

**SAFE FROM SUBPOENA? THE IMPORTANCE OF
CERTIFICATES OF CONFIDENTIALITY TO THE VIABILITY
AND ETHICS OF RESEARCH**

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I. INTRODUCTION

A man who is HIV positive participates in a local hospital's HIV research study designed to advance medical knowledge of the disease. A sexual partner who contracts HIV then seeks to subpoena information the man provided in the research study with the goal of using the information in a lawsuit to prove the man knew he was HIV positive when he had unprotected sex with her without informing her of his HIV positive status.

A woman volunteers for a research study conducted by a sociologist collecting information from prostitutes about safe sex practices, hoping to improve knowledge and safety for other women in the same position. Later, when the volunteer is arrested and charged with prostitution, the prosecutor attempts to force the researchers to disclose that the woman participated in the study in order to bolster its case.

One thousand individuals participate in a drug trial for an ulcerative colitis medication to see if it is effective for treatment-resistant colitis. Substantial debilitating side effects are discovered that were unknown before the drug was FDA-approved. Many people who were prescribed the drug and experienced these side effects—none of whom participated in the study—initiate a class-action lawsuit against the drug's manufacturer and cite the published results of the research study as evidence. The drug's manufacturer seeks to subpoena all of the research records and data, including the participants' identities and complete medical histories, to defend itself against the suit.

In all of these situations, the individuals involved chose to participate in research to advance medical or scientific knowledge. They volunteered their time to contribute to the fields in which the research was being conducted and to advance science. The participants consented to provide their information only after the researchers conducting the studies promised confidentiality. Disclosure of this "confidential" information during legal proceedings threatens to harm the participants in a variety of significant ways by violating their privacy and harming their interests in pending legal cases. With all of these studies, the researchers felt confident that the data they were collecting would remain confidential because they had applied for and received Certificates of Confidentiality ("Certificates")—which allow researchers to protect data from subpoena—from the National Institutes of Health (NIH).¹

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Although the above scenarios are all hypothetical, they illustrate very real concerns about privacy and confidentiality related to research and Certificates. Researchers have long recognized the importance of ensuring anonymity of research participants and the confidentiality of the data participants provide. Researchers have an ethical obligation to protect the identities of their research subjects: they are obligated to “do no harm,” which in many cases requires the protection of participants’ data.² They also are obligated to treat research participants as autonomous agents and support their ability to exercise that autonomy, which includes the right to control the privacy of their personal information.³

Researchers of human subjects are ethically obligated to maintain participant confidentiality, and this requirement is often explicitly stated in profession-specific ethics codes. For instance, psychologists who are members of the American Psychological Association (APA) are bound by the APA’s Ethical Principles of Psychologists and Code of Conduct, which require psychologists to maintain confidentiality.⁴ The majority of states have adopted some iteration of the APA Ethics Code for all psychologists licensed in the state, which also makes the Code legally binding.⁵ The American Medical Association’s (AMA) Code of Medical Ethics instructs physicians to maintain confidentiality of patient information and, when disclosure is required by law, recommends that physicians “seek a change in the law.”⁶ Researchers’ ethical obligation

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The authors would like to thank Dr. Donald Bersoff for his invaluable assistance in article conceptualization.

1. *See infra* Part II.
2. NAT’L COMM’N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979), *available at* <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>. The Belmont Report, created in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (which itself was created by the National Research Act), was written in response to abuses by researchers of the rights of their participants. It outlines the basic ethical obligations of human-subjects researchers, including the general principles of Respect for Persons, Beneficence, and Justice. *Id.*
3. *Id.*
4. AM. PSYCHOL. ASS’N, ETHICAL PRINCIPLES OF PSYCHOLOGISTS AND CODE OF CONDUCT, standard 4 (2010 amendments) (2003), *available at* <http://www.apa.org/ethics/code/index.aspx?item=11> [hereinafter APA CODE].
5. Stephen Behnke, *Responding to a Colleague’s Ethical Transgressions*, 37 MONITOR ON PSYCHOL., no. 3, 2006, at 72, 72.
6. *Opinion 5.05 - Confidentiality*, AM. MED. ASS’N, <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion505.page?> (last updated June 2007).

to protect participant confidentiality is analogous to the obligations of psychologists or physicians to resist subpoenas to protect patient confidentiality. For example, a psychologist's unauthorized disclosure of patient information is serious, not just because of ethical obligations, but also because patients may be successful in suing the psychologist for breach of contract or malpractice as a result of the disclosure.⁷ Therefore, psychologists and researchers are in a similar position of needing to carefully protect confidentiality.

In addition to maintaining confidentiality for ethical and legal reasons, researchers are concerned about confidentiality for practical purposes. To successfully complete studies involving human subjects, researchers must be able to find individuals willing to participate in the studies, and those individuals need to be willing to provide accurate, complete information in response to research questions.⁸ The promise of confidentiality encourages people to participate by decreasing the research-related risks and ensures their forthrightness is more likely.⁹

Courts generally have not recognized researchers as having a researcher-participant privilege, which might offer similar protection as the doctor-patient privilege.¹⁰ A recent case involving research at Boston College has renewed researchers' concerns about their ability to offer confidentiality to participants.¹¹ The Belfast Project, conducted by historians at Boston College, collected oral histories from members of paramilitary organizations involved in conflicts in Northern Ireland to

7. See generally Ellen W. Grabis, *The Liability of Psychotherapists for Breach of Confidentiality*, 12 J.L. & HEALTH 39, 68 (1998).

8. Peter David Blanck et al., *Scientific Rewards and Conflicts of Ethical Choices in Human Subjects Research*, 47 AM. PSYCHOL. 959, 960-61 (1992).

9. *Id.*

10. A legal privilege "grants someone the legal freedom to do or not to do a given act. It immunizes conduct that, under ordinary circumstances, would subject the actor to liability." BLACK'S LAW DICTIONARY 1390 (9th ed. 2009).

For a thorough discussion of the case law regarding researcher-participant privilege, see Paul G. Stiles & John Pettila, *Research and Confidentiality: Legal Issues and Risk Management Strategies*, 17 PSYCH. PUB. POL. & L. 333, 339-43 (2011). For an analysis of the ethical and legal issues related to confidentiality of research data, see Gary B. Melton, *When Scientists Are Adversaries, Do Participants Lose?*, 12 LAW & HUM. BEHAV. 191 (1988) (taking the position that participants' privacy interests should be the paramount consideration in any case compelling disclosure and assessing whether the case law reflects those interests). For a thorough discussion of the ways in which researchers might choose to respond to subpoena, as well as an explanation of the problems subpoena of research data may pose, see Michael Traynor, *Countering the Excessive Subpoena for Scholarly Research*, 59 LAW & CONTEMP. PROBS. 119 (1996). For a discussion of the importance of creating a researcher privilege and a proposal for such a privilege, see Katherine Adams, *The Tension Between Research Ethics and Legal Ethics: Using Journalist's Privilege State Statutes As a Model For a Proposed Researcher's Privilege*, 27 GEO. J. LEGAL ETHICS 335 (2014).

11. Peter Schmidt, *Case Puts Researchers' Confidentiality Pledges on Trial*, CHRON. HIGHER EDUC. (Jan. 5, 2012), <http://chronicle.com/article/Case-Puts-Researchers/130232/>.

“provide insight into those who become personally engaged in violent conflict.”¹² Forty-one interviewees participated and signed an agreement that stated the “ultimate power of release” of the tapes and transcripts rested with the participant.¹³

Authorities in the United Kingdom then requested, pursuant to a mutual legal-assistance treaty, that the United States furnish information related to a UK criminal investigation of a 1972 murder in Northern Ireland, for which one of the Belfast Project participants was a suspect.¹⁴ Accordingly, the Belfast Project materials were subpoenaed, and the researchers moved to quash the subpoenas.¹⁵ The United States District Court for the District of Massachusetts denied the motion to quash.¹⁶ The First Circuit affirmed, recognizing the decision might have a chilling effect on research but stating, “The choice to investigate criminal activity belongs to the government and is not subject to veto by academic researchers.”¹⁷ The decision of the First Circuit was stayed pending a grant of a writ of certiorari.¹⁸ The petitioners requested certiorari from the United States Supreme Court, but the petition was denied.¹⁹

In light of this case, and considering the high stakes for the interviewee (i.e., a possible murder conviction), researchers have expressed renewed concerns about the confidentiality of their data and the privacy they are able to offer participants.²⁰ The lack of researcher-participant privilege makes other protections of research confidentiality even more critical and creates concern about whether such protections will be sufficient to prevent subpoena.²¹ Certificates of Confidentiality

12. United States v. Moloney (*In re Price*), 685 F.3d 1, 4 (1st Cir. 2012).

13. *Id.* at 5.

14. *Id.* at 6.

15. *Id.* at 7.

16. *Id.* at 3.

17. *Id.* at 19.

18. Moloney v. United States, 133 S. Ct. 9, 9 (U.S. 2012).

19. Moloney v. United States, 133 S. Ct. 1796, 1796 (U.S. 2013).

20. See, e.g., Robert Dingwall, *Informant Confidentiality in the Corporate University*, SOC. SCI. SPACE (Jan. 30, 2012), <http://www.socialsciencespace.com/2012/01/informant-confidentiality-in-the-corporate-university/>; Scott Jaschik, *Confidentiality Right Rejected*, INSIDE HIGHER ED (July 9, 2012), <http://www.insidehighered.com/news/2012/07/09/appeals-court-rejects-researchers-bid-protect-oral-history-confidentiality>. For a discussion of the burdens placed on researchers by subpoenas for data, regardless of whether they comply, see Elizabeth C. Wiggins & Judith A. McKenna, *Researchers' Reactions to Compelled Disclosure of Scientific Information*, 59 LAW & CONTEMP. PROBS. 67, 75-88 (1996).

