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Could Tuskegee Happen Today?

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COULD TUSKEGEE HAPPEN TODAY?

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The federally financed Tuskegee Study of African American men with syphilis casts a long shadow on the conduct of research involving human subjects in the United States. Even seventy-five years after the study began and thirty-five years after it was publicly exposed by an enterprising reporter,[1] overstating its impact remains difficult. In 1997, while issuing a formal apology to the eight remaining survivors of the study, President Clinton characterized the study with these words:

> [These survivors] are a living link to a time not so very long ago that many Americans would prefer not to remember, but we dare not forget. It was a time when our nation failed to live up to its ideals, when our nation broke the trust with our people that is the very foundation of our democracy. It is not only in remembering that shameful past that we can make amends and repair our nation, but it is in remembering that past that we can build a better present and a better future.[2]

The spectacle of federal researchers standing by and watching hundreds of poor black men suffer the ravages of syphilis while denying them information about a newly discovered treatment had a profound effect on

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1. *See Remembering Tuskegee: Syphilis Study Still Provokes Disbelief, Sadness*, NAT'L PUB. RADIO, July 25, 2002, www.npr.org/programs/morning/features/2002/jul/tuskegee/ (last visited May 19, 2008) [hereinafter NPR, *Remembering Tuskegee*] (describing Associated Press reporter Jean Heller's July 25, 1972 story that exposed the study).

2. Press Release, The White House, Office of the Press Sec'y, Remarks by the President in Apology for Study Done in Tuskegee (May 16, 1997), *at* http://clinton4.nara.gov/textonly/New/Remarks/Fri/19970516-898.html (last visited May 19, 2008) [hereinafter Presidential Apology].

the development of rules to ensure that no such "shameful" episode could happen again in the United States.

Given this past experience, it is more than somewhat surprising to discover that leaders and academics at the highest and most respected levels are supporting regulatory reforms and interpretations that would, in effect, allow modern-day researchers to conduct studies that could duplicate in large part the core wrongs that took place in the Tuskegee Study. Specifically, these movements would lead to a particular and relatively narrow interpretation of the duties that a researcher owes to research subjects. Thus far, these movements have not highlighted their possible impact on allowing Tuskegee-like studies to take place. This Article explains that impact and brings greater awareness to these important changes that have been taking place largely under the radar.

Part I of this Article briefly summarizes the facts of the Tuskegee Study and the federal regulations its disclosure prompted. Part II describes the recent initiative to revise the regulations to lessen their impact on certain types of so-called low-risk research based on the allegation that, among other things, the current regulations violate the First Amendment. Part III describes the recent debate about the conduct of certain types of public health studies and the issues that debate has highlighted regarding the duties owed by researchers to research subjects. Part IV demonstrates the impact that both of these developments would have on modern-day researchers' ability to conduct a Tuskegee-like study and explores whether these developments are acceptable in our society. The Article concludes that the regulatory system is far from perfect and should be reformed to minimize wasted efforts and avoid the creation of unnecessary barriers to conducting research while still recognizing the important basic duties to disclose risks, including those not created by the researchers, to research subjects.

I. THE TUSKEGEE STUDY AND THE PATH TO THE FEDERAL REGULATIONS

The Tuskegee Study began in 1932, when researchers at the U.S. Public Health Service partnered with the Tuskegee Institute to learn more about the natural pathology of syphilis.[3] The disease had long been referred to as "the great mimic" because it has the ability to imitate the symptoms of many other diseases.[4] Its symptoms change over the course of long periods of

3. CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. PUBLIC HEALTH SERVICE SYPHILIS STUDY AT TUSKEGEE: THE TUSKEGEE TIMELINE (2008), *at* www.cdc.gov/tuskegee/timeline.htm (last visited May 19, 2008) [hereinafter TUSKEGEE TIMELINE].

4. LOIS N. MAGNER, A HISTORY OF MEDICINE 227 (2nd ed. 2005); CTRS. FOR DISEASE CONTROL & PREVENTION, CDC FACT SHEET: SYPHILIS, at WHAT IS SYPHILIS? (2007), *available at*

time, producing three distinct stages of infection: primary, secondary, and late or latent.[5] Accordingly, when the study began, researchers had very good reasons to want to learn more about the consequences of being infected with syphilis.

The study enrolled 399 black men who had latent syphilis and 201 black men without the disease to serve as the control group.[6] The subjects were told merely that they had "bad blood," and at no time during the decades-long study were those infected with the disease ever informed that they had syphilis.[7] The government physicians conducting the study went to great lengths to ensure that no one who interacted with the subjects told them they had syphilis.[8] One reason for withholding that information was to minimize the likelihood that the subjects would obtain treatment for the disease.[9] Even when the study began, researchers knew that existing treatments, such as the use of arsenic compounds, could substantially reduce symptoms.[10] Furthermore, beginning in the 1940s, the medical community determined that penicillin therapy was an even more effective treatment. However, that treatment was also withheld.[11]

On July 25, 1972, Associated Press reporter Jean Heller brought the study massive public exposure.[12] Major newspapers throughout the nation

www.cdc.gov/std/syphilis/syphilis-fact-sheet.pdf (last visited May 19, 2008) [hereinafter CDC FACT SHEET].

5. *See* CDC FACT SHEET, *supra* note 4 (describing the symptoms of each stage).

6. U.S. DEP'T. OF HEALTH, EDUC., & WELFARE, FINAL REPORT OF THE TUSKEGEE SYPHILIS STUDY AD HOC ADVISORY PANEL 12 (1973) (quoting VENEREAL DISEASE BRANCH, CTRS. FOR DISEASE CONTROL & PREVENTION, BACKGROUND PAPER ON THE TUSKEGEE STUDY (1972)), *available at* www.research.usf.edu/cs/library/docs/finalreport-tuskegeestudyadvisorypanel.pdf (last visited May 19, 2008) [hereinafter FINAL REPORT].

7. TUSKEGEE TIMELINE, *supra* note 3.

8. *See* JAMES H. JONES, BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT 5 (1993) (stating that "neither the interns nor the subjects knew what the study involved"). CARL H. COLEMAN ET AL., THE ETHICS AND REGULATION OF RESEARCH WITH HUMAN SUBJECTS 41 (2005) (quoting and describing various accounts of the study and the information withheld from the subjects); FINAL REPORT, *supra* note 6, at 14; TUSKEGEE TIMELINE, *supra* note 3.

9. JONES, *supra* note 8, at 5; FINAL REPORT, *supra* note 6, at 14; TUSKEGEE TIMELINE, *supra* note 3.

10. FINAL REPORT, *supra* note 6, at 9. In 1932, existing data showed that 35% of untreated patients with late latent syphilis were disease-free and in good health, compared to 85% of those who had received treatment. *Id.* (citing Joseph Earle Moore et al., *Cooperative Clinical Studies in the Treatment of Syphilis: Latent Syphilis*, 13 VENEREAL DISEASE INFO. 317, 379 (1932)).

