2005

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Repository Citation

Palmer, Larry I., "Should Liability Play a Role in the Social Control of Biobanks?" (2005). *Faculty Publications*. 78.
https://scholarship.law.wm.edu/facpubs/78

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Larry I. Palmer

Repositories of tissues, cell lines, blood samples, and other biological specimens are crucial to genomics, proteomics, and other emerging forms of biomedical research.[1] Creation of these repositories by individual researchers and their affiliated organizations,[2] commercial entities, and even governments[3] has been labeled "biobanking" in the bioethics literature. Biobanking as a metaphor for the collection, transfer, and use of these specimens suggests a framework for the legal response to conflicts that may arise – one embedded in principles of contract law and property ownership with an overlay of legislatively authorized regulation of the "industry."

The decision by the federal district court in *Greenberg v. Miami Children's Hospital Research Institute*[4] illustrates how the current framework operates in practice. This case involved a dispute over the control of the gene and genetic test for Canavan disease, a rare neurological disorder. Plaintiffs furnished blood, tissue, and other specimens to the researcher who discovered and patented the gene and genetic test. Their "deposits" in the researcher's biobank provided the foundation for their claim that they should be allowed to participate in decisions about how the test was marketed and distributed. The court explored a number of legal theories for resolving the dispute over control of the patent. The court dismissed all of the plaintiffs' claims for control over the actions of the researcher and his associated hospitals and research institutes based on tort theories – lack of informed consent, conversion, fraudulent concealment – but allowed that the plaintiffs might be able to recover under an unjust enrichment theory.[5] This theory, more like a contract without consideration in terms of its possible remedy, allows courts to balance the interests of researchers and subjects[6] and implies that prospective contracts between subjects and researchers are the preferred mode for sharing the benefits and the risks of biobanking.[7]

I propose an alternative way of constructing a framework for a legal response to the collection and transfer of specimens. Rather than thinking of blood, DNA, cell lines, etc., solely in terms of their materiality – assets subject to control – I propose that these specimens (whether derived from humans, animals, or plants) renewed as *data* with the potential to become useful knowledge.

The ethical challenge involved in this line of analysis is to articulate the role of law in the growth, distribution, and use of professional knowledge in society. The legal framework should be built on distinctions among

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the various types of "entitlements" that law uses to resolve disputes about transfers gone awry from someone's perspective. I am using the term "entitlement" as used in the classic article by Calabresi and Melamed to describe the various legal rules or doctrines used to optimize the risks and benefits of the transfer of various kinds of assets. They distinguish liability rules, rules of inalienability, and property rules.[8]

An interest is protected by a property rule when individuals can sell or otherwise transfer their interests to others, and legal disputes would be determined by reference to contract rules or property rules. Remedies for a proven breach of the agreement are aimed at restoring the parties to their pre-exchange position through damages, and sometimes through an injunction. Furthermore, these types of remedies are generally designed to protect a market in the particular kind of assets. It is thus not surprising that some aspects of the transfer of specimens, particularly among researchers, universities, and companies, are in fact governed by written contracts that the parties believe to be legally enforceable.[9]

Social and technological change, particularly in science and medicine, poses a challenge to a strict prohibition of any transfers involving the human body as illustrated by organ and tissue transfers from living and dead human beings.

In contrast, when the legal system prohibits the selling of a particular asset, Calabresi and Melamed would say that the entitlement is governed by a rule against its sale, thus a rule of inalienability. As pointed out in their article, the United States Constitution's prohibition against selling humans into slavery, even if alleged to be "voluntary," is an example of society's interest in the integrity of the human body being protected by a rule of inalienability.[10] Social and technological change, particularly in science and medicine, poses a challenge to a strict prohibition of any transfers involving the human body, as illustrated by organ and tissue transfers from living and dead human beings.[11] Through positive legislative enactment, law in the United States allows the "gift" of a human body part, but not its sale in a commercial transaction[12] - leading to the notion that the prohibited transfer is a prohibition of *market* inalienability.[13] Similarly, by statutory enactment, the transfer of blood is a "service" that can only be provided by a licensed professional.[14] When a contract is void as against public policy, for instance when a legislature prohibits surrogate parenting contracts, the better rationale for the decision is that the transfer of parenting entitlements (or more accurately in lay terms "obligations") is to be done through adoption rather than the market.[15]

