

PROMOTING FREE SPEECH IN CLINICAL QUALITY IMPROVEMENT RESEARCH

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INTRODUCTION

There is merit to having a body of peers review the value of proposed and ongoing research from an ethical perspective. However, the current structure of the Institutional Review Board (“IRB”), the local body designated by the federal government to review research with human subjects,¹ is ill-suited to address the great diversity of research that is generally conducted. The Office of Human Research Protections (“OHRP”), the federal agency of the Department of Health and Human Services created to supervise research with human subjects, primarily designed the structure of the IRB with biomedical research in mind. However, the enabling Common Rule regulations, 45 C.F.R. § 46,² sweep broadly, reaching any systematic investigation involving human subjects “designed to develop or contribute to generalizable knowledge.”³

The Common Rule presents significant free speech barriers to clinical quality-improvement research (“CQIR”), the evaluation and dissemination of efforts to improve the quality of the delivery of health care. Application of the Common Rule to CQIR has the potential to affect negatively the quality of care patients receive, by preventing quality improvement work from being produced in the first place or by inhibiting its dissemination. This Paper will review the free speech issues raised by CQIR. Applying the Common Rule to CQIR undermines First Amendment principles because it is insufficiently tailored to meet the minimal risk presented by CQIR.⁴ The government fails to have a compelling state interest in regulating research that presents no greater risk than that encountered in everyday life. More-

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¹ National Research Act of 1974, Pub. L. No. 93-348, 88 Stat. 342 (codified at 42 U.S.C. § 289(a)).

² The regulations are commonly referred to as the Common Rule since they have been embraced by multiple federal agencies throughout the government. *See* Federal Policy for the Protection of Human Subjects, 56 Fed. Reg. 28,012 (June 19, 1991).

³ 45 C.F.R. § 46.102(d) (2005).

⁴ Research is minimal risk if it poses risks “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.” *Id.* at § 46.102(i).

over, stretching the regulations to encompass CQIR violates the principle of unconstitutional conditions. Lastly, application of the Common Rule to CQIR violates equal protection by selectively restricting the rights of administrators of academic institutions to disseminate their quality improvement work. The ideal solution would be a change in the regulations eliminating minimal risk human subjects research from IRB review.⁵ Barring such changes, quality-improvement investigators should be prepared to defend and articulate First Amendment rights as IRBs impose unnecessary regulatory review.

I. THE PURSUIT OF QUALITY IN MEDICINE

The pursuit of quality has been of growing importance for medicine with the recognition of the hidden dangers, inequities, and inefficiencies of the healthcare system.⁶ Medicine has turned to insights from industry, where quality-improvement methodologies were first developed, and incorporated these quality-improvement approaches into the daily practice of medicine. Quality improvement in the practice of medicine, or clinical quality improvement (“QI”), is best understood as the systematic management of clinical operations to produce immediate, beneficial change. QI is continuous and ongoing, occurring in iterative cycles of planning, implementation, and analysis. It is inherently embedded into the routine acts of caring for patients.⁷

QI bears some resemblance to traditional biomedical research in that both involve the use of data methodologically to come to conclusions about how best to provide care. However, a primary distinction is that biomedical research generally involves the study of an agent or intervention devoid of the particular setting. For example, whether or not beta blocker medications prolong life after a heart attack is a question of empirical science that has been convincingly demonstrated. Rather than answering this first order question of whether an agent is effective for some purpose, QI aims to determine the second order question of how best to implement this knowledge into daily practice. In the example above, the key question for QI is what is

⁵ Such a change has the added benefit of removing many of the First Amendment barriers to survey and social science researchers. *See generally* Phillip Hamburger, *The New Censorship: Institutional Review Boards*, 2004 SUP. CT. REV. 271 (arguing that federal regulations on Institutional Review Boards violate the First Amendment to the Constitution).

⁶ The quality problems in modern health care have been well documented in recent years. *See generally* INSTITUTE OF MEDICINE, *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (1999) (documenting the problem of preventable medical errors in American healthcare as a product of fragmented health care systems narrowly focused on individual performance rather than system organization); INSTITUTE OF MEDICINE, *CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY* (2001) (proposing methods to redesign the health care system, aiming to make health care safe, effective, patient-centered, timely, efficient, and equitable).

⁷ Mary Ann Baily et al., *The Ethics of Using QI Methods to Improve Health Care Quality and Safety*, 36 HASTINGS CENTER REP. S1-40 (2006).

the best approach to improve the standard processes of routine care so that beta blockers are prescribed after a heart attack in all patients without a contraindication.

Determining what system-based interventions are best suited for implementation are questions for QI. For example, in some cases physician education may be sufficient, but in others more aggressive interventions such as automated computer order systems or public accountability may be needed to impact care. Since QI provides a structured method for determining the most effective or efficient processes to improve the routine delivery of care, QI is inherently local.⁸ It is focused on the provision of care within the context of a local or particular system of care, and, unlike traditional research, the investigators conducting QI must include institutional administrators, such as hospital executives and managers, with the desire and authority to initiate change within the particular health system based on the findings.

