

Research Biological Materials – Who Owns Them?



by Yi-Kang Hu, Ph.D., JD

Ownership of biological specimens stored in research repositories has been claimed by the institutions that maintain them, the researchers who collected the specimens, and the research subjects from whom the specimens were collected. Federal regulations governing the use of human subjects do not address the issue of ownership of stored biological specimens. In this vacuum of federal regulations, disputes over ownership have been decided by the courts in private litigation. At present, case law on this issue is thin but consistent. The recent case of *Washington University v. Catalona* is the latest of only a few cases that addressed ownership issues of research biological materials.¹ The holding of this case has important implications for research institutions that are invested in maintaining ownership of research repositories created through research conducted at their institutions.

Ownership Dispute

The ownership dispute between William Catalona, M.D. and Washington University (WU) arose when Dr. Catalona, a urologist and prominent researcher at WU from 1976 to 2003, accepted a faculty position at Northwestern University and wanted to transfer biological specimens stored in a tissue repository maintained by WU to Northwestern. Before he left, Dr. Catalona mailed consent forms directly to his former patients who had donated their biological materials for the purpose of prostate cancer research, requesting that they direct WU to transfer the stored biological materials to Northwestern. About 6,000 people signed the forms indicating that they wanted to transfer their biological materials.² In response, WU filed suit in federal court, asserting ownership over the materials.

WU maintained that the human subjects made voluntary donations to WU, and that once the biological materials were delivered to WU, the university became the sole owner with full control over their use and storage. The core of Dr.

Catalona's argument was that his patients retained ownership of their biological, allowing them to direct WU to transfer the materials to Northwestern. Alternatively, Dr. Catalona argued that his patients donated their biological materials with the intent that the materials stay with him.³

Informed Consent Forms

In reaching its decision that WU is the rightful owner of the donated biological materials, the court considered the informed consent forms (ICFs) one of the key factors of the case. Specifically, the following elements of the ICFs played a determinative role in the court's analysis:

First, the ICFs stated that the research subjects were agreeing to participate in medical research at WU, and that the collection of samples was for research and not for treatment.⁴ This was an important distinction because it clarified that the biological materials were not entrusted to a physician for treatment purposes. Rather, WU, as the entity responsible for research, was the intended recipient.

Second, the ICFs established WU's oversight over the research in connection with the biological materials. Specifically, the forms bore the logo of WU and were not valid without the stamp of approval of the university. The research subjects were advised to contact WU administration directly with any concerns. Additionally, the form listed what the university would do to protect the subjects' privacy.⁵

Third, the forms stated that the subjects could not "claim ownership rights" to any medical or scientific product that results from the research.⁶ Although Dr. Catalona contended that this provision violated the Common Rule prohibition against exculpatory language,⁷ the court held that the prohibi-

*Dr. Hu is an Associate at Preston Gates & Ellis, LLP,
Portland, OR.*

tion did not apply because the ICFs did not contain “language involving release from malpractice or other negligence.”⁸

Finally, the forms stated that the research subjects could withdraw their participation in the research at any time, but their samples would be treated only in one of three ways: 1) WU could destroy the samples; 2) WU could store the samples indefinitely without any further use; or 3) WU could remove all identifying markers and use the samples in exempt “anonymized” research.⁹

Equally important in the court’s analysis was what was not addressed in the ICFs: the issue of human subjects withdrawing biological materials from the tissue repository or requesting the materials to be sent to another institution.¹⁰ The lack of this affirmative representation that the subjects retained any ownership interests in the biological materials further indicated that the subjects surrendered their rights to withdraw or redirect the use of their biological materials.

Intellectual Property Policy

Another key factor in the *Catalona* case was WU’s intellectual property policy, which stated 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.”¹¹

The court also referred to the material transfer agreements of the university. In those agreements, WU “clearly exerted its ownership interest without objection by Dr. Catalona. Even in the instance wherein Dr. Catalona attempted to change the language of [an agreement] to reflect ‘co-ownership’ with WU, and WU refused to modify the language ... Dr. Catalona still signed.”¹²

Additional Factors

The court also pointed to WU’s control and responsibilities over the biological materials in establishing the university’s ownership interests of the materials. Specifically, the materials were kept in WU’s central repository, which was funded and administered by the university. Access to and use of the materials by investigators was only allowed through the university’s Institutional Review Board and Subject Research Committee. According to the court, there was no evidence indicating that anyone other than WU bore the legal, regulatory, and compliance risks with respect to all research done in connection with the repository.¹³

Conclusion

The *Catalona* case offers guidance to research institutions on ownership issues associated with research biological materials. The court ruled that WU was the true and rightful owner of the materials because its policies and procedures relating to ICFs, intellectual property, and tissue repositories properly defined the ownership rights and expectations of the research institution, investigators, and human subjects. Research institutions should understand the full implications of this case and take appropriate steps to protect their rights in biological materials collected for research purposes. Δ

¹ *Washington University v. Catalona*, Case No. 4:03CV1065SNL (E.D. Mo. Mar.31, 2006).

² *Id.* at 10-11.

³ *Id.* at 12.

⁴ *Id.* at 5.

⁵ *Id.*

⁶ *Id.*

⁷ See 45 CFR Part 46, Subpart A.

⁸ *Catalona* at 20-21.

⁹ *Id.* at 22.

¹⁰ *Id.* at 5-6.

¹¹ *Id.* at 14.

¹² The template material transfer agreement provided that WU, as the “Provider” of the biological material, shall remain the owner of the material.

¹³ *Id.* at 13-14.

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