UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

THE WASHINGTON UNIVERSITY	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 4:03-CV-01065 SNL
	)	
WILLIAM J. CATALONA, M.D., et al.	)	
	)	
Defendants.	)	

PLAINTIFF'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

Plaintiff Washington University hereby submits the following proposed findings of fact and conclusions of law in connection with defendant Catalona's motion for permanent injunction.

Findings Of Fact

1. Plaintiff Washington University is a Missouri not-for-profit corporation with its principal place of business in St. Louis, Missouri. Washington University has a Medical School that includes a Department of Surgery and a Division of Urologic Surgery.

2. Defendant William J. Catalona, M.D. is a citizen of Illinois. He was employed at the Washington University Medical School from 1976 to 2003. Dr. Catalona was Chief of the Urology Division from 1984 to 1998 (Tr. 1:32, 70-71). In late February 2003, he left Washington University to accept a position at Northwestern University in Chicago (Tr. 1:56).

3. Defendants Richard Ward, Thomas McGurk, Luis Garcia, Antonio Castro, Phillip Wilard, Ivan Parson, James Ellis, and Michael Missios were patients of Dr. Catalona's and participants in one or more research projects at Washington University in which Dr.

Catalona was involved. The Court granted these patient defendants leave to join in as additional defendants on March 14, 2005. The patient defendants are citizens of the following states: Florida (Garcia, Castro, Parson), Kansas (Ward), Indiana (McGurk), Colorado (Wilard), Texas (Ellis), and Alabama (Missios).

4. Dr. Catalona is a well-known urologic surgeon with an interest in prostate cancer research. In or about 1983, while employed at Washington University, he began collecting tissue and blood samples for such research (Tr. 1:33). He did so as one of many physicians within the Urology Division who contributed to that effort. The Washington University Urology Division has nineteen faculty members, two fellows, twelve residents and approximately 100 supporting personnel (Tr. 2:86-87). Although Dr. Catalona was named Principal Investigator on some of the prostate cancer studies undertaken within the Urology Division, other doctors in that Division were Principal Investigators on other such studies (Pl. Exs. 56, 57, 58, 59; Tr. 1:80-82; 2:94-97).

5. Dr. Catalona had co-investigators on studies in which he was the Principal Investigator, and many persons other than Dr. Catalona made significant contributions to the research. Virtually all of the scientific research in which Dr. Catalona was involved was done in a collaborative way and was a team effort involving substantial work by many, including co-investigators and clinicians (Pl. Ex. 3, 75; Tr. 1:74; 2:4-8; 2:88). Other faculty members co-authored papers with Dr. Catalona (Tr. 2:7) or have authored such papers individually (Tr. 2:86). At Dr. Catalona's request and encouragement to his Washington University faculty colleagues in the Urology Division, their patients contributed biological specimens for prostate cancer research (Tr. 1:92; 2:97). The resulting collection of prostate tissue, blood, and DNA samples at issue in this case is referred to as the GU Biorepository.

6. There are approximately 3,500 prostate tissue samples in the GU Biorepository. Tissue samples came from patients of Dr. Catalona and from patients of other Washington University physicians within the Division (Tr. 1:82-83).

7. There are more than 100,000 serum samples in the GU Biorepository taken from approximately 28,000 men (Tr. 1:83). Approximately 75% of those who contributed serum samples to the GU Biorepository were not patients of any Washington University doctor (including Dr. Catalona) but were instead volunteers recruited through notices in the St. Louis media (Tr. 1:70, 1:86; 2:91).

8. Approximately 4,400 men contributed DNA samples to the GU Biorepository. Some were patients of different faculty members at Washington University while others were siblings or other relatives of such patients (Tr. 2:91-92). Washington University faculty members other than Dr. Catalona had been Principal Investigators for the study in which the DNA samples were contributed (Tr. 1:89).

9. In total, there were more than 30,000 research participants enrolled in the prostate cancer research studies. About 2,500 to 3,000 of these participants had been patients of Dr. Catalona (Tr. 1:69-70; 1:85).

10. All of the research that Dr. Catalona did and all of his efforts to collect samples for the GU Biorepository were undertaken as an employee of Washington University (Tr. 1:78-79). Washington University paid all his salary, benefits, and liability insurance premiums (*Id.*). Dr. Catalona practiced medicine and conducted research solely as a Washington University employee (*Id.*).

11. At all times, the GU Biorepository has been housed in one or more buildings owned by Washington University (Tr. 1:79 1:87; 2:90). At all times, Washington

University employees have administered the GU Biorepository (Tr. 1:80). Washington University faculty members conducted a variety of research protocols using the samples (Pl. Exs. 55, 57, 58).