Nevertheless, because healthcare systems are similarly structured across the nation and, to a large extent, internationally, the insights gained from clinical operational improvements in one healthcare setting have the potential to be generalizable to other similarly situated settings. The dissemination of QI work transforms a local, systematic investigation into one offering generalizable knowledge about the provision of healthcare.⁹ Thus, dissemination is the critical step in elevating QI into CQIR.

II. QUALITY IMPROVEMENT AND THE PURSUIT OF RESEARCH

The IRB regulations define research in terms of intent: “a systematic investigation . . . *designed* to develop or contribute to generalizable knowledge.”¹⁰ The intent implicit in the “designed” requirement makes it difficult to categorize QI programs as research.¹¹ Since QI work is not geared towards contributing to generalizable knowledge—instead seeking primarily to improve local systems of care—QI should not be regulated as research. However, sometimes intent evolves. Thus, QI work may start with only the motivation to improve the local delivery of care. Later, though, as more knowledge is gained about its value, the desire to share the work more broadly emerges. In such cases, the investigation was never “designed” to develop generalizable knowledge. Yet there is little doubt that the QI work

⁸ *Id.*

⁹ For the knowledge gained from the QI intervention to be truly generalizable, however, the intervention must be repeated in multiple settings with similar results to know for sure that the results were obtained as a result of the intervention and not some special attributes of the local system.

¹⁰ 45 C.F.R. § 46.102(d) (2005) (emphasis added).

¹¹ David Casarett et al., *Determining When Quality Improvement Initiatives Should Be Considered Research: Proposed Criteria and Potential Implications*, 283 J. AM. MED. ASS'N 2275, 2276 (2000); Bernard Lo & Michelle Groman, *Oversight of Quality Improvement: Focusing on Benefits and Risks*, 163 ARCHIVE INTERNAL MED. 1481, 1483 (2003).

becomes a systematic investigation that contributes to generalizable knowledge once the researchers disseminate the results. It is also possible that individuals will pursue QI work with the joint intention both to improve the local system of care and to generate useful knowledge about improving care that others can use.¹² Whether the IRB regulations exclude systematic investigations when obtaining generalizable knowledge is not their primary intent is less clear.

There has been an unresolved debate in the medical literature regarding the proper role for ethical oversight of QI work. Practically speaking, the growing consensus in medicine is that QI is research that must be approved by an IRB.¹³ IRBs have generally taken a conservative stance requiring review.¹⁴ For example, the policy of the University of Chicago IRB is that QI work is research:

Unlike case reports, Quality Assurance (QA) processes often involve reporting on a large number of individuals. Quality Assurance studies are done to verify the quality of current hospital tests or procedures. These are usually designed to contribute to generalizable knowledge, and as such most QA protocols are considered research and subject to IRB review.¹⁵

Others argue that routine IRB approval for most QI work is unnecessary.¹⁶ In a recent report published by the Hastings Center, it is argued that an IRB does not need to review most QI work because QI is not a knowledge-based enterprise independent of ongoing clinical care.¹⁷ QI already receives oversight through traditional operational and administrative channels, and health professionals engaged in QI have an ethical obligation to develop and maintain systems providing safe care for patients by virtue of their administrative role. In addition, the report notes that the formal processes of IRB approval can be particularly burdensome for QI work. Unlike traditional biomedical research, QI does not proceed by a fixed protocol but

¹² The Privacy Rule, regulations designed to protect identifiable health information under authority of the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936, does envision the possibility of joint intent. In fact, the Privacy Rule allows for protected health information to be used freely within institutions engaged in quality improvement as part of health care operations “provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities.” 45 C.F.R. § 164.501 (2005).

¹³ See Casarett et al., *supra* note 11, at 2279.

¹⁴ See generally Peter K. Lindenauer et al., *The Role of the Institutional Review Board in Quality Improvement: A Survey of Quality Officers, Institutional Review Board Chairs, and Journal Editors*, 113 AM. J. MED. 575 (2002) (survey of IRB chairs and others demonstrating that over 70% of IRB chairs think IRB review for quality improvement work is indicated when there is an intent to publish).

¹⁵ THE UNIVERSITY OF CHICAGO DIVISION OF BIOLOGICAL SCIENCES & THE UNIVERSITY OF CHICAGO HOSPITALS INSTITUTIONAL REVIEW BOARD, POLICIES AND PROCEDURES MANUAL 57 (2006), available at <http://ors.bsd.uchicago.edu/IRB/2PandP01312006.pdf>.

¹⁶ NATIONAL BIOETHICS ADVISORY COMMISSION, 1 ETHICAL AND POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS 36–37 (2001).

¹⁷ Baily et al., *supra* note 7, at S18–S21.

is a dynamic and iterative process of evaluation and intervention. According to the IRB regulations, all changes to research protocols must be approved by the IRB in advance.¹⁸ Particularly given the historic inefficiencies of IRB review systems at many institutions,¹⁹ subjecting each iteration of QI work for IRB review would be problematic. In fact, such review may create perverse incentives for researchers to either refuse to disseminate relevant local findings or decline to engage in QI work altogether. These disincentives are particularly acute for individuals in academic settings where promotion is based on publication and developing a national reputation.

