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Protecting human subjects and preserving academic freedom:

Prospects at the University of Chicago

A B S T R A C T
Within the terms of the federal regulatory scheme requiring institutional review board (IRB) oversight of federally funded research with human subjects, projects that are not federally funded are not mandated for IRB review. Eighty percent of social-science projects at the University of Chicago are not federally funded. This article is a critique of the overextension of federal regulations by university and college administrators and provides some suggestions for reform. [*academic freedom, IRB, human-subjects protection, research ethics*]

> The basic policies of the University of Chicago include complete freedom of research and the unrestricted dissemination of information.
>
> —University of Chicago Articles of Incorporation, Bylaws and Statutes, p. 44

> We regret to inform you that IRB approval for your research Protocol has expired. Please note that research related activities (including interaction with human subjects, data collection, and/or data analysis) may not continue or be initiated until the IRB has approved the continuation of this research.
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> —Official communication from the University of Chicago Social and Behavioral Science Institutional Review Board to the faculty sponsor of a personally funded research project, September 2005

The federal regulatory scheme specifically requiring institutional review board (IRB) oversight of federally funded research at U.S. universities and colleges (Department of Health and Human Services [DHHS] "Code of Federal Regulations, Title 45 'Public Welfare,' Part 46 'Protection of Human Subjects' " [2005] rules and definitions, also known as the "Common Rule") was initiated by an act of Congress in 1974 and is currently enforced by the Office for Human Research Protections (OHRP). The original act of Congress was motivated by concerns over perceived ethical violations in biomedical research conducted by the Public Health Service, and its aim was to make sure that all federally sponsored research is ethically sound and respectful of the rights of the human beings involved in the research. Within the terms of those federal regulations, research that is not federally funded is not mandated for "Common Rule" regulation. Alternatively stated, within the terms of the 45 CFR 46 regulations, the scope and depth of OHRP enforcement is limited to federally funded projects; it is legally possible for academic research institutions to shield and protect privately funded, personally funded, and unfunded projects from the reach of the IRB surveillance and research licensing process (and its

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various definitions, rules, and regulations) while at the same time assuring by other means that all research with human subjects is guided by ethical principles. In this article, I provide a brief account of the overextension of the 45 CFR 46 regulations by university and college administrators, a process of overregulation that has been labeled "mission creep" (University of Illinois Center for Advanced Study 2005). I also defend a defining proposition associated with the tradition of academic freedom at the universities and colleges of the United States, namely, that a university is a place where the life of the mind of individual scholars is granted very high degrees of autonomy; hence, proposed restraints (even well-intended ones) on faculty and student research and other suggestions for regulating, monitoring, controlling, or constricting scholarship that are not mandated by law should be viewed with a very skeptical eye and resisted, rather than uncritically embraced, by members of the academy. A monumental (even if small) first step in that direction, restricting the legally required range of application of the 45 CFR 46 regulations to federally funded projects, has been taken at my own academic home, the University of Chicago, as I describe below.

The news: The limited scope of IRB authority

The news that research with human beings that is not federally funded is not federally mandated for IRB oversight will probably come as a surprise to many scholars in the United States. Until rather recently, academic administrators at almost all U.S. research universities have voluntarily signed away and (as I suggest in this article) unwisely surrendered their legal rights to restrict the IRB regulations to federally funded research and to create their own alternative ethical-oversight procedures for research that is not federally funded.

Typically, this discretionary extension of the DHHS regulations to all research (regardless of funding source) has been done without the benefit of an open and robust debate about its implications for academic values or research performance. Indeed, at many (perhaps most) colleges and universities today, the decision to extend the regulations has been taken by academic administrators without the full knowledge, involvement, and direct consent of faculty ruling bodies. It has been a completely elective internal administrative action: voluntary endorsement of an optional clause in a formal contract with DHHS and OHRP agreeing to subject all researchers to the ethical licensing system tied to federally supported projects, including federal definitions of exempt research and the authority of an IRB to demand and evaluate project proposals and dispense or withhold permission to do research. Consequently, many research scholars, including those social scientists who grumble about the IRB and trade horror stories, appear to be totally unaware that they have no one to blame but themselves (and their own academic administrators) for the wholesale application of the DHHS regulations to the vast majority of social scientists, humanists, and legal scholars who conduct research without a reliance on federal funds.

That there is no federally mandated legal requirement to universalize the 45 CFR 46 regulations (or any of their subparts) beyond federally funded projects has been a well-kept secret among academic administrators, most of whom have done very little to educate their faculty in this regard or to bring the matter forward for appropriate deliberation and a vote; but it is also welcome news, especially for researchers in the social sciences, humanities, and law, in which many scholarly projects involving other human beings are not federally funded. At the University of Chicago, for example, nearly 80 percent of all research projects reviewed by the Social and Behavioral Science IRB are either personally funded, privately funded, or unfunded. Indeed, the news might be viewed as an eye-opening invitation to faculty ruling bodies around the country to scrutinize their own institutions' history of administrative decision making concerning IRB policy and to reform their internal procedures for the promotion and maintenance of research ethics.

A first step in that direction has been taken at the University of Chicago. The occasion was the most recent three-year renewal of the university's ethical-oversight agreement with DHHS and OHRP, which went into effect on January 1, 2004. All U.S. universities and colleges that receive federal research funding enter into this type of contract or agreement, which was previously known as the Multiple Project Assurance (MPA) and is currently titled the Federalwide Assurance (FWA). From the point of view of the federal funding agencies, it is the FWA agreement that legally enables them to sponsor and support research involving human volunteers at research institutions that are not part of the federal government. By means of its FWA form (in the section on "Statement of Principles"), DHHS and OHRP offer research institutions the option to either adopt the DHHS Belmont Report (a document written largely by bioethicists that highlights various moral ideals: respect for persons, beneficence, justice, and informed consent [National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 1979]) as the ethical standard governing research or else propose an alternative set of ethical guidelines to govern research at that institution. By means of that assurance form, DHHS and OHRP inform a university that all federally funded research must be reviewed and approved by an IRB applying the 45 CFR 46 regulations, rules, and definitions.