21. See generally John Lowman & Ted Palys, *The Ethics and Law of Confidentiality in Criminal Justice Research: A Comparison of Canada and the United States*, 11 INT'L CRIM. JUST. REV. 1 (2001) (providing an overview of all major legal challenges to research confidentiality in the U.S. and Canada).

are perhaps the most likely source of legal protection from subpoena.

This Article addresses legal issues related to Certificates, recognizes that Certificates face an uncertain future if challenged in court—based on the statutory history and limited relevant case law—and proposes that changes should be made to ensure Certificates actually offer the protection they promise. Part II reviews the background of Certificates of Confidentiality. Part III explores how Certificates fulfill vital functions by encouraging research participation, satisfying ethical obligations of researchers to protect participant data, and promoting the accuracy of data provided by participants in research studies. Part IV observes that the case law relevant to Certificates of Confidentiality, though limited, presents cause for concern. Part V explores the potential threats to Certificates of Confidentiality. Part VI argues that, for legal and public policy reasons, courts and Congress should consider changes in the way they approach Certificates of Confidentiality in order to offer broad protection for participants involved in sensitive research studies. Additionally, this section provides recommendations for researchers to secure sensitive data.

II. CERTIFICATES OF CONFIDENTIALITY: DEVELOPMENT AND USE

What are now known as Certificates of Confidentiality were first authorized because of a belief that researchers and the government needed to be able to offer guarantees of confidentiality to successfully conduct research on what was seen as an emerging drug epidemic.²² The Comprehensive Drug Abuse Prevention and Control Act of 1970 amended the Public Health Service Act to provide protection from disclosure of identifiable research data on illegal drugs.²³ In 1974, that protection was expanded to include mental health research and research on the use of alcohol²⁴ and, in 1988, an amendment was passed to allow Certificates to cover health research more broadly.²⁵

The current Public Health Service Act enables the Secretary of the Department of Health and Human Services (DHHS) to authorize

22. Kristin F. Lutz et al., *Use of Certificates of Confidentiality in Nursing Research*, 32 J. NURSING SCHOLARSHIP 185, 186 (2000). For a detailed legislative history related to Certificates, see Leslie E. Wolf et al., *Certificates of Confidentiality: Protecting Human Subject Research Data in Law and Practice*, 14 MINN. J. L. SCI. & TECH. 11, 21-26 (2013).

23. Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, § 3(a), 84 Stat. 1236, 1241.

24. Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Amendments of 1974, Pub. L. No. 93-282, § 122(A), 88 Stat. 125.

25. Health Omnibus Programs Extension of 1988, Pub. L. 100-607, 102 Stat. 3048 (codified as amended at 42 U.S.C. § 201).

“persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health [and] including research on the use and effect of alcohol and other psychoactive drugs)” to withhold “the names or other identifying characteristics” of “individuals who are the subject of such research.”²⁶ This allows researchers to promise confidentiality to research participants by establishing legal ground for refusing to identify participants. This authorization, essentially, was designed to withstand subpoena, as those authorized to protect the privacy of research participants “may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.”²⁷ The DHHS has authorized twenty-four institutes and centers of the NIH, as well as the Centers for Disease Control, the Food and Drug Administration, the Health Resources and Services Administration, the Indian Health Service, and the Substance Abuse and Mental Health Services Administration, to grant Certificates to research institutions for this purpose.²⁸

Under DHHS regulations, Certificates are granted for “sensitive” research, defined as research for which “disclosure of identifying information could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation.”²⁹ Sensitive research includes:

Information relating to sexual attitudes, preferences, or practices; information relating to the use of alcohol, drugs, or other addictive products; information pertaining to illegal conduct; information that, if released, might be damaging to an individual’s financial standing, employability, or reputation within the community or might lead to social stigmatization or discrimination; information pertaining to an individual’s psychological well-being or mental health; and genetic information or tissue samples.³⁰

26. 42 U.S.C. § 241(d) (2006).

27. *Id.* A distinction should be made between subpoenas, which are issued by attorneys when they would like to compel an individual to appear in court either to provide them access to documents or to testify, and court orders, which are issued by a judge. When an attorney issues a subpoena for the production of documents, the receiver must supply the items sought unless the subpoena is challenged in court, but courts have some level of discretion when determining whether to enforce a particular subpoena. BLACK’S LAW DICTIONARY, *supra* note 10, at 1654.

28. *Certificates of Confidentiality Contacts at NIH and Other DHHS Agencies that Issue Certificates*, NAT’L INST. OF HEALTH, <http://grants.nih.gov/grants/policy/coc/contacts.htm> (last updated Feb. 19, 2015). The DHHS has delegated this power to issue Certificates, rather than issuing Certificates directly. *Id.*

29. *Certificates of Confidentiality: Background Information*, NAT’L INST. OF HEALTH, <http://grants.nih.gov/grants/policy/coc/background.htm> (last updated Jan. 20, 2011) [hereinafter *Background Information*].

30. *Frequently Asked Questions, Certificates of Confidentiality*, NAT’L INST. OF HEALTH,

Identifying characteristics are defined as “name, address, social security or other identifying number, fingerprints, voiceprints, photographs, genetic information or tissue samples, or any other item or combination of data about a research participant which could reasonably lead, directly or indirectly by reference to other information, to identification of that research subject.”³¹

Researchers must apply for a separate Certificate for each research study, and a Certificate issued to the research institution covers all data from that individual study.³² Certificates protect only data that are collected after the Certificate is issued but before the Certificate’s expiration date, though Certificates can be renewed to last through the conclusion of data collection.³³ For data collected while the Certificate is active, protection from subpoena is supposed to be permanent.³⁴ Certificates do not prevent researchers from *voluntarily* disclosing child abuse, communicable diseases, suicide risk, or threats of violence, but such disclosures must be explained in the consent form signed by participants before the start of research.³⁵ Certificates, however, do allow researchers to choose to forego disclosures otherwise compelled by law, including mandatory reporting laws for child abuse.³⁶ Essentially, this allows researchers to decide whether or not to disclose in situations in which disclosure would normally be compelled by law.

Only one study has collected data on requests for and issuance of Certificates. In that study, ten NIH institutes responded to requests from

<http://grants.nih.gov/grants/policy/coc/faqs.htm> (last updated June 20, 2011) [hereinafter *Questions*].

31. *Id.*

32. *Id.*

33. *Background Information*, *supra* note 29.

34. *Id.*

35. *Questions*, *supra* note 30.

36. Because Certificates protect against involuntary disclosures by researchers of personally identifiable data, Certificates protect researchers from being compelled by mandatory reporting requirements, as well. *Id.* *C.f.* Kimberly Hoagwood, *The Certificate of Confidentiality at the National Institute of Mental Health: Discretionary Considerations in its Applicability in Research on Child and Adolescent Mental Disorders*, 4 ETHICS & BEHAV. 123, 127 (1994) (distinguishing between moral considerations and policy considerations and encouraging researchers to avoid reporting past abuse only in cases in which “strong scientific justification for such an action exists,” and arguing that even though Certificates offer protections from reporting abuse, researchers should nevertheless always choose to report recent or ongoing abuse). *But see* Alan M. Steinberg, Robert S. Pynoos, Armen K. Goenjian, Haleh Sossanabadi, & Larissa Sherr, *Are Researchers Bound by Child Abuse Reporting Laws?*, 23 CHILD ABUSE & NEGLECT 771, 773-74 (1999) (arguing that Certificates may not exempt researchers from mandatory reporting laws and contending that, regardless of whether researchers are legally exempt, researchers have an ethical obligation to report child abuse); Roland M. Larkin, *Federal Regulations for Prison-Based Research: An Overview for Nurse Researchers*, 14 J. NURSING L. 17, 19 (2011) (arguing that *Tarasoff* duties to protect third parties supersede Certificates in some cases).

researchers for data regarding issuances of Certificates between January and October 2002: the National Institute of Mental Health issued the most Certificates (146), followed by the National Institute on Alcohol Abuse and Alcoholism (100), the National Cancer Institute (67), and the National Institute of Allergy and Infectious Diseases (30-40).³⁷ The National Eye Institute issued the least (2).³⁸ The ten responding institutes provided Certificates for “behavioral research (2 [out of 10 responding institutes]), research on substance use/abuse and other illegal behavior (2/10), research on sexual attitudes, preferences and behaviors (1/10), clinical research (1/10), psychological research (1/10), research on elder abuse (1/10), biodefense research (1/10), and research on Alzheimer’s disease (1/10).”³⁹ Between 2009 and 2011, an average of 1,016 new Certificates were issued annually—24% by the National Institute on Drug Abuse, 22% by the National Institute of Mental Health, 12% by the National Institute of Child Health and Human Development, and 10% by the National Institute of Alcohol Abuse and Alcoholism.⁴⁰ This demonstrates that, although Certificates have become more common in recent years and are clearly more prevalent in certain research areas than in others, they remain relatively rare; considering the large number of research studies conducted, a small number of Certificates have been obtained.

Institutes reported denying applications for a Certificate very infrequently. Fewer than five applications were reportedly denied in a two-year period, with denials usually made for procedural reasons or because the research did not fulfill the statutory purpose for Certificates (e.g., the research did not collect participants’ identifiable data).⁴¹ All institutes reported granting Certificates within three months of the original application, and most institutes indicated they were often able to process applications within a much shorter timeframe.⁴² Researchers conducting studies within the designated scope of Certificates, therefore, appear to be able to acquire this protection with relative ease—though it is important to note that the only data available on this topic are from 2004, and it is possible that the ease of gaining a Certificate has changed

37. Leslie E. Wolf, Jola Zandecki, & Bernard Lo, *The Certificate of Confidentiality Application: A View from the NIH Institutes*, 26 IRB: ETHICS & HUM. RES., no. 1, 2004, at 14, 16.

