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CONSTITUTIONAL ANALYSIS OF RESEARCH ETHICS REVIEW LAWS: THE UNITED STATES AND BEYOND†

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The ethics review mechanism has long been accepted as a safeguard for the rights and welfare of human research participants. However, where the ethics review requirement is compelled by law, the constitutional concern of free research arises. To respond to this constitutional concern, this Article argues that the authority of research ethics committees should be cautiously designed to tailor to the protection of participants and avoid undue intervention in research content. The current federal regulation vests overly broad discretion to institutional review boards (IRBs) and constitutes a content-based prior restraint. This Article therefore urges a reform to achieve appropriate constraint of IRB review power, which would render the regulation constitutional and legitimize expanding the IRB requirement to encompass equal application regardless of funding source.

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I. INTRODUCTION

Incorporating an ethics review mechanism into the process of research involving human subjects has been widely accepted as the norm. For example, the Declaration of Helsinki states that "[t]he research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins."[1] The International Ethical Guidelines for Biomedical Research Involving Human Subjects also states that "[a]ll proposals to conduct research involving human subjects must be submitted for review of their scientific merit and ethical acceptability to one or more scientific review and ethical review committees. . . . The investigator must obtain their approval or clearance before

1. WORLD MEDICAL ASSOCIATION, WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI: ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS art. 23 (2013), *available at* http://www.wma.net/en/30publications/10policies/b3/.

undertaking the research."[2] This mechanism intends to establish a line of defense, allowing a special committee consisting of members from diverse backgrounds to review research proposals from ethical perspectives in order to safeguard the rights and welfare of research subjects.[3]

This ethics review requirement is currently not only an ethical norm but also a legal mandate. It is legally associated with clinical drug trials in most countries.[4] More importantly, several jurisdictions have established comprehensive research regulation laws that extend the ethics review requirement to wide-ranging applications. For example, the requirement is part of the Common Rule, a federal regulation that applies to basically all research involving human subjects conducted or supported by federal agencies. Certain states such as New York, Virginia, and Maryland and countries such as Denmark, Norway, and Taiwan have enacted research regulation statutes governing not only state actions but also private research practices.[5] Similarly, ethics review is a core mechanism in those statutes.

Where the ethics review requirement is compelled by law, the constitutional concern of free research arises. The freedom of research, an element of constitutional academic freedom, guarantees people an unfettered autonomy to select research topics and methods, formulate and execute research plans, and publish research results and interpretations.[6] A law that requires research to receive approval in advance apparently burdens this freedom and even possibly constitutes a prior restraint of free expression, which carries a heavy presumption against its constitutional validity. If lawmakers do not pay sufficient attention to the concern of academic freedom, they may rashly create ethics review laws that hinder this constitutional right beyond the necessity of pursuing human subject

2. COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES (CIOMS), INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS guideline 2 (2002), *available at* http://www.cioms.ch/publications/layout_guide2002.pdf.

3. *See id.* at 25, 27.

4. *See* THE EUROPEAN FORUM FOR GOOD CLINICAL PRACTICE (EFGCP), THE PROCEDURE FOR THE ETHICAL REVIEW OF PROTOCOLS FOR CLINICAL RESEARCH PROJECTS IN EUROPE (2012), *available at* http://www.efgcp.eu/Downloads/EFGCPReportFiles/United%20Kingdom%20definitive%20Updated.pdf ; THE EUROPEAN FORUM FOR GOOD CLINICAL PRACTICE (EFGCP), DATA ON RESEARCH ETHICS COMMITTEES IN SEVEN COUNTRIES OUTSIDE EUROPE, *available at* http://www.efgcp.eu/Downloads/EFGCPReportFiles/United%20Kingdom%20definitive%20Updated.pdf (last visited Dec. 1, 2014).

5. *Infra* II.A.

6. *Infra* III.A.

protection. Furthermore, the failure to appropriately address the concern of academic freedom may become an obstacle to advancing the rights and welfare of human subjects. If lawmakers cannot offer a scheme that prevents unreasonable intervention, ethics review laws may encounter increasing opposition, and consequently, effective protection of human subjects may stall.[7] This Article intends to analyze current ethics review laws from the perspective of academic freedom and determine a balanced solution that safeguards the rights and welfare of research subjects and preserves adequate breathing space for academic freedom.

This Article argues that to conform to the constitutional value of respecting academic freedom, the authority of research ethics committees (RECs) should be cautiously designed to tailor to the protection of participants and avoid undue intervention in research content. The current federal regulation vests overly broad discretion to institutional review boards (IRBs) and constitutes content-based prior restraint, posing severe problems regarding constitutional validity. This Article urges a reform toward appropriate restraint of IRB review power, which would render the regulation constitutional as well as legitimize expanding the IRB requirement to encompass equal application regardless of funding source.

The discussion is presented in three parts. Part II surveys research ethics laws in different jurisdictions. This part encompasses not only the federal regulations but also several state laws and national laws in other countries to present a broad description and diverse regulatory models of ethics review laws. Part III discusses the constitutional discourse. After the implications of constitutional academic freedom are identified, this part applies the long-established jurisprudence of free expression to research ethics review laws and raises substantial constitutional concerns. Part IV focuses on the Common Rule, presents an analysis of its problems, and provides potential solutions. The analysis includes three dimensions, namely the failure to adequately restrain IRB discretion, defects of responding to constitutional questions by applying soft regulatory models, and a lack of guarantee of effective remedy.

Before the discussion, terminology should first be clarified. The body responsible for research ethics review has different names

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7. It can be evidenced by the fact that the attempt of the U.S. Department of Health and Human Services to extend the application of the Common Rule has incurred strong opposition. *See* AMERICAN ANTHROPOLOGICAL ASSOCIATION, COMMENTS ON PROPOSED CHANGES TO THE COMMON RULE (76 FR 44512), at 22–23, *available at* http://www.aaanet.org/issues/policy-advocacy/upload/Human-Subjects-Research.pdf (last visited Aug. 6, 2014).

in different jurisdictions. U.S. law and literature generally use the term *institutional review board*,[8] whereas *research ethics committee* is used in European countries.[9] The term *research ethics committee*, which clearly presents its primary function, is used in this Article when referring to ethics review bodies in a general sense. Conversely, *institutional review board*, which the U.S. Common Rule specifically adopts, is used in this Article when discussing U.S. regulations.

II. VARIATIONS OF RESEARCH ETHICS REVIEW LAWS IN DIFFERENT JURISDICTIONS

A. Overview

Different countries incorporate the ethics review requirement into their legal systems to different extents. As mentioned, some countries established comprehensive research regulation laws that extend the mandate of ethics review beyond the context of clinical trials. Those laws are particularly the focus of this Article in consideration of their effect on the freedom of research. Countries adopting such comprehensive legal regulations are relatively few.[10]

Several examples are examined as follows. First, the United States has a federal regulation—the Common Rule—to protect human subjects. The rule applies to basically "*all research involving human subjects* conducted, supported or otherwise subject to regulation by any federal department or agency."[11] Regarding the concept of research involving human subjects, the rule determines its scope by defining a *human subject* as "a living individual about

8. E.g., 45 C.F.R. § 46.102(g) (2009). There are exceptions. For example, New York law and Virginia law use the term "human research review committee." N.Y. Pub. Health Law § 2444 (Mckinney, 2012); VA. CODE ANN. § 32.1–162.19 (2014).