11. FINAL REPORT, *supra* note 6, at 11-12; *see also* NPR, *Remembering Tuskegee*, *supra* note 1.

12. NPR, *Remembering Tuskegee*, *supra* note 1.

quickly picked up her article.[13] As part of the fallout from the exposure, the Assistant Secretary for Health and Scientific Affairs of the Department of Health, Education, and Welfare (HEW) made a public pledge "to investigate the circumstances surrounding" the study.[14] In fulfilling that pledge, the Assistant Secretary, only two months later, established the Tuskegee Syphilis Study Ad Hoc Advisory Panel to investigate several issues.[15] The nine-member committee was asked to determine: (1) whether the study was justified at the time it began and whether it should have been continued after penicillin became widely available (in the 1950s); (2) whether the study should be continued, and, if not, how to best terminate it in a way that respected the participants; and (3) "whether existing policies to protect the rights of patients participating in health research conducted or supported by [HEW were] adequate and effective" and, if necessary, what improvements could be implemented.[16]

The panel's conclusions on the final issue, which it released in a 1973 report, were rather damning of the then-existing policies to protect human research subjects:

> [T]he Tuskegee Syphilis Study, despite its widespread publicity was not an isolated phenomenon. We believe that the revelations from Macon County merely brought to the surface once again the unresolved problems which have long plagued medical research activities. Indeed, we hasten to add that although we refer in this report almost exclusively to physicians and to biomedical investigations, the issues we explore also arise in the context of non-medical investigations with human beings, conducted by psychologists, sociologists, educators, lawyers and others. . . .
>
> Our initial determination that the protection of human research subjects is a current and widespread problem should not be surprising, especially in light of the recent Congressional hearings and bills focusing on the regulation of experimentation. In the past decade the press has publicized and debated a number of experiments which raised ethical questions: for example, the injection of cancer cells into aged patients at the Jewish Chronic Disease Hospital in Brooklyn, the deliberate infection of mentally retarded children with hepatitis at Willowbrook, the development of heart transplantation techniques, the enormous amount of drug research conducted in American prisons, the whole-body irradiation treatment of

13. *See, e.g.*, Jean Heller, *Syphilis Victims in U.S. Study Went Untreated for 40 Years*, N.Y. TIMES, July 26, 1972, at 1 [hereinafter Heller, *Syphilis Victims Untreated*]; Jean Heller, *U.S. Testers Let Many Die of Syphilis*, WASH. POST, July 26, 1972, at A1 [hereinafter Heller, *U.S. Testers*].

14. FINAL REPORT, *supra* note 6, at 1; *see also* Special, *H.E.W. Will Study Syphilis Project*, N.Y. TIMES, Aug. 25, 1972, at 40.

15. COLEMAN ET AL., *supra* note 8, at 41-42; *see also* Special, *supra* note 14.

16. FINAL REPORT, *supra* note 6, at 1; *see also* Special, *supra* note 14.

> cancer patients at the University of Cincinnati, the advent and spread of "psychosurgery," and the Tuskegee Syphilis Study itself.[17]

The panel proceeded to provide a comprehensive critique of the many holes in the then-existing federal regulatory system for protecting research subjects.[18]

Within a year of the report, Congress passed the National Research Act of 1974 that created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.[19] The Commission authored *The Belmont Report*, which provides the foundation for the regulations the government subsequently adopted for protecting research subjects.[20] Thus, the current regulatory system for protecting research subjects owes a great deal to the government's response to the disclosure of what happened in the Tuskegee Study.[21]

The current system is largely based on a set of federal regulations,[22] the core section of which is called the "Common Rule" because most federal agencies that fund human subject research have adopted identical versions of it.[23] These regulations apply to most human subject research funded by the federal government and also have substantial influence over much research that is not government funded.[24] At the heart of the rules are a set of requirements that researchers must meet before conducting a study involving human subjects. In particular, the proposed subjects must receive

17. FINAL REPORT, *supra* note 6, at 21.

18. *Id*. at 29-37.

19. National Research Service Award Act of 1974, Pub. L. No. 93-348, 88 Stat. 201, *available at* http://history.nih.gov/01docs/historical/documents/PL93-348.pdf (last visited May 19, 2008).

20. NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RES., THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH, *available at* www.fda.gov/OHRMS/DOCKETS/AC/05/briefing/2005-4178b_09_02_Belmont%20Report.pdf (last visited May 19, 2008) [hereinafter BELMONT REPORT].

21. For a comprehensive timeline of legislation and regulations involving human subjects, see Joel Sparks, Historical Resources: Timeline of Laws Related to the Protection of Human Subjects, National Institutes of Health, (June 2002), *at* http://history.nih.gov/01Docs/historical/2020b.htm (last visited May 19, 2008).

22. Protection of Human Subjects, 45 C.F.R. pt. 46 (2007), *available at* www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm (last visited May 19, 2008).

23. COLEMAN ET AL., *supra* note 8, at 106. Sixteen agencies have adopted these regulations. Sparks, *supra* note 21. Subpart A of 45 C.F.R. Part 46, the so-called Common Rule, contains the Department of Health and Human Services' basic policy for protection of human research subjects.

24. Philip Hamburger, *Getting Permission*, 101 NW. U. L. REV. 405, 406-07, 441 (2007). For guidance on the interpretation of 45 C.F.R. Part 46, see OFFICE FOR HUMAN RESEARCH PROTS., U.S. DEP'T OF HEALTH & HUMAN SERVS., OHRP 45 CFR PART 46 FREQUENTLY ASKED QUESTIONS (FAQS), *at* www.hhs.gov/ohrp/45CFRpt46faq.html (last visited May 19, 2008).

adequate information so that they can make informed choices about whether to participate and can only be enrolled in a study after freely and voluntarily providing their informed consent.[25] In addition, the balance between the risks to the subjects and the benefits to the subjects and society from conducting the study must be appropriate.[26]

This regulatory system's administrative structure is somewhat unusual in that an entity called an institutional review board (IRB), composed of at least five members with various backgrounds,[27] is required to review and determine whether a study conforms with the regulations.[28] While most major research institutions in the United States have one or more IRBs, researchers can also hire independent IRBs.[29] Every year in the United States, thousands of IRBs review many thousands of research studies.[30]

Consistent with the previously quoted conclusions from the Tuskegee Syphilis Study Ad Hoc Advisory Panel's 1973 Report that biomedical research is not the only potentially problematic type of research,[31] the regulations are not limited to a particular type of research. They include a broad definition of what constitutes "research" and of when research involves "human subjects."[32] On the other hand, the regulations do recognize that not all research requires the same level of scrutiny.[33] Thus, certain types of research, such as most research involving surveys or questionnaires, is exempt from most of the requirements.[34] Instead, such low-risk research is merely required to comply with the less-specific ethical principles embodied in *The Belmont Report*.[35]

25. 45 C.F.R. § 46.116; *see also* JERRY MENIKOFF WITH EDWARD P. RICHARDS, WHAT THE DOCTOR DIDN'T SAY: THE HIDDEN TRUTH ABOUT MEDICAL RESEARCH 8, 85, 96-97 (2006).

26. 45 C.F.R. § 46.111(a)(2); MENIKOFF, *supra* note 25, at 51-60.

27. 45 C.F.R. § 46.107(a).

28. *See id.* § 46.103(b).

29. *See* OFFICE OF THE INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., INSTITUTIONAL REVIEW BOARDS: THE EMERGENCE OF INDEPENDENT BOARDS 3 (1998), *available at* www.oig.hhs.gov/oei/reports/oei-01-97-00192.pdf (last visited May 19, 2008).

30. *Id.* at i, 4.

31. *See* FINAL REPORT, *supra* note 6, at 21 (stating that issues involving human subjects research "also arise in the context of non-medical investigations with human beings, conducted by psychologists, sociologists, educators, lawyers and others").

32. 45 C.F.R. § 46.102(d), (f); *see also* MENIKOFF, *supra* note 25, at 24-36.