Liability rules protect an entitlement by using after-the-fact determinations of judges and juries to determine the value of the disputed transaction. Thus, the remedies are objective in the sense that the parties to the transaction, such as a physician and a patient, generally are not allowed to agree in advance on the damages or specific remedy for a medical misadventure. Rather, the law views the patient/physician exchange as governed by a duty of care to the patient that cannot be waived. More important, the determination of the amount of damages is made by reference to criteria external to the parties at the time they entered the transaction, such as the amount of lost wages, additional medical expenses, and pain and suffering incurred by the plaintiff. The fact that the duty or liability rules dominate our thinking about the physician/patient relationship does not preclude a physician from recovering for the value of his or her services because law recognizes that the physician's entitlement to professional services is protected by a property entitlement. But we should remember that once the physician/patient relationship has been established, the physician risks a suit for abandonment if he or she discharges a patient for lack of payment without ensuring that the plaintiff has an alternative.[16]

Although disease management has generally been dominated by liability rules,[17] it is not yet clear in the era of genomics whether and how liability rules should operate with regard to biobanking. There are in fact few if any fully litigated tort-based cases dealing directly with the transfer of specimens, tissues, DNA, etc., in either the research or clinical context. Most of these cases are not about the remedies or the amount of damages, but rather about the first line of inquiry: has the plaintiff stated a cause of action? Under my proposed analysis, the question is really whether the plaintiff's interest in the data is protected by a liability rule. Rules of liability - properly understood as distinct from property rules - raise this question: under what circumstances should courts or legislatures authorize individuals (and groups) to exercise control over professionals and their organizations?[18]

Despite the jurisprudential support for a contractual approach to issues involving research,[19] a systemic view of the function of liability rules in research and health care delivery could be used to justify liability rules as a basis of limited social control over the research/clinical enterprise by forcing the research enterprise to account for its practices before a court. Under this view, the results sometimes favor plaintiffs, but at other times favor researchers, depending upon how institutional decision makers want to strike the balance. When litigants or scholars use ownership in tissue, blood, or DNA as the basis of a tort action, they are asserting that the entitlement to their tissue should be characterized by reference to property rules. Conversion protects a property entitlement through a tort action, but is not an example of general liability theory represented primarily by actions in negligence. My thesis is that the use of tort theories, or more generally liability rules, in the biobanking context is an attempt to optimize the benefits and risks of knowledge distribution.

A patient such as John Moore, who was successfully treated for a serious form of leukemia, would have a hard time convincing a jury that he would not have undergone the treatment had he been aware of the research interests or the financial interests of his treating physician.

The center piece of this analysis is a rejection of the attempts to use conversion theory as a basis of liability in disputes over blood, tissue, DNA, etc. Under my analysis, *Moore v. Regents of California*[20] rightly rejected the conversion theory. On the other hand, *Moore's* use of the theory of lack of informed consent as a possible basis for liability is foundational to understanding the role of liability in the biobanking context. A lack of informed consent action in the clinical context is nearly impossible for a plaintiff to win because plaintiffs have the nearly impossible task of convincing a jury they would not have undergone a procedure - often life-saving as in *Moore* - had they been informed of some financial or research interest of the clinician. Nonetheless, ruling on motions to dismiss a lack of informed consent count as in *Moore* requires a court to articulate the underlying purpose of the informed consent doctrine. The purpose in a liability action, as opposed to the purpose of regulations on informed consent, is to provide incentives for physician/researchers to *disclose* information to patients/subjects/consumers[21] - not to promote patient/subject autonomy.[22]

Grimes v. Kennedy Krieger Institute,[23] where blood samples from children were collected as part of a lead abatement study, illustrates the role of liability in a pure research context or knowledge discovery process, independent of apparent commercial interests implicit in the biobank metaphor. *Grimes* illustrates that other courts, when faced with vulnerable populations, such as children, depart from the contractual model underlying the bank metaphor.