9. *See* European Network of Research Ethics Committees, Welcome to EUREC, http://www.eurecnet.org/index.html (last visited July 27, 2014).

10. Existing literature has mentioned some examples of such countries. *See* Marie Hirtle et al., *A Comparative Analysis of Research Ethics Review Mechanisms and the ICH Good Clinical Practice Guideline*, 7 EUR. J. HEALTH L. 265, 268, 289 (2000) (mentioning French, Denmark, Hungary, and the United States); Dominique Sprumont & Gytis Andrulionis, *Effectiveness of Protection of Biomedical Research Subjects under International and National Law*, JURISPRUDENCIJA, 2009 Nr. 2 (116), at 245, 258 (mentioning Lithuania). As far as the knowledge of this Article, Norway and Taiwan are also examples of such countries.

11. 45 C.F.R. § 46.101(a) (2009) (emphasis added).

whom an investigator (whether professional or student) conducting research obtains (1) [d]ata through intervention or interaction with the individual, or (2) [i]dentifiable private information,"[12] thereby providing extensive coverage. At the state level, New York, Virginia, and Maryland have established their own laws that extend requirements to all or at least a wide range of human subject research, regardless of the characteristics of the research entity or funding source. To determine the scope of application, Maryland law borrows the definition of human subject from the Common Rule and applies to "all research using a human subject." [13] Comparatively, New York and Virginia laws associate the requirement with "human research" and directly define that concept.[14] For example, New York law defines human research as:

> any medical experiments, research, or scientific or psychological investigation, which utilizes human subjects and which involves physical or psychological intervention by the researcher upon the body of the subject and which is not required for the purposes of obtaining information for the diagnosis, prevention, or treatment of disease or the assessment of medical condition for the direct benefit of the subject.[15]

Denmark, Norway and Taiwan, among others, have enacted statutes to regulate an extensive range of human subject research. In Denmark, the Act on Research Ethics Review of Health Research Projects mandates that, subject to certain exceptions, health research projects shall comply with the requirement of research ethics evaluation.[16] A *health research project* is defined as a "project that includes trials involving liveborn human individuals, human gametes intended for fertilization, fertilized human eggs, embryonic cells and embryos, tissue, cells and genetic material from humans, embryos etc. or deceased persons." [17] In Norway, the Act on Medical and Health Research "applies to all medical and health

12. 45 C.F.R. § 46.102(f) (2009).

13. MD. HEALTH-GEN. CODE ANN. §§ 13-2001(c), 13-2002 (2014).

14. N.Y. CLS PUB. HEALTH §§ 2441, 2444 (2014); VA. CODE ANN. §§ 32.1–162.16, 32.1–162.19 (2014).

15. N.Y. CLS PUB. HEALTH § 2441 (2014).

16. Act on Research Ethics Review of Health Research Projects, 2011, §§ 13, 14 (Den.) (An English version of the Act is available at http://www.cvk.sum.dk/English/actonabiomedicalresearch.aspx).

17. Act on Research Ethics Review of Health Research Projects, 2011, § 2 (Den.).

research on human beings, human biological material or personal health data."[18] The act further provides a concise definition for *medical and health research* as "activity conducted using scientific methods to generate new knowledge about health and disease."[19] In Taiwan, the Human Subjects Research Act regulates all "research involving obtaining, investigating, analyzing, or using human specimens or an individual person's biological behavior, physiological, psychological, genetic or medical information."[20] To clarify the scope of this definition, the Department of Health (currently the Ministry of Health and Welfare) promulgated an interpretative rule excluding social and behavioral research and humanities research, consequently implying that all other types of research involving human subjects are in the scope of the Act.[21] Although the Act does not cover all types of research, the funding policy of the Ministry of Science and Technology includes the document certifying a submission for ethics review as one of the requirements for granting funding to even social science and humanities research involving human subjects.[22]

Although the aforementioned countries and states share the same goodwill to protect human subjects through ethics review, the design of ethics review mechanisms varies. To facilitate later analysis, this Article presents two sets of design comparisons that might be salient from the perspective of academic freedom. One set concerns the strategy of regulating private entities; the other concerns the affiliation of RECs. The following two sections present these sets of comparison.

B. Direct Regulation Versus Indirect Regulation

In some jurisdictions, such as Denmark, Norway, Taiwan and the aforementioned U.S. states, the legislatures enacted statutory law to protect human subjects. Naturally, the laws have direct force on not only public but also private research actors. It follows that a violation triggers criminal, administrative, or civil penalties. For example, the Denmark law imposes "a fine or up to 4 months of

18. Act on Medical and Health Research, 2008, § 2 (Nor.) (An English version of the Act is available at http://www.ub.uio.no/ujur/ulovdata/lov-20080620-044-eng.pdf).

19. Act on Medical and Health Research, 2008, § 4 (Nor.).

20. Human Subjects Research Act, 2011, art. 4, ¶ 1 (Taiwan).

21. Directions Wei-Shu-Yi No.1010064538, Department of Health (Mar. 22, 2012) (Taiwan).

22. Directions on the Ministry of Science and Technology Funding Research Projects, 2014, § 11 (Taiwan).

imprisonment" on anyone who fails to comply with the requirement of ethics review evaluation.[23] The penalties according to the Norway law are "fines or imprisonment not exceeding one year or both" and for "particularly aggravating circumstances," the sentence could be up to 3 years.[24] In Taiwan, the punishment for research institutions and researchers who violate the requirement is an administrative fine ranging from NT$100,000 to NT$1 million.[25] In New York, the liability is generally "a civil penalty . . . not to exceed two thousand dollars."[26] In Virginia, the law makes a violation a Class 1 misdemeanor.[27] (The laws in these jurisdictions are labeled "direct regulation" in this Article because they directly exert "command and control" over private sectors.)

Conversely, the federal law in the United States—the Common Rule—exists in the form of an administrative regulation instead of a statute passed by Congress. The rule certainly has internal effects, directly restraining the research conducted by the federal government itself. Furthermore, the rule also applies to private research supported by the federal government.[28] The rationale is that a government may provide support for research with conditions and therefore may impose restrictions on private recipients through its research funding conditions. In nature, the rule is a funding policy that sets forth such conditions and requires recipients of support to follow them.[29] Legally, a violation of the IRB requirement by a private entity triggers funding-related consequences—specifically, early termination or suspension of research support[30]—rather than criminal or civil sanctions. In addition to the U.S. Common Rule, the funding policy, in the nature of administrative rule, promulgated by the Ministry of Science and Technology in Taiwan, is an example of this type of regulation. Through this administrative rule, submission for ethics review becomes a precondition to receive research grants from the Ministry of Science and Technology.[31] (Laws of this type are labeled "indirect

23. Act on Research Ethics Review of Health Research Projects, 2011, § 41 (Den.).

24. Act on Medical and Health Research, 2008, § 54 (Nor.).

25. Human Subjects Research Act, 2011, art. 22, 25 (Taiwan).

26. N.Y. CLS PUB. HEALTH § 12. (2014).

27. VA. CODE ANN. § 32.1-27 (2014).

28. 45 C.F.R. § 46.101(a) (2009).