33. *See* 45 C.F.R. § 46.110 (outlining "[e]xpedited review procedures for certain kinds of research involving no more than minimal risk"); *see also* Jerry Menikoff, *Where's the Law?: Uncovering the Truth about IRBs and Censorship*, 101 NW. U. L. REV. 791 (2007) (arguing that because many research studies fall into regulatory categories that are either subject to cursory review or not subject to review at all, the IRB system should pose minimal burden on these researchers in the majority of cases).

34. *See* 45 C.F.R. § 46.101(b).

35. *See* Menikoff, *supra* note 33, at 795-96 (describing the *Belmont Report*'s reference to basic ethical principles of respect for persons, beneficence, and justice).

II. DISSATISFACTION WITH IRB "MISSION CREEP" AND THE FIRST AMENDMENT CHALLENGE TO THE REGULATIONS

For various reasons, in recent years both the visibility and impact of the federal regulations have increased. The primary reason is the sudden burst in enforcement of the regulations by the federal Office for Protection from Research Risks (OPRR) between 1998 and 2000.[36] This upswing in regulatory action likely was motivated, at least in part, by a June 1998 report from the Office of the Inspector General (OIG) of the Department of Health and Human Services.[37] The OIG report concluded that the system for protecting research subjects was in serious trouble, largely because IRBs were having a difficult time fulfilling their responsibilities.[38] As the report stated, the "effectiveness of IRBs is in jeopardy."[39] Among the reasons for that conclusion were that (1) the research environment had changed dramatically from the classic model of a single investigator performing a study on her own; (2) IRBs were required to take on increased workloads, with pressures to approve studies quickly; (3) IRBs were paying insufficient attention to the annual "continuing review" required of previously approved studies; (4) IRBs were subject to growing conflicts of interest as institutional pressures to conduct research grew; (5) IRB members and staffs received relatively little training; and (6) neither IRBs nor the Department of Health and Human Services had a system for evaluating how effectively the IRBs actually protect human subjects.[40]

In October 1998, OPRR took the first of several high-profile enforcement actions, suspending research at Rush-Presbyterian-St. Luke's Medical Center in Chicago.[41] During the subsequent two years, OPRR brought enforcement actions against a number of prominent institutions, most notably Duke University and the University of Pennsylvania.[42] Since 2001, after OPRR's reorganization that gave it greater independence and renamed it the Office for Human Research Protections (OHRP), the level of such enforcement actions has dropped back to the pre-1998 level.[43] Nonetheless, the short burst of activity was sufficient to put the human research protections program on the radar screens of most institutions that

36. COLEMAN ET AL., *supra* note 8, at 57-58.

37. *See* OFFICE OF INSPECTOR GEN., DEP'T OF HEALTH & HUMAN SERVS., INSTITUTIONAL REVIEW BOARDS: A TIME FOR REFORM (June 1998), *available at* www.oig.hhs.gov/oei/reports/oei-01-97-00193.pdf (last visited May 19, 2008) [hereinafter OIG, TIME FOR REFORM]; *see also* COLEMAN ET AL., *supra* note 8, at 57.

38. OIG, TIME FOR REFORM, *supra* note 37, at 4-9.

39. *Id*. at 4.

40. *Id*. at 4-9.

41. COLEMAN ET AL., *supra* note 8, at 58.

42. *Id*.

43. *Id*. at 60-61.

conduct substantial amounts of human subject research. As a result, institutions have increased internal compliance activities and have made greater efforts to encourage researchers to be aware of and comply with the rules.[44]

Given that the regulations apply not solely to biomedical research, this increased compliance activity soon percolated down to what are generally perceived as the relatively low-risk types of studies, namely those in behavioral and social science. Over time, various anecdotal reports began circulating among researchers in those fields, suggesting that IRBs would occasionally impose burdensome requirements on researchers.[45] These reports eventually reached members of this group who were not only researchers, but also experts in regulatory issues: legal academics.

A small panel discussion at the 2004 Association of American Law Schools Annual Meeting[46] led some law professors to begin exploring the appropriateness of the federal regulations for protecting research subjects. In particular, the law professors raised the issue of whether the regulations violate the First Amendment.[47] Perhaps the earliest extended work on this issue is Philip Hamburger's 2004 article, entitled *The New Censorship: Institutional Review Boards*.[48] Hamburger argues that "IRB laws unconstitutionally require licensing of speech and the press but that . . . doctrines of the U.S. Supreme Court have diminished the clarity of the Constitution's obstacles to licensing and thus have emboldened the

44. *See id.* at 59. For example, "Duke University made a number of changes in the ten months immediately following the four-day suspension of its authority to conduct research with human subjects. These changes included: (a) increasing the number of IRBs, from one to two, and making plans to add at least two more; (b) sponsoring a ninety-minute course on the regulation and history of medical research with human subjects and requiring that all 1,350 clinical investigators at the medical center take the course; (c) providing up to forty hours of training for each IRB member; (d) increasing the size of the support staff for its IRBs, from two full-time positions to 11; and (e) increasing the staff support budget from approximately $100,000 to about $1 million." *Id.*

45. *See* COMM. A ON ACADEMIC FREEDOM & TENURE, AM. ASS'N OF UNIV. PROFESSORS, RESEARCH ON HUMAN SUBJECTS: ACADEMIC FREEDOM AND THE INSTITUTIONAL REVIEW BOARD (2006), *at* www.aaup.org/AAUP/comm/rep/A/humansubs.htm (last visited May 19, 2008) [hereinafter AAUP COMM. A] (giving examples of "more or less familiar horror stories" drawn "from experiences of prospective researchers in a variety of different disciplines in the social sciences and humanities").

46. Association of American Law Schools, Section on Law and the Social Sciences 2004 Annual Meeting, Institutional Review Boards and You (Jan. 5, 2004), *at* http://aalsweb.aals.org/am2004/programs/details/6360.shtml (last visited May 19, 2008).

47. *Id.*

48. Philip Hamburger, *The New Censorship: Institutional Review Boards*, 2004 SUP. CT. REV. 271 (2004).

government to impose IRBs and have left academics and universities without the confidence to resist."[49]

Around the same time Hamburger's article was published, the University of Illinois Center for Advanced Study took a prominent step to continue the debate about the IRB system by holding a conference on *Human Subject Protection Regulations and Research Outside the Biomedical Sphere* in 2003.[50] The conference's purpose was described as follows:

> The invitational conference asked for advance position papers . . . addressing "When does a person become a human subject?" in order to analyze more closely who we are seeking to protect, from what, and why. Some of the questions considered included:
>
> - When a faculty member writes about students and the teaching process, when is that an "interaction" with human subjects that is or should be covered by federal research regulations?
> - Is it appropriate or a good use of resources for a central institutional review board to govern the questions to be asked and how records are kept and used by faculty and graduate students conducting oral history interviews?
> - Why can a journalist working for a newspaper interview and publish articles and books about sensitive issues, subject only to professional ethical guidance and legal consequences, while a journalism professor must additionally seek prior approval from those outside journalism (i.e., an IRB) for the same activities?
> - Is it good public policy to base the regulation of activities involving humans on where the research is performed (in terms of institutional affiliation or field setting), rather than on the nature of harm that might result?
>
> Nationally, these questions and others like them in anthropology, business, sociology, English, psychology, law, history, education, and journalism, among other disciplines, have been causing increasing controversy over the last five to 10 years.[51]

The Illinois White Paper, the conference's product, has substantially impacted the debate about the IRB system. Its executive summary provides a good statement of a particular viewpoint:

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49. Hamburger, *supra* note 24, at 406 n.6.