Finally, a pending case involving the use and distribution of blood and handprints from members of the Havasupai tribe illustrates why the contractual or property model clearly breaks down.[24] Contract rules do not provide an appropriate backdrop for ethical resolution in the legal context where the supposed contractual parties may have different concepts of property and the nature of the human body. This analysis is not meant to suggest that the Havasupai or other groups around the globe should not use contract rules to negotiate with researchers about the use of human tissue in research or how commercial profits should be distributed. Rather, this analysis seeks to highlight the unique role that liability rules can play in the exercise of social control over researchers, clinicians, and their affiliated organizations in the Human Genome Era[25] as data distribution becomes global.

A regulatory model that seeks to balance various interests ignores the potential "progressive" role of liability in allowing individuals and groups to question the existing paradigms.[26] With the growing popularity of a property rights approach to conflicts about the use of human tissues among legal scholars[27] and pressure to procure more organs and tissue,[28] this article is a plea for more attention to the role of liability rules in arriving at the appropriate institutional balance between research goals and promises versus individual and group desires to have some degree of social control over the research enterprise.

Part I: Data to Knowledge

Moore v. Regents of California[29] illustrates how part of the human body is in fact "data" that allegedly was transformed into professional knowledge. John Moore was Dr. Golde's patient at the University of California at Los Angeles Medical Center in 1976.[30] Dr. Golde recommended the removal of Moore's spleen as part of the successful treatment of his hairy cell leukemia. It turned out upon examination of Moore's excised spleen, that his DNA was unique because it overproduced proteins that regulate the immune system. Over the course of the next seven years, Moore provided Dr. Golde with blood, skin tissue, bone marrow, and sperm. Dr. Golde developed a cell-line from tissue, blood, and other body fluids that Moore provided, and filed a patent application on the cell-line, granted a license to a biotechnology company, and received other economic benefits from the biotechnology company.[31] After Moore discovered that the "Mo cell line" had been used to develop drugs for the treatment of several forms of cancer, he sued Dr. Golde, the University of California, the assignee of the patent, and the various biotechnology firms involved in the development and distribution of the drugs.

Moore argued thirteen theories of liability,[32] including that the defendants had misappropriated his "property" by using his DNA to develop the cell-line and drugs. The court rejected this claim in conversion, which was based on the theory that the various defendants had interfered with Moore's possessory interest in his spleen, tissue, blood, etc.[33] When it rejected the claim based on Moore's alleged property interest in his unique DNA, the California Supreme Court accordingly dismissed the claims against the assignee of the patents - the biotechnology companies. The court did, however, hold that a physician/scientist has a duty to disclose his research and financial interests in the patient's cells, tissue, and DNA.[34] Presumably, this means that Dr. Golde should have told John Moore of his interest in developing the cell-line and pursuing the patent, as well as of his financial arrangements with the companies developing the drugs. Although the case was settled after this ruling, the court's result uses the judicially developed doctrine of lack of informed consent to balance the interests of patients and physician/scientists.[35] The result in *Moore* protects scientific innovation because the duty to disclose established by the court exempts the companies - those who might bring successful products to market - while protecting the patient's interest in autonomy by granting a theoretical right not to participate in the research.

