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HUMAN SUBJECT PROTECTIONS

Some Thoughts on Costs and Benefits in the Humanistic Disciplines

I. INTRODUCTION: PROTECTION OF HUMAN SUBJECTS AND THE HUMANISTIC DISCIPLINES

The federal protection of human subjects of research in the United States has from the start been scandal-driven, shaped by media attention and political reactions. The first of many Congressional hearings were catalyzed by the revelations of the 1966 Beecher Report that described experiments on unsuspecting patients from the previous year of published medical literature,¹ the Tuskegee Syphilis Study that tracked the course of the disease untreated for 40 years in 400 African-American men even after treatment became available,² and advances in medical research that were challenging religious and societal concepts of life and death.³ Regulations in this area have grown by fits and starts, with bouts of intense study and scrutiny following newsworthy events interspersed with quiescent periods. These cycles have had a self-perpetuating quality, for lack of follow-through on policy recommendations⁴ and frequent under-funding of protection mechanisms during the fallow periods have heightened rhetorical levels and the sense of urgency in the active periods. As the result of the cyclic but inconsistent nature of this process, we have been left with regulations that both under-reach and over-reach, that are both too broadly and too narrowly applied. While some people are subject to "experimentation" without any federal protections because the activities in which they are involved are not federally funded, in other places, the reach of the regulations has been so far extended that innocent "interactions" posing no risk to

¹ Dr. Beecher published information on and citations to twenty-two experiments. Examples include Case 2, in which physicians withheld penicillin from servicemen with strep infections without their knowledge or consent (published in the *Journal of the American Medical Association*); Case 16 that involved the administration of live hepatitis virus to residents of a home for the retarded (including children) to study the etiology of the disease (*New England Journal of Medicine*); and Case 17 in which live cancer cells were injected into hospitalized elderly and senile patients to study their immunological responses (need publication information). Information summarized from Rothman.

² Jones, *Bad Blood*.

³ Rothman, 148.

⁴ See Appendix A, "Examples of Studies with Multiple Unimplemented Recommendations."

anyone are regulated, scrutinized and restricted. Both are costly side-effects of a system out of balance.

We are now in the midst of another period of scrutiny catalyzed by scientific advances and ethical concerns about their applications—cloning, modifying human genetics and stem cell research—and sustained by reports of deaths in medical research such as that of Jesse Gelsinger at the University of Pennsylvania, and the consequent media coverage.⁵ Once again, a “crisis management” dynamic⁶ is in play, with the additional effect that some institutions have become hyper-cautious as the financial, legal and reputational costs of problems escalate. On the positive side, this attention can lead to needed improvements in human subject protections. But there is also danger that we will impose even more unneeded and costly regulatory burdens with little gain in protections. The equation is a delicate one and we seem to have gotten it wrong in some places.

Human Subject Protections in the Humanistic Disciplines

How did we come to be regulating “interactions” in the humanistic disciplines, when the original focus of the rules was on experimentation in biomedical and behavioral research? Such regulation in the humanistic disciplines seems to be the result of recent scandals in biomedical and behavioral research, which caused federal officials to focus intently on activities within their reach, namely, federally-funded research, which occurs primarily at universities. With each cycle of scandal-driven attention, universities, seeing the costs for mistakes at other places, have in turn ratcheted up the intensity of their internal scrutiny, to avoid program shut-downs and costly investigations and attention drawn by scandals. Both to be and to seem “ethical,” universities have, over time, voluntarily extended the application of federal regulations from covering only research supported by federal funding to all research conducted at the institution or under its auspices. Thus have more and more university-based endeavors come to be subject to federal regulation.

The stakes are high because the “fit” of the regulations to the humanistic disciplines is not always good; the nature of scholarship in the humanities is such that thoughtless application of regulations appropriate to biomedical research can cause harm, not only to the scholarship, but also to important principles including First Amendment protections and academic freedom.

Examples of this conflict abound. An historian working on oral histories of the civil-rights movement was cautioned not to ask subjects about the laws they might have broken in the course of civil disobedience.⁷ An Institutional Review Board (IRB, the term of art for human subject protection boards) administrator directed that an English professor's in-press article be withdrawn because it contained an account of a student who submitted a paper describing his alleged participation in a murder,

⁵ National Bioethics Advisory Commission, “Ethical Issues in Human Stem-Cell Research” and National “Cloning Human Beings: Ethical Considerations”; “Researchers Seek Answers After Gene-Therapy Patient Dies”; and Elmer-Dewitt.

⁶ Nishimi.

⁷ “Protecting Human Beings: Institutional Review Boards and Social Science Research.”

and the article had not been submitted for IRB review.⁸ Joan Sieber and her colleagues have reported such "mis-regulation" as:

...a linguist seeking to study language development in a pre-literate tribe was instructed to have them read and sign a consent form...a political scientist purchased appropriate names for a survey of voting behavior (of people who had consented to such participation) and was initially required by their IRB to get the written informed consent from subjects before mailing them the survey; a Caucasian Ph.D. student, seeking to study career expectations in relation to ethnicity, was told by the IRB that African American Ph.D. students could not be interviewed because it might be traumatic for them to be interviewed by the student....⁹

And journalism faculty have found both their own and the investigative projects of their students limited or prohibited by IRBs concerned about embarrassment to prospective subjects.¹⁰

While we have several decades of close analysis starting from fundamental ethical principles to provide guidance to researchers and regulators in biomedical and behavioral research, there is no such body of work in the humanistic disciplines. Yet the federal research regulations have come to apply to "all" types of federally-supported research within regulated institutions. These regulations, while framed expansively, emerged from an analytical context limited to certain categories of research (namely, biomedicine), whilst excluding almost totally other forms of interactions with human subjects. The increasing application of the literal meaning of the regulations to endeavors where the effects have not been analyzed—i.e., the humanistic disciplines—is a matter needing immediate attention and close analysis.

