

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

THE WASHINGTON UNIVERSITY,)
)
 Plaintiff,)
)
 v.) Case No. 4:03CV01065SNL
)
 WILLIAM J. CATALONA, et al.)
)
 Defendants.)

PLAINTIFF’S PRE-HEARING BRIEF

Introduction

The Court scheduled this permanent injunction hearing to address “the primary determinative question: who owns the GU Biorepository materials at issue in this case?” The answer is simple and clear: Washington University (“WU”) owns the GU Biorepository and the materials in it. Catalona admits that he does not own them. The research participants (“RPs”), who have explicitly acknowledged that they donated the materials to WU for medical research, do not own them either. Missouri property law makes it clear that WU owns these materials. The RPs donated them to WU. WU accepted them and has possessed, maintained and paid for the costs associated with maintaining these samples.

The Court should not create a new right personal to former principal research investigators to direct how, where, and by whom donated samples will be handled, stored and used. It should not fashion an unprecedented form of ownership rights in order to make donors the ultimate arbiters of Catalona’s claim that his research receive preference over others. It should leave those matters where the federal regulations put them — in the

hands of the Institutional Review Board (IRB) and the Office of Human Research Protection (OHRP).

The Court should declare that WU owns the GU Biorepository. It should deny any injunction Catalona seeks. It should also enjoin Catalona from (a) interfering with WU's relationship with the national Cancer Institute ("NCI") and other researchers desirous of access to GU Biorepository materials and (b) communicating any further with the research participants about research without IRB approval.

The Parties

WU is one of the country's leading private research universities. Its medical school is widely recognized as one of the best in the United States. The medical faculty regularly pursue and publish significant original medical research. The Department of Surgery is one of the larger departments within WU's medical school. The Division of Urologic Surgery is within that department. As with the rest of the faculty, WU physicians in the Urology Division treat patients, teach students and residents, and conduct medical research. The Urology Division maintains a bank of blood and tissue samples for research purposes called the GU (genito-urinary) Biorepository.

William Catalona was an employee of WU from 1976 to 2003. Working at the WU medical school, he was an associate professor (1976-1982) and professor (1982-2003). He was also chief of the Urology Division from 1984-1998 until the chairman of the Department of Surgery appointed a new chief in 1998. Dr. Catalona remained on the faculty as a professor until 2003, when he left for Northwestern University.

Catalona is a talented urologic surgeon who has published studies on the use of the prostate-specific antigen (PSA) to detect prostate cancer. As a division chief at WU's medical school, he engaged in medical research and sought grants to help fund the division's

research. As division chief, he also encouraged similar research by the rest of the WU faculty in the division.

Just weeks ago, eight of Catalona's patients asked for and obtain leave to join as parties defendant to support his position. Some of them will apparently testify that they want the biological specimens that they previously donated for prostate cancer research at WU sent to Catalona at Northwestern. These patients are only eight of the approximately 36,000 RPs who contributed blood, tissue, or DNA samples to the GU Biorepository. These eight patients represent no one other than themselves. They have not sought class certification. For due process reasons, they cannot postpone the decision whether to do so until after the case is decided. *American Pipe Construction Co. v. Utah*, 414 U.S. 538, 547 (1974); *Jimenez v. Weinberger*, 523 F.2d 689, 697 (7th Cir. 1975); *Wilson v. American Cablevision of Kansas City, Inc.*, 130 F.R.D. 404 (W.D. Mo.)

The Dispute

When Catalona left WU to join Northwestern, the GU Biorepository remained at WU. To this day, nothing prevents Catalona from applying to the Peer Review Panel for continued use of GU Biorepository materials in his research. In fact, Catalona successfully applied for use of such materials at least twice after he was no longer division chief.

Catalona, however, is not satisfied with access. He demands control. He wants the ability to prevent other qualified researchers from using the materials, even though he himself has no open studies using those materials. Although no longer Chief of the Urology Division or even a WU employee, he wants to remain personally the gatekeeper over the GU Biorepository. He wants the unilateral and unfettered right to send GU Biorepository materials to other researchers across the country with whom he can collaborate and publish papers, and he has solicited support of his cause from some RPs. His current position,

however, is inconsistent with his past conduct. When he was Chief of Urology, Catalona repeatedly signed agreements with his collaborators at other institutions acknowledging WU's ownership of the materials.

Recently, WU approved a request from distinguished scientists at the NCI for use of a limited quantity of GU Biorepository material. Catalona contacted NCI, disputed WU's ownership of those materials, asserted his personal possessory right to them, and dissuaded NCI from using those materials for fear of legal action by Catalona.