50. CTR. FOR ADVANCED STUDY, THE ILLINOIS WHITE PAPER: IMPROVING THE SYSTEM FOR PROTECTING HUMAN SUBJECTS: COUNTERACTING IRB "MISSION CREEP" 6 (2003), *available at* www.law.uiuc.edu/conferences/whitepaper/whitepaper.pdf (last visited May 19, 2008) [hereinafter ILLINOIS WHITE PAPER].

51. *Id*.

> Our system of research self-regulation, designed to provide internal checks and balances for those who participate in research involving human subjects, is under considerable stress. Study after study recently has reported that this is a system "in crisis," "in jeopardy," and in need of thoughtful re-examination.
>
> Much of this crisis has been caused by what we call mission creep, in which the workload of IRBs has expanded beyond their ability to handle effectively. Mission creep is caused by rewarding wrong behaviors, such as focusing more on procedures and documentation than difficult ethical questions; unclear definitions, which lead to unclear responsibilities; efforts to comply with unwieldy federal requirements even when research is not federally funded; exaggerated precautions to protect against program shutdowns; and efforts to protect against lawsuits.
>
> Honest IRB specialists admit that they operate under constant concern about the one case in a thousand that might slip through review — with the consequence that the other 999 receive exaggerated reviews and risk rejection in an effort to err on the side of caution.
>
> As a consequence, mission creep is causing IRBs to lose the respect and "buy-in" of the very people they are meant to regulate; they are misdirecting their energies, threatening both academic and first amendment freedoms; and most importantly, mission creep is taking needed resources from the most risky research, which truly does need IRB oversight.[52]

The *White Paper* presents a number of specific recommendations. First, it recommends conducting empirical research to gather additional information, both about "good" and "poor" practices.[53] It suggested developing a "clearing house" that would provide workable solutions to what might otherwise appear to be inappropriate administrative barriers.[54] Second, it recommends refining the existing system to create a set of regulations that are better tuned to the issues raised by social and behavioral research.[55] Finally, it recommends removing certain endeavors from IRB review altogether.[56] The removed category might include certain fields, such as journalism and ethnography, and certain methodologies, such as oral history,[57] that "pose virtually no risk to the subjects."[58]

In April 2006, the symposium entitled *Censorship and Institutional Review Boards* at Northwestern University School of Law brought together a

52. *Id*. at 2.
53. *Id*. at 2, 18.
54. *Id*. at 2, 19.
55. ILLINOIS WHITE PAPER, *supra* note 50, at 3, 18-19.
56. *Id*. at 3, 22.
57. *Id*.
58. *Id*. at 3.

wide range of people, including those who were previously involved in analysis of IRB issues and others who were new to the topic but had a professional interest in the legal issues it raises.[59] The *Northwestern University Law Review* published the symposium contributors' work: nineteen articles spanning almost five hundred pages.[60] The articles address topics ranging from the specific legal issue of whether the IRB system violates the First Amendment[61] to anecdotal accounts of how IRBs have hindered the work of researchers.[62] Defenders of the current system also presented their viewpoints.[63]

The most recent, and perhaps most prominent, report examining IRB operation was approved in June 2006 by a subcommittee of Committee A on Academic Freedom and Tenure of the American Association of University Professors (AAUP).[64] This report, prepared by a truly stellar list of leading academics,[65] begins by noting that the federal regulations "have generated an increasing number of complaints over the years, and there is a by-now enormous literature that points to their objectionable features."[66] After recounting assorted examples of demands IRBs have placed on researchers that range from silly to absurd, the report evaluates the system and proposed changes to it and makes a recommendation for policy makers.[67] The report states that "[w]hat is deeply troublesome is the fact that research on human subjects must obtain IRB approval whether or not it imposes a serious risk of harm on its subjects."[68] While some commentators have

59. James Lindgren et al., *Foreword: Symposium on Censorship and Institutional Review Boards*, 101 NW. U. L. REV. 399, 399 (2007), *available at* www.law.northwestern.edu/lawreview/issues/101.2.html (last visited May 19, 2008).

60. *See* Symposium, *Censorship and Institutional Review Boards*, 101 NW. U. L. REV. 399 (2007).

61. *See* Hamburger, *supra* note 24; James Weinstein, *Institutional Review Boards and the Constitution*, 101 NW. U. L. REV. 493 (2007); Philip Hamburger, *Two-Dimensional Doctrine and Three-Dimensional Law: A Response to Professor Weinstein*, 101 NW. U. L. REV. 563 (2007); James Weinstein, *The Dimensions of Constitutional Analysis: A Reply to Professor Hamburger*, 101 NW. U. L. REV. 569 (2007).

62. *See, e.g.*, Fredric L. Coe, *The Costs and Benefits of a Well-Intended Parasite: A Witness and Reporter on the IRB Phenomenon*, 101 NW. U. L. REV. 723 (2007).

63. *See, e.g.*, Menikoff, *supra* note 33; Jonathan Moss, *If Institutional Review Boards Were Declared Unconstitutional, They Would Have to Be Reinvented*, 101 NW. U. L. REV. 801 (2007).

64. AAUP COMM. A, *supra* note 45.

65. The report was prepared by Judith Jarvis Thomson, Massachusetts Institute of Technology; Catherine Elgin, Harvard Graduate School of Education; David A. Hyman, University Of Illinois at Urbana-Champaign; and Philip E. Rubin, Yale University School Of Medicine and Haskins Laboratories. *Id*.

66. *Id*. at 95.

67. *Id*. at 96-98.

68. *Id*. at 97.

suggested that all research in the social science and humanities be exempted from IRB review and that the system be limited to regulating "only biomedical research,"[69] the report's authors conclude that it would be inappropriate to make that change for two reasons.[70] First, some social science research has the potential to cause significant psychological harm to subjects.[71] Second, some biomedical research does not have the potential to cause any serious harm to subjects because it does not consist of bodily interventions and only requires obtaining survey data.[72]

Accordingly, the report's authors conclude that the best reform would not involve looking at the type of research, but rather at the methodology used in a study.[73] Specifically, the authors conclude that research "whose methodology consists entirely of collecting data by surveys, conducting interviews, or observing behavior in public places [should] be exempt from the requirement of IRB review."[74] They note that the current regulations, in fact, already exempt such studies from requiring IRB review except under limited circumstances, but that, currently, a researcher has to file a request for exemption which must in turn be reviewed and approved by the IRB.[75] The report's authors believe that studies involving these methodologies should, in effect, be automatically exempted, without any need to obtain prior approval.[76]

III. THE PUBLIC HEALTH DILEMMA AND THE DUTIES OF RESEARCHERS TO DISCLOSE EXISTING RISKS

While all of the discussions were taking place concerning how the IRB system created inappropriate, and perhaps unconstitutional, burdens on the conduct of research in the social and behavioral sciences, a seemingly very different aspect of the system was being debated elsewhere. An appropriate

69. AAUP COMM. A, *supra* note 45, at 97.

70. *Id*.

71. *Id*. In this context, the report mentions the famous experiment conducted by Stanley Milgram, where he asked subjects to control a machine that they believed would deliver pain to people in another room. *Id*.

72. *Id*.

73. *Id*.