12. Washington University itself has provided most of the funding to maintain and operate the GU Biorepository (Tr. 2:99-100). The external funding that was obtained came in the form of public and private grants made to and administered by Washington University as the grantee (Pl. Exs. 54, 72, 73; Tr. 1:79-80; 2:100). It is a matter of policy at Washington University that "[t]he funding agency . . . awards funds *to the University* in the form of a grant, contract or cooperative agreement, for the investigator to conduct the project" (Pl. Ex. 54; Tr. 1:79). Although Dr. Catalona claims that he raised $3-4 million in outside funding for the GU Biorepository, he did so in his capacity as a WU faculty member. Moreover, Dr. Gerald Andriole, Dr. Catalona's successor as Urology Division Chief, has raised much more external funding for WU than did Dr. Catalona (Tr. 1:44-45; 2:86).

13. Washington University has certain policies that apply to its faculty members, such as Dr. Catalona. Washington University's Policies and Procedures expressly state: "Investigators who leave the University are prohibited from taking . . . blood or tissue samples . . . unless they have prior written approval from the Vice Chancellor for Research" (Deft's Ex. U; Patients Ex. 55).

14. Washington University'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" (Pl. Ex. 17; Tr. 1:102-03). The GU Biorepository was collected and has been maintained with

significant University resources, in the form of both internal Urology Division funds and grants provided to and administered by Washington University from external sponsors (Tr. 2:99-100).

15. A Material Transfer Agreement is a contract between two research institutions in which one party transfers material to the other for collaborative research purposes. As Principal Investigator on several studies for Washington University, Dr. Catalona personally signed at least seven such agreements in which he explicitly acknowledged Washington University as the owner of the biological samples at issue in this case (Tr. 1:04-05; 2:20-25, 27-28; Pl. Exs. 7, 8, 9, 10, 12, 13, 14). On the single occasion when Dr. Catalona sought to insert contract language conferring proprietary rights upon him, Washington University rejected his proposal, and Dr. Catalona nevertheless signed that Material Transfer Agreement (Tr. 2:25-27).

16. The research participants clearly intended at the time they provided their prostate tissue and blood samples to make a gift of those samples to Washington University for medical research.

17. The informed consent documents that the research participants signed indicated that the research participants were agreeing to provide their samples for medical research (*See e.g.,* Patient Ex. 4, 5; Tr. 1:164). By signing those documents, the research participants agreed to their terms.

18. The research participants agreed to participate in research studies at Washington University (Tr. 2:10). The informed consent documents typically bore the WU Medical Center logo (Pl. Exs. 27, 58, 59, 60, 61, 98; Patients' Exs. 4, 7, 10, 13, 19, 54 59, 60; Tr. 1:99). Those documents stated that they were not valid without the stamp of approval of the Washington University Human Studies Committee. *Id.* The informed consent forms advised the

participants that they could contact the Chairman of Washington University's Human Studies Committee with any concerns *(id.)*. They advised the participants what Washington University would do to protect their privacy and to minimize the burdens of participating in the study *(id.)*.

19. Delivery of the prostate tissue and blood samples by the research participants to Washington University occurred when the research participants authorized Washington University physicians to take and keep specimens of their prostate tissue or allowed nurses to take blood samples. Washington University's Urology Division has had possession of the samples since they were taken (Tr. 1:79, 1:87, 2:9). The research participants have not had possession of them since that time.

20. Washington University accepted the samples when its physicians and nurses collected them. It has kept the samples in the offices of the Urology Division (Tr. 1:79, 1:85) and has split some of the samples with the tissue procurement core of the Siteman Cancer Center, which is also part of the Washington University Medical School (Deft. Ex. FFFF). Washington University faculty members have conducted a variety of research protocols using the samples (Pl. Ex. 55, 57, 58).

21. Certain of Washington University's informed consent documents provide that a sample will be destroyed if a research participant discontinues participation in the study and requests destruction of his sample (Pl. Ex. 27; Deft's Exs. Y and Z; Tr. 1:51-52). Washington University, however, has the discretion to destroy a sample when a participant withdraws even if the consent form is silent on the matter (Tr. 1:135-36; 2:224).

22. While serving as Division Chief at WU, Dr. Catalona regularly ordered that blood samples contributed by research participants be purged from the GU Biorepository when there was insufficient storage capacity or when Dr. Catalona determined there was an

excess numbers of samples. He did so without ever seeking the consent of the research participants who had contributed those samples (Tr. 1:87-89). Defendants' own experts acknowledged that a research institution is free to destroy samples that it does not believe it needs for research (Tr. 1:135-37; 1:194). Moreover, research participants cannot prevent the consumption of an entire sample during research (Tr. 1:135). Similarly, after a research protocol is completed, the institution may destroy the samples without obtaining the consent of the research participants (Tr. 1:135-36).

23. Washington University also has the discretion to continue to store samples after a research participant discontinues participation in the research (Tr. 1:194; 2:164-65).

24. Washington University may also "anonymize" samples by removing all links to the participant's personal identifying information and continue to use them in research after a research participant elects to discontinue participation in research (Deft's Exs. B, C, D; Patients' Ex. 66; Tr. 2:164-65; 2:224). The Informed Consent form Dr. Catalona is now using at Northwestern University recognizes this and properly advises the research participants that: "If you withdraw your permission to use any blood or tissue obtained for the Study, the Principal Investigator will ensure that these specimens are destroyed or will ensure that all information that could identify you is removed from these specimens" (Pl. Ex. 16; Tr. 2:43-44). From time to time samples have been completely anonymized at Washington University (Pl. Ex. 93; Tr. 142-43).