The holding in *Moore* that a patient who provided DNA used in the discovery of a patent for a new pharmaceutical could *not* recover in conversion has become infamous in the legal literature. The underlying reasoning by the California Supreme Court that the patient had no "property interest" in his DNA precluded his recovery on that theory. This ruling has given birth to a host of critical articles[36] although most courts facing the issue have generally followed the California Supreme Court's reasoning that the tort of conversion assumes a "property interest."[37]

The court's alternative holding that a patient could recover from the physician/scientist on the basis of lack of informed consent or breach of fiduciary duty has not received similar attention or, in my opinion, the praise it deserves. There are at least two reasons for the lack of critical acclaim for liability claims in the biomedical research and clinical settings. First, lack of informed consent cases are nearly impossible for plaintiffs to win. A patient such as John Moore, who was successfully treated for a serious form of leukemia, would have a hard time convincing a jury that he would not have undergone the treatment had he been aware of the research interests or the financial interests of his treating physician. The plaintiff appears to have a "right" to recovery on the basis of the physician's failure to disclose his research and financial interests. But the plaintiff has little prospect of interesting a good contingency-based plaintiff's attorney to even take the case, since the actual damages provable under the theory are minimal as long as the liability theory is grounded in negligence as opposed to gross negligence.

The second, and perhaps more serious objection, comes from bioethicists and others who consider the informed consent doctrine an essential means of promoting individual autonomy. The individual autonomy proponents do not object to expansion of the informed consent doctrine by the *Moore* court. Rather, these scholars rely upon the famous statement by Justice Cardozo, "Every person has the right to decide what should be done with his body" to conceptualize a person's DNA as part of the patient's body that she or he should be able to control throughout the research and knowledge discovery process. A patient has little ability to exercise control under the *Moore* case once the DNA has been used to create new drugs unless the patient somehow shares in the future profits.

The individual autonomy justification for the lack of informed consent in my view is mistaken if one analyzes what even a relatively liberal court like the California Supreme Court has done with its own doctrine. In a case decided after *Moore*, the court adopted what I have previously called a duty to disclose purpose for the lack of informed consent doctrine when it held an oncologist had no duty to disclose to a patient the statistical chances of surviving pancreatic cancer with experimental treatment.[38] The duty to disclose rationale for the doctrine focuses on trying to articulate the specific rules for defining the scope of what physicians (and perhaps researchers) should have disclosed in the course of their encounters with patients in the modern health care system. In the pancreatic cancer case, the court limited the physician's duty to disclose because a physician's duty does not include estate planning or other matters beyond the physician's expertise.[39]

This more limited rationale for the lack of informed consent doctrine recognizes two aspects of legal institutions sometimes ignored by scholars. When other courts began to examine the modern version of lack of informed consent grounded in negligence rather than battery, it is worth remembering that not all courts followed California in declaring the standard of disclosure to be what a reasonable patient would want to know. Some courts thought that the standard for disclosure should be what a reasonable professional told patients.

Although the literature has tended to concentrate on famous informed consent cases based on the reasonable patient theory, such as *Cobbs v. Grant,*[40] it is worth noting that about half the states have adopted a professional standard for evaluating the duty to disclose.

In addition, legislatures often imposed limits on the scope of the informed consent doctrine. New York, for instance, limited the scope of recovery under the doctrine to "intrusive invasions." Thus, a New York court has ruled that a person who consented to the drawing of blood could not recover for lack of informed consent when the physician ordered additional tests that revealed a condition that stigmatized the patient.[41] This interpretation of the New York statute highlights the need to avoid the commoditization of the health care and human research systems either to protect physician/scientists or patient/subject interests.

To create a more systemic view of the role of liability as the assets in biobanks are transferred and distributed around the globe, I suggest we think of this biological material as data that might be transformed into knowledge. John Moore's DNA in the *Moore* case is a bit of data gathered in a social context - the health care delivery system - where courts impose retrospectively determined duties of disclosure as a prerequisite for using the data. Such retrospective rules, along with certain market forces, such as more highly educated patients with access to information, have changed institutional practice in medicine. Informed consent forms are a part of health care practice today, whereas the seeking of patients' consent was not a routine practice in health care settings a half-century ago. Informed consent also seems to be a touchstone of best practices in the collection of tissue for repositories, but with perhaps a different legal influence. Federal regulations on research impose an obligation of obtaining informed consent, but leave open what role liability should play in enforcing those rules.

