UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

THE WASHINGTON UNIVERSITY,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	**Case No. 4:03CV1065SNL**
	)	
WILLIAM J. CATALONA, ET. AL.,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION

Plaintiff Washington University (hereinafter referred to as "WU") has filed this declaratory judgment action seeking to establish "ownership", and thereby, the destiny of certain research biological materials currently stored in the GU Biorepository. Central to the several pending summary judgment motions, and preliminary injunction motion(s) is the issue of "ownership"; thus, the Court determined that the most logical and efficient manner in which to address this issue was to hold a permanent injunction hearing in which all interested parties, including research participants who "donated" the subject biological materials, could coherently present their argument to the Court. On April 9 through 11, 2005, such a hearing took place before this Court. At the conclusion of the hearing, all parties were permitted to file post-hearing briefs, and this matter is now ripe for disposition.

After careful consideration of all objections to exhibits and testimony taken with the case, all said objections are hereby overruled, and all exhibits offered into evidence at the hearing are received into evidence. All testimony will be considered by the Court and given its due weight. This Court, having now considered the pleadings, the testimony of witnesses, documents in evidence, and any other evidentiary materials submitted for the Court's consideration, and being

fully advised in the premises, hereby makes the following findings of fact and conclusions of law as required by Rule 52, Federal Rules of Civil Procedure.

FINDINGS OF FACT[1]

Plaintiff Washington University (WU) is a Missouri not-for-profit corporation with its principal place of business in St. Louis, Missouri. WU is one of the leading private research universities in this country, if not in the world. As a research university, it has a medical school (Washington University School of Medicine) that includes a Department of Surgery and a Division of Urologic Surgery. The medical faculty regularly pursues and publishes significant original medical research. Within the Division of Urologic Surgery, WU physicians treat patients, teach students and residents, and conduct medical research.

Defendant William J. Catalona, M.D.[2] is a highly respected urologist and urologic surgeon, as well as a well-established medical researcher regarding prostate cancer. He was employed by WU from July 1, 1976 until February 23, 2003. Dr. Catalona was Chief of the Urology Division from 1984 to 1998. While at WU, Dr. Catalona performed thousands of surgeries, including prostate cancer surgeries. He was instrumental in establishing the GU[3] Biorepository for the collection and storage of biological research materials. In 2003, Dr.

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[1]The Court's factual findings are derived from the transcripts of the permanent injunction hearing (Vols. 1-3); the parties' exhibits, deposition testimony, and the parties' briefs. Where necessary, the Court will cite to specific evidence and/or testimony. Where more than one copy of the same exhibit has been filed by different parties, the Court will cite to only one exhibit; however, the reference should not be considered any indication of bias on the part of the Court. Referring to only one of duplicative (in some cases, triplicative) exhibits is simply a matter of judicial efficiency.

[2]Defendant Catalona is also a Counterclaim Plaintiff.

[3]genito-urinary

Catalona left his position with WU to take a similar position with Northwestern University in Chicago, Illinois and to continue his prostate cancer research.

The GU Biorepository houses biological specimens of prostate tissue, blood, and DNA samples for prostate cancer research. Patients of Dr. Catalona, as well as several other WU physicians, contributed biomaterials for prostate cancer research. As of the date of the hearing, there were more than 30,000 research participants enrolled in prostate cancer research studies; of these, 2500-3000 had been patients of Dr. Catalona. There are approximately 3500 prostate tissue samples in the GU Biorepository taken from patients of Dr. Catalona and other WU physicians within the Urologic Surgery Division. There are approximately 100,000 serum samples in the GU Biorepository; 75% of these contributions were made from research participants who were not patients of Dr. Catalona or any other WU physician. Approximately 4400 men contributed DNA samples to the GU Biorepository; again, some were patients of Dr. Catalona, while others were not. The GU Biorepository is not used for clinical care or follow-up care; it is strictly used for research purposes. At times, other research institutions have requested and received samples from the GU Biorepository for research projects outside of WU (or in partnership with WU). The transfer of such material is made pursuant to a Material Transfer Agreement (MTA). At least seven (7) of these MTAs personally signed by Dr. Catalona acknowledge WU as the owner of the biological samples at issue in this case. Plaintiff's Exhibits 7-10, 12-14.

At all relevant times, the GU Biorepository has been housed in one or more buildings owned by WU. At all relevant times, WU employees have administered the GU Biorepository. WU has provided the majority of funding necessary to operate and maintain the GU Biorepository. External funding for the GU Biorepository is in the form of public and private grants made to and administered by WU as the grantee. Dr. Catalona, as a WU employee and

physician, has raised several million dollars in outside funding for the GU Biorepository. Other WU employees, most notably Dr. Gerald Andriole (Dr. Catalona's successor as Urology Division Chief), have raised substantial funds for the GU Biorepository.

WU's Intellectual Property Policy states that "all intellectual property (including . . . tangible research property) shall be owned by the University if significant University resources were used or if it is created pursuant to a research project funded through corporate, federal, or other external sponsors administered by the University." Plaintiff's Exhibit 17, §I..3(a). It further states "[G]enerally, creators and research investigators will retain custody of tangible research property while at the University." Plaintiff's Exhibit 17, §I.3(a).

