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Certificates of Confidentiality and the Compelled Disclosure of Research Data

Laura M. Beskow, PhD, MPH^{1,2}, Lauren Dame, JD, MPH^{2,3}, and E. Jane Costello, PhD⁴

¹Duke Translational Medicine Institute, Duke University, Durham, NC 27710.

²Duke Institute for Genome Sciences and Policy, Duke University, Durham, NC 27708.

³Duke University School of Law, Durham, NC, 27708.

⁴Developmental Epidemiology Program, Department of Psychiatry and Behavioral Sciences, Duke University Medical Center, Durham, NC 27710.

Abstract

Certificates of Confidentiality have gained prominence in the context of efforts to build large-scale research platforms and new requirements for an unprecedented degree of data sharing. There is, however, a remarkable paucity of evidence upon which to base conclusions about the strength, applicability, and durability of the legal protections a Certificate affords. Here we describe a recent legal challenge in which a research participant's data, collected under a Certificate, were subpoenaed as part of a criminal case that reached the North Carolina Court of Appeals. We show how, despite the legal protections ostensibly afforded by the Certificate and the vigorous objections of the Principal Investigator and institutional counsel, the research subject's confidentiality was ultimately compromised in the course of the legal proceedings; further, we discuss the broader implications of this case for the research enterprise as a whole.

Ethical principles and professional codes of conduct require that researchers protect research participants' privacy, as well as the confidentiality of their information (1,2). Certificates of Confidentiality are intended to help meet these obligations by preventing forced disclosure of identifiable data during legal proceedings (3). Certificates are authorized by federal law and granted by units of the U.S. Department of Health and Human Services (DHHS) for studies collecting information that, if disclosed, could have adverse consequences or damage subjects' financial standing, employability, insurability, or reputation.

The use of Certificates has been promoted by the National Institutes of Health (NIH), particularly recently in the context of biorepositories and large-scale data sharing, but there is a remarkable paucity of evidence upon which to base conclusions about the strength of the protections they afford. In the only commonly cited court opinion, the provisions of a Certificate were upheld—contributing to the ubiquitous belief that Certificates offer “near absolute privacy protection” (4)—but there was little analysis of their scope or situations in which they could be superseded.

We report a criminal case that reached the North Carolina Court of Appeals in which research data collected under a Certificate were subpoenaed by the defense in an attempt to impeach the credibility of a prosecution witness. The outcome of this case raises concerns about the

protections Certificates provide, and has implications for research that depends on participants' confidence that sensitive information will be protected.

Background

Certificates were established by the Comprehensive Drug Abuse Prevention and Control Act of 1970, which amended the Public Health Service Act to provide protection for identifiable research data on "the use and effect of drugs." This amendment was motivated by concern that research on important health issues would be stymied by subjects' unwillingness to participate (4). Further amended in 1974 (5) and 1988 (6), the Act allows the DHHS Secretary to authorize persons engaged in biomedical, behavioral, clinical, or other research ... to [withhold] from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized ... may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals (7).

Certificates are applicable to any IRB-approved research involving personally identifiable, sensitive information, but few reported court cases document their effectiveness (3). In the oft-cited *People v Newman* (8), a Certificate was successful in preventing disclosure of the identities of drug treatment program participants despite a grand jury subpoena in a murder investigation. Both sides in this case assumed that confidentiality protections granted under the 1970 Act were absolute; the dispute focused on whether later legislation (9) repealed these protections. The Court held that the subsequent law did not do so, but provided little additional analysis of the scope of the 1970 Act or how different facts might change the outcome.

Case presentation

In the early 1990s, Duke University Health System (DUHS) researchers began a longitudinal study of psychiatric disorders and the need for mental health services among rural and urban youth (the "Study"). Researchers obtained a Certificate from the National Institute of Mental Health because they planned to gather information about psychosocial adversities, substance abuse, illegal behaviors, and genetic information.

The challenge to the Study's Certificate arose in 2004 from a criminal proceeding in which the defendant was charged with indecent liberties with a minor and statutory rape. His attorney believed that a prosecution witness was a Study participant and requested a court order directing DUHS to supply all Study records about the witness.