29. *See* James Weinstein, *Institutional Review Boards and the Constitution*, 101 NW. U. L. REV. 493, 550–51 (2007).

30. 45 C.F.R. § 46.123 (2009).

31. Directions on the Ministry of Science and Technology Funding Research Projects, 2014, § 11 (Taiwan).

regulation" in this Article because they generate regulatory effects through a funding condition instead of directly imposing restrictions on the private sector.)

C. Government-Based RECs Versus Institution-Based RECs

In some countries, RECs are established by governments or through delegation of power by governments.[32] For example, in Denmark, regulated research projects must be submitted to the national or regional research ethics committees based on the areas involved. [33] The law mandates the regional councils, the governmental bodies that govern the affairs of the regions in Denmark,[34] to establish the regional research ethics committees[35] and mandates the Minister for the Interior and Health to establish the national research ethics committee. [36] In Norway, research regulated by the Act on Medical and Health Research must be approved by the regional committees for medical and health research ethics,[37] which was established by the Ministry according to the Act on Ethics and Integrity in Research.[38] In these cases, government-based RECs, and only they, bear the responsibility and authority of ethics review.

By contrast, some countries adopt a system that assigns the task of ethics review to institution-based RECs. For example, the U.S. Common Rule provides the requirements regarding the establishment of an IRB and mandates an institution conducting regulated research to submit written assurance that specifies the "[d]esignation of one or more IRBs established in accordance with the requirements."[39] The rule allows each research institution to establish its own IRB for ethics review. Although IRBs located at separate entities exist, reviews performed by the IRBs established

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32. Marie Hirtle et al., *supra* note 10, at 269.

33. Act on Research Ethics Review of Health Research Projects, 2011, § 15 (Den.).

34. About Municipalities and Regions, http://english.oim.dk/responsibilities/governance-of-municipalities-and-regions/about-municipalities-and-regions.aspx (last visited Sept. 16, 2014).

35. Act on Research Ethics Review of Health Research Projects, 2011, § 35 (Den.).

36. Act on Research Ethics Review of Health Research Projects, 2011, § 37 (Den.).

37. Act on Medical and Health Research, 2008, §§ 9, 10 (Nor.).

38. Act on Ethics and Integrity in Research, 2006, § 4 (Nor.) (An English version of the Act is available at https://www.etikkom.no/In-English/Act-on-ethics-and-integrity-in-research/).

39. 45 C.F.R. §§ 46.103(a), (b), 46.107, 46.108 (2009).

inside institutions at which research is conducted has long been a typical practice.[40] In other words, the rule creates a dispersive review system that develops from institutions. The feature of such a system is even more evident in the provision of New York law, which maintains that "[e]ach public or private institution or agency which conducts, or which proposes to conduct or authorize, human research, shall establish a human research review committee."[41] The same model is adopted in Taiwan. The Human Subjects Research Act provides that the review of research protocols "shall be conducted by the research entity's IRB," unless the entity does not have an IRB.[42] Unlike the public, concentrated review system in Denmark and Norway, the review systems in the United States and Taiwan are institution-based and dispersive.

III. CONSTITUTIONAL IMPLICATIONS OF RESEARCH ETHICS REVIEW LAWS

A. Rise of the Academic Freedom Concern

In *Keyishian v. Board of Regents*,[43] the U.S. Supreme Court declared:

> Our Nation is deeply committed to safeguarding academic freedom, which is of transcendent value to all of us, and not merely to the teachers concerned. That freedom is therefore a special concern of the First Amendment, which does not tolerate laws that cast a pall of orthodoxy over the classroom.[44]

This statement clearly establishes that academic freedom is guaranteed by the Constitution under the protection of free expression. Although the Court does not explain the content of academic freedom, the Declaration of Principles on Academic Freedom and Academic Tenure has satisfactorily identified three elements of this freedom since 1915: (1) freedom of research, (2) freedom of teaching, and (3) freedom of extramural utterance and

40. NATIONAL BIOETHICS ADVISORY COMMISSION, ETHICAL AND POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS 6 (2001).

41. N.Y. CLS PUB. HEALTH § 2444 (2014).

42. Human Subjects Research Act, 2011, art. 5, ¶ 2 (Taiwan).

43. 385 U.S. 589 (1967).

44. *Id.* at 603.

action.[45] Regarding the freedom of research, the 1940 Statement of Principles on Academic Freedom and Tenure further elaborates that "[f]reedom in research is fundamental to the advancement of truth" and lists it first among various aspects of academic freedom to emphasize that "[t]eachers are entitled to full freedom in research and in the publication of the results, subject to the adequate performance of their other academic duties." [46] The 1915 Declaration and 1940 Statement have been widely accepted as shared norms by the communities of both professors and universities[47] and have been endorsed by several courts.[48] They fill the blank left by the U.S. Supreme Court, which extends constitutional protection to academic freedom but has not clearly defined it. Based on that shared understanding in the academic community, when the U.S. Supreme Court gains opportunities to address the claim of infringing on free research in the future, it could easily find that the freedom of research is an elemental aspect of academic freedom and, therefore, protected by the Constitution under the provision of free expression.[49]

The freedom of research guarantees an autonomy to engage in research, including selecting research topics and methods, formulating and executing research plans, and publishing research results and interpretations. As a member of the family of free expression, freedom of research undoubtedly protects research activities with a communicative property, such as publication and presentation. As to activities that do not involve communication or

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45. Am. Ass'n of Univ. Professors, 1915 Declaration of Principles on Academic Freedom and Academic Tenure, *available at* http://www.aaup.org/report/1915-declaration-principles-academic-freedom-and-academic-tenure (last visited July 31, 2014).

46. Am. Ass'n of Univ. Professors, 1940 Statement of Principles on Academic Freedom and Tenure, *available at* http://www.aaup.org/report/1940-statement-principles-academic-freedom-and-tenure (last visited July 31, 2014).

47. Browzin v. Catholic Univ. of America, 527 F.2d 843, 847 n.8 (D.C. Cir. 1975).

48. *E.g., id* (citing both the 1915 Declaration and 1940 Statement); Hulen v. Yates, 322 F.3d 1229, 1239 (10th Cir. 2003) (citing the 1940 Statement); Otero-Burgos v. Inter American University, 558 F.3d 1, 10 (1st Cir. 2009) (citing the 1940 Statement); Keiser v. State Bd. of Regents of Higher Ed., 193 Mont. 35, 44–45 (1981) (citing the 1940 Statement); Barnes v. Washington State Community College Dist. No. 20, 85 Wash.2d 90, 93–94 (1975) (citing the 1940 Statement).