Defendants Richard Ward, Thomas McGurk, Luis Garcia, Antonio Castro, Phillip Wilard, Ivan Parsons, James Ellis, and Michael Missios[4] are/were patients of Dr. Catalona and participants in one or more research projects at WU in which Dr. Catalona was involved.[5]

During the relevant time-period, several prostate cancer studies have been undertaken by Dr. Catalona and other doctors in the Urology Division. Dr. Catalona, as well as other WU physicians, were named "Principal Investigators" on these studies. Dr. Catalona testified that the principal investigator "is in charge of conducting [a] research protocol." Tr.1:46.[6] The testimony at the hearing established that regardless of who was listed as the "Principal Investigator", the

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[4]Ward, McGurk, and Ellis testified at the hearing.

[5]In order for simplicity and judicial efficiency, the persons who contributed samples to the GU Biorepository are collectively referred to as "research participants" and include the eight (8) men who have been allowed to intervene in this case and refer to themselves as "patient/defendants".

[6]When citing to hearing testimony, the Court will use the following notation: "Tr" stands for transcript; the number following TR stands for Vol. 1, 2. or 3; and the number after the colon is the page number. Thus, the referenced testimony can be found in Vol. 1 of the hearing transcript on page 46.

research studies were a collaborative effort involving substantial work by many individuals, all of whom were/are employees of WU.

In order to carry out the subject prostate cancer research studies[7], surgical and non-surgical research participants (hereinafter referred to as "RPs") were invited to participate in genetic cancer research. If they agreed to participate, they had to sign "informed consent" forms. Although the informed consent forms differed slightly due to variances in the protocol and the particulars of each Principal Investigator, generally they all contained the similar language. The informed consent forms typically bore the WU Medical Center logo. Plaintiff's Exhibits 27, 58, 59, 60, 61, and 98; Catalona Exhibit UUU; RP Exhibit 1. The informed consent forms state that the collection of samples is for medical research and not for patient care. They typically stated that the RP could not "claim ownership rights" to any medical or scientific product that results from research with the sample. They typically use the word "donate" to characterize the delivery of the sample (blood, tissue and/or DNA) from the RP to the WU physician or another WU medical technician. They typically state that by participating, the RP "make[s] a free and generous gift of your [blood, tissue and/or DNA] to research that may benefit others." Furthermore, the typical WU informed consent form states that "[y]our participation is voluntary and you may choose not to participate in this research study or withdraw your consent at any time." Some forms use the phrase "withdraw my consent and discontinue participation." None of the submitted WU informed consent forms address the issue of the RP withdrawing samples from the GU Biorepository or the RP requesting samples be sent to another institution.

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[7]Testimony and documents refer to the cancer research studies as "protocols", a term which the Court may use from time to time.

Along with the informed consent forms, RPs are given a WU Genetic Research Brochure (to also sign) which generally addresses the issues of primary importance to the RP. Catalona Exhibit X. Under the section: **What if you change your mind?**, the brochure states the following: "To request that your tissue no longer be used for research, you should call the investigator listed on the consent form. Your tissue will be identified and destroyed upon request. Any research results already obtained cannot be destroyed or recalled." Nowhere in the brochure does it state anything about a RP withdrawing his/her sample or a RP requesting that his/her sample be transferred to another facility.

WU is a federally approved and regulated institution for the human-subject research involving the GU Biorepository. The Department of Health and Human Services (HHS) office known as the Office for Human Research Protection (OHRP) is responsible for the oversight of compliance by WU, and all other federally-funded institutions, engaging in human-subject research studies.[8] The OHRP requires that such institutions and facilities comply with the federal regulations set forth at 45 C.F.R. Part 46, a.k.a. "The Common Rule".[9] Among other things, the Common Rule requires every institution conducting and/or sponsoring human-subject research to create and maintain an institutional review board a.k.a. IRB. 45 C.F.R. 46.103. "An IRB shall review and have authority to approve, require modifications, in (to secure approval), or disapprove all research activities covered by this policy." 45 C.F.R. 46.109(a). "An IRB shall require that information given to subjects as part of informed consent is in accordance with Sec.

[8]Prior to 1999, this office was known as the Office for Protection from Research Risks (OPRR).

[9]See Attachment A - 45 C.F.R. Part 46, Subpart A.

46.116." 45 C.F.R. 46.109(b). The IRB relevant to the GU Biorepository is known as the Human Studies Committee a.k.a. HSC.

The federal regulations also require WU to provide written assurance to the OHRP of its compliance with the Common Rule. 45 C.F.R. 46.103(a). Such "assurance" should include "(1) a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself"; (2) the designation of one or more IRBs established in accordance with the requirements of this policy; (3) a list of IRB members; and (4) "[w]ritten procedures which the IRB will follow (I) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject." 45 C.F.R. 46.103(b)(1)-(4).

In compliance with the federal regulations, as stated before, WU has created and maintained an IRB known as the HSC. The HSC has created and maintained a written document entitled **Policies/Procedures for Protection of Human Research Subjects.** Catalona Exhibit O. The HSC has also created and maintained a written document entitled **Washington**

University School of Medicine - Human Studies Committee - Standard Operating Procedures. Catalona Exhibit P. Finally, the DHHS has approved the relevant Multiple Project Assurance submitted by WU. Catalona Exhibit I.

The Common Rule also sets forth certain requirements for informed consent. 45 C.F.R. 46.116. Foremost, the Common Rule requires that:

> "Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence."