38. *Id.*

39. *Id.* No data have been published on the number and types of Certificates obtained in the past decade; therefore, it is not clear whether these figures are representative of current use of Certificates, as well.

40. Bryon Adinoff, Robert R. Conley, Stephan F. Taylor, & Linda L. Chezem, *Protecting Confidentiality in Human Research*, 170 AM. J. PSYCHIATRY 466, 466 (2013).

41. Wolf, *supra* note 37.

42. *Id.* at 15.

since that time.

The NIH maintain a Certificates of Confidentiality Kiosk webpage, which provides information about Certificates, their scope, and the application process and answers frequently asked questions.⁴³

III. CERTIFICATES OF CONFIDENTIALITY THROUGH THE EYES OF RESEARCHERS, INSTITUTIONAL REVIEW BOARDS, AND PARTICIPANTS

In order for Certificates to improve investigators' abilities to collect data on sensitive topics, it is critical for those involved in implementing and participating in eligible studies to understand and trust the protection Certificates provide. Individuals involved in research express concerns about the protections offered by Certificates and whether those protections would withstand legal challenges. Very little research has been conducted regarding Certificates, and most scientific literature on Certificates offers no actual data.⁴⁴ However, a few studies have been conducted on the experiences of research investigators, Institutional Review Boards (IRBs),⁴⁵ and research participants with Certificates.⁴⁶

The vast majority of IRBs report use of Certificates at their institutions, though many IRB chairs seem to hold misconceptions about Certificates and their legal ramifications.⁴⁷ IRB chairs indicated they would require a Certificate only for studies in which they could foresee a risk of subpoena and in which the sensitive information collected in the research was not also located elsewhere (for example, in a medical file); they recognized little point in acquiring a Certificate to protect data they believed could easily be subpoenaed from another source.⁴⁸

43. *Certificates of Confidentiality Kiosk*, NAT'L INST. OF HEALTH, <http://grants.nih.gov/grants/policy/coc/index.htm> (last updated May 15, 2014) [hereinafter *Kiosk*].

44. Leslie E. Wolf & Jolanta Zandecki, *Sleeping Better at Night: Investigators' Experiences with Certificates of Confidentiality*, 28 IRB: ETHICS & HUM. RES., no. 6, 2006, at 1, 1.

45. IRBs are mandated by 45 C.F.R. § 46.101–124 to review all human subject research conducted at their institutions before data collection begins. IRB approval is required as an ethical safeguard; approval is contingent upon a number of factors, including that the risk to participants is minimized, the risks are reasonable given the expected benefits of the research, selection of participants is equitable so that either the benefits or risks of participation are not distributed unfairly to one group, and informed consent is sought from each participant enrolled in the study. 45 C.F.R. § 46.111 (2014).

46. See generally Laura M. Beskow et al., *Institutional Review Boards' Use and Understanding of Certificates of Confidentiality*, 7 PLOS ONE, no. 9, 2012, at 1, available at <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0044050>; Wolf & Zandecki, *supra* note 44; Joseph A. Catania et al., *Research Participants' Perceptions of the Certificate of Confidentiality's Assurances and Limitations*, 2 J. EMPIRICAL RES. ON HUM. RES. ETHICS: INT'L J. 53 (2007).

47. Beskow et al., *supra* note 46, at 3.

48. *Id.* at 4.

IRB chairs hold mixed opinions about the effectiveness of Certificates. Only 45% of responding chairs agreed with the statement, “Certificates provide nearly absolute protection against compelled disclosure of identifying research data.”⁴⁹ Some chairs expressed that Certificates have a deterrent effect on lawyers, making them much less likely to attempt to subpoena data if a Certificate covers the study.⁵⁰ However, some chairs asserted that Certificates were only as good as an institution’s or researcher’s willingness to fight a subpoena, suggesting that Certificates might protect data, but only after money and time have been invested in a legal battle.⁵¹ Many chairs expressed concern that Certificates have not been tested in court often, stating this made it difficult to know whether they would actually be upheld if challenged.⁵² Accordingly, one-third of chairs agreed that Certificates give researchers a false sense of security.⁵³ Nonetheless, two-thirds of chairs endorsed the statement, “Certificates are an important tool for facilitating participation in studies involving the collection of sensitive information.”⁵⁴

Researchers also indicated the importance of Certificates for protecting research data and for encouraging participant enrollment in the study by reassuring participants of confidentiality.⁵⁵ Researchers who had faced attempts to force them to disclose research data protected by Certificates indicated the Certificates were highly effective in resisting such disclosure—though only three investigators out of a sample of 19 had such an experience.⁵⁶ However, some researchers also expressed concern about whether a Certificate would actually withstand a direct challenge in court.⁵⁷ Researchers also confirmed that Certificates reduced their anxiety, as well as that of their participants, and that Certificates encouraged participants to be more forthright in providing information.⁵⁸

Finally, in a study of research participants who were asked to provide feedback on consent forms for a hypothetical study, the vast majority of participants understood the language regarding the

49. *Id.* at 5.

50. *Id.* at 6.

51. *Id.*

52. *Id.* at 7.

53. *Id.*

54. *Id.* at 8.

55. Wolf & Zandecki, *supra* note 44, at 4.

56. *Id.*

57. *Id.* at 5.

58. *Id.*

Certificate.⁵⁹ However, only a minority of participants indicated they felt protected by the Certificate.⁶⁰ Participants were especially confused and concerned about language that indicated the Certificate did not prevent disclosure in cases of federal audit of the study or in cases in which state law requires reporting.⁶¹ It is worth noting that the possibility of federal audit certainly does not apply to all studies,⁶² and researchers are released from the obligations of state mandatory reporting laws by the Certificate; therefore, researchers could choose to forego reporting in order to promise participants complete confidentiality.⁶³ Despite potential confusion that explanations of Certificates may cause during the consent process, a study randomizing participants to one of four conditions—quasi-anonymous, fully anonymous, traditional consent, and traditional consent with a Certificate—found that having a Certificate either did not impact or slightly increased participant disclosure of sensitive information.⁶⁴

59. Catania et al., *supra* note 46, at 55.

60. *Id.* at 55-56.

61. *Id.* The researchers could have chosen to write consent forms explaining that the Certificate exempted the researchers from mandatory reporting. However, in order to reserve the right to comply with state mandatory reporting laws, researchers must include language indicating this possibility in consent forms. *See, e.g., Questions, supra* note 30; APA CODE, *supra* note 4, at standard 8. Researchers may feel an ethical obligation to at least maintain the possibility of reporting in extreme situations of abuse.

62. *Questions, supra* note 30. An audit may occur when the research is funded by a federal agency, as the agency then has the right to audit study records to ensure compliance with requirements related to the funding and to ensure funding was appropriately allocated. Catania et al., *supra* note 46, at 55. Additionally, for drug trials, the FDA may audit records to ensure compliance with requirements under the Food, Drug, and Cosmetic Act, including protocol deviations, recordkeeping, accountability, and subject protections. U.S. DEPT. OF HEALTH & HUMAN SERV., FOOD & DRUG ADMIN., INFORMATION SHEET GUIDANCE FOR IRBS, CLINICAL INVESTIGATORS, AND SPONSORS: FDA INSPECTIONS OF CLINICAL INVESTIGATORS 4 (2010), available at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126553.pdf>.

63. Sue Rovi & Erica Olson, *Obtaining an NIH Certificate of Confidentiality to Protect the Identities of Research Participants*, 24 VIOLENCE & VICTIMS 414, 416 (2009).

64. Jessica R. Beatty, Sara K. Chase, & Steven J. Ondersma, *A Randomized Study of the Effect of Anonymity, Quasi-Anonymity, and Certificates of Confidentiality on Postpartum Women's Disclosure of Sensitive Information*, 134 DRUG & ALCOHOL DEPENDENCE 280, 282-83 (2014). This study randomly assigned 200 women to one of the four conditions and then asked them to report, via computer, their alcohol and drug use, risky sexual behaviors, intimate partner violence, and emotional distress. In the anonymous condition, participants were never asked for their name. In the quasi-anonymous condition, participants used their names on the consent document, but were told their answers could not be linked to their identity. In the traditional consent condition, participants were told that their names and answers would be kept separately, but that there would be a file linking the two; they were also told that researchers were required to report things such as child abuse. The Certificate condition matched the traditional consent condition, with the inclusion of an explanation that researchers had received a Certificate from the government that protected information related to substance use. Women in the anonymous and quasi-anonymous conditions reported significantly more sensitive information than did women in the other two conditions.

Participant reactions to the Certificate may depend, in part, on the way in which the Certificate is presented in consent materials. In a qualitative study that presented participants with consent materials for a hypothetical study, participants were assigned to read either the standard language suggested by the NIH regarding Certificates or a simplified version written by researchers.⁶⁵ Though the majority of participants in both groups said the Certificate would not impact their decisions about whether to participate in the study or how much truthful information to provide, those who read the standard NIH language were more likely to find the information confusing, say they might choose not to participate, and say they might withhold sensitive information from researchers.⁶⁶

For Certificates to effectively advance investigators' abilities to conduct research on sensitive topics, it is important for those involved to have confidence in the protection offered by Certificates. The concerns of IRBs, researchers, and research participants that Certificates may not actually protect data as securely as the language of the statute, NIH guidelines, and consent forms suggest are largely hypothetical; at this point, there have been only three published challenges to Certificates in court. However, these concerns are not without merit, as the more recent of those cases indicates cause for concern and suggests caution in assuming that protections offered by Certificates can truly stand up to legal challenges.⁶⁷

IV. LEGAL CHALLENGES TO CERTIFICATES OF CONFIDENTIALITY

Certificates of Confidentiality have faced a number of important legal challenges since they were first created. Taken together, these challenges suggest that researchers should be cautioned against relying heavily on Certificates. Examining each of the relevant cases is critical to developing a clear understanding of the ability of Certificates to truly protect participants' data.