Quite crucially, the FWA form (in the section "Applicability") also offers a university the option to either agree or not agree to legally bind itself to apply the IRB process to all research regardless of funding source. Thus, the FWA form officially and explicitly asks university administrators whether they would like to retain their legal right to apply the IRB process only to federally funded research. For almost three

decades following the creation of the IRB system, almost all academic institutions voluntarily renounced their legal right to apply the federal regulations only to federally funded research projects, and, until January 1, 2004, the University of Chicago was no exception!

On the occasion of its most recent three-year renewal of its ethical-oversight agreement with DHHS and OHRP, however, the University of Chicago became one of an early batch of U.S. research institutions electing to retain their legal right to opt out of any or all of the 45 CFR 46 regulations with regard to research projects that are not federally funded. Although it would be instructive to know who gets the honor of having been the first academic institution to opt out, over the past few years the trend seems to have grown. On the basis of information received from OHRP in response to a Freedom of Information Act request submitted by Jonathan Knight on behalf of the American Association of University Professors (AAUP), it appears that, as of January 2006, at least 174 universities and colleges—including Princeton University, Yale University, and the University of Chicago—have declined to legally bind themselves to apply the 45 CFR 46 regulations to research projects that are not federally funded.

That is the good news. The bad news is that, to date, neither the administrations nor the faculties at most of those 174 universities and colleges have fully thought through the implications of their decision to legally opt out of an IRB review requirement for research that is not federally funded; indeed, most faculty members at the University of Chicago are not even aware of the decision, and one guesses this is the case at most of the other academic institutions at which the IRB legal environment now has room for alternative modes of ethical review for non–federally funded projects. In other words, despite the lack of any federal legal requirement, despite the recent removal of any contractual FWA requirement, and (as I argue below) despite the want of any statutory authority traceable to the bylaws of the University of Chicago, IRB surveillance of privately funded, personally funded, and unfunded research at the university proceeds as though it were business as usual. Nevertheless, where there is a way, there may be a sufficient will to go beyond business as usual. Given the terms of the University of Chicago's most recent FWA, its ethical-oversight system is now legally well prepared for internal reform.

In the light of the University of Chicago's decision to retain its legal right to not apply the 45 CFR 46 regulations to research that is not federally funded (a decision based on recommendations from a committee of administrators and faculty appointed by the provost of the university), this article has two aims. The first is to imagine some of the reforms of the ethical review process that are now legally possible and academically desirable at the university. The second is to argue that, when DHHS and OHRP offer an academic institution the option to limit the scope of federal surveillance over faculty and student research (thereby acknowledging that universities and colleges have a legal right to decide for themselves how to uphold ethical standards for research that is not federally funded), it should be in the character of any institution that truly values academic freedom to seize the day and embrace that opportunity.

An unsettling irony: When those who value academic freedom give it away

Notice the unsettling irony in the current IRB regulatory situation at most U.S. universities and colleges. There is no legal requirement to universalize the IRB process beyond federally funded projects. Consequently, OHRP, DHHS, and other federal agencies have structured the FWA form in such a way that academic administrators are offered the opportunity to decide for themselves whether to overregulate their own faculties, which they typically do; at the same time, preoccupied members of faculty ruling bodies, unaware of the legal alternatives, allow this to be done. Those who value academic freedom (university faculty and university administrators) just give it away, readily, passively, and unnecessarily.

That irony is brought to the attention of researchers (and gets rubbed in a bit, I think) by Stuart Plattner (2004), the anthropology program officer at the National Science Foundation (NSF). His remark is addressed to the broad academic community of anthropologists, most of whom are not supported by federal grants: "Practically all universities and research organizations in the US," Plattner writes,

> have agreed to follow a set of regulations called "The Common Rule" (technically, "Federal Policy for the Protection of Human Subjects," DHHS' 45 CFR 46 or the equivalent regulations for other federal agencies). The regulations specify how institutional review boards are to be operated; while they specifically apply only to federally funded research, most institutions have voluntarily extended their coverage to all research. So individual researchers have no choice in the matter. You must follow the federal regulations because your employer requires you to. [2004:5]

The disingenuousness of that communication ("researchers have no choice in the matter"; "you must follow the federal regulations because your employer requires you to") from an officer of a federal funding agency addressed to academic researchers in anthropology, most of whom do not seek federal funds, will not be lost on academic anthropologists, almost all of whom are committed to the idea of faculty, rather than "employer," control over the educational and research work of U.S. universities and colleges. Neither will it be lost on academic research administrators. For, in some significant measure, academic administrators have overextended the application of the 45 CFR 46 regulations precisely because that is what they guessed the federal agencies (including NSF) really wanted them to do (even if

it was not required by law) and because that is what academic administrators at their peer institutions were guessing and doing, too, largely out of fear of the federal funding agencies. Academic administrators typically worry a lot about the financial well-being and liability of their beloved (yet vulnerable) institutions, do not like to make waves (at least not on their own), and (given the limited bargaining power of most universities and their dependency on federal funds) have not necessarily been inclined (or rewarded) to stand up, stand out, and fight the federal government over academic-freedom rights. So they have boxed themselves (and researchers) in, ironically preparing the way for an officer at a federal funding agency to point his finger at their box.