74. AAUP COMM. A, *supra* note 45, at 97.

75. *Id*. This claim is not completely correct. Nothing in the regulations requires the filing of a request for exemption, nor its approval by the IRB. OHRP merely provides guidance that researchers should not make their own determination of exempt status. Furthermore, even under OHRP's guidance, the IRB (or even an IRB member) is not required to make the determination. Rather, the guidance says that some appropriately trained person other than the investigator must make the determination. *See* Office for Protection from Research Risks, Exempt Research and Research That May Undergo Expedited Review (1995), *available at* www.hhs.gov/ohrp/humansubjects/guidance/hsdc95-02.htm (last visited May 19, 2008).

76. AAUP COMM. A, *supra* note 45, at 97.

introduction to this simultaneous debate is an examination of a particular public health lead paint study that began in inner city Baltimore in the early 1990s.[77]

At that time, many of the homes in Baltimore's low-income, high-risk neighborhoods had paint with high lead content on their walls.[78] It was no longer legal to use such paint, but the costs of fully removing the lead paint already on walls—often more than the value of the homes—was prohibitive and the existing public health laws allowed these buildings to be used as housing, even by families with young children.[79] Indeed, poorer families in inner-city Baltimore often had no choice but to live in such housing.

The Kennedy Krieger Institute, a research organization affiliated with The Johns Hopkins University, played a major role in earlier years performing landmark work to uncover the problem of lead poisoning in children.[80] The Institute continued research in that field and, in the early 1990s, began a study to determine if there might be low-cost methods of reducing the risk to children of living in lead-contaminated housing.[81] The researchers devised several methods to reduce those risks, each costing between $1,650 and $7,000, and then conducted a randomized study that assigned homes to one of the interventions.[82] Some families were enrolled by applying the intervention to the home in which they were already living; others were enrolled when the researchers applied the interventions to vacant homes and asked landlords to rent the homes to families with young children.[83]

Two families who participated in the study sued the Kennedy Krieger Institute in state court, claiming, among other things, that the researchers

77. *See* Joanne Pollak, *The Lead-Based Paint Abatement Repair & Maintenance Study in Baltimore: Historic Framework and Study Design*, 6 J. HEALTH CARE L. & POL'Y 89, 96 (2002), *available at* www.hopkinsmedicine.org/Press_releases/2004 (follow "Grimes v Kennedy Krieger Institute: Facts About the KKI Lead Paint Study" hyperlink) (last visited May 19, 2008); *see also* Tamar Lewin, *U.S. Investigating Johns Hopkins Study of Lead Paint Hazard*, N.Y. TIMES, Aug. 24, 2001, at A11, *at* http://query.nytimes.com/gst/fullpage.html?res=9405E1DF1331F937A1575BC0A9679C8B63 (last visited May 19, 2008).

78. KENNEDY-KRIEGER INSTITUTE, LEAD-BASED PAINT STUDY FACT SHEET (2001), *at* www.hopkinsmedicine.org/press/2001/SEPTEMBER/leadfactsheet.htm (last visited May 19, 2008) [hereinafter KKI FACT SHEET].

79. *Id*.

80. Pollak, *supra* note 77, at 93; Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 811-12 (Md. 2001).

81. KKI FACT SHEET, *supra* note 78.

82. *Id.*; *see also* TECHNICAL PROGRAMS BRANCH, U.S. ENVTL. PROT. AGENCY, LEAD-BASED PAINT ABATEMENT AND REPAIR AND MAINTENANCE STUDY IN BALTIMORE: PRE-INTERVENTION FINDINGS 13, 16 (1996), *available at* http://epa.gov/oppt/lead/pubs/r95-012.pdf (last visited May 19, 2008) [hereinafter EPA STUDY] (describing study design and sample collection procedures).

83. KKI FACT SHEET, *supra* note 78; *Grimes*, 782 A.2d at 813, 821.

did not obtain appropriate informed consent.[84] The case reached Maryland's highest state court, which issued a scathing, landmark ruling, condemning not only the researchers but the IRB system that approved the study.[85] According to the court, this study was shockingly similar to many of the most shameful studies in history, including the Nazis having exposed residents in the Buchenwald concentration camp to typhus during World War II.[86] The court included the Tuskegee Study in its list, noting that these studies all involved the use of especially vulnerable subjects and took inappropriate advantage of their vulnerabilities.[87] In fact, the court's ruling went beyond the allegations in the complaint and concluded that it would not have mattered even if there was appropriate informed consent by the children's parents: "[N]o degree of parental consent, and no degree of furnished information to the parents could make the experiment at issue here, ethically or legally permissible."[88]

The court's ruling that there was no permissible way to conduct this study, even if appropriate informed consent was obtained, has received much criticism. Many have commented that the ruling is inconsistent with the existing understanding of the acceptable conditions for conducting research with children. They have also noted that this study was an important one and relatively low risk, compared to hundreds of other studies that are regularly allowed to proceed in the United States with little controversy.[89] Thus, the issue of whether this study was somehow "too risky" to be permissible remains unsettled.

But a very different aspect of the study, and of the court's opinion, is highly relevant to the issues discussed in this Article. As noted above, the plaintiffs' core claim was the inadequacy of informed consent, and the court concluded that they stated a claim on that issue and the case should be allowed to go to trial.[90] In deciding that the plaintiffs stated a viable claim, the court concluded that researchers owe a variety of legal duties to research subjects because of the special relationship such studies normally

84. *Grimes*, 782 A.2d at 818.

85. *See id.* at 813-14, 817.

86. *Id*. at 816-17.

87. *Id*.

88. *Id*. at 857-58.

89. *See, e.g.*, Leonard H. Glantz, *Nontherapeutic Research with Children:* Grimes v Kennedy Krieger Institute, 92 AM. J. PUB. HEALTH 1070, 1071-72 (2002); Anna C. Mastroianni & Jeffrey P. Kahn, *Risk and Responsibility: Ethics,* Grimes v Kennedy Krieger*, and Public Health Research Involving Children*, 92 AM. J. PUB. HEALTH 1073, 1073-74 (2002); Efi Rubinstein, Comment, *Going Beyond Parents and Institutional Review Boards in Protecting Children Involved in Nontherapeutic Research*, 33 GOLDEN GATE U. L. REV. 251, 276-77 (2003).

90. *Grimes*, 782 A.2d at 832-33.

create.[91] Specifically, the court held that, under Maryland law, researchers "have a duty to warn [research subjects] regarding dangers present when the researcher has knowledge of the potential for harm to the subject and the subject is unaware of the danger[.]"[92]

An article by two leading health law scholars, Diane Hoffmann and Karen Rothenberg, analyzes the court's comments about this duty at length.[93] Hoffmann and Rothenberg argue that, depending on how one interprets the court's statements, the court might have been creating a new duty and one that could have troubling consequences for conducting future research, including important public health studies.[94] At the heart of their analysis is the distinction between risks that are created by the researchers' actions and pre-existing risks that subjects were exposed to prior to the researchers' involvement and that the researchers do not alter.[95] They acknowledge that researchers are under a duty to inform a proposed research subject about any risks that are created (or made worse) by participating in the study.[96] This duty is straightforwardly embodied in the federal regulations' requirement of disclosure of "any reasonably foreseeable risks or discomforts to the subject."[97] No one familiar with those rules would contend that such risks do not have to be disclosed.

But what about risks that the researchers do not create? In the *Grimes* case, the plaintiffs claimed that, among other things, the researchers should have informed them about the risk of lead exposure to their children from continuing to live in lead-contaminated housing,[98] a risk that the researchers did not create.[99] Many of the families were already living in lead-contaminated housing even before the researchers' involvement, and nothing the researchers did made the risk of exposure any worse.[100] Thus, the following question arises: Did the researchers have a duty to disclose the background risk, one that they did not create?