Among the basic elements to be included in an informed consent are:

> "(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

45 C.F.R. 46.116(a)(8).

Additional elements of informed consent, when appropriate, may include:

> "(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject; . . ."

45 C.F.R. 46.116(b)(4).

The federal regulations do not elaborate as to what is involved when a RP "discontinue[s] participation" and/or "withdraw[s] from the research". The federal regulations do not address the matter of a RP's "right" to physically possess their samples upon termination of their participation in a research study; or, a "right" to direct their sample[s] transfer to another institution or Principal Investigator.

The OHRP publishes a guidance document addressing the issue of prohibited exculpatory language in informed consent forms. Catalona Exhibit Q. This document was the result of a 1996 Cooperative Oncology Chairperson Group meeting. The guidance document provides examples of "exculpatory language" that should not be considered for use in informed consent forms pursuant to 45 C.F.R. 46.116. One of the examples given states: "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." These examples are not listed anywhere or referred to anywhere in the relevant federal regulations.

Finally, 45 C.F.R. 46.117 requires that informed consent be documented as follows:

> "(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form."
>
> (b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:
>
> (1) A written consent document that embodies the elements of informed consent required by §46.116."
> **(remainder of paragraph omitted)**

As of the date(s) of the hearing, no regulatory agency, including the OHRP, has taken any action against WU regarding the informed consent forms used during the relevant time-period.

If a RP chooses to discontinue participation, federal and state regulations govern the options WU has regarding the tissue/blood/DNA sample. The undisputed testimony was that 1) WU may destroy samples it no longer needs for research; 2) store the samples indefinitely; and/or 3) choose to "anonymize" the samples and continue to use them in certain areas of research[10]. Furthermore, if a prostate cancer surgical patient elects not to participate in research at the time of his prostate surgery, that portion of the diseased tissue not needed for clinical use must, in accordance with federal and state regulations, be treated as hazardous medical waste and prohibit returning the excised tissue to the patient. 29 C.F.R. §1910.1030 (bloodborne pathogens); §§260.200 R.S.Mo., 260.203 R.S.Mo. (infectious waste disposal); 10 C.S.R. §80-7.101 (infectious waste management).

In early 2003, Dr. Catalona left WU for Northwestern University in Chicago, Illinois. He intended to continue his research in the area of prostate cancer. In connection with his anticipated departure and continuation of his research at Northwestern University; on or about February 18, 2003, he sent a letter to all research participants, whether or not they had been his patients, who had participated in his research protocols at WU. Catalona Exhibit HH. This letter informed these RPs of his departure from WU on or about February 24, 2003, of his continued availability for consultation and/or treatment, and his continuation for prostate cancer research. The letter was also included in a newsletter known as **"Quest"**, published quarterly by the Urological Research Foundation, of which Dr. Catalona was the Medical Director. Dr. Catalona testified that he believed that approximately 60,000 people received his February 18th letter either directly or via the Quest newsletter. Tr.2:32-33.

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[10]To "anonymize" a sample, all links to the RP's personal identifying data is removed and the sample is no longer "linked" to a particular RP.

In apprising the recipients of the letter of his intention to continue his prostate cancer research, Dr. Catalona stated "[T]o succeed in these goals, I need to have the tissue and blood samples that patients, their relatives, and other research volunteers have contributed to me over the years. You have entrusted me with samples, and I have used them for collaborative research that will help in your future medical care and in the care of others for years to come." Attached to the February 18th letter was a "Medical Consent& Authorization" form stating:

> "I have donated a tissue and/or blood sample for Dr. William J. Catalona's research studies. Please release all of my samples to Dr. Catalona at Northwestern University upon his request. I have entrusted these samples to Dr. Catalona to be used only at his direction and with his express consent for research projects."

The letter asks the recipient of the letter to sign this "authorization for release" form and return it promptly to Dr. Catalona. Catalona Exhibit HH. Approximately 6000 recipients signed the form and returned it to Dr. Catalona. Tr.1:61; Tr.1:101; Catalona Exhibit JJJJ.

At the time that Dr. Catalona sent the February 18, 2003 letter and release form, he was still an employee of WU. Furthermore, he was no longer the Principal Investigator on any of the research protocols involving the samples he sought to have transferred to Northwestern University. He had transferred the role of Principal Investigator on his remaining active research protocols to another WU faculty member/researcher, Dr. Brian K. Suarez. Plaintiff's Exhibit 29. The letter and release form was sent by Dr. Catalona without prior approval of any WU administrators or the approval of the HSC. At the time he sent the letter and release form, Dr. Catalona did not have any approved research protocol at Northwestern University nor had he obtained the approval of the Northwestern University IRB prior to sending the letter and release form.

In 2002 WU formed a Peer Review Panel to consider requests from researchers, both within WU and outside of WU, to obtain and use biological samples from the GU Biorepository. Prior to leaving WU, Dr. Catalona had submitted three (3) such requests, and all three (3) have been approved and the requested biological materials provided to him for his research. As of the date of the hearing, Dr. Catalona had not made any additional requests for biological materials from the GU Biorepository to the Peer Review Panel for consideration.

