

dividuals affiliated with universities. I call these situations “two people talking,” although they could easily encompass more than two people at a time (e.g., focus groups).

The Illinois White Paper (in press) described the “mission creep” that has afflicted IRBs across the country in recent years. As problems (especially program shutdowns) are publicized, IRBs and their administrators become more cautious: What, they ask themselves, can we do to avoid being in *that* situation? One symptom of this caution is ever more attention to harms that can be imagined, the implementation of safeguards to protect against them, and documentation of all actions. Examples abound: IRBs have required written consent forms before surveys are mailed to individuals or before students participate in normal classroom demonstrations, such as writing down linguistic utterances. The focus on documentation of compliance expands, and the scope of review broadens. Over time, the cumulative effect is that more and more activities are reviewed, and paperwork becomes more elaborate.

The process of hypothesizing every conceivable harm in ever more fields outside the biomedical and behavioral arena and devising protections against them has led to a widening perception among university-based researchers that IRBs are overly bureaucratic. Resultant anecdotes about IRB actions across the country collectively undermine confidence in and respect for the IRB system, ranging from an IRB that sought to require written consent forms from members of a preliterate tribe (Sieber, Plattner, & Rubin, 2002) to English professors being “investigated” for not seeking IRB approval before writing autobiographical accounts (Nelson & Watt, 2004).

This hyperzealous regulation can be seen as an effect of the rise of the nanny state where we step in to “protect” people from themselves. How many IRB meetings have gone from the imagined possibilities of what *might* go wrong to devising protections against these possibilities (e.g., requiring a political scientist to get written consent before mailing registered voters a survey with possibly disturbing questions, or preventing interviews that might be traumatic; Sieber et al., 2002)? In how many of those meetings have members imagined that “the lawyers” might require such protections or that people “might be sued” if the protections were not in place? I call this concern about possible legal ramifications “serial mind reading” because it often involves a chain of people all supposing what might be legally required. When tracking down some of these actions, however, one finds that no lawyer was ever consulted before the decision to protect against issues that were never legally problematic. It seems likely that the rise of the nanny state combined with the serial mind-reading effect has intensified IRB mission creep while normal bureaucratic accretion and inertia have exacted their own tolls.

A comment attributed to Albert Einstein is that “Not everything that can be counted counts and not everything that counts can be counted.” Sadly, in our IRB system, we too often see counting replacing substantive ethical review. The most fre-

quently cited lapses in IRB audits by the two main federal oversight agencies, the Office of Human Research Protection (OHRP) and the FDA, are “poor or missing standard operating procedures” (28%) and “poor minute keeping” (21%), together accounting for almost half of the citations. Quorum failures account for an additional 13%. Eleven percent of the citations are for consent elements not properly included. By overlooking that consent is a process rather than an event or a consent form, these findings emphasize the importance that has come to be placed on *pro forma* compliance as opposed to review of fundamental ethical issues. Only 12% of the citations are for poor review of research. Although it is hard to count fundamental ethical compliance, it is very easy to count how many people were present at any given meeting. Even more worrying is the cumulative effect of intensified regulatory oversight in situations where no individuals have been harmed—nor are likely to suffer harm. The Harvard Medical School IRB was recently cited for an incident in which a researcher began work on anonymous data collected by another researcher before having IRB approval (Borror, 2002). In news reports based on the federal citation, this was referred to as a “major incident of noncompliance.” Is this where our energies should be going? Is this a good policy?

Is the resulting regulatory system accomplishing its mission? The National Academy of Sciences Panel Report (Committee on National Statistics, 2003), “Protecting Participants and Facilitating Social and Behavioral Sciences Research,” concluded that it is not. Of four major problems with IRBs identified in that report, two are that IRBs focus too much on documenting consent instead of substantive ethical reviews and that they delay research and impair integrity of research designs without improving ethics. Sieber (2003) recently noted that, in dealing with the conundrum of adapting biomedically derived rules to social and behavioral research, some researchers

circumvent their IRBs illegally to conduct their research validly and ethically. Some others comply with inappropriate IRB requirements resulting in such unprofessional and unethical behavior as thrusting incomprehensible consent forms at people who are afraid to sign documents (p. 1)

We can and must do better than this. One clear way is to rethink how we are dealing with two people talking situations.