91. *Id*. at 841-42.

92. *Id*. at 818-19.

93. *See* Diane E. Hoffmann & Karen H. Rothenberg, *Whose Duty Is It Anyway?: The* Kennedy Krieger *Opinion and Its Implications for Public Health Research*, 6 J. HEALTH CARE L. & POL'Y 109, 129-47 (2002) (discussing the effects of such a duty from the perspectives of research participants as well as researchers).

94. *Id*. at 110, 130-31, 144-45.

95. *Id*. at 130.

96. *Id*. at 130-31.

97. Protection of Human Subjects, 45 C.F.R. § 46.116(a)(2) (2007).

98. Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 844 (Md. 2001).

99. Hoffmann & Rothenberg, *supra* note 93, at 135.

100. *Id*.

As quoted above, the court appears to have concluded that yes, such a risk does have to be disclosed.[101] What is especially interesting is the conclusion of these two distinguished scholars that the court's recognition of such a duty should be considered controversial and a significant expansion of the duties of a researcher to a subject.[102] Thus, under the scholars' view, the law prior to this case would have allowed the Kennedy Krieger researchers to conduct their study and not inform the parents about the known danger of lead poisoning in children and how continuing to live in lead-contaminated housing is very unhealthy for children.

Hoffmann and Rothenberg describe other scenarios that would raise similar ethical issues. For example, a study might involve enrolling members of a population that "exposes its children to a diet without certain nutrients."[103] They ask whether the researcher should be "required to tell the subjects of the risks of such a diet."[104] They discuss a study "on the effects of second-hand smoke on children living in housing with parents who smoke" and ask whether it should "be the obligation of the researchers to inform the parents at the start of the research of the risks to children of second-hand smoke[.]"[105]

Not only do Hoffmann and Rothenberg find that the court's apparent recognition of a duty to disclose these background risks is a change in the law, but they also are seriously concerned that it may be a bad change.[106] In particular, they are concerned that such a duty may make it harder to conduct certain types of public health studies.[107] They assert that "the real danger of the Court's Opinion is the possibility that it will significantly reduce major public health studies that could be the basis of revising our public health and environmental laws."[108]

IV. THE APPROVABILITY OF MODERN-DAY TUSKEGEES

What do the two themes discussed in Parts II and III tell us about the ability to conduct a modern-day study that shares some of the core

101. *Grimes*, 782 A.2d at 852, 858; *see also* Hoffmann & Rothenberg, *supra* note 93, at 130. Hoffmann and Rothenberg do note that it is possible to interpret the court's opinion in a way that suggests these risks were, indeed, attributable to participation in the study, in which case the opinion would have been making a narrower claim about the duty to warn. *Id.* at 129-39.

102. *See* Hoffmann & Rothenberg, *supra* note 93, at 139.

103. *Id*. at 145.

104. *Id*.

105. *Id*.

106. *Id*. at 146.

107. Hoffmann & Rothenberg, *supra* note 93, at 145-46.

108. *Id*. at 145.

characteristics of the Tuskegee Study? Consider the following hypothetical study, which might be called "Tuskegee Today":

> A researcher proposes to study the natural history of disease X. It is a relatively rare genetic disease, but it has certain unusual characteristics. Due to these unusual characteristics, a better understanding of it may be helpful in learning more about the underlying biomedical mechanisms of several other more common diseases. A treatment exists that substantially reduces the otherwise severe and irreversible consequences of disease X.
>
> The researcher has been able to find several groups of black men who have disease X. They are poorly educated, have limited incomes, and do not have access to good healthcare. They are not aware that an effective treatment for disease X exists. The researcher proposes to conduct the study by having regular interviews with the subjects over a period of several years. He will obtain written informed consent from the subjects, describing all of the interviews in which subjects will participate. The researcher does not plan to voluntarily tell the subjects that disease X has an effective treatment, though he will not lie to them if they ask about possible treatment options.

Could researchers conduct such a study today and fully comply with the existing federal rules for protecting research subjects?

Before analyzing the permissibility of Tuskegee Today, it bears mentioning that this hypothetical does not embody all of the wrongs that were involved in the actual Tuskegee Syphilis Study. In the actual study, the researchers actively took steps to ensure that the subjects did not learn about their disease or the various treatment options.[109] Without doubt, the deceptive aspect of the Tuskegee Study involved an *active* wrong—the researchers acted to make the subjects worse off. The researchers, themselves, imposed a new "risk" on the subjects. Thus, a study-created risk existed.

But the Tuskegee Study involved another wrong that history seems to find equally troubling—standing by and allowing the men to live untreated because they did not know a treatment was available. This consequence could have occurred even without the researchers actively deceiving or lying to the subjects. And this element of the study comes through in many descriptions of its wrongs, even if more detailed facts of the active deception are not mentioned. Consider the July 26, 1972 *Washington Evening Star* headline for the article that first exposed the Tuskegee Study: *Human Guinea Pigs: Syphilis Patients Died Untreated*.[110] Associated Press reporter Jean Heller explained that "[f]or 40 years the United States Public Health

109. JONES, *supra* note 8, at 5; *see also* FINAL REPORT, *supra* note 6, at 14; TUSKEGEE TIMELINE, *supra* note 3.

110. Jean Heller, *Human Guinea Pigs: Syphilis Patients Died Untreated*, WASH. EVENING STAR, July 25, 1972, at A1.

Service . . . conducted a study in which human beings with syphilis, who were induced to serve as guinea pigs, have gone without medical treatment . . . and a few have died of its late effects, even though an effective therapy was eventually discovered."[111] Both the headline and that simple sentence conveyed the core of the wrongdoing that stunned readers. And this core wrong still would have occurred merely by failing to let the men know that treatment existed.

So would the Tuskegee Today hypothetical study encounter any regulatory stop signs under the view of the world discussed earlier in this Article? Consider, for example, the proposal from the AAUP that would apply to studies whose methodology consists entirely of collecting data and conducting interviews.[112] The proposed Tuskegee Today study would clearly comply with the AAUP proposal and, thus, would not require review by anyone who is part of the IRB system. This outcome takes place largely because of the main proposition on which the AAUP rules are constructed: studies that are low risk—meaning that the researchers are not creating a risk by enrolling the subjects in the study—should not require ethical review.[113] The Tuskegee Today hypothetical does not itself impose any risks on the subjects. Therefore, it falls squarely within the category of studies the AAUP proposal exempts from ethical review.

Similarly, when considering the concerns about public health research raised in the wake of the *Kennedy Krieger Institute* case, the Tuskegee Today hypothetical study would likely fall squarely within the parameters that Hoffmann and Rothenberg propose to address such concerns. Hoffmann and Rothenberg contend that, at the least, it is "unclear" whether researchers have any duty to disclose risks that they do not create.[114] They worry that creating such a duty, if it does not exist, might have a negative effect.[115] In the Tuskegee Today hypothetical, no risks would indeed be created by the researchers, and so Hoffmann and Rothenberg's discussion would, at the least, lead to some doubt about the existence of a duty for the researchers to give the subjects any information about disease X, including that an effective treatment exists.

And lest the reader think that surely no one would try to apply these themes to allow a new version of the Tuskegee Study to take place—that if that fact pattern were raised, arguments would be made to ensure that such a proposed study receives appropriate review—there is direct evidence suggesting that this is not the case. For example, leading IRB critic Philip

111. *Id.*
112. AAUP COMM. A, *supra* note 45, at 97.
113. *See id.* at 97-98.
114. Hoffmann & Rothenberg, *supra* note 93, at 143-44, 147.
115. *Id.* at 144-47.