As this litigation progressed, however, Catalona has conceded that he has no ownership interest in the GU Biorepository materials. He argues instead that the federal regulations governing human subject research permit only the research *he* wants to do. Of course, if this were true, Catalona or any of his patients that he has enlisted to support his cause could have complained to OHRP about WU's continued control of the GU Biorepository. OHRP could have then have investigated and determined the issue. To WU's knowledge, no one — neither Catalona nor any of his patients — has ever complained to OHRP.^{1/}

Because Catalona intimidated NCI and challenged WU's ownership of the materials, WU filed this action. The Court has properly focused this hearing on the issue of ownership. The Court should declare that WU owns the GU Biorepository materials, and it should enjoin Catalona from further interference with the use of those materials.

GU Biorepository

The Urology Division maintains the GU Biorepository as a collection of blood and tissue samples for medical research on prostate disease. While faculty physicians do treat

^{1/} Rather than file such a complaint, he unsuccessfully sought OHRP's testimony in support of his position in this litigation.

patients, the GU Biorepository is not used for clinical care or follow-up. It is used solely as a resource for medical research.

The GU Biorepository contains prostate tissue samples, blood serum samples, and DNA samples. Specifically, it contains about 3,500 frozen or paraffin-embedded prostate tissue samples from men who had their prostates removed by WU Urology Division surgeons. It also contains serum samples from the blood of about 28,000 men who participated in research programs led by WU physicians. It further contains DNA samples from about 4,400 men collected and analyzed by WU physicians at WU-affiliated hospitals and at other medical facilities across the country.

The GU Biorepository is not Catalona's personal collection. The collection includes samples gathered in studies led by other WU faculty physicians such as Drs. Gerald Andriole and David Keetch as well as samples collected by numerous WU faculty physicians whose patients agreed to participate in one or more of these studies.

Personal Property

An "owner" is generally defined as "the person who has one or more interests." RESTATEMENT PROPERTY § 10 (1936). The three primary indicia of ownership of personal property are title, possession, and control. *Id.* Where property is of a type that is not subject to title, exclusive possession and control of personal property creates a presumption of ownership. *Valentine v. St. Louis Union Trust Co.*, 250 S.W.2d 167 (Mo. 1952) (exclusive possession and control over property raises a presumption of ownership in the possessor, and anyone else claiming the property has the burden of proof); *Foltz v. Pipes*, 800 S.W.2d 14, 15 (Mo. App. 1990) (same).

WU has the indicia of ownership. Because he is well aware of that, Catalona has retained an expert witness, Kenneth Goodman, to testify that "[t]he very idea that one might

own a quantity of another's body (cells, organs, genes) is at least ethically problematic and at worst preposterous.” Goodman Aff. ¶ 19 (emphasis in original). But Dr. Goodman is the one who is off base. Again, the sole issue established by the Court for this hearing is *ownership*. This case involves excised cells that have been given away or blood samples that have been donated. These items are entirely capable of being owned. The law does not recognize Dr. Goodman's ethical quandary in this circumstance. *Kurchner v. State Farm Fire & Cas. Co.*, 858 So. 2d 1220 (Fla. App. 2003) (cryopreserved sperm is personal property); *Hecht v. Superior Court*, 16 Cal. App. 4th 836, 20 Cal. Rptr. 2d 275, 283 (Cal. App. 1993).

Donation of Samples

Blood and tissue samples are added to the GU Biorepository when an RP gives a sample for medical research. In other words, RPs donate their samples to WU for medical research. Although federal regulations govern how a physician may ask a patient to participate in human subject research, the participant clearly makes a gift to WU for medical research.

A gift requires only donative intent, delivery by the donor, and acceptance by the donee. *Donnelly v. Donnelly*, 951 S.W.2d 650, 653 (Mo. App. 1977). “The essentials of an inter vivos gift of personal property are as follows: a present intention to make a gift on the part of the donor, a delivery of the property by the donor to the donee, and an acceptance by the donee, whose ownership takes place immediately and is absolute.” *Wantuck v. United Savings & Loan Ass'n*, 461 S.W.2d 692, 694 (Mo. banc 1971).

The RPs have clearly expressed their donative intent in providing their samples for medical research. The informed consent forms they signed plainly state that the collection of samples is for medical research and not for patient care. Those consent forms specifically advise the RPs that the tissue sample will be used for research and will not be available with

their treatment files for any follow-up analysis. Some of the forms even use the word “donate,” a non-technical term with a common everyday meaning: i.e., a gift without expectation of return or continued ownership rights.