As we approach that task, we might start with developing a rough taxonomy of the differences in and among these situations. Without careful thought about what unifies and distinguishes these situations from each other and from other “interactions” with human beings, our regulatory efforts will continue to be inefficient and inappropriate. As a starting place, human interactions falling under the two people talking umbrella include surveys (predetermined questions), structured interviews, interviews done within disciplinary frameworks (oral history), and informal conversations later cited within a published work (anecdotes about classroom ex-

changes published by a faculty member at a later date). Key elements in each of these settings are the willing participation in the conversation and the ability of the *participant* to break off the interaction at any time.

TWO PEOPLE TALKING SITUATIONS ARE NOT RISKY FOR DECISIONALLY CAPABLE ADULTS

The federal regulations governing the use of human participants in research define *minimal risk* activities using the benchmark first suggested by the Belmont Commission:

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (Federal Policy, 2001, § 46.102i)

If we consider the indignities of a routine physical exam or the wear and tear on our psyches in the challenges of daily life, it becomes harder to understand the extent to which some IRBs have undertaken to protect adult participants in various activities from their own choices—in effect violating the Belmont Report’s foundation principle of respect for the autonomy of persons and their decision-making capacity.

Few would deny the need for IRBs in biomedical or behavioral research or the important role they play in protecting vulnerable populations from exploitation. It is even arguable that the need for the IRB gatekeeping function is greater now than ever as the frontiers of research raise increasingly difficult ethical choices. Although, perhaps we should pull back from prior review and approval requirements for activities in which capable adults are asked to participate in interviews from which they can withdraw at any time with no adverse consequences. The OHRP has already indicated that “most” oral history interviewing is “not research as defined by the HHS regulations” (Carome, 2003). Now is the time to consider extending this ruling to other interviewing projects in fields from law, to English, to journalism. The rationale used to document oral history’s noncoverage by the regulations—that it is not intended to contribute to generalizable knowledge—is hard to extend when so many IRBs tend to use a rule of thumb that anything intended for publication is *ipso facto* intended to contribute to generalizable knowledge. A better approach might be to differentiate between “covered research involving human participants” and other research and scholarship that is not covered.

Our colleagues in Canada are considering some of these same policy matters. The Social Sciences and Humanities Research Ethics Special Working Committee (SSHWC) submitted to the Interagency Advisory Panel on Research Ethics (PRE) a report proposing a number of changes. Although they label a root cause of prob-

lems we are seeing as “ethics drift” instead of mission creep, the analysis and solutions sound strikingly similar chords to those of the policy discussion under way in the United States. The SSHWC (2004) proposed:

In some scholarly domains, default assumptions regarding risk should be reconsidered, with the biomedically appropriate concept of “minimal risk” being reformulated as “identifiable harm,” with the attendant need for clarification of which “harms” in the social sciences and humanities might warrant attention. (p. 6)

At the very least, moving to a situation in which an identifiable harm must be identified (perhaps from a preexisting list of harms) would be an improvement over protecting people in two people talking situations from imagined harms.

The SSHWC (2004) report went a step further to propose that we redefine “human subject” as requiring a

power differential between researcher and participant that arises from the nature of the relationship, conflict of interest, clear subject incapacity and/or opportunity for coercion. In the absence of such indicators, we suggest that PRE exempt such research from ... review ... (p. 47)

Although this concept of “power differential” is an important one, it probably needs to be altered before importation to the United States where power differential has come to mean many things to many people. Note that IRBs in the United States are often reported to perceive power differentials in a large number of settings where others might not. I know of a law professor who sought advance approval for a survey of partners in the law firms of a major city on a particular topic. In their first response, the IRB staff suggested the survey be broadened to partners of law firms across the region, to better protect the participants of the survey. Leaving aside the fundamental change in the project this would have entailed, do we really need a system in place to protect partners in major law firms? (Query: Is there a less vulnerable population anywhere than partners in major law firms?) After an appeal for a reconsideration, the IRB staff withdrew its proposed changes and the information-gathering process continued with no risk or harm to any save the IRB’s own reputation for good sense.