OHRP has yet to provide any specific guidance on this issue. One case may throw some light on the opinion of the OHRP. It ruled that a published QI project that evaluated the quality of dialysis treatments within Medicare's End-stage Renal Disease ("ESRD") Network was research and should have received IRB approval prior to initiation of the project.²⁰ As chair of the local ESRD Network's Medical Review Board, the investigator did have administrative responsibility for the quality of dialysis treatments and was under contract with Medicare, the primary funder of dialysis care in the United States, to administer the project.²¹ More importantly, although the project qualified as research and QI, Medicare viewed the research primarily as a QI project. Nevertheless, at least from OHRP's perspective, joint intent appeared to be irrelevant.

Nevertheless, for the purposes of this paper, CQIR is understood within a broad framework in which the simple reporting of QI work is deemed to be research. Certainly finer distinctions can be made. In the

¹⁸ See OFFICE OF HUMAN RESEARCH PROTECTIONS, DEPARTMENT OF HEALTH AND HUMAN SERVICES, GUIDANCE ON WRITTEN IRB PROCEDURES (2002), <http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd702>.

¹⁹ Ezekial J. Emanuel et al., *Research: Identifying Problems to Evaluate Reform Proposals*, 141 ANNALS INTERNAL MED. 282, 282–86 (2004); see generally Lee A. Green et al., *Impact of Institutional Review Board Practice Variation on Observational Health Services Research*, 41 HEALTH SERVS. RES. 214 (2006) (study of IRB review for a multi-site observational study across forty-three sites that documented tremendous variability and inconsistency in the manner of IRB review).

²⁰ J. Lynn, *When Does Quality Improvement Count as Research?* *Human Subject Protection and Theories of Knowledge*, 13 QUALITY & SAFETY IN HEALTH CARE 67, 67 (2004); see also Baily, *supra* note 7, at S4.

²¹ It should be noted that OHRP came to its decision that the dialysis program was research requiring IRB approval in spite of an applicable exemption to IRB review for research or demonstration projects by federal departments or agencies designed to study or evaluate "public benefit or service programs" or "procedures for obtaining benefits or services under those programs." 45 C.F.R. § 46.101(b)(5) (2005). This exemption, which Medicare apparently attempted unsuccessfully to claim, would appear to apply to provision of dialysis care by Medicare.

Hastings Center report, the mere reporting of QI was not deemed to constitute research.²² In the paradigm suggested by the report, QI projects become research only when techniques designed to lead to generalizable knowledge are added to QI measures. However, it does not appear that the OHRP or many local IRBs interpret the regulations to allow such liberties. Such lack of clarity is unsettling. Failure to obtain review may result in legal and professional repercussions. Violating institutional policies about performing research may jeopardize faculty appointments, and investigators may be unable to publish their work without clear IRB approval.²³

III. THE MINIMAL RISK OF QUALITY-IMPROVEMENT RESEARCH

The Common Rule broadly applies to all research at all levels of risk, including research of minimal risk. CQIR poses only minimal risk to the extent that CQIR is the systematic evaluation and dissemination of local QI efforts that are part of the routine operations of healthcare facilities. QI is simply part of the daily life of running a healthcare institution; the only risk to subjects is the potential breach of confidentiality. However, the possible breach of confidentiality is really no different from that experienced by patients within the context of routine operations, and, moreover, patients' health information remains protected by the Privacy Rule.²⁴

Occasionally, QI will be mixed with an additional research component. For example, an administrator may implement a program and wish to survey patients on their experience. But in these cases patients are not being exposed to new or unproven interventions outside the range of routine care. Thus, most mixed research and QI still qualifies as minimal risk, with breach of confidentiality being the only major risk of both the QI and survey components.

Research that poses even a minimal risk is still quite regulated by the IRB. The requirements for minimal risk research differ from those for research of greater risk in two important regards. First, expedited procedures exist to approve minimal risk research. The chairperson of the IRB or an experienced committee member may individually review and approve (but not disapprove) the protocol in an expedited time frame. However, minimal risk research must still comply with all the substantive criteria required for approval. Second, informed consent requirements are not as strict, allowing for modification from the standard written informed consent to allow either oral consent or waiver of consent altogether.

However, these differences are relatively unavailing, particularly because informed consent presents a particular challenge for CQIR. QI aims to evaluate and improve actual practice in the routine provision of care.

²² See Baily, *supra* note 7, at S11–S18.

²³ See Hamburger, *supra* note 5, at 303–04.

²⁴ See *supra* note 12.