Conclusions of Law

As stated previously, the sole issue determinative of this permanent injunction; in fact of this lawsuit; is the issue of ownership. That is, once having made voluntary donations of biological materials for medical research to a research institution, do the research participants retain ownership rights in such materials in that they can direct said materials' use and transfer to third-parties. WU argues that the RPs made voluntary donations; i.e. gifts, of biological materials and once these "gifts" were delivered to WU, WU became the sole owner with control as to use and storage (pursuant to applicable federal and state regulations). Dr. Catalona and the RPs argue that the RPs had donated their biological materials with the "intent" that such materials stay with Dr. Catalona for his research.[11] The RPs believe that they have retained ownership rights in their donated biological materials and can withdraw said materials and have them transferred to Dr. Catalona and/or Northwestern University via their discontinuation of participation in any research at WU and their signing of Dr. Catalona's consent form.

Missouri law governs the substantive issues of ownership and "gift/donation". It is well-settled that exclusive possession and control of personal property is *prima facie* evidence of

[11]It is undisputed by all the parties, and previously held by this Court, that Dr. Catalona has abandoned any legal argument as to his personal ownership of the subject biological materials.

ownership, and anyone else claiming such property bears the burden of proof. Foltz v. Pipes, 800 S.W.2d. 14, 15 (Mo.App. 1990); State v. Patchen, 652 S.W.2d. 265, 267 (Mo.App. 1983). The burden by the non-possessor asserting an ownership interest is met only by a preponderance of the evidence. Foltz, at 15; Patchen, at 267.

It is undisputed that at all times WU has been in exclusive possession of the subject biological materials. WU has supplied all facilities housing the GU Biorepository. WU personnel has consistently maintained and administered the GU Biorepository. Although some funding of the GU Biorepository has been provided through Dr. Catalona's efforts, it was done so via his position at WU. The majority of funding for the GU Biorepository has been through the financial reserves of the Urology Division of the WU Medical School. It is undisputed that Dr. Catalona had access to the subject materials, but so did other researchers, both inside and outside of WU. Furthermore, such access was only through the IRB and HSC of WU. There was no evidence provided to this Court that any RP had access to his or her biological materials once such materials were made a part of the GU Biorepository.

WU had exclusive control over the subject biomaterials. As stated before, WU is solely responsible for deciding who can have access to the GU Repository and the use for such biomaterials. Even as Chief of the Urology Division, any decisions made by Dr. Catalona were made as a WU employee. WU alone bears all legal, regulatory, and compliance risks with respect to all research done in connection with the GU Biorepository. WU is a federally approved and regulated institution for the carrying out of human-subject research, for which the Biorepository was established. As such, it is continually responsible for ensuring that the GU Biorepository meets all necessary requirements; and does this through audits and substantial internal compliance programs. Due to the nature of the GU Biorepository, WU is subject to

federal and state laws and regulations governing the disposal and storage of human biological matter, and it alone is responsible for compliance with such laws and regulations. There was no evidence presented to this Court that any RP is equally responsible for the control of the use of these materials in human-subject research.

WU has continually asserted its ownership interests in the materials stored in the GU Biorepository. Its Intellectual Property Policy[12], in existence prior to this dispute arising, states that tangible research property, including biological materials, belong to WU if significant university resources were used or such property was obtained pursuant to a research project funded by an external sponsor administered by WU. Furthermore, in all MTAs concerning these materials, including those wherein Dr. Catalona was the "Provider's Scientist", WU clearly exerted its ownership interest without objection by Dr. Catalona.[13] Even in the instance wherein Dr. Catalona attempted to change the language of a MTA to reflect "co-ownership" with WU, and WU refused to modify the language in the MTA, Dr. Catalona still signed.[14]

There is little dispute as to the scarcity of legal precedent to assist the Court in addressing the situation that presently stands before the Court. The two (2) cases which provide the most guidance concluded that research participants retain no ownership of biological materials they contribute for medical research.[15] Greenberg, et. al. v. Miami Children's Hospital Research

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[12]Plaintiff's Exhibit 17.

[13]Eg. Plaintiff's Exhibit 14 - MTA dated June 1, 2001 between WU and the University of Cincinnati.

[14]Albeit Dr. Catalona testified that he felt he had no choice but to sign; yet still felt he had proprietary interest in the subject biological materials, the Court finds that the document speaks for itself.

[15]Dr. Catalona and the patients/defendants have cited several other cases which the Court has reviewed and finds inapplicable. These cases involved sperm donation, possession of a dead body, and tax liability for donated blood, among other issues. None of the cases cited by Dr.

Institute, Inc., et. al., 264 F.Supp. 1064 (S.D.Fla. 2003); Moore v. The Regents of the University of California, et. al., 51 Cal.3d. 120, 793 P.2d. 479, 271 Cal.Rptr. 146 (CA. 1990).

In Greenberg, *supra.*, donors of human tissue and fluids (among others) sued the physician who received the biological materials, used them to isolate the gene causing Canavan disease, and then obtained patent and attempted to license the patent. The plaintiff donors claimed, among other things, that they had a property interest in their excised body tissue and in the genetic information extracted from such tissue; as well as the registry which contained the donors' personal and genetic information. They asserted that the defendant(s) had "converted" such information for the defendant(s)' own exclusive economic benefit. Id., at 1074. The Court held that it "disagrees and declines to find a property interest for the body tissue and genetic information voluntarily given to Defendants. These were donations to research without any contemporaneous expectations of return of the body tissue and genetic samples, and thus conversion does not lie as a cause of action." Id., at 1074.