25. All Washington University Informed Consents before the Court in this case properly advised the research participants that they may withdraw their consent at any time (Pl. Exs. 27, 56, 57, 58, 59, 61, 98; Deft's Exs. 4, EEE, UUU, JJJJJ; Patients' Exs. 1, 7, 10, 13, 16, 19, 22). None of the informed consent documents provided for or promised that Washington

University would return the samples to the research participant or transfer the samples at the research participant's direction (Tr. 2:174). No Informed Consent document utilized by Washington University provided that a research participant may have his physical sample removed from the research. Nothing in the applicable federal regulations set forth at 45 C.F.R. Part 46 refers to or purports to create any right of a research participant to remove samples or to re-direct samples from one researcher to another (Tr. 1:132-33; 2:222-24).

26. The research participants had no expectation that their tissue or blood samples would ever be returned to them (Tr. 1:34; 1:88-89; 2:78). Washington University Informed Consents described the research participants' conduct as a "donation" (Patients' Ex. 4, p.2; Tr. 1:164). No witness in this case was aware of any instance in which a research participant either requested that a sample be returned to him or has had a sample returned to him (Tr. 2:101-02; 2:166; 2:222). Nothing in the federal regulations allows research participants to have the physical samples removed (Tr. 2:222-24). Even Dr. Catalona could recall only one or two instances over the years where a research participant requested the transfer of his physical sample, and that was for clinical rather than research purposes (Tr. 2:16-17).

27. When a sample is used for clinical work rather than research, the Washington University Pathology Department typically analyzes and evaluates parts of it and discards the remainder. The "Consent For Surgery" form signed by the patient states that unused biological material will be discarded. Absent the informed consents authorizing use of the samples for medical research purposes, the tissue specimens at issue in this case would have been destroyed shortly after the surgical procedure had been completed (Tr. 2:17; 2:92-93).

28. Federal and state regulations prohibit the return of cancerous prostate tissue or human blood to research participants (Tr. 1:133). Tissue from prostatectomies that is not saved for research must be destroyed as biological waste (Tr. 2:17).

29. In those instances when Dr. Catalona was named as the Principal Investigator on a research study, the Informed Consent signed by the research participant did not purport to give or entrust the samples to Dr. Catalona personally. Those Washington University informed consent documents merely stated: "You are invited to participate in a research study conducted by Dr. William Catalona and/or colleagues."

30. At Northwestern University, Dr. Catalona uses a consent form that asks research participants to "donate" tissue, blood, and urine (Pl. Ex. 19; Tr. 2:46).

31. On June 6, 2003, Dr. Catalona, using the letterhead of the Northwestern Medical Faculty Foundation, wrote Dr. Emmanuel Petrocoin of the National Cancer Institute asking for the return of some 400 blood samples that Washington University had shipped to it for prostate cancer research (Pl. Ex. 6; Tr. 2:35-36). In that communication, Dr. Catalona referred to the research participants as "donors." He used the term "donated" elsewhere to describe the original contribution of samples by the research participants to Washington University (Pl. Ex. 18; Tr. 2:45-46).

32. The Office of Human Research Protection (OHRP) in the Department of Health and Human Services is charged with enforcing the federal regulations set forth at 45 C.F.R. Part 46, sometimes referred to as "the Common Rule" (Tr. 1:143; 2:161-62; 2:219). OHRP has the power to impose severe sanctions for non-compliance with the regulations (Tr. 2:162-63; 2:218-19). OHRP has reviewed Washington University for its regulatory compliance and has not taken any action against WU for refusing to turn over to Dr. Catalona

the samples in the GU Biorepository (Tr. 2:163-64). Neither Dr. Catalona nor any research participant has filed a complaint against Washington University with OHRP (Tr. 2:29).

33. OHRP has posted on its website a guidance document which provides examples of what a 1996 Cooperative Oncology Chairperson Group believed constitutes "exculpatory language" in Informed Consents prohibited by 45 C.F.R. 46.116 (Deft's Ex. Q). The examples cited in the guidance document do not appear anywhere in the federal regulations. One of the examples is: "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." The guidance document speaks of rights the participants "may have," not "do have." A prohibition against waiving a right that one "may have" does not imply that the participant has an underlying right (Tr. 1:189-90).

34. Defendants' own expert concedes that OHRP guidance documents are not binding and do not have the force of law (Tr. 1:144).

35. In a 1995 letter to the Chairman of the Washington University Human Studies Committee (its Institutional Review Board or "IRB"), Dr. Catalona suggested that research participants waive their rights in tissue samples used for commercial purposes (Pl. Ex. 15; Tr. 37-39).

36. As Principal Investigator on certain research protocols, Dr. Catalona, assisted by his staff, prepared the informed consent documents to be used in connection with those studies (Tr. 1:48). One such informed consent document stated: "By agreeing to participate in this study, you agree to waive any claim you might have to the bodily tissue you donate." Two of the three patient defendants who testified on his behalf signed such an Informed Consent (Pl. Ex. 98; Patients' Exs. 1, 7; Tr. 1:217; 2:19-20; 2:75; 2:169-70).

