



The Illinois White Paper

## **Improving the System for Protecting Human Subjects: Counteracting IRB “Mission Creep”**

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We also wish to acknowledge the assistance with research and cite-checking of:

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Website for conference: <http://www.law.uiuc.edu/conferences/whitepaper>

## Executive Summary

Our system of research self-regulation, designed to provide internal checks and balances for those who participate in research involving human subjects, is under considerable stress. Study after study recently has reported that this is a system “in crisis,” “in jeopardy,” and in need of thoughtful re-examination.

Much of this crisis has been caused by what we call mission creep, in which the workload of IRBs has expanded beyond their ability to handle effectively. Mission creep is caused by rewarding wrong behaviors, such as focusing more on procedures and documentation than difficult ethical questions; unclear definitions, which lead to unclear responsibilities; efforts to comply with unwieldy federal requirements even when research is not federally funded; exaggerated precautions to protect against program shutdowns; and efforts to protect against lawsuits.

Honest IRB specialists admit that they operate under constant concern about the one case in a thousand that might slip through review — with the consequence that the other 999 receive exaggerated reviews and risk rejection in an effort to err on the side of caution.

As a consequence, mission creep is causing IRBs to lose the respect and “buy-in” of the very people they are meant to regulate; they are misdirecting their energies, threatening both academic and first amendment freedoms; and most importantly, mission creep is taking needed resources from the most risky research, which truly does need IRB oversight.

Following an invitational, national, interdisciplinary conference held at the University of Illinois, recommendations were formulated to strengthen and reinvigorate the functioning of the internal review boards (Institutional Review Boards or IRBs) at universities and research centers and to gather accurate data on the scope of the problem. Our recommendations focus on *fields and methodologies* of coverage, and they apply primarily to research outside the biomedical arena.

### **We recommend collecting data.**

The greatest irony of the entire IRB debate is how little of it is informed by actual, reliable research about the facts of the problem. Experts from across the nation have identified very few studies that could even provide accurate descriptive national data (numbers of cases reviewed; numbers of serious abuses; etc.), let alone a more systematic examination of effort and effectiveness of the IRB system. We propose gathering information, both examples of good practices and examples of poor practices. We suggest the latter because the rumors and stories that make their way through the academic or national grapevine are, of course, the most sensationalistic or outrageous — cases where abuses have been most egregious and the punishments or censure have been particularly severe. Such a clearing house of information will ensure that the examples of practices that reduce bureaucratic overhead in ways that still comply with ethical and regulatory mandates are shared and will provide information helpful to other institutions seeking to improve procedures as well as substantive ethical oversight.



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IRBs need examples of methodologies that have warranted IRB oversight and those that are exempt. These examples will enable IRBs to determine such things as what is meant by risk and harm, how practice differs from research, and when a subject needs to be kept anonymous and when that is not required. These refined regulations would provide appeal procedures, guidelines specific to social sciences and humanities proposals, and lists of approved exemptions, among other things. Universities might develop different tracks and methods by which to review research proposals, tailoring the review process depending on such criteria as the field and methods of research, as well as the vulnerability of the subjects. This process would allow us to discard the current “one-size-fits-all” approach that relies so heavily on criteria and procedures developed for biomedical research.

**We recommend removing some kinds of activity from IRB review altogether.**

We recommend focusing on those areas of research that pose the greatest risk, such as biomedical research, while removing or reducing scrutiny of many fields within the social sciences and humanities that pose minimal risk. Some fields, such as journalism and ethnography, and methods, such as oral history, have their own, well-established sets of ethical guidelines and appeal procedures. In addition, they pose virtually no risk to the subjects. In the case of journalism, where a subject might be harmed with the exposure of their activities, as in the case of President Nixon and Watergate, the goal is to benefit the greater good, not the individual. This is another argument for removing journalism and similar fields from IRB oversight.

In conclusion, members of the invited conference and others affected by the IRB system recognize that the system, if not broken, is seriously straining at the seams. It is imperative that we have a respected and effective system in place to protect human research subjects, so that much-needed research into the causes and prevention of disease and other research expanding the boundaries of knowledge can proceed. We hope that this White Paper will further the discussion about what reasonable procedures can be instituted to help get IRBs back on track and do what they were originally meant to do — protect the rights and welfare of human subjects, while allowing the research enterprise to progress and its benefits to society to accrue.

The system of protecting human subjects of research in the United States rests on the efforts of dedicated, hard-working individuals devoted to fundamental principles of ethical research. Their work is vital. Our system, though, is not working as it should: it is time to refine and refocus regulations, policies, and practices in order to rededicate our energies and attention to fundamental ethical goals.



## I. IRBs are Suffering from Mission Creep

### Background

Thirty years ago, a comparatively small research community negotiated a system of human subject protections with the U.S. Congress in response to specific historical events and medical developments. These included memories of the Nuremberg trials, where the public heard about inhumane and grotesque experiments conducted on concentration camp prisoners; revelations of abuses of infected subjects during the Tuskegee syphilis study; the Beecher report describing patients unwittingly turned into research subjects by their physicians; and concerns about the meaning of life and death in light of medical advances. The system that emerged balances a number of complex, competing considerations, based upon three core ethical principles articulated by an 11-member, presidentially appointed commission in a seminal work, the Belmont Report,<sup>1</sup> and then encapsulated in a federal regulation known as “the Common Rule.”<sup>2</sup> To enforce these regulations, an entire system of locally administered review bodies,

Institutional Review Boards (IRBs), has come into being at universities, hospitals, and other research sites across the nation, operating under federal oversight.

In the decades since IRBs were first created, the biomedical research enterprise has vastly expanded in many directions, from the number of participants, to levels of funding, to the substantive and methodological issues it addresses. Technology and knowledge continue to advance across many fields, straining our understanding and confronting us with new and sometimes unprecedented choices: the dilemmas of stem cell research; the possibilities and dangers of genetic modification and cloning; the complexities of large-scale clinical trials.

### Today: A System Under Strain

IRBs have accordingly seen their responsibilities mushroom. Not only have the number and specialization of protocols IRBs review increased as the biomedical research enterprise has grown dramatically, but IRBs have expanded their jurisdiction to encompass additional fields and methodologies. As IRBs expand their responsibilities, terminology that might have been very clear in its original context is strained or ambiguous when applied to new areas, leading to imprecision and unreasonable regulatory burden as well as inappropriate regulation and restriction. For example, IRBs have imposed constraints on historians conducting oral history interviews of such stressful events as Holocaust memories or participation in civil disobedience during social protest movements and have made procedural requirements for conducting surveys that make them impractical: requiring signed consent forms before sending a survey form to participants, for example. Restrictions of this sort were never anticipated in the original regulatory framework and all too frequently have no ethical foundation to justify their application today. Our goals are getting lost in our activities.

Furthermore, IRBs are now often being asked to serve as gatekeepers for “responsible” research in a broader sense, with assignments including checking for potential financial conflicts of interest, methodological soundness, scientific merit, health record privacy, and waiver of regulations, each of which may go well beyond the ethical implications of serving as subjects of the research IRBs are designed and funded to address.

IRBs’ blizzard of paperwork is getting in the way of their fundamental mission: to protect the dignity and well being of human subjects. Without attention, somehow, priorities have shifted from fundamental ethical questions to regulatory documentation. Money, the time of researchers and IRB personnel, and good faith are squandered when IRBs require researchers

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to comply with policies that are seen as window dressing and busy work. The anecdotal litany of IRB zeal includes members of preliterate tribes being asked to sign consent forms; faculty members “investigated” for writing about their classroom experiences years earlier without advance IRB approval; projects so delayed that students were unable to complete their degrees... No comprehensive compilation exists. But, when, for this project, officials of national disciplinary societies were polled to discern the nature and extent of problems, one official refused to respond absent certification of IRB review<sup>3</sup>.

If we can redirect this zeal to its proper object, our system would be much improved. The suggestions in this White Paper are designed to facilitate this redirection.

The original tasks assigned to IRBs required a complex, delicate balancing of academic freedom and faculty autonomy with ethical and institutional constraints intended to protect the institution and research subjects. There are natural tensions between these tasks that make them difficult under the best of circumstances. The growing burden of vastly expanded responsibilities and accountability requirements makes the fulfillment of all of these goals simultaneously a virtual impossibility.

