

Ownership and Use of Tissue Specimens for Research

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HUMAN BIOLOGICAL SPECIMENS HAVE BEEN THE FOUNDATION of pathological inquiry ever since Rudolf Virchow propounded the cellular basis of disease in 1858. Today, the study of human tissue affords unique and increasingly sophisticated molecular and genetic insights that progressively illuminate the detailed mechanisms and pathways of human diseases.¹

Academic and industrial scientists conduct research on tissues collected and archived in the laboratories of medical centers, individual investigators, and in publicly funded repositories without delineating the rights of ownership of the specimens, patient data, or research products. Historically, no clear ownership interests were established; therefore, the assumed right of researchers and institutions to collect, study, store, transfer, or dispose of tissue specimens and associated patient data as they wish has remained unsettled and sometimes contentious. As sophisticated and informative analytical tools have developed, researchers and industry sponsors have sharply increased their demand for properly prepared and clinically annotated tissue samples. In some areas of research, for example cancer genomics, insufficient quantity of such resources has been described as a "rate-limiting step."² In this environment of seemingly limitless demand and finite resources, it is not surprising that new questions are being raised about ownership and control of these valuable resources.

In the first examination by a US federal court of the rights of individuals and investigators when human tissue samples are used for research, a Florida judge ruled in May 2003 that individuals do not retain rights to own or control biological materials contributed for research, even if commercial benefit accrues as a result.³ This decision is, to our knowledge, the first published judicial decision to examine ownership and use of biological materials for research since 1990 when the California Supreme Court handed down its oft-cited *Moore* decision⁴ holding that individuals retain no property rights in their excised cells that are used to develop new products. Thus, in the only 2 instances when the courts were asked to adjudicate, they found no basis to establish individual ownership of or right to control the use of excised tissue collected or used to develop research products, even

Academic and industrial scientists have sharply increased their demand for properly prepared and clinically annotated tissue samples that yield valuable insights into the origins and expressions of human disease. Historically, research on human tissue samples has been relatively unencumbered by federal regulations and occurred without delineation of ownership rights to the specimens, patient data, or research products. As regulations have become increasingly restrictive, and because clear ownership interests have never been established, the presumed right of researchers and institutions to collect, use, and dispose of specimens and their associated patient data has remained undefined and occasionally contentious. Recent examination of these issues by a US federal court resulted in a ruling that individuals do not retain rights of ownership or control of biological materials contributed for research, regardless of whether commercial benefit accrues. This article examines the legal, regulatory, and ethical framework within which human tissue research is currently conducted. We contend that because the benefits of medical knowledge derived from tissue research potentially accrue to all individuals and future generations (rather than a single recipient), society may justify an expansive use of these valuable resources for future studies.

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while affirming the applicable principles of informed consent. Yet the issue is far from resolved.

The Florida case reopens interest in the panoply of rules governing ownership and use of human tissue samples.³ The research community, private industry, patient advocacy groups, ethicists, and regulators have expressed concerns

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about the control and use of these samples. At the same time, standards used by the courts, state legislatures, and federal regulators in determining these rights often conflict or diverge, leading to ambiguity and confusion. Until there is greater consensus, scientists and their institutions should proceed cautiously when navigating the discordant legal and regulatory standards in this area.

Legal and Regulatory Models for the Control, Ownership, and Use of Tissue and Associated Data

Federal Regulations. Human subjects research conducted or supported by federal agencies that have adopted the Federal Policy for the Protection of Human Subjects, (termed the *Common Rule*),⁵ or that falls under the jurisdiction of the Food and Drug Administration (FDA),⁶ is governed by federal regulations. These rules require prospective review by institutional review boards (IRBs) (unless the research is exempt)⁷ and the informed consent of participants. The *Common Rule* permits informed consent to be waived if an IRB determines that waiver criteria are met, although the FDA rules do not include parallel provisions.^{6,8}

According to the *Common Rule* and guidance from the Office for Human Research Protections (OHRP), the entity within the Department of Health and Human Services responsible for interpretation and oversight of the *Common Rule*, IRB review and informed consent are required when researchers obtain from living individuals identifiable private information, or data through intervention or interaction.⁹

Ambiguity has long existed in the research community regarding whether studies of human tissue samples constitute human subjects research requiring IRB review, whether that review may be expedited, and whether informed consent may be waived. Typically, when informed consent to a surgical or diagnostic procedure was obtained, the consent forms included buried language conveying the patient's permission to use any "extra" or "remaining" portions of the excised specimens for unspecified future research and educational purposes, and to be disposed of as the clinician or institution saw fit.