Hamburger directly addresses some aspects of what happened in the actual Tuskegee Syphilis Study in his Northwestern University School of Law Symposium article.[116]

In critiquing *The Belmont Report*, which, as discussed above, laid the foundation for much of the current federal regulations,[117] Hamburger concludes that it perpetuated a misunderstanding of "what was wrong about the Tuskegee Study."[118] His analysis, addressing issues similar to those raised in Part III above, explains that *The Belmont Report*'s analysis of the duties owed by researchers to subjects was mistaken.

> The *Belmont Report*'s version of Tuskegee raises questions as to whether the researchers there violated any duty to their subjects. . . . Of course, if it is recognized that the researchers were doctors and others who held themselves out as offering health care, then the breach of a Hippocratic and fiduciary duty is obvious. The *Belmont Report*, however, overgeneralizes about Tuskegee in terms of a general duty of researchers, and it thus leaves room for doubts as to what went wrong there.[119]

Under Hamburger's analysis, then, the primary wrong in the Tuskegee Study was due to the fact that the researchers were doctors and were violating the duties that they, as doctors, owed to patients.[120] Thus, had the study been conducted by non-clinicians, such as PhDs who were experts in public health, presumably there would have been no similar duties owed to the research subjects flowing from their role as researchers. This basis for the duties owed turns the wrongs committed in the Tuskegee Syphilis Study into mainly an issue of having chosen the wrong people to conduct the study. According to Hamburger's viewpoint, it is a serious mistake to conclude that researchers owe a wide range of duties to subjects, particularly any that might fall under the category of "fiduciary" duties.[121] Only professionals

116. Hamburger, *supra* note 24, at 405.

117. *See supra* text accompanying note 20.

118. Hamburger, *supra* note 24, at 458.

119. *Id*. Hamburger further notes that recently there have been articles revisiting what happened in the Tuskegee Study and concluding that, in fact, it may not have been as shameful as many portray it. *Id*. at 458 n.139. One of the scholars whose work he cites is Richard Shweder, a University of Chicago professor who has also been an active critic of the IRB system. *Id*. at 458 n.139 (citing Richard A. Shweder, *Tuskegee Re-Examined: A Cultural Anthropologist Offers a Counter-Narrative to the Infamous Story of U.S. Government Scientists Allowing Black Men to Suffer from Untreated Syphilis*, SPIKED, Jan. 8, 2004, *at* www.spiked-online.com/Articles/0000000CA34A.htm (last visited May 19, 2008)).

120. Hamburger, *supra* note 24, at 453-59. Hamburger similarly analyzes what happened to the concentration camp victims at the hands of the Nazis, noting that their captors already owed them duties that have traditionally been recognized as owed by a government to people under its control, and, thus, there was no need to create a new fiduciary duty owed by a researcher to a subject. *Id*. at 456-57.

121. *See id*. at 452-59.

such as physicians and attorneys have such duties, and, he notes, "[r]esearchers are not professionals."[122]

The Tuskegee Today hypothetical study raises, at the least, two important questions: First, could it be conducted without violating the existing rules for protecting research subjects? Second, regardless of its status under the current rules, should society allow such a study to be conducted? Both questions can be answered with a reasonable degree of certainty.

A. Could Tuskegee Today be conducted without violating the existing rules for protecting research subjects?

The history of the current rules recounted above provides a solid argument for concluding that the Tuskegee Today hypothetical study would violate current protections for human research subjects. Admittedly, the wording of the federal regulations requiring the disclosure of "reasonably foreseeable risks"[123] certainly suggests that this provision is mainly referring to risks created by a person's participation in a study. However, we are not interpreting this provision in a vacuum. We must remember that what happened in the original Tuskegee Study was one of the motivating forces that led to the current rules.

As noted above, there are revisionist analyses of the events in the Tuskegee Study that suggest that what happened was not as shameful as is generally claimed.[124] But those analyses remain minority viewpoints. The Tuskegee Syphilis Study likely still stands out as the research study in the United States that deserves the distinction of most "shameful."[125] Its legacy is not merely the current rules, but a persisting wariness among many African-Americans about whether they will be treated fairly by the medical system.[126] A current demonstration of its continuing impact is the wide interest and debate generated by Harriet Washington's recent book, *Medical Apartheid: The Dark History of Medical Experimentation on Black Americans from Colonial Times to the Present*.[127]

While there certainly can be a debate about the outer limits of a researcher's duty to disclose to subjects risks not created by the researchers, surely that duty is embodied in the current regulations when (1) the

122. *Id. at* 452.

123. Protection of Human Subjects, 45 C.F.R. § 46.116(a)(2) (2007).

124. *See supra* notes 116 to 122 and accompanying text.

125. *See* Presidential Apology, *supra* note 2 (describing the Tuskegee Study and what the U.S. Government did as "shameful").

126. *See id.*; *see also* HARRIET A. WASHINGTON, MEDICAL APARTHEID: THE DARK HISTORY OF MEDICAL EXPERIMENTATION ON BLACK AMERICANS FROM COLONIAL TIMES TO THE PRESENT (2006).

127. WASHINGTON, *supra* note 126.

undisclosed risks relate to the very disease the researchers are studying, and (2) there would be substantial harms to the subjects from being kept ignorant of those facts.

There is a word that every first year law student learns in studying contracts law, a word that provides an appropriate description of what it would mean to watch these men become sicker and sicker and withhold from them the single piece of information that could prevent that from happening: unconscionable. Unconscionable contracts are those that shock the conscience.[128] The relationships created in research studies do, to some extent, involve contract-like elements, as courts are beginning to recognize.[129] They involve voluntary agreements entered into by researchers and subjects, describing the terms of what will happen during a research study.[130] However, as with all contracts, there are limits to what society will accept in a very one-sided agreement.

What happened in the original Tuskegee Study did indeed shock people when it was finally made public in 1972. There is little reason to think that society has changed to so great an extent that such behavior would be less shocking to a modern-day audience. Moreover, there is no reason to think that the shocking elements of the Tuskegee Study were confined to the intentional lies made to the subjects.[131] Now that we have taken great steps to protect research subjects, and are proud of those protections, presumably we should be far less tolerant of behaviors by researchers that appear questionable.

The core protection that the federal regulations afford research subjects is informed consent.[132] Something would be very wrong if we interpreted the limits of that protection to allow people to participate in a study where the researchers are, in essence, shamefully exploiting the subjects' ignorance. Many aspects of modern research are troubling, including the fact that much of what we learn, we often learn from people who are in unfortunate circumstances. For example, people may enroll in studies because they are poor and cannot afford healthcare. By participating in the study they may receive treatments that they could not otherwise access.

But however troubling other aspects of the research system may be, it is especially troubling, given the system's emphasis on the protections of informed consent, to allow a study's key element to rely on withholding a simple but critically important piece of information. That circumstance would indeed be unconscionable and it is hard to believe that any current

128. BLACK'S LAW DICTIONARY 75, 1561 (8th ed. 2004).
129. *See, e.g.*, Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 843 (Md. 2001).
130. *See id*. at 843-44.
131. *See supra* notes 110-11 and accompanying text.
132. *See* Protection of Human Subjects, 45 C.F.R. § 46.116 (2007).