The first legal challenge to what later became known as Certificates of Confidentiality was in 1973 in the Court of Appeals of New York. In *People v. Newman*, the director of a methadone treatment program appealed an order to produce photographs of patients enrolled in the program, which had been the subject of a subpoena in order to identify a

Women in the Certificate condition reported significantly more sensitive information about drug use but not about the other categories. *Id.* at 281-83.

65. See generally Laura M. Beskow, Devon K. Check & Natalie Ammarell, *Research Participants' Understanding of and Reactions to Certificates of Confidentiality*, 5 *AJOB EMPIRICAL BIOETHICS*, no. 1, 2014, at 12.

66. *Id.*

67. *State v. Bradley*, 634 S.E.2d 258 (N.C. Ct. App. 2006).

murder suspect who had been seen at the clinic.⁶⁸ On appeal, Newman, the program director, relied on the Comprehensive Drug Abuse Prevention and Control Act of 1970 to argue that the clinic's records were exempt from subpoena, as the patients were also research participants in drug research.⁶⁹

The court, granting Newman's motion to quash the subpoena, noted an individual would likely refuse to participate in a methadone maintenance treatment program "because his picture might be exhibited to an eyewitness to a crime."⁷⁰ In an amicus curiae brief submitted on behalf of the United States, the Department of Health, Education and Welfare argued that the "long range success [of drug research programs] depends on the ability of each program director to promise to each participant, [u]nconditionally, that his participation in the program will not be disclosed."⁷¹ The Department also indicated that the Act of 1970 granted "absolute confidentiality."⁷² The court, quoting this language, found it is "well settled that the construction given statutes and regulations by the agency responsible for their administration, if not irrational or unreasonable, should be upheld."⁷³ The U.S. Supreme Court denied a petition for writ of certiorari.⁷⁴

It is noteworthy that this case was decided based on an old version of the statute that authorizes the issuance of Certificates. The current statute appears to offer even broader protection than the initial Act of 1970, and much of the language remains the same.⁷⁵ However, because the case was based on a statute that has since undergone several revisions, the case is not binding even on courts in New York; because the Supreme Court did not hear the case, the decision, at most, is persuasive to courts in other jurisdictions.⁷⁶ Accordingly, this outcome in favor of Certificates offers no assurance of a similar outcome in future challenges in New York or elsewhere.

The decision in *Newman* was, however, cited in another New York case just two years later. In *People v. Sill*, an individual was charged with possession of a controlled substance—methadone—which the

68. *People v. Newman*, 298 N.E.2d 651, 653 (N.Y. 1973). Photographs of patients were maintained to prevent administration of methadone to anyone other than the registered patient. *Id.*

69. *Id.* at 654-55.

70. *Id.* at 656.

71. *Id.*

72. *Id.*

73. *Id.* (quoting *Matter of Howard v. Wyman*, 271 N.E.2d 528, 530 (N.Y. 1971)).

74. *New York v. Newman*, 414 U.S. 1163, 1163 (1974).

75. *See supra* Part II.

76. Leslie E. Wolf & Bernard Lo, *Practicing Safer Research Using the Law to Protect the Confidentiality of Sensitive Research Data*, 21 IRB: ETHICS & HUM. RES., no. 5, 1999, at 4, 6.

defendant stated he had received from a methadone clinic where he was a patient.⁷⁷ The prosecutor then subpoenaed the methadone clinic, which refused to provide records on the basis of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and Drug Abuse Office and Treatment Act of 1972.⁷⁸ However, the subpoena was ultimately enforced, as the court determined that the defendant had waived his “statutory right to anonymity” by disclosing that he was a patient in the program.⁷⁹ This case stands for the proposition that a Certificate may not protect an individual if he or she voluntarily discloses his or her identity as a research participant, though it also does not bind other jurisdictions.⁸⁰

Despite the lack of binding precedent from these two cases, these rulings and the subsequent denial of certiorari for *People v. Newman* were apparently sufficient to deter any further challenges to Certificates in court for more than 30 years.⁸¹ However, in 2006, the Court of Appeals of North Carolina heard a challenge to Certificates by a defendant in a child sexual abuse case.⁸² The defendant was convicted of indecent liberties and committing a sexual offense with a child.⁸³ At his trial, in addition to the purported victim, three other girls testified, indicating the defendant had also engaged in sexual contact with them.⁸⁴ The defendant subpoenaed research records from a study in which he believed one of the girls who testified had participated, which he wished to use to impeach her testimony.⁸⁵

The trial court ordered that the research data “remain confidential unless used at trial or sentencing,” but allowed “the state’s chief investigating officer, the witness, the District Attorney’s office staff, the defendant and his wife, the Public Defender’s office staff, the Assistant Public Defender, and any expert the defendant or state might consult” to

77. *People v. Still*, 369 N.Y.S.2d 759, 761 (N.Y. App. Div. 1975).

78. *Id.*

79. *Id.* at 765.

80. *See Adinoff et al.*, *supra* note 40, at 467.

81. One additional challenge occurred during this period, but the study in question did not have a Certificate. In 2000, in *Murphy v. Phillip Morris Inc.*, Phillip Morris subpoenaed data from a study on the link between secondhand smoke and lung cancer, data that were not protected by a Certificate but which researchers claimed should receive the protections a Certificate would have provided. The federal district court granted access to redacted data in order to protect the identities of the research participants, though the data were not protected. *Murphy v. Philip Morris Inc.*, No. CV 99-7155-RAP(JWJx), 2000 U.S. Dist. LEXIS 21128 (C.D. Cal. Mar. 17, 2000). For a detailed analysis of this case, see Wolf et al., *supra* note 22, at 34-36. *See also Adinoff et al.*, *supra* note 40, at 467.

82. *State v. Bradley*, 634 S.E.2d 258, 260 (N.C. Ct. App. 2006).

83. *Id.* at 261.

84. *Id.*

85. *Id.* at 262.

review the data.⁸⁶ Although this allowed many individuals to access the data, it prevented the data from becoming part of the public record or being made known to the gallery or the press. The subpoena was issued for study documents referencing any of the girl's statements related to the experience of abuse. Duke University Health Systems (DUHS), which controlled the research data, sought to suppress the subpoena.⁸⁷

The researchers filed a motion for a protective order, claiming the research study data were protected from subpoena by their Certificate.⁸⁸ The judge was unfamiliar with Certificates and viewed the subpoena the same as any other discovery motion. "He told DUHS that he had not realized 'what kind of egg [he was] cracking open,' but 'obviously it had lit a fire under somebody.'"⁸⁹ The judge was unconvinced by the argument that the information was protected by statute and by the policy arguments for maintaining confidentiality. As a result, he engaged in a weighing analysis to determine whether the information should be protected from subpoena, rather than automatically protecting the data based on the Certificate.⁹⁰

After the trial concluded and the defendant was convicted and sentenced, the defendant again sought access to the records on appeal; this led to a hearing, before the same judge, on the sealed records.⁹¹ This time, the trial court ordered that the data be given to the defendant's attorney, but "[d]issemination of the contents of the documents to anyone other than counsel for the parties was prohibited."⁹² The researchers again appealed the disclosure order, though they complied with production to defendant's counsel.⁹³ The researchers argued before the North Carolina Court of Appeals that the trial court's order to produce the research records violated the federal statute authorizing the

86. Laura M. Beskow, Lauren Dame, & E. Jane Costello, *Certificates of Confidentiality & Compelled Disclosure of Data*, 322 Sci. 1054, 1054 (2008).

87. *Bradley*, 634 S.E.2d at 260. The research study in question was the Great Smoky Mountains Study, conducted by the Center for Developmental Epidemiology of the Duke University Health System in collaboration with the North Carolina State Division of Developmental Disabilities, Mental Health, and Substance Abuse Services. The longitudinal study of 1,073 children and their parents sought to "estimate the number of youth with emotional and behavioral disorders, the persistence of those disorders over time, the need for and use of services for emotional and behavioral disorders, and the possible risk factors for developing emotional and behavioral disorders." *The Great Smoky Mountains Study*, DUKE U. HEALTH SYS., <http://devepi.duhs.duke.edu/gsms.html> (last visited July 22, 2014).

88. *Bradley*, 634 S.E.2d at 260.

89. Beskow et al., *supra* note 86, at 1054 (quoting Transcript of the hearing on Duke's Motion for Protective Order, Aug. 8, 2004, at 9).

90. *Bradley*, 634 S.E.2d at 262.

91. Beskow, *supra* note 86, at 1054; *Bradley*, 634 S.E.2d at 261.

92. *Bradley*, 634 S.E.2d at 261.

93. Beskow, *supra* note 86, at 1055.

study's Certificate.⁹⁴ In their notice of appeal, the researchers cited *People v. Newman* and argued that participants "must be given genuine assurances of confidentiality for investigators to obtain candid, meaningful, and wide participation in the study."⁹⁵

The defendant, on the other hand, maintained that, at a minimum, the trial court was obligated to review the requested data in camera to determine whether they were of an exculpatory nature.⁹⁶ Additionally, the defendant argued that *Newman* should not be persuasive because "[*Newman*] involves the State seeking information for use in a criminal prosecution as opposed to [this] case which involves a criminal defendant who has been afforded the Constitutional right to due process and confrontation to gain favorable and material information for his defense."⁹⁷ The defendant maintained that his right to access the information was a result of his constitutional rights as a criminal defendant and that, accordingly, he should have much greater access to materials protected by a Certificate than criminal prosecutors who are not exercising a constitutional right.