Nevertheless, Plattner's taunt is substantially correct. Given the options now explicitly offered by the DHHS and OHRP on the FWA form, we (members of the academy: administrators, faculty, and students) can no longer blame the federal government for our own internal ethical-oversight policies with regard to research that is not federally funded. It is not DHHS or OHRP (or NSF) that requires everyone who does research with human beings (regardless of funding source) to fully formulate and declare what they are doing before they do it. It is not DHHS or OHRP (or NSF) that stipulates that privately funded, personally funded, and unfunded researchers (faculty and students) must annually seek and receive permission from an appointed board of local academics and a member of the nonacademic public (an IRB is composed of both) to do research at all. We have only ourselves to blame, which is not necessarily a bad thing, because it means we have the option to reform the system.

The choice is ours, but it carries with it responsibilities. Any research institution receiving federal funds can elect to retain its legal right to restrict the federal regulations to federally funded grants by simply renegotiating the terms of its FWA the next time it comes up for renewal. That is what has happened at the University of Chicago and at 173 other academic institutions in recent years. Nevertheless, it is one thing to decide to retain one's legal right to opt out of any or all of the 45 CFR 46 regulations with regard to research projects that are not federally funded; it is quite another thing to sensibly figure out whether or how to go about doing things differently, for example, with regard to privately funded, personally funded, and unfunded research in the social sciences, humanities, and law. Legally clearing the way is a monumental (even if small) step in the right direction; the next step is to begin considering alternative ways to maintain ethical standards without relying on the federal regulations and without compromising the academic freedom of those many investigators in all areas of the university who do not seek federal support and do not wish to be bound and constricted by the strings tied to federally funded projects.

Academic freedom and self-governance at the University of Chicago

Whatever one's opinion of the ethical-oversight system that DHHS and OHRP have tied to federally funded research projects, the decision whether or not to universally apply the 45 CFR 46 regulations to everyone regardless of funding source is for faculty members to make, at least at those universities and colleges where faculty self-governance is a ruling norm. In making the decision whether to limit the IRB process to federally funded projects, at least one major consideration is whether the process and the 45 CFR 46 rules and definitions are compatible with the traditions of academic freedom at one's own university.

Legal scholar Philip Hamburger (2005) has recently argued that even for federal grants, the IRB process is an unconstitutional censoring and licensing of human activities that are protected by the First Amendment. I do not address the constitutional issue in this article. If Hamburger is right, his analysis might support the conclusion that U.S. universities should not be accepting funds that have such strings attached or at least that the strings should be contested in court. If he is wrong, and the regulatory strings tied to federally supported research projects pass constitutional muster (e.g., on the grounds that the government does not require one to apply for federal funds), the question still remains: Does a gratuitous university decision (by which I mean one that is not mandated by law) to impose the 45 CFR 46 regulations on research scholars who do not themselves seek federal funds run afoul of that university's commitments to both itself and its faculty and students, especially in the area of academic freedom?

What is the proper answer to that question for an academic institution such as the University of Chicago? And what if the answer is yes? What if the 45 CFR 46 regulations offend some of the University of Chicago's deepest and most valued conceptions of its relationship to its faculty and students and its own identity as a university? Would that not be a good reason (there may be others) for minimizing the reach of the regulations by actually exercising the now-existing legal option to limit IRB review only to research projects seeking or receiving federal support?

Speaking as a member of the faculty at the University of Chicago (I arrived in 1973), what conceptions of its institutional identity do I have in mind? Perhaps the most basic is the idea of a University of Chicago whose highest ideals include the unrestricted pursuit of truth, both in inquiry and in research. Not surprisingly, that ideal is also a right formally and customarily granted by the university to its students and faculty. Statute 18 of the University of Chicago Articles of Incorporation, Bylaws and Statutes (a statute concerned with patent policy, of all things) begins with the explication of an understanding that is presupposed by the very act of incorporating a university and that is all too easily taken for

granted: "The basic policies of the University of Chicago include complete freedom of research and the unrestricted dissemination of information" (University of Chicago Board of Trustees 2005). The tradition of academic freedom at the University of Chicago is also addressed (and in somewhat greater detail) in two hallowed official university policy statements on the topic, both of which were voted on and endorsed by the Council of the University Senate, which is a faculty ruling body.

The first policy statement, colloquially known as the "Kalven Committee Report," was completed on November 11, 1967. It was originally intended as a statement on the role of the university with respect to calls for collective social and political action. But it has lived on as an eloquent and well-known official account of the two fundamental principles of academic freedom at the University of Chicago. The first principle entrusts the university with the defense of the "autonomy" of its faculty and students "in the discovery, improvement and dissemination of knowledge" (including critical and even unpopular inquiry into all aspects of social life). Indeed, Harry Kalven Jr. and the illustrious members of his committee (John Hope Franklin, Gwin Kolb, George Stigler, Jacob Getzels, Julian Goldsmith, and Gilbert White) identify the very mission of the university with the pursuit of knowledge by a community of independent-minded, disputatious, and autonomous scholars (faculty and students) and note that, "by design and by effect, it [the university] is the institution which creates discontent with the existing social arrangements and proposes new ones. In brief, a good university, like Socrates, will be upsetting" (Kalven Committee Report 1967).

The second academic-freedom principle mentioned in the Kalven Committee Report is perhaps less obvious, for it is a justification for the idea of "institutional neutrality" and the notion that a university is a "community" in only a very limited and special sense, namely, one that promotes and defends the intellectual autonomy of its faculty and students. The report notes that the "university is the home and sponsor of critics; it is not itself the critic" (Kalven Committee Report 1967). It notes that the university thrives because of the freedom of its members to hold unpopular or eccentric views and that the university must avoid the temptation to make institutional or collective judgments concerning matters that have an impact on the activities of its faculty and students in the discovery, improvement, and dissemination of knowledge. Quite crucially, the report states that the neutrality of the university as an institution "arises out of respect for free inquiry and the obligation to cherish a diversity of viewpoints" (Kalven Committee Report 1967).