As IRBs are being asked to do more and more, they are becoming less effective. These developments form the backdrop for a situation in which the human subject protection system in the United States has been described as in “crisis,” “compromised,” or “at risk.”<sup>4</sup> Certainly the faculty members and community representatives who comprise IRBs, as well as the university administrators charged with their oversight, are feeling the strain.<sup>5</sup> Here we argue that the natural tensions of the IRB system are being exacerbated by mission creep, which we define as a more and more expansive variety of cases needing to be reviewed, a consequently burgeoning workload, and an increasingly ambiguous set of criteria by which decisions must be made. This mission creep makes it difficult to focus on the most important cases. Those cases that pose the greatest chances for risk and harm are, and always have been, in the fields of biomedical research in general and clinical trials in particular.

It is time to re-examine the goals of the system, improve its definitions, and develop better common understandings of how to prioritize the dangers that need the closest scrutiny, oversight, and intervention. We see a mismatch between legitimate goals on the one hand and actual procedures and reward systems on the other. By itemizing these problems and their chief causes, we hope to alleviate some of the conflicting demands on IRBs, to counteract mission creep, and to improve the ethical protections of human research subjects.

### Illinois Conference Examines Situation

In April 2003, a multi-disciplinary group of scholars convened by the Center for Advanced Study at the University of Illinois and, with the support of the Colleges of Law and Liberal Arts and Sciences and the Vice Chancellor for Research, held a conference on *Human Subject Protection Regulations and Research Outside the Biomedical Sphere*.

The invitational conference asked for advance position papers (see appendices) addressing “When does a person become a human subject?” in order to analyze more closely who we are seeking to protect, from what, and why. Some of the questions considered included:

- When a faculty member writes about students and the teaching process, when is that an “interaction” with human subjects that is or should be covered by federal research regulations?
- Is it appropriate or a good use of resources for a central institutional review board to govern the questions to be asked and how records are kept and used by faculty and graduate students conducting oral history interviews?<sup>6</sup>
- Why can a journalist working for a newspaper interview and publish articles and books about sensitive issues, subject only to professional ethical guidance and legal consequences, while a journalism professor must additionally seek prior approval from those outside journalism (i.e., an IRB) for the same activities?
- Is it good public policy to base the regulation of activities involving humans on where the research is performed (in terms of institutional affiliation or field setting), rather than on the nature of harm that might result?

Nationally, these questions and others like them in anthropology, business, sociology, English, psychology, law, history, education, and journalism, among other disciplines, have been causing increasing controversy over the last five to 10 years. Although we have several decades of close analysis to provide guidance to researchers and regulators in biomedical and laboratory behavioral research, there is no such body of work in the humanities disciplines.

What follows is a review of the causes and consequences of the current situation (Parts II and III) and recommendations for improvement (Part IV).

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## II. Causes of IRB Mission Creep

### Rewarding the Wrong Behaviors

Nearly 30 years ago, Steven Kerr argued that organizations often founder due to faulty reward systems. The current state of IRB programs may be attributed, in part, to an incentive structure that rewards one behavior, but expects something else — a phenomenon Kerr described as “The folly of rewarding for ‘A’ while hoping for ‘B’<sup>7</sup> and lists many reasons such a system may have developed. At least four of these reasons are at play in the current difficulties plaguing IRBs.

First, because the standards IRBs are given and the values they are expected to express are ill-defined, they are difficult to measure and reward. In such cases, organizations often take intangibles and attempt to quantify them, and in the process, the original values get lost. It may be easier, for example, to measure the paperwork that apparently documents ethical behavior than it is actually to identify and reward ethical research (or punish unethical research).

According to Ken Getz, a researcher of clinical trials, the most frequently cited lapses in IRB audits by the two main federal oversight agencies, OHRP and FDA, are “poor or missing Standard Operating Procedures” (28%) and “poor minute-keeping” (21%), together accounting for about half the citations. Quorum failures account for an additional 13%.<sup>8</sup> Thus, most citations have to do with internal IRB processes and are relatively trivial, not directly related to actual research protocols. Eleven percent of the citations are for consent elements not properly included. By overlooking that consent is a *process* and not an event or a consent form, these findings emphasize the importance that has come to be placed upon *pro forma* compliance instead of the review of fundamental ethical issues. In addition, research has shown that consent forms have become so long that participants no longer read them before signing them. Only 12% of the citations are for poor review of research. Although it is difficult to tally fundamental ethical compliance systematically, it is very easy to count how many people were present at a meeting.

Second, research proposals and designs are often more visible than the actual collection of data. Rewarding completion of onerous forms but hoping for ethical research may have undesired consequences (e.g., that researchers will try to bypass IRBs because it has become too much trouble to accommodate apparently irrelevant processes). The dynamic nature of the research process and the experience of the human subjects may be very different from what is presented in the proposal and protocol even though there is no intent to deceive the IRB. (Sieber personal communication)

Third, there is a contradiction inherent in the IRBs’ mission. Unless an IRB representative is present during all data collection, researchers must be trusted at some level to act ethically. Yet a reason for the IRB system is the belief that researchers have inherent conflicts of interest and other incentives that mean they cannot always be trusted to conduct research ethically without oversight.

Ultimately, we have to ask whether this — or any — system of sanctions or rewards can function alone to promote moral behavior. Should our IRBs be assuming this role so entirely and becoming the ethics police? In a system that trusts researchers to behave morally, and can do nothing else, researchers must internalize such values. It has always been the responsibility of our disciplinary societies and university departments to enforce these values. Is the enforcement of ethical behavior inappropriately being shifted away from these societies and departments to IRBs?

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The current state of IRB programs may be attributed, in part, to an incentive structure that rewards one behavior, but expects something else — a phenomenon Kerr described as “The folly of rewarding for ‘A’ while hoping for ‘B’.

The fourth reason is the so-called “death penalty” or program-shutdown consequence. When a university or other research institution is found to violate human-subject requirements at a certain level, all research involving human subjects within that institution can be halted on the inference that the institution is exercising insufficient oversight to sustain the privilege of using humans as subjects of research. This consequence is so extreme that it is no surprise that so much time and effort are expended to prevent it from happening. IRBs bend over backward to make sure all “t’s” are crossed, but this inevitably leads to overzealous demands that impede research and discredit the IRB. In other work examining faulty reward systems, Hamner observes that it is not beneficial to punish in public.<sup>9</sup> This is, of course, essentially what is occurring when a university’s ability to conduct research is suspended. This public “punishment” violates good practice and often leads to misunderstandings because the individuals outside of the situation do not know the details — which in turn lead to unintended consequences, including having a chilling effect. It also violates the principle that there should be some balance between the severity of the infraction and the severity of the punishment. Yet another principle not respected is that it is better to reward than punish.

### **Unclear Definitions**

Compounding the problem of there being a faulty reward system, key terms in the federal regulations governing “interactions” with human beings are simply not defined. Among the terms not defined are “risk,” “harm,” and even “research.” Only “minimal risk” is defined, as not greater than those “ordinarily encountered in daily life...” with an analogy drawn to “routine physical or psychological examinations.”<sup>10</sup> “Regulated research” is defined, circularly, as encompassing “those research activities, for which a federal department or agency has specific responsibility for regulating as a research activity.”<sup>11</sup>

This absence of key definitions was — apparently — not strongly felt when the primary application of the regulations was within the biomedical sphere. Essentially everyone within that group knew what they were talking about. However, as the biomedical research universe exploded in size and complexity, and as the biomedical model was extrapolated to other disciplines, problems began to arise. Fuzzy terminology leads to fuzzy guidelines.

The Association for the Accreditation of Human Research Protection Programs (AHRPP), for example, has an accreditation standard that reinforces and potentially extends existing misinterpretation of an IRB’s duties with respect to low-risk humanities interviews:

STANDARD II.4: The Research Review Unit systematically evaluates risks to participants and potential benefits as part of the initial review and ongoing review of research.<sup>12</sup>

ELEMENTS II.4.A. The Research Review Unit has and follows written policies and procedures for identifying and analyzing potential sources of risk and measures to minimize risk, including physical, psychological, social, legal, or economic risks. The analysis of risk includes a determination that the risks to participants are reasonable in relation to potential benefits to participants and to society.<sup>13</sup>

In other words, AHRPP standards create another layer of incentives to be over-cautious in seeking out “potential sources of risk,” even those not necessarily covered by federal regulations, thus seemingly endorsing and expanding the hyper-vigilant review by IRBs.

