

WHERE'S THE LAW? UNCOVERING THE TRUTH ABOUT IRBs AND CENSORSHIP

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INTRODUCTION

Are Institutional Review Boards (“IRBs”) censoring researchers? In trying to answer that important question, we might take a lesson from the world of research. Researchers know that it is often inappropriate to rely primarily on anecdotal evidence, on the isolated results of what happened in only one or another instance. We need better, more representative information to get the most meaningful answer to a question. Or, in shorthand terms: garbage in, garbage out.

To determine whether IRBs are censoring researchers, an analysis of the law relating to IRBs is an appropriate starting point.¹ This Symposium is, after all, taking place at a law school, and the question it poses is a legal one. Yet it is striking (at least to me) how few of the claims about IRB censorship practices specifically reference the law of human subjects research. If a similar discussion were taking place in a law school classroom, no doubt there would be many references to the applicable law. Regulations would be cited. Key sentences would be parsed. Administrative interpretations would be subjected to scrutiny. All of that would take place before moving on to secondary conclusions (for example, that the black letter law governing IRBs should only be a starting point for analysis because everyone is over-interpreting its requirements).

This article will attempt to demonstrate that an examination of the law relating to human subjects research provides compelling answers to many of the claims about IRB censorship. A very large percentage of the research studies on which this Symposium is focused fall within regulatory categories that are subjected to, at most, a cursory level of IRB review. Many other research studies do not come within the jurisdiction of IRBs, and so should be subject to no review at all. Accordingly, the IRB system should in the great majority of cases be a minimal burden to these researchers.

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¹ In the spirit of full disclosure, I am co-author of a recent textbook on that very topic: CARL H. COLEMAN, JERRY A. MENIKOFF, JESSE A. GOLDNER & NANCY NEVELOFF DUBLER, *THE ETHICS AND REGULATION OF RESEARCH WITH HUMAN SUBJECTS* (2005).

And that burden should rarely be substantial enough to trigger constitutional protections against censorship.

I. LOOKING AT THE FEDERAL LAW REGULATING IRBS

An example taken from this Symposium can provide a useful introduction to how the actual law governing IRBs helps us better evaluate the extent of censorship. During one of the panel discussions, conference organizer James Lindgren made a comment regarding the notebook computer on the table in front of him.² He noted that he had quite a few databases loaded on the hard drive of the computer (fifty or more, if I remember correctly). He observed that even though he had permission to possess those databases, and even though they only contained de-identified information, he would need to get the permission of an IRB before using any of the databases to conduct research.

The federal regulations that govern most IRB operations³ determine the accuracy of this claim.⁴ One of the key jurisdictional elements of these regulations is that they apply only to “research involving human subjects.”⁵ If an activity either (1) doesn’t involve research, or (2) doesn’t involve the use of human subjects, and if the regulations are properly followed, there shouldn’t be any possibility of an IRB censoring that activity. Simply stated, in either of those circumstances, the IRB has no authority over the activity.⁶ There are a huge number of situations in which this will indeed be the case.

Both “research” and “human subject” are terms that are defined in the regulations. There are two ways that a study can involve the use of a human subject. The first is when a researcher obtains data through “interven-

² James Lindgren, Remarks at the Northwestern University Law Review Symposium: Censorship and Institutional Review Boards (Apr. 7, 2006).

³ Although a number of federal agencies have adopted these regulations (often referred to as the “Common Rule” because of their widespread adoption), perhaps the most widely applicable version is the one adopted by the Department of Health and Human Services, which appears as 45 C.F.R. Part 46, Subpart A (2005).

⁴ The analysis in the text assumes that the institution where the research is taking place has chosen to apply the requirements of the federal regulations to all research, and not only to those research studies that are federally funded. See Office for Human Research Protections, Federalwide Assurance (FWA) for the Protection of Human Subjects for Institutions Within the United States, section 4(b), available at <http://www.hhs.gov/ohrp/humansubjects/assurance/filasur.htm>. In an institution that chose not to adopt that course of action, the burdens imposed by the IRB system would of course be even less than are discussed in the text.

⁵ 45 C.F.R. § 46.101(a) (2005).

⁶ This comment assumes that the institution is merely implementing the federal regulations. An institution can choose to impose rules that are more restrictive than those regulations. But complaints about censorship resulting from such a circumstance would seem more appropriately directed at the specific institutions that are choosing to do this, rather than the IRB system itself, as created by the federal regulations.

tion” or “interaction” with a subject.⁷ “Interaction” is commonly understood to be interpreted in a broad manner, and can encompass collecting information by merely talking to people and asking them questions. Even with that broad of an interpretation, a researcher, like Professor Lindgren—who uses databases that were likely obtained directly from another person or from an organization—would not have had sufficiently direct “interaction” to make his subsequent research subject to IRB approval.