Delivery of the specimens occurred when each RP allowed his blood to be drawn or tissue excised and kept in a freezer or file drawer at the WU medical school. The donors gave up possession of the samples from that point forward. The RPs gave their samples to WU, not to Catalona individually. They did so, in many cases, a decade or more ago. Many of the participants were treated by other WU physicians and provided their samples for research in which other faculty members were the principal investigators. While a number of RPs (including the eight individual defendants) were Catalona’s patients, their samples were collected for research, not patient care, and a separate research consent form was required from them. The consent forms identifying Catalona as the principal investigator do not provide permanent or proprietary rights with that designation. Indeed, Catalona ceased being the principal investigator on several studies and turned them over to other researchers at WU without seeking the RPs’ consent. Other studies started by other principal investigators were later handed off to Catalona.

The consent forms typically bore the WU Medical Center logo. They all stated they were not valid without the current stamp of approval of the WU Human Studies Committee. These forms advised the participants they could contact the Chairman of the Human Studies Committee (IRB) with any concerns. They advised the participants what WU would do to protect their privacy and minimize the burdens of participating in the study. WU accepted each donation when its personnel took the samples and stored them in the GU Biorepository. WU’s ownership became absolute and was no longer revocable by the donor at that time.

There is no dispute that an RP retains a right under the federal regulations to discontinue further participation in the research. That regulatory limitation on the scope of use is not inconsistent with WU's ownership of the samples and does not require WU to return the samples. *See* 45 C.F.R. 46.116(a)(8). Goodman, Catalona's own expert, agrees the RPs would have no reasonable expectation of ever retrieving their donated tissue or blood. Rather, if an RP chooses to discontinue participation, WU has several options. It can remove all personally identifying information from a donor's samples and continue to use them for research without further informed consent. 45 C.F.R. 46.101(b)(4) (research on specimens exempt if persons cannot be identified); 45 C.F.R. 46.102(f) (not "human subject" research if researcher does not obtain identifiable private information); 45 C.F.R. 164.514 (de-identified samples excluded from HIPAA protected information). Or it can destroy the samples in compliance with medical waste laws. *See* 29 C.F.R. 1910.1030.

In other words, an RP retains a limited but valuable right to control the use of his personal **information** by choosing to discontinue participation in research, but he has no right to control the handling, storage and location of the donated **physical specimen**. The gift is made, and WU owns it as a matter of state property law. Nothing in the federal regulations or state personal property law lets a donor take it back. Catalona's position (and the eight RPs too) would effectively create rights on the part of serum contributors to direct the physical location and shipments of their blood — an absurd and highly disruptive outcome.

If a patient had not elected to participate in research at the time of his prostate surgery, that portion of the diseased tissue not needed for clinical use would have been discarded as biological waste. Federal and state regulations require that the samples be treated as hazardous medical waste if not used for research and prohibit returning the samples to the donors. *See, e.g.,* 29 C.F.R. § 1910.1030 (bloodborne pathogens); R. S. Mo.

§§ 260.200, 260.203 (infectious waste disposal); 10 C.S.R. § 80-7.010 (infectious waste management). The patient would have had no claim to ongoing ownership, nor would he have had any expectation that the research institution would maintain and preserve that biological waste. The mere fact that the patient elected to participate in medical research cannot give him any greater rights to that biological waste. What the patient does get is the right to elect, through the informed consent process, whether or not to participate in the research and the right to discontinue such participation without penalty. If he elects to discontinue participation, the research institution can either destroy or anonymize his samples. In either event, the samples are no longer considered “human subject research.”

Catalona has alleged that the RPs are bailors who merely provide their samples to WU temporarily. In doing so, he fails to recognize the fundamental distinction between a gift and a bailment: the bailor’s intent to get the same property back. Indeed, a bailment is made on the condition that the goods be restored to the bailor according to his directions as soon as the purposes for which they were bailed are served. *Seitz v. Lemay Bank & Trust Co.*, 959 S.W.2d 458, 461 (Mo. banc 1998). Moreover, “an implied contract of bailment can arise only when the natural and just interpretation of the acts of the parties warrants such a conclusion.” 8A Am. Jur. 2d, *Bailments* § 36, at 499 (1997); see also 8 C.J.S., *Bailments* § 22 (2003) (“No bailment can be implied where it appears that it was the intention of the parties that the property was to be held by the party in possession in some capacity other than as bailee”).