Even the executive director of AHRPP notes that IRBs are reaching too far, and that accreditation site visits note this often. Marjorie Speers reports that: “One of the most prevalent issues that leads to unnecessary burden for IRBs and investigators is the lack of understanding of the definition of human subjects research. Many institutions are including activities, such as use

of anonymous secondary data in studies or surveys in which no information is collected about the respondent, as human subjects research. Although these activities are research as defined by regulation, they do not involve human subjects as defined by regulation. Therefore, they do not meet the federal definition of human subjects research.”<sup>14</sup>

Still, federal regulatory guidance invites IRBs to consider the “stress and feelings of guilt or embarrassment” that “may arise simply from . . . talking about one’s . . . behavior or attitudes” to the researcher. IRBs are invited, in effect, to reject a research proposal entailing just such a conversation, one that could be carried on in the ordinary course of human interaction absent investigative intent, when they believe the good of what might be learned does not justify the risk of that “harm.” Yet such a conversation is normally not at all beyond the risks of everyday life. From anthropology to business, history, and law, IRBs straining to interpret and apply these regulations sometimes have taken peculiar stands. One IRB, for example, told “a Caucasian Ph.D. student seeking to study career expectations in relation to ethnicity that African-American Ph.D. students could not be interviewed because it might be traumatic for them to be interviewed by the student.”<sup>15</sup>

Even the term “research” has led to confusion regarding what is within an IRB’s purview. For example, many IRBs currently ask, “Was it intended for publication?” as a way of assessing whether a project falls under the definition of “research” that contributes to “generalizable knowledge.” But clearly, much scholarly work intended for publication neither can nor should be brought under IRB purview. Journalism, oral histories, and other, similar fields and methodologies are examples where material is published but does not pose risks in the same way that biomedical research does. Such work may pose risks, for the author or for others, and may conceivably do harm — but those considerations alone do not justify unduly expanding the scope of review. This is misdirected.

This is not to suggest that such work should be exempt from any sort of review or standards, but it should not be treated in the same manner as “covered research,” requiring prior approval by a research review board. Based on all of our conversations, we believe that IRBs want and need clearer guidelines for differentiating what research should and should not be within their scope of responsibility.

### **Practice/Research Distinction**

The Belmont Report itself made room for exceptions to IRB oversight. That report distinguished between “practice” and “research,” using, again, the biomedical model. The framers imagined that a doctor, searching for a last ditch cure for a terminal patient, might prescribe medicine not officially used for that disease. That would come under the heading of practice and would be considered exempt from research regulations. While a doctor, wanting to know about the efficacy of a certain medicine and prescribing it to some patients but not others to observe its effect, on the other hand, would come under regulatory review. Translating that distinction to other spheres has not occurred.

The nebulous description of “covered research” even embroils us in peculiar metaphysical speculations about when something becomes research. What if, after a lifetime of classroom activity and observations as a practicing teacher, an academic decides to write a memoir of recollections, anecdotes, and general lessons learned. When does this become research? Must the academic retroactively obtain permission from every student whose foibles might be anonymously exposed in such an account? Does it mean that a perspicacious teacher should be routinely collecting informed consent documents from every student in every class, across the years, just in case she might some day choose to write about them? While there are regulatory

options covering this kind of work, the fact that they are not well understood or implemented underscores the ambiguity in the distinctions between practice and research that exists for IRBs.

A related issue is who counts as a research subject, and when does someone become one.<sup>16</sup> There are clear examples where selected individuals are subjected to intentional interventions in order to observe particular kinds of foreseeable effects (control subjects receiving a placebo in a drug trial, for example); but then each of these terms gets stretched. Why would people sharing their memories for posterity become research subjects? When does observing passersby on a crowded city street become covered research? What actions or comments can be considered sufficiently public and voluntary to be automatically eligible for research purposes, with no further permission or review? What kinds of interpersonal interaction are simply part of the fabric of daily social life, even if in certain instances they might also be the subject of research scrutiny; or, on the other hand, does the immediate moment at which someone starts systematically observing them with an eye toward possible scholarly publication instantly transform them into something else? A literature exists on each of these questions to varying degrees, but there is not enough clarity or consensus available to resolve the issues raised above.

## Two People Talking

Considerations of what is research, when inquiry becomes research, and who we are trying to protect bear especially upon certain areas of academic effort. There are many cases where two people are talking with each other: in journalism, oral history, anecdotal research, and so on. When the participants are capable adults and understand that their words are being recorded, why should the special obligations of the researcher not end with honesty and truthfulness?<sup>17</sup> Many such conversations cannot even be categorized as an “interview” in any direct or intentional sense — or it may not be clear who is primarily interrogating whom (maybe both parties intend to write about the encounter!).

Further, despite the good intentions of protecting the human subject, there are areas of scholarly activity to which this aim of avoiding harm or embarrassment is simply not appropriate. In journalism, for example, harm or embarrassment may well come to certain individuals who are the subject of investigative studies; requiring their advance permission is inappropriate, when the primary ethical obligation is to the public rather than to the data source.

Many works of history or social and political critique have similar effects. These are knowledge-generating activities, and so in some broad sense “research,” but they are also driven by the aims of public service as a critic, a gadfly, or a public watchdog. Such areas, such as journalism, do need professional and ethical standards, and journalism has them, but in our estimation their identification and enforcement do not properly fall within IRB purview. Trying to make them fit a biomedical research does fundamental damage to the definitions and criteria that define “covered research,” contributes to mission creep, and creates an unwieldy and unnecessary duplication of effort. Even worse, it misunderstands and threatens the distinct values and purposes to which such work is dedicated; threatening, for example, the fundamental principle of freedom of the press.

An IRB panel, no doubt composed of well-meaning academics and members of the public restricting or opposing unfettered journalistic inquiry is a chilling and menacing prospect. IRB purview leaves legitimate journalistic inquiry vulnerable to capricious decisions and creates confusion in the minds of students as to what is legitimately journalistic practice and what are the restraints of biomedical and even social science human subject research. Journalism is a clear example of a field that does not fit within the IRB review process.

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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.

Expansive notions of “research” and institutional commitments to the IRB reviewing “all” human research are untenable. Regulatory definitions and their scope must be clarified.

**General Assurance versus Limited Assurance**

Another cause of mission creep is pressure universities have felt to give the federal government authority over all research involving human subjects, not just research that is federally funded.

During periods of scrutiny following the publicity of egregious problems, the instinct is to agree to apply the Common Rule universally, fueled by the desire not simply **to be** ethical but also to **appear** ethical.

This has further increased IRB workloads, often increasing IRB centralization and costs at the same time. In addition, applying federal regulations to all research has created vast unintended consequences, because, while everyone wishes to be ethical, one discipline’s guidelines for ethical behavior is another’s violation of ethics. For example, where a journalist would be bound to attribute a quote, a psychologist having the same conversation might well be bound to keep the subject’s name confidential. Furthermore, it is not always clear what constitutes a human research subject and thus what the scope of “all human subject research” is, as we have discussed. Again, the problem arises when the rules for being ethical were developed with a mindset embedded in biomedical research and then extrapolated to other areas later without sufficient analysis of suitability or, later, of the problems arising from a lack of fit.

One solution to this dilemma is to file a Limited Assurance (which applies only to federally funded projects), then to create an internal set of guidelines that follow the federal standards, but can be locally administered in more flexible and appropriate ways, and without the pressures of excessive and unwieldy bureaucracy popping up to protect against all possible harms or any conceivable procedural misstep. We return to this suggestion in our recommendations section.

**Legal Risk: Weak Argument for IRB Expansionism**

Another consideration advanced to justify the expansion of IRB review is the need for legal risk management. Because institutions may be held vicariously liable for injuries resulting from research conducted as part of the researcher’s university obligations, and because universities have often assumed the responsibility to defend and indemnify researchers sued for such damages, vetting research through IRBs is thought to protect the university by filtering out overtly or unjustifiably risky research protocols.

Yet there is almost no experience of litigation in social science or humanities research involving human subjects. And, in the biomedical area, where there has been some litigation, observers have pointed out that aggressive plaintiffs’ counsel have simply added IRBs and individual IRB members as defendants for wrongful approval.<sup>18</sup> 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.

### III. The Pernicious Consequences of Mission Creep

The combination of IRBs being pressured to cover more and more cases, and more diverse cases, without commensurate clarification of how (or even whether) traditional notions of biomedical research can be interpreted or applied, has had several pernicious consequences.

#### **Reduces “Buy In” and Effectiveness**

One could assume that mission creep might amount to a mere annoyance, but in reality it has far-reaching and expensive consequences. Compliance systems like the IRB require respect and buy-in by the regulated to function. Mission creep damages the entire compliance system, because researchers find IRB requirements to be overwhelming and sometimes illogical. One example of this is consent forms running 20 pages or more. They are so long and detailed that most subjects, it has been observed, sign without reading them. As IRBs continue to be stretched thin and make decisions seen by others as inappropriate, IRBs get demonized, and their credibility is undermined.