The other policy statement, the "Statement on Academic Freedom," was adopted even earlier, on November 15, 1949. It identifies the mission of the University of Chicago with the unfettered pursuit of truth and offers this caution: "It is important that American universities resist political dictation. Each concession encourages new encroachments and makes further resistance more difficult" (University of Chicago Archives 1949). The statement notes, "The purpose of a university is defeated in proportion as its members are prevented from pursuing and proclaiming the truth as they see it and are required to conform to views held at the moment by the public or by influential groups among the public" (University of Chicago Archives 1949).

Compare those proud and official statutory and policy statements about faculty and student autonomy, institutional neutrality, the complete freedom of research, the unrestricted dissemination of information, and the pursuit of truth uninfluenced by public opinion with the standard communication (the "Notice of Termination") that in recent years has been sent by the Social and Behavioral Science IRB at the University of Chicago to all students and faculty (regardless of funding source) when "their IRB approval" has expired. (Remember that the IRB functions as an institutional or collective surveillance board in both a critical and licensing capacity vis-à-vis the research process and that the members of the IRB include both faculty and nonacademic representatives of the views of the general public.) The Notice of Termination reads, "We regret to inform you that IRB approval for your research Protocol [title of project] has expired. Please note that research related activities (including interaction with human subjects, data collection, and/or data analysis) may not continue or be initiated until the IRB has approved the continuation of this research."

Here, something like an order to cease and desist from research and inquiry is issued in the name of the IRB (its members are appointed by academic administrators, typically deans) in direct contradiction to the basic policies of academic freedom upheld by the university and endorsed by its Council of the University Senate. This is done without any showing of misconduct on the part of the researcher. The Notice of Termination appears to presuppose the legitimacy of institutional monitoring and prior restraint when it comes to the life of the mind. That a command of that sort gets issued at all and sent to faculty and students seems unconscionable in the context of the intellectual traditions of the University of Chicago. Indeed, not only is it unconscionable but, within the statutory framework for faculty self-governance at the university, the authority of an IRB to issue such an order (esp. to a researcher who is not supported by federal funds) is also without foundation; it is not hard to imagine plausible arguments that might be advanced in defense of an unfunded, personally funded, or privately funded member of the University of Chicago research community who simply ignores the cease-and-desist order, claiming that the IRB is a supernumerary entity that has no authority to issue the order in the first place.

An internal challenge of that sort has not yet surfaced. Nevertheless, for the sake of highlighting the need for reform of the ethical-oversight system at the University of Chicago

(esp. for privately funded, personally funded, and unfunded researchers in the social sciences, humanities, and law), it is useful to imagine how the arguments in defense of that hypothetical non–federally funded researcher might go. For example, one might skeptically ask, what precisely is the source of the authority of an IRB at the University of Chicago to issue an order to cease and desist from research and data analysis in a case in which there is no showing of serious wrongdoing and the researcher is not federally funded? There would seem to be three possible answers: (1) the authority derives from the federal government (e.g., the DHHS regulations); (2) the authority derives from a contract between the university and the federal government (e.g., the FWA); or (3) the authority derives from the statutes and bylaws of the university as a private corporation. None of those answers survives critical analysis.

The authority does not derive from the federal government because the federal government has no authority to tell researchers who do not apply for federal grants to stop talking to people, associating with people, recording the things people tell them, thinking about the things people tell them, or writing it all up and publishing it. That would be a blatant transgression of various protected First Amendment liberties (of association, speech, and press), which all citizens should be very concerned to safeguard; and concern with constitutionality is probably a major reason DHHS and OHRP make it clear in their FWA form that recipients of federal funds are under no legal obligation to universalize the 45 CFR 46 regulations beyond federally supported projects and that they give recipients the contractual opportunity to opt out.

Neither does the authority derive from the FWA. As repeatedly noted above, as of January 1, 2004, at the time of its most recent renewal of its FWA, the University of Chicago entered into an agreement with DHHS and OHRP in which the university has retained its legal right not to subject privately funded, personally funded, and unfunded research to IRB surveillance. So the IRB authority in this case cannot be derived from a contractual arrangement between the university and the federal funding agencies.

The authority to issue that cease-and-desist order is also not readily derivable from the statutes and bylaws of the University of Chicago. Statute 12.1 states, "All advisory, legislative, and administrative powers in the University concerning its educational work, except those vested in the President by the Board of Trustees [which do not include powers related to the licensing of faculty and student research projects], shall be exercised by, or be under the authority of, the Ruling Bodies specified in article 12" (University of Chicago Board of Trustees 2005).

"Local ruling bodies" (e.g., the social-science faculty) are given authority and jurisdiction over educational matters of local (divisional or college) concern and the Council of the University Senate (an elected faculty body representing the entire university faculty) is given authority and jurisdiction over educational issues of relevance to the whole university.

So how does the IRB fit in this statutory scheme of things? Clearly, the IRB is not a ruling body in a statutory sense, yet its decisions have a direct bearing on the educational work of the university. Is the Social and Behavioral Science IRB, then, a creation of the faculty of the Division of the Social Sciences, of the Council of the University Senate, or of some other body with authority to make educational decisions? The answer appears to be no! As far as one can judge from the historical record (and from collective memory), the IRB system at the University of Chicago (and its application to all research projects with human subjects, regardless of funding source) grew up as an administrative response to the DHHS regulations (perhaps in consultation, at times, with particular faculty members who may have served on advisory committees appointed by the provost), but its character and charge have never been debated, brought to a vote, or given final approval by any ruling bodies. I should note here that even a ruling body at the University of Chicago could not so readily tell a faculty member to cease and desist from the pursuit of knowledge, because a ruling body cannot violate those academic-freedom policies that are so essential to the identity of the university as an academic institution and definitive of the relationship of faculty and students to the institution as a whole.