The ethical principles underlying current regulations are so rooted in considerations related to invasive or risk-laden medical procedures that even discussions of behavioral research, which have been explicitly included within the regulatory scope since early in the consideration process, can seem "tacked" on. Again, this is rooted in a scandal-driven history: much of the consideration of behavioral research followed public debate about the Milgram authority/shocking experiments¹¹ and the Humphrey's "tearoom" research.¹² As a result, the initial

⁸ Personal communication with the author. Details omitted to protect privacy.

⁹ Sieber, Plattner, and Rubin, 1-4.

¹⁰ "Protecting Human Beings: Institutional Review Boards and Social Science Research."

¹¹ In 1961-62 at Yale University, Professor Stanley Milgram recruited subjects to participate in research about "punishment and learning" through a newspaper ad. Subjects administered increasing levels of what they thought were electric shocks to the learners, who were actually part of the experimental team and did not receive shocks, although it appeared to the subjects that they did. In advance of the research, through consultation with psychiatrists nationwide, Milgram anticipated that a large majority of subjects would refuse to administer painful or harmful shocks to the "learners." In actuality, 65% of the subjects continued increasing the level of the shock to 450 volts in obedience to the researcher/authority figure, even when they could hear what they thought to be screams of pain from the "learners" and in the absence of any coercion other than the instructions of the researcher.

¹² For his 1970 Washington University Ph.D. thesis, Laud Humphrey conducted research on impersonal male sex in public restrooms in which some participants were interviewed at the time, and others only later. Those interviewed later were tracked through their license plate numbers, and Humphrey a year later (in disguise) contacted participants to conduct a "mental health" survey, resulting in findings about the demographics and motivations of participants. The research was hugely controversial at the

analyses of applicable ethical principles for regulation of human subjects were primarily focused on behavioral research in medical settings, with the remaining analyses driven by the scandals appended as the process unfolded.¹³ The articulation of the ethical principles applicable to research with human subjects, and the very wording of the regulations themselves, trumpet their quantitative focus and orientation. The definition of “research” in the regulations, for example, hinges on endeavors designed to contribute to “generalizable knowledge,” which is appropriate for biomedical research, but not necessarily scholarship in the humanities, where this can be read so broadly as to be meaningless.

Novel applications of existing regulations are also illuminating different aspects of their shortcomings, some of which are potentially more costly and perhaps less tolerable than previously thought. For example, procedural shortcomings in existing regulations—most notably the lack of any appeal mechanism from IRB decisions about permissible research activities—that are worrisome for any scholarly endeavor are even more so when applied, for example, to the investigations of journalism faculty and students, where they become a form of prior restraint particularly odious to our democratic systems. And disturbing examples are emerging of instances in which IRBs seem to have been used as tools by those opposed to the findings of some researchers.¹⁴

Before this cycle of attention closes, we have an opportunity to bring thoughtful consideration to how current regulations apply to scholarly activities in the humanistic disciplines and, perhaps, to improve the balance of protection and burden in the overall public policy equation. What is needed is to develop guidance on a range of questions, within and across disciplines and with the engagement of national disciplinary societies and other appropriate bodies such as the American Association of University Professors (AAUP) and Public Responsibility in Medicine and Research (PRIMR). The sections that follow provide a case study to illuminate the problem of oversight for the humanistic disciplines; an overview of existing regulatory scope and procedures; a summary of the policy issues presented by examples of over- and under-reaching of the current human subject protection regulations; and possible approaches for improving our protection system while taking these issues into account.

II. A DESCRIPTION OF THE PROBLEM: WRITING ABOUT TEACHING

Given their original limited focus to biomedical and behavior research, the definition employed in the federal regulations is that a “human subject” is a living person about whom “an investigator... conducting research obtains (1) data through intervention or interaction” with the individual, “or (2) identifiable private information.” Clearly, the definition of “conducting research” here is key. We will return to that point

time, with a number of faculty members petitioning the President to withhold Humphrey’s degree on the grounds that its deceptive elements were unethical.

¹³ Levine.

¹⁴ Tavis; Begley, B1.

later, because it has been largely skipped over as universities and IRBs have focused upon the "interaction" portion of the regulatory language. While the responsible federal oversight agency has recently concluded that oral history interviews are *not* covered by the federal regulations in a feat of bureaucratic logic (briefly, that they are not seeking to contribute to generalizable knowledge),¹⁵ the assumption has been that all faculty members who are publishing are "conducting research" and so are covered by the regulation. Consider the application of the regulatory definition of "human subject" to the humanistic disciplines by the case of a faculty member writing about his or her professional activities.

When is teaching a class (or conducting research and then writing about the process) an "interaction" with a human subject? When a faculty member writes an essay about an experience teaching a class, when is this an autobiographical essay and when does it become research? Consider the regular essays in the *Chronicle for Higher Education* detailing the perspective of various academicians about different aspects of their own institutions, from hiring to departmental politics. If a faculty member writes about a particularly illuminating classroom exchange, or discourses anecdotally about the difference between freshmen now and twenty-five years ago, these are clearly "interactions" with human beings. Is it, or should it be, covered "research" such that an IRB can or should require advance review and approval of the project?

If a faculty member writes an essay about one semester's teaching experience at the end of a semester that contains anecdotes (suitably altered to protect individual identification), is that research? What if the faculty member writes several essays that are published throughout the semester? What if the arrangement to write the essays is made in advance of the semester and the faculty member constructs the syllabus to enhance interactions that might generate memorable anecdotes? What if the faculty member makes notes on each class session as an aid to the drafting of the essay? What if the professor records each class to save memorable phrases?