Since QI methodology alters actual systems of care, subjects in CQIR are not simply subjects, as is the case in traditional biomedical research, but are, first and foremost, patients. Requiring consent in QI implies that individual patients receiving care in the system have choices and options not to participate. But options not to participate, short of seeking a different healthcare institution, are simply not available. Of course, patients have rights to refuse unwanted medical treatment and can enforce the standard of care provided by institutions through tort law, but patients cannot insist that institutions provide routine care in a specified manner.²⁵

On the other hand, consent could be limited to allowing individual medical information to be used for research purposes. However, allowing patients to have an absolute property right in their own medical information is problematic. A healthcare system routinely accesses patient information for its own operational purposes. To prevent such actions is to prevent the normal functioning of the healthcare system. Patients recognize that institutions require open access to the medical records of the patients that they serve precisely so they can provide safe care. Thus, patients implicitly consent to the use of their medical information within the institution for operational purposes—of which quality improvement is one aspect—simply by seeking care within the institution.²⁶ Indeed, the federal regulations governing the protection of patient's health information specifically allows institutions to utilize protected health information for quality-improvement activities as part of routine healthcare operations.²⁷ Thus, to even imply that patients should consent to QI efforts is inappropriate.

IRB review inevitably places heightened importance on consent and, in fact, forces administrators to obtain consent of their patients that is otherwise unwarranted and unnecessary. The forced speech involved in providing informed consent would not otherwise be necessary but for the fact that an administrator intends or may intend to disseminate the findings of QI. More importantly, such speech wrongly implies that the care being provided to the patient is experimental in nature when it is, indeed, routine.

The option to apply for waiver of consent provides little consolation to administrators wishing to perform CQIR. According to the regulations, informed consent may be waived when four criteria are met:

²⁵ There are emerging theories of tort for failure to provide quality in the standard provision of care. See George J. Annas, *The Patient's Right to Safety—Improving the Quality of Care Through Litigation Against Hospitals*, 354 NEW ENG. J. MED. 2063, 2063 (2006); see also Aaron S. Kesselheim et al., *Will Physician-Level Measures of Clinical Performance Be Used in Medical Malpractice Litigation?*, 295 J. AM. MED. ASS'N 1831, 1832–33 (2006).

²⁶ Baily, *supra* note 7.

²⁷ The Privacy Rule, *supra* note 12.

- (1) The research involves no more than minimal risk to the subjects;
- (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- (3) The research could not practicably be carried out without the waiver or alteration; and
- (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.²⁸

The impracticability criterion poses the greatest challenge for waiver of consent if CQIR is held to require IRB review. Impracticability is not easily demonstrated and involves much more than being impractical; it denotes that the research is simply not feasible with informed consent. Of course, there are gradations, and much QI work straddles this border. Since QI is about altering systems of care for patients, it is possible that every patient who receives care at a particular facility may be the proper target for an informed consent discussion if required. In traditional biomedical research, particularly research that is greater than minimal risk, such precautions are appropriate because patients are not directly benefiting from participation and because the costs of the research are being borne by the sponsors of the research. However, in minimal risk CQIR that involves modifications in the delivery of routine care, asking consent of patients may be particularly burdensome given the possible number of patients involved, the lack of direct contact between the administrative investigator and the patient, and the costs involved. It should be noted that the costs of CQIR are generally borne by the institution itself, which then must pass these costs on to its patients. If institutional resources are limited enough, the costs involved in obtaining the consent of every patient may prevent a QI project from moving forward in the first place. Nevertheless, such burdens are not necessarily infeasible, thus, effectively triggering the requirement for informed consent and forcing investigators to demonstrate in actual practice that requiring informed consent for the research makes the research impracticable. Such a threshold of proof for impracticability is likely simply too high for the limited resources available for most CQIR.

IV. FREE SPEECH RIGHTS TO QUALITY IMPROVEMENT

Generally, an administrator with institutional authority to direct operations of a healthcare institution need not seek IRB approval before implementing a particular QI initiative within the institution. For example, the quality officer of a health system may decide to implement a policy of routine immunizations to be performed at all outpatient visits based on appropriate indications for all willing patients. An administrator sits in a very

²⁸ 45 C.F.R. § 46.116(d) (2005).

different capacity than that of a traditional researcher; the researcher interacts with research subjects to generate new knowledge and not to provide care. This fact is most obvious when the researcher has no prior direct relationship with subjects. But even when there are pre-existing clinical relationships with subjects, the researcher cannot be said to be engaging in the provision of care when conducting research that solely generates new knowledge. The administrator, on the other hand, is directly providing care by overseeing the operations of the particular healthcare institution.

Perhaps the quality officer in the example above finds the immunization initiative significantly reduced hospitalizations for respiratory infections and subsequently wants to share the success of the program formally with her colleagues at an industry meeting. Many collaborative organizations, such as the American Hospital Association and the University HealthSystem Consortium, at least partly serve to facilitate the exchange of ideas. More recently, the Institute for Healthcare Improvement has aggressively sought to disseminate knowledge in healthcare QI, often utilizing knowledge gained from local QI efforts. Such dissemination is typical of any industry sharing its insights to similarly situated individuals.