Furthermore, as IRBs’ reputations decline and their workloads burgeon, good people grow increasingly reluctant to serve on them, compounding and magnifying any pre-existing problems or difficulties. IRB staff at one major university recently drew up a list of 20 experienced senior faculty thought to be especially suitable for appointment as IRB chair but could find no one willing to serve. Even among the entire IRB membership there are virtually no full professors.

Perhaps most disturbingly, when the workload for IRBs mushrooms, real problems are more likely to slip through. Our system as it currently stands has become more susceptible to misuse, because it so often does not have its eye on the right ball. These real problems may have serious consequences to human subjects and are the very ones IRBs were created to prevent. The disproportionate attention to problems that can be easily addressed, such as counting signatures, filing forms, refining consent forms over and over, and editing protocols for typos, means that complex ethical questions on which people of good will can disagree may get short shrift.

#### **Misdirects Energies**

IRBs are wasting their energies on non-risky research. In biomedical research, the nature of harm that might be done is clear: the infliction of pain or physical or mental impairment of potentially long, even lifelong, duration that may affect one’s ability to earn a living, to relate to others, to function in life. In the social sciences and humanities, the regulatory instruments draw attention far more broadly to general categories of economic loss, stress and emotional distress, invasion of privacy, in the sense of both unwarranted intrusion and dissemination of personally identifiable information, and deceit, which is sometimes taken as a harm in itself and sometimes as a multiplier of other harms.

But, unlike in biomedical research, these very risks and harms can, conceivably, be inflicted without ever interacting with the human subjects of the research. For example, a social science or humanities investigation may well result in one or more of the very harms that would permit an IRB to reject the project if it involved collecting data from personal interaction with a human subject. But, if all data is collected from public sources, then IRB approval is not required, even though these same risks exist. Why, we must ask, should IRBs be given the power to deny research, based upon their weighing of a given set of harms, when a research project posing the same risks but involving publicly available data rather than individual interaction does not require IRB review?

More than 20 years ago, Edward Pattullo, director of the Center for Behavioral Sciences at Harvard, observed: “To single out one sphere of social activity and to subject it to legal constraints based on a concept of harm that the law does not recognize elsewhere is, at least, unusual. The need should be clear and compelling.”<sup>19</sup> That concern has gone unaddressed. The major concern with the harms identified in the regulatory guidelines applicable to the social sciences and the humanities flows far more from breach of confidentiality after the research has been completed than from the conduct of research itself. As Eleanor Singer and Felice Levine explain:

Unlike clinical research, which at times involves the risk of physical injury and even death as a direct result of a research intervention, the most severe harms likely to befall subjects in social science research arise from potential breaches of the confidentiality of the data collected. Thus, for example, loss of job, criminal prosecution, and public humiliation are all potential consequences of revealing damaging information that a research subject has disclosed to an investigator.<sup>20</sup>

Insofar as confidentiality is the nub of regulatory concern, it can be dealt with without invoking the machinery of IRB research review and approval at all. The institution could (and should) promulgate a rule prohibiting the public disclosure of all harmful, personally identifiable information in which the public has no interest unless the person concerned has given consent or in response to lawful process — *i.e.*, the institution could simply adopt the law’s standard and require its observance. We are by no means arguing that such harms are negligible or that protections should not be in place to prevent them; but they are harms of a significantly different order, predominantly temporary in their impact, more continuous with the risks “encountered in everyday life,” and, we suggest, beyond the proper scope of the IRB. Attaching to them the same degree of severity as the risks to life and health posed by biomedical research is, in the vast majority of cases, counterproductive and even incoherent. Worse, outside of the broad protections of informed consent and confidentiality, their predicted likelihood in any particular case is incalculable in advance. IRBs have no reasonable way to assess these harms.

The federal regulations governing the use of human subjects in research define “minimal risk” activities using the benchmark first suggested by the Belmont Commission: “Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”<sup>21</sup> Have you had a cancer screening test lately, whether mammogram, prostate check, or colonoscopy? How did it feel the last time you struggled to get your taxes done on time? Or to be in a major traffic jam when driving to an important appointment, or when work and family responsibilities were in serious conflict? If we consider the indignities of a routine physical exam or the wear and tear on our psyches in the challenges of daily life, it becomes harder to understand the extent to which some IRBs have undertaken to protect adult participants in various activities from their own choices — in effect violating the Belmont Report’s foundation principle of respect for the autonomy of persons and their decision-making capacity.

### **Canadian Response**

Our colleagues in Canada are considering some of these same policy matters. The Social Sciences and Humanities Research Ethics Special Working Committee (SSHWC) submitted to the Interagency Advisory Panel on Research Ethics (PRE) a report proposing a number of changes. Although they use the term “ethics drift” instead of mission creep, the analysis and solutions sound strikingly similar to the policy discussion underway in the United States.

The SSHWC proposes that, “In some scholarly domains, default assumptions regarding risk should be reconsidered, with the bio-medically appropriate concept of ‘minimal risk’ being reformulated as ‘identifiable harm,’ with the attendant need for clarification of which ‘harms’ in the social sciences and humanities might warrant attention.”<sup>22</sup> At the very least, moving to a situation in which a harm must be identified, perhaps from a pre-existing list of harms, would be an improvement over protecting people, for example, in two-people-talking situations from imagined harms.

The SSHWC report goes a step further to propose that we redefine “human subject” as requiring a “power differential between researcher and participant that arises from the nature of the relationship, conflict of interest, clear subject incapacity, and/or opportunity for coercion. In the absence of such indicators, we suggest that PRE exempt such research from...review...”<sup>23</sup> Although this concept of “power differential” is an important one, it probably needs to be altered before importation back to the United States, where “power differential” has come to mean many things to many people. Note, for example, that IRBs in the U.S. are often reported to perceive power differentials in a large number of settings where others might not.

### **Covers Some Fields, Such as Journalism, Unnecessarily**

Unfortunately, the combination of mission creep and excessive regulatory caution, coupled with the deeply flawed but all-too-common IRB rule of thumb for detecting the presence of research (intended for publication), leads IRBs to assume oversight of projects that are far afield of truly risky or harmful projects.

We argue that there are many cases where IRB oversight is not needed, either because a certain field or methodology already has well-established ethical guidelines or that a given field or methodology does not carry with it any of the threats of risk or harm that requires human subject protection. Those fields and methodologies include but are not limited to journalism, oral history, and ethnography. Take, for example, one IRB, which heard about an essay by an assistant professor of English and African American studies and threatened to block its publication. The creative non-fiction essay was about a class taught at another school, though neither the school nor the students were named. The professor’s current school demanded permissions and reports of events described in the essay, which had already been accepted by a distinguished literary journal. Several senior campus administrators and members of other national organizations had to intervene to restore a balanced perspective.<sup>24</sup>

When it comes to the practice of journalism and how journalism is taught in a university setting, for example, the IRBs strictures are particularly onerous.

Journalists teaching journalism to university students emphasize the public service aspect of the craft and impress upon students that their first obligation is to the public, just as practicing physicians’ first obligation is to their patient. This concept is essential to journalistic ethics. That obligation to the public means, for example, that interviewees must be clearly identified by name and meticulous attention be given to the accuracy of their quoted remarks. Only in rare instances should an interviewed person be granted confidentiality and then, only when the interviewed person has a legitimate fear of job-related retaliation or societal condemnation. Confidentiality is granted to rape victims, who could suffer unwanted public attention. Corporate and government officials are often granted confidentiality when leaking information that provides the public with information but could lead to a punitive response against the sources if their names were known. Journalists go to jail to protect this principle. These are examples of the well-developed ethics code that professional journalism has developed and that academic journalists teach.

Consequently, IRBs' frequent requirement that interviewees be entirely anonymous directly conflicts with journalism's ethical code and reduces the credibility of the journalist and the student of journalism. This is an intolerable position for the journalist and the student, forcing them to violate the ethical consensus of their discipline.

IRB regulations distinguish teaching from research: the conduct of the latter requires clearance, the former does not. But research is defined as a systematic effort to contribute to a body of knowledge. Journalists do that by reporting on events, large and small, their causes and consequence. As a result, the doing of non-instructional investigative journalism could enmesh the journalist—teacher or student—in the regulatory scheme, but the teaching (and learning) of the doing would not. It is difficult to find a principled ground for this gossamer distinction in terms of the harms human subjects are supposed to be protected from; and in practical terms, it is asking far too much of an IRB to apply.