49. Some courts have explicitly or implicitly considered that freedom in research is a part of academic freedom. *E.g.*, Barnes v. Washington State Community College Dist. No. 20, 85 Wash.2d 90, 94 (1975); Omosegbon v. Wells, 335 F.3d 668, 676–77 (7th Cir. 2003). *See also* ROBERT C. POST, DEMOCRACY, EXPERTISE, AND ACADEMIC FREEDOM: A FIRST AMENDMENT JURISPRUDENCE FOR THE MODERN STATE 61, 65–66 (2012).

are generally considered "conducts," particularly research planning and implementation actions, scholarly opinions also mainly agree on their protected status, based on a precondition rationale. [50] Specifically, research planning and implementation activities are essential preconditions to produce research results. If the Constitution guarantees free publication but allows the State to arbitrarily intervene in those precondition activities, that guarantee would be nearly meaningless. This precondition rationale is not foreign to the U.S. Supreme Court, which has applied the First Amendment in ensuring the protection of newsgathering activities by stating that "without some protection for seeking out the news, freedom of the press could be eviscerated" in *Branzburg v. Hayes.*[51] Moreover, the entire process of a research project actually consists of numerous impartible expressive and non-expressive elements. For example, formulating and executing research plans may involve numerous communications among members of a research team and between the research team and participants and wider academic communities. Therefore, different aspects and stages of research should be considered as a whole to be covered by the constitutional freedom of research, regardless of whether research is completed or published.

Research ethics review laws inevitably raise concerns of academic freedom because they impose notable burdens on research. Ethics review processes can delay research implementation and cost researchers additional resources for preparing review applications and subsequent reports. More substantially, an REC may direct or order researchers to change their research plans in a manner with which they disagree. Numerous researchers and commentators have therefore discussed the negative effects caused by the review system or questioned the wisdom of the current regulation.[52]

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50. James R. Ferguson, *Scientific Inquiry and the First Amendment*, 64 CORNELL L. REV. 639, 649–54 (1979); John A. Robertson, *The Scientist's Right to Research: A Constitutional Analysis*, 51 S. CAL. L. REV. 1203, 1216–18 (1977); Roy G. Spece, Jr. & Jennifer Weinzierl, *First Amendment Protection of Experimentation: A Critical Review and Tentative Synthesis/Reconstruction of the Literature*, 8 S. CAL. INTERDISC. L.J. 185, 213–19 (1998); Michael Davidson, *First Amendment Protection for Biomedical Research*, 19 ARIZ. L. REV. 893, 899–900 (1977); Richard Delgado et al., *Can Science Be Inopportune? Constitutional Validity of Governmental Restrictions on Race-IQ Research*, 31 UCLA L. REV. 128, 160–62 (1983).

51. Branzburg v. Hayes, 408 U.S. 665, 681 (1972).

52. *E.g.*, Malcolm M. Feeley, *Legality, Social Research, and the Challenge of Institutional Review Boards*, 41 LAW & SOC'Y REV. 757, 762–75 (2007); Robert

Because academic freedom is not only a social interest but also a constitutional right, the controversy extends beyond the adequacy of research ethics review laws; the constitutionality of those laws, which is the focus of this Article, has attracted heated debate. A constitutional law scholar has contended that the ethics review requirement constitutes licensing of speech and conflicts with the First Amendment.[53] By contrast, some scholars defend the constitutional validity of the current regulation by maintaining that the regulation does not aim at communicative elements of research or impose a requirement on researchers by force of law.[54] In contrast to these opinions, this Article argues that a research ethics review law is not unconstitutional *per se*, but it could become an unconstitutional prior restraint if it is inadequately designed and the current regulations may be an example of this. Because academic freedom is rooted in the First Amendment and is subject to the same principles as other members of the family of free expression,[55] the constitutional boundary based on free expression jurisprudence is first explored in the following section in order to pave the way for the analysis and argument on research ethics review laws.

B. Constitutional Boundary Based on Free Expression Jurisprudence

The long development of free expression case law and scholarly deliberation in the United States has formed a

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Dingwall, *"Turn off the Oxygen ..."*, 41 LAW & SOC'Y REV. 787, 790 (2007); John H. Mueller, *Ignorance Is Neither Bliss Nor Ethical*, 101 NW. U. L. REV. 809, 822 (2007); Richard A. Epstein, *Defanging IRBs: Replacing Coercion with Information*, 101 NW. U. L. REV. 735, 735 (2007); Todd J. Zywicki, *Institutional Review Boards as Academic Bureaucracies: An Economic and Experiential Analysis*, 101 NW. U. L. REV. 861, 864–72 (2007); Jack Katz, *Ethical Escape Routes for Underground Ethnographers*, 33 AM. ETHNOLOGIST 499, 500 (2006); Zachary M. Schrag, *The Case against Ethics Review in the Social Sciences*, 7 RES. ETHICS 120, 122 (2011); C. K. Gunsalus et al., *The Illinois White Paper: Improving the System for Protecting Human Subjects: Counteracting IRB "Mission Creep"*, 13 QUALITATIVE INQUIRY 617 (2007); AMERICAN ANTHROPOLOGICAL ASSOCIATION, *supra* note 7; Am. Ass'n of Univ. Professors, *Research on Human Subjects: Academic Freedom and the Institutional Review Board*, http://www.aaup.org/AAUP/comm/rep/A/humansubs.htm (last visited Aug. 7, 2014).

53. Philip Hamburger, *The New Censorship: Institutional Review Boards*, 2004 SUP. CT. REV. 271, 271 (2004) [hereinafter *New Censorship*]; Philip Hamburger, *Getting Permission*, 101 NW. U. L. REV. 405, 407 (2007) [hereinafter *Getting Permission*].

54. Weinstein, *supra* note 29, at 550–51. *See also* Epstein, *supra* note 52, at 736–37.

55. Omosegbon v. Wells, 335 F.3d 668, 676–77 (7th Cir. 2003).

comprehensive analytic structure in addressing free expression scenarios. The structure primarily consists of content-based and content-neutral distinction, high-value and low-value speech distinction, and prior restraint doctrine. Before applying this analytic structure, using the right of assembly, another member of the family of free expression,[56] as an analogy helps elucidate the big picture. A feature of the freedom of research has been asserted as the reason that this right requires stricter regulation—that is, the exercise of the right involves *conducts* that affect others and society—and the right of assembly shares this feature. Therefore, what the U.S. Supreme Court has ruled in cases pertaining to the right of assembly provides a pertinent starting point to understanding the constitutional boundary of research ethics review laws.