Although a faculty member having the power to award a grade or provide a recommendation for a student clearly has a power differential over a student, a professor calling a partner in a big-city law firm does not hold power over the “informant,” nor really does any inquirer hold special power over a decisionally capable adult who may, at any time, freely terminate the interaction. In oral history interviews, for example, Linda Shopes (personal communication, July 6, 2004) pointed out that there are often power differentials (income, class, education) between the interviewer and narrator, but that the narrator always retains enormous power: the

power to refuse to be interviewed, the power of refusing to be identified, of refusing to answer questions, or not answering them fully. She also pointed out that narrators often have the power that age confers. Shopes (personal communication, July 6, 2004) asked:

In the situation of a young, naïve grad student interviewing an elderly, poor resident of Appalachia about her experiences in a rural community, who has more power, who has less? The student's power may well reside in how she uses or interprets what she has learned in the interview to present a particular view of Appalachian life—but in the exchange itself, the issue of who has the power can get quite complicated.

Devising indicators of power differentials meriting special attention would be an important aid to IRBs. Many respected observers of our system of protection have called for the development of guidelines to assist IRBs in this way.

Neither the SSHWC nor I propose that willing participants in information-gathering research should be left without recourse or that scholars should be left without ethical guidance or professional requirements for the conduct of their activities. We should and must continue within our universities and disciplinary societies to provide education and resources for the professional and responsible conduct of research. However, perhaps the primary recourse of decisionally capable, autonomous adults for concerns about interactions with a university-based interviewer should be post hoc complaint procedures provided by the employing institution, rather than advance review and approval by an IRB with its other attendant costs.

WHAT ARE THE COSTS AND BENEFITS OF OUR CURRENT APPROACH?

It is worth considering the costs and benefits associated with an overexpansion of the prior review requirements of an IRB. Taking on faith for a moment that *we are* overreviewing some university-based activities, let us tally some of the costs.

Burden on Researchers

At the University of Illinois, the form required of researchers wishing to assure that their work is exempt or qualified for expedited review is 11 pages long (retrieved August 2004 from <http://www.irb.uiuc.edu/forms/irb1.asp>). Although this compliance burden is not overwhelming, such burdens tend to accumulate faster than each individual instance might seem to imply.

Burden on IRBs

There are many indications that our IRBs are, as a group, overworked and underresourced (Office of Inspector General, 1998). The forms that are filled out and submitted must be reviewed on behalf of the IRB; counted for statistical reasons; reported to, or reviewed by, the IRB; and filed (not to mention the time required for developing the written response to each submission). To include in the workload of IRBs situations involving two people talking—when other, less burdensome mechanisms could suffice to provide ethical and professional protection—seems counterproductive.

Destruction of Researcher Trust and Buy-In

Our system relies on the buy-in and trust of researchers to function. When there are widespread concerns, especially when concentrated within disciplines, that IRBs are overreaching, there are broad consequences such as the loss of respect of researchers for our ethical system, the chilling effects of work that is not undertaken because of concern about the “overhead” or hassle factor of dealing with an IRB (Protecting Human Beings, 2001), and work that is unnecessarily modified in response to what an IRB might require (mind reading works both ways).

Prior Restraint of Speech

Finally, consider how advance review and approval requirements for two people talking situations challenge some of our most cherished principles in terms of restraints on speech and academic freedom (M. W. Finkin, personal communication, August 4, 2004). A major concern in the two people talking situation is that compliance with many existing implementations of the Common Rule (Federal Policy, 2001) constitutes prior restraint of speech. Finkin has written about this more extensively; and although the argument is more complex, consider the following (M. W. Finkin, personal communication, August 4, 2004):

If academic investigation, akin to journalistic investigation, is an aspect of intellectual freedom, of freedom of inquiry, the imposition of this system should trigger much the same concern the first amendment triggers when faced with analogous prior restraints on free speech. As Thomas Emerson pointed out almost half a century ago, the special evils of prior restraint lie in “the institutional dynamics” of its administration: “a tendency to expand in coverage, zealous or wooden enforcement, a predilection for the easy adverse decision, low public visibility, and limited independent review” as well as in the general first amendment concern for vagueness and overbreadth in the regulatory language that abets these specific evils.