But the fact remains that the interviewing (a.k.a. reporting) done by journalists is fundamentally different from the individual human subject focus of biomedical and some social science research. Again, journalists' first obligation is to the public's right to know and not to the *human subject* interviewed. Journalists hold government officials and employees publicly accountable for their actions and inactions. An unrestricted range of private citizens is approached for comment and interviews on any public interest topic within the universe of human experience. No topic or individual is sacrosanct from the inquiring reporter. If things were otherwise, Richard Nixon would not have been the first president ever to resign from the American presidency in August 1974, after his complicity in the Watergate burglary cover-up was published for the entire world to read on the front pages of *The Washington Post*.

### Threatens Academic Freedom

Finally, academic freedom is threatened through a chilling effect in which some studies are not even proposed for fear that they will be rejected, while others are reframed simply in order to obtain IRB approval. The literature is replete with anecdotal examples of work scaled back or never attempted because IRB reviews are too burdensome or unresponsive, as in this situation described in a journalism department:

This faculty member, in a survey course he taught regularly, wanted to study drug use on campus, but the IRB was worried about embarrassing students or perhaps causing them legal problems as a result of their being asked about their use of drugs. The university's attorney eventually cleared the project, but the professor has had similar problems getting approval for surveys on binge drinking, date rape, and academic dishonesty. These topics are of critical importance to the university community, yet each could lead to problems for the participants. Because of these potential problems, IRB roadblocks have multiplied. The professor says he now limits his class projects to "bland topics and archived records."<sup>25</sup>

The exercise of academic freedom implies a responsibility to adhere to the discipline's ethical norms when conducting research. In the biomedical and closely related laboratory behavioral sciences, these norms have assimilated the Belmont principles, so the application of them by the IRB system has not proven objectionable. So, even though IRB approval is linked to funding, the IRB system corresponds closely enough with those disciplines' ethical norms that there is generally no conflict, and the question of academic freedom is not challenged.

And academic departments have the power to censure or discipline faculty who are not following these rules. When IRBs then try to apply regulations developed for traditional biomedical research, they overlook these guidelines that are already in place and have proven effective. Some would argue that self-regulation, as within a department, is not reliable, but the

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Finally, academic freedom is threatened through a chilling effect in which some studies are not even proposed for fear that they will be rejected, while others are reframed simply in order to obtain IRB approval.

restraints IRBs impose are so much worse that it makes the “cure,” i.e., IRB oversight, worse than the disease, i.e. difficulties in self-regulation.

### **Threatens First Amendment**

IRB restrictions on academic investigation should trigger much the same concern as when First Amendment freedom of speech is constrained. As the late Thomas Emerson, professor at Yale Law School, pointed out almost half a century ago in his seminal work, *The System of Freedom of Expression*, the special evils of prior restraint lie in “the institutional dynamics” of its administration: “a tendency to expand in coverage, zealous, or wooden enforcement, a predilection for the easy adverse decision, low public visibility, and limited independent review” as well as in the general concern about vague and overly broad regulatory language that encourages these specific evils.<sup>26</sup>

The vagueness of the standards emerges directly from the text of the regulations. IRBs are directed to determine whether or not:

Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.<sup>27</sup>

In making the latter assessment, the IRB is directed to disregard “possible long-range effects of applying knowledge gained in the research,”<sup>28</sup> for example, the effect of the research on public policy. This ostensibly insulates research from institutional censorship on the ground of the potential political reaction to it; but the IRB is also directed to be sensitive “to such issues as community attitudes”<sup>29</sup> in striking the balance. These dual directives are incompatible: What effect does the bringing of “community attitudes” to bear in the process of decision-making have if not to weigh local sensibilities regarding the propriety of the inquiry or of what it might reveal? The history of academic freedom is of a struggle very much to free research from the constraints of “community attitudes” toward the propriety of the subject investigated. The threat to academic freedom here is palpable and is not assuaged by anything else in the system. IRBs are given final discretion to disapprove proposed research under the most arbitrary balancing of potential benefit against risk of harm in light of the community’s perceived attitudes. And there is no independent process in place to appeal those decisions. The system bears the seeds of all the evils Emerson identified.<sup>30</sup>

### **Prevents Oversight of Truly Risky Research**

Clearly, biomedical research generally carries with it far more risk of harm to human subjects and, thus, requires more scrutiny. The growing expansion of IRB oversight of non-biomedical research has had the unintended consequence of decreasing involvement and effectiveness in the original purpose of the initiative, namely preventing risky uses of humans in research. IRB regulation of very low-risk social science and humanities research diverts needed resources from areas of greatest need to those areas with minimal or no risk. This dynamic threatens the fundamental issues of human subject safety that IRBs were created to address.

The need for IRB oversight in medicine, particularly clinical trials, continues to grow. Clinical trials alone have grown in number and complexity and now frequently encompass multiple sites. The protocols for these studies are vast and complex. Not only are research institutions conducting these sorts of trials, but pharmaceutical companies need IRB oversight. Not only are IRBs being asked to review these more complex protocols, they are being expected to monitor the trials for safety. It is IRBs that receive the “adverse effects” forms from clinical trials, yet many have no system to manage these data. Some have suggested developing a different system to monitor these large trials, but until that happens this is just one more area where IRBs are being swamped and where mistakes can be damaging.

In addition, four other factors within the biomedical research community appear to further increase IRB workload. The first factor involves funding concerns, such as potential conflicts of interest when a researcher has a financial stake in a drug being tested. (Research shows that clinical trials funded by those with an interest in the outcome tend to have more positive results than others.<sup>31</sup>) This results in the need for extra care and scrutiny. A second factor requiring increased IRB activity is the political environment with intensified scrutiny of biomedical approaches that attract attention from activists concerned about a particular view of the sanctity of human life.<sup>32</sup> A third consideration is the need to protect at-risk groups.<sup>33</sup> Finally, the malpractice environment poses risks never before considered, including concerns about malpractice suits against researchers involved in clinical trials and the desire of insurance companies to exclude coverage for these activities from standard contracts. Based on all these factors, there is clearly an urgent need for careful, thorough, adequately resourced IRB review of biomedical research. If resources devoted to IRB activities are not to be constantly increased without end for additional staffing, course reductions, or payments to IRB members in consideration of the increased workload, etc., resource diversion to low-risk research in non-biomedical disciplines cannot be supported.

### **IRB Power: Censorship or Rubber Stamp?**

When people have criticized the IRB system, their concerns have often been met with two responses, which, ironically, proceed from opposite assumptions: The first is that all research with human subjects is so potentially dangerous that the IRB has no choice but to scour every project *a priori* and to have final authority regarding its safety. The second response is that the process of obtaining approval is so trivial, like a rubber stamp, that complying should be no big deal.

The first argument says that what is involved is action, not speech, which the institution is free (or, at least, freer) to regulate. Yet this response rests on a false dichotomy between speech and action. There is no doubt that biomedical research involving the administration of drugs and some kinds of laboratory behavioral research, potentially involving the subjection of the person to similarly unpleasant conditions, is physical action of such a nature as to legitimate some form of regulation. But speech may also involve physical action — leafleting the public, dancing in a state of undress, burning a flag. These “speech acts” are protected by the first amendment. Suffice it to say, most of what is done by human interaction in the social sciences and the humanities involves nothing more than speech: a conversation, a questionnaire. To be required to secure a permit before one can have a conversation is the antithesis of freedom of expression or inquiry.

The second response involves the claim that the harm of (over)regulation to the investigative process is quite rare. At the UIUC conference, a figure of 1%-2% rejection rate in the social sciences was suggested. All that is really involved, says this camp, is a bit of “paper shuffling” of no great consequence. But this response, asserting mere “inconvenience,” could be said of any system of censorship: The vast majority of mundane magazines, books, plays, and films required to be submitted under such regimes present no issue to trigger censorship. But it is inherent in all such systems that we cannot know the degree of self-censorship the artist, or scholar, exercises, what avenues of expression, or investigation, are eschewed or detoured around. Given the absolute power, devoid of checks and balances, exercised by each IRB, that consequence cannot be quantified; but, as all such systems are devised to deter conduct that would fall afoul of them, the threat of self-censorship, as an inherent component of the system, cannot be so easily dismissed. Beyond such fundamental if less obvious censorship, the cost to projects of delays in approval is often far from trivial.