Even when investigators obtain informed consent to study a sample, the consent forms typically do not address directly the issue of tissue ownership, either by the individual who is the source of the specimen, the investigator, or the institution. This stance reflects the lack of clarification concerning ownership rights, as well as the legal truism that one cannot convey a greater interest than one has (ie, if an individual does not own the sample, ownership cannot be transferred).

Possibly as a result of the unsettled framework surrounding future uses of tissue and medical data by academic and commercial researchers,¹⁰ federal regulators have added little to clarify the rights of researchers or individuals. In 1987, the US Office of Technology Assessment published a study of the legal, economic, and ethical considerations pertain-

ing to ownership of human cells and tissue.¹¹ Examining possible sources of individual legal rights of ownership, the authors considered laws governing cadavers and autopsies, sales of semen and ova, and organ transplantation before concluding "there is great uncertainty about how courts will resolve disputes between the human sources of specimens and specimen users."¹¹

The FDA addresses ownership of excised tissue in a single reference in an IRB information sheet. The FDA states that use of the term *donation* is prohibited because it implies abandonment of property rights,¹² although the informed consent document may state that specimens will be used for research purposes.

In 1996, the OHRP published guidelines explaining a regulatory provision¹³ that prohibits the use of language in informed consent documents in which participants are made to waive or appear to waive any legal rights. The new guidelines stated that the use of informed consent language asking prospective research participants to relinquish "any property rights . . . in tissue" was forbidden because asking participants to forgo their property rights in blood or tissue is "exculpatory" (notwithstanding that no such legal rights have been established).¹⁴ In 2001, the OHRP reiterated this stance in response to an inquiry asking whether researchers could incorporate a statement in the informed consent document that individuals do not possess continuing ownership rights in excised tissue. In an e-mail communication to the inquirer, which was shared with research institutions, the OHRP affirmed that participants could not be asked or required to relinquish putative property rights in tissue due to the "lack of clarity in the law" (Michael Carome, MD, OHRP, e-mail communication to Jennifer Kulynych, JD, PhD, Association of American Medical Colleges, December 17, 2001). The OHRP was asked to reconsider this position again in 2003, following the publication of the *Greenberg* case¹⁵ in Florida, but declined. Therefore, researchers presently may not use informed consent language that either confers or curtails individual ownership rights in tissue samples.

State Statutes. No state laws establish individual ownership rights in excised human tissue specimens used for research. However, some states regulate more stringently than the federal government in areas such as confidentiality of medical information, the conduct of medical research, informed consent, the ability of clinicians to demand predictive genetic tests or insurers and employers to require, obtain, or use genetic information. Most of these state statutes are designed to limit the use of information acquired for clinical and diagnostic purposes, to protect against discrimination, or to prevent commercial trading of medical information, but these limits can affect the conduct of research using tissue specimens.¹⁶

While no states have declared an individual to be the owner of excised tissue or DNA per se, 4 states have statutes declaring the individual to be the exclusive owner of his/her

genetic information, which tends to be defined broadly. In fact, more than half of all the states have passed additional privacy protections exclusively for “genetic information.”¹⁷ These statutes largely address genetic information collected during clinical tests, restricting its uses and disclosures and forbidding its use to discriminate or deny insurance coverage or employment. A majority of these laws permit research-related uses of genetic information when the identity of the subject is not released, or, alternatively, when IRB approval is obtained.