After recognizing that a claim of conversion was first predicated upon an ownership interest, the Florida district court, in adopting the reasoning of the Moore case, found that the plaintiff donors had no cognizable property interest in body tissue and genetic matter donated for medical research. Greenberg, at 1074. After reviewing Florida state court opinions regarding property rights and body tissue, as well as Florida statutes regarding genetic materials, the Florida district court found that "the property right in blood and tissue samples also evaporates once the sample is voluntarily given to a third party." Id., at 1075. It refused to recognize a claim of

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Catalona and/or the patients/defendants involved the donation of biological materials for **medical research**.

conversion because the blood and body tissue were "voluntary donations to medical research" and were donated "without any contemporaneous expectations of return." Id., at 1075-76.

In Moore, *supra.*, a patient undergoing treatment for hairy-cell leukemia had portions of his removed spleen, and samples of his blood, blood serum, skin, bone marrow aspirate and sperm utilized in medical research without his knowledge and/or consent. This research resulted in a cell line which was patented by the defendants. The defendants ultimately entered into commercial agreements for the commercial development of the cell line and the resulting products. The patient plaintiff brought suit alleging conversion and breach of physician's disclosure obligations. As for his conversion claim,

> "[H]e theorizes that he continued to own his cells following their removal from his body, at least for the purpose of directing their use, and that he never consented to their use in potentially lucrative medical research. Thus, to complete Moore's argument, defendants' unauthorized use of his cells constitutes a conversion. As a result of the alleged conversion, Moore claims a proprietary interest in each of the products that any of the defendants might ever create from his cells or the patented cell line."

Id., at 134-35.[16]

The California Supreme Court did an exhaustive review of the law relating to the ownership and use of human biological materials. Having noted that Moore could not reasonably expect to retain possession of his excised cells, his claim for conversion had to rest upon retaining an ownership interest in them; however, the Court could find no reported judicial decision which would support a finding that he retained such an interest. Id., at 136-37. Instead the Court found that the laws governing human tissues, blood, and other biological materials were better suited, than court cases dealing with the law of conversion, to deal with regulating

[16]For judicial economy and clarity, the Court will short cite to the California 3rd Reporter.

their disposition. Id., at 137. "It is these specialized statutes, not the law of conversion, to which courts ordinarily should and do look for guidance on the disposition of human biological materials." Id., at 137. One of the things making Moore's ownership claim "problematic" for the California Supreme Court was California's statutory law which severely limits a patient's control over excised cells. Essentially, California's laws negate any ownership rights a patient may have to excised cells since such biological materials are considered to be potentially hazardous biological waste materials and have to be disposed by a method approved by the state to protect the public health and safety. Id., at 140. Ultimately, the California Supreme Court refused to bestow ownership rights to the patient/plaintiff for several reasons, including that it felt that even if a patient had "some limited right to control use of excised cells" such a "right" is already protected because "[A] fully informed patient may always withhold consent to treatment by a physician whose research plans the patient does not approve." Id., at 141.

Both the Greenberg and the Moore cases found the research participant to be a "donor" who had parted with any semblance of ownership rights once their biological materials had been excised for medical research. Both courts reviewed relevant caselaw, addressed policy considerations, and addressed the implications of applicable federal and/or state laws dealing with biological materials. The Court finds their analysis to be persuasive, and in light of its own review of applicable Missouri law, finds that WU has met its burden in establishing ownership of the subject materials and that the RPs have not put forth adequate evidence to challenge WU's ownership claim.

Furthermore, the Court finds that the RPs are "donors" and the subject biological materials constitute an *inter vivos* gift. The elements of an *inter vivos* gift are: 1) present intention of the donor to make a gift; 2) delivery of property by donor to donee; and 3)

acceptance by donee whose ownership takes effect immediately and absolutely. In re Herman Jerome True, 285 B.R. 405, 413-14 (Bankrpcy Ct., W.D.Mo. 2002); Wantuck v. United Savings and Loan Assn., 461 S.W.2d. 692, 694 (Mo. 1971); In the Estate of Mary F. Campbell, 939 S.W.2d. 558, 562 (Mo.App. 1997); Duvall v. Henke, 749 S.W.2d. 714, 716 (Mo.App. 1988). The person claiming that the gift exists has the burden of proving it with clear, cogent and convincing evidence. In re Herman Jerome True, at 414; In the Estate of Mary F. Campbell, at 562; Duvall, at 716.

"Specific language is not required to reflect present intent to make a gift on the part of donor." Duvall, at 716. The circumstances surrounding the donation can create an inference that the donor had the present intent to make the *inter vivos* gift to the donee. Duvall, at 716. In fact, "[c]onduct can be an enlightening ingredient in discerning intent." In the Estate of Mary F. Campbell, at 562.

The RPs all signed informed consent forms that clearly stated that they were agreeing to participate in medical research studies at WU. Tr.2:10. Many of the RPs were patients of WU doctors other than Dr. Catalona. Tr.1:83 Many of the RPs donated biological materials for research protocols having someone other than Dr. Catalona as the Principal Investigator. Plaintiff's Exhibits 56, 57, 58, 59; Tr.1:80-82; Tr.2:94-97. The informed consent forms typically bore the WU Medical Center logo. The informed consent forms stated that they were not valid without the stamp of approval of the WU Human Studies Committee. The forms advised the RPs that they could contact the Chairman of the WU Human Studies Committee with any concerns. The forms advised the participants what WU would do to protect their privacy and minimize the burdens of participating in the study.