The second way that a study can involve a human subject occurs when a researcher obtains “identifiable private information.”⁸ Information is considered to be private if it was obtained in a context where the person would reasonably expect no one to be recording it, or if the person provided that information with the reasonable expectation that it would remain private.⁹ This part of the definition recognizes that people’s privacy interests might be at stake in a research study even if the researcher does not interact with them. A common example of this situation is research involving medical records: when a researcher is given access to a person’s medical records, and is permitted to see information about the person that is not available to the public generally, any subsequent research involves human subjects and requires some form of IRB review.¹⁰

In the fact pattern raised during the conference, the researcher has not employed identifiable private information that would bring his study within the category of using human subjects. It was stated in James Lindgren’s scenario that these databases do not contain any identifiable private information. They contain only “de-identified” information: information that has been stripped of identifiers (such as names and addresses and social security numbers and medical record numbers). As such, using these de-identified databases for research would not meet the definition of research with human subjects, and would not come within the jurisdiction of IRBs. There should generally be no need for Professor Lindgren to obtain IRB approval.

⁷ 45 C.F.R. § 46.102(f)(1) (2005).

⁸ 45 C.F.R. § 46.102(f)(2).

⁹ As discussed later in this paper, there are surely too many instances in which IRBs and others fail to understand, and properly administer, the regulations. An interesting set of observations appears on the Empirical Legal Studies blog, where, for example, one commentator notes his IRB’s incorrect conclusion that research based on public documents (in particular, trial transcripts) required IRB approval. Empirical Legal Studies: Working with IRBs, http://www.elsblog.org/the_empirical_legal_studi/2006/02/working_with_ir.html (last visited on Nov. 10, 2006). That blog also contains a set of FAQs regarding legal scholarship and IRBs (though, for the reasons provided in this paper, I believe their perhaps slightly tongue-in-cheek observations about the burden imposed on researchers are highly overstated). Mark Hall & Ronald Wright, FAQs re. Legal Scholarships and IRBs, http://www.elsblog.org/the_empirical_legal_studi/irb.html (last visited on Nov. 10, 2006).

¹⁰ Even in this circumstance, where the investigator is permitted to see identifiable private information, a study will often meet the requirements for being an “exempt” study, and, thus, there should be a relatively minimal and non-burdensome review of the study. This issue is discussed in the following section of this article.

During the discussion following Professor Lindgren's presentation of this fact pattern, participants from some institutions noted that they were indeed being required to file such studies with their institutions' IRBs. However, as the discussion progressed, other participants clarified the nature of this requirement. These institutions had created master lists that would include information about all databases that were being used at the institution. The purposes of the master lists include, for example, enabling a prompt resolution of any issues regarding whether researchers have the appropriate permission to use a particular database (which might be proprietary). At those institutions, no "review" of these studies was taking place by the IRB or its personnel. There was merely the requirement that researchers submit some brief information so that the database could be entered into the list. This modest requirement seems highly unlikely to be any deterrent to the use of these databases for research, let alone a deterrent significant enough to raise the specter of censorship that would fall within the proscriptions of the U.S. Constitution.

II. FEDERAL REGULATORY *EXEMPTIONS* FROM IRB OVERSIGHT

Professor Lindgren's example provides a natural segue for discussing another important category of research studies: those studies that meet the requirements for being "exempt" from the federal regulations.¹¹ While researchers conducting exempt studies will often have to file some documents with their institution's human subjects protection office, as will be explained below, those documents merely have to be reviewed by IRB staff for a determination that the exemption criteria are met, and that some very general ethical requirements have been met. Accordingly, such studies, in a properly functioning IRB system, should receive relatively rapid and non-burdensome review.

Exempt studies fall into one of six specified categories. These categories are designed to weed out many low-risk studies that do not need to be subjected to the detailed requirements the federal regulations impose upon riskier studies. Indeed, under the terms of the regulations, studies meeting the exemption criteria are not subject to *any* of those detailed requirements.¹² Thus, for example, there is no requirement that subjects receive written consent forms; there is no requirement that there must be written documentation that the subject has consented to enroll in the study; and there is no requirement that the researchers make an annual filing for re-approval of the study. There is no requirement that a determination has to be made by anyone about there being a particular relationship between the risks and benefits of participation. There is no requirement that exempt

¹¹ The six categories of research that are considered exempt are described in 45 C.F.R. § 46.101(b) (2005).