IRB would ever approve such a study. A current IRB would recognize that, in at least some circumstances, the federal regulations, consistent with the lessons of the Tuskegee Syphilis Study that helped shape them, do require researchers to disclose risks beyond those the researchers create themselves.

B. Should our rules allow Tuskegee Today to be conducted?

In evaluating whether our rules should allow researchers to conduct a study such as the Tuskegee Today hypothetical, we must first comment on the law of unintended consequences. Much of the current debate about reforming the IRB system, and eliminating administrative reviews that do little to protect subjects, supposes that society should only care about those risks that are imposed on subjects by participation in a study. For example, this supposition is the central premise of the AAUP's proposed reforms.[133]

However, as this Article has demonstrated, the roots of our system for protecting human subjects actually lie in studies where some of the most troubling aspects were due not to risks the researchers imposed, but rather to failure to disclose information about other risks not created by the study. There is no reason to believe that those concerns, and the reasons why we condemned such behaviors decades ago, have gone away. Thus, we need to be wary of looking solely at the risks caused by participation in a study and concluding that when such risks are minimal, a study is minimal risk and, thus, requires no ethical review. Some of the reformers might have inadvertently missed these types of concerns. If these concerns were brought to their attention, they might well modify their proposed reforms to provide appropriate protections.

Others, however, are raising the issue squarely but argue that by imposing certain disclosure duties on researchers, the government makes it harder to conduct some types of research, including studies that might have a substantial impact on public health.[134] The first response to this proposition should be to ask, where is the empirical evidence that such disclosure duties will indeed substantially deter research?

An excellent example for evaluating this issue is the Kennedy Krieger Institute lead paint study. While the consent forms used in the study were far from ideal, they did provide information about the risks of lead poisoning in children.[135] Furthermore, there is little reason to think that if that information had been provided more clearly it would have significantly altered the enrollment of families in the study. After all, the reason the researchers conducted the study in the first place was that lead

133. *See* AAUP COMM. A, *supra* note 45, at 97-98.

134. *See, e.g.*, Hoffmann & Rothenberg, *supra* note 93, at 146.

135. Pollak, *supra* note 77, at 102; *see also* KKI FACT SHEET, *supra* note 78.

contamination was endemic in inner-city Baltimore homes.[136] Low-income parents had few choices other than to live in these homes.[137] The underlying problem being studied had nothing to do with lack of information. Rather, it was caused by the lack of money needed to remove the lead.[138]

Thus, a family that was told the full details about the consequences of lead poisoning had no reason to change its behaviors. Additionally, there is no reason to think that public health officials had been hiding the lead paint problem from Baltimore residents or that such residents were especially poorly informed about it. The ultimate problem—and a very difficult one—was that these residents had few other affordable choices for housing. Therefore, full disclosure about the hazards of lead poisoning would have had little impact on the study.

On the other hand, failing to impose a disclosure duty on researchers could have a major, even crippling, consequence on public health and other research. The concerns raised about the Kennedy Krieger Institute lead paint study, including claims that the researchers were trying to take advantage of the parents' ignorance about lead poisoning,[139] demonstrate how public outrage about researcher behavior may lead to a backlash that ultimately shuts down critically important studies.

Another very prominent example of this phenomenon is the Environmental Protection Agency's (EPA) attempt to study the health effects on children of home pesticide use. In 2004, the EPA designed an observational study called the Children's Environmental Exposure Research Study (CHEERS), which would have involved families with young children that were using substantial amounts of pesticides in their homes.[140] Scant information is available about whether currently available home pesticides might be causing medical problems in children.[141] This study aimed to produce that information.[142]

136. KKI FACT SHEET, *supra* note 78; *see also* Pollak, *supra* note 77, at 92.

137. KKI FACT SHEET, *supra* note 78.

138. *Id*.

139. *See* Hoffmann & Rothenberg, *supra* note 93, at 143 (citing Brief for Appellants at 9, Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 809 (Md. 2001) (No. 1177)).

140. NAT'L EXPOSURE RESEARCH LAB., FACT SHEET: A CHILDREN'S ENVIRONMENTAL EXPOSURE RESEARCH STUDY – CHEERS 1 (2004), *available at* www.fluoridealert.org/pesticides/cheers/cheers.epa.nov.8.04.facts.pdf (last visited May 19, 2008) [hereinafter CHEERS FACT SHEET]; *see also* Press Release, Envtl. Prot. Agency, Statement by Stephen L. Johnson, Acting Administrator of the Environmental Protection Agency (Apr. 8, 2005), *at* www.epa.gov/cheers/ (last visited May 19, 2008) [hereinafter EPA Statement].

141. Jerry Menikoff, *Human Subject Testing: Of Babies, Bugs, and Bombast: A Look Behind the Crash-and-Burn of the CHEERS Pesticide Study*, 4 MED. RES. L. & POL'Y REP. (BNA) 586 (July 20, 2005).

142. *Id*.

The study became a political hot potato, embroiled in complicated claims and counterclaims, as Senate Democrats attacked it for inappropriately exposing young children to pesticide risks.[143] Ultimately, in order to gain Senate confirmation of the nominee for the EPA permanent administrator, the EPA agreed not to conduct the study.[144] What is especially interesting was the resonance this political in-fighting generated among various segments of the public, including certain religious groups, who vocally condemned the study.[145] Even the usually staid *New York Times* editorialized that the study was "macabre."[146]

Two issues this debate raised were whether the researchers would inform parents of the known risks of pesticide use, and, if they saw parents incorrectly using pesticides, whether they would inform the parents of the misuse.[147] The EPA indicated that it only wanted to study the "correct" use of pesticides and that it would inform parents about the known hazards from pesticide use and correcting misuse.[148]

However, as noted, even with these clarifications, the study was so controversial that it never took place.[149] Imagine the uproar if the EPA had tried to follow the approach outlined in Parts II and III of this Article under which researchers have no duty to disclose risks they do not impose themselves. If the *New York Times* characterized the study as "macabre" before, what headlines might it write about a study in which EPA researchers observe parents misusing pesticides, expose children to such misuse, and take no action, relying on their "lack of a duty" to do anything?

Or consider the hypothetical study that Hoffmann and Rothenberg propose where researchers want to study a population that uses a diet that exposes its children to certain nutritional deficiencies. Imagine, for example, that children on this diet are suspected to have a high incidence of heart failure in the teen years. What would the societal reaction be to learning that researchers stood by and conducted this study without even letting the parents and children know about these concerns?

V. CONCLUSION

The current IRB system is far from perfect, and there are many appropriate reforms that the government should make to ensure that it minimizes wasted effort and does not create unnecessary barriers to the

143. *Id*.
144. *Id*.
145. *Id*.
146. Editorial, *The Worst of the Bad Nominees*, N.Y. TIMES, Apr. 5, 2005, at A26.
147. Menikoff, *supra* note 141.
148. CHEERS FACT SHEET, *supra* note 140, at 3.
149. EPA Statement, *supra* note 140.

conduct of research. However, in making those reforms, society needs to recognize that researchers owe important basic duties to research subjects that require them to disclose information about certain risks, even if the risks are not created by the researchers or preexisted the study.

These basic duties reflect the core value of decent behavior that society expects from researchers. The researchers breached these duties in the Tuskegee Study, resulting in appropriate public condemnation. As President Clinton asserted, in the Tuskegee Study, our "nation broke the trust with our people that is the very foundation of our democracy."[150] We need to be careful that decades later we do not somehow lose sight of these basic disclosure duties in the race to make conducting research more efficient.

150. Presidential Apology, *supra* note 2.