The recent ruling in the Canavan disease case, *Greenberg v. Miami Children's Research Institute,*[42] suggests that under Florida's law of informed consent, the duty to disclose financial interests is not a part of liability doctrine. The dispute in *Greenberg* arose after the "holder" of the patent for the Canavan disease gene and its accompanying genetic test had attempted to enforce it patents. The plaintiffs claimed that when they and their affiliated organizations had provided tissue, blood, and DNA samples from their children and themselves the researcher should have informed them of his intent to patent the genetic discovery. The district court dismissed the plaintiffs' claim on this count.

On the other hand, the court's suggestion that the plaintiffs might recover on the basis that the researcher and his affiliated organizations unjustly enriched themselves could be seen as a blow to a contractualist approach to biobanking. The theory of unjust enrichment is built on the assumption that no valid legal contract governs the exchange between the parties. On the other hand, modern theorists, such as the authors of the *Restatement on Restitution and Unjust Enrichment,* affirm that claims based on validly executed contracts are superior to the unjust enrichment claims and their remedies based in equitable notions of restitution.[43]

A more concise framing of the issue in *Greenberg* is in terms of data acquisition and transformation. It is clear that the plaintiffs and their affiliated organizations provided crucial data that led to the discovery and patenting of the Canavan gene and test. Whether or not the defendants had a duty to disclose certain information to the plaintiffs would depend upon how the court views the market for data transfer and transformation. As between the particular plaintiffs and defendants in *Greenberg,* the district court may have made a pragmatic judgment that some form of diffuse liability would lead to a rough settlement and a future of contracts.[44] The important point is that *Greenberg* is not the definitive ruling on the role of liability. Furthermore, the existence of liability as a retrospective method of delineating the duties of disclosure does not preclude some individuals and groups who provide biological samples to researchers from using contracts as a method of social control.[45]

The more systemic way of viewing the lack of informed consent doctrine, however, is to see its development in terms of various stages. What some scholars have called the "second revolution in informed consent"[46] essentially conceptualizes the doctrine in terms of when courts may impose the obligation to disclose information that is readily accessible to providers. In clinical settings this might mean information about how many operations or procedures a particular provider has done relative to other providers. I suggest in the research or data collection settings that these duties might include disclosure about provider intentions to use the data or conveying information relevant to individual health risks to participants in research projects.

Part II: Collecting Data from Vulnerable Subjects

Grimes v. Kennedy Kreiger Institute, Inc.[47] also involves the collection of data, including blood samples. The plaintiffs in *Grimes* were low income, predominantly minority group members, who were recruited by the research team and the collaborating government agencies to live in certain rental units. The data at issue in that case was not directly relevant to the underlying research objective - determining whether less than full lead abatement was cost-effective and relatively risk free from an environmental health perspective – but potentially highly relevant to the plaintiffs. The elevated level of lead in the children's blood did not put the children at any immediate risk of physical damage, but the data could be used by parents to reduce the risk of future harm.

The plaintiffs in *Grimes* claimed that the researchers breached their duty of disclosure by failing to *promptly* inform them of the elevated lead levels in their children's blood. The Maryland Court of Appeals held that research organizations could not rely upon the consent of parents when they put children at risk, however minor, in a non-therapeutic setting. The potential flaw in the informed consent process used by the researchers should be understood in the larger social context of this particular research project, with some useful contrasts to *Greenberg*, starting with the plaintiffs.

> To create a more systemic view of the role of liability as the assets in biobanks are transferred and distributed around the globe, I suggest we think of this biological material as data that might be transformed into knowledge.

In contrast, the *Greenberg* plaintiffs were members of an ethnic group with an interest in using genetics to prevent harm to their particular community. It is clear that they were more educated than the *Grimes* plaintiffs, but more important, shared with researchers a certain faith in scientific progress. On the other hand, the children/plaintiffs in *Grimes* would certainly meet the federal research regulations' definition of a "vulnerable population." The *Grimes* court may have viewed access to courts in the form of a liability action as especially important for groups who suffer from many social disabilities, including being among those who experience disparate health care outcomes and access to health care.