WHAT ARE THE DOWNSIDES TO EXEMPTING TWO PEOPLE TALKING SITUATIONS FROM ADVANCE REVIEW AND APPROVAL REQUIREMENTS?

What harms can occur in two people talking situations? If you ask someone a question that rakes up old trauma, that could be harmful. Betrayal of trust by a researcher who promises confidentiality but breaches it could be damaging to participants who agree to talk to that person collecting information. Deception by the information seeker could damage the participant: If I agree to talk to you because you tell me you are studying X, but you are actually trying to prove Y (with which I vehemently disagree), then not only might I be harmed, but the reputation of information seekers from universities in general (the only regulated group of inquirers) might be harmed.

Raking up trauma is, of course, a risk of any investigation; yet, surely, consenting adults should be able to make decisions about whether to discuss touchy subjects with investigators. When should we be protecting people from themselves? Do we, sitting in committee meetings imagining possible harms in isolation, know what will be harmful to any given participant in a scholarly study better than the participant? If, after many years of silence, an elderly person wishes to speak about an experienced trauma, such as the Holocaust or Japanese–American internment, is this not a choice that person should be able to make; balancing his or her own goals and life circumstances? Under what circumstances should we be imposing prior restraints on conversations between adults or regulating interactions that might potentially prove harmful to the participants? In addition to disrespecting the decisions of participants and negating their autonomy, such decisions by IRBs contradict the research that has shown that the study of victimization does not revictimize the victims. This issue has been examined in a wide variety of contexts, for example, sexual and physical abuse (Walker, Newman, Koss, & Bernstein, 1997); acutely injured motor vehicle accident and assault survivors (Ruzek & Zatzick, 2000); participants in a trauma-focused health survey (Newman, Walker, & Gefland, 1999); Bosnian refugee families who had experienced severe crisis, bereavement, and trauma (Dyregrov, Dyregrov, & Raundalen, 2000); and parents of stillborn babies (Brabin & Berah, 1995). The results across such varied contexts consistently show that although a minority of participants found the interview more distressing than they had anticipated, nearly all reported that they had found their participation in the interview clearly helpful, conferring beneficial effects for them overall. In short, adverse effects of such interviews are grossly overestimated; and IRBs should not focus on whether some participants might become distressed, but rather on whether the final outcome of the interview is a positive one for participants.

If oral history is “not research,” can we agree that projects pursued by university-based journalists or journalism students are not “covered research?” Why should a market researcher, who asks questions of participating adults for money, be exempt from IRB advance review and approval requirements, but a university

survey researcher not be exempt? Perhaps IRBs should receive guidance on identifiable harms and leave capable adults to making their own decisions about when to talk to interviewers about what topics.

Deception and betrayal present different issues. Deception involves the interviewer lying about the purpose, method, or use of the information being collected. Betrayal, also cited as one of the primary dangers of unregulated, two-person talking interactions, occurs when an interviewee expects the interviewer to use information one way and it is used another, perhaps risking disclosure of sensitive personal information. Is centralized advance regulation the answer to these issues? Are these risks so serious that they must be prevented? What harms arise from two people talking that cannot adequately be covered by localized (i.e., departmental, disciplinarily rooted) guidance, reviews, or post hoc complaint systems? If a researcher obtains information under false pretenses, that is a serious breach of professionalism (and a legal wrong under certain circumstances) and should be handled as such by the institution of the researcher as well as by his or her professional society and licensing body, where applicable.

Deception and betrayal of human participants of research call into question our professionalism and ethics as a community of scholars. One benefit of requiring advance review and approval of two people talking interactions could be to assure ethical conduct by members of our own professional community. However, if this is the case, is requiring advance review and approval by an IRB achieving this goal? If we believe that it is professionally and ethically appropriate for researchers to talk to each other about their research designs, are the advance approval requirements of IRBs serving that purpose? Are we using our resources in the best way to improve research design? There is considerable anecdotal evidence—potentially concentrated in certain disciplines—that IRBs are not seen as helpful ethical advisors, but instead as barriers. Maybe focusing our energy on mechanisms for increasing collegial interactions about research design, especially in fields adopting new methodologies, would be more productive. Our universities and professional societies have the obligation to attend to ethical education both general and specific to methodologies used within disciplines, and to respond when those standards are breached.