The court granted this request, noting that the defendant was entitled to the documents for any exculpatory evidence they might contain, citing Constitutional rights under the 14th and 6th Amendments (due process and the right to confront and cross-examine witnesses), as well as the court's inherent authority to provide for discovery. Although the order directed that documents remain confidential unless used at trial or sentencing, it allowed them to be read by 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 (10).

The judge issued this order without knowledge of the Certificate; DUHS first learned of the attempt to obtain Study records upon receiving the subpoena. DUHS filed a motion for a protective order, asserting that the records were protected by a Certificate and should not be disclosed. DUHS also argued that the person whose records were sought was only a witness, not the alleged victim; therefore, Study records were unlikely to contain exculpatory evidence.

Consistent with the Certificate, DUHS took no position regarding whether the witness was a Study participant.

Based on its review of the motions, an affidavit from the Principal Investigator (PI), and arguments made at the hearing, the court vacated its initial order and granted DUHS's motion for a protective order, but instructed DUHS to maintain a sealed copy of the records until the final resolution of the case.

A review of the hearing transcript (11) shows that the judge regarded the defendant's initial request to access Study records as a routine discovery motion, and was unfamiliar with Certificates. 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" [p. 9]. Further, although the DUHS attorney and the PI forcefully argued the critical importance of upholding the Certificate, the judge seemed to be most swayed by the argument that the defense was unlikely to find exculpatory evidence. When the judge queried defense counsel about this, the attorney responded that if the witness had never mentioned anything to researchers concerning events about which she was to testify, it would be highly probative. The judge responded, "You mean to say ... that you plan to use that in some sort of negative way by impeaching her that she didn't tell it to [the researchers] but she told it to others? ... Well, under those circumstances ... I'm reversing the order" [p. 21]. Thus, despite the Certificate, the court weighed other interests and issued the protective order only after deeming the defendant's reasons for seeking the records insufficient.

The defendant was tried and convicted of all charges. Months later, the defendant's appellate lawyer filed a motion requesting access to the sealed records. DUHS responded that no information had been presented that justified altering the court's previous decision, and that the records were not relevant to the issues on appeal.

A hearing was held before the same judge who had previously denied the defendant access to the documents. This time, however, he ordered that a copy of the sealed documents be given to the defendant's counsel. The judge limited dissemination of the materials to the defendant's counsel and the state's counsel. They could not be disclosed to anyone else and arguments based on their contents could only be made in a separate sealed brief or addendum.

The hearing transcript (12) again provides insight into the judge's reasoning. He suggested that it would be puzzling to ask the appellate court to decide if the sealed records were relevant when the defense attorney arguing their relevance had never seen them. The judge decided, "Let's just produce [the records]; let [the defense] review it. If there's something in there for them, fine. If not, close them up and send them back" [p. 8]. Again, the court balanced the importance of confidentiality against the defendant's interests, but this time resolved the conflict by allowing the defense attorney tightly restricted access.

DUHS filed a notice of appeal, again asserting the Certificate and citing *Newman* as particularly relevant, arguing that participants "must be given genuine assurances of confidentiality for investigators to obtain candid, meaningful, and wide participation in the study" (13). DUHS also argued that the defendant had failed to show the documents were relevant to his defense. Pursuant to the court order, however, DUHS delivered the documents to the defendant's appellate counsel.

The defendant's brief contained an 83-page sealed appendix based on the Study records. In the unsealed portion of the brief, the defendant's attorney argued that *Newman* did not govern this situation 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” (14).

After hearing from DUHS and defense counsel, the Court of Appeals concluded that the Study records were not material. It vacated the order granting defense counsel access, but confidentiality had already been compromised. Having decided the defendant was not entitled to the records because they were not material, the Court declined to consider DUHS’ argument that the confidentiality of the documents was statutorily privileged (15), thus failing to address whether the Certificate would have protected the records, had they been material to the defendant’s case.