Serious professional and ethical issues can arise in writing about teaching and classroom interactions, but they are not necessarily issues illuminated by federal regulations about interacting with human subjects. Faculty members must grapple with how to treat deeply personal disclosures made by students,¹⁶ stay within the boundaries of academic integrity, respect intellectual property, and adhere to the laws governing student privacy. These issues are receiving careful attention in the literature of some disciplines,¹⁷ but there has been little consideration of the global considerations that may apply across disciplines. Thus, when we do arrive at the ethical issues implicated by the human subject regulations, humanistic disciplines seem to be lacking systematic consideration of the elements that move from personal reflection to "research" (e.g., a piece of writing by a faculty member about classroom experiences). By extension, we also lack clarity on how to weigh considerations of academic freedom and prior restraint.

¹⁵ Office for Human Research Protection.

¹⁶ Morgan.

¹⁷ "Guidelines for the Ethical Treatment of Students and Student Writing in Composition Studies."

In thinking about how to define "research" in writing about teaching, the ends of the spectrum are relatively easy to identify: a faculty member who begins a semester with the intent of comparing student grades and outcomes in a skills course, for example, with overall grade point averages of each student, with the goal of correlating expertise in the skill with the remainder of the students' graded coursework, is surely conducting research. This would seem to be an "experiment" with "human subjects." The professor is approaching the class with the intent to collect data in a systematic way and to publish the results, presumably with the hope of being able to come to generalizable conclusions. Here some of the central issues are raised: there are ethical aspects of this conduct to explore, including the power relationship of the faculty member over the students, but given the nature of the potential harm, what levels of protection and regulatory action are appropriate? But between that faculty member's planned "research," and the other end of the spectrum where a faculty member is musing about a lifetime of teaching in an autobiographical fashion, the lines are fuzzy. In between those two extreme cases, authors "interact" with other humans; they must also approach their thinking and writing systematically (one presumes). This brings the activity under the current language of the federal regulations. What, exactly, are the characteristics that do or should make it "research" requiring IRB review? What moves an activity across the line? When do we care? And why?

If the driving purposes of our human subject protection system are to protect individuals from harm and to "be ethical," what are the harms from which we are protecting people in these settings? Are they on the same plane as protecting patients in clinical trials? Do they require the same levels of oversight and regulation?

Finally, in any number of forms of professional education outside medicine, clinical training is provided to students where both the student and the student's patient or client have the potential to become "subjects" when the supervising faculty member later writes about the educational process. Thus, in a clinic associated with a law school, when should the student and the client provide informed consent for the supervision provided by the faculty member?¹⁸ Where students are being trained to become licensed social workers? Or doctors? Are the potential harms commensurate with the regulatory burdens we impose?

Clinical educators are increasingly alarmed with such IRB rulings that students may not, without informed consent, write about experiences with clients during internships, even for course papers to be submitted to and read only by supervising faculty members, and even with no identifying information.¹⁹ And, because there are no appeal mechanisms for IRB decisions, there is no recourse when a local IRB adopts such an interpretation. The lack of consistency we are seeing in the application of regulations is likely rooted in the absence of well-understood and broadly accepted ethical principles and guidelines.

Until we can articulate the answers to these questions with clarity, we continue to run the risk that various IRBs will each invent their own answers for each activity

¹⁸ Anderson, 1.

¹⁹ Tarr.

presented for review, with little consistency. At the very least, this is an ineffective use of resources. At most, IRB conclusions (or those of their administrators, as many questions are not even presented to, or considered by, an IRB as a whole) that are inconsistent (or unreasonable or silly) will increase disrespect for compliance systems in universities, to the detriment of the important policy purposes that these systems serve.

III. A BRIEF SUMMARY OF HUMAN SUBJECT PROTECTION: HISTORY AND SCOPE

Federal regulation of research with human subjects in the United States is restricted to 1) research funded by certain federal agencies, 2) conducted at institutions filing assurances with the Office of Human Research Protection, and 3) studies to be submitted to the Food and Drug Administration for drug, biologics and device approvals.²⁰ These regulations look first, to the source of funding for the work, and second, to the site *where* the work is performed (rather than upon the risk/harm to the subjects regardless of funding or locale of performance). This last consideration is an issue to which we will return.

In the United States, most (but not all) federally funded research on humans is governed by a regulation now known as the Common Rule that has been in effect since 1974.²¹ Although the National Institutes of Health issued the first *publicly available* federal regulations in 1966,²² current regulations are rooted in the work of a congressionally mandated body, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The National Commission was formed as a reaction to well-publicized scandal and controversy over scientific advances and it was strenuously resisted by the scientific community. Working from 1974 to 1978, the Commission produced a seminal report known as the "Belmont Report,"²³ identifying the ethical principles that still serve today as the foundation of all U.S. human subject regulation: "respect for persons," "beneficence", and "justice."²⁴ In practice, "the principle of *respect for persons* underlies the need to obtain informed consent; the principle of *beneficence* underlies

²⁰ Federal Food, Drug and Cosmetic Act.

²¹ Code of Federal Regulations, Title 45.

²² The work of the Advisory Committee on Human Radiation Experimentation (1994-95) reported that the Atomic Energy Commission and the Department of Energy issued regulations governing human experimentation in the 1940s and 1950s, but since the regulations were classified, few but very high-ranking officials ever knew of their existence. (See Moreno's essay in this volume for a discussion of human subjects protections in the military. *Ed.*)

²³ That report also cites the foundation provided by both the Nuremberg Code and the Helsinki Declaration.

²⁴ *Respect for persons* involves recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy. *Beneficence* entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm. *Justice* requires that the benefits and burdens of research be distributed fairly. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, "The Belmont Report."

the need to engage in a risk/benefit analysis and to minimize risks to human subjects; and the principle of *justice* requires that subjects be fairly selected.”²⁵

The Common Rule grew directly from the Belmont report.²⁶ Of the twenty-three federal agencies that fund research, seventeen subscribe to the Common Rule, and the others are—and have been for some time—under executive order to come into compliance.²⁷ Why does this inconsistency across the federal government continue? Might the mismatch of regulation to disciplines outside the biomedical arena be a contributing factor? That is, perhaps one reason that it has been so hard to get all federal funding agencies “on the same page” is because those in endeavors outside the biomedical arena see the mismatch of the regulations to the nature of the work they support—and the general absence of ethical dilemmas in those areas that are helpfully addressed by current implementations of the Common Rule.