¹² 45 C.F.R. § 46.101(b) (stating that "research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy").

studies ever be reviewed at a meeting of the convened IRB, or even by a single member of the IRB. In recognition of the assumed low risks of exempt studies, all of the review requirements can be performed by administrative personnel.

What requirements *do* apply to exempt studies? The institution should have in place some mechanism for having appropriately trained personnel review the filed documents to determine that the study does indeed fall into one of the exempt categories. Most researchers are far from being expert at understanding the wording of the exempt categories. Leaving the determination of exempt status to the researchers themselves is an invitation to incorrect exemption determinations (and is discouraged by federal regulators).

Beyond the determination of exempt status, there is only one other regulatory requirement imposed on exempt studies. As part of the contractual agreement that an institution conducting federally funded research is required to sign with the federal government,¹³ the institution must agree that the conduct of exempt studies (indeed, of all studies at that institution) be “guided by” the ethical principles outlined in a document known as the *Belmont Report*,¹⁴ or by other appropriate and recognized ethical standards. The *Belmont Report*, written in 1979, is a relatively vague document that spells out the general ethical principles—most importantly, three core concepts relating to respect for persons, beneficence and justice—that later were implemented in creating the far more specific federal regulations.

Given the vagueness of the criteria, minimal efforts should generally suffice for demonstrating compliance with them. Indeed, it seems to be the case that most institutions assume that any study which falls within one of the exemption categories would automatically be in compliance with the *Belmont Report* criteria. This attitude seems consistent with the view of this requirement that is taken by the Office for Human Research Protections (“OHRP”), the federal agency that oversees and enforces most of these rules. In its extensive list of the significant noncompliance findings that the agency might make during its review and investigation of an institution’s human subject protection program, there is not a single mention of the *Belmont Report*.¹⁵ Thus, the requirement that the conduct of studies be “guided

¹³ This contractual agreement is known as a Federalwide Assurance. See Office for Human Research Protections, Federalwide Assurance (FWA) for the Protection of Human Subjects § A(1), available at <http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm>.

¹⁴ NAT’L COMM’N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, U.S. DEP’T OF HEALTH, EDUC. & WELFARE, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979), available at www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm.

¹⁵ See DIV. OF COMPLIANCE OVERSIGHT, OFFICE FOR HUMAN RESEARCH PROTS. (OHRP), OHRP COMPLIANCE OVERSIGHT ACTIVITIES: SIGNIFICANT FINDINGS & CONCERNS OF NONCOMPLIANCE (2005), available at <http://www.hhs.gov/ohrp/compliance/findings.pdf>.

by” the *Belmont Report* principles is likely to lead to little, if any, burden on the approval and conduct of research studies.

It would seem that many of the research studies that are the main focus of this Symposium would qualify as exempt studies. One important exemption category relates to doing research based on information that already exists.¹⁶ For example, imagine that Professor Lindgren, instead of being handed a de-identified set of data, wanted to access databases that included *identifiable* private information. The exemption criteria allow him to do that—and do not even require him to get permission from the people whose private information he is accessing¹⁷—if he merely creates a separate research database for himself which cuts out the identifying information. For example, if the information he initially accessed included names and addresses of people, in addition to their medical information, he could create a duplicate of that database with the names and addresses removed. He would then be free to do all the research he wanted with that database.

Moreover, he could even go one step further. Imagine that he needs to use information about these subjects that does not yet exist, but will be collected by others (for non-research purposes) over a period of time. The exemption category for extant information discussed above does not apply to this research because it requires that all of the information be in existence at the time the study begins. However, the Federal Office for Human Research Protections has provided a mechanism that permits researchers to use newly obtained information to, among other things, supplement an extant database. That office has issued a guidance statement interpreting the term “human subjects” (as discussed in the previous section of this article) and concluding that it is permissible for a researcher to obtain new information under a “coding” system through which they are never told the actual identity of the subject, nor given identifying information. As a result, a researcher can, over time, continue to collect a great deal of information about that subject. The OHRP reasoning is that in a scenario in which the researcher never obtains any identifying information, there is no research involving human subjects taking place. Significantly, this OHRP interpretation appears to be quite generous in allowing such research to take place with minimal or no review.¹⁸

¹⁶ 45 C.F.R. § 46.101(b)(4). This exemption category applies primarily to the research use of “existing” data, documents or specimens.