The Court of Appeals ruled that the defendant did not meet his burden of proving the materiality of the evidence and therefore was not entitled to in camera review or to release of the records.⁹⁸ Accordingly, the court declined to rule on the researchers' argument that the Certificate made the data statutorily privileged.⁹⁹ This leaves open the question of whether the court would have allowed the researchers to maintain the confidentiality of their data, based on the Certificate, if the research data were determined to be material. Because the court ultimately did not order the researchers to completely violate confidentiality, DUHS had neither grounds nor reason to seek certiorari from the U.S. Supreme Court. Additionally, the Certificate in this case did not completely protect the confidentiality of the research subject; though the data were not made completely public, the attorneys on both sides of the case ultimately were granted access to the study records.¹⁰⁰

The lack of court challenges may suggest that Certificates are

94. *Bradley*, 634 S.E.2d at 262.

95. Beskow, *supra* note 86, at 1055 (quoting Brief of Appellant/Subpoenaed Non-Party Duke University Health System, Inc. at 16, *Bradley*, 634 S.E.2d 258 (No. COA05-1167)).

96. *Bradley*, 634 S.E.2d at 262. An in camera review is one which takes place privately in the judge's chambers, without becoming part of the public record. BLACK'S LAW DICTIONARY, *supra* note 10, at 878.

97. Beskow, *supra* note 86, at 1055 (quoting Defendant-Appellee's Brief at 17, *State v. Bradley*, 634 S.E.2d 258 (N.C. Ct. App. 2006) (No. COA05-1167)).

98. *Bradley*, 634 S.E.2d at 262.

99. *Id.*

100. Beskow, *supra* note 86, at 1055.

assumed to be resistant to challenge, and a study of legal counsel for research institutions somewhat supports this view.¹⁰¹ Of twenty-four legal counsel interviewed, fifteen had experienced legal requests for data from a study with a Certificate.¹⁰² Eight of these fifteen reported that informing the requester of the protection provided by the Certificate sufficiently resolved the issue.¹⁰³ Counsel also reported several cases in which some of the data sought were ultimately disclosed, either through consent or negotiated compromise among all parties, and one participant reported, “I guess the prevailing thought or position is that we don’t want to challenge [Certificates] in court and set precedent for the court saying they’re not protective.”¹⁰⁴

Clearly, researchers and participants alike still have cause for some concern. *State v. Bradley* indicates that at least some judges are unfamiliar with Certificates and unpersuaded by them. In light of recent court decisions—such as the one regarding the Belfast Project at Boston College—that reiterate that researchers have no common law grounds for asserting confidentiality between them and their participants,¹⁰⁵ challenges to Certificates may become more likely,¹⁰⁶ and case law offers little guarantee that Certificates will prevail.¹⁰⁷

V. POTENTIAL THREATS TO CERTIFICATES OF CONFIDENTIALITY

Opponents to Certificates may assert challenges in a number of ways, leaving vulnerable research data protected by Certificates.

101. See generally Leslie E. Wolf et al., *Certificates of Confidentiality: Legal Counsels’ Experiences and Perspectives on Legal Demands for Research Data*, 7 J. EMPIRICAL RES. HUM. RES. ETHICS, no. 4, 2012, at 1, 1.

102. *Id.*

103. *Id.* at 4.

104. *Id.*

105. See *supra* notes 10-18 and accompanying text.

106. But see Patrick P. Gunn et al., *Certificates Should Be Strengthened*, 323 SCI. 1289, 1289 (2009) (arguing that researchers’ recognition of the potential weakness of Certificates may in fact itself lead to court decisions that weaken Certificates further). “Given the limited case law bearing on Certificates of Confidentiality, we also worry that, by qualifying confidentiality assurances in consent forms, researchers are potentially creating factual scenarios that, if ultimately reviewed by appellate courts, are more likely to result in unhelpful precedent affording only limited protection to Certificate holders.” *Id.*

107. One final unpublished case illustrates this point. In an unpublished, unrecorded case in the Connecticut Superior Court for Juvenile Matters, a Yale University researcher voluntarily reported, to the Connecticut Department of Children and Families, concerns related to the abuse of children participating in a research study covered by a Certificate. In this case, because the researcher had disclosed the children’s identities as participants, the protection offered by the Certificate was considered waived, and the Department of Children and Families was permitted to access study records. Adinoff et al., *supra* note 40, at 468. For a detailed analysis of identified unpublished opinions related to Certificates, see Wolf et al., *supra* note 22, at 36-46.

Although the federal statute authorizing Certificates supersedes state laws requiring researchers to respond to subpoenas,¹⁰⁸ Certificates may still face threats from other federal statutes pertaining to subpoenas or conflicts between Certificates and constitutional rights. First, in criminal cases, grounds for challenging Certificates may be found in the criminal defendants' rights to collect evidence and prepare a defense. Second, grand juries may have grounds to subpoena research data protected by a Certificate. Third, rights to discovery may also pose threats to Certificates in civil suits. Fourth, narrow statutory interpretation is a concern in any type of legal challenge to Certificates. Fifth, challengers may argue that newer statutes, such as the PATRIOT Act, supersede or modify the statutory grounds for Certificates. Finally, in all of these situations, regardless of the final decision by the court, in camera review may violate the privacy of data before a decision is even made regarding the strength of the Certificate.

A. *Defendants' Constitutional Rights*

The defendant's brief in *State v. Bradley* emphasizes that Certificates may be susceptible to challenge on the grounds that they conflict with a defendant's constitutional rights. Every criminal defendant is "afforded the Constitutional right to due process and confrontation to gain favorable and material information for his defense."¹⁰⁹ Specifically, under the Fifth Amendment, criminal defendants cannot be deprived of "due process of law."¹¹⁰ Additionally, under the Sixth Amendment, "[i]n all criminal prosecutions, the accused shall enjoy the right . . . to be confronted with the witnesses against him [and] to have compulsory process for obtaining witnesses in his favor . . ."¹¹¹ However, "[t]here is no general constitutional right to discovery in a criminal case."¹¹² Despite this, "the defendant has certain constitutionally protected rights to collect relevant evidence and to fully develop his or her defense."¹¹³ In *Davis v. Alaska*, where a defendant sought to introduce into evidence an adverse witness's record as a

108. Because Certificates are authorized by federal statute, as long as the statute is not ruled unconstitutional, state law conflicting with the privacy guarantees of Certificates will be superseded by the federal statute under the Supremacy Clause of the Constitution. U.S. CONST. art. VI, cl. 2.

109. Beskow, *supra* note 86, at 1055 (quoting Defendant-Appellee's Brief at 17, *State v. Bradley*, 634 S.E.2d 258 (N.C. Ct. App. 2006) (No. COA05-1167)).

110. U.S. CONST. amend. V.

111. U.S. CONST. amend. VI.

112. *Weatherford v. Bursey*, 429 U.S. 545, 559 (1977).

113. Adrienne Kotowski, "How Confidential Is This Conversation Anyway?": *Discovery of Exculpatory Materials in Sexual Assault Litigation*, 3 SUFFOLK J. TRIAL & APP. ADVOC. 65, 71 (1998).

juvenile offender, the confidentiality interest of protecting the privacy of the record was held to be insufficient to “require yielding of so vital a constitutional right as the effective cross-examination for bias of an adverse witness.”¹¹⁴ This may indicate that, were a criminal defendant to seek to subpoena research records covered by a Certificate to impeach an adverse witness, the defendant’s constitutional rights would override the statutory authority for Certificates, especially “if there is a reasonable probability that, had the evidence been disclosed to the defense, the result of the proceeding would have been different.”¹¹⁵

A defendant’s right to confer a subpoena *duces tecum* on a non-party is codified in the Federal Rules of Criminal Procedure and allows the defendant to subpoena “any books, papers, documents, data, or other objects,” though “the court may quash or modify the subpoena if compliance would be unreasonable or oppressive.”¹¹⁶ Though this right to issue a subpoena is statutory in nature, in certain cases courts may consider the information sought to be necessary to a defendant’s constitutional right to a fair trial, in which case the court’s discretion to quash the subpoena would be substantially limited.¹¹⁷ Although such a challenge related to a Certificate has not yet occurred, the possibility remains that, under the right circumstances, a court would find the defendant’s constitutional rights in conflict with a Certificate, and the Certificate would likely yield.¹¹⁸

B. Grand Jury Subpoenas

Rule 17(c) of the Federal Rules of Criminal Procedure also governs a grand jury’s ability to subpoena documentary evidence,¹¹⁹ leaving uncertainty about whether Certificates would withstand subpoena by grand jury. However, when a grand jury issues a subpoena, a “motion to quash must be denied unless the district court determines that there is no reasonable possibility that the category of materials the Government

114. Davis v. Alaska, 415 U.S. 308, 320 (1974).

115. Pennsylvania v. Ritchie, 480 U.S. 39, 57 (1987).

116. FED. R. CRIM. P. 17(c). A subpoena *duces tecum* is a subpoena issued in order to compel disclosure of “documents, records, or things.” BLACK’S LAW DICTIONARY, *supra* note 10, at 1654.

117. Courts “must not shrink from their obligation to ‘enforce the constitutional rights of all ‘persons,’ including prisoners.” Brown v. Plata, 131 S. Ct. 1910, 1928 (U.S. 2011) (quoting Cruz v. Beto, 405 U.S. 319, 321 (1972)). See also Briggs v. Connecticut, 447 U.S. 912, 915 (1980) (Marshall, J., dissenting) (“Our judicial system relies on conscientious trial and appellate courts to assure that all persons accused of criminal offenses receive the full protections guaranteed them by the Constitution.”).