The Common Rule defines “research” very broadly, as “[a] systematic investigation, including research, development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”²⁸ In order to focus upon activities seen as holding the highest risk for the subjects of that research, it defines a number of categories of activities that are “exempt”²⁹ from review if certain procedures are followed, and a number of others that qualify for “expedited”³⁰ review on the theory that they present only minimal risk to the subjects. The concept and implications of assessing risk to subjects was the focus of much of the early ethical analysis of proposed regulatory systems. Yet, it is remarkable that neither “risk” nor “harm” are defined in the regulation.³¹

The Common Rule mandates that people who conduct research involving humans must establish local review and approval bodies known as Institutional Review Boards (IRBs). As a result, there are an estimated 3,000-5,000 IRBs in the United States.³² Broadly speaking, wherever an IRB has jurisdiction, its review and approval are required before research involving human subjects can begin.³³ IRBs are intended to be qualified to assess proposed research both professionally and from a lay perspective, so that (theoretically, at least) the sensibilities of the community are consulted before research begins, not just in the aftermath of scandal. Thus, the Rule specifies that each IRB must have a

²⁵ National Institutes of Health.

²⁶ National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, “The Belmont Report.”

²⁷ Gunsalus, “An Examination of Issues,” D-6.

²⁸ Code of Federal Regulations, Title 45.

²⁹ Code of Federal Regulations, Title 45 § 46.101. See Appendix B.

³⁰ Code of Federal Regulations, Title 45 § 46.110. See Appendix B.

³¹ Finkin.

³² Estimates of the number of IRBs operating in the U.S. range from around 3,000 to more than 5,000. Puglisi.

³³ Some federal agencies have come to require evidence of IRB approval before a proposal will be considered for funding, a development leading to many complaints, as it increases the workload of IRBs in that they must review research that may never be performed because it does not get funded.

diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel; and... shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas...Each IRB shall include at least one member who is not otherwise affiliated with the institution...³⁴

By virtue of the bureaucratic mechanism by which universities commit to comply with federal requirements and as a result of pressure from the scandal cycles over the years, most agree to extend the federally mandated rules to *all research* conducted at their institutions. This encompasses research conducted by students, faculty, and any employees under university auspices. This broad assent to regulatory jurisdiction brings virtually all work conducted at universities under federal regulation, regardless of its source of funding.

Since virtually all consideration and enforcement of human subject policy has been focused upon biomedical and behavioral research, it may seem simple to rectify the over-application of human subject regulations in the humanistic disciplines. Yet simplicity eludes us. From the onset, it has been clear since the Common Rule was intended to apply to "all" research. It was just that other areas of research were not generally federally funded at the time and the applications were not as carefully analyzed as was work in the biomedical arena. Indeed, the National (Belmont) Commission and its successor the Presidential Commission (1980-1983), and the Advisory Committee on Human Radiation Experimentation (1994-1995), were all chartered to examine "biomedical and behavioral research" and focused their work in those areas. The National Bioethics Advisory Commission (1995-2001) was similarly charged with advising and making recommendations on "bioethical issues arising from research on human biology and behavior." Until the work of the National Human Research Protection Advisory Committee (NHRPAC) in 2001, I cannot find any federal commission or agency that examined the application of federal regulations to humanistic disciplines. The emergence of regulation of humanistic research is recent.

In 1977, the Presidential National Bioethics Advisory Commission (NBAC) maintained that "No person in the United States should be enrolled in research without the twin protections of informed consent by an authorized person and independent review of the risks and benefits of the research."³⁵ Whether the researcher is a neurologist or a poet, if the research involves interaction with a human subject, this suggests that work should be subject to regulation. Legislation to this effect is introduced regularly on Capitol Hill. The concerns are not idle and the significance of the shift from the Belmont Report's focus on "subjects of biomedical and behavioral research" to the current focus on "research" writ large should not be underestimated. This expansion from biomedical and behavioral research to "all" research raises questions of what our public policy goals are and should be with regard to human subjects protection.

³⁴ Code of Federal Regulations, Title 45 46.107.

³⁵ National Bioethics Advisory Commission, Full Commission Meeting.

David Rothman's *Strangers at the Bedside: A History of How Law and Bioethics Have Changed Medical Decision-Making* provides a valuable foundation for considering policies governing human subjects of research. Rothman primarily focuses on the trends that coalesced to wrest medical decision-making control from physicians (especially at the beginning and end of life), and toward patients, families, lawyers and courts. Nonetheless, his work illuminates the forces that have shaped most U.S. research regulation in recent decades, including a steadily growing mistrust of experts. The prevailing cynicism about "experts" will immensely complicate the resolution of current questions. In particular, this developing cynicism suggests that referring development of standards or responsibility for oversight solely to disciplinary communities for internal deliberations will not be an acceptable outcome. Instead, consensus will need to be developed systematically and endorsed across disciplines and by national advisory groups that include members from outside the affected fields. The challenge is to assure that all participants in the process have a sufficient base of understanding, such that the outcome is sound public policy.

In a 1998 paper commissioned by the National Bioethics Advisory Commission (NBAC), I addressed some of the dilemmas we face in balancing regulatory costs and benefits in the area of human subjects of research. Due to threats of litigation and society's mistrust of experts, the incentive is toward ever-increasing scrutiny and regulation of research involving human subjects. This often occurs without examination of the correlative costs, either in direct regulatory infrastructure or in scholarship forgone—especially if one attempts to add in the question of "how will these changes affect research outside the biomedical arena?" Usually, that question is not even considered, as the focus continues to be upon biomedical work, again driven by scandals. In light of the increasing problems seen from the imposition of the biomedical model on the humanistic disciplines, aggregated with the other issues raised in recent years, it seems past time to rebalance the regulatory equation.