37. Dr. Catalona and the patient defendants rely on the principles governing human subject research set forth in 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 (Deft's Ex. MMMM). The World Medical Association developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians in connection with human subject research (Deft's Ex. NNNN). The Nuremberg Code, developed from the war criminal trials before the Nuremberg Military Tribunals, also dealt with ethical principles governing human subject research (Deft's Ex. OOOO). The Belmont Report, the Declaration of Helsinki, and the Nuremberg Code have not been enacted into law in this country (Tr. 1:129). 45 C.F.R. Part 46 has been adopted instead.

38. Under the regulations set forth at 45 C.F.R. Part 46, no human subject research supported by federal funding may be performed unless approved by an IRB (Tr. 2:145). The research institution must provide a written assurance that it is in compliance with these regulations in order to receive federal funding for human subject research (Tr. 2:145-46). Because its human subject research is frequently funded over time through a combination of federal funds and private sources, Washington University has voluntarily undertaken to apply the regulatory requirements to all such research, whether covered by federal funding or not (Tr. 2:147-48).

39. An individual researcher at Washington University Medical School may only conduct human subject research pursuant to a protocol reviewed and approved by the Human Studies Committee (Tr. 2:145). The Human Studies Committee must also review and approve all changes and all communications to research participants about those changes

(Tr. 2:156-57*)*. It must approve all requests to research participants to sign Informed Consents (Tr. 1:56; 2:158).

40. Over the years, Dr. Catalona regularly applied to the Human Studies Committee for approval of research protocols and changes thereto. He was familiar with the regulatory requirements and the Human Studies Committee procedures (Tr. 2:172-73).

41. On February 18, 2003, Dr. Catalona caused a letter ("the Letter") to be mailed to all research participants who had been involved in prostate cancer research studies at Washington University. The Letter was also included in a newsletter known as "Quest," published quarterly by the Urological Research Foundation, of which Dr. Catalona was Medical Director. This newsletter was mailed to approximately 50,000 people (Tr. 1:59-60). Dr. Catalona estimated that more than 60,000 people received this Letter either by direct mailing or as a subscriber to the newsletter (Tr. 2:32-33).

42. The Letter advised that Dr. Catalona would be joining the medical staff at Northwestern University and that he would continue to see patients and perform surgeries there: "I will continue to be available to you for consultation or treatment, and I plan to continue to collect follow-up information on all of my radical prostatectomy patients." Dr. Catalona went on to state that he would continue his prostate cancer research in his new position. He specifically stated: "To 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 your 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." The "Medical Consent & Authorization" form attached to the Letter recited that the research participants had previously "donated" their samples (Pl. Ex. 4, p.3).

43. Approximately 6,000 recipients signed that "Medical Consent & Authorization" form and returned it to Dr. Catalona (Tr. 1:101).

44. Neither the Letter nor the "Medical Consent & Authorization" form purports to suggest that any research participant declare that he desired to discontinue participation in research.

45. The Letter does not disclose that Dr. Catalona had already transferred the Principal Investigator role in all ongoing studies to another researcher at Washington University or that Northwestern had not approved any research protocol involving samples maintained in the GU Biorepository. The Letter improperly links research and clinical care, implying that Dr. Catalona would no longer provide medical treatment unless the subject agrees to have his research sample transferred to him (Tr. 2:177; 2:235-36).

46. The "Medical Consent & Authorization" attached to the Letter stated:

> "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."

47. At the time the Letter was sent, Dr. Catalona was still an employee of Washington University. He did not disclose the Letter to Washington University before sending it. Dr. Catalona had no approved research protocol at Northwestern University, and he did not obtain the approval of the Northwestern IRB before sending the letter (Tr. 2:33).

48. At the time he sent the Letter, Dr. Catalona was no longer the Principal Investigator on any of the studies involving the samples he sought to have transferred. He had transferred the role of Principal Investigator on remaining active studies to another Washington University faculty member (Pl. Ex. 29). Dr. Catalona does not claim to have secured the consent

of the research participants before doing so. Northwestern University had not approved any protocol or informed consent (Tr. 211). Thus, Dr. Catalona was asking research participants to consent to someone who was no longer the Principal Investigator and to a different institution that did not have an IRB approved protocol for the study in question (Tr. 231-32).

49. The expert witnesses both for plaintiff and defendants agreed that the "Medical Consent & Authorization" was not a valid informed consent (Tr. 1:38; 1:189-90; 1:200-01; 2:175-76; 2:233-35). Dr. Catalona conceded that the Letter did not constitute a valid informed consent (Tr. 1:58; 1:73; 2:10-11). He never submitted the Letter or the "consent" form for IRB review or approval (Tr. 1:34; 2:156-58; 2:174-76; 2:232). Neither the Letter nor the "Medical Consent & Authorization" explained any alternatives to the consent Dr. Catalona requested, including continuation in the research at Washington University (Tr. 2:234). Those documents did not explain that the participant could discontinue participation in Dr. Catalona's research without any penalty. They did not describe the research to be conducted, its purposes, or its expected duration (Tr. 2:233-34). They implied that transfer of the samples to Dr. Catalona would be necessary for continued medical care even though that was not the case (Tr. 2:235-36).