Without an agreement to redeliver the diseased tissue or blood to the RPs, there can be no implied bailment. 8A Am. Jur. 2d, *Bailments* § 37, at 500 n.57 (1997); see also *Scope Enters., Ltd. v. United States*, 18 Cl. Ct. 875, 884 (Cl. Ct. 1989) (holding no implied bailment because there was no expectation of return of the property delivered); *Welding Metals, Inc. v. Foothill Capital Corp.*, No. 3:92CV00607, 1997 WL 289671, at *7 (D. Conn. Apr. 14, 1997) (finding no bailment

existed because “there was no requirement or expectation that Seymour would return the items bailed”); J. Story, *Commentaries on the Law Of Bailments*, ch. 1, § 2 (9th ed. 1878) (bailments are transactions in which the owner of a chattel transfers possession of the chattel with the expectation of its return). The bailment theory is completely inconsistent with the purpose of the research studies and the applicable regulations. It is also inconsistent with the proponent’s own conduct, as Catalona has acknowledged, that he himself directed the destruction rather than the re-delivery of serum samples when the repository began to exceed storage capacities.

The only cases that have addressed this issue have concluded that the RPs are donors who parted with any proprietary rights to their samples. In *Greenberg v. Miami Children’s Hospital Research Institute, Inc.*, 264 F.Supp.2d 1064 (S.D. Fla. 2003), the plaintiffs supplied tissue and blood samples to the defendants for research on Canavan disease. The Court observed that “these Plaintiffs are more accurately portrayed as donors rather than objects of human experimentation” *Id.* at 1071. The Court held that the plaintiffs “have no cognizable property interest in body tissue and genetic matter donated for research under a theory of conversion.” *Id.* at 1074. As the Court explained, “the [RP’s] property right in blood and tissue samples also evaporates once the sample is voluntarily given to a third party.” *Id.* at 1075. The Court distinguished other cases recognizing property rights in genetic material, such as a couple’s stored frozen embryos, saying: “These cases, however, do not involve voluntary donations to medical research.” *Id.*

Similarly, in *Moore v. Regents of the University of California*, 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990), the California Supreme Court exhaustively reviewed the law relating to the ownership and use of human tissue. It observed that, because the plaintiff who provided cells for certain research “clearly did not expect to retain possession of his cells following their removal, to sue for conversion he must have retained an ownership interest in them.” 51 Cal. 3d

at 136-37; 271 Cal. Rptr. at 155-56. “If the use of cells in research is a conversion, then with every cell sample a researcher purchases a ticket in a litigation lottery.” 51 Cal. 3d at 146. *See Miles v. Scrippel Clinic And Research Foundation*, 810 F. Supp. 1091, 1097 (S.D. Cal. 1993). The court held the plaintiff had no ownership interest, observing that no reported decision had ever held that a plaintiff retained an ownership interest in cells excised for medical research. 51 Cal.3d at 137, 271 Cal. Rptr. at 156. The court also noted that the plaintiff could not have an ongoing ownership interest in removed tissue because of the laws requiring the disposal of such materials as hazardous biological waste. 51 Cal. 3d at 40-41, 271 Cal. Rptr. at 158-59. Again, Missouri has statutes and regulations mandating the controlled disposal of such waste.

Our research has disclosed no reported case contrary to *Moor* and *Greenberg*. To date neither Catalona nor his eight patients have cited any such case.

Maintaining the Collection

After the participants gave their samples, WU acted as owner of the collection. It kept the GU Biorepository at the medical school. WU personnel administered it. The Urology Division’s internal budget paid for much of it. Some of the research projects received external grant funding, but WU policy requires those grants to be made to and administered by the University. It was part of Catalona’s job as division chief to seek such funding for the division.

WU also bears legal, regulatory, and compliance responsibility and risk for all research its faculty performs. *See, e.g.*, 42 C.F.R. Part 50 (governing conflicts of interest); 45 C.F.R. Part 689 and 42 C.F.R. Part 50 (governing research integrity and scientific misconduct); 45 C.F.R. Part 46 (human research protections); 45 C.F.R. 46.103 (Assurance). WU is the federally approved and regulated institution under whose auspices the human-subject research involving the GU Biorepository is conducted. It has been subject to complex and costly regulation

throughout the life of the GU Biorepository, implemented through audits and a substantial internal compliance program. In addition, WU is subject to federal and state laws and regulations governing the disposal and storage of human biological material, and it is responsible for compliance with such laws and regulations. *See, e.g.*, 29 C.F.R. § 1910.1030 (“Bloodborne Pathogens”); 10 C.S.R. § 80-7.010 (“Infectious Waste Management”).