118. “[A] law repugnant to the Constitution is void. . . .” Marbury v. Madison, 5 U.S. (1 Cranch) 137, 180 (1803).

119. FED. R. CRIM. P. 17(c).

seeks will produce information relevant to the general subject of the grand jury's investigation."¹²⁰ Grand juries are generally not restricted in the information they can demand, and a grand jury's decisions are generally not reviewed by the judiciary; "[t]he grand jury may compel the production of evidence or the testimony of witnesses as it considers appropriate, and its operation generally is unrestrained by the technical procedural and evidentiary rules governing the conduct of criminal trials."¹²¹

However, the Supreme Court noted that the grand jury is limited in some ways. A grand jury "may not itself violate a valid privilege, whether established by the Constitution, statutes, or the common law."¹²² Under this rule, if Certificates are construed as creating a "privilege" for the research they cover, grand juries would presumably be unable to overcome the barrier a Certificate presents to subpoena. An evidentiary privilege, however, is not automatically created when there is a statutory basis for confidentiality or when a professional has an ethical duty to maintain confidentiality; rather, privilege is a legal term of art that indicates the granting of a particular type of absolute exemption with a foundation in evidentiary rules of a statutory, common law, or constitutional nature.¹²³ Therefore, though a subpoena does not override a privilege, it may override a statutory or ethical justification for refusing to produce documents. Unfortunately, the lack of case law in this area still creates uncertainty about the way in which Certificates would be interpreted and the degree to which protected research would be immune to grand jury subpoena.

C. *Right to Discovery in Civil Suits*

Under the Federal Rules of Civil Procedure, civil litigants also enjoy a statutory right to issue subpoenas *duces tecum* commanding a person to "produce designated documents, electronically stored information, or tangible things in that person's possession,"¹²⁴ and it is unclear whether this may compromise data protected by a Certificate. Courts are obligated to quash or modify any subpoena that "requires disclosure of privileged or other protected matter, if no exception or waiver applies."¹²⁵ However, to successfully quash a subpoena "under a

120. *United States v. R. Enter., Inc.*, 498 U.S. 292, 301 (1991).

121. *United States v. Calandra*, 414 U.S. 338, 343 (1974).

122. *Id.* at 346.

123. EDWARD J. IMWINKELRIED, *THE NEW WIGMORE: A TREATISE ON EVIDENCE: EVIDENTIARY PRIVILEGES* §§ 3.2.3, 3.2.4 (2014).

124. FED. R. CIV. P. 45(a)(1)(A)(iii).

125. FED. R. CIV. P. 45(c)(3)(A)(iii).

claim that it is privileged,” the person must “expressly make the claim; and . . . describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.”¹²⁶ In some cases, especially those in which the identity of a research participant is already known, the information that must be provided to quash a subpoena may itself be of such a nature that it may negatively impact a participant or cause more information to be known about him or her.

D. *Narrow Statutory Interpretation*

Even if a Certificate is found to bar a subpoena in some cases, narrow statutory interpretation threatens to significantly limit the information a Certificate would protect. Because the Public Health Service Act has, from the beginning, only protected “names or other identifying characteristics” of individuals who participate in sensitive research,¹²⁷ there is a question regarding what is encompassed by “identifying characteristics.”¹²⁸ The Act has never provided statutory definitions; rather, terms relevant to the Act have been defined by regulations enacted by the departments or agencies tasked with issuing Certificates.¹²⁹ Earlier definitions under the Department of Health, Education and Welfare protected all data from disclosure if it “refers to or can be identified with a particular subject.”¹³⁰ The definition provided by the NIH today is much broader and protects “name, address, any identifying number, fingerprints, voiceprints, photographs or any other item or combination of data about a research subject which could reasonably lead directly or indirectly by reference to other information to identification of that research subject.”¹³¹

No court has issued a ruling on the scope of data protected by Certificates, so there is uncertainty regarding what types of data would be covered. If a challenge were to arise, it is unclear whether a court would find that the Public Health Service Act authorized the NIH to

126. FED. R. CIV. P. 45(d)(2)(A).

127. Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, § 3(a), 84 Stat. 1236, 1241.

128. Melton, *supra* note 10, at 196 (quoting 42 U.S.C. § 242(a) (1982)) (“Research data per se are not protected. Therefore, although Congress expressed its intent ‘to protect the privacy’ of participants, a subpoena for data of a known participant may be enforceable.”).

129. *E.g.*, Protection Identity – Research Subjects, 42 C.F.R. § 2a.2 (2014).

130. Natalie Reatig, *Confidentiality Certificates: A Measure of Privacy Protection*, IRB: REV. HUM. SUBJECTS RES., May 1979, at 1, 1 (quoting 45 C.F.R. § 46.119 (1979)).

131. 42 C.F.R. § 2a.2(g).

define terms within the Act itself—the NIH codified these definitions in the Code of Federal Regulations. If not, the court may be left to interpret the meaning of “identifying characteristics.” This leads to uncertainty about the protection of identities in certain ambiguous situations. For example, a prosecutor, aware of a woman’s participation in a study on risk factors for prostitution, could subpoena de-identified data the woman provided when participating in the study, including information about the woman’s engagement in prostitution—data that could then be used to prosecute her. Since the woman’s identity is already known, would her answers to specific research questions be protected? Additionally, consider a study involving data collection from individuals incarcerated in a prison, a study in which only ten individuals have participated at the time a subpoena is issued; would subpoena of the entire dataset be allowed if names were removed, so that participant names were not directly associated with the corresponding data? Such data may not be viewed as containing “identifying information” but, within this small sample, the data may be sufficiently detailed to identify the specific individuals who provided the information.

Even if the definition of “identifying characteristics” provided by the NIH is enforced, it is unclear how courts would interpret certain terms in that definition. In the previous example, it is unclear whether a complete dataset with names and identifying numbers removed, but with details about previous arrests included, would be considered data that “could reasonably lead” to the identification of a research participant.¹³² It also is not clear whether “reasonableness” should be determined objectively or whether it may change depending upon who seeks the data. If the prison has subpoenaed the small research dataset, identification is extremely likely, given that prison administrators or staff may know who spent time with researchers and, therefore, who participated in the study. If the District Attorney’s office sought the data, it could be assumed that its personnel would be less likely to identify individual participants based on the data if names were removed, but it could also be “reasonable” to assume that prison officials may share with them information about who participated. As was asked in the earlier scenario, what happens if the identities of the participants are already known and only their answers to particular questions are sought?¹³³ In that case, is *any* information protected by the Certificate?

132. For a discussion of the general ability to de-anonymize electronic data, see, e.g., Paul Ohm, *Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization*, 57 UCLA L. REV. 1701, 1703 (2010).

133. Gary B. Melton & Joni N. Gray, *Ethical Dilemmas in AIDS Research: Individual Privacy and Public Health*, 43 AM. PSYCHOL. 60, 62 (1988). “Faced with a subpoena for the data of a known

As long as these questions remain unanswered, there is a substantial likelihood that courts could interpret the statutory and regulatory language narrowly, in a way that would allow for release of extremely sensitive research data.

E. Superseding Statutes

Statutes granting the government broad authority to compel disclosure of documents relevant to investigations may also create vulnerability for Certificates.¹³⁴ Especially since the September 11, 2001 terrorist attacks, Congress has passed statutes granting broad authority to federal agencies in the collection of information necessary for the investigation of terrorism or other law enforcement goals.¹³⁵ Although “repeals by implication are not favored,”¹³⁶ it is possible that more recent legislation granting authority to certain agencies to access all records may be considered an implied modification of the protections offered by Certificates. In an attempt to “reconcile the two . . . and to give effect to each,”¹³⁷ courts may interpret newer legislation as introducing a limitation to the previously limitless authority granted to the DHHS to offer protection from subpoena of research data. The New York Court of Appeals in *Newman* noted that,

Generally speaking, a statute is not deemed to repeal an earlier one without express words of repeal, unless the two are in such conflict that both cannot be given effect. If by any fair construction, a reasonable field of operation can be found for two statutes, that construction should be adopted.¹³⁸

However, a “reasonable field of operation” could either be determined to consider the earlier Public Health Service Act as creating

participant, a court probably would hold that they were covered by the certificate of confidentiality because enforcement of the subpoena would frustrate the express intent of Congress to protect participants’ privacy. However, without litigation to resolve the issue, the level of assurance of confidentiality that can be given to participants involved in litigation is unclear.” Gary B. Melton, *Certificates of Confidentiality Under the Public Health Service Act: Strong Protection but Not Enough*, 5 VIOLENCE & VICTIMS 67, 69 (1990).

134. See Beskow, *supra* note 86, at 1055 (citing Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act), Pub. L. No. 107-56, 115 Stat. 272).

135. See, e.g., 50 U.S.C. § 1861 (2006), which authorizes the director of the FBI to apply to a special court for “an order requiring the production of any tangible things (including books, records, papers, documents, and other items)” for any investigation of international terrorism and prevents the individual receiving such order from disclosing the existence of the order.

136. Fed. Trade Comm’n v. A.P.W. Paper Co., 328 U.S. 193, 202 (1946).

137. *Id.*

138. *People v. Newman*, 298 N.E.2d 651, 653 (N.Y. 1973) (quoting *In re Bd. of Educ. of City of N.Y. v. Allen*, 160 N.E.2d 60, 67-68 (N.Y. 1969)).

an exception to otherwise broad authority by various government agencies to compel production of documents or could interpret the newer statutes, which authorize compelled disclosure under certain circumstances, as creating an exception to the otherwise broad protections offered by Certificates. Although *Newman* found a way to reconcile two contradictory statutes without infringing on the protection of sensitive data offered by Certificates, it remains unclear whether future challenges would be resolved in a similar manner.