However, if the administrator seeks to disseminate any knowledge obtained from such QI work, questions of IRB review may be raised by conference organizers or journals requiring pre-approval, or as happened in the Medicare ESRD case, by the IRB itself if it learns of the publication. Thus, the IRB regulations present a bizarre First Amendment paradox: The administrator can freely pursue QI work unless there is an attempt to disseminate the results.

This paradox that results from applying the Common Rule to CQIR violates the First Amendment principle that limitations on free speech should be narrowly tailored. First Amendment precedents require a compelling state interest to limit speech,²⁹ and thus any such limits need to be narrowly tailored.³⁰ As Justice Brennan asserted in *Sherbert*:

We must next consider whether some compelling state interest . . . justify[d] the substantial infringement of appellant's First Amendment right. It is basic that no showing of merely a rational relationship to some colorable state interest would suffice; in this highly sensitive constitutional area, "[o]nly the gravest abuses, endangering paramount interest, give occasion for permissible limitation."³¹

The Common Rule is insufficiently tailored to the minimal risk that CQIR presents. Unlike research that presents more than minimal risk by involving direct physical intervention on the human body, the risk presented

²⁹ *Sherbert v. Verner*, 374 U.S. 398, 403 (1963); *Gibson v. Fla. Legislative Investigative Comm.*, 372 U.S. 539, 551 (1963); *NAACP v. Button*, 371 U.S. 415, 439 (1963).

³⁰ See generally ERWIN CHEMERINSKY, CONSTITUTIONAL LAW: PRINCIPLES AND POLICIES 902–03 (2d ed. 2002) (discussing strict scrutiny as it applies to First Amendment law).

³¹ *Sherbert*, 374 U.S. at 406 (quoting *Thomas v. Collins*, 323 U.S. 516, 530 (1945)).

to subjects by CQIR is no greater than that experienced in ordinary life. Thus, the state's interest in limiting free speech in this arena is fairly weak. The state's interest is even weaker when considering that applying the Common Rule to CQIR prohibits the dissemination of QI work that may already occur as a result of routine health care operations. Thus, complying with the Common Rule simply to allow for dissemination of the results of QI work forces administrators to pursue consent, in other words, engage in forced speech with potential subjects, which otherwise would not be necessary. Such a requirement can hardly be viewed as a narrowly tailored restriction on speech.

Some may argue that the restrictions the Common Rule places on CQIR are actually voluntarily assumed, and thus, that they do not violate the First Amendment. In fact, the Common Rule on its face appears to apply only to federally funded research. However, in practice the OHRP requires that institutions that receive any federal research funds embrace ethical principles for protecting human subjects in research, regardless of whether the research itself is federally funded.³² OHRP achieves specific compliance with the Common Rule as the guiding rules of choice by leveraging its certification process known as the Federalwide Assurance. Since all federal agencies can rely on the Federalwide Assurance in their own grant-making deliberations, institutions must seek a Federalwide Assurance if they are to seek governmental funding.³³ Although the terms of a Federalwide Assurance allow institutions the option of not adopting the Common Rule to non-federally funded research, the vast majority of institutions accept the Common Rule as the standard for all institutional research when providing their Federalwide Assurance, apparently under some pressure or perceived pressure from the OHRP.³⁴

³² 45 C.F.R. § 46.103(b)(1) (2005).

³³ There is no alternative to the Federalwide Assurance if an institution seeks to win federal grants or awards.

³⁴ See Hamburger, *supra* note 5, at 328–29. It should be noted that even if the Common Rule is not adopted by the institution for all of its research, the terms of the Federalwide Assurance require that all of the institutions' research activities be guided by the ethical principles articulated in the Belmont Report, a statement of ethical principles for the protection of human subjects in research. See OFFICE OF HUMAN RESEARCH PROTECTIONS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, FEDERALWIDE ASSURANCE (FWA) FOR THE PROTECTION OF HUMAN SUBJECTS, available at <http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm>. Specifically, the *Report* articulates three major ethical principles: respect for persons, beneficence, and justice. NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH 4–10 (1978). Applying these principles to the context of research with human subjects, the *Report* presents three major requirements for the ethical consideration of human subjects research: informed consent, a balanced assessment of risk and benefits, and fairness in the selection of subjects. *Id.* at 10–20. The *Belmont Report* was crafted by National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which was created by the National Research Act of 1974. See 42 U.S.C. § 300v-1(b) (2000).