University Policy

WU’s Intellectual Property Policy makes clear to its employees that WU owns the GU Biorepository. While primarily concerned with intellectual property, the Policy states that tangible research property — including biological materials — belong to WU if (a) significant University resources are used or (b) the research was funded by an external grant made to and administered by the University. The GU Biorepository was collected and is maintained with Urology Division funds and grants provided to WU from external sponsors. It is WU’s property, not Catalona’s.

Catalona protests that he never signed an employment agreement with Washington University and never personally agreed to the Intellectual Property Policy. However, similar university intellectual property policies are widely recognized as a valid and enforceable condition of employment. *Chou v. University of Chicago*, 254 F.3d 1347, 1356-57 (Fed. Cir. 2001); *University of West Virginia v. Van Voorhies*, 84 F. Supp. 2d 759, 769-71 (N.D. W.Va. 2000); *Fenn v. Yale University*, 283 F.Supp.2d 615, 628-29 (D. Conn. 2003).

Sharing the Collection

Even when Catalona was division chief, the GU Biorepository was not limited to his personal use. Other faculty could use the materials in their research, although they had to justify their proposed uses directly to Catalona as division chief. The current division chief, Dr. Gerald Andriole, is less autocratic. Dr. Andriole established a Peer Review Panel to evaluate and

approve proposed uses of GU Biorepository materials. The Peer Review Panel has approved all the requests Catalona has made for use of GU Biorepository materials. Thus, the only real difference between the Catalona regime and that of his successor is the inclusion of other faculty members on the Peer Review Panel that decides on the appropriate uses of the materials. Sharing the resources of the GU Biorepository with researchers outside WU is also nothing new. Nothing would prevent Catalona from seeking similar use of GU Biorepository materials even though he is at Northwestern.

Material Transfer Agreements

When WU sends proprietary tangible personal property to researchers at other institutions, the transfer must be properly documented.^{2/} WU's Office of Technology Management (OTM) administers such transfers. It prepares a material transfer agreement (MTA) to be signed by the receiving institution. Catalona participated in many such MTAs when he wanted to send GU Biorepository materials elsewhere. These agreements identify Dr. Catalona as the "Provider Scientist," but they define WU as the "Provider." Each agreement states: "The material shall remain the property of the Provider." Thus, Catalona recognized and made his collaborators agree that the GU Biorepository materials are WU's property.

Catalona himself signed at least eight MTAs in which he expressly acknowledged WU as the owner of the GU Biorepository. His correspondence with OTM demonstrates he also received and reviewed other similar MTAs. In his last signed agreement, entered at a time when

^{2/} While he was Division Chief, Catalona frequently sent samples from the GU Biorepository to researchers at other institutions across the country. These researchers analyzed the serum or tissue samples in their own laboratories. Catalona often collaborated with these other researchers on the publication of the paper describing the results of the shared research.

he was preparing to leave WU, Catalona tried to insert language making himself “co-owner,” but WU refused that request. Catalona signed the agreement, though he protested in a separate message that he believed he “had proprietary rights” to the materials. On all prior occasions, he admitted WU owned the materials.

The ownership provisions of these agreements constitute admissions by Catalona that WU owns the biological materials. *See, e.g., Pillsbury Co. v. Cleaver-Brooks Div. of Aqua-Chem. Inc.*, 646 F.2d 1216, 1218 (8th Cir. 1981) (by signing report, defendant adopted plaintiff’s statement even though he was not present during conversation that formed basis for report); *United States v. McCulley*, 178 F.3d 872, 876 (7th Cir. 1999) (defendant adopted FAA inspector’s written report of his interview by signing it); *McQueeney v. Wilmington Trust Co.*, 779 F.2d 916, 930 (3d Cir. 1985) (plaintiff’s signature on copies of records constituted an adoption); *See also, Schering Corp. v. Pfizer, Inc.*, 189 F.3d 218, 238-39 (2d Cir. 1999); *Perzy v. Intercargo Corp.*, 827 F. Supp. 1365 (N.D. Ill. 1993). This conclusion is supported not only by the agreements Catalona actually signed but also by those of which he had actual knowledge. A party is deemed to have adopted an admission if he heard, understood, and acquiesced in the statement. *See, e.g., Pillsbury Co.*, 646 F.2d at 1218; *McCulley*, 178 F.3d at 876; *Schering Corp.*, 189 F.3d at 238-39.

