

## Tissue Banks: Part I

### Access, Control, and Regulatory Issues

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Tissue banks are repositories of human specimens such as tissue, blood, or other bodily fluid samples that have been collected from human beings. A provider may have a pre-existing collection of tissue resulting from patient care, such as stored biopsy samples. A provider may also create a tissue bank prospectively in connection with a research study and may even bank samples for future, undetermined research use (but note the privacy law restrictions discussed below).

Regardless of the reason for their creation, tissue banks have tremendous value for research and product development. A tissue bank and its associated patient information may be used to study genetic patterns in a patient population and to compare genetic makeup to a patient's clinical course. A bank of tissue samples may be used to test or to confirm the effectiveness of a new diagnostic test and can minimize the cost and shorten the duration of a research project by eliminating the need to collect samples prospectively. A tissue bank is also invaluable for retrospective research.

But before a bank may be mined for any information, critical questions of control and access must be addressed. Unfortunately, there is not one set of regulations, but rather overlapping laws and often complicated federal guidance documents that must be assessed to answer these questions in any given case.

#### Who Controls Tissue in the Bank?

The question of who controls tissue samples in a bank is most easily addressed by first considering who does *not* control the tissue. Case law has made fairly clear that the patients from whom tissue was originally removed have no right to control or access tissue once it has been excised from their bodies. The 1990 case of

*Moore vs. the Regents of the University of California* is the seminal case on this point. The *Moore* court reasoned that to permit patients to control tissue once it is excised from their bodies would risk impeding medical progress.<sup>1</sup> The *Moore* case is a state law case binding in California only, although other cases have generally

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supported its analysis and prohibited patients' ability to control the use of excised tissue.

It is important to note that patients do generally have an opportunity to control further uses of their tissues when collected for clinical or research purposes. Most often, treatment consent forms will request a patient's express permission to use left over tissue samples for research or educational purposes. Unless a patient has refused such permission, the tissue may be banked and accessed for future use. Similarly, research consent forms must disclose all potential research activities, including tissue use, and a potential participant always has the right to refuse to join a study. Sometimes, research consent forms allow participants to prohibit future tissue use but still participate in a study.

If patients do not own or control tissue once it is removed from their bodies, who does? Recent case law has shed some light on this question. The 2006 case of *Washington University v. William Catalona*<sup>2</sup> involved a dispute between a researcher and an institution over a bank of tissue. The litigation arose when the researcher attempted to obtain permission from several thousand patients to transfer their tissue samples from one insti-

tution to another. The *Washington University* court followed the *Moore* analysis and held that patients had no right to control their excised tissue, so any patient consent to transfer would be meaningless. The court also held that since the University funded the personnel and other resources necessary to create the bank, the University ultimately owned the bank and not the researcher. Again, the *Washington University* case is a state law case of limited applicability. What it demonstrates, however, is that in any given case, the right to control a tissue bank will be determined on a fact-specific basis with consideration to the resources used in creating the bank and the contractual and financial relationships among the disputing parties.

Of course, ownership of a tissue bank does not equate with the unfettered right to use or to permit others to use it. Whether or not it is appropriate for someone to access and use the tissue in a bank is determined by a combination of federal research laws, guidance documents and also the privacy provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

In the next Legal Corner (May/June 2008) "Tissue Banks: Part 2," we will focus on regulations related to the use of banked tissue, and when tissue use does and does not equal human subject research. ☐

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#### References

<sup>1</sup> *Moore v. Regents of the University of California*, 51 Cal. 3d 120, 793 PO2d 479, Cal. Repr. 146.

<sup>2</sup> *Washington University v. William Catalona*, 437 F. Supp. 2d 9895 (E.D. Mo 2006).