Thus, within the terms of the statutes and bylaws of the University of Chicago, it is not implausible to argue that, with regard to researchers who are not federally funded, the IRB has been issuing its cease-and-desist orders without a license, or at least without any obvious authority traceable to the university's established principles of governance.

Other reasons to favor reform

Given that the university (by means of its FWA) has secured the legal right to restrict IRB surveillance and licensing to federally funded projects and devise alternative means to maintain ethical research standards for non–federally funded projects, what other reasons favor actually exercising that right and opting out of the 45 CFR 46 regulatory scheme? Before answering that question, it is important to clarify one point.

Six years ago, Christopher Shea noted that, "technically, research that is not federally funded is not subject to the 45 CFR 46 rules, but most universities hold all research to the federal standard, reasoning that it makes no sense to have two moral yardsticks" (2000:4). It would be comforting to really believe that most university administrators actually went through a systematic reasoning process (and considered various alternatives) before deciding to voluntarily universalize federal regulations that were legally mandated only for federal grants. That argument, however (if it really was widely enunciated)—that one must apply the 45 CFR 46 rules

and definitions to everyone regardless of funding source because to do otherwise is to have two moral yardsticks—is rather weak.

If, by a moral yardstick, one means the 45 CFR 46 regulations, then the reasoning is vacuous or empty because it does not say why it makes no sense for a university to limit the application of the regulations to the only research for which it is legally mandated to do so, namely, to federally funded projects. If, by a moral yardstick, one means something like the principles of the Belmont Report and its ethical ideals (such as beneficence, justice, and respect for persons), then the reasoning is beside the point. Why? Because the University of Chicago remains legally committed (by the terms of its FWA) to make sure that all of its activities related to human-subject research, whatever the funding source, will be guided by the principles of the Belmont Report, regardless of any conceivable future reforms in the ethical-oversight process for non–federally funded projects. (Even with regard to the ethical standards that guide research at any particular university, the FWA form invites proposals for alternative yardsticks.) What the university is not bound to do (for research that is not federally funded) is use the "Common Rule" and IRB surveillance and licensing system as the procedure or means to assure that human-subject research is guided by a common set of ethical principles—the Belmont Report, in this instance. So, if the single moral yardstick is the Belmont Report, the argument that one must apply the 45 CFR 46 rules to everyone is a rather glaring non sequitur.

Or else the argument is just fallacious. It can make perfectly good sense to have more than one moral yardstick for judging the ethics of any particular project, and different areas of inquiry and different disciplines may legitimately develop somewhat different traditions of value. Even the Belmont Report is composed of several moral yardsticks, and it is widely acknowledged that they require local interpretation and cannot literally and uniformly be applied to all types of research without qualification. There is a difference between promoting the interests of those one studies (the interpretation of "beneficence" in the Belmont Report) and not doing deliberate harm to those one studies. The former type of beneficence (actually promoting the interests of research subjects) might well be relevant in some kinds of medical research yet undesirable or irrelevant in many types of social research (e.g., in a study of the family-life practices of different religious communities in the United States or a study of social and political conflict in Nepal).

A far more cogent argument, although one based exclusively on concerns about institutional liability for harms that might occur in a non–federally funded research project, is the claim that a litigant (in this case, someone suing the university) might be able to claim that the university acted unreasonably in not applying the regulations that federal funding agencies devised for their own grantees. Perhaps a litigant might claim that the 45 CFR 46 rules should be viewed as a national standard, even though the regulations are not universally mandated by law. Something like this argument is discussed in the AAUP report titled "Protecting Human Beings: Institutional Review Boards and Social Science Research" (n.d.). The report goes on to say, "Whatever the merits of these arguments, the university's legally prudent course of action, so the lawyers will advise, is for its policy to apply to all research on human subjects, irrespective of the source of funding" (AAUP n.d.:7).

Whether that argument really does have merit needs to be debated. Viewing the question strictly from a liability point of view, there would seem to be considerable advantages to shielding the numerous researchers who conduct privately funded, personally funded, and unfunded research from the radar screen and sanctioning power of the federal government, which is one of the practical advantages of limiting the application of the 45 CFR 46 regulations to federally funded projects. Moreover, with regard to research in the social sciences, humanities, and law, during recent decades the number of successful litigations and major awards of damage based on claims of serious harm has been very small, and (in principle) there should be other ways to protect institutions and individual researchers from financial liability (e.g., establish some form of "Socratic research insurance"—see below). The University of Illinois Center for Advanced Study white paper concerning IRB reform makes the following point with regard to biomedical research: "Observers have pointed out that aggressive plaintiff's counsel have simply added IRBs and individual IRB members as defendants for wrongful approval. In other words, it may be that whatever salutary effect the IRB system has as a legal prophylactic may be offset by the complementary consequence of including IRBs as co-defendants of litigation" (2005:11). The most important point to make in this context, however, is that it is reasonable for universities not to universalize the federal regulations. Advising lawyers' time would be well spent producing a legal memorandum outlining precisely why the federal regulations should not constitute a national (or even minimum) standard for ethical oversight and why several features of the regulations are actually harmful to academic and research institutions like the University of Chicago.

Below, I enumerate several types of considerations that ought to arise in any discussion about possible reforms of the ethical-oversight system at the University of Chicago (and similar academic institutions).