Alleged “Medical” Consents

The answer to the determinative question of ownership is clear. WU owns the GU Biorepository materials. Catalona admits he does not own them. He admitted in the MTAs that WU owns them. WU’s Intellectual Property Policy mandates its ownership. WU personnel collected and maintain the materials. WU funds or funds granted to the University paid for the corporation and upkeep of the collection. WU and its IRB are responsible to the federal regulators for the proper use of the materials.

The RPs do not own the materials. They donated them to WU for medical research, in many cases as long as a decade ago. The implied bailment theory is nonsense. The donors never intended to get the materials back. They signed consents agreeing that the materials could be consumed in research. Missouri statutes and regulations on biological waste preclude returning the materials to the donors. 10-C.S.R. 80-7.010; R. S. Mo. §§ 260.200, 260.203.

The only remaining question then, is whether Catalona can change the outcome by privately soliciting RPs to sign his February 2003 document misleadingly entitled “medical consent & authorization.” Clearly, he cannot. The RPs cannot give WU’s property to Catalona or Northwestern. The RPs already gave away the samples. They do not own them. Catalona’s stealth solicitation of RPs without notice to or involvement of the IRB violated federal human subject research regulations (*see infra*) and represented a sharp departure from his own practice in seeking IRB approval for even small changes in a study. His “consents” are, therefore, entirely ineffective to deed the samples over to him or to Northwestern.

Right to Discontinue Participation

Participants in human medical research projects always have a right to “discontinue participation” in further research. 45 C.F.R. 46.116(a)(8). All of the informed consent forms used in the collection of the GU Biorepository advised the RPs of their right to discontinue participation. This right to discontinue participation, however, is irrelevant to the February 2003 “consent” forms Catalona procured from some of the RPs. Catalona’s form does not say the RP can (1) discontinue his participation in current research, (2) forego participation in future research, or (3) have his samples destroyed — the alternatives which the regulations confer. Instead, it asks the RP to state that he wants research to continue, albeit at a different location under different auspices. Because the forms do not purport to exercise any right to discontinue participation from research, they are utterly ineffective.

Instead of exercising any rights the RP may have, Dr. Catalona’s “consent” form attempts to rewrite the past. It says, in language tailored to his new-found bailment theory, “I have entrusted these samples to Dr. Catalona” But each RP signed a *real* informed consent form before donating his samples to WU, and the language purporting to give Catalona personal control over the samples does not appear in any of those forms. Catalona’s attempt to have the RPs recharacterize what they did when they donated their samples is ineffective.

An effective decision by an RP to discontinue participation in research still would not affect ownership of the samples. The federal regulations permit WU to destroy the samples, or remove all personally identifying information from them and continue to use them in research without any further informed consent from the donor. 45 C.F.R. 46.101(b)(4) (research on existing specimens is exempt from regulation if researcher records information in such manner that subjects cannot be identified directly or through identifiers linked to the subjects); 45 C.F.R. 164.514 (HIPAA rules exclude de-identified specimens from protected health information and provide how samples may be de-identified). The regulations permit such de-identification because research on tissue or blood samples requiring no further interaction with the patient is considered human subject research only if there is identifiable private information associated with the samples. 45 C.F.R. 46.102(f) (human subject research defined as involving living individual about whom researcher obtains identifiable private information, which would not apply if researcher receives de-identified samples).

Thus, WU has the right to keep the tangible property. The RP only has the right to discontinue his participation in a specific research project and, if there is identifiable private information associated with the samples, to withhold consent to future research projects that would use his donated specimens.

Proxy Battle

If the personally crafted, unreviewed and privately sent “consent” forms Catalonia drafted could defeat WU’s ownership of the biorepository and require it to ship the samples to Catalonia at Northwestern, that would just be the beginning of the disputes — not the end of them. Other urologists at WU could ask the RPs to sign forms directing Northwestern to send the samples back to WU. The scientists at NCI who had arranged with WU to use some of the samples before Catalonia interfered could correspond directly with the RPs, and ask the RPs to sign forms directing that the samples be sent to NCI. Nothing would prevent this chaotic effect upon scientific research, which increasingly relies on the aggregation of large collections of biological materials.

Catalonia is engaging in such chaotic conduct here. He was not the principal investigator on any open study for which any of the samples were originally collected when, in his individual capacity, he solicited the RPs to sign his “consent” forms. He had been the treating physician for some, but far from all, of the men who signed the consent forms, but consent for participation in human research is entirely separate from consent for treatment, and a treating physician relationship is not needed to ask someone to participate in a study that provides no treatment.