## IV. Recommendations

### **Recommendation One: Empirical Research is Urgently Needed to Inform Our Policies and Choices**

Perhaps the greatest irony of the entire IRB debate is how little of it is informed by actual, reliable research about the facts of the problem. The Illinois conference, a national conference of experts on this problem, identified very few studies that could even provide accurate baseline national data, let alone a more systematic examination of the effort and effectiveness of the IRB system. Undertaking such studies should be an immediate priority of faculty committed to the ethical conduct of human research and a high funding priority for the agencies setting national policies in this area.

In fact, examination reveals that virtually no scientific evidence is brought to bear on any aspect of the debate about how IRBs function. Unrealistic and untested assertions abound. At the micro level, this includes, for example, how IRBs decide what is adequate and respectful informed consent, what subjects perceive as risk, and what kinds of benefits to subjects and their communities make the relationship fair. At the macro level, there is virtually no research on the functioning of IRBs (numbers of protocols reviewed, numbers of serious abuses by discipline, common turnaround time, etc.) or of the effectiveness of the IRB system in protecting human subjects.

The National Research Council has strongly recommended that systematic research be undertaken on both of the micro and macro questions.<sup>34</sup> Fundamental issues must be addressed in order to act on this urgent recommendation: What rewards are there for doing such research? How many IRBs would heed the findings of a competent investigator on such questions? Where would one publish research on IRBs and related topics? Fortunately, the new Journal of Empirical Research on Human Research Ethics (JERHRE) has international standing, has already gained a wide readership, and may foster much needed evidence-based ethical decision making and dissemination of best practices. See [www.JERHRE.org](http://www.JERHRE.org). This venue and more are needed.

We urge investigators and agencies to turn energies to this area so that our policy making is rooted in both careful ethical analysis and grounded research about how to make our policies congruent with our goals.

### **Recommendation Two: IRBs need more than a set of regulations that were designed for biomedical research.**

IRBs need access to guidance on three dimensions: (A) applications of the definitions such as “risk” and “harm” in specific instances, (B) examples of best practices in use at other institutions on procedural matters, and (C) organizational guidance designed to streamline review and make it more efficient and effective. Each social/behavioral discipline or methodology raises different issues and raises difficult problems of interpretation of 45 C.F.R. 46. Social/behavioral IRBs need better information and better processes — and to know, with confidence, appropriate limits for their deliberations.

One way to achieve this is to gather and share practical guidelines on how IRBs should operate, differentiated by discipline and methodology, acknowledging that the mission creep experienced in many places is neither good policy nor a good use of resources to protect human research subjects.

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In fact, examination reveals that virtually no scientific evidence is brought to bear on any aspect of the debate about how IRBs function.

This guidance should be vigorously disseminated, not allowed to die on the vine, as has happened with the “clarification” issued by the Office of Human Research Protection (OHRP) that “most” oral history should not be considered “research” under the purview of an IRB. Since this policy clarification was issued, it has been little noticed nor put into practice. Oral historians continue to struggle to do their work and deposit it in archives; indeed, according to one IRB, even analyzing Ronald Reagan’s taped speeches deposited at the Reagan Presidential Library would require IRB approval because Reagan (at that time) was still alive—and this was almost a year after OHRP issued its ruling.

With federal leadership — or, if necessary, without — the IRB community should develop nationally shared understandings of “best practices” in both substance and procedure that are shared widely. Accreditation agencies are one possibility for promulgating such practices, but there is considerable concern that present standards and efforts to pursue an accreditation mechanism are intensifying and institutionalizing, not mitigating, mission creep.

## **2A. Methodological Guidance: IRBs need methodologically grounded examples to use in their deliberations and decisions.**

IRBs need access, organized by research methodology, to examples of risk, harm, practice vs. research, confidentiality vs. anonymity, etc. This means being clearer about the severity of various kinds of outcomes and setting priorities accordingly. In part, that requires clarifying the application of certain keywords, such as “risk” and “harm,” in non-biomedical settings. Minimal or every-day risk is supposed to be a kind of ambient risk that should not concern IRBs, yet many IRBs make decisions as though life can be risk free. Presently, the words “risk” and “harm” are used routinely, and often unreflectively, in IRB discussions.<sup>35</sup>

An important aspect of approaching the review process by research methodology is that the IRBs become more sensitive to ways in which they can do more harm to society at large by muddling investigators’ sampling strategies and thus forcing the investigator to gather inaccurate data — on which social policies would then be based.

We must clarify, perhaps in a best practices compendium, information for IRBs so that they can more confidently identify cases when they might exempt activities because they are practice, not research. If IRBs could look to a clearing-house to see that a number of other institutions were also adopting the interpretation — or a beleaguered scholar could cite such information in an application or appeal — this could be widely useful.

We also need to re-examine the scope of what counts as “covered research.” Meanwhile, if a clearing-house of cases and methods of treating them could be established, that could at least provide concrete data for better-informed deliberations at a local level. Such a clearing-house would also contribute to providing a more precise measure of the scope of the IRB problem.

Currently we have often “policy-by-anecdote,” essentially gossip that frequently exaggerates worst-case scenarios, so that more and more expansive policies and procedures get adopted. Experiences from elsewhere, if carefully documented, can provide a very reliable guide to local action, especially in grappling with the very difficult and complex task of differentiating cases and drawing workable distinctions to allow the assignment of research to different types and degrees of formal review. Such a clearing-house might provide not only guidance but protection (legal and otherwise) for IRBs and institutions that can cite concordance with “best practices” reflecting a variety of contexts.

**2B: Procedural Best Practices: We must foster development of best practices in the operation of IRBs.**

One of the pernicious consequences of mission creep discussed above is the pressure for ever-more centralization of IRB review, in part driven by fear of the heavy penalties that institutions found not in full compliance with federal regulations might face. There has been a trend in recent years for institutions to move toward filing legal assurances with the federal government that they will apply the Common Rule to all research conducted under their auspices, rather than just federally funded research, as is the requirement of federal law. This practice has the unfortunate effect of adding to the pressure to centralize and to homogenize review.

Shared “best practice” understandings should encompass such items as:

- Appeal procedures
- IRB membership for considering social sciences and humanities proposals
- Method-specific review tracks
- Different levels of intensity of review so that careful analysis can be given where it is needed
- Policy seminars for the IRB that bring cross-disciplinary views to bear
- Lists of approved exemptions
- Circumstances in which waivers of consent are not only appropriate but ethically preferred or required

**2C: Limited Assurances: Universities should file assurances limited to federally funded research to combat mission creep while maintaining the highest ethical standards.**

We have few illusions that the present big-picture recommendations will be easy to implement. Thus, we propose some additional steps that can be taken within institutions that do not require concerted action before implementation. Concerted national action based on other recommendations in this report will reinforce and support micro solutions that are within the reach of every local IRB right now.

One solution is for institutions to limit mission creep without compromising ethical practices by filing a Limited Assurance (which applies only to federally funded projects). This does not mean that the institution will apply a lesser ethical standard for other research: the institution can (and should) then create an internal set of guidelines that commit to the highest ethical standards. Under this approach, however, local research can be overseen in more flexible and appropriate ways, without the pressures of excessive and unwieldy bureaucracy popping up to protect against all possible harms or any conceivable procedural misstep.

This model is already in use in most research universities for matters of research misconduct and financial conflicts of interest in research. Thus, the federal regulations apply only to federally funded research, but virtually all institutions promulgate their misconduct policies (for example) to apply to all those conducting research under institutional auspices. Further, many institutions treat the federal standard as a minimum — an ethical floor — not as an ethical ceiling. The main difference, should an allegation of misconduct arise in research that is not federally funded, is that there is no obligation to report the matter to any federal agency, nor is there federal oversight of the handling of the matter.

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institutions treat the federal standard as a minimum — an ethical floor — not as an ethical ceiling.

Institutions could apply this model — one they are likely already using — to research involving human participants and then move to more appropriate models for review of research outside the biomedical arena.

This report has framed the central problem with human subject review as one of mission creep, meaning that more and more types of research are subjected to closer and closer IRB scrutiny, with no evidence that serious abuses have been made less likely. The effect of mission creep has been not only to make the workloads of these committees increasingly onerous but to make it — ironically — *less* likely that truly troublesome cases will be identified or prevented in advance.

We call for a different approach, one using the classic “optimize/maximize” distinction. Filing a limited assurance and rethinking the local review circumstances — guided by information on national best practices — is achievable even now.