To do so, we must 1) identify with specificity the harms/risks against which we seek to protect subjects; and 2) articulate the ethical, principled basis for governmental and/or institutional provision of those protections. In pursuing those analyses, we must be able to define which activities constitute "research" subject to regulation, who "human subjects" are, and why we are choosing to devote resources to those ends. But first, there are some definitional problems to address.

IV. THE COMPLICATION OF DEFINITIONS

In order to articulate the problems and risks of research, we need to know what "research" is and who the "human subjects" are for whom we need to prevent exposure to risks and harms. Recall that "research" is "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." This definition grew out of the Belmont Report and has been in use for more than thirty years. The application of regulation is always (or should be) contingent upon whether an activity constitutes "research" under the federal definition. Sensibly enough, the federal rules provide

that wherever a question exists on this point, it must be resolved by an independent individual (not the individual pursuing the activity) to protect against conflicts of interest in the determination.³⁶ The process by which these decisions are reached is left to the institution's IRB. In practice, there is generally no appeal from the determinations of an IRB or its administrator. We will revisit this last point later.

Once it has been determined that an activity *is* research, the rest of the definition then applies: a human subject is "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."³⁷

The regulations do *exempt* specified activities, such as comparisons of the efficacy of educational techniques, observations in public settings, and examination of existing records where no individual will be specifically identified. (The validity of the premises upon which many forms of research in educational settings were exempt have been called into question, and may warrant re-examination.)³⁸ Other categories of research qualify for *expedited* review on the grounds that they pose no more than minimal risk to the subjects of research. The regulations also specify how IRBs should be constituted and how they should operate: how they keep their records; establish criteria and procedures for review; characterize elements of informed consent; and address a number of more specialized topics, especially those involving vulnerable populations (prisoners, fetuses, children).³⁹

It is generally left to the IRB to decide whether or not something is "research." One major rule of thumb regularly used by IRB members to determine whether an activity is "research" is whether the efforts were undertaken with an eventual eye to publication; this mode of determination stems from the ethical analyses commissioned for the Belmont Report.⁴⁰ This approach works fairly well in biomedical research: if a practitioner or scientist planned a project, began it and assembled data in a way that would support publication in the peer-reviewed literature, the likelihood is reasonably high that some kind of "research" was underway. Consequently, those upon whom hypotheses were tested had an ethical right to knowledgeable participation. This approach can be problematic, however, when applied in other settings.

One of These Things is Not Like the Others: Problems Specific to Research in the Humanistic Disciplines

It is hard to argue that any writing by a humanist or scholar in the humanistic disciplines is not, broadly speaking at least, intended to contribute to "generalizable knowledge." When an English professor writes about interactions with students and

³⁶ Code of Federal Regulations, Title 45 § 46.102.

³⁷ Ellis.

³⁸ Howe and Dougherty.

³⁹ Code of Federal Regulations, Title 45 § 46.101. See Appendix B.

⁴⁰ Levine.

muses about how that experience shaped his thinking about teaching, does that not contribute to generalizable knowledge? What about a journalist's exposé of the excesses of local government?

There are multiple examples of this dilemma: is it, for instance, research when physicians write newspaper columns about their experiences with and reactions to various patients or diseases? Is it research when a journalist interviews a series of public officials (clearly these are "interactions" with "individuals") and publishes a story about corruption at city hall? If not, why would the same work pursued by a graduate student in a journalism program become research? And why would we consider it "research" when a faculty member writes in a professional journal about classroom teaching experiences? The logical extension of the "intended for publication" guideline is that all human activities that end in (or are intended for) publication are subject to federal oversight in the same way as biomedical endeavors are. Indeed, the latter two examples have both been defined as "research" in universities by institutional officials. Is this the correct application and desired outcome? Is it one we should support? Does this approach contribute to the public policy goal of protection of human subjects?

One troubling aspect of addressing these questions is that the determination often correlates to the location of the research activity—not just the source of funding. If a pollster calls and asks about your preferences for laundry detergent or political candidates, that is not "research" governed by the federal regulations—unless the pollster happens to be a university student or faculty member. Then, the exact same activities *do* constitute "research" on "human subjects" and must receive IRB approval (or exemption confirmation) before they begin—otherwise, the data collected may not ethically be published.⁴¹ A clear problem emerges: Should activities that are not research if performed in the private sector become research for the sole reason that they are performed in a university setting? While there may be other aspects of their performance in universities that might transform them into research, the setting alone surely does not. The obverse situation also raises questions. In my NBAC paper, I suggested that a published comparison of two different techniques for facial surgery undertaken by a cosmetic surgeon was research on human subjects, and that the "patients" deserved protection, regardless of the fact that the research was privately funded, was conducted outside a university, and thus was not presently regulated as "research."

V. REGULATORY AND PROCEDURAL ISSUES

Inconsistent Regulation

For my NBAC paper, I assembled examples of both unregulated research carrying serious risks to its participants as well as examples of activities that have been placed under current or proposed regulatory language but that do not expose

⁴¹ Gunsalus, "An Examination of Issues."

participants to risks that would seem to warrant oversight.⁴² That is, there are activities fitting the definition of “research” involving human subjects—and about which complaints have been filed with federal agencies—that are not covered by federal protective regulations, regardless of the “risk” or “harm” to which they expose subjects. And on the other hand, there are activities subject to regulation that seem to have little harm or risk for the participants. The examples I assembled were based primarily upon Freedom of Information Act Requests filed with the Office of Protection from Research Risks (OPRR)⁴³ involving complaints over which the office had no jurisdiction.