Discussion

Researchers obtain Certificates to help meet their ethical and legal obligations to safeguard privacy and confidentiality (16). In turn, they provide decisive assurances to prospective participants during the informed consent process.

Certificates have gained prominence over the last decade. In March 2002, NIH announced a new policy encouraging broader use of Certificates (17). The National Cancer Institute recommends that biorepositories consider obtaining a Certificate (18), and NIH suggests Certificates as part of its data-sharing policy for genome-wide association studies (GWAS) (19). The centralized GWAS repository created under this policy has no access to direct identifiers, although investigators submitting data likely will. Thus, NIH notes that law enforcement agencies could seek to compel disclosure of identifying information from investigators or their institutions, but such disclosure might be prevented if a Certificate protected the original study (20). New developments concerning the possibility of detecting a specific individual’s genomic profile within aggregate GWAS data further heightens confidentiality concerns (21,22).

Given such reliance on Certificates by investigators, research participants, and policymakers, their effectiveness in preventing forced disclosure deserves rigorous evaluation. Because the U.S. case law system relies heavily on precedent, attorneys and judges will consider the results of previously decided cases when deciding how to handle future legal demands for research data. In the case presented here, the Certificate helped convince the court—after vigorous legal intervention—to refrain from ordering broad disclosure of Study records, permitting instead restricted disclosure to attorneys for use under seal, but did not provide absolute protection. This result highlights several important issues.

First, requests for research data may arise from legal proceedings unrelated to a study’s focus. A PI or institution may unexpectedly receive a subpoena and need swiftly to engage a lawyer with appropriate expertise. When notified of a Certificate dispute, the Office 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.

Second, a Certificate is granted to the research institution, not the PI, and their interests may not be identical. In this case, the PI felt a strong moral obligation to protect participants’ data; DUHS agreed and was willing to go to court. It is conceivable, though, that an institution could decide that a costly legal battle is unwarranted, or might be unwilling to defy court-ordered disclosure, even if the PI wants to do so.

Third, seeking to enforce a Certificate may result in some disclosure, even if records are not released. For certain kinds of research, simply revealing the fact of a person’s participation (*e.g.*, by fighting a subpoena or putting documents in a sealed box) could itself cause adverse

consequences. But institutions or investigators who refuse to follow a court order may be found in contempt, resulting in fines or imprisonment.

Fourth, parties in both criminal and civil lawsuits have rights to obtain material relevant to their case. Courts have broad powers to enforce these rights and attempt to resolve disputes by balancing each side's interests. When doing so, courts may give insufficient weight to society's interest in protecting research records. As recent cases demonstrate (23,24), the public has significant interest in protecting confidentiality throughout the research process, but the connection between the integrity of scientific information and the release of a particular study record may seem remote to a court. Further, when the attempt to obtain study records comes from a criminal defendant, a Certificate may be especially vulnerable if the records sought could affect a defendant's Constitutional rights to a fair trial or to confront and cross-examine witnesses. In the North Carolina case, the court did not find that the facts implicated Constitutional rights, but in other cases, different facts could raise such questions. Finally, attempts by the government itself to obtain study records may raise particularly difficult challenges if the records are claimed to be relevant to "national security." Since 9/11 and the passage of the Patriot Act (25), government agencies have increasingly broad legal powers to obtain otherwise confidential information, and under such circumstances, researchers may have great difficulty resisting disclosure.

Elucidating Certificates' practical utility in preventing compelled access to study data is a critical area for future research. Because of the absence of published cases, investigators' direct experience is essential for understanding the ambit of protections Certificates provide (16, 26). Empirical evidence about how frequently research data are subpoenaed and by whom, how often investigators assert a Certificate to protect data, and the outcomes are needed to help set realistic expectations about Certificates' role and value.

In the meantime, the full legal effect of Certificates remains unclear. If courts weigh the value of confidentiality against competing claims rather than treating Certificates as absolute, the scope of the protection afforded will be uncertain at the time informed consent is obtained. Thus, caution is warranted when representing the likely impact of a Certificate to potential research participants.

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