50. In 2002, a Peer Review Panel was formed to consider requests from researchers, both within and outside of Washington University, for use of GU Biorepository samples in research. Before resigning his employment at Washington University, Dr. Catalona made three such requests to the Peer Review Panel. All were approved and the requested materials were provided to Dr. Catalona (Tr. 2:103-04). The Peer Review Panel advised Dr. Catalona in writing that it would consider any request he made (Pl. Ex. 95; Tr. 2:105-06).

Since departing Washington University, Dr. Catalona has made no requests of the Peer Review Panel to use any of the materials in the GU Biorepository.

Conclusions Of Law

1. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1332(a) by virtue of diversity of citizenship of the plaintiff and defendants and the requisite amount in controversy.

2. Washington University filed this action seeking a judgment declaring, among other things, that it has ownership rights over the GU Biorepository and enjoining Dr. Catalona from interfering with the use of the GU Biorepository. The matter presently before the Court is Dr. Catalona's motion to permanently enjoin Washington University from using any of the materials in the GU Biorepository.

3. By Order dated February 11, 2005, this Court determined that the primary dispositive question on Dr. Catalona's motion for permanent injunction is: Who owns the GU Biorepository materials at issue in this case?

4. In that same Order, this Court found that Dr. Catalona had conceded that he does not own the subject materials. In his Answer, Dr. Catalona denied that he has a personal ownership interest in the GU Biorepository (Answer, ¶¶ 3, 22, 31). He and the eight patients of his who have joined with him as co-defendants now maintain that the research participants, rather than Dr. Catalona, own and control the samples contributed to the GU Biorepository. Based upon these facts and the reasons that follow, the Court concludes that Dr. Catalona has no ownership interest in any of the materials contained in the GU Biorepository. Thus, the remaining question is whether the materials contained in the GU Biorepository are owned by Washington University or by the research participants.

5. Missouri law governs the issue of ownership. *See e.g., Zaiser v. Miller*, 656 S.W.2d 312, 316 (Mo. App. 1983). Where, as here, personal property is of a type that is not subject to title, exclusive possession and control of such property creates a presumption of ownership. *Valentine v. St. Louis Union Trust Co.*, 250 S.W.2d 167 (Mo. 1952); *Foltz v. Pipes*, 800 S.W.2d 14, 15 (Mo. App. 1990). Because Washington University has had exclusive possession and control of the Biorepository, defendants were required to overcome the presumption of ownership by Washington University.

6. The Court concludes that the research participants have failed to overcome the presumption that Washington University became the owner of the materials in the GU Biorepository when the research participants contributed those materials to the University for purposes of medical research.

7. Under Missouri law, the elements of a gift are donative intent, delivery and acceptance. *Donnelly v. Donnelly*, 951 S.W.2d 650, 653 (Mo. App. 1977); *Wantuck v. United Savings & Loan Ass'n*, 461 S.W.2d 692, 694 (Mo. banc 1971).

8. The research participants intended to donate their prostate tissue and blood samples to Washington University for medical research. The research participants knew from the informed consent forms that they provided these samples for purposes of medical research and not for patient care. The research participants knew the research would not benefit them personally as they had already undergone radical prostatectomies, but they hoped the research would benefit future generations.

9. Delivery occurred when Washington University urologists, having the research participants' informed consent, took and preserved for use in future prostate tissue research that would otherwise have been destroyed as medical waste after a prostatectomy.

Delivery of serum samples occurred when the research participants came to the Washington University Urology Division to give their blood and allowed nurses and Urology Division staff, again with informed consent, to take and store blood samples for future research purposes.

10. Washington University accepted the samples at the time of delivery, and Urology Division personnel and funds have maintained the samples ever since.

11. The desire now expressed by the eight patient defendants to have their samples transferred to Dr. Catalona does not determine whether they made a gift years ago when they donated tissue for medical research. The dispositive issue is their intent as manifested at the time the samples were contributed, not what they say well after a dispute has arisen. *LeMehaute v. LeMehaute*, 585 S.W.2d 276, 281 (Mo. App. 1979) "It is . . . well established that once a gift is made the donor may not revoke the gift upon a change of mind"); *Donnelly*, 951 S.W.2d at 653.

12. The samples were gifts to Washington University, not in trust to Dr. Catalona individually. The Informed Consents typically bore the name and logo of the Washington University Medical School and were approved by the University's Human Studies Committee. Many of the samples were contributed by research participants who were either patients of Washington University physicians other than Dr. Catalona or who were not patients at all. In a number of instances, someone other than Dr. Catalona was the Principal Investigator on the study in which the research participant became involved. All of the research studies were collaborative efforts involving a number of physicians. Washington University has borne the legal, regulatory, and compliance responsibility and risk for the research. 42 C.F.R. Parts 46 and 50; 45 C.F.R. Part 689 45 C.F.R. 46.103.