Examples of the former category (presently unregulated but risky activities) include genetic tests; *in vitro* fertilization research; and experimental surgical procedures developed without IRB oversight (because the work is performed at unregulated for-profit or not-for-profit entities); research funded by a pharmaceutical company involving children of short stature identified by private physicians for payment; and “fright response” research in which subjects were subjected to disturbing stimuli.⁴⁴

At the same time, activities that seem low-risk are regulated, primarily because they are performed at universities or by faculty or students. These include any number of interviewing protocols conducted under disciplinary ethical protocols (e.g., anthropology, journalism) or aspects of clinical education and scholarship that involve writing about teaching and experiences in the classroom, as discussed above. It is crucial to note that none of these “regulated” activities have engendered scandal or controversy and, absent specifically unethical aspects (deception, fraudulent conduct, etc.), seem unlikely to do so. Of course, an argument could be made that these activities are ethical because they have been vetted through an IRB. Whether or not that objection holds in all cases (I believe it does not), it is clear that we do not clearly define the risks and harms against which we wish to protect subjects of research—especially outside the biomedical realm. As a result, our regulatory efforts both over- and under-reach. Surely a sounder public policy would work to cover the highest risk activities before sweeping into the scope of regulation activities that are low risk. Additional analysis of regulation of humanistic research, on a level at least as rigorous as that devoted over decades to biomedical and behavioral research, seems warranted. This would assure that both the costs and benefits of regulations serve intended public policy ends.

Procedural Issues

In addition to the substantive challenges presented by regulation of research in the humanistic disciplines, there is increasing controversy across the country on procedural aspects of IRB oversight of research. Because of the lack of consistency in IRB function and decision-making, researchers have contended that IRBs have

⁴² Ibid., 24-28.

⁴³ This is the precursor office to the current Office of Human Research Protections within the Department of Health and Human Services.

⁴⁴ Gunsalus, “An Examination of Issues,” D14-15.

been used as tools to attack work with unpopular conclusions; that IRB decisions are not subject to any form of appeal or review; that inter-university research proposals must be approved by multiple IRBs that do not communicate with each other and that may come to different conclusions; and that the traditional mechanism for determining whether an activity is exempt from IRB review is insufficient (since it requires submitting the proposal to the IRB, or its administrator, without an appeal mechanism for these *ad hoc* decisions). Decisions made by IRBs without an adequate or clear reasoning mechanism are among those creating controversy and distrust among researchers in the humanities.

Carol Tavis, a fellow of the American Psychological Association, suggests (in an article describing the tribulations of two psychologists studying recovered memory) that:

Today, many of the IRBs originally established to protect subjects have instituted so many Byzantine restrictions and rules that even good scientists cannot do their work. Some have become fiefdoms of power—free to make decisions based on caprice, personal vendettas, or self-interest, and free to strangle research that might prove too provocative, controversial or politically sensitive.⁴⁵

VI. HUMANISTIC DISCIPLINES: DISCIPLINARY CONCERNS AND PROPOSALS

Recall the puzzling questions raised in the discussion of writing about teaching. When such questions emerge in the humanistic disciplines, it seems useful to concentrate first on trying to articulate what activities comprise “research” and to codify guidance on that point to improve consistency of IRB judgments. It is possible that many of the current controversial rulings by IRBs that raise matters of principle could be resolved by disseminating guidance on, first, the substance and criteria for decision-making and, second, improved and consistent procedures for reaching such decisions. Failing that, better guidelines for how the federal regulations and local IRBs relate to scholarship in the humanities, journalism and some branches of social science would solve many of our present quandaries. There is one overarching question to ask of the goals of the protection system: who are we aiming to protect, and from what?

The American Association of University Professors (AAUP), in a 2001 report on the oversight of social science research by IRBs, highlighted a number of these issues.⁴⁶ Responses to that report, including comments made by panelists during the January 2002 NHRPAC meeting and published in *Academe*, continue the discussion. These inquiries explore the emerging view that “the government’s regulations, known as the Common Rule, as applied by campus institutional review boards to humanities and social science research, sweep too broadly.”⁴⁷ The AAUP initiative explores the problems that have arisen from the application of the biomedical

⁴⁵ Tavis.

⁴⁶ American Association of University Professors.

⁴⁷ “Should All Disciplines Be Subject to the Common Rule?”

research paradigm to ethnographic research, to oral history interviewing, and to the teaching of journalism and mass communication. The participants propose a variety of solutions, from specialized IRBs with appropriate expertise for reviewing work in these disciplines, to discipline-based guidelines for best practices and expedited reviewing procedures,⁴⁸ to excluding all research from oversight unless it poses "a risk of physical harm."⁴⁹ More recently, a Canadian national body has proposed that their equivalent of IRBs should be required to demonstrate "identifiable harm" before regulations apply.⁵⁰

Some of these proposed solutions are more realistic than others. Discipline-based guidelines are sorely needed and should provide local IRBs with guidance on ethical and practical matters in areas that may frequently be beyond the expertise of their members. At larger institutions, specialized IRBs may be both practical and possible, although we should carefully consider the possible advantages and disadvantages of this approach. In addition to concerns about inconsistent application, one question is what might be lost by reducing the cross-fertilization across disciplines in the discussion of protection of human subjects. The proposal to exclude all research that does not pose a risk of physical harm seems unlikely and naïve in light of the history in this area. It may be, though, that a shift to the concept of "identifiable harm" holds promise and should be explored.

The AAUP conversations, moreover, may be conflating issues that should be examined separately. First, we must be able to articulate the point at which work performed by university-based teachers and scholars becomes "research" warranting review and oversight by an IRB. This then invokes the second question: Who are the human subjects, and what are the risks and harms to which they are susceptible? Only then should the third question arise, as to what provisions or guidelines should apply to that research.

There are further disciplinary complexities, as well. Whenever the conclusion is reached that an activity is "research," by what guidelines should it be determined that the activity falls under the exemption for educational research? These issues have yet to be considered in any comprehensive way.