F. *In Camera* Review

In all of these possible legal challenges, there is a risk that the *litigation* over whether the requested data are subject to subpoena may itself result in a breach of confidentiality, regardless of the outcome of the proceedings. To determine whether to quash a subpoena of research data protected by a Certificate, courts may decide to conduct an *in camera* review of all documents to assess the arguments for and against compelled disclosure.¹³⁹ Such review is considered appropriate regardless of the need to protect privilege or confidentiality of such materials “[a]bsent a claim of need to protect military, diplomatic, or sensitive national security secrets,” given “all the protection that a district court will be obliged to provide.”¹⁴⁰ When courts conduct an *in camera* review, the information is protected from further release or publication.¹⁴¹ The Supreme Court noted that it has “approved the practice of requiring parties who seek to avoid disclosure of documents to make the documents available for *in camera* inspection . . . and the practice is well established in the federal courts.”¹⁴² The judiciary may perceive *in camera* review as a way to determine the applicability of a Certificate and the merits of a subpoena, but researchers and their participants are unlikely to consider their confidentiality protected when a judge reviews sensitive data protected by a Certificate, even if it is not shared with others.

Taken together, these threats to Certificates suggest caution in reliance on Certificates and may mean that research records on sensitive topics are less secure than researchers and participants would hope. To

139. See, e.g., *State v. Bradley*, 634 S.E.2d 258, 262 (N.C. Ct. App. 2006).

140. *United States v. Nixon*, 418 U.S. 683, 706 (1974) (holding that *in camera* review was appropriate even when countered with claims of constitutional presidential privilege; “[W]e find it difficult to accept the argument that even the very important interest in confidentiality of Presidential communications is significantly diminished by production of such material for *in camera* inspection with all the protection that a district court will be obliged to provide.”).

141. *Id.* at 714.

142. *United States v. Zolin*, 491 U.S. 554, 569 (1989) (citation omitted).

strengthen the protections afforded by Certificates—and, therefore, fulfill their statutory purpose—a number of steps should be taken.

VI. RECOMMENDATIONS

A. *Recommendations for Ensuring the Efficacy of Certificates of Confidentiality*

Congress, the NIH, and courts all play roles in ensuring that Certificates offer broad protection to research participants who choose to participate in research on private topics or topics with potential legal repercussions. The changes proposed below, coupled with a greater awareness by researchers of the potential weaknesses of Certificates, should allow for greater security of research data protected by Certificates.

1. Recommendations for Legislative Change

Because the statute protects only “names or other identifying characteristics,”¹⁴³ uncertainty remains about the security of “de-identified” data that may, in fact, still lead to a participant’s identification. “There have been several cases in which courts have granted subpoenas for confidential research data with the caveat that the data be provided in de-identified form.”¹⁴⁴ The legislature should recognize this presents a potential loophole that could allow courts to interpret the statute narrowly and, therefore, put participant data at risk. The Public Health Service Act should be amended to remove the reference to names and, instead, should protect all individual data. Subpoenas should be prohibited when data are sought about only one individual, even if that person’s identity is already known. Data should, in fact, only be subject to subpoena in the aggregate, to prevent identification by default.¹⁴⁵

Amendments to the Act also should reflect the legislature’s

143. 42 U.S.C. § 241(d) (2006).

144. Peter M. Currie, *Balancing Privacy Protections with Efficient Research: Institutional Review Boards and the Use of Certificates of Confidentiality*, 27 ETHICS & HUM. RES., no. 5, 2005, at 7, 8 (citing *Deitchman v. E.R. Squibb & Sons, Inc.*, 740 F.2d 556, 566 (7th Cir. 1984); *Farnsworth v. Procter & Gamble Co.*, 758 F.2d 1545 (11th Cir. 1985)).

145. The amount of data that would need to be included in an aggregated release of de-identified research records varies by project and by requested disclosure, based on factors such as the heterogeneity of the research participants and the information already possessed by the requesting individual or organization. However, guidelines should be statutorily provided to assist judges in determining what types of data should be open to subpoena and what types of data are likely to be covered.

intention to protect research participants from the release of sensitive information even when their identities as research participants are already known. Additionally, definitions of key terms, such as “person,” “research,” and “identifying characteristics” should be included directly in the statute or, alternatively, the statute should explicitly establish that the NIH has the authority to define such terms. This would substantially decrease ambiguity in the statute and, consequently, limit the ability of courts to interpret the statute and its terms in ways that may be contrary to the actual legislative intent of offering broad protection for research data.

2. Recommendations for Administrative Change

Changes can also be made by the DHHS, the NIH, and other issuing agencies and institutes in the ways in which they implement their statutory authority to issue Certificates in order to broaden protections granted by Certificates.¹⁴⁶ If Certificates become more widespread, they may be seen as more difficult to successfully challenge in court. Additionally, the more research studies covered by Certificates, the greater the number of research participants whose data are protected. Accordingly, Certificates should be required for federally-funded research projects involving human subjects before data collection can begin.¹⁴⁷ The NIH should also provide case analysis on the Certificates of Confidentiality Kiosk website.¹⁴⁸ As the issuing agency, the NIH should take a vested interest in ensuring that Certificates are less vulnerable to challenge in court.¹⁴⁹ An analysis of *Newman and Bradley*

146. Some researchers have suggested that Certificates, as they currently exist, serve to offer a false sense of security to participants and that “obtaining a Certificate of Confidentiality might be viewed as, paradoxically, contrary to the interests of the subject.” Mary F. Marshall, Jerry Menikoff & Lynn M. Paltrow, *Perinatal Substance Abuse and Human Subjects Research: Are Privacy Protections Adequate?*, 9 MENTAL RETARDATION & DEV. DISABILITIES RES. REV. 54, 57 (2003). The authors suggest that, to strengthen privacy of participants, consent forms for studies with Certificates should promise not to disclose even in cases of abuse or other mandated reporting. *Id.* This requirement could also be implemented into DHHS guidelines.

147. See Melton, *supra* note 10, at 197 (suggesting that Certificates should be issued automatically for all federally funded research). Whether or not the DHHS chooses to make issuance automatic for such projects, a requirement that researchers obtain a Certificate could be added as a provision of all federal research dollars for research projects that meet the characteristics of research eligible to receive a Certificate.

Although an argument can be made that if too many research projects acquire Certificates courts will see Certificates as an attempt to assert a general researcher privilege even though courts have held that no such privilege exists, the statutory requirement that research must be of a sensitive nature to receive a Certificate protects against Certificates becoming so widespread as to be more vulnerable to challenge on that basis.

148. *Kiosk*, *supra* note 43.

149. *C.f.* Beskow, *supra* note 86, at 1055 (“When notified of a Certificate dispute, the Office

could emphasize the resistance of Certificates to legal challenge and make attorneys researching Certificates less likely to pursue such challenges. Currently, on the Certificates of Confidentiality Kiosk website, the entirety of information related to legal challenges includes two questions and answers on the FAQs page:

1. Has the legality of Certificates been challenged?

There have been very few reported court cases. In 1973, the certificate's authority was upheld in the New York Court of Appeals. The U.S. Supreme Court declined to hear the case.

2. What should an investigator do if legal action is brought to release personally identifying information protected by a certificate?

The researcher should immediately inform the Certificate Coordinator who issued the Certificate and seek legal counsel from his or her institution. The Office of the NIH Legal Advisor is willing to discuss the regulations with the researcher's attorney.¹⁵⁰

Although providing this information is better than not recognizing the possibility of legal challenges, it is possible that providing additional legal analysis—of the sort the NIH Legal Advisor would give to requesting counsel—to *all* visitors to the Certificates of Confidentiality Kiosk website would allay researchers' concerns and deter lawyers from considering legal challenges.¹⁵¹

3. Recommendations for Judicial Change

Finally, courts can play a role in protecting research data and upholding Certificates when cases arise. First, courts should use principles of statutory interpretation, especially legislative intent,¹⁵² to

of the NIH Legal Advisor provides citation to the statute and case law of which it is aware, but does not ordinarily involve itself in third-party litigation or provide legal advice to non-NIH entities.”).

150. *Questions, supra* note 30.

151. While it is possible that providing legal analysis on the Certificates website may alert potential challengers of Certificates to the legal grounds for such a challenge, this analysis could be presented in a way that emphasizes arguments defending Certificates and minimizes the likelihood that a challenge to a Certificate would be able to succeed.

152. *See, e.g.,* *Philbrook v. Glodgett*, 421 U.S. 707, 713 (1975) (“Our objective . . . is to ascertain the congressional intent and give effect to the legislative will.”).

construe the statute authorizing Certificates of Confidentiality as providing protection of *all* individual research data,¹⁵³ with the understanding that all data have the potential to be “identifying.”¹⁵⁴ Congress’s intent to protect research participants’ privacy to avoid creating a chilling effect on research participation and to foster researchers’ abilities to collect accurate information should serve as the basis for such an interpretation. Such a view of Certificates would also limit in camera review of individualized research data because the presumption would be that such data include “identifying characteristics” as intended by Congress. This would mean that, when Certificates are upheld, they would offer absolute protection of participants’ private, sensitive information.

Courts should also construe the interest in research privacy achieved through Certificates as an important government interest. When upholding a Certificate comes into conflict with the procedural rights of a criminal defendant or a civil litigant, the statutes establishing Certificates and the granting of a Certificate by the issuing agency should be interpreted as substantially related to the important government interest in enabling accurate research to further scientific knowledge. This would allow for the constitutional rights of criminal defendants to be considered paramount while also emphasizing the

153. Though a full discussion is outside the scope of this article, it is important to note that the balance between protection of research data and criminal defendants’ rights is very complex, and there are possible situations in which the Certificate should yield.