When addressing the licensing systems of a parade, procession, or demonstration, the Court neither regards them as unconstitutional *per se* nor consistently maintains their validity. In *Cox v. New Hampshire*,[57] the Court sustained a statute that requires prior permission for parades or processions because the licensing authority is limited to account for only "considerations of time, place and manner so as to conserve the public convenience" and is "not vested with arbitrary power or an unfettered discretion." [58] Comparatively, in *Cox v. Louisiana*, the Court invalidated a statute regarding obstructing public passages because the system provides local officials broad discretion to "determine which expressions of view will be permitted and which will not."[59] Citing precedents, the Court asserts that "appropriate, limited discretion, under properly drawn statutes, or ordinances, concerning the time, place, duration, or manner of use of the streets for public assemblies may be vested in administrative officials" and "a State or municipality cannot require all who wish to disseminate ideas to present them first to police authorities for their consideration and approval, with a discretion in the police to say some ideas may, while others may not, be disseminated."[60]

The aforementioned opinions regarding right of assembly are consistent with well-established free expression jurisprudence.

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56. JOHN E. NOWAK & RONALD D. ROTUNDA, CONSTITUTIONAL LAW §16.53(c) (8th ed. 2010) (citing the Supreme Court cases to present that the freedoms of speech, association, assembly, and petition all "are elements of a broad right to freedom of expression").

57. Cox v. New Hampshire, 312 U.S. 569 (1941).

58. *Id.* at 575–76.

59. Cox v. Louisiana, 379 U.S. 536, 557 (1965).

60. *Id.* at 557–58 (quotation and citation omitted).

When a law targets the non-expressive part of conducts, it is content-neutral regulation, which requires only intermediate scrutiny and therefore can be justified if the interests preventing the harms caused by the conducts are substantial. Conversely, when a law intervenes in the content of expression, it is content-based regulation, which has to pass strict scrutiny and therefore is very difficult to survive judicial review, unless the targeted speech is in one of the low-value speech categories, such as defamatory, obscene, commercial, or hate speech.[61] Furthermore, when content-based regulation constitutes a prior restraint (not only aiming at the content of expression but also requiring a prior review), the standard is even higher than strict scrutiny. The regulation carries a heavy presumption against its constitutionality and survival is extremely limited.[62]

Applying this understanding to research ethics review naturally leads to the conclusion that the constitutional validity of the law depends on whether the power of RECs has been carefully restrained. The law granting extensive discretion to RECs to allow them to intervene in the content of research arbitrarily constitutes a prior restraint and could not defeat its heavy unconstitutional presumption. To conform to the constitutional value of respecting academic freedom, the authority of RECs must be cautiously tailored to protect: (1) participants' interests regarding their life, liberty, body integrity, health, privacy, and property or (2) participants or society from negative communicative effects of certain low-value speech. In pursuit of the first end, the regulation is content-neutral and the governmental interests involved are sufficient to pass intermediate scrutiny. In pursuit of the second end, although the regulation targets expression, it may be justified because the governmental interests involved may outweigh the interest of low-value speech. In summary, the constitutionality question primarily rests on how a research ethics review law crafts the power of RECs and, in this test, problems of the current regulation become evident.

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61. *See generally*, JEROME A. BARRON & C. THOMAS DIENES, FIRST AMENDMENT LAW 28–44 (4th ed. 2008); LAURENCE H. TRIBE, AMERICAN CONSTITUTIONAL LAW 789–94, 832–41 (2d ed. 1988); KEITH WERHAN, FREEDOM OF SPEECH 72–79 (2004); DAVID M. O'BRIEN, CONGRESS SHALL MAKE NO LAW: THE FIRST AMENDMENT, UNPROTECTED EXPRESSION, AND THE U.S. SUPREME COURT 11–13 (2010); Geoffrey R. Stone, *Content Regulation and the First Amendment*, 25 WM. & MARY L. REV. 189, 190–97 (1983); Geoffrey R. Stone, *Content-Neutral Restrictions*, 54 U. CHI. L. REV. 46, 47–48 (1987).

62. *See generally*, Werhan, *supra* note 61, at 138–39; TRIBE, *supra* note 61, at 1039–41, 1045–54; NOWAK & ROTUNDA, *supra* note 56, at § 16.16(c).

IV. PROBLEMS OF THE CURRENT RESEARCH ETHICS REVIEW LAW AND POTENTIAL SOLUTIONS

This part analyzes the problems of the current regulatory status and proposes potential solutions. The first section concerns the failure of the regulation to adequately restrain IRB discretion, which may allow IRBs to intervene in the content of research. Although the Common Rule regulates in soft manners, the second section presents the insufficiency of adopting those soft regulatory models to avoid a constitutional challenge. The third section turns to the remedy issue, revealing the lack of access to effective remedy for individual researchers when they suffer undue intervention from IRBs.

A. Failure to Adequately Restrain REC Discretion

Several scholars have criticized IRBs as "lawless" and questioned their conformity with legality.[63] According to current regulations, IRBs are subject to only a few rules. These rules concern various types of affairs, such as record maintenance, membership, and procedure and provide only limited and abstract guidance toward evaluating research to make a review decision.[64] Specifically, the Common Rule establishes several criteria that IRBs must use to determine whether a research proposal has been satisfied.[65] However, some of the criteria, such as whether risks are minimized, risk–benefit balance is reasonable, and adequate measures for monitoring safety data and protecting privacy and confidentiality have been considered, are abstract and allow different and subjective judgments. More importantly, the Common Rule requires IRBs to examine the satisfaction of those criteria but does not restrain IRBs to examine only those criteria. Although a provision in the Common Rule mentions certain matters for which IRBs should not account,[66] the boundary of IRB authority remains vague and unclear.

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63. *E.g.*, Feeley, *supra* note 52, at 770–72; Katz, *supra* note 52, at 504–05; Zywicki, *supra* note 52, at 863; Gunsalus et al., *supra* note 52, at 634–36; Malcolm M. Feeley, *Response to Comments*, 41 LAW & SOC'Y REV. 811, 814–15 (2007); Jack Katz, *Toward a Natural History of Ethical Censorship*, 41 LAW & SOC'Y REV. 797, 805–08 (2007).

64. *See* Daniel G. Stoddard, Note, *Falling Short of Fundamental Fairness: Why Institutional Review Board Regulations Fail to Provide Procedural Due Process*, 43 CREIGHTON L. REV. 1275, 1285–89 (2010).

65. 45 C.F.R. § 46.111 (2009).

66. 45 C.F.R. § 46.111(a)(2) (2009) ("The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the

From the perspective of constitutional free expression, this "lawless" situation suggests that IRBs have excessive discretion and can avoid accusation of law violation even when their refusing approval of research is based on their disagreement with the viewpoints of applicants. Confronted with the unconstitutionality challenge, some scholars have argued that the requirement of IRB prior review is a content-neutral regulation imposing only an incidental burden on speech because the requirement does not aim at the expressive elements of research.[67] However, this argument overlooks that the regulation in its nature allows IRBs to review and intervene in the expressive content of research. Whereas the non-expressive elements are the target of the regulation, expressive elements are equally the target and cannot be considered incidental casualties. To be precise, when the law does not adequately restrain the discretion of IRBs and creates ample room for arbitrary rejection of viewpoints, this law can only be conceptualized as content-based on its face.[68] Because a content-based prior restraint triggers a considerably high standard of judicial review, as the jurisprudence of the right of assembly satisfactorily presents, lawmakers should avoid this type of regulation to conform to constitutional values.