The enactment of legal protection for genetic information was greatly stimulated by the Genetic Privacy Act,¹⁸ which proposed that access to genetic information be tightly regulated. The model was created after deliberations by the joint committee of the National Institutes of Health and the US Department of Energy on ethical, legal, and social implications of human genome research, which proposed legislation to eliminate discrimination in insurance and employment on the basis of a person’s genetic composition.¹⁹ The Genetic Privacy Act is derived from the principle of genetic *exceptionalism*, which identifies genetic information as a unique subset of medical information requiring enhanced protections.²⁰ Some scholars and policy makers, while supporting prohibitions against genetic discrimination, strongly disagree with such a bifurcation, arguing for enhanced protection of all health information rather than establishing higher standards for genetic privacy (with accompanying prohibitions against genetic discrimination).²¹

Use of Tissue Specimens Following the Health Insurance Portability and Accountability Act

Enacted under the Health Insurance Portability and Accountability Act of 1996,²² the Standards for Privacy of Individually Identifiable Health Information (termed the *Privacy Rule*)^{23,24} imposes severe restrictions on uses and disclosures of all individually identifiable health information. Although the Health Insurance Portability and Accountability Act does not address ownership or the use of tissue samples per se, when tissue is accompanied by clinical information containing specified patient identifiers, the samples and information may constitute “protected health information” (depending on whether it is held by a “covered entity”) and its use or disclosure requires specific authorization by the individual for most purposes including research.²²⁻²⁴ The Privacy Rule tightly circumscribes the content of such authorizations, and requires that they be “specific” and “meaningful.”^{23,24} The latter term is neither well understood nor consistently applied, but the former tends to be construed strictly.

Prior to enactment of the Privacy Rule in April 2001, a patient could and commonly did indicate his/her intention to permit the use of his/her samples and clinical data for unspecified future research. However, the Rule effectively restricts disclosures of most patient information to single, specified uses for which authorization is obtained or compels

debilitating stripping of accompanying identifiers.^{23,24} These strictures were only partially mitigated in the amended version of the Privacy Rule issued in August 2002, which permits authorization for research to be without specific time limitations, and deposition of protected health information or annotated tissue specimens into disease-specific registries or repositories.^{10,25}

Case Law: Tissue in the Courts

The courts have examined the question of ownership of human tissue samples used for research purposes in only 2 published decisions. In the case of *Moore v Regents of the University of California*,⁴ George Moore signed a consent form for a splenectomy during treatment for hairy-cell leukemia at the University of California, Los Angeles. Moore’s physician noted his unique response to therapy and embarked on a research project necessitating repeated visits to the clinic by Moore. Unknown to Moore, the physician discovered that Moore’s spleen cells produced an unusual blood protein and cultured Moore’s cells to develop a cell line. In January 1983, the Regents of the University of California filed a patent application for a “unique T-lymphocyte line and products derived therefrom,” listing the physician and his research assistant as inventors (US patent No. 4 438 032; March 20, 1984). Moore sued his physician and the University of California, claiming 13 separate causes of action including “conversion” (deprivation of a property interest), lack of informed consent, and breach of fiduciary duty for the use of his excised tissues and for the failure to disclose personal interests.⁴

In a determination of far-reaching import, the California Supreme Court found that individuals do not retain rights of ownership in excised tissue used to develop new products, holding that even if the excised cells initially belonged to an individual, those cells were legally and factually distinct from the resulting research product. The court analyzed state health and safety statutes addressing tissue and other biological materials, finding that excised tissues are treated according to principles of public policy and public health, rather than property law. Furthermore, the court analyzed the case law permitting the patenting of organisms that are the result of “human ingenuity,”²⁶ finding that Moore’s claim that he continued to own his cells from which the patented cell line derived contradicted the notion that a cell line is the product of invention. The court did find that when a research relationship exists along with a therapeutic relationship, it is necessary to notify the patient of additional research or economic interests. While binding precedent only in California, the *Moore* decision⁴ has been widely influential and no other state or federal court ruled on the ownership of tissue samples in research for more than a decade.

In the 2003 case of *Greenberg et al v Miami Children’s Hospital*,¹⁵ a group of plaintiffs sued an investigator and the hospital when the investigator developed and patented a pre-

dictive prenatal genetic test for Canavan disease from research on blood and tissue samples taken from afflicted children, their parents, and relatives. In this case, as distinguished from *Moore*,⁴ tissues were donated voluntarily and knowingly for research and not obtained surreptitiously during medical treatment. The judge characterized the individual plaintiffs as tissue donors who were aware that research was being conducted on their tissues, and whose donations were designed to further that endeavor.¹⁵ In fact, the judge found no duty to disclose to participants the potential for future economic benefits from the research, and thus, no misuse or fraud by the investigator.