Current exemptions encompass: "(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods."⁵¹ Within the literature on educational research, some have questioned whether the premises underlying the exemption for pedagogical research are valid, or were when they were drafted. Howe and Dougherty, for example, note that the special exemptions for educational research were formed before qualitative research methods were introduced, and suggest that aims and methods are a more important way to distinguish types of research than topics or settings. It should be noted that the current official IRB

⁴⁸ Ibid.

⁴⁹ Ibid.

⁵⁰ "Giving Voice to the Spectrum," 6.

⁵¹ Code of Federal Regulations, Title 45 § 46.101, et seq.

Guidebook issued by the federal agency with enforcement responsibility has only one paragraph on "fieldwork" and one paragraph on "social policy experimentation," in all of its eleven (total) paragraphs on behavioral research, out of hundreds of pages.⁵² This scant guidance focuses on the intimacy and open-endedness of qualitative research as requiring special scrutiny and perhaps new regulatory approaches.

The circumstances that gave rise to the educational exemptions also included the assumption that educational institutions (especially elementary and secondary schools where the students are generally under 18 years old) already exercised oversight over research performed in their settings, and that additional review by IRBs could be redundant, an operating assumption about which questions can be raised. Other rationales for the exemption focused on the very low risk nature of much educational research, and also strayed into the research vs. therapeutic treatment analysis used by the National Commission in its Belmont Report and commissioned papers. Perhaps these assumptions also warrant re-examination.

Another issue bearing consideration is the frequency with which anonymity and confidentiality are confused in the literature on educational research. Anonymity, privacy and confidentiality are each separate principles that address different issues. To use them interchangeably, as appears to be occurring in some debates on the ethics of writing about teaching—as has occurred in some of the internal discussions within the Modern Language Association, for example—complicates coming to a crisp and clear articulation of the ethical challenges to be addressed and the array of possible approaches to them.⁵³

Possible Solutions?

In 1998, I came to the conclusion, perhaps too quickly, that a fundamental change in the federal definition of "research" was not warranted. The practical difficulties alone in changing the definition upon which our entire regulatory system rests are immense. Achieving consensus for a change in such a fundamental, longstanding definition, which involves researchers from all disciplines, is a daunting task. And yet the problems with oversight in the humanities make clear that the *status quo* is insufficient and that these unique concerns must be addressed.

One way to circumvent the problem of attempting to redefine "research" might be to discuss what covered research is *not*. Things that are *not* covered research would not be subject to oversight and regulation in the first place. If we embark on such a *definition by exclusion*, it would be important to consider the ramifications and possible unintended consequences of labeling certain activities as scholarship without *federal* regulation. (Institutional and disciplinary regulation are always still possible.) If we are uncomfortable "defining out" certain categories of research, perhaps we may suggest that development of *additional exemptions* would be a stronger approach than to "define out" certain activities in totality. That is, if we

⁵² Howe and Dougherty.

⁵³ National Institutes of Health.

concede that some activities are “research,” but that we do not believe they pose sufficient risks to adults, might we say without exception or prior review that they warrant an *ex-ante* protection system?

Possible categories of research needing careful analysis in this respect include ethnographic studies, oral history,⁵⁴ survey research (on the grounds that participants consent by filling out the surveys) and journalism. These are all activities that involve interviews or “interactions” with individuals for which decisionally-capable adults ought to be able to understand and assess—and accept—the “risks” of participation (whatever they might be) without paternalistic protection from an IRB.⁵⁵ This presumes that the activities are ethically and correctly conducted according to professional disciplinary standards. Others may claim that disciplinary standards have no regulatory clout, so IRBs are necessary watchdogs. However, institutions certainly have tools for responding to unprofessional and unethical behavior on the part of their members, and perhaps for abuses of those standards, the recourse ought to be made available through an *ex-post* complaint mechanism, but not an *ex-ante* review.

Along with the question of exemption is the issue of expedited review. If we believe an activity is “research” that should *not* be exempt from IRB review, who decides—and how—whether it qualifies for “expedited” review? In this form of review, only the IRB chair (or designated member) and administrator review the research protocol, generally on the grounds that the research poses minimal risk to the participants. Is it possible to assemble guidelines that clarify categories of research to which only expedited review requirements ought apply? Can we refine procedures so these responsibilities can be more broadly distributed within institutions? Can the ethical principles implicit in the Common Rule be so interpreted and applied? If so, it seems important to systematize, on a national basis, the concepts and methods so we can avoid the current system of *ad hoc* application within each individual IRB. Consistent definitions and review criteria grounded in disciplinary consensus that are followed by all IRBs would alleviate considerably some of the more serious problems now seen.

Several disciplines are working on guidelines internal to their discipline, as the AAUP case illustrates, but this does not go far enough. We need a multidisciplinary assessment of guidelines. Developing ethical principles that apply to educational researchers, for example, may or may not translate well to social psychologists studying organizational behavior in corporate workplaces or to the issues that arise in ethnographic studies in international settings. Only by focusing on the ethical issues that arise in methodological groupings, with multidisciplinary collaboration, will we be able to devise generalizable rules that can guide IRBs across the country. Otherwise, we will be left with either a highly particularized, university-specific regulatory system (the current situation) or a set of sweeping “one size fits all” federal statements that fail to comprehend the complexity of these issues.

As one step in this direction, an interdisciplinary working group at the University of Illinois has tentatively developed an overarching set of categories within which

⁵⁴ Since exempted by the Office of Human Research Protections, September 22, 2003.

⁵⁵ Gunsalus, “Thinking About Two People Talking.”

these questions might be asked.⁵⁶ Those categories are: a) survey research; b) observational/interactional research (e.g., ethnography); c) biographical work, including oral history and reality-based fiction; d) autobiographical work (including writing about teaching); and e) interventional research methodologies, including those that employ non-invasive as well as invasive protocols.