Despite this problem, abolishing research ethics review is not an adequate solution. Sitting in any IRBs long enough would enable anyone to recognize that researchers without sufficient respect for participants and practices deviating from ethical tracks do exist. Because the self-interests of researchers in research implementation are involved, researchers cannot be relied upon to protect the best interests of participants. Against this backdrop, IRBs serving as an external safeguard have been a highly valuable innovation. It is the arbitrary use of research ethics review, and not the idea of research ethics review itself, that deserves the blame.

Slight changes would save the regulation from invalidity. Unlike other criticism of IRBs, this Article indicates that a research ethics review law (i.e., the requirement of IRB prior review) is not necessarily unconstitutional. Its constitutionality depends on how the power of IRBs is designed. First, the regulation should limit the authority of IRBs to consider, in principle, only content-neutral aspects such as the time, place, and manner of research activities. In

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possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.").

67. Weinstein, *supra* note 29, at 526–27.

68. *See supra* Part III.B; *see also, e.g.*, Forsyth County, Ga. v. Nationalist Movement, 505 U.S. 123, 130–33 (1992); City of Lakewood v. Plain Dealer Publ'g Co., 486 U.S. 750, 755–57 (1988).

addition, because a law that burdens expression for the purpose of diminishing secondary effects, rather than communicative effects, of the expression is still considered a content-neutral regulation and is subject to only intermediate scrutiny,[69] the regulation may allow IRBs to intervene in certain expressive parts of research if the purpose is to protect participants or third parties from the secondary effects of such expressive parts. For example, if a proposed consent form contains false, deceptive, or misleading information on material matters, then the interests of participants regarding their life, liberty, body integrity, health, privacy, and property would be at stake, because their decisions to surrender these interests would be based on a problematic foundation and would not be truly autonomous. Therefore, vesting power in IRBs to address false, deceptive, and misleading information and, for similar reasons, to address plagiarism and copyright infringements is justifiable.

Second, if the regulation allows IRBs to intervene in certain expressive parts of research for the purpose of suppressing their communicative effects, it should restrain the authority of IRBs in this regard to counteract only low-value speech. Because scientific inquiry is presumed high value under the rationale of the "marketplace of ideas,"[70] the situations that fall into low-value categories are limited and should be carefully identified. For example, if the language fashioned to communicate to participants seriously expresses "an intent to commit an act of unlawful violence" to participants or the group that participants belong to, it constitutes a "true threat."[71] The regulation may grant IRBs the power to diminish this type of unprotected hate speech, although the

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69. City of Renton v. Playtime Theatres, Inc., 475 U.S. 41, 47–48 (1986). *See also* EUGENE VOLOKH, THE FIRST AMENDMENT AND RELATED STATUTES 342–43 (3d ed. 2008); KATHLEEN M. SULLIVAN & GERALD GUNTHER, CONSTITUTIONAL LAW 1130–38 (15th ed. 2004).

70. The nature of scientific inquiry is to pursue truths. And the "marketplace of ideas" theory, an influential rationale in support of the First Amendment guarantee, establishes that government should not suppress free speech because placing ideas in a free marketplace is the best way to search for truth. Regarding the "marketplace of ideas" or search-for-truth rationale, *see* GEOFFREY R. STONE ET AL., THE FIRST AMENDMENT 9–10 (3d ed. 2008); Robert C. Post, *Reconciling Theory and Doctrine in First Amendment Jurisprudence, in* ETERNALLY VIGILANT: FREE SPEECH IN THE MODERN ERA 152, 154–64 (Lee C. Bollinger & Geoffrey R. Stone eds., 2002). The U.S. Supreme Court has protected academic freedom on the ground of the "marketplace of ideas," *see* Keyishian v. Board of Regents, 385 U.S. 589, 603 (1967).

71. For the definition of true threats, *see* Virginia v. Black, 538 U.S. 343, 344 (2003). *See also* O'BRIEN, *supra* note 61, at 62–67; NOWAK & ROTUNDA, *supra* note 56, at § 16.39(d); VOLOKH, *supra* note 69, at 166–67.

opportunity to exercise this power is likely extremely rare. For another example, if research is conducted by pharmaceutical companies and investigates a product or potential product,[72] the research project may fall within the scope of commercial speech.[73] Since commercial speech receives less protection than ordinary speech, the regulation would have broader room to allow IRBs to address potential problems accompanied by commercial speech, such as possible distortion of information.

B. Defects of Responding to the Constitutional Question By Applying the Soft Regulatory Models

A certain uniqueness of the U.S. Common Rule warrants further discussion. The Common Rule has not attracted considerable constitutional concern until recently, partially because it regulates in a mild manner.[74] As mentioned in the previous section, the Common Rule adopts indirect regulation and an institution-based REC system. Both the models of indirect regulation and institution-based RECs leave some space for academic freedom to breathe and therefore may relax the alertness of many people. However, could the regulation really avoid allegations of unconstitutionality because of the models it adopts? Would these models pose other problems?

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72. Pharmaceutical companies have recognized and utilized research as a valuable resource to affect opinions regarding diseases and drugs for marketing purposes. The problem of pharmaceutical companies manipulating medical knowledge through ghost-managed research and publications has attracted serious attention in recent years. *See, e.g.*, Sergio Sismondo, *Ghosts in the Machine: Publication Planning in the Medical Sciences*, 39 SOC. STUD. SCIENCE 171 (2009); David Healy & Dinah Cattell, *Interface between Authorship, Industry and Science in the Domain of Therapeutics*, 183 BRIT. J. PSYCHIATRY 22 (2003); Sergio Sismondo, *Ghost Management: How Much of the Medical Literature Is Shaped Behind the Scenes by the Pharmaceutical Industry?*, 4 PLOS MED. 1429 (2007); Joseph S. Ross et al., *Guest Authorship and Ghostwriting in Publications Related to Rofecoxib: A Case Study of Industry Documents From Rofecoxib Litigation*, 299 JAMA 1800 (2008).

73. For the definition of commercial speech, *see* Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 762 (1976); Bolger v. Youngs Drug Products Corp., 463 U.S. 60, 66–68 (1983). However, where exactly the line between commercial speech and non-commercial speech is remains unclear. DANIEL A. FARBER, THE FIRST AMENDMENT 157 (2d ed. 2003); VOLOKH, *supra* note 69, at 190; BARRON & DIENES, *supra* note 61, at 171. In my view, two elements are crucial for the definition of commercial speech: (1) the speech refers to a specific product or service; and (2) the speaker has an economic motivation for promoting that product or service.