The judge held that if individuals could curtail research uses of biological materials retroactively, such “dead hand” control was likely to “chill” medical research by permitting participants to dictate the progress and direction of research.¹⁵ The judge adopted the reasoning used in *Moore*⁴ that a research product developed using human tissue is “legally and factually distinct” from the original excised tissue such that a tissue specimen could become the property of the researcher and prevent the source from asserting reach-through rights in a patent or commercial product.

Of note, the *Greenberg*¹⁵ judge analyzed Florida state law that deems an individual the exclusive owner of his/her genetic information, and held that the statutory language stating that the results of DNA analysis are the “exclusive property of the person tested” only applies to “DNA tests” (presumably for clinical testing purposes, although the reasoning is neither explicit nor clear) and not to research activities.³ Therefore, the judge held that in this case, the Florida statute conferring individual ownership rights in DNA results did not apply.

A third case contesting ownership rights in human tissue specimens was filed in 2003 in federal district court in St Louis, Mo, by Washington University.²⁷ The university seeks to enjoin a former professor (and head of urology) from translocating to his new institution a large repository of human prostate specimens collected by him and his colleagues for their research by asserting the university’s sole right of ownership of the collection.²⁷ The former faculty member maintains that the individuals who enrolled in the prostate studies waived their rights to their tissue samples through language in the informed consent document, and granted him, not the university, rights of ownership and control of the specimens. He claims that he is entitled to use these samples and data in furtherance of his research studies at his new institution. The merits of this case, which raise important legal and ethical issues, have not yet been argued. Other new cases are 2 lawsuits^{28,29} filed by members of the Havasupai tribe of Native Americans in Arizona contesting researchers’ rights to use blood samples and claiming fraud, breach of fiduciary duty, intentional infliction of emotional distress, negligence, conversion, and lack of informed consent. While not yet decided, these cases will require the courts to delve into the issues of informed con-

sent and rights to future uses (or possibly ownership) of samples and data.

A New Industry

Reaching a broad consensus on the question of ownership of human tissue specimens in research will become increasingly urgent as the commercial value of specimens and resulting research products continues to increase. Both public repositories and private sources are supplying tissue samples to industry at a growing pace.³⁰ Some academic medical centers have struck deals with biotechnology companies that provide the companies, in return for financial benefits, exclusive access to entire pathology archives for commercial exploitation primarily aimed at identifying new molecular targets for diagnostic and therapeutic development.³¹

Historically, ethical considerations of autonomy, beneficence, and justice have animated the discussion of informed consent, and an individual’s decision to participate in a research study could be considered at least partially altruistic.^{32,33} Contributions of biological materials for research (either explicitly via informed consent or implicitly via general institutional consent forms) were thought to advance the public interest through their support for biomedical research and teaching. Concomitantly, until the advent of the genetic revolution and the stirring of public unease about genetic privacy, neither the existence nor the research uses of the vast, fully annotated tissue archives that have accumulated for more than 100 years in leading academic medical centers were a matter of public concern, or even notice.

When the results of tissue research become patentable and potentially lucrative, and when tissue archives derived in the provision of medical care become commercial assets, the altruistic context of witting and of after the fact pro bono justification of unwitting tissue contributions may become strained. Even if individuals are not considered the owners of their excised tissues or data, other legal rights in equity may accrue when commercial benefit results from research using their tissues. In the *Greenberg* case,¹⁵ for example, the judge did permit the plaintiffs to proceed on a single count of unjust enrichment because he deemed that their numerous actions in support of the research might deserve compensation. However, because the parties reached a confidential settlement, the merits of this single claim were not analyzed further by the court.³⁴