This forced application of the Common Rule to CQIR violates the principle of unconstitutional conditions. The principle of unconstitutional conditions states that the government cannot use its spending power in a manner that it could not so do directly.³⁵ As the Supreme Court noted in *Rust v. Sullivan*, “[t]he Government can, without violating the Constitution, selectively fund a program to encourage certain activities it believes to be in the public interest.”³⁶ However, the Court distinguished between conditions on a specific program versus conditions on a recipient’s activities beyond the federally funded program.³⁷ Conditions on use of federal funds within a specific program are constitutional,³⁸ but conditions placed on the recipient beyond the activities of a federally funded program violate the First Amendment.³⁹

For the purposes of this discussion, I limit the concerns that the Common Rule violates the principle of unconstitutional conditions only to the application of the Common Rule to CQIR. The government may have legitimate interests in extending the Common Rule to non-federally funded research that is greater than minimal risk. To the extent that the practice of non-federally funded research that is greater than minimal risk is unsafe or unethical, such behavior jeopardizes the government’s interest in its own very large investment in conducting research for the public good. Following this line of reasoning, conditioning federal funds to the practice of non-federally funded research may be required to secure the very nature of federally funded research itself. In this manner, the apparent condition is not external to federally funded research but directly related. In other words, there may be a large enough negative externality by the conducting of unsafe or unethical non-federally funded research on federally funded research to justify the condition.

This argument need not be resolved here, however, because even assuming its validity, this argument certainly cannot be extended to minimal risk research and, in particular, CQIR. The vast majority of CQIR is non-federally funded and of minimal risk. Given its low risk equal to that of everyday life and the fact that the underlying QI work leading to CQIR may already be performed as a matter of routine health care operations, it cannot be said that CQIR jeopardizes the public interest in research.

Yet if institutions wish to access federal funds for research, the obvious path of least resistance is to accept the Common Rule for all research, regardless of the source of funding, and perhaps more importantly, regardless

³⁵ See generally CHEMERINSKY, *supra* note 30, at 946–50 (discussing application of the unconstitutional conditions doctrine); Kathleen Sullivan, *Unconstitutional Conditions*, 102 HARV. L. REV. 1413 (1989) (discussing the contours of the unconstitutional conditions doctrine).

³⁶ 500 U.S. 173, 192–94 (1990).

³⁷ *Id.* at 197.

³⁸ *Regan v. Taxation with Representation*, 461 U.S. 540, 548–49 (1983).

³⁹ *FCC v. League of Women Voters of Cal.*, 468 U.S. 364, 399–400 (1984).

of the level of risk presented by the research. Even if institutions wished only to extend the Common Rule to non-federally funded research that posed more than a minimal risk to subjects, OHRP does not actively allow this option.⁴⁰ Thus, OHRP's pressured expectation to use the Common Rule in order to regulate CQIR stretches beyond constitutional boundaries.

Of course, administrative investigators may still pursue QI activities. But to the extent that their institutions perceive such work to be research and IRB review committees effectively preclude the research through unnecessary precautions such as consent, the work cannot be disseminated outside the institution. If administrators engage in QI activities and then seek to disseminate knowledge outside their institutions, such actions may indeed bring legal jeopardy to their institutions—particularly universities engaged in federally funded research. Investigators potentially violate the very terms of the Federalwide Assurance by disseminating QI work without IRB review. With millions of dollars in federal funding at stake, institutions understandably take a very conservative view of the need for IRB review.

The unconstitutionality of such requirements is perhaps more apparent when analyzed under equal protection principles. A wide variety of hospitals and healthcare systems engage in QI work, but only institutions regularly engaged in research, namely large academic medical centers and affiliated hospitals, tend to have federally designated IRBs. Thus, it is very possible that an administrator at a small healthcare institution without an IRB could conduct and publish the exact same QI project as contemplated by a counterpart at an academic medical center with an IRB, but the academic administrator is forced to comply with IRB review and fails to obtain it. In such a case, equal protection principles under the Fourteenth Amendment are violated because similarly situated individuals are treated unequally under the law. First Amendment rights of administrators to share their operational insights should not be selectively denied simply because their institutions receive federally funded support for research. Although there may be a rational basis for conditioning federal research funds, curtailing of First Amendment rights beyond the research actually supported by federal funds should require a compelling state interest more narrowly tailored than this gerrymandered approach.

More insidiously, QI work may not even occur, as the very incentive to do the work may be lost. Administrators often delegate important clinical responsibilities to providers with special expertise. Within academic institutions, providers will assume administrative responsibilities with the hope of leveraging these responsibilities into scholarly work through presentations and publication. If academic providers cannot translate their administrative work into scholarly product, their incentive to assist administrators

⁴⁰ For further discussion of the leveraging of the Common Rule to non-federally funded research and the unconstitutional conditions doctrine, see Hamburger, *supra* note 5, at 314–27.

in quality improvement is diminished, and quality improvement work may not even proceed in the first place, leaving patients worse off rather than better off.

V. TAILORING THE STATE INTEREST IN HUMAN SUBJECTS PROTECTION

The best way to avoid the First Amendment problems that the Common Rule presents for CQIR is with formal changes to the Common Rule. A simple exclusion for QI work could be devised, but that may be more difficult to apply than it seems. QI work sometimes involves research components that are an addition to routine care. These mixed research and QI projects may be the proper subject of review if the risk involved is greater than minimal risk, but this situation is generally not the case.

The better mechanism to remedy the constitutional deficiency of IRB review, as currently defined, is to narrow the scope of IRB review to research that is greater than minimal risk.⁴¹ All research that falls below this threshold should simply be exempt from IRB review. The vast majority of CQIR is minimal risk and, thus, would simply be exempt under this framework.