74. Hamburger, *The New Censorship*, *supra* note 53, at 276.

First, although the regulation of the Common Rule appears indirect on paper, it actually leads to a result close to direct regulation. Theoretically, research institutions may freely decide not to follow the IRB requirement and are confined by the requirement because they voluntarily accept it in exchange for receiving federal funding.[75] Consequently, accusing the regulation of imposing a mandatory restriction on people and infringing on their constitutional rights appears to be difficult. However, the Common Rule in reality has a sweeping effect instead of affecting only federally funded research through funding conditions.[76] A research institution that has established an IRB mechanism for federally funded research naturally applies the mechanism to all research conducted in the institution;[77] in particular, an IRB as a bureaucratic measure has a tendency to expand its regulatory territory.[78] Moreover, since the Common Rule sets IRB review as a standard mechanism for protecting participants, institutions are pressed to follow the IRB requirement regardless to make their research *appear* ethical and avoid the risk of tort liability.[79] Consequently, numerous universities have applied the IRB requirement to all research regardless of funding source.[80] For a regulation with such powerful and extensive influence, naming it indirect regulation is only an excuse that deserves no merit to escape from the constitutional challenge.

Furthermore, this regulatory model poses the problem of inequality. Legally, institutions may refuse to follow the IRB requirement as long as they do not receive federal support and may apply the requirement to only federally funded research and exempt other research from the restraint of the requirement. However, non-federally funded research can pose the same severe ethical problems or risks to participants as federally funded research. Funding source is irrelevant for separating research that requires ethical safeguarding from research that does not. Commentators have proposed various

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75. *See* Epstein, *supra* note 52, at 736–37; Weinstein, *supra* note 29, at 550–51.

76. Hamburger, *The New Censorship*, *supra* note 53, at 324; Gunsalus et al., *supra* note 52, at 634–36; Feeley, *supra* note 52, at 765.

77. Feeley, *supra* note 52, at 765.

78. David A. Hyman, *Institutional Review Boards: Is This the Least Worst We Can Do?*, 101 NW. U.L. REV. 749, 764 (2007).

79. Hamburger, *The New Censorship*, *supra* note 53, at 329–31; Gunsalus et al., *supra* note 52, at 634–36.

80. Feeley, *supra* note 52, at 765; Hyman, *supra* note 78, at 752; Richard A. Shweder, *Protecting Human Subjects and Preserving Academic Freedom: Prospects at the University of Chicago*, 33 AM. ETHNOLOGIST 507, 508 (2006).

boundaries, based on types or characteristics of research, in determining the IRB jurisdiction.[81] The optimal balance between protecting participants and preserving academic freedom is contestable. However, the inequality of treatment between federally funded research and non-federally funded research is undoubtedly unjustifiable.

Second, adopting an institution-based REC system does not remove the threat to individual academic freedom. Compared with a government-based REC system, the current decentralized system reserves some extent of autonomy for research institutions and likely enables self-governance in academic communities. However, institutions themselves can infringe on individual rights. Although governmental agencies do not directly review research proposals, they delegate the authority of review to other organizations, namely IRBs. For individual researchers, their freedom of research is subject to as much external constraint as in a centralized REC system. In particular, as the subsequent section further elaborates, an IRB decision sufficiently constitutes state actions, and therefore, the constitutional concern of academic freedom infringement does not vanish.

In summary, responding to the constitutional challenge by arguing that the current law adopts soft regulatory models fails. Such models not only cannot excuse the law from becoming an unconstitutional prior restraint but also create problematic discriminatory applications. The real solution should instead rest on, as this Article has shown, an appropriately designed authority of IRBs. In addition to saving the law from invalidity, if lawmakers appropriately draw the boundary of the authority, then they can embrace the expansion of regulation to apply equally to research with and without federal funding. At this moment, in which the U.S. Department of Health and Human Services is proposing to extend

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81. AMERICAN ASSOCIATION OF UNIVERSITY PROFESSORS, REGULATION OF RESEARCH ON HUMAN SUBJECTS: ACADEMIC FREEDOM AND THE INSTITUTIONAL REVIEW BOARD 6 (2013), *available at* http://www.aaup.org/file/IRB-Final-Report.pdf (suggesting that "Research on autonomous adults should be exempt from IRB approval" "*if* its methodology either (a) imposes no more than minimal risk of harm on its subjects, or (b) consists entirely in speech or writing, freely engaged in, between subject and researcher"); AMERICAN ANTHROPOLOGICAL ASSOCIATION, *supra* note 7, at 1, 3 (suggesting application of the Common Rule only to "biomedical procedures" and "human experimentation"); Gunsalus et al., *supra* note 52, at 638–39, and 645 (suggesting the exclusion of certain fields such as journalism and oral history); Shweder, *supra* note 80, at 517 (suggesting reconsideration of "the types of research in the social sciences, humanities, and law that should be viewed as exempt from ethical oversight").

the Common Rule to all research involving human subjects regardless of funding source but has encountered strong opposition,[82] the solution proposed in this Article is particularly critical.

C. Lack of a Guarantee of an Effective Remedy

Ubi jus, ibi remedium.[83] As long as IRBs are granted power to review research projects, cases in which review decisions wrongfully infringe on researchers' academic freedom are unavoidable. Thus, a channel for researchers to access an effective remedy should be guaranteed. However, the current regulation does not establish any appeals process, and the path to judicial review is also obstructed. Vesting unfettered discretion to IRBs has created a constitutional problem, and lack of a guarantee of an effective remedy renders the law even more unfavorable in terms of constitutionality.

Several commentators have criticized the current law for providing no mechanism to appeal an IRB decision.[84] Even when an IRB rejects a proposal, preventing the research from proceeding, no formal process for the researcher to contest exists. By contrast, the laws in some other countries have established appeals mechanisms. For example, the Act on Research Ethics Review of Health Research Projects in Denmark requires the Minister of the Interior and Health to establish a national research ethics committee[85] and provides that after receiving a decision of a regional research ethics committee, the investigator and sponsor may submit a complaint to the national research ethics committee seeking a renewed process and decision.[86] The Act on Medical and Health Research in Norway contains a similar provision, providing that "[d]ecisions regarding prior approval of the research project may be appealed to the National Committee for Medical and Health Research Ethics."[87] The establishment of national committees responsible for appeals processes in these countries provides novel

82. *See* AMERICAN ANTHROPOLOGICAL ASSOCIATION, *supra* note 7, at 22–23.

83. Where there is a right, there must be a remedy.

84. C. K. Gunsalus et al., *supra* note 52, at 640; Hamburger, *Getting Permission*, *supra* note 53, at 426; Stoddard, *supra* note 64, at 1309–10.

85. Act on Research Ethics Review of Health Research Projects, 2011, § 37 (Den.).

86. Act on Research Ethics Review of Health Research Projects, 2011, § 26 (Den.).

87. Act on Medical and Health Research, 2008, § 10 (Nor.).

insight into future reform toward an appeals mechanism with sufficient expertise.