154. The legislative intent of the statute authorizing Certificates is understood to be, from the statutory language, to protect research participants in order to facilitate the collection of data on sensitive topics, and is widely recognized to be for that purpose. *See, e.g., Protecting Health Information: Legis. Options for Medical Privacy: Hearing Before the Subcomm. on Government Management, Information, and Technology of the H. Comm. of Government Reform and Oversight*, 105th Cong. 2 (1998) (statement of Dr. David Korn, Senior Vice President, Biomedical and Health Sciences Research, Association of American Medical Colleges). “The Certificate of Confidentiality was created in 1970 to enable research projects on drug use patterns by Vietnam War combatants and veterans. It was incorporated into the Public Health Service Act in the mid-1970s, and was expanded in 1988 to embrace a wide range of research projects on human subjects, which generated sensitive or potentially stigmatizing information. To our knowledge, the confidentiality protections afforded by this certificate have never been breached, even though they were originally enacted to facilitate studies of activities and behaviors that were often criminal.” *Id.* *See also Confidentiality of Health Information: Hearing Before the Subcomm. on Health of the H. Comm. on Ways and Means*, 106th Cong. 1 (1999) (statement of Dr. Richard Smith, Jr., Professor, Psychiatry and Medicine, University of Arkansas for Medical Sciences, representing Association of American Medical Colleges). “The origin of the Certificate of Confidentiality dates back to the Vietnam era. Scientists and policy makers were very concerned about the extent of heroin use by our soldiers in Vietnam—and the danger that they might be permanently addicted when they returned to the United States. Since heroin possession was then—and is—a crime, it would have been impossible to enlist the subjects necessary to conduct a follow-up study of heroin use in the U.S. by these ex-GIs. The grant of confidentiality enabled scientists to track a cohort of former service men, to collect urine to screen for drugs, and to conduct detailed interviews.” *Id.*

importance of Certificates and allowing them to be upheld when in conflict with less paramount rights. Without such confidentiality assurances, the chilling effect on research could severely and negatively impact the collection of data, which would be harmful to society. Sound data collected from a large number of honest and willing participants leads to sound public policy grounded in high-quality research. Without confidentiality, both the quantity and quality of data may be compromised.

Though these changes are necessary to ensure that Certificates fulfill their intended purpose in protecting sensitive participant data, filling these gaps in the statute and clarifying the ways in which the statutorily granted authority is implemented will likely take considerable time. Given that these changes are unlikely to be made in the immediate future, it is important for researchers and IRBs to consider the potential limitations of Certificates when determining how they will be used.

B. Recommendations for Researchers Collecting Sensitive Data

Despite the potential legal vulnerabilities of Certificates, they currently offer the best protection available for sensitive research data that meet the Certificate eligibility requirements. Though the degree to which Certificates would withstand legal challenge is unknown, it is possible that the potential vulnerabilities identified above would be decided in favor of upholding the Certificate and protecting research data. Additionally, Certificates may deter legal challenges; anecdotally, this seems to be true, based on the very small number of reported cases in which a Certificate was subject to legal challenge.

Nonetheless, given the potential legal threats Certificates may face, researchers and IRBs should be aware of the possible limits to the protections offered by Certificates. If researchers receive a subpoena for data covered by a Certificate, they should seek legal advice and challenge the subpoena in court before complying.¹⁵⁵ Additionally, researchers collecting extremely sensitive data should take extra precautions to ensure that data are as secure as possible and to decrease their liability. These precautions include generating and maintaining appropriate documentation, consulting with colleagues about possible methods for protecting and handling requests for data, consulting with the overseeing IRB, and sending sensitive data outside of the United States for storage where it would be beyond the reach of a standard

155. NATIONAL HUMAN RESEARCH PROTECTIONS ADVISORY COMMITTEE, RECOMMENDATIONS ON CONFIDENTIALITY AND RESEARCH DATA PROTECTIONS 4 (2002), available at <http://www.hhs.gov/ohrp/archive/nhrpac/documents/nhrpac14.pdf>.

subpoena, as relevant to the situation. These steps, which are generally good practice and recommended in ethics codes,¹⁵⁶ become especially critical when collecting sensitive data, such as that protected by Certificates.

Researchers may also benefit from familiarity with the literature on psychologists' or physicians' management of subpoenas.¹⁵⁷ Researchers should ensure the subpoena carries the force of law (i.e., the subpoena does not have any deficiencies, such as the court's lack of jurisdiction over the recipient of the subpoena), negotiate with the attorney issuing the subpoena to explore whether the attorney's goals can be met without disclosure, and discuss with research participants who might be affected by receipt of the subpoena the potential implications if the subpoena is enforced.¹⁵⁸ These steps may make it less likely that researchers will ultimately be compelled to disclose records and may minimize the damage if disclosure is ultimately required.

Finally, researchers should consider carefully the issue of how to present the protection offered by a Certificate when discussing data security with participants. Before a Certificate is issued, consent forms submitted for the study must "include a description of the protections and limitations of the Certificate of Confidentiality, including instances in which the investigators plan to disclose voluntarily identifying information about research participants (e.g., child abuse, harm to self or others, etc.)."¹⁵⁹ The NIH suggests language to be included in consent forms,¹⁶⁰ but this language may give participants a potentially false

156. See, e.g., APA CODE, *supra* note 4.

157. See, e.g., Grabois, *supra* note 7; Committee on Legal Issues of the American Psychological Association, *Strategies for Private Practitioners Coping With Subpoenas or Compelled Testimony for Client Records or Test Data*, 37 PROF. PSYCHOL.: RES. & PRAC. 215 (2006) [hereinafter *Strategies*].

158. See generally *Strategies*, *supra* note 157.

159. *Detailed Application Instructions for Certificate of Confidentiality: Extramural Research Projects*, NAT'L INST. HEALTH, http://grants.nih.gov/grants/policy/coc/appl_extramural.htm (last updated Jan. 16, 2014).

160. "To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your

sense of security. A researcher, therefore, may wish to carefully develop a structured approach to providing participants with an additional brief, oral explanation of the level of protection the researcher understands the Certificate offers. Such language may include telling participants that their data will be protected “to the fullest extent permitted by law,” so that participants are neither unnecessarily cautioned nor unrealistically reassured.¹⁶¹ However, researchers should also be mindful that courts might be reluctant to protect research data in cases in which participants were not promised confidentiality.¹⁶²

VII. CONCLUSION

Although the lack of legal challenges to Certificates may lead to the assumption that they would withstand attack in court, they may be vulnerable to legal challenge in the variety of ways described above. Amendments to the Public Health Service Act, which authorizes Certificates, changes in methods of implementation of Certificates by the issuing agencies, and a shift by courts to interpret Certificates in ways that make them more impervious to legal challenge would, individually or taken together, substantially strengthen the security provided by Certificates to research data. These changes would provide researchers with more confidence in the protective nature of Certificates and allow them to rely even more heavily on the protections offered by Certificates. Increased confidence and reliance would, in turn, encourage research on sensitive topics with greater assurances of privacy for participants. The validity of the responses provided by research participants may hinge on their confidence that information they provide will truly remain confidential. As a result, strengthening Certificates is critical both to ethically conducting sensitive research and to obtaining accurate data.

Given this analysis, we can revisit the hypothetical examples with which this Article began.¹⁶³ Take the case of the HIV positive man who participated in a research study on HIV: the sexual partner who contracted HIV sought to subpoena study information to use in a

involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Id.

161. Ellen Auriti, Nancy Greenan Hamill, Sunil Kulkarni, & Margaret Wu, *Who Can Obtain Access to Research Data? Protecting Research Data Against Compelled Disclosure*, 11 NAT'L ASS'N OF C. & U. ATTY'S, no. 7, 2013, at 1, 6.

162. *Id.*

163. *See supra* Part I.

negligence suit maintaining the man knew of his HIV positive status prior to their involvement. In this case, clarification of the definitions of Certificates would increase protection of all study information about this man, even though his identity as a research participant was already known. Even if a challenge to the Certificate went forward, legal precedent construing research privacy through Certificates as an important government interest may persuade the court to uphold the Certificate and protect the privacy of the research data. Legal analysis of Certificates made available on the NIH website may assist the man's lawyer, as well as counsel for the researchers, in defending the Certificate in court—and it may even deter the plaintiff from challenging the Certificate.

The next example involved a woman volunteering to participate in a study about safe sex practices among prostitutes. When she was arrested and charged with prostitution, the study data were sought to prove her involvement in the sex industry. More detailed definitions of the protections offered by Certificates would clarify that her data should be safe from subpoena even though prosecutors may already know of her identity and her participation in the study. If the court construes the Certificate in light of the legislative intent to protect participant privacy, in camera review should also be avoided in this scenario, protecting the woman's privacy as well as assisting her legal case.

Finally, in the situation of a class-action lawsuit against a drug manufacturer based on a study showing side effects of a colitis medication, the changes recommended in this Article would result in protection of the private medical records of study participants. If data can only be subpoenaed in the aggregate, participants will be truly protected from possible identification, especially if definitions of "identifying characteristics" are clarified to ensure that participants cannot be indirectly identified, even from aggregated data. Taken together, these changes to the ways the legislature, the courts, and the NIH approach Certificates would greatly increase the security of data and the confidence of researchers and research participants, both hypothetical and real.

Until such changes are made, researchers should continue to seek Certificates for studies collecting sensitive data but should remain informed of the legal landscape and carefully consider whether sensitive data could still be at risk of subpoena. In order to limit their own legal liability, researchers should strictly adhere to best practices in collecting, protecting, and documenting all activities involving sensitive data. Additionally, researchers should consider how Certificates are presented to potential research participants. These practices will enable

participants to make informed choices and will limit researcher liability.