Academic values, academic pride

This consideration is obviously related to the academic-freedom principles discussed earlier, although here I draw attention to the potentially corrosive effect of the overextension of the federal regulations on the academic pride of university administrators and faculty. Academic values can

and should be distinguished from political and commercial values; and, indeed, there is a history of trying to do so at the University of Chicago (even university statute 18 states straight out that "research done primarily in anticipation of profit is incompatible with the aims of the university"). I do not mean to presume anything here about individuals, their characters, or their motives; the forces and trends I have in mind, weakening the will of those who value the idea of a university, have been in the works for decades, and academic administrators try to do their best in a very complex political and commercial environment. I simply point to some examples directly connected to the 45 CFR 46 regulations that reveal a loss of confidence concerning the once-cherished ideal that the borders of the university's value system must be defended against value incursions from outside (and value dissolution from inside).

The first example comes from a document circulated a few years ago at an ethics training session run by the University of Chicago Social and Behavioral Science IRB. It contained the following take-home point: "Conducting research is a privilege and NOT a right." Given the character and substance of the University of Chicago official policy statements and traditions concerning academic freedom, that take-home point is an outrage. At a meeting of the Council of the University Senate, Don Randel, the president of the University of Chicago, was invited to comment on the general claim that, at the University of Chicago, the conduct of research is a privilege and not a right. He carefully and eloquently distanced himself from the remark viewed as an unqualified proposition, yet there is some reason to believe that among some research administrators around the country that take-home message is emerging as a categorical slogan.

The second example is also a revealing symptom of the erosion of academic self-confidence, even among stalwart research administrators. As of January 1, 2004, the University of Chicago had officially renewed its FWA and entered into a new contract with DHHS and OHRP, but, for the first time ever, it retained its legal right to limit the application of any and all of the 45 CFR 46 regulations to federally supported research projects. Yet, even today, relatively few members of the faculty are aware of this fact or of its full implications. It was 20 months after the renegotiation of the FWA before the university finally updated its website on human-subject protection, and this is what it initially said:

> The University of Chicago is authorized to do research involving human volunteers through an agreement with the U.S. Department of Health and Human Services. This agreement assures that all research involving human subjects conducted at the University or by University faculty, students, or staff, will be conducted in accordance with the ethical principles spelled out in the Belmont Report. Our agreement assures that the University complies with all federal regulations and policies for prior review and continuing approval by an IRB of federally-funded research. The University has chosen as matter of institutional policy to extend such review to non-federally-funded research. The agreement is called a Federalwide Assurance. [University of Chicago n.d.]

In other words, the first sentence of that official University of Chicago website message is basically akin to the claim that conducting research is a privilege and not a right, although in this elaboration of the outrage the claim is specifically that the privilege (to do research with human volunteers) is granted to the University of Chicago by the DHHS. That utterly remarkable notion—that the University of Chicago (a private university that is under no legal obligation to accept federal funds at all) has no right to conduct research with human subjects except through a dispensation granted to it by the funding agencies—is elevated to the status of an official University of Chicago website statement, available for the whole world to read! In that one sentence, the entire tradition of academic freedom (and its likely constitutional foundation in the First Amendment of the Bill of Rights) is simply set to the side, as the university announces to the world that its authority to be a research institution in which scholars may study other human beings derives from the executive branch of the federal government, in particular, the DHHS, which, the university casually yet mistakenly avers, authorizes it to do research. A more accurate way to describe the nature of the FWA and a more academic-value-friendly way to formulate that first sentence might be as follows: "Through an agreement between the U.S. Department of Health and Human Services and the University of Chicago, government agencies who subscribe to the agreement are legally permitted by Congress to sponsor and fund research at the University of Chicago that involves human volunteers."

The remainder of that website formulation is quite artful in its avoidance of any direct or recognizable mention of the legal capacity of the university, by virtue of the new FWA, to restrict the IRB surveillance system to federally funded research. Only a very knowledgeable and discerning reader will be in a position to infer the existence of this capacity, and then only if she or he understands that what is done "as a matter of institutional policy" (in contrast to what is done because that is what "our agreement assures") does not really have to be done and that the institution is free to decide not to do it. Even the phrase "the University has chosen as a matter of institutional policy to extend such review to non-federally-funded research" throws into the shade the fact that, since the January 1, 2004, renewal of the FWA, there has been no reconsideration of "institutional policy" with regard to non–federally funded research (e.g., in the social sciences, in which most research is not federally funded).

In fact, the current "institutional policy" is not a considered choice; it is just old business ripe for reform.

Fortunately, at the University of Chicago, if enough faculty members in the social sciences, humanities, and law really care about the issues described in this article, reform can happen, and enlightened administrators are listening. Indeed, on September 22, 2005, after I e-mailed them arguing that the University of Chicago was at risk of representing itself, to itself and the world, as a satellite of the federal government, research administrators at the university—to their great credit—dropped the unfortunate first sentence from the website, and much more recently, the Committee of the Council of the University Senate has held very preliminary discussions about academic freedom and possible IRB reforms. Yet the incident is instructive. A vassal mentality, entailing that one walk on eggshells and show extreme deference to the federal funding agencies, has become almost habitual among research administrators at many U.S. universities, and it is not likely to change on its own. One counts on one's own university to be the exception. One counts on members of one's own faculty to be active in communicating their views to their administrative leaders.

The third example reveals the threat to academic values that arises from self-generated regulatory conservatism. Academic-research administrators and ethical-oversight bureaucracies within universities have a strong tendency to be risk averse, presumably because they are terrified by the very thought of a freeze on the flow of federal money or even the prospect of an audit. Many types of research in the social sciences, humanities, and law are "exempt" from IRB review, even within the terms of the 45 CFR 46 rules and definitions (see USAID 1999). For example, all of the following types of projects are exempt from IRB surveillance: writing the biography of a living person; journalistically interviewing someone for the sake of writing a social critique; observational studies of public behavior (including Internet chat rooms); survey research and other forms of interviewing with adults when the identity of the interviewee is not revealed and its disclosure would not place the interviewee in jeopardy; and studies based on data originally collected for nonresearch purposes, such as school attendance records, crime statistics, pathologic specimens that had been originally collected for therapeutic purposes, and so on. Nevertheless, most IRB committees have been very hesitant to identify and declare exemptions. Instead, most arguably exempt projects in the social sciences get put in a category called "expedited review" (which means a project can be approved by the IRB chair and does not require full IRB committee review); that initial classification decision manages to keep the research project in the IRB system and subjects it to continual surveillance and annual relicensing. In other words, because of academic administrative anxieties about dotting every *i* and crossing every *t*, the federal surveillance system indirectly generates a bias favoring overregulation, or "mission creep." This is much less likely to happen in an ethical-oversight system that shields privately funded, personally funded, and unfunded research projects from the 45 CFR 46 regulations and that is generated from within the university rather than from without.

