Introduction

Human biological tissue samples are an invaluable resource for biomedical research designed to find causes of diseases and their treatments. Controversy has arisen, however, when research has been conducted with laboratory specimens either without the consent of the source of the specimen or when the research conducted with the specimen has expanded beyond the scope of the original consent agreement. Moreover, disputes have arisen regarding which party, the researcher or the source of the specimen, has control over who may use the specimens and for what purposes. The purposes of this article are: (1) to summarize the most important litigation regarding the use of laboratory specimens, and (2) to demonstrate how legal theory regarding control of laboratory specimens has evolved from arguments based upon property interests in biological samples to claims that the origins of laboratory specimens have privacy interests in their genetic information that should be protected.

Moore v. Regents of University of California (1990)

The seminal case regarding consideration of rights associated with the research use of human biological samples is Moore v. Regents of University of California. John Moore underwent treatment for hairy cell leukemia at the UCLA Medical Center in the late 1970s and early 1980s. His spleen was removed in October 1976 as part of his medical care, but his treating physician, Dr. Golde, arranged to use portions of the spleen for biomedical research without Moore’s knowledge or consent. Dr. Golde established a cell line from Moore’s T cell lymphocytes, and the Regents of the University of California (Regents) applied for a patent on the cell line. When Moore learned about what had been done with his cells, he brought suit against Dr. Golde and the Regents.

Moore attempted to characterize the invasion of his rights as a conversion. Conversion is a tort that protects against interference with ownership interests in personal property. Moore theorized that he continued to own his cells after they had been removed from his body, at least for purposes of directing their use, arguing, “How could one not have a right in one’s own genetic material?”

The California Supreme Court noted that no court had ever imposed conversion liability for the use of human cells in medical research and that extension of the theory of conversion to this context would have profound policy implications for biomedical research in this country. Consequently, the court held that the use of excised human cells in medical research did not amount to conversion and that Moore did not retain any ownership interest in his cells after they left his body.

In dicta, the court implied that an action based upon privacy rights might have been more appropriate when it argued that a desire to protect Moore’s privacy did not necessitate acceptance of the conclusion that interference with privacy interests amounts to a conversion of personal property. The court continued, “Nor is it necessary to force the round pegs of ‘privacy’ and ‘dignity’ into the square hole of ‘property’
in order to protect the patient, since the fiduciary-duty and informed-consent theories protect these interests directly by requiring full disclosure." The court held that by failing to disclose his personal research and economic interests, Dr. Golde performed a medical procedure without first having obtained informed consent.

A federal court characterized the next major case involving a dispute over research with human biological samples as “a successful research collaboration gone sour.” The plaintiffs in Greenberg v. Miami Children’s Hospital were families and not-for-profit organizations that provided tissue samples and research funding to support research to discover the gene that causes Canavan disease. Using the resources provided by the plaintiffs, the researchers successfully isolated the gene and then, without the knowledge of the plaintiffs, obtained a patent for their results. When the defendant researchers and hospital began enforcing the patent, plaintiffs became aware of the patent and brought suit again under a conversion theory, claiming that they were never informed that the defendants had intended to obtain a patent on the research results.

The plaintiffs argued that they had a property interest in their body tissues and genetic information. They claimed that defendants had converted their names and genetic information by utilizing them for the hospital’s “exclusive economic benefit,” and sued under the theory of conversion. The court declined to find a property interest in the body tissues and genetic information that had been voluntarily given to the defendants holding that any property right in the samples evaporated once the sample is given voluntarily to a third party.

The plaintiffs also asserted that when they contributed tissue for genetic analysis, they did not relinquish ownership of the results of the analysis. They cited a Florida genetic privacy statute8 that holds that the results of DNA analysis are the exclusive property of the person tested. The court declined to follow this line of reasoning and held that the statute was inapplicable under the common law theory of conversion.

In Washington University v. Catalona, when Dr. Catalona, a leading prostate cancer researcher and a faculty member at Washington University, accepted a position at another institution, he sent a letter to his patients and their family members asking them to sign a release form that directed the release of their archived tissue samples to Dr. Catalona for transfer to his new institution. Washington University objected and sued Dr. Catalona to prevent the transfer of the samples. The legal question was “whether individuals who make an informed decision to contribute their biological materials voluntarily to a particular research institution for the purpose of medical research retain an ownership interest allowing the individuals to direct or authorize the transfer of such materials to a third party.” Using property language, the court relied upon the language in the informed consent documents signed by the research participants when the tissue samples were donated and determined that the donations of samples were inter vivos gifts but that participants had limited recourse as determined by the consent forms. Participants had the right to revoke their voluntary participation and in some cases, the right to request destruction of their samples; however, they did not retain the right to physically repossess the samples or to direct the transfer of the biological materials after their donation.