The Common Rule

There are seventeen federal agencies or offices that conduct or fund human subject research. In addition, the FDA regulates drugs and medical devices that may require clinical trials constituting human subject research. These agencies have adopted a uniform set of regulations, known as the Common Rule, for the conduct of human subject research. *See* 45 C.F.R. Part 46 (HHS agencies Codification of Common Rule); 21 C.F.R. Parts 50 & 56 (FDA adoption of Common Rule). Indeed, every institution, including WU, that conducts any

federally supported research must submit a Federalwide Assurance in which it commits that all human subject research it conducts, regardless of the source of funding, will comply with the Common Rule. 45 C.F.R. 46.103(a).

The Common Rule requires each institution to establish an Institutional Review Board. At WU, the IRB is called the Human Studies Committee. It includes a cross-section of the community, not just WU staff. The IRB must approve any research protocol involving human subjects before research begins, and it must review on-going protocols at least annually. 45 C.F.R. 46.109(a), (e). The researchers must obtain informed consent from any human subjects before they participate in the research, and the IRB must approve the informed consent form both before it is used and again in any periodic reviews of the research protocol. 45 C.F.R. 46.111(a)(4), 46.116(a)(7). The IRB must also approve any modification to an approved consent form or any meaningful communication with RPs. 45 C.F.R. 46.109(a), (b); 45 C.F.R. 46.103. Catalona knew this and routinely sought IRB approval for changes to consent form on studies where he was Principal Investigator.

No IRB Approval

The valid informed consent forms WU used to gather the samples in the GU Biorepository all bear a stamp saying that the consent form has the current approval of the Human Studies Committee. Catalona's letter and "consent" form have no IRB stamp. He did not submit them for IRB approval. The IRB would not and could not have approved them even if he had done so. Consequently, the form is utterly invalid to obtain any kind of consent to use of the samples in Dr. Catalona's research.

The IRB could not have approved the form Catalona drafted because it did not comply with the Common Rule. It did not contain the required elements of a valid informed consent. *See* 45 C.F.R. 46.116. It is misleadingly entitled "medical consent & authorization" when, in fact,

no medical treatment was involved. The form itself explains nothing. The letter sent with the form falsely suggests that the participant's medical care could be adversely affected if his samples were not sent to Catalonia. The letter did not explain that research using the GU Biorepository could continue at WU. (In fact, four studies for which University personnel collected samples are still ongoing at WU.) It also did not disclose that Catalonia could continue to have access to the materials for studies approved by the Peer Review Panel. Finally, it also failed to state, as required by the Common Rule, that "refusal to participate [would] involve no penalty or loss of benefits." 45 C.F.R. § 6.116(a)(8). Moreover, it didn't ask the RPs what is permitted by the federal regulations, i.e., whether they wanted to discontinue participation. Instead, it asked them for something not permitted — redirecting the control and use of the physical samples.

Comprehensive federal regulations, already in place, are available to resolve disputes like this. These regulations impose stringent requirements on the process of obtaining a person's informed consent for participation in human subject research. They clearly forbid what Catalonia did in seeking the so-called "medical consent & authorization" forms from the RPs.

Exculpatory Language

An HHS regulation, set forth at 45 C.F.R § 46.116 states that:

"No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive any of *the subject's legal rights*, or releases or appears to release the investigation, the sponsor, the institution or its agents from liability for negligence." (emphasis added)

Nothing in this or any other regulation confers ownership rights to RPs in excised or donated materials. Moreover, nothing states what "the subject's legal rights" are or what constitutes "exculpatory language." Catalonia thinks the answers are contained in an OHRP web posting regarding "exculpatory language." This web posting cites examples put together at a Cooperative Oncology Group Chairpersons Meeting on November 15, 1996, of "exculpatory

language” that should not be put into an informed consent. Catalona relies upon the following “example of exculpatory language” listed therein: “By consent to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research.”^{3/} His interpretation of this example is that (1) the cited regulation and OHRP’s guidance document somehow affirmatively confers ongoing property rights to RPs in the donated serum and tissue samples and (2) the guidance document is binding on this Court.

Catalona is wrong on both scores. The website example takes no position on the issue of ownership. OHRP’s position on that issue is neutral. It talks of “any property right *I may have*,” not “do have.” Even Dr. Goodman contradicts Catalona’s position. In Goodman’s view, an informed consent form should not say that a participant waives any property rights he may have, but it can affirmatively confirm that the participant is freely donating his tissue for medical research. Goodman also concedes that the prohibition against “exculpatory language” contained in this regulation does not attempt to confer any property rights upon RPs that don’t already exist. OHRP has not conferred or even recognized any right of ownership on the part of RPs.