Such an approach properly narrows IRB review to activities that pose a true potential danger to human subjects beyond the level that individuals regularly accept in their daily life. The real question for individuals seeking to protect human subjects is whether the risk involved in the research is greater than minimal risk. Life itself is inherently risky. We should not be seeking to protect individuals from the risks of daily life. Certainly, the government may utilize its police powers to restrict activities, including speech, if a true danger is posed to subjects. Thus, a compelling state interest may be demonstrated when research involves greater than minimal risk to human subjects. But, as in the case of CQIR, research that only presents a minimal risk to subjects cannot meet this compelling state interest standard. In addition, eliminating minimal risk research from review simply removes the concern that applying the Common Rule to CQIR violates the principle of unconstitutional conditions and resolves any equal protection concerns for CQIR. This approach of raising the threshold for IRB review to research that imposes greater than a minimal risk also eliminates many of the free speech problems that IRB review presents in survey and social science research.

Of course, the approach of raising the threshold of review to greater than minimal risk means that some traditional biomedical research of

⁴¹ It should be noted that his proposal is not meant to affect research with vulnerable populations, such as children or prisoners, which is handled separately by the Common Rule.

minimal risk would now be exempt from review.⁴² But this should not cause concern precisely because the research is of minimal risk. The purpose of the IRB is to protect patients from potential harm, and the resources of the IRB should not be wastefully expended reviewing minimal risk research.⁴³

It should be noted that institutions may respond to these problems without necessarily waiting for changes in the regulatory structure. Institutions could limit the terms of their Federalwide Assurance to federally funded research and not apply the Assurance to all human subjects research. Thus, institutions could become free to develop their own internal policies to regulate non-federally funded research in which, for example, an institution could decide to implement the Common Rule for research of greater than minimal risk but exempt from review minimal risk research. This approach, however, remains an underutilized legal option, presumably because of fear of repercussions by OHRP.⁴⁴

VI. SECOND BEST SOLUTIONS

Although removing minimal risk research from the proper scope of IRB review is appropriate, it is unlikely that the OHRP would take such action any time in the near future. This unwillingness to act puts investigators and members of IRBs in an awkward position. QI investigators are wrongly forced to submit their work for review. Members of IRBs feel compelled to apply the rules without recognition that the rules are unconstitutional. IRBs, as a creation of the federal government, cannot act unconstitutionally, but of course, IRBs are first accountable to the OHRP and the irresistible goal of their institutions to satisfy the OHRP. Until the OHRP recognizes these flaws, either on its own or as the result of actions by institutions, members of IRBs will simply implement the rules they are given.

Nevertheless, investigators should be prepared to press these issues with IRBs even as they comply with ill-conceived requirements for review. In submitting prospective proposals, administrative investigators must clearly articulate and explain throughout the application that the work they are submitting for review is work that they will implement regardless of the

⁴² Though under the current process of the IRB, the IRB is the arbiter of exempt status. Thus, the IRB would still review the research to ascertain the level of risk. For the purposes of this discussion, it is assumed that this level of review does not constitute a violation of free speech.

⁴³ To the extent that minimal risk research that is not CQIR requires access to identifiable patient information, written authorization for access to medical records must still be obtained under the Privacy Rule. 45 C.F.R. § 164.512(i)(1)(i) (2005). This requirement is otherwise subsumed by the process of IRB approval.

⁴⁴ In addition, there may be collective action problems in attempting to create individual institutional policies, as the obligation to comply with the Common Rule may derive not only from agreement with the federal government but with external funding institutions, particularly pharmaceutical companies. These organizations may have created their own obligations to the federal government to comply with the Common Rule and, thus, tie their private funding to Common Rule compliance.

decision of the IRB. For approval of retrospective work, administrative investigators must confront the perception that they are gaming the system. Administrators may only recognize the generalizable value of a QI project later in the course of the project. Administrative investigators should not be barred from presenting such work for IRB review on the grounds that the research has already begun and approval would simply constitute retrospective review of a prospectively conducted project. It is true that such an approach is generally suspect in traditional biomedical research and, in general, is not allowed. However, since traditional biomedical research is always conducted apart from the routine provision of care, it has a clear beginning. Quality improvement, however, evolves. A plan may go through ten iterations before arriving at one worthy of dissemination. If and when that point arrives, an administrator should be free to share the findings.

Administrative investigators also need to make sure that IRBs understand their primary role as administrators and that such spontaneous discovery is possible. In making this point, it is important that administrative investigators note to IRBs that as administrators they can implement changes in the delivery of care and have full access to patient data to monitor such operations regardless of the decision of the IRB. In addition, investigators should note that their failure to approve the research does not forbid the research itself but simply the dissemination of its findings. Such an argument should make the First Amendment problems more apparent to reviewers.