We must accept that no system of review can be made perfectly safe and should, instead, focus on proposed work that has the greatest potential for harm. Given these resource constraints and the dangers posed by the unintended consequences of mission creep, our proposals below seek to increase the likelihood that the cases *most likely* to have *serious* consequences will be *most likely* to receive the *most thorough* level of review. Each of these highlighted terms reflects a selective judgment that needs to be made, and the proposals detailed below are directed toward facilitating these judgments.

We return to our recurring theme: it is important to focus IRB scrutiny and resources where they are most needed and where they are most appropriate. We must abandon the “one-size-fits-all” mindset for identifying and reviewing covered research.

**(1) Different tracks/pathways.** Not all scholarly writing for publication should be treated the same way or be subject to the same kinds of review. IRB procedures should include explicit criteria by which work can be assigned to different types and levels of review. Work from different disciplines and methodologies might go through entirely distinct review processes.<sup>36</sup> One possibility would be to create small review committees organized around disciplines and research methods. As one possible model, distinct from standard IRB implementation, researchers could complete a short checklist with a few sentences of description and then meet with the committee members about the protocol. This would have the added benefit of reducing paperwork on both sides and reduce the effort to anticipate all possible objections on the investigator’s side. The committee would have at least one outsider to make sure the process is not simply a formality. This model would allow, rather than a generic community member sitting for all submissions, a different community member on each committee, each more appropriate for reviewing a given type of work. Some types of work would still undergo full, traditional, rigorous review, but other types should be assigned to different procedures.

Such a model would require some up-front decisions and ongoing consideration. For example: Who decides what work can be assigned to subcommittees of the IRB board, and what work requires complete vetting and full committee approval? What work can be assigned to within-discipline review committees (guided by their own profession’s formal ethical standards) and left out of the formal IRB process entirely? What work, finally, should be left up to the professional judgment and discretion of individual investigators, operating under the protections of academic freedom, unless and until there is some demonstrable reason to treat it otherwise?

We do not pretend that these are easy questions. We argue that they must be asked, rather than assuming that a single model fits all types of scholarship. They must be asked, because the present national IRB trajectory is unsustainable.

**(2) Different degrees of intensity.** IRBs also should vary the closeness of review in relation to the level and type of risk and to the vulnerability of the subject group. These interrelated criteria begin with the assumption that for autonomous adults acting in presumptively public domains, a certain level of risk is unavoidable — and that the illusory pursuit of zero risk inevitably comes at the cost of other important goals. This assumption is clearly part of the Belmont principles. IRBs typically have a very coarse version of this notion, separating proposals as having more than or no more than minimal risk. We advocate a finer-grain model. Consequent questions are: (i) what types and levels of risk properly fall under IRB concern (such as emotional upset, or more serious trauma—where the research shows this is a realistic danger?<sup>37</sup> damage to self-image, privacy, or reputation? physical harm or injury?) and (ii) what distance from “autonomous adulthood” justifies the paternalistic intervention of IRBs, over and above the requirement of informed consent? We do not minimize the difficulty of adjudicating these twin criteria, especially as they are interdependent. But without some procedures and demarcations, IRBs will face, as we have argued, an unending mountain of projects to review, in the process squandering attention on cases where there is little risk of serious harm.

Having determined what cases they will review, and how intensely each will be reviewed, IRB members can then determine how to handle cases that require after-the-fact adjudication. They should establish a campus appeal process, including sanctioning guidelines, as well as articulating other legal recourse subjects might have.

**(3) Distributed review processes.** These twin procedures (multiple pathways of review and multiple degrees of intensity of review) provide the basis for what can be called a “distributed model” of research review, one based on shared responsibility and delegated tasks, and one that draws sharper distinctions between research that poses genuine risks and hence requires close inspection and the vast bulk of studies that merit much less intense types and levels of review — or no prior review at all.

Our aim here is not only to alleviate the workload of IRBs but to assure that the cases posing the greatest risk are most likely to receive the most rigorous attention. Related to these concerns, we also have argued that certain types of research appropriately merit very different kinds of review, according to very different criteria; and that the “one size fits all” approach is both counterproductive and threatens certain kinds of academic freedom and/or professional discretion.<sup>38</sup>

### **Recommendation Three: Some Activities Should Not Be Reviewed By IRBs.**

We believe that most journalism and oral history cannot be appropriately reviewed under the Common Rule (45 C.F.R. 46). Our conference and other work nationally makes this clear. There may be other disciplines and methodologies where the fundamental purpose of the work is not or should not be measured in terms of the rights of the subject. Despite good intentions to protect the human subject, there are areas of scholarly activity for which this aim is simply not appropriate. In journalism, for example, harm or embarrassment may well come to certain individuals who are the subject of investigative studies. Does their permission need to be obtained in advance, when the primary ethical obligation is to the public rather than to the data source? Such professional activities, and their goals, are quite distinct from biomedical research. Concerns about the conduct of these activities are better left to those bodies that are competent to review them.

In summary, expansive notions of university “research” and institutional commitments to the IRB reviewing “all” human research are untenable. The scope and purpose of IRB review must be clarified.

This paper lays out a number of the issues on which the Illinois conference focused. We have argued that well-motivated traditions have come to be applied in inappropriate ways to domains for which they were never designed. Furthermore, we have argued that this mission creep not only compromises an increasing array of disciplines but undermines efforts to deliver appropriate protection even in traditional biomedical domains. Mission creep, if unchecked, will only spiral further out of control, potentially rendering human subjects protection efforts ineffectual. We believe that mission creep must be addressed openly, thoughtfully, and systematically. The recommendations offered here pose difficult challenges of principle, policy, and implementation, but action is urgently needed to ensure that IRBs successfully balance the many considerations involved in protecting human research participants.

## Endnotes

<sup>1</sup> National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. “The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.” Washington, D.C.: U.S. Government Printing Office (1978). DHEW Publication No. (OS) 78-0008.

<sup>2</sup> Code of Federal Regulation, Title 45. Public Welfare Department of Health and Human Services, Part 46: “Protection of Human Subjects.” (Revised June 23, 2005; Effective June 23, 2005; also known as the Common Rule).

<sup>3</sup> The questions being posed were:

- Is your professional society/organization tracking problems your members are encountering with IRBs? If so, what form does this take?
- Do you have any data you would be willing to share?
- If not, do you have any indicia of problems, such as complaints from members, sessions at annual meetings, etc?
- If you are not the right person within your organization, can you send me to the person who is the right person?

One response (not meant ironically) was: “I’m happy to answer your questions, but before I do so, and as chair of a social, humanist and behavior IRB, I must ask: Does Professor Gunsalus have IRB approval for her study???? (I believe people who investigate IRBs should model the elements of the Belmont Report that we require of our investigators who study other problems.” Personal interaction. C. K. Gunsalus and Megan Rudd, 28 August 2003 with unnamed IRB official (name on file).

<sup>4</sup> The findings of the Advisory Committee on Human Radiation Experiments (1995).

U.S. Advisory Committee on Human Radiation Experiments. “Advisory Committee on Human Radiation Experiments: Final Report.” Washington, D.C.: U.S. Government Printing Office (October 1995).

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Levine, R.J. "Institutional Review Boards: A Crisis in Confidence." *Annals of Internal Medicine* 134:2 (2001): 161-163.

Citro, C., D. Iglan, and C. Marrett. *Protecting Participants and Facilitating Social and Behavioral Sciences Research*. Washington, D.C.: National Academies Press (2003).

<sup>5</sup> Gunsalus, C.K. "The Nanny State Meets the Inner Lawyer: Overregulating While Underprotecting Human Participants in Research." *Ethics & Behavior* 14:4 (2004): 369-382.

<sup>6</sup> This was raised before the new federal interpretation that oral history is usually not "generalizable research" and thus not covered by the human subject regulations. However, reports suggest that this interpretation has been little heeded and, at best, is being implemented unevenly.

Shopes, L. Remarks before the National Bioethics Advisory Commission, Washington D.C. (April 2000); subsequently published in *Perspectives*, the publication of the American Historical Association.

Townsend, Robert B. and Mériam Belli. "Oral History and IRBs: Caution Urged as Rule Interpretations Vary Widely." *Perspectives* 42:9 (December 2004).

<sup>7</sup> Kerr, Steven. "On the folly of rewarding A, while hoping for B." *The Academy of Management Executive* 9:1 (1995): 7-16.

<sup>8</sup> Getz, Kenneth. (Research fellow, Tufts Center at Tufts University). "Prevention of Fraud and Non-Compliance in Clinical Research." DIA Annual Meeting, Washington D.C. (June 2004).