Even if the example were interpreted Catalona’s way, however, it is not the law and is entitled to no deference. The website example is not contained in any statute or regulation. Unlike agency rules and adjudications, such informal agency pronouncements “lack the force of law.” *Christensen v. Harris County*, 529 U.S. 576, 587 (2000). They are not entitled to judicial deference under the doctrine of *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). See *United States v. Mead Corporation*, 533 U.S. 218 (2001). Such

^{3/} Catalona’s counsel found a few informed consent forms approved by the WU IRB which uses this language. Rather than try the issue of “ownership,” they now want to divert attention from the question delineated by the Court and try the IRB instead.

interpretations are entitled to respect only to the extent they have the “power to persuade.”
Christensen, 529 U.S. at 587.

The OHRP web posting has no persuasive power. It is a blanket statement without any reasoning or analysis. It is in stark contrast to *Moore, Greenberg*, and the other authorities we have cited which set forth the legal and policy reasons why RPs can have no continuing proprietary interest in their excised and donated samples. Even if the Court were to adopt Catalona’s reading, the web posting would be entitled to no weight.

Injunction Against Catalona

WU owns the GU Biorepository and the materials in it. Catalona and the RPs do not. Catalona’s self-constructed “consent” forms cannot change these facts. The RPs have the right to cease participating in research altogether, but even those who signed Catalona’s defective “consents” have not done so. Consequently, there is no reason for the Court to enjoin anything WU has done or to grant any of the relief Catalona or his eight patients have requested.

On the other hand, Catalona has interfered with the efforts of other researchers at WU and NCI to conduct serious medical research using samples from the GU Biorepository. As against NCI, Catalona asserted a proprietary interest in the samples that he does not have. The Court should enjoin him from interfering further with WU’s relationship with the NCI researchers or any other qualified researchers seeking access to GU Biorepository materials.

Administrative Remedies

In his affidavits and prior motion papers, Catalona has raised several concerns that are still largely hypothetical about what uses can be made of GU Biorepository materials for research projects that might move beyond the scope of the original and now closed research protocols pursuant to which many of the samples were collected. The Court need not address those questions here because they do not affect the ownership issue. In any event, the Court

need not issue advisory opinions now on all the permissible future uses of the GU Biorepository.

Nor should this Court have to resolve such detailed issues down the road. Once the Court declares that WU owns the GU Biorepository materials and enjoins Catalona from asserting any proprietary rights to those materials, then WU will be free to use the materials for appropriate research projects and to transfer such materials to qualified researchers at other institutions pursuant to material transfer agreements recognizing WU's ownership of the materials — just as it did fifteen times during Catalona's tenure.

None of this means that it will be open season to use GU Biorepository materials for any imaginable purpose. The comprehensive federal regulatory regime governing human subject research is still in place. In addition to the Peer Review Panel determination that a proposed new research project has scientific merit, the Human Studies Committee (IRB) must determine whether the project is permissible under the strictures of the Common Rule, particularly whether further informed consent of the RPs is or is not required. The IRB's determinations are always subject to oversight by OHRP.

The regulations contain detailed rules on when informed consent is required and when it may be waived. For research involving the use of an existing collection of tissue samples, both the Common Rule and HIPAA regulate what informed consent is required if the tissue studied can be linked to the donor. The regulations also spell out when research can proceed without further informed consent if the samples are anonymized (the researcher cannot identify the donor) or completely de-identified (stripped of all personal identifiers).

The regulations provide that these judgments are to be made by a properly constituted IRB. The decisions of the IRB are final. No one in WU's administration can dictate these or overrule them.

The IRB's determinations are always subject to review by the OHRP in the Department of Health and Human Services. OHRP is responsible for monitoring compliance with WU's Federalwide Assurance that it conforms to the regulations on human subject research. OHRP conducts random and targeted audits, but it will also respond to any complaint from any source. It has authority to suspend research programs, to terminate federal funding for a particular research program or an entire institution, and to shut down all human subject research at an institution.

Decisions regarding future uses of the GU Biorepository materials should go not to this Court but to the Peer Review Panel and the Human Studies Committee and, if necessary, OHRP, but they should go there free of any claim that those bodies have no business fulfilling their roles under the regulatory framework because parties other than WU's claim proprietary rights to the materials.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the 4th day of April, 2005, the foregoing was filed electronically with the Clerk of the Court to be served by operation of the Court's electronic filing system upon the following attorneys for the Defendant:

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