Nowhere in the forms were RPs advised that they were entrusting their samples to Dr. Catalona only. In fact, in those research protocols wherein Dr. Catalona was the Principal Investigator, the forms merely stated: "You are invited to participate in a research study conducted by Dr. William J. Catalona and/or colleagues." Plaintiff's Exhibits 27, 61, 98; Catalona Exhibits UUU (McGurk and Ellis informed consent forms); Patients' Exhibit 1 - Ward informed consent form.

The Court finds that the RPs had the present intent to make *inter vivos* gifts; i.e. donations of their biological materials to WU for medical research.

Furthermore, the Court finds that for the reasons stated in establishing WU's ownership of the subject biological materials, WU took delivery of these materials and its acceptance of said materials immediately and absolutely effectuated WU's ownership of these materials.

Dr. Catalona and the RPs challenge WU's ownership rights by asserting the following grounds: 1) that no gift was made because of "exculpatory language" in the informed consent forms; 2) no gift was made to WU because the RPs "intended" for their samples to go with Dr. Catalona wherever he may go to conduct research; 3) that the RPs have retained their ownership rights to their excised biological materials because their "right to discontinue participation" includes a "right to control the samples' use" and a "right to transfer their samples" to a specific person or entity; 4) that the informed consents are invalid as being violative of certain ethical documents regarding human-subject research; and 5) the RPs made a bailment of their biological materials, not an *inter vivos* gift to WU. The Court has carefully reviewed each of these arguments and finds them meritless.

As stated before, an *inter vivos* gift only requires donative intent, delivery, and acceptance. There is no requirement that the gift be made pursuant to any written document.

See, Ridenour v. Duncan, 246 S.W.2d. 765, 769 (Mo. 1952)("Language, written or spoken, expressing an intention to give does not constitute a gift unless the intention is executed by a complete and unconditional delivery of the subject matter or a delivery of a proper written instrument evidencing the gift."); In re Estate of Gladys Piper, 676 S.W.2d. 897, 899 (Mo.App. 1984)(*citing* Ridenour, *supra.*). Since delivery of the subject biological materials was made and accepted by WU, the existence of the informed consent forms in inconsequential.

However, because of the nature of the gift, federal regulations require some form of informed consent. Dr. Catalona and the RPs argue that the presence of "exculpatory language" invalidates the informed consents and therefore, negates the gifts. In support of this argument, they point to the OPRR guidance document (Defendant's Exhibit Q). As this Court has already determined, this document is not legally-binding upon WU. It merely presents an opinion by the OPRR regarding exculpatory language in informed consent forms and provides examples. These examples are not found in any of the federal regulations governing the GU Biorepository.

The governing federal regulation (as to informed consent), 45 C.F.R. §46.116, only prohibits exculpatory language in the form of a waiver or release from liability.

> "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."

It is clear that the only legal obligation WU had was not to include exculpatory language in its informed consent forms which waived any legal rights the RP may have or relieve any party from liability for negligence. Hearing testimony from all experts indicated that the research community consistently understood 45 C.F.R. §46.116 to bar exculpatory language involving releases from malpractice or other negligence. The OPRR's opinion as to exculpatory language

does not govern the informed consents and therefore, does not affect the ownership interest of WU in the materials stored in the GU Biorepository.

Next, Dr. Catalona and the RPs argue that the RPs never intended for WU to have ownership rights to the donated biological materials; i.e. that their intent was to retain such rights and continue to exercise their ownership rights as to the use and location of their excised biological materials.

As stated earlier, one of the elements of a gift is **present** donative intent. Present donative intent is assessed by determining if a gift was intended at the time of the initial transaction. Michaelson v. Wolf, 261 S.W.2d. 918, 925 (Mo. 1953). A completed *inter vivos* gift cannot be revoked by the donor once the gift is delivered and accepted by the donee. Clippard v. Pfefferkorn, 168 S.W.3d. 616, 619 (Mo.App. 2005); Donnelly v. Donnelly, 951 S.W.2d. 650, 653 (Mo.App. 1997). "An afterthought of regret does not nullify the passage of title by a delivery and made by the grantor." LeMehaute, et. al. v. LeMehaute, 585 S.W.2d. 276, 281 (Mo.App. 1979).

The Court finds that the RPs had the present intent to donate their biological materials to WU to be maintained in the GU Repository. The informed consent forms repeatedly asserted WU's ownership of the donated materials and only listed Dr. Catalona as the Principal Investigator. Although the Court respects the testimony given by Messrs. Ward, Ellis, and McGurk, it was clear that these gentlemen all had a deep personal connection to Dr. Catalona, and believed that they owed their lives to him. The Court understands and appreciates these feelings but their testimony regarding intent, especially now after getting Dr. Catalona's letter, is suspect or at least, shows nothing more than an "afterthought of regret". There was no testimony by any of these gentlemen that they did not read nor understand the informed consent forms prior

to signing. The forms spoke of "donation" and at least two (2) forms (Ward and McGurk) referenced a waiver of any claim to the excised body tissues. Since Ward, Ellis, and McGurk were presumably testifying on behalf of the eight (8) patients who joined the case, and reflect the opinion of all RPs who signed Dr. Catalona's "consent to transfer" form, the Court finds that all RPs who donated biological materials to the GU Repository, whether or not patients of Dr. Catalona, donated such materials with the present intent of making an *inter vivos* gift to WU.