The fourth example points to one of several ways the 45 CFR 46 rules and regulations constrict freedom of inquiry. With respect to federal grants, the federal rules and regulations require that approval of a research project only be granted after an assessment is made by an IRB of the "importance of the knowledge that may reasonably be expected to result" and "the anticipated benefits to the subjects and others." Although federal funding agencies may define their funding mission and justify it to Congress and the public on that basis (and although that standard may be appropriate for certain kinds of biomedical research), it is a misguided general norm for a research university. Complete freedom of research is the more appropriately recognized standard at leading colleges and universities. At a true university, many scholars (faculty and students) engage in research just because they are intellectually curious about a question, or even just for the fun of it. They often engage in research that other members of the faculty and the public at large may find upsetting or do not think is coherent, important, or particularly beneficial to society. In one sense, that is what the norm "complete freedom of research" is about: being able to conduct research that others think is worthless or offensive (in the hope that, in the long run, knowledge will be advanced). It is not fanciful to suggest that the extension of the IRB surveillance and licensing system beyond federally funded projects (its overextension) has the potential to inhibit or distort the life of the mind at a great university. At least with regard to non–federally funded research in the social sciences, humanities, and law, it may be a rather bad idea to empower the members of an IRB to make early and consequential judgments about the importance of the knowledge that will result from a project, or even to weigh and measure its benefits to those who are studied.

Creativity in research

This consideration is really an expansion of the last. One is tempted to note that, in the case of research that is personally funded or unfunded, investigators often begin their research long before they have worked out in their own minds a project that would be systematic enough to be formulated as a "protocol" or a "proposal." That is true even in the case of research that is ultimately funded by a private foundation or by a federal agency but was unfunded or personally funded in its initial stages. It happens to be the way the creative process frequently works in both the human and the nonhuman sciences; the creative research process is not necessarily compatible with demands for early public justification and prior review.

Privacy

Universities are legally mandated by the 45 CFR 46 regulations to report the research activities of any federally supported project to DHHS and OHRP, including complaints or accusations of wrongdoing. The extension of the regulations to all researchers, regardless of funding source, vastly expands the reporting requirement and is a burden on research administrators and a violation of the privacy of scholars who have not sought funds from the government. By retaining its legal right to not apply any or all of the federal regulations to non–federally funded research projects, a university is able to protect the privacy of privately funded, personally funded, or unfunded researchers and to respond to complaints without making it the business of the federal government. This has advantages from several points of view (privacy, liability, paperwork, administrative costs, etc.). Indeed, at the time of the most recent FWA renewal, it was primarily this consideration that motivated the University of Chicago to retain its legal right to limit the application of any or all of the IRB system to federally funded research.

Where does one go from here?

Perhaps one day a federal judge will rule it unconstitutional for federal agencies to condition a research grant to a member of a university on a commitment by that person's institution that it will engage in the ethical oversight of the research activities of all members of the institution (even those who do not have federal grants). Until that time, some form of ethical oversight at universities is likely to be legally required by DHHS and OHRP, if a university wants to receive federal funds. For research projects that are not federally funded, the exact form of the oversight is a matter for universities to decide, and they need not be bound by the 45 CFR 46 regulations, assuming they exercise their legal option to retain that legal right when they renew their FWA. Given that assumption (which now holds for the University of Chicago and at least 173 other academic and research institutions worldwide), the university's only legal obligation with regard to non–federally funded projects is to responsibly assure that all research activities related to human subjects be guided by some agreed-on set of ethical principles (e.g., the Belmont Report). Thus, here viewing things from the perspective of a privately funded, personally funded, or unfunded researcher at the University of Chicago, it ought to be possible to assure the ethical responsibility (and, ultimately, the accountability) of one's research project and to do so without subjecting one's mind and work to the procedures, definitions, and surveillance and licensing processes (the IRB) associated with the 45 CFR 46 regulations.

With an eye on possible reforms, the challenge is to honor a commitment to assure the ethical integrity of all research with human beings while minimizing the detrimental effects of ethical-oversight processes on the noble tradition of academic freedom. This should be possible at a place like the University of Chicago while still operating within the letter of the law of the original federal statute, the 45 CFR 46 regulations, and the FWA; but it will require a good deal of internal discussion and planning by appropriate ruling bodies (e.g., the faculty of the Social Science Division, the faculty of the Humanities Division, and the faculty in the Law School).

What type of reforms might be considered for the 80 percent or so of social scientists, humanists, and legal scholars (faculty and students) who are not federally funded (and are for the most part not engaged in risky biomedical research)? (Because it seems likely that some personally funded or unfunded projects are never brought to the attention of the IRB, the 80 percent figure is probably an underestimation. It is also the case that the vast majority of projects are graduate-student projects related to thesis work at the M.A. or Ph.D. level.) The overall aim of such a process of reform is presumably to maximize the autonomy of academic research scholars while at the same time educating faculty and students about their ethical responsibilities as researchers, verifying that appropriate judgments have been made about the ethical integrity of every research project, and devising mechanisms for personal and institutional liability protection that are appropriate for any university that says of itself, "By design and by effect, it [the university] is the institution which creates discontent with the existing social arrangements and proposes new ones. In brief, a good university, like Socrates, will be upsetting" (Kalven Committee Report 1967). One should not forget that the "public" put Socrates to death for being annoying and for asking questions that powerful members of the community did not want asked, which suggests the need for some form of "Socratic research insurance" to protect the Socratic style of research of many social scientists, humanists, and legal scholars.