¹⁷ The requirements imposed by the federal privacy rules under HIPAA are part of a regulatory framework distinct from the federal regulations discussed in the text, and, in any event, were not a topic discussed at the conference. See Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462–829 (Dec. 28, 2000) (codified at 45 C.F.R. pts. 160, 164).

¹⁸ A leading commentator on research ethics, Ellen Wright Clayton, Rosalind E. Franklin Professor of Genetics and Health Policy at Vanderbilt University, described the promulgation of this guidance as “a dramatic shift” from prior thinking. She noted that “it is safe to say that virtually everyone agreed that some level of IRB review was required and that IRBs generally had at least to consider whether it was necessary to obtain informed consent” in these types of studies. Ellen Wright Clayton, *So What Are*

III. AN ESPECIALLY IMPORTANT EXEMPTION CATEGORY: COLLECTING INFORMATION BY *TALKING TO PEOPLE*

A second important exempt category applies, among other things, to certain types of research involving “survey” or “interview” procedures.¹⁹ There are two relatively broad situations to which this exemption category applies. In the first situation, a study is exempt if a researcher conducts anonymous surveys or interviews (meaning that she does not keep a record of the identities of the subjects). In most institutions, a researcher conducting this type of anonymous study only needs to file some papers (such as a brief protocol) and answer some questions, to allow IRB administrative personnel to verify that the exemption criteria are met. As noted above with regard to exempt studies, there would be no requirement under the federal regulations for any substantive review by the convened IRB or even a single IRB member. Again, the likelihood of censorship resulting from this procedure seems extremely low.

Sometimes, a researcher will not be able to conduct an anonymous study. She might have a reason for wanting to keep identifying information about her informants. For example, perhaps she wants to contact them again in the future, and get additional information about changed events. Even in that circumstance, there is an excellent chance that the study will *still* be exempt, as a result of the second exemption rule that applies to surveys and interviews.

Under this second exemption rule, even when a researcher conducts a study that is not anonymous, that study *will* be exempt unless the information that is collected “could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.”²⁰ Certainly, many (and perhaps even most) studies that social science researchers conduct involve collecting information that does not fall into any of these “risk-creating” categories.

Finally, it is again worth noting that many of these survey and interview studies may fail to meet the definitional criteria for “research with human subjects” (and thus will often not even require any form of filing with, or review by, an IRB). This occurs primarily because the definition of “research” is, in fact, quite narrow: an activity must be a “systematic investigation” that is “designed to develop or contribute to generalizable knowledge.”²¹ Some types of studies may not involve the type of “systematic” inquiries that are encompassed by this definition. Others, even if they are “systematic,” may involve the collection of types of information that do not constitute “generalizable knowledge.” Officials at OHRP have acknowl-

We Going to Do About Research Using Clinical Information and Samples, IRB: ETHICS & HUMAN RESEARCH, Nov.–Dec. 2004, at 14.

¹⁹ 45 C.F.R. § 46.101(b)(2) (2005).

²⁰ 45 C.F.R. § 46.101(b)(2)(ii).

²¹ 45 C.F.R. § 46.102(d) (2005).

edged this possibility in various pronouncements, concluding, for example, that much of the work performed by oral historians, in sitting down with people and getting information from them, does not fall within the category of doing “research.”²²

IV. PUTTING IT ALL TOGETHER

What are the preceding observations intended to demonstrate? That in the great majority of instances, the types of studies that this Symposium is focusing on should—at an institution that is adhering to the federal regulations and has a knowledgeable and adequately staffed IRB system—be subjected to minimal (or no) burden.

Having said that, I want to emphasize that in many respects, I *agree* with the complaints about the system voiced by both conference organizers and many of the participants. At some institutions, the IRB staff may not be adequately educated about the applicable regulations, and may be placing inappropriate burdens on researchers. At other institutions, there may be insufficient IRB staffing, leading to inappropriate delays in the review of studies.