The *Greenberg* judge made clear that the act of contributing tissue or blood did not entitle individuals to rights in a research product because any property interest was relinquished at the time of donation.¹⁵ Strict application of this reasoning argues that if an individual’s intent to donate tissue were not clearly expressed, it would not be possible to ascertain ensuing legal rights with confidence. Furthermore, it is uncertain whether individuals will continue to be so willing to donate tissue or blood for research that may

have explicit or implicit commercial intent. Because of the long-running and bitter Canavan dispute,³⁴ families of patients who have rare genetic diseases may form nonprofit entities to control and allocate their own and their children's tissue samples, as well as share in any financial rewards that may arise from research. A nonprofit entity formed by the families of individuals with pseudoxanthoma elasticum created and maintains a large blood and tissue repository for research to classify the mutations in the responsible gene, and controls the terms and conditions of use of that tissue, including retention of intellectual property rights in commercializable discoveries.³⁵

The potential for commercialization and financial gain from tissue research will undoubtedly spur the need for more extensive disclosure and clarification of financial interests. Federal regulations already require disclosure by investigators of certain financial conflicts of interest to their institutions, which must assure the federal sponsor of their oversight and management of conflicts, and the FDA, either directly or through their industry sponsors, if the research falls under the jurisdiction of that agency. Recently, many organizations³⁶ and professional societies involved in medical and health research^{37,38} have called for enhanced institutional oversight of the financial interests of investigators and their institutions, especially in research involving human participants, and mandatory disclosure of those interests to potential participants.³⁹ In the case of research using human tissues, routine disclosure of relevant financial ties and the possibility or intent to commercialize research products might help to alleviate ethical concerns that research participants are not aware of the intended uses of their tissues, and bolster the credibility of researchers' claims that consent is truly voluntary and fully informed.

Conclusion

In the last decade, increasingly restrictive interpretations of federal regulations have imposed new limits on the ability of researchers to use tissue specimens. Yet, in the 2 cases that the courts have adjudicated to date, they found no basis to establish individual ownership of tissue specimens. They also did not find that individuals retained the right to control the use of excised tissue for research while affirming the applicable principles of informed consent. Although 2 court decisions cannot be considered dispositive of such a contentious matter, the *Moore*⁴ and *Greenberg*¹⁵ decisions provide a reasonable framework to recognize individuals' initial interest in their corporal tissues, while denying ongoing individual property interests in excised tissues, even when scientific research transforms them into sources of valuable diagnostic or therapeutic products.

What remains to be done with some urgency is to bring the interpretation of applicable federal regulations into conformity with the court findings. Confusing and conflicting standards of ownership and control of tissue samples in the states, the courts, and federal regulations confound the ef-

forts of scientists and IRBs to ensure that research is conducted legally and ethically.

Indeed, sound ethical principles exist to support the logic of the court decisions. The principle of respect for persons demands that individuals be treated as autonomous agents with rights of self-determination.⁴⁰ Satisfying this principle in research requires that participants, to the degree that they are capable, be given the opportunity to choose what will or will not happen to them.

Thus, obtaining informed consent from participants (or waiver, when permitted by federal regulations) is necessary for the initial collection of tissue samples and to notify participants of the intended uses of their biological materials. However, adopting the reasoning used by the courts that a research product derived from a sample is legally and factually distinct from the original tissue leads to a conclusion that the ethical principle of autonomy, which governs the collection and initial use of the tissue, is not relevant to subsequent uses because the nexus between the samples and the individual self is lost. This differs from the circumstances in which rights of self-determination continue to exist, for example in the use of sperm and ova for extracorporal reproduction, or of organs for transplantation, in which the legal, regulatory, and ethical framework confers continuing individual interests that permit restrictions on certain future uses.

The more general use of excised tissue samples in biomedical research is different from these donations, mainly because these samples are not intended for a single purpose (or for the benefit of a single recipient), but rather constitute an invaluable and enduring library of human disease to which ready access should be preserved for future research studies.⁴¹ Because the benefits of medical knowledge derived from tissue research potentially accrue to all individuals and future generations, society may justify the expansive use of these valuable resources based on the principle of justice.⁴² Human tissue specimens are a unique and irreplaceable research resource, and society's strong interest in the advancement of medical knowledge deserves a coherent and internally consistent legal, regulatory, and ethical framework to govern specimen use.

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