In 1989, members of the Havasupai tribe approached an anthropology professor at Arizona State University...
(ASU) for assistance in determining whether there was a genetic component to the high rates of Type II diabetes amongst the tribe members. The anthropologist consulted an ASU geneticist, who conducted the agreed upon research. The geneticist also conducted additional research regarding schizophrenia and evolutionary genetics without the knowledge or consent of the tribe members.

When tribe members learned of the additional research that had been conducted using their samples without their consent, they sued ASU for $50 million, claiming that ASU had published papers that disclosed private genetic data derived from their blood samples and that ASU actions had invaded the personal privacy of tribal members. The lawsuit alleged that as a result of the unauthorized research, many of the tribe members now feared “going to the health clinic, seeking medical attention, or providing blood samples for medical diagnosis or treatment.” The parties agreed to settle their dispute, and as part of the settlement agreement, the ASU Board of Regents agreed to pay 41 tribe members $700,000, to return the blood samples, and to provide other forms of assistance to the tribe. Although the legal issues in this case were not fully adjudicated, the settlement implies that the privacy rights of research participants can be violated when they are not fully informed about genetics research conducted with their samples.

**Beleno v. Texas Department of State Health Services (2009)**

In *Beleno v. Texas Department of State Health Services*, five families brought a class action lawsuit against the state department of health on behalf of all infants born in the state claiming that the state practice of retaining and using de-identified residual newborn screening dried blood samples (DBS) for biomedical research without explicit parental consent violated their right to privacy and the right to be free from unreasonable search and seizure as guaranteed by the U.S. Constitution and the Texas Constitution. When the *Beleno* lawsuit was initiated, under then current Texas law, no consent was required to retain DBS and use them for secondary research, and parents were not given the option to refuse to allow the retention and use of their child’s residual sample.

During the course of the litigation, new legislation was passed that implemented an opt-out procedure by which parents were to be told that their child’s residual sample may be retained and used for research unless the parents object. The parties settled the lawsuit, and as part of the settlement agreement, the Department of State Health Services agreed to destroy over five million archived DBS. Shortly after the settlement was reached, it was reported that the Department of State Health Services had given DBS to the U.S. Armed Forces Pathology Laboratory for inclusion in a mitochondrial DNA database. Plaintiffs from the *Beleno* case claimed that this information had been withheld from them during the settlement negotiations, and a second lawsuit was filed. The second lawsuit was determined to be moot since the state provided evidence that the DBS of the named plaintiffs in the case had never been released to any other entity and had been destroyed pursuant to the *Beleno* settlement.

Texas law has subsequently changed again and now requires explicit parental permission to retain and use DBS for biomedical research. The legal issues raised by the two Texas DBS cases were never adjudicated.


In a similar lawsuit, *Bearder v. State of Minnesota*, nine families sued the Minnesota Department of Health, claiming that the state practice of storing and disseminating DBS without parental consent was a violation of the state Genetic Privacy Act (GPA). The GPA specifies that genetic information about an individual may be collected by a government entity only with the written, informed consent of the individual and may be used only for purposes to which the individual has given consent. The decision by the Minnesota Supreme Court hinged upon the court’s interpretation of the definition of “genetic information.” The court determined that an individual’s blood samples are biological information subject to protection under the Genetic Privacy Act and that it is the DNA within the blood sample that brings the sample within this protection. The court further held that the definition of genetic information includes a blood sample collected from an individual as biological information.

The court concluded that the “use of genetic information for purposes other than the screening of newborn children and for follow-up services requires written informed consent.”

**Conclusion**

There are many types of laws that may impact the research use of laboratory specimens, including laws that deal with medical waste, medical information, and genetic privacy. All states have enacted some type of legislation to address genetic privacy issues, but many of these laws were intended to prevent discrimination based upon the misuse of genetic information in the workplace or health insurance settings. As demonstrated by the *Greenberg* case, the extent to which these laws may be applicable in the context of research with laboratory specimens is unclear.
What is clear is that the law in this area remains unsettled. In disputes regarding who retains control over the use of laboratory specimens, property claims have not fared well, but claims based upon genetic privacy have been more successful, indicating an evolution in legal theories regarding these issues. However, recognition of broader privacy rights in laboratory specimens could have profound implications for biomedical research.

References
1. Moore v. Regents of University of California, 793 P.2d 479 (Supreme Court of California, 1990).
2. Id.
3. Id.
4. Id.
5. Id.
7. Id.
11. Id.
12. Id.
14. Id.
15. Id.
17. Id.