I have suggested elsewhere that the *Grimes* court may have been concerned that the routine practice of promising a referral to a physician, in this case for evaluation when the blood level rose above a certain point, was ineffective for low income individuals. Those without health insurance (or adequate health insurance) do not necessarily have access to health care generally, or coverage for the type of risk assessment and follow-up required for lead poisoning. An acute paradigm for health care intervention – seeking health care advice when clearly "sick" or symptomatic from emergency rooms – may not include having a family doctor for oneself or one's children. The court may have implied that the researchers had a duty to ensure access to health care if needed, particularly since the defendants were affiliated with a major academic medical center.[48]

Furthermore, the nature of the research, not just the intention to use the blood for future research and development, may have triggered the court's imposition of greater duties in *Grimes* than *Greenberg*. In the latter, the objective of the research – discovery of a test for Canavan disease – was clear to all parties involved in the case and the court. The genetic nature of the research meant it was "high profile" even though the actual disease is relatively rare. By contrast, *Grimes* involved "low visibility" research in that public health research has traditionally not enjoyed the same media and public visibility as genetics. Recent threats of bioterrorism and the emergence of new types of infectious diseases such as Severe Acute Respiratory Syndrome (SARS) may increase the visibility of public health, but at present law's response to public health must deal with the historic tensions inherent in a public health approach: the interests of the community versus the interests of individuals. Public health approaches to housing carry with it the historical burden of failed public housing policies that have disproportionately impacted the poor and minorities in urban settings.

Grimes is somewhat of a paradox. In one sense, it is a pure research case where a court finds a duty to disclose within the pure research context. The duty is apparently founded in negligence, dependant upon the particular facts, and is somewhat independent of the "lack of informed consent doctrine" developed in clinical settings. On the other hand, *Grimes* is an indication that the research must be placed in a larger social context of whether the particular plaintiffs are in need of access to courts in order to maintain the appropriate institutional balance between science and medicine.

Part III: Data Collection and Health Care Disparities

The Havasupai Tribe in Arizona and some of its members recently filed suit against the Arizona State University and some of its researchers regarding the use of blood samples originally collected in the early 1990s reflecting the high incidence of diabetes among members of the tribe.[49] The plaintiffs have alleged that blood and other samples were used in studies of schizophrenia, and in ancestry and human migration, without their knowledge or consent. There are multiple counts in the complaints involving fraud, intentional infliction of emotional distress, conversion, violation of civil rights, lack of informed consent, and breach of fiduciary duties.

The lack of informed consent claim best illustrates why liability has a role in social control regardless of who the court ultimately determines should prevail on the issue. Liability highlights the limitations of contractual analysis for disputes involving biobanks, especially when applied to a group such as a Native American tribe, or indigenous people anywhere.

The major harm alleged by the tribe was the publication of scientific articles alleging that the tribe had its origins in Asia, in contrast to the religious and cultural beliefs of the Havasupai that their origin is "Red Butte" located in the Grand Canyon.[50] Despite the oversight of the Institutional Review Board of Arizona State University, the plaintiffs allege that non-diabetes research was not authorized and that the researchers had unauthorized access to medical records and unapproved access to hand prints of some members of the tribe from 1990 to 1994 when blood samples were collected.

I will not attempt to analyze here the complex issues involved with the application of federal research regulations on federally recognized reservations and other aspects of law governing relationships with Native Americans.[51] I do, however, note that Native Americans have had a disproportionately high rate of diabetes for a number of years and access to appropriate health care for the condition has been on the policy agenda long before the Healthy People 2010 goals were established.[52] Furthermore, in understanding the social context under which judges will decide these claims, one factor ought to be considered in urging courts to view this issue as a matter of data transmission and disclosure.