Next, Dr. Catalona and the RPs argue that the RPs right to discontinue participation includes the right to continue control over the use and location of their excised biological materials. There is nothing stated in the governing federal regulations which equates a right to discontinue participation with a right to control the disposition and use of the excised biological materials. The relevant testimony at the hearing indicated that only three (3) things happen when a RP chooses to "discontinue participation": 1) WU may destroy the sample; 2) WU may store the sample indefinitely without any further use; or 3) WU may remove all identifying markers and use the sample in exempt "anonymized" research. Dr. Goodman and Dr. Clayton both agreed that research samples can be destroyed even without approval of the RP; and in fact, Dr. Catalona has done this on several occasions. No one questioned WU's ability to simply store the samples indefinitely after a RP discontinues participation in a research project. Finally, Drs. Ludbrook and Prentice both testified that anonymization is a response available to WU when a RP chooses to discontinue participation in research.[17]

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[17]Although not particularly relevant to the matter at hand, the Court does note that even Dr. Catalona, as a researcher at Northwestern University, testified that he is using informed consent forms which only state two (2) options upon a RP's decision to withdraw participation: 1) destruction of the sample or 2) anonymization of the sample. Northwestern University's consent form interestingly does not provide the third option advocated by Dr. Catalona and the RPs; i.e. return of the sample to the RP or transfer of the sample to a location chosen by the RP.

The Court finds that the right to discontinue participation in a research project means nothing more that the RP has chosen not to provide any more biological materials pursuant to one or more research protocols; i.e., not to make any more *inter vivos* gifts of donated biological materials to WU. Nothing more can or should be read into this right possessed by the RPs at all times.

Next, Dr. Catalona and the RPs argue that WU's refusal to transfer the donated biological materials violates the Belmont Report, the Declaration of Helsinki, and the Nuremberg Code. The Belmont Report is the 1979 report of a Presidential Commission that summarizes the basic ethical principles underlying the conduct of biomedical and behavioral human subject research. Defendant's Exhibit MMMM. The Declaration of Helsinki is a statement of ethical principles to provide guidance to physicians in connection with human subject research. Defendant's Exhibit NNNN. The Nuremberg Code, developed as a result of the war criminal trials before the Nuremberg Military Tribunals following World War II, and in response to the human experimentation experiments of Nazi Germany, similarly deals with ethical principles governing human subject research. Defendant's Exhibit OOOO. All of these documents set forth international ethical principles relating to human subject research.

Although WU does have an agreement with DHHS to be guided by the ethical principles in the Belmont Report[18], said agreement fails to provide a basis for the claims of Dr. Catalona and/or the RPs wishing to transfer their samples (including the eight patients who are parties to this lawsuit) because they are not parties to or the third-party beneficiaries of this government contract. They have no private cause of action to enforce the terms of the contract. *See*, Wright v. Fred Hutchinson Cancer Research Center, 269 F.Supp.2d. 1286, 1290 (W.D.Wash. 2002).

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[18]Defendant's Exhibit I.

Furthermore, the Court finds that Dr. Catalona and the RPs have failed to make an adequate showing that the refusal of WU to transfer the subject samples constitutes a violation of the DHHS Assurance Contract; and therefore, a violation of the Belmont Report.

There is no private right of action for an alleged violation of international law for the protection of human research subjects based upon the Declaration of Helsinki and the Nuremberg Code. White v. Paulsen, 997 F.Supp. 1380, 1383 (E.D.Wash. 1998); Hoover v. West Virginia Dept. of Health and Human Services, 984 F.Supp. 978, 980 (S.D.W.Va. 1997) *aff'd* 129 F.3d. 1259 (4th Cir. 1997); *see also*, Abdullahi, et. al. v. Pfizer, Inc., 2005 WL 1870811 (S.D.N.Y. 2005)[19]. Furthermore, this Court agrees with the conclusions reached by its fellow district courts in Michigan and Oklahoma that the standard in the United States for conducting research on human subjects is contained in the Code of Federal Regulations and therefore United States federal courts have no need to resort to international law to impute a standard. Ammend v. Biopart, Inc., 322 F.Supp.2d. 848, 872-73 (W.D.Wash. 2004); Robertson v. McGee, 2002 WL 535045 (N.D. Okla 2002).

Finally, Dr. Catalona and the RPs assert that the RPs did not make a "gift" of the subject biological materials but instead made a "bailment" and that WU stands only in the position as a bailee.[20] This argument fails for the simple reason that when a "gift" is made, the giftor/donor has no expectation of getting the "gift" back; however, when a "bailment" is made, the bailor has

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[19]Although it is not this Court's common practice to cite to unpublished opinions, it will do so in the rare instance wherein such opinion offers guidance helpful to this Court on a particular issue.

[20]Actually, Dr. Catalona and the RPs assert an "implied bailment". "A contract for bailment may be written, oral, express, or implied." D.S. Sifers Corp. v. Hallak, et. al., 46 S.W.3d. 11, 16 (Mo.App. 2001) *quoting* Stone v. Crown Diversified Indus. Corp., 9 S.w.3d. 659, 669 (Mo.App. 1999).

every expectation of receiving back the subject of the bailment. A bailment is made on the condition that the property (after delivery by bailor and acceptance by bailee) be restored to the bailor according to his/her directions as soon as the purpose for the bailment ceases. Seitz v. Lemay Bank & Trust Co., 959 S.W.2d. 458, 461 (Mo. 1998); Stone v. Crown Diversified Indus. Corp., at 669. There was no evidence presented to this Court that any of the RPs, including the three (e) RPs that testified, had ever informed WU, at the time of "delivery" of the subject biological materials that they wanted the samples returned to them. Furthermore, the RPs could not have had a reasonable expectation of restoration of the subject biological materials to them because applicable federal and state regulations governing the disposal of medical waste prohibit the return of such biological materials to the RPs. *See*, 29 C.F.R. §1910.1030; §§ 260.200, 260.203 R.S.Mo.; 10 C.S.R. §80-7.010.

