



Body of Research — Ownership and Use of Human Tissue

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For better or worse, we have irretrievably entered an age that requires examination of our understanding of the legal rights and relationships in the human body and the human cell.

—*Moore v. Regents of the University of California*,
California 2nd District Court of Appeals, 1988

Nearly 20 years after the California courts decided *Moore v. Regents* — a seminal case concerning a patient's interest in the profits derived from patents on a cell line generated from his spleen tissue — U.S. jurisprudence still has no coherent answer to a deceptively simple question: Do we own our own bodies?

Why deceptively simple? Because the meaning of “property” is unclear. Because the question must be asked about our relationships both to our bodies and to our excised body tissue. And because it must be asked about those relationships both before and after we die.

No brief article or single court opinion could address all the complexities of the legal notion of “property.” But simple or not, the question of whether we “own” our bodies must be answered soon: courts now face multiple controversies concerning the use of bits and pieces of bodies — and their derivatives — that are scattered among pathology laboratories, state hygiene laboratories, museums, archives, sperm banks, fertility clinics, and forensic DNA collections. One recent controversy concerns William Catalona, a prostate cancer surgeon and researcher formerly employed by Washington University in St.

Louis. Over the course of decades, and with his patients' consent, Catalona amassed more than 3500 tissue samples, developed the prostate-specific antigen test, and led clinical trials to improve testing for prostate cancer. When he left for another university, Catalona asked his patient-donors to write to Washington University requesting that their tissue samples be sent to his new place of employment. Washington University refused to send them, and a dispute arose about the patients' right to control the tissue.

On the basis of the terms of the consent documents signed when the patients originally released their tissue, the court ruled that control belonged to Washington University and that although patients might ask that their samples be destroyed, they could not direct that they be delivered to Catalona or to another university. Left unclear in the court's opinion is whether the patients ever

had a property interest in their tissues. One reading suggests they did but that they relinquished it upon donation; another suggests that they never had such an interest, even while the tissues were in their living bodies.

The court's ruling on the narrower issue of control of the excised tissues had some basis in precedent. A smattering of other decisions, concerning state laws covering presumed consent for the donation of cadaveric corneas, management of frozen embryos whose progenitors are still alive, and postmortem control of stored semen, suggested that donors might have some property rights in their tissues. But in two other decisions, the *Moore* case of 1988 (concerning rights to share in commercial gain from derivatives of tissue taken without proper informed consent) and the *Greenberg* case of 2003 (concerning property rights in tissue and genetic information derived from patients' tissues), courts found that state law provided little basis for granting patients a property interest in their voluntarily donated, excised tissue.

Those courts did not delve deeply into the possible existence of property rights to such tissue before excision. If, on the one hand, there are no such rights, then the *Catalona* decision is not a question of the evaporation of a property interest after donation but a finding that we have no property right to our tissues before or after they leave our bodies. According to this view, any right we may have to control the use of our tissue rests on other considerations, such as the privacy of medical information or entitlements created through the regulation of research on human subjects. If, on the other hand, such

a property right does exist, then any conclusion about whether donation constitutes a relinquishment of that right depends on the fairness of the transaction and the quality of the information provided before consent is given. Such distinctions have powerful implications for medical research.

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At present, research regulations are built on a theory of autonomy that is independent of any property right in one's tissue. Thus, although in general patients can refuse or consent to the donation of tissue samples for research, such rights are quite limited. Common law protects people from involuntary excision of body tissue, which would be considered battery. But after the tissue has been properly excised, its use without the patient's consent may be permitted under federal research regulations, if the patient's identity is unknown or adequately obscured.¹

Federal regulations are based on a notion of voluntarism, but the right to refuse participation in research is based more on ensuring that subjects can be the ones to judge how to protect their own interests than on a pure form of autonomous decision making, which would include a right to refuse for any reason or no reason at all. Hence, no consent is required for research deemed to

pose minimal risk to subjects — or for research in which identifying information is obscured or from which it has been deleted (which protects privacy and minimizes social risks such as stigmatization or discrimination, but does nothing to recognize subjects' autonomy). And when patients' preferences regarding the kinds of research that may be performed on their tissue are ascertained, this is done as a courtesy, rather than as recognition of patients' rights to prohibit the use of their tissues for purposes of which they disapprove. In a battle over such rights, the Havasupai tribe is suing researchers who took blood for a diabetes-control project and later used it in research about schizophrenia within the tribal community.² Although institutions may be disciplined by federal authorities for regulatory lapses, courts have so far refused to recognize a private legal claim based on this sort of alleged violation of the requirements of consent for research.