It also suggests the need for some critical reflection on the meaning and importance of "public trust," a notion frequently invoked by IRB administrators and biomedical scientists, especially those involved in recruiting subjects for drug trials and other medical experiments, who argue that there is a public-relations benefit to the IRB system. This type of concern with public opinion—and related comments often heard about not doing things that might upset people who are being studied—would appear to be in tension with the notions that a great university will do things that are upsetting and that it is in the nature of such a university to remain independent of the pressures of public opinion (the "views held at the moment by the public") and to resist political interference with its mission. How far it is possible to convince the public to have trust in the Socratic research tradition is an open issue, but, at the very least, it should be possible to devise ethical education and verification procedures that help keep to a minimum the likelihood that NON-Socratic harms to the public will be committed

by non–federally funded researchers in the social sciences, humanities, and law. It should (and must) be possible to do so without looking at all research projects through the eyes of a public-relations agent.

The Kalven Committee Report on the University of Chicago's role in social and political action begins by saying, "The Committee conceives its function as principally that of providing a point of departure for discussion in the University community on this important question." I can only hope that this article serves that same function with regard to the questions of whether all universities should rethink their FWA and do what the University of Chicago did—retain the legal right to limit the application of the 45 CFR 46 regulations to federally funded projects—and whether the University of Chicago should now take the next step and devise its own more academic-freedom-friendly ethical-oversight system for research in the social sciences, humanities, and law (and potentially other areas as well) that is not federally funded. That is an obvious place to start, because the vast majority of projects in the social sciences, humanities, and law are not federally funded and do not involve biological or medical interventions. Why not take them out of the 45 CFR 46 surveillance and licensing system after asking faculty ruling bodies to devise a reasonable system of ethical oversight more consistent with the intellectual traditions of the academy, which, of course, have always included notions of human decency and ethical limits?

Very tentatively, one can begin to imagine some possible reforms. One of them, restricting university reports to DHHS and OHRP to information about federally funded projects only is already in place and has long been a concern of research administrators at the University of Chicago. Other reforms might involve a rethinking of the types of research in the social sciences, humanities, and law that should be viewed as exempt from ethical oversight as well as the creation of an effective system of ethical education and research integrity verification in which there is no presumption of authority to license research and issue cease-and-desist orders. According to the rules internally generated by academic and IRB administrators at most universities, research investigators, regardless of funding source, cannot themselves make the determination of whether their research is officially exempt from IRB surveillance but must appeal for an exemption from the chair of the IRB. Yet (even for federally funded projects) there is no federal legal requirement that the determination of exemption must be handled that way or that the concept of "exempt" research that might arise out of deliberative processes within faculty ruling bodies at the University of Chicago (and get applied to non–federally funded research) must be the same as the DHHS–OHRP concept of what is exempt for research that uses federal money.

With regard to education in research ethics, the Belmont Report is (for the time being) the ethical standard at the University of Chicago, although, in principle a different ethical standard can be proposed when an FWA is renewed. The Belmont Report is a thoughtful text that should be known, engaged, and interpreted with regard to concrete cases. It should be distributed to every researcher and discussed in appropriate ways by faculty and students in every relevant research program.

Verifying that appropriate ethical considerations have been brought to bear on any particular research might be done in many ways. Most privately funded, personally funded, or unfunded projects reviewed by the Social and Behavioral Science IRB at the University of Chicago are student research projects, many of which are already reviewed at the time of a thesis proposal; in such instances, ethical review could be verified with a note from the chair of the thesis committee placed on file in some central location. These are the kinds of issues that would have to be discussed, hammered out, and justified as part of the process of reforming and limiting the current IRB surveillance and licensing system.

Finally, it is worth noting again that most research in the social sciences, humanities, and law is not risky or potentially harmful in the way medical experiments might be risky or harmful, although, as any good journalist (or survey researcher) knows, people may be offended or embarrassed by the questions they are asked, distressed by perceived invasions of their privacy, or annoyed at the very idea of some particular kind of research project. Nevertheless, even though the exposure to litigation and damaging lawsuits seems minor, at best, everyone might feel less anxious about defending academic-freedom ideals if the university helped create some form of "Socratic research insurance." It would protect nonbiomedical researchers in the social sciences, humanities, and law (people who do research by asking questions and observing human behavior) from lawsuits related to the practice of their potentially annoying trade, and it would enable individual research scholars to release the University of Chicago from any financial responsibility in the unlikely event of a costly lawsuit. One imagines that this type of liability insurance would be quite affordable, given the scant history of litigation against Socratic researchers in recent decades and that many research scholars might sign up for protection. If the existence of Socratic research insurance makes it easier for all members of the academy to stand up and be counted in the defense of the very idea of a university and its traditions of academic freedom, it is well worth the price.

I hope these brief, preliminary reflections on the protection of human subjects and the preservation of academic freedom at U.S. universities and colleges are useful to concerned scholars around the country. I hope that this article prompts productive discussions or internal reviews of ethical-oversight policies. Writing a detailed program for reform of the ethical-oversight system at the University of Chicago (with special attention to areas of the university in

which most research is not federally funded) is a collective project for the future. Nevertheless, it is comforting to know that, where there is a collective will, there is now a legal way and that the tide is beginning to turn against "mission creep."

Note

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