Finally, the medical research community itself has never considered the relationship between an RP and a medical research institution to be one of bailment. All the experts testified that they knew of no instance wherein a research participant had his/her samples returned to them. Even Dr. Catalona testified that he could only recall one or two instances wherein a biological sample had been returned to a patient, for clinical purposes.[21] The Court finds that no implied bailment existed, at any time, in connection with any RP, as to the samples stored in the GU Repository between an RP and WU.

In connection with their argument that the RPs "own" their excised biological materials and can transfer them to any institution or person of their choosing, Dr. Catalona advances the notion that his letter and "Medical Consent and Authorization" form allegedly signed by

[21]Dr. Catalona's testimony was that out of approximately 40,000 research participants he had one or two who requested their samples back and the samples were processed and actually sent to a clinical laboratory (of the RP's choosing), not the RP's home. Tr.2:16-17.

approximately 6000 RPs effectively legally carries out the RPs' "right to discontinue participation". However, one views this document(s), it in no way provides a legal vehicle by which any RP can "discontinue participation" in any research protocol at WU.

Every expert and even Dr. Catalona testified that the letter/form did not constitute "informed consent" pursuant to the applicable federal regulations. It was never submitted to any IRB, either at WU or Northwestern University, for prior approval. Contrary to Dr. Catalona's opinion, the Court finds that his communication to the RPs was a "change" to his research protocols. He was no longer the Principal Investigator on any of the studies involving the samples he sought to have transferred; he was no longer an employee of WU nor continuing to conduct his research at WU, and Northwestern University (at that time) had not approved any "new" research protocols for him which would involve use of the biological materials he wanted transferred. Furthermore, the context in which this form was sent is troubling to the Court. He sent it to RPs, many of whom were his patients and emotionally tied to him, advising them of his move, of his desire to continue his consultation/treatment practice, and then describing his need to use these samples to further his help to them. Such a communication smacks of undue influence. Quite simply, the letter and form did not act in any legal authoritative manner to effectuate a transfer of the subject biological materials as part of a RP's right to discontinue participation.

As a final note, the Court wishes to address the possible (if not, probable) public policy ramifications of Dr. Catalona and the RP's position. The amicus brief filed by the Association of American Medical Colleges[22] succinctly mirrors the Court's concerns. Currently, these materials are housed and maintained by institutions federally and state regulated. A "check and balance"

[22]Document #106, filed April 6, 2006.

system is in place to monitor the research being conducted using these materials. The safety and welfare of human subject participants is protected through a variety of legal and professional standards administered by committees of persons schooled in the fields most privy to the needs of the medical/science community. Medical research can only advance if access to these materials to the scientific community is not thwarted by private agendas. If left unregulated and to the whims of a RP, these highly-prized biological materials would become nothing more than chattel going to the highest bidder. It would no longer be a question of the importance of the research protocol to public health, but rather who can pay the most. Selling excised tissue or DNA on E-Bay would become as commonplace as selling your old television on E-Bay. The integrity and utility of all biorepositories would be seriously threatened if RPs could move their samples from institution to institution any time they wanted. No longer could research protocols rely on aggregate collections since individual samples would come and go. Accountability would no longer exist since institutions would merely be warehouses filling purchase orders.

More alarming is the great potential for prejudicial influences into medical research. Allowing an RP to choose who can have the sample, where the sample will be stored, and/or how the sample can be used is tantamount to a blood donor being able to dictate that his/her blood can only be transfused into a person of a certain ethnic background, or a donated kidney being transplanted only into a woman or man. This kind of "selectiveness" is repugnant to any ethical code which promotes medical research to help all of mankind.

Accordingly, the Court finds that 1) defendants; i.e. Dr. William Catalona and the eight (8) research participants who are parties to this action, have failed to demonstrate that they are entitled to any injunctive relief; 2) that plaintiff Washington University owns all biological materials, including but not limited to blood, tissue, and DNA samples, in the GU Repository; 3)

that neither Dr. William Catalona nor any research participant in connection with any research protocol conducted under the auspices of Washington University has any ownership or proprietary interest in the biological samples housed in the GU Repository; and 4) that the "Medical Consent & Authorization" forms authored by Dr. William Catalona and either directly or indirectly delivered to any research participant and signed by any research participant are void and ineffective to transfer ownership and/or possession of any biological samples housed in the GU Repository to Dr. William Catalona, Northwestern University, any other research facility/institution, or any or all research participants.[23]

Dated this 31st day of March, 2006.

Stephen N. Limbaugh

SENIOR UNITED STATES DISTRICT JUDGE

[23]Nothing in this opinion or the Court's ultimate findings shall be construed to prohibit Dr. William Catalona from seeking said samples through the ordinary and regular channels normally available to any medical researcher requesting approval of a research protocol from WU.