13. Prior to this controversy, Dr. Catalona repeatedly and over a period of many years acknowledged and admitted that Washington University owns the materials in the GU Biorepository. He personally signed various Material Transfer Agreements, which so state. His execution of these contracts constitute admissions binding on him. *Pillsbury Co. v. Cleaver-Brooks Div. of Aqua-Chem, Inc.*, 646 F.2d 1216, 1218 (8th Cir. 1981); *McQueeny v. Wilmington Trust Co.*, 779 F.2d 916, 930 (3d Cir. 1985). Moreover, he continued his employment at Washington University in the face of its published and binding policies setting forth Washington University's continuing ownership of intellectual property maintained or developed with its own funds or with third party funds it administered (including tangible research materials such as the GU Biorepository). *Chou v. University of Chicago*, 254 F.3d 1347, 1356-57 (Fed. Cir. 2001); *Fenn v. Yale University*, 283 F. Supp. 2d 615, 628-29 (D. Conn. 2003); *University of West Virginia v. Van Vorhies*, 84 F. Supp. 2d 759, 769-7 (N.D. W. Va. 2000).

14. In the only two reported cases dealing with the question presented, both Courts concluded that research participants retain no ownership of specimens they contribute for medical research. *Moore v. Regents of the University of California*, 51 Cal. 3d 120, 271 Cal. Rptr. 146, 793 P.2d 779 (1990); *Greenberg v. Miami Children's Hospital Research Institute, Inc.*, 264 F. Supp. 2d 1064 (S.D. Fla. 2003).

15. In *Moore*, the California Supreme Court exhaustively reviewed the law relating to the ownership and use of human tissue. It observed that no reported decision had ever held that a research participant 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 a research participant could not have an ongoing ownership interest in excised 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.

16. In *Greenberg*, where the plaintiffs supplied blood and tissue samples to the defendant for research purposes, the Court observed that "these Plaintiffs are more accurately portrayed as donors rather than objects of human experimentation." 264 F. Supp. 2d at 1071. The Court explained that "the research participant's property right in blood and tissue samples . . . evaporates once the sample is voluntarily given to a third party." *Id.* at 1075. "At the core, these were donations to research without any contemporaneous expectations of return." *Id.* at 1076.

17. Both *Moore* and *Greenberg* held that the research participants had parted with all ownership rights in the tissue samples when they donated them to the research institutions, even though there was no statement in the Informed Consents they signed stating that the participants donated their tissue. The Court believes *Moore* and *Greenberg* to be highly persuasive, finds that they are consistent with the Missouri common law of gifts and personal property, and follows them here in concluding that Washington University owns the samples in the GU Biorepository.

18. The Court rejects defendants' contention that the research participants made a bailment rather than a gift of their samples. A bailment is made on the condition that the property 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). Because the research participants had no expectation of the return of their samples, there was no bailment. In fact, Washington University could never return the samples to the research participants because the samples are subject to the laws and regulations governing the disposal

of medical waste – and these provisions prohibit WU from returning the samples to the participants. R.S.Mo. § 260.200, 260.203 (infectious waste disposal); 10 C.S.R. § 80-7.010 (infectious waste disposal); 29 C.F.R. § 1910.1030 (blood borne pathogens).

19. Defendants maintain that, because the Washington University Informed Consents uniformly advise the research participants that they have the right to discontinue participation in the study, the research participants should also have the right to control the disposition and use of the physical samples. But a right to withdraw from participation in a research study does not imply a right to transfer physical samples. If the participant decides to withdraw from participation in a study, the research institution simply cannot use the sample any longer (unless it is anonymized) (Tr. 2:229-30).

20. The regulations merely require that the research participant be told he or she can "discontinue participation" in research at any time without penalty. 45 C.F.R. § 46.116(a)(8). Washington University complied with this regulation. The right to "discontinue participation" in a study, however, neither states nor implies any right to control the future use or disposition of the physical specimen. Neither the regulations nor the Informed Consents used by Washington University confer any right to withdraw samples or to re-direct samples from one researcher to another (Tr. 1:132-33). The regulations say nothing about such a "right" (Tr. 1:132-33; 2:222-24). No such "right" to transfer samples appears in the medical or ethical literature (Tr. 1:181-83). "Discontinue participation" or "withdraw your consent" mean exactly that — nothing more. If a participant withdraws his consent to participate, any one of three things may happen: Washington University may (1) destroy the sample, (2) store the sample without using it any further in the research protocol, or (3) remove all personal identifiers from the sample and continue to use it in exempt anonymized research.

21. Dr. Catalona and his co-defendants contend that the language contained in some Informed Consents was "exculpatory" and thus prohibited by 45 C.F.R. § 46.116. From this premise, they maintain that the research participants did not make a gift to Washington University. Defendants are in error for the following reasons:

(a) The presence of alleged "exculpatory language" is unnecessary to make a gift. Indeed, no writing whatever is necessary to make a gift. *Donnelly*, 951 S.W.2d at 653. Both *Moore* and *Greenberg* concluded that research participants donated their tissue samples to the research institution even though there was no express statement to that effect in the consent forms. *Moore*, 51 Cal.3d 120, 132, 27 Cal. Rptr. 146, 152, 154, 159; *Greenberg*, 264 F. Supp. 2d at 1074-76.