In other settings, however, calls for increased control by patients over the use of their tissue would suggest that only subsuming the matter under property law would suffice.³ In the emerging field of regenerative medicine, for example, California's new funding regulations require researchers to honor the limits set by donors of embryos or gametes on the kinds of work that can be done even with donated tissue that has been "anonymized" — a rule consistent with a theory of property rights in tissue. In the field of biobanking (the collection and distribution of tissue and DNA samples), some have called for caution in the common practice of asking donors to waive all rights, on the assumption that property rights

exist and waivers may be ineffective if they do not satisfy all the legal rules for property transfers.⁴

Investigators and universities have argued that recognizing property rights in excised tissue would threaten their ability to use stored tissue samples effectively⁵ — a use that is essential to everything from advances in pharmacogenomics and genetic epidemiology, to the development of new tests for clinically significant mutations, to the investigation of historical events and epidemics through the medical testing of cadavers.

Ultimately, the debate is less about whether the management of human tissue should be governed by property laws or by a more robust regulatory scheme than about the proper balance between respect for persons and the collective interest in promoting research involving human tissue. Respect for persons and their autonomy can be promoted through many legal frameworks. In one framework, autonomy is premised on the notion that one's body is one's property and that uninvited removal or use of tissue is theft or trespass. In the other, autonomy is premised on the liberty interests of the person within the body (such as the freedom from assault), and the uninvited removal or use of tissue is an injury and a deprivation of liberty.

Despite its apparent clarity, the property-based approach creates new dilemmas that we are hardly ready to confront. If I “own” my tissue, do I have all the rights usually associated with property? Calling something property does not necessarily mean that its owner has all possible rights to its exclusive use, donation, sale, alteration, and destruction, but this is a common bundle of rights as-

sociated with ownership of property. If this pattern were extended to tissues, then selling organs might become a matter of right. And cadaveric tissue could become the property of heirs, rendering unusable even old repositories such as the one used to sequence the 1918 influenza virus. Of course, labeling something as “property” does not foreclose limitations on its use: governments can sometimes take property for public purposes or forbid its sale or alteration. But generally, calling something “property” will enhance the owner's interests considerably, especially with regard to prohibiting others from using it.

Alternatively, our relationship with our bodies may be viewed as a trusteeship: even if they are not our property, we nonetheless have extensive and exclusive rights with respect to them, at least while we are alive and our bodies are intact. Even with such a view, bodies and tissues may also be viewed as part of a common heritage of humanity, to be used for the collective good if such use does not unduly infringe on our liberties. This leads to arguments for a public right to use excised tissue, provided that due care is taken to protect the privacy and social interests of the person from whom it comes. Such arguments also support a policy of “presumed consent” for the use of cadavers for tissue and organ transplantation.

Moving in this direction would still require attention to respecting the interests of persons who do not wish to be research subjects or who fear the invasion of privacy or social interests that examination of their tissues might entail. Regulation of the management of banked tissue could address these questions. But rechar-

acterizing our bodies as a public resource would also suggest an ethical duty to work toward a just distribution of the benefits of such research, both financial and therapeutic. Without some symmetry between the burdens and the benefits of research, the social compact underlying such an imposition on personal interests would be undermined.

Although treating our bodies and tissues as property would offer an avenue toward strong protection of personal autonomy, it is not the only way to accomplish this goal. Nor is it without costs, in terms of possible losses to the collective interest in research and organ donation. Other systems, whether based on enhanced regulations protecting human subjects or a theory of trusteeship, could serve as well. But whichever system is chosen, it is long past time for the country to choose. State laws vary, federal regulations do not apply to all privately funded research, and a patchwork of rules cover the myriad laboratories and biobanks in the United States. Our tissue may be scattered. Our laws ought not to be.

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4. Winickoff DE, Winickoff RN. The charitable trust as a model for genomic biobanks. *N Engl J Med* 2003;349:1180-4.
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