The more substantial problem is that the remedy from the judiciary remains unwarranted or at least uncertain. Theoretically, researchers can resort to courts, as a guardian of individual rights, for counteracting the undue intervention of IRBs to preserve their academic freedom. However, although an investigator did file a suit against an IRB, the court opinion in that case appears to largely block the possibility for investigators to pursue such remedy in general. In reaching summary judgment in favor of the defendants, the University of Minnesota and its IRB, the U.S. District Court in the District of Minnesota maintains that "[t]here is no substantive due process right to conduct human-subject research, nor would the claimed right extend to a bar against dissemination of an IRB investigation's results."[88] This is consistent with the viewpoint of at least some IRBs that human-subject research is a privilege, rather than a right, and that "[i]t is up to the PI to convince the IRB of the allowability of the research he or she proposes, rather than the obligation of the IRB to find a flaw in order to deny approval."[89] If later courts follow the same viewpoint, then unless IRBs violate certain procedural requirements identified in that court opinion, researchers would not have any chance to prevail in challenging IRB decisions.

Courts should play a crucial role in safeguarding the freedom of research. Even if that specific IRB decision in the aforementioned case is adequate for protecting participants and supportable, completely rejecting that researchers have a right implicated goes too far. As the discussion in Part III suggests, research ethics review laws substantially affect academic freedom, a constitutional right based on the First Amendment. Research must be regulated to diminish risks to human subjects, and IRB discretion must also be restrained to prevent undue intervention in academic freedom. Without the check and balance of judicial review, IRBs cannot be assumed to exercise their power within the boundary.

Although the freedom of research is undoubtedly at stake, another legal difficulty for challenging IRBs in private institutions

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88. Halikas v. University of Minnesota, No. 4-94-CV-448, (D. Minn. June 9, 1996), *available at* https://zacharyschrag.files.wordpress.com/2011/06/halikas_summary_judgement.pdf (last visited Sept. 7, 2014).

89. Dale E. Hammerschmidt, *"There Is No Substantive Due Process Right to Conduct Human-Subject Research": The Saga of the Minnesota Gamma Hydroxybutyrate Study*, 19(3/4) IRB: ETHICS AND HUMAN RESEARCH 13, 13–14 (May–Aug. 1997).

arises. Contested decisions may be made by IRBs in private institutions, because the United States adopts an institution-based, rather than government-based, REC system. Because generally constitutional guarantees of individual rights restrict only governmental actions,[90] IRBs in private institutions may argue that their decisions do not trigger any constitutional claims and researchers cannot find any causes of action against them. Nevertheless, deeming IRB decisions as pure private actions is unreasonable. IRBs are the creation of federal law. Their composition and procedures are specified by the regulations, they gain the authority to review, approve, and monitor research because of the regulations, and they are not merely subordinate units of their institutions according to the regulations—institutions cannot approve research that has not been approved by IRBs.[91] It appears that the government intends to establish a regulatory mechanism overseeing research but selects an indirect strategy: delegating the duty and power to private institutions instead of fulfilling the task itself. Accounting for all that, IRBs are best understood as acting according to the delegation of a public function and should be considered state actors. Actually, in dicta of *Missert v. Trustees of Boston University*,[92] the U.S. District Court in the District of Massachusetts declared that "an IRB's decision may well constitute state action."[93]

In summary, courts should acknowledge and shoulder their responsibility in ensuring a research ethics review in compliance with laws, certainly including the Constitution. Although currently the litigation against IRBs, particularly those in private institutions, may encounter certain fundamental legal challenges, the previous discussion indicates that those opposing arguments do not stand. Some IRBs may contend that once courts open the door for lawsuits against IRBs, increased litigation would devastate the entire research ethics review system. However, judicial review of administrative actions has not been suspended because of the concern for increasing litigation. The same concern should not hinder judicial review of IRB decisions. Moreover, considering the expertise of IRB judgments, courts should reduce their scrutiny in reviewing IRB decisions, similar to what courts have managed in reviewing

90. NOWAK & ROTUNDA, *supra* note 56, at § 10.4; TRIBE, *supra* note 61, at 1688.

91. *See* Missert v. Trustees of Boston University, 73 F. Supp. 2d 68, 70–71 (D. Mass. 1999).

92. *Id.*

93. *Id.* at 72.

administrative actions.[94] Consequently, the problem of increased litigation would largely diminish. In addition to providing a remedy through judicial review, establishing a special appeals mechanism may increase the effectiveness of the remedy system. As mentioned, some countries have created national RECs, which have the responsibility of reviewing cases appealed from RECs by researchers. Such an adjudicative body composed of members from diverse backgrounds and sufficient knowledge of research ethics would typically be competent in addressing review disputes. Therefore, this additional mechanism would reduce the caseload of courts and, when cases are presented in courts, provide valuable reasoning and judgments that facilitate judicial function.

V. CONCLUSION

Based on the foregoing analysis, this Article identified the constitutional boundary for research ethics review, revealed the problems of the current regulations, and proposed potential solutions. To conform to the constitutional value of respecting academic freedom, the authority of RECs must be adequately designed to tailor to the protection of participants and avoid undue intervention in research content. The current federal regulation fails to meet this standard. By vesting overly broad discretion to IRBs, the regulation constitutes a content-based prior restraint and struggles to survive the triggered heavy presumption against its constitutional validity. Although the regulation imposes the IRB requirement by applying soft regulatory models, the threat to the academic freedom of individual researchers remains substantial. Furthermore, the soft regulation through funding conditions creates unjustifiable inequality of treatment. In addition to the problem arising from unfettered discretion of IRBs, the difficulty of obtaining a judicial remedy further inhibits the protection of academic freedom. The solutions are simple; lawmakers should ensure the appropriate restraint of IRB review and courts should enable researchers to seek necessary remedies. When adequate boundaries of IRB authority have been drawn and the guarantee of an effective remedy has been established, legislating a comprehensive law governing research regardless of funding source acquires legitimacy.

Although the primary analysis of this Article focused on the U.S. Common Rule, the insights are equally applicable to research ethics review laws in other jurisdictions. The failure to account for

94. *See* ALFRED C. AMAN, JR. & WILLIAM T. MAYTON, ADMINISTRATIVE LAW 446–47 (2d. ed. 2001).

the jurisprudence of academic freedom is so common that the laws in many other jurisdictions also fail to appropriately limit the review power of IRBs. For example, Maryland law and Virginia law do not establish additional criteria to provide IRBs with more constraints than the Common Rule does, and New York law provides IRBs with similarly abstract criteria of review to the Common Rule.[95] In Taiwan, the Human Subjects Research Act contains no provisions regarding how IRBs should evaluate a research project. Although an administrative rule in the delegation of that statute provides the items that IRBs should review, it specifies no criteria or factors for determining approval.[96] These jurisdictions impose the research ethics review requirement by force of law, making the constitutional challenge they encounter even more inescapable. Moreover, the remedy from the judiciary in these jurisdictions is also unwarranted or at least uncertain. It is therefore time for governments worldwide to reconsider their research ethics review laws, widen the protection of participants, and safeguard academic freedom.

95. 45 C.F.R. § 46.111 (2009).

96. Regulations Governing the Organization and Operational Management of the Institutional Review Board for Human Subject Research, 2012, § 9 (Taiwan).