<sup>9</sup> Tosi, Henry L. and W.C. Hamner. *Organizational Behavior and Management: A Contingency Approach*. Chicago: St. Clair Press (1974).

<sup>10</sup> *Supra* note 3, § 46.102(i).

<sup>11</sup> *Id.* § 46.102(e).

<sup>12</sup> Association for the Accreditation of Human Research Protection Programs. "AAHRPP Accreditation Standards." AAHRPP (May 2004).

<sup>13</sup> *Id.* at 7.

<sup>14</sup> Marjorie Speers. Executive Director, Association for the Accreditation of Human Research Protection Programs, Personal Communication October 15, 2005.

<sup>15</sup> Sieber, J., S. Plattner, and P. Rubin. "How (Not) to Regulate Social and Behavioral Research." *Professional Ethics Report* 15:2 (Spring 2002): 1-4.

<sup>16</sup> Steele, Robert M. "What Turns a Person Into a Human Subject? How Do We Find and Then Draw the Lines? & Is There a Difference Between Those Who Do Academic Research and Those Who Practice Journalism?" *Illinois Conference Proceedings* (2003). (Unpublished position paper, on file with the University of Illinois College of Law Human Subject Policy Conference website <http://www.law.uiuc.edu/conferences/humansubject/index.asp>).

<sup>17</sup> Gunsalus, *supra* note 5.

<sup>18</sup> In one case in which reliance on IRB approval was argued, the highest court of Maryland castigated the IRB for its failure to appreciate the need for more fully informed consent even as the IRB seemed conscientiously to have considered the balance of interests the regulations required.

<sup>19</sup> E.L. Pattullo, Modesty is the Best Policy: The Federal Role In Social Science Research, in *ETHICAL ISSUES IN SOCIAL SCIENCE RESEARCH* 373, 379 (Tom Beauchamp et. al. eds 1982); Pattullo, Edward. "Institutional Review Boards and Social Research: A Disruptive, Subjective Perspective, Retrospective and Prospective." *NIH Readings on the Protection of Human Subjects in Behavioral and Social Sciences Research* (1984).

<sup>20</sup> Singer, E., and F. Levine. "Research Synthesis: Protection of Human Subjects of Research: Recent Developments and Future Prospects for the Social Sciences." *Public Opinion Quarterly* 67:1 (Spring 2003): 148-164.

<sup>21</sup> *Supra* note 3, § 46.102(i).

<sup>22</sup> Report of the Social Sciences and Humanities Research Ethics Special Working Committee to the Interagency Advisory Panel on Research Ethics. "Giving Voice to the Spectrum" (June 2004).

<sup>23</sup> *Id.* at 22, 47.

<sup>24</sup> Nelson, Cary. "Can E.T. Phone Home?: The Brave New World of University Surveillance." *Academe* 89:5 (Sept/Oct 2003): 30-35.

Wright, David. "Creative Nonfiction and the Academy: A Cautionary Tale." *Qualitative Inquiry* 10:2 (2004): 202-206.

<sup>25</sup> Blanchard, Margaret A. "Protecting Human Beings: Institutional Review Boards and Social Science Research." *Academe* (May/June 2001). Available on Academe website: <http://www.aaup.org/publications/Academe/2002/02mj/02mjfr.htm>.

<sup>26</sup> Emerson, Thomas. *The System of Freedom of Expression*. New York: Random House (1970).

<sup>27</sup> *Supra* note 3, § 46.111(a)(2).

<sup>28</sup> *Id.*

<sup>29</sup> *Id.*

<sup>30</sup> Note that much stronger arguments are made against IRB regulation by Philip Hamburger in his paper "The New Censorship: Institutional Review Boards." *Supreme Court Review* 271 (2004).

<sup>31</sup> Dickersin, Kay and Drummond Rennie. "Registering Clinical Trials." *JAMA* 290:4 (July 2003): 516-523.

Rennie, Drummond. "Trial Registration: A Great Idea Switches from Ignored to Irresistible." *JAMA* 292:11 (September 2004): 1359-1362.

Als-Nielsen (2003) has detailed concerns with private funding, namely that conclusions of privately funded research are more positive than a randomized trial would merit. Von Elm (2004) has brought attention to the problem of duplicate publications of similar results coming from one or more than one study. (It is a reality that researchers need to publish to maintain their own funding services, and thus there are incentives for duplicate publication.). In calling for a novel public-private partnership for structuring clinical research, Crowley (2004) sets forth a mechanism for enhancing funding that could lead to a large increase in the workload of existing IRBs.

Als-Nielsen, Bodil, W. Chen, C. Gluud, and L. L. Kjaergard. "Association of Funding and Conclusions in Randomized Drug Trials: A Reflection of Treatment Effect or Adverse Events?" *JAMA* 290:7 (August 2003): 921-928.

Von Elm, E., G. Poggia, B. Walder and M.R. Tramèr. "Different Patterns of Duplicate Publication: An Analysis of Articles Used in Systematic Reviews." *JAMA* 291:8 (February 2004): 974-980.

Crowley, William F., et al. "Clinical Research in the United States at a Crossroads: Proposal for a Novel Public-Private Partnership to Establish a National Clinical Research Enterprise." *JAMA* 291:9 (March 2004): 1120-1126.

<sup>32</sup> President Bush, in recently restructuring the President's Council on Bioethics, has raised this issue. Blackburn (2004) has recently written on this concern. The IRB must be diligent to override purely partisan initiatives.

Blackburn, E. "Bioethics and the Political Distortion of Biomedical Science." *N. Engl. J. Med.* 350:14 (2004): 1379-1380.

<sup>33</sup> A recent policy statement of the Academy of Pediatrics (2004) speaks to some of these concerns. Walsh (2003) has questioned the overall low representation of black subjects in studies and Coffey (2004) has expressed concern about the involvement of children in asthma trials. The bibliographies of the last two citations include other examples.

American Academy of Pediatrics. Policy Statement: "Ethical Considerations in Research with Socially Identifiable Populations." *Pediatrics* 113:1 (January 2004): 148-151.

Walsh, Catherine and L. F. Ross. "Are Minority Children Under- or Overrepresented in Pediatric Research?" *Pediatrics* 112:4 (October 2003): 890-895.

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<sup>34</sup> Citro, C., D. Iglén, and C. Marrett. *Protecting Participants and Facilitating Social and Behavioral Sciences Research*. Washington, D.C.: National Academies Press (2003).

<sup>35</sup> Campbell, Richard T. "Risk and Harm Issues in Social Science Research." *Illinois Conference Proceedings* (2003); (unpublished position paper, on file with the University of Illinois College of Law Human Subject Policy Conference website. <http://www.law.uiuc.edu/conferences/humansubject/index.asp>).

<sup>36</sup> Denzin, Norman K. "IRBs and the Turn to Indigenous Research Ethics." *Illinois Conference Proceedings* (2003); (unpublished position paper, on file with the University of Illinois College of Law Human Subject Policy Conference website <http://www.law.uiuc.edu/conferences/humansubject/index.asp>).

<sup>37</sup> Note that trauma researchers have found that interviewing people about old traumas (e.g., rape, dismemberment, fleeing a draconian regime) does not, in general, reopen trauma but is generally experienced as therapeutic, contrary to widely prevailing misconceptions among many IRB members.

Gunsalus, C.K. "The Nanny State Meets the Inner Lawyer: Overregulating While Underprotecting Human Participants in Research." *Ethics & Behavior* 14:4 (2004): 369-382, citing E.A. Walker, E. Newman, M. Koss, D. Bernstein, *Gen. Hosp. Psych.* 19:2 (1997): 403-410. J.I. Ruzek, D.F. Zatzick, *Gen. Hosp. Psych.* 22:1 (2000): 27-36. K. Dyregrov, A. Dyregrov, M. Raundalen, *J. of Traumatic Stress* 12:3 (2000): 413-426. P.J. Brabin, E.F. Berah, *Psychiatry, Psychology and Law* 2 (1995): 165-171. E. Newman, E.A. Walker, A. Gefland, *Gen. Hosp. Psych.* 1 (1999): 187-196.

<sup>38</sup> Finkin, Matthew W. "Academic Freedom and the Prevention of Harm in Research in the Social Sciences and Humanities." *Illinois Conference Proceedings* (2003); (unpublished position paper, on file with the University of Illinois College of Law Human Subject Policy Conference website <http://www.law.uiuc.edu/conferences/humansubject/index.asp>).

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