WHAT NEXT?

We did not take any steps to collect data on the risks of exempting oral history research from the definition of research covered by federal regulations, and we probably ought not do so before exempting journalism activities in universities (for a fuller explanation of this policy recommendation, see the Illinois White Paper, in press). By its nature, journalism (like oral history) is devoted to documenting what is (or was) and presenting that information in specified venues. That the crooked alderman, for example, might suffer reputational damage from public revelation of

his activities is not reason to suppress the reporting; yet some university-based IRBs have moved in precisely that direction. This is insupportable, and we must retract the reach of our system in this respect.

At the same time, we must consider whether any research is needed before contracting our system's "reach" back from other activities that pose no identifiable harms to willing, adult participants in two people talking situations. What resources should we expend to protect which human participants?, or, as raised by the Illinois White Paper (in press), "who are we protecting from what, and why?" These are all questions that should be receiving vigorous attention from participants in our human participant protection system rather than simply permitting ever more mission creep with its attendant costs. It is a simple matter to query participants as part of debriefing on whether they felt at risk and what, if any, harms they experienced as participants in the research.

We have expanded our regulatory scope without good data on any number of important questions. For example, we do not have empirical research on the costs and benefits of the "protections" we provide for individuals who participate in projects primarily involving interviewing—although we do know that responses to surveys are declining and that many of the risks against which consent forms warn are not only low probability events, but *extremely* low probability events (Fendrich, 2004). We do not know how many people turn to IRBs for ethical guidance as they are considering research design. We do not know the numbers and natures of activities submitted to IRBs that are found to be exempt. It would be interesting to gather a nationwide sample to examine—particularly for social science and humanities IRBs and those at institutions without resident medical schools—information on submitted-but-exempt activities. We have expanded our regulatory coverage without any of these data and, apparently, without any clear thoughts or indications of harm other than imagined ones.

If we cannot contract our current regulatory scope to a more manageable level so that we can concentrate our stretched resources on the areas of greatest need, then at the very least, there should be a concerted effort to collect data on what we are currently doing. We do not know what proportion of information-collecting projects covered by the federal regulations involves decisionally capable adults. We do not know how many participants are paid to participate as opposed to those who participate for other reasons. Sieber (2004/*this issue*) suggested several fruitful lines of research that might add to our knowledge of such situations, including asking people about the immediate emotional effects of their interviews in a debriefing, from which one could collect formal data for publication. Other possibilities are to conduct follow-ups weeks or months later asking similar questions, actively urging people to phone an appropriate institutional official requesting that participants report any noteworthy effects of their research participation (good or bad), and offering an opportunity for some kind of counseling outreach to those who desire it. Keeping a record of the percentage of participants who take the time to call and the nature of the responses

could be a most interesting addition to our knowledge in this arena (J. E. Sieber, personal communication, June 23, 2004).

In addition to legal remedies for invasions of privacy, emotional distress, and libel, universities and disciplines could assist in rebalancing our system by attending to complaint procedures for those with whom their students and faculty interact in the name of scholarship and research. These are not simple issues, but given the plethora of grievance mechanisms already in place in the modern American educational system, such mechanisms are likely more adaptable and more appropriate to what problems do arise than the prior review system we have established by stretching the IRB system in ways that we know do not work and that are costly in several dimensions.

The foundation principles underlying the IRB system are respect for persons, beneficence, and justice. The Belmont Report (National Commission, 1979) told us the following:

Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so. (p. 4)

By extending our regulatory reach into two people talking situations—beyond the kind of experimentation envisioned when our system was established—we have created an unreasonable regulatory burden, undermined respect for an important ethical oversight, and diverted resources from more pressing ethical matters. If we were to scale back in this area (sending clear messages to IRBs, their universities, and professional societies) concerning increased attention to ethical issues and the importance of responsive complaint mechanisms, perhaps we could make more progress on extending IRB protections to currently unprotected populations.

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