(b) The presence of "exculpatory language" in the Informed Consents does not negate a gift. The requirements for the content of an informed consent are governed by 45 C.F.R. § 46.101(a) if federal funds are used for the research. But whether the research participants donated their samples for medical research is a question of state law. *See Phillips Petroleum Co. v. Mississippi*, 489 U.S. 469, 484 (1988). As indicated above, the research participants' transfers contained all the elements of a gift under Missouri law. Both *Moore* and *Greenberg* found the research participants had made a gift even though 45 C.F.R. § 46.116 prohibits the use of "exculpatory language" in informed consent forms.

(c) The 1996 OHRP guidance document upon which defendants rely does not say or imply that research participants retain ownership rights to the samples they contributed. The example of "exculpatory language" defendants rely upon states: "By consent to participate in this research, I give up any rights *I may have* in bodily fluids or tissue samples obtained in the course of the research." This example speaks of rights the participants "*may*

have" not "*do* have." Nothing in the federal regulations or any document presented to the Court indicates that OHRP has taken any position as to the actual ownership of excised tissue and other such samples (Tr. 2:226-27).

(d) Dr. Catalona is in no position to advance this contention because he sanctioned and even promoted such language when it was to his benefit. As Principal Investigator, he used the same language he now decries as "exculpatory" in informed consents for which he was responsible, and he advocated "exculpatory language" to the Human Studies Committee.

(e) In any event, the OHRP guidance relied on by defendants is not the law. It comes from a Cooperative Oncology Group Chairpersons Meeting on November 15, 1996. The examples of allegedly "exculpatory language" cited in the guidance document do not appear anywhere in the regulations themselves. The guidance document was not adopted pursuant to notice and comment rule making. 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. *United States v. Mead Corp.*, 533 U.S. 218 (2001). Informal guidance is entitled to respect only to the extent it has the "power to persuade." *Christensen*, 529 U.S. at 587. But the guidance document in question is not persuasive because it gives no rationale or explanation for its examples and is contrary to well-accepted definitions of "exculpatory" language.

(f) Indeed, the example cited in the non-binding OHRP guidance document and relied upon by the defendants is not "exculpatory language" within the meaning of 45 C.F.R. § 46.116. That provision states:

> "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 investigator, the sponsor, the institution or its agents from liability for negligence."

An "exculpatory" provision normally relieves a party from liability arising from a negligent or wrongful act. *Valhal Corp. v. Sullivan Associates, Inc.*, 44 F.3d 195, 202 (3d Cir. 1995); *Hornbeck v. All American Indoor Sports, Inc.*, 898 S.W.2d 717, 721 (Mo. App. 1995). The regulation's express prohibition against an advance release of liability for negligence reinforces the common meaning of "exculpatory." Under the principle of *ejusdem generis*, the general reference to "exculpatory language" in the regulation must be construed consistent with the specific example given. NORMAN J. SINGER, SUTHERLAND, STATUTORY CONSTRUCTION, § 47.16 (6th ed. 2000).

22. The Court also rejects defendants' contention that the research participants maintain a right to control the samples because their identifying information is currently linked to the samples and, under those circumstances, the samples may not be anonymized. Defendants have cited no legal authority for the proposition that identified samples may not be anonymized. In fact, defendants' expert conceded that, where the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects, the research is not "human subject research" governed by the federal regulations. 45 C.F.R. § 46.101(b)(4) (Tr. 1:140-41). In any event, the right to anonymize is not necessary to establish Washington University's ownership because the University can destroy or continue to hold the samples that have been contributed.

23. Washington University has the discretion to destroy a sample when a participant discontinues participation (Tr. 1:135-36; 2:224). In addition, the experts for both Dr. Catalona and the defendant patients conceded that the research institution can properly destroy samples that are not needed for research without the approval of the participants who

contributed the materials (Tr. 1:135-36; 1:194). That is exactly what Dr. Catalona did. He frequently purged and destroyed excess blood samples collected in the PSA Study and maintained in the GU Biorepository without obtaining any consent from the contributing participants (Tr. 1:87-89). Washington University's admittedly lawful right to destroy samples is wholly inconsistent with the research participants' retaining ownership of the samples.

24. Alternatively, Washington University can elect simply to store samples indefinitely after the participant discontinues participation (Tr. 1:194; 2:164-65).

25. Defendants argue that Washington University's refusal to transfer the physical specimens to Dr. Catalona violates the Belmont Report, the Declaration of Helsinki and the Nuremberg Code. This argument misses the mark entirely. While Washington University did agree to follow the principles in these documents in agreements with the Department of Health and Human Services, neither Dr. Catalona nor his co-defendants were third party beneficiaries to those agreements and have no right to enforce them. *Klamath Water Users Protective Ass'n v. Patterson*, 204 F.3d 1206, 1211 (9th Cir. 1999); *Wright v. Fred Hutchinson Cancer Research Center*, 269 F. Supp. 2d 1286, 1290 (W.D. Wash. 2002).