I also agree that there are appropriate reforms that should be made to the IRB system. There is certainly a need to collect more information with regard to the benefits of various aspects of that system, particularly as they relate to behavioral and social science studies.²³ To the extent that we learn that IRB review sometimes provides minimal or no protections to participants in these studies, then some of the burdens imposed upon researchers, even if they are minimal, can nonetheless be relaxed or even eliminated. The Illinois White Paper makes a number of reasonable suggestions for improving the IRB system that are worthy of consideration.²⁴ Many people

²² See, e.g., Linda Shopes & Donald Ritchie, *Exclusion of Oral History from IRB Reviews: An Update*, PERSPECTIVES, Mar. 2004, available at <http://www.historians.org/Perspectives/Issues/2004/0403/0403new1.cfm> (quoting Michael Carome, Associate Director for Regulatory Affairs at OHRP, as stating that “OHRP yesterday reaffirmed its concurrence with your policy statement that oral history interviewing activities, in general, are not designed to contribute to generalizable knowledge and therefore do not involve research”); Robert B. Townsend & Mériam Belli, *Oral History and IRBs: Caution Urged as Rule Interpretations Vary Widely*, PERSPECTIVES, Dec. 2004, available at <http://www.historians.org/Perspectives/Issues/2004/0412/0412new4.cfm>; UCLA Office for Protection of Research Subjects, Oral History and Human Subjects Research (Dec. 10, 2003), http://www.oprs.ucla.edu/human/news/item?item_id=127350 (providing criteria for determining when oral history activities would constitute research).

²³ With regard to medical research, there is substantial evidence justifying the need for the core aspects of the IRB system. Indeed, that system should probably be strengthened, to assure that people make truly informed choices about participating in research, as I have argued at length elsewhere. See JERRY MENIKOFF, *WHAT THE DOCTOR DIDN'T SAY: THE HIDDEN TRUTH ABOUT MEDICAL RESEARCH* (2006).

²⁴ Ctr. for Advanced Study, *The Illinois White Paper: Improving the System for Protecting Human Subjects: Counteracting IRB “Mission Creep,”* (Univ. Ill. Law & Econ. Research Paper No. LE06-016, 2005), available at <http://www.law.uiuc.edu/conferences/whitepaper/whitepaper.pdf>.

who are part of the system—including those in the federal government administering it—share the desire for appropriate reform.

But—to return to the specific question that motivated this conference—does any of this rise to the level of censorship? Does the current system of federal IRB regulations violate the First Amendment? That conclusion seems highly doubtful.²⁵ To the extent that social and behavioral scientists find themselves facing inappropriate burdens in conducting their research, the most likely cause of that problem is their institution's flawed operations. The main solution would be for those researchers to work at improving those IRB operations.²⁶ Even with its imperfections, the current set of regulations, if implemented correctly by an institution, should be causing at most a minimal burden to social and behavioral scientists. Yes, there is likely some degree of wasted effort that, when aggregated to include all research activity across the entire country, argues in favor of a *policy* determination that certain reforms should be implemented. But that fact does not alter the *legal* conclusion that individual researchers are not subject to a regulatory burden rising to the level of constitutional concern.

Those who think otherwise might take a look at OHRP's recent enforcement actions. Redacted versions of that agency's determination letters for the past seven years are posted on the agency's web page.²⁷ One has to search far and wide among those letters to find any actions taken against institutions with regard to non-medical research studies. The bottom line is that social and behavioral scientists who maintain appropriate communication with their institution's IRBs need not be shaking in their boots, fearing some career-ending enforcement action is about to come down from Washington. Nor should their institution's administrators be taking actions based on similarly unreasonable fears. Both the regulators, and the regulations they enforce, reflect a system that, properly understood and implemented, already imposes a fairly minimal burden on individual researchers in the area of social and behavioral research.

²⁵ Not only did several of the constitutional scholars at this Symposium find it unlikely that the IRB system violates the First Amendment, but it is noteworthy that much of conference co-organizer Philip Hamburger's critique of the IRB system is based on his conclusion that the U.S. Supreme Court has been wrong in its analysis of First Amendment issues, and thus even he might acknowledge that the existing case law does indeed support a conclusion that the IRB system is constitutional. See Philip Hamburger, *The New Censorship: Institutional Review Boards*, 2004 SUP. CT. REV. 271, 278–81.

²⁶ Note the comments of former OHRP official Jeffrey Cohen in his HRPP Blog, after observing that yes, many of the “horror stories” told by social science and humanities researchers are true: these situations are taking place because of “IRBs that a) don't understand social and behavioral research, b) don't know how to use or are afraid to use the flexibility in the regulations, and c) don't pay sufficient attention to the efficiency of their procedures.” Posting of Jeffrey Cohen to HRPP Blog, <http://hrpp.blogspot.com/2006/03/mission-creep.html> (Mar. 4, 2006, 10:14 EST).

²⁷ Office for Human Research Protections, 2006 Determination Letters, <http://www.hhs.gov/ohrp/compliance/letters/index.html>.