Recent litigation over whether DNA testing could be used to determine the origins of human remains in Oregon illustrates that researchers and indigenous peoples may have very different concepts of the human body.[53] Attempting to use common law rules of contract as an attempt to solve in advance the ethical dilemmas of the future are likely to fail if alleged parties to the contract start with fundamentally different notions of the human body and its constituent parts. The possibility of prospecting for biological samples among indigenous peoples should make us cautious of the contractual approach to biobanking. We are aware that some religious groups within our society object to the practice of autopsy.[54] New rules are needed at all levels, such as university rules prohibiting the removal of samples collected when a researcher leaves the university.[55]

More generally, if courts only infrequently enter into this system of collecting and transferring of DNA, tissue, or blood, a liability rule focusing on the transfer of data into knowledge will highlight rather than obscure the ethical issues and provide appropriate focus on the context. In the case of the Havisupai, it is clear that researchers were after "data" even though they may have believed their research would assist the tribe in dealing with its members' diabetes. From the investigation jointly authorized by Arizona State University and the Havisupai, it is clear that the standards for securing the informed consent of the subjects and the community as well as the supervision of the consent process were inadequate by today's standards – less than fifteen years from the date of the earliest collection.[56]

Furthermore, the uses and alleged misuses of the samples stored in numerous laboratories in university and commercial enterprises may not become sources of conflicts for years to come when results are published or patents are obtained. One of the functions of liability rules is to give access to courts where the harms and benefits of certain actions are not equally distributed. Or to put the matter in terms of comparative institutional analysis, forcing an isolated tribe in Arizona to seek legislative or regulatory reform appears unfeasible or a defense of the status quo. Allowing a liability suit to move forward – or to get past the motion for summary judgment or dismissal – merely realigns the negotiating postures of the parties.

Liability rules, as I stated before, do not preclude tribes from negotiating with researchers and their organizations about the scope of research and what their duties of disclosure might be. There are, however, limitations on the scope of contracting embedded in federal research regulations. In the collection of samples, researchers should be aware that exculpatory clauses about negligence are prohibited.[57] Researchers and their lawyers should be leery of assuming that all encompassing clauses will be upheld by courts once a liability-based claim is filed.

Second, the ethical standards for research, and thus for disclosure, are still evolving. Hindsight judgment of the ethics of research is the norm, rather than what researchers thought or reasonably believed at the time. The public health researchers in the Tuskegee Study of Untreated Syphilis of Negro Men[58] may have believed their study was justified at the time. Nonetheless, political leaders and scholars generally condemned the lack of informed consent in the studies using a post-Tuskegee theory of the role of informed consent in research.[59]

Third, it is necessary and proper to give donors of biological samples the option to withdraw their samples in consent documents. It is also appropriate for researchers to begin to consider what to do with samples once the particular study is halted, either because of lack of funds, the movement of key research personnel, or lack of interest on the part of researchers who remain. Even if an institution decides to prohibit researchers from taking samples with them, how can such a limitation be imposed in smaller laboratories as opposed to large scale sequencing facilities?

Conclusion

Biobanking is a powerful metaphor for conceptualizing the role of law in the distribution and control of data used in genomic research. Once tissue or blood is thought of as an "asset," courts and legal scholars are naturally attracted to contract and property rules as a means of balancing the interests of individuals and groups, on the one hand, and those of researchers and their affiliated professional organizations on the other. In addition, carefully drafted contracts to cover the use of biological samples give the illusion of orderliness and certainty that appears to reduce litigation risk.