Another major issue for administrative investigators is preserving flexibility in study design. In traditional biomedical research, clear and fixed protocols must be devised to guarantee reliability in the interpretation of results. Such precision is appropriate when subjecting individuals to risks from which they receive no direct benefit.⁴⁵ Often, IRBs insist on such well-developed protocols from all research submitted for review, including CQIR. However, QI work is conducted very differently. It occurs in rapid, iterative cycles. Since QI involves the delivery of actual care in real time, decisions to alter care must be made and implemented in real time. Any delay to seek approval by an IRB may indeed place patients at risk of harm. Thus, investigators should insist on describing their research design in very broad terms, focusing more on generally stated outcomes of interest than on actual approaches or precise methods of measurement. Such an approach minimizes the need to submit later amendments. More importantly, investigators should highlight that the routine policies of the institution will be followed while noting their administrative right and responsibility to alter

⁴⁵ If the protocol of the experiment is not precise, then the results are not valid. If they are not valid, then patients have been exposed to risk for no reason. The patients are not directly benefiting nor has new knowledge been generated. At least in QI, patients should be benefiting from the routine provision of care.

institutional policies of care as necessary in the interest of providing patients appropriate care.

Lastly, administrative investigators need to make a compelling argument for waiver of informed consent, which as previously noted, primarily rests on making an argument that obtaining consent makes the research impracticable. When QI work involves multitudes of patients, it is infeasible to obtain consent from each of them while simultaneously providing necessary care, particularly in the absence of a direct administrator–patient relationship. But the strongest argument in favor of impracticability is that asking consent undermines the science of quality improvement itself. Quality improvement aims to measure the provision of actual care by the system itself. Traditional biomedical science, on the other hand, aims to answer a particular question about the mechanism of disease or the effect of treatment in isolation from the effects of the healthcare system. As long as inclusion criteria for subjects are appropriately chosen, the need to approach more subjects in biomedical research to obtain an adequate sample for study does not undermine the scientific validity and generalizability of results. However, the process of consent itself may jeopardize the scientific validity of results in the context of CQIR because the object of study is the system itself. If non-consenting and unconsenting⁴⁶ patients differ from consenting patients systematically in a way that alters the validity of conclusions drawn from the research, then the generalizability of results from CQIR is suspect and cannot be improved by the simple recruitment of additional patients.

Indeed, there is good reason to believe that unconsenting and non-consenting patients do differ from consenting patients in systematic ways that can significantly bias results and undermine the scientific validity of the study. In a study of whether consent affects a patient's willingness to participate in a registry for stroke victims—which is essentially what the data collection component of CQIR entails—the requirement of consent significantly altered the findings.⁴⁷ Specifically, unconsenting and non-consenting patients were three times more likely to have died during the hospitalization than consenting patients.⁴⁸ Other epidemiologic and registry studies have also demonstrated the perverse effects of requiring consent.⁴⁹

⁴⁶ Non-consenting subjects are those who are solicited for participation but refuse. Unconsenting subjects leave the system prior to being approached for consent.

⁴⁷ See Jack V. Tu et al., *Impracticability of Informed Consent in the Registry of the Canadian Stroke Network*, 350 NEW ENG. J. MED. 1414, 1414 (2004).

⁴⁸ Incidentally, only about 20% of the nonparticipating patients or surrogates outright refused. Enrolling some patients was simply infeasible. The major reasons for inability to obtain consent included patient death, discharge prior to a successful attempt at consent, and inability to perform consent despite at least three attempts. It should also be noted that approximately 25% of the costs of the registry were related to consent issues alone. *Id.* at 1416.

⁴⁹ See David Armstrong et al., *Potential Impact of the HIPAA Privacy Rule on Data Collection in a Registry of Patients With Acute Coronary Syndrome*, 165 ARCHIVES INTERNAL MED. 1125, 1125 (2005); Pekka Jousilahti et al., *Total and Cause Specific Mortality Among Participants and Non-*

The scientific validity of CQIR is dependent on analyzing the entire population or a representative sample of patients receiving care within the system. But since non-consenting and unconsenting patients are systematically different than consenting patients, then performing CQIR only on consenting patients generates nongeneralizable and invalid results. Thus, performing scientifically valid CQIR is impracticable without waiver of consent. Administrative investigators need to make this argument strongly and forcefully in order to secure access to patient information for the purposes of the dissemination of project results while emphasizing their present right to access the same data for internal operational purposes.

CONCLUSION

Important free speech rights are at stake in disseminating the results of CQIR. Past discussions of whether quality improvement is research that requires IRB review have ignored this important and fundamental issue. The current regulations governing the protection of human subjects violate constitutional principles by being insufficiently tailored to further state aims. Currently, administrative investigators may pursue QI work but may risk legal and professional repercussions for failure to obtain IRB review if they attempt to disseminate the results of the work. Narrowing the focus of IRB review to research that presents more than a minimal risk would properly avoid the unconstitutionality of applying current regulations to clinical quality improvement research. Until such changes in the regulations are made, administrative investigators should forcefully articulate to IRBs their right to free speech as they perform their administrative responsibility to improve the quality of patient care.