26. There is no private right of action for an alleged violation of international law for the protection of human research subjects based upon Declaration of Helsinki and the Nuremberg Code. *White v. Paulsen*, 997 F. Supp. 1380, 1383 (E.D. Wash. 1998); *Hoover v. West Virginia Department of Health and Human Services*, 984 F. Supp. 978, 980 (S.D. W. Va. 1997), *aff'd* 129 F.3d 1259 (4th Cir. 1997). This Court agrees with the conclusion reached in *Ammend v. Biopart, Inc.,* 322 F. Supp. 2d 848, 872-73 (W.D. Wash. 2004), and *Robertson v. McGee*, 2002 WL 535045 (N.D. Okla.), that the standard in the United States for conducting

research on human subjects is contained in the Code of Federal Regulations and thus there is no need for the courts to resort to international law to impute a standard.

27. The Court further concludes that defendants have failed to show that the conduct of Washington University in refusing to transfer the GU Biorepository to Dr. Catalona at Northwestern University violates the Belmont Report, the Declaration of Helsinki, or the Nuremberg Code.

28. Dr. Catalona concedes that only about 6,000 of the more than 30,000 research participants signed his "Medical Consent & Authorization." The Letter and that accompanying form was not a valid Informed Consent because it failed to meet the requirements of 45 C.F.R. 46.116(a), including subpart (1) [description of the research, its purposes and its expected duration], subpart (4) [a disclosure of appropriate alternative procedures or course of treatment, if any, that might be advantageous to the subject], and (8) [explanation that the participant could discontinue participation in Dr. Catalona's research without any penalty]. By implying that consent to transfer was necessary for continued medical care, the Letter also failed to minimize the possibility of undue influence in violation of 45 C.F.R. § 46.116 (Tr. 2:177; 2:235-36).

29. The Letter was also invalid because it was sent to the research participants without any IRB approval (Tr. 1:200-01; Tr. 2:176; 2:232). No reasonable IRB could find that the Letter satisfied the requirements for a valid Informed Consent under § 46.116 (Tr. 1:117-78; 2:236).

30. 45 C.F.R. § 46.103(b)(4) requires that a research institution have an approved assurance on file with OHRP, which includes written IRB procedures for ensuring that changes in approved research not be initiated without IRB approval. Defendants err in

contending that the letter was not a "change" requiring IRB (Tr. 2:11). To the contrary, one of defendant's experts conceded that such a letter would in fact require IRB approval (Tr. 1:138). The Court concludes that a communication with research participants seeking to transfer control of samples to Dr. Catalona when he was no longer the Principal Investigator on any of the research studies at Washington University was a "change" requiring IRB approval. The Court also concludes that a communication with research participants seeking to transfer samples to Northwestern University when it did not have any approved protocol of its own for the study in question was also a "change" requiring IRB approval (Tr. 2:231-32).

31. Moreover, even if the Letter and the "Medical Consent & Authorization" forms that Dr. Catalona sent to the research participants were not invalid for lack of IRB approval, they would still be ineffective to accomplish defendants' purposes here. As set forth above, Washington University owns the materials as a matter of Missouri gift and personal property law. The research participants' continuing rights in connection with the donated samples are limited to those in the federal regulations, which is limited to their right to discontinue participation in research. Nowhere in the "Medical Consent & Authorization" form does any research participant express the desire to discontinue participation in any research. Rather, the research participants who signed that form purport to assert a right that is not available to them pursuant to federal regulations – a right to direct or transfer possession of the materials. Because the research participants are not owners and because the "Medical Consent & Authorization" forms purport to exercise non-existent rights, the signed "consents" are of no force or effect.

32. Finally, the Court is persuaded that defendants' position is bad policy. If research participants who had contributed biological specimen to a research institution could

subsequently direct that their samples be transferred to a third party, then researchers could engage in unregulated proxy battles for human subject specimens, and research participants could sell their specimens to the highest bidder (Tr. 2:228). Moreover, scientific research could be thwarted because collections of biological materials could not readily be kept and maintained. Defendants' interpretation would balkanize large collections of biological materials, discourage investment in collecting and maintaining them, and promote instability at the expense of scientific progress.

33. Accordingly, the Court concludes (a) that the defendants have failed to demonstrate that they are entitled to any injunctive relief, (b) that Washington University owns the tissue and blood samples in the GU Biorepository, (c) that neither Dr. Catalona nor any of the research participants has any ownership interest in the samples, and (d) that the "Medical Consent & Authorization" forms are void and ineffective to transfer ownership or possession of any samples to Dr. Catalona, Northwestern University, or the research participants.

Dated: _____

_____
Stephen N. Limbaugh
United States District Judge

Dated: June 15, 2005

Respectfully submitted,

By:/s/ Thomas E. Wack

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the 15th day of June, 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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