I have argued that contracts have their role in the control of samples, but that liability should be the primary source for the legal framework for three reasons. First, liability rather than contract raises an important ethical issue *after* there has been an alleged injury: what degree of social control should *individuals* have over researchers and their organizations? This is essentially a question of whether the courts as opposed to the market, legislators, or administrative agencies are the least detrimental forum for optimizing the use of biological samples in the creation of professional knowledge.[60] This institutional question generates a host of empirical inquiries, rather than questions of social values or rights.[61]

Second, liability rules are after-the-fact tools that may influence the actions of other individuals and organizations as they try to negotiate and reduce the risk of liability in the future. Contracts may play a role in some instances, but the liability framework helps us to question critically circumstances surrounding the collection or use of biological samples derived from human beings. Liability rules - crude as they may be - adjust to changing social mores and attitudes and are more similar to the evolving ethical rules regarding biobanks. Conflicts over biobanking cannot be reduced to a code or a set of rules because of the dynamics of the market driving the use of human samples in knowledge creation.

Finally, liability rules are a means of demonstrating that the function of the lack of informed consent doctrine in health care delivery or research is to impose duties of disclosure on professionals. Rather than see the purpose of informed consent in liability law as promoting individual autonomy, the purpose is to provide incentives for disclosure by providers and researchers. Under my analysis, liability has an important role to play in the distribution of professional knowledge. Particularly where there is an alleged misuse of samples, the donor - or the seller, perhaps in the future - could not have known of the misuse when in good faith he or she entered the arrangement for use of one's own blood, tissue, etc. The residual power of liability as a tool for social control is thus dramatically illustrated when the providers of human biological material and recipients have different cultural and religious beliefs - perhaps more common in the Human Genome Era of bioprospecting than we might wish. We should not ignore the role of liability as part of a system of accountability in the current rush to "reform" the medical liability system[62] or to adopt "systems views" of medical and research misadventures.[63]

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15. L. I. Palmer, *Endings and Beginnings: Law, Medicine, and Society in Assisted Life and Death* (Westport, CT: Praeger, 2000): at 21-24.
16. *Cox v. Jones,* 470 N.W. 2d 23 (Iowa 1991).
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23. 782 A. 2d 807 (Md. 2001).
24. *The Havasupai Tribe v. Arizona State University*, No. CV2004-0416 (Superior Court, Coconino County, Arizona, filed March 12, 2004) and *Tilousi v. Arizona State University, No.* CV2004-01115 (Superior Court, Coconino County, Arizona, filed February 26, 2004).
25. See Palmer, *supra* note 17.
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27. D. M. Gitter, "Ownership of Human Tissue: A Proposal for Federal Recognition of Human Research Participants' Property Rights in Their Biological Material," *Washington and Lee Law Review* 61, no 1 (2004): 257-345.
28. G. Calabresi, "An Introduction to Legal Thought: Four Approaches to Law and the Allocation of Body Parts," *Stanford Law Review* 55 (June 2003): 2113-2151.
29. 51 Cal. 3d 120 (1990).
30. *Id.* at 125.
31. *Id.* at 127-29.
32. *Id.* at 127 n.4.
33. *Id.* at 134-146.
34. *Id.* at 131-33,146-48.
35. *Id.* at 129 (citing *Cobbs v. Grant*, 502 P.2d 1 (Cal. 1972)) (stating that the scope of a physician's duty to communicate to the patient must be measured by the patient's need, and that need is whatever information is material to the decision).
36. See Gitter, *supra* note 27 at 304-310.
37. *Wilson v. Adkins*, 941 S.W.2d 440, 442 (Ark. Ct. App. 1997).
38. *Arato v. Avedon*, 5 Cal 4th 1172 (Cal. 1993).
39. *Id.* at 1179 n. 1, 1186-1187.
40. 502 P. 2d 1 (Cal.1972).
41. *Hecht v. Kaplan*, 645 N.Y. S. 2d 51 (N.Y. App. Div. 1996).
42. 264 F. Supp 2d 1064 (S. D. Fla. 2003).
43. Restatement (Third) of Restitution and Unjust Enrichment §1.1.2 comment f.
44. The case was settled, but the terms are confidential.
45. See Gitter, *supra* note 27, at 263 note 29.
46. See Twerski and Cohen, *supra* note 21.
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48. See Palmer, *supra* note 18 at 250.
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