For each methodology examined, there are three core questions to be addressed in formulating recommendations about which research ought to be subject to what level of IRB advance review and approval. 1) In work using this method, what constitutes research and experimentation under the federal definition? 2) What turns a person into a "human subject" in this area? We all interact with other people every day. How do we distinguish between interactions that do and do not require regulation? Is the "intent to publish" rule of thumb a fair or prudent standard? And 3) From what "risks" or "harms" are we protecting potential subjects, and why? And, of course, there is the underlying question of whether work conducted in university settings should be subject to regulations that are not imposed on the rest of society; or conversely, if the rest of society should be subject to the same ethical controls as those within the IRB system.

Until we can develop broad consensus across scholarly disciplines and produce guidance documents for IRBs, we continue to run the risk of wasteful use of valuable time and expertise for little demonstrable gain, to increase disrespect for important protective systems, and to delay or even impede altogether the pursuit of important research. Even the *Wall Street Journal* has commented that

IRBs...are cracking down on social sciences, where the risk to volunteers amounts to hardly more than bruised feelings...Surely we can protect people in medical trials without strangling legitimate social-science research.⁵⁷

Procedurally, we must address the composition of IRBs as well as the procedures by which determinations are made and reviewed—or not. Do we need specialized IRBs that focus on limited research areas (i.e., specific methodologies or fields) if we develop better guidance on what constitutes research and guidelines developed with disciplinary input that helps to address some of the most vexing issues and that provides first ethical principles for assessment of less-commonly arising problems? Is more oversight apparatus really a good use of resources? Does the "problem" justify this?

One approach might be to develop models for different sizes and types of institutions. What activities constitute "research" could be encompassed in this

⁵⁶ The Illinois project involves a set of structured, multi-disciplinary conversations designed to address and define the lines between research and scholarship in the humanistic disciplines, much the way that medicine has worked to define the difference between treatment and research. For example, what scholarly activities constitute "research" on human subjects that should be subject to advance review and approval? When an activity falls within the regulatory scope, what should the review process be and who should be involved? What disciplinary guidelines exist or need to be developed to guide these developments? At a national, invitational conference held in April 2003, these structured conversations were held across a variety of disciplines. The Illinois White Paper is forthcoming on these and related issues to continue the dialogue within and across disciplines, all of which are designed to affect how research outside the biomedical arena is reviewed and overseen.

⁵⁷ Begley.

model, since different sizes and types of institutions will have different types of research. Factors to consider include: How should we preserve the principle that decisions about what counts as "research" should not be made by the individual whose work is under consideration? And, on the opposite extreme, how do we place a system of checks and balances on the IRB or its administrator – perhaps by implementing a system of recourse or appeal? The new accrediting body for human subject protection programs, the Association for the Accreditation of Human Research Protection Programs, may well provide information and possibilities in this area as its accreditation criteria evolve.

It seems uncontroversial to assert that low-risk activities performed at universities or other covered entities should be a lower priority for regulators than high-risk activities outside the reach of present regulations. Yet with present trends for campus-based IRBs to encompass more activities under their review and with raised standards for review, we seem to be heading in the wrong direction. Various legislative proposals to expand protections for human subjects similarly over-reach, and leave low-risk activities over-regulated.⁵⁸

VII. CONCLUSIONS

IRBs across the country need clear, consistent guidance about whom we are seeking to protect against what risks, why, and how to accomplish that goal. IRBs should not spend their resources reviewing activities that pose no more risk than is commonly encountered in daily life, and we should provide examples and standards so that more consistent, predictable decisions can be made nationwide. To this end, we must continue discussions within and across fields and disciplinary communities to develop common understanding of the goals, purpose and implementation of our necessary regulations. These conversations should involve disciplinary societies, national advisory committees and individual scholars. Recommendations must be both feasible and rooted in ethical principles.

Once (if) these conversations result in a reasonable national consensus, we will need both a mechanism for recording the outcome and for educating local IRBs. In this process, we must consider whether there are some areas that should not be subject to pre-approval procedures, but instead should have post-research complaint mechanisms as the appropriate check and balance for problems that arise.

We need an analytical framework that improves the current cost-benefit ratio of our protection systems for human subjects of research, especially regarding scholarship outside the biomedical realm. This framework must be applied using sound procedures that are seen as fair, even-handed and content-neutral. Without such structural revisions, we will continue to have a system that imposes costs disproportionate to benefits in a large number of scholarly areas, and if not corrected, that will call our entire regulatory apparatus into disrepute.

⁵⁸ Research Revitalization Act of 2002.

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APPENDIX A:

Examples of Studies with Multiple Unimplemented Recommendations

- Office of the Inspector General, Department of Health and Human Services. "Institutional Review Boards: Their Role in Reviewing Approved Research" (OEI-01-97-00190); "Institutional Review Boards: Promising Approaches" (OEI-01-98-00191); "Institutional Review Boards: The Emergence of Independent Boards" (OEI-01-07-00192); "Institutional Review Boards: A Time for Reform" (OEI-01-97-00193). Washington, D.C.: U.S. Government Printing Office, June 1998.
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APPENDIX B:

Basic Policy for the Protection of Human Subjects. Department of Health and Human Services, 45 CFR §46.101 and §46.110. Revised June 18, 1991; Effective August 19, 1991.

Subpart A: Federal Policy for the Protection of Human Subjects.

"b) Unless otherwise required by Department or Agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture."

§46.110

Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research:

"(a) The Secretary, HHS, has established, and published as a Notice in the Federal Register, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the Federal Register. A copy of the list is available from the Office for Protection from Research Risks, National Institutes of Health, DHHS, Bethesda, Maryland 20892.

(b) An IRB may use the expedited review procedure to review either or both of the following:

(1) some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

(2) minor changes in previously approved research during the period (of one year or less) for which approval is authorized. Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among

members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §46.108 (b).

- (c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.
- (d) The Department or Agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure."