LEGAL CORNER

Tissue Banks: Part II
Access, Control, and Other Regulatory Issues

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The March/April 2008 "Legal Corner" discussed tissue bank creation, control, and ownership issues, as well as the potential value of a tissue bank to research scientists. In this column, we review regulations that govern tissue use and provide some practical recommendations for evaluating a request to access tissue in your control.

Regulations Potentially Governing Tissue Use

Unfortunately, no single set of regulations apply when a researcher seeks access to tissue. Access to, and the use of, tissue is governed 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).

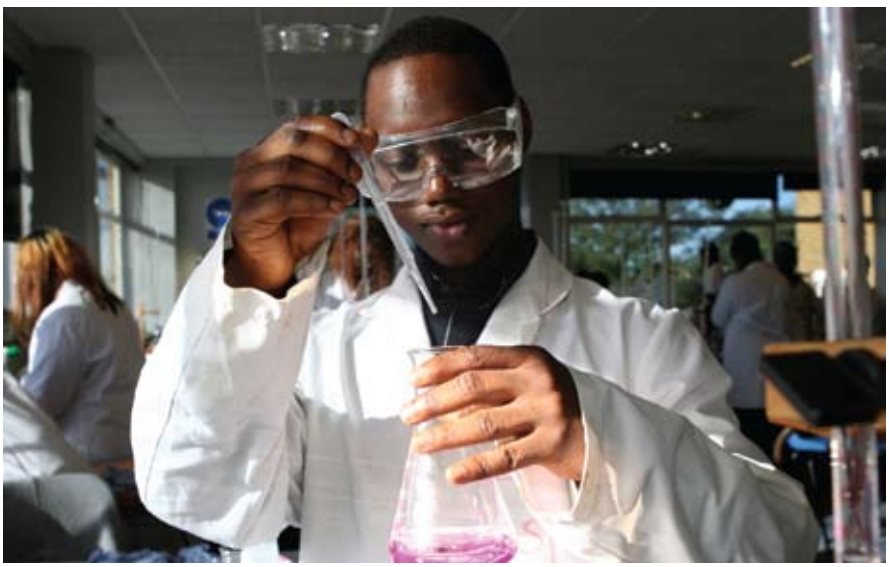
The Common Rule. The Common Rule protects the rights and welfare of human subjects involved in research that is conducted or supported by the Department of Health and Human Services.[1] The Common Rule is the source of requirements for institutional review board (IRB) review and informed consent in connection with clinical research. Certain types of research are exempt from coverage under the Common Rule, including "research involving the study of existing data, documents, records and pathological specimens if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects."[2] If a proposed tissue use meets the exemption criteria, no informed consent or IRB approval is required. Federal guidance confirms this analysis and provides additional information for researchers covered under these regulations (for more information go to: *www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf*).

Food and Drug Administration (FDA) Regulation. FDA research regulations apply to research that will result in a submission for marketing approval to the FDA (drug or device research). FDA rules are very similar to the Common Rule and include IRB review and informed consent requirements. However, key differences do exist. One difference is the agency's approach to regulating tissue use. FDA regulations do not contain an exemption for de-identified tissue use. Rather, the FDA has announced that it would exercise "enforcement discretion," or that it would not object to the use of de-identified remnant tissue specimens under some circumstances (For more information go to: *www.fda.gov/cdrh/oivd/guidance/1588.html*).

Specifically, the FDA will not object to the use of tissue specimens that were collected for routine clinical care or analysis in investigations that meet the criteria for exemption from the Investigational Device Exemptions (IDE) regulation at 21 CFR 812.2(c)(3), as long as subject privacy is protected by using only specimens that are not individually identifiable. The guidance also applies to specimens collected from other, unrelated clinical research, as long as the specimens are not individually identifiable.

HIPAA. Although this law does not govern research or the use of blood or tissue samples, it does control the use of patient information that is associated with blood or tissue. Therefore, HIPAA compliance is an important consideration in the evaluation of any proposal to use tissue.

Interestingly, HIPAA *does* permit the creation of a research database or research repository.[3] HIPAA does not, however, permit patients to authorize the use of their information for unspecified future research purposes. Thus, the creation of a database or research repository and the subsequent use of that repository are viewed as two separate activities—each potentially requiring authorization from the subject. The initial authorization would be for the creation of a tissue bank and/or repository of patient information. Any future authorizations would have to be specific to the proposed tissue use. And as discussed above, the need to access identifiable patient information will trigger FDA research rules or Common Rule requirements, so



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an IRB-approved consent document will likely be needed along with a valid authorization.

Access to *Your* Tissue Bank

So what do you do if a researcher seeks access to a bank of tissue in your control? First, if the bank contains remnants of tissue that were collected for clinical use, you should review any treatment consent forms that may have discussed the possibility of future tissue use. It would be helpful to know, for example, if any patients expressly refused permission for their tissue to be used other than in connection with treatment. Even though courts generally recognize that patients do not have the right to control tissue excised from their bodies, it would be inappropriate to use the tissue after a consent form represented to a patient that he or she had the ability to control such future use. Similarly, you should review any research consent forms associated with a repository of tissues collected for a specific research project.

Next, you should evaluate any proposed use of patient information. If identifiable patient information is being requested along with tissue, either Common Rule or FDA rules will apply and confirming compliance with applicable requirements—including IRB review and informed consent—will be important.

Finally, you will need to ensure that any authorization required under HIPAA is in place or that the person seeking access to the tissue can demonstrate that authorization requirements have been waived in accordance with the law. Note that it is possible for a proposed tissue use to fall outside of FDA, Common Rule and HIPAA regulations. In such a case, the transaction may constitute a simple biological materials transfer. If you find yourself in such a situation—and first be very careful to confirm that other regulations do *not* apply—make sure that any transfer is consistent with your organizational policy. For example, your program may require form agreements to accompany tissue or institutional policies for recouping the costs of preparing and shipping the tissue.

The patchwork of regulations and guidance on the use of banked tissue can make the analysis of any proposed tissue use seem daunting. However, the government's goal is to facilitate research and improve patient care. If you are diligent about reviewing the regulations applicable to your situation, and obtain guidance from legal counsel with expertise in this area of the law, you may find that the path to compliance is more straightforward than you think.

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References

[1]45 C.F.R.§ 46. Note that most institutions apply Common Rule protections to human subject research regardless of whether or not it is conducted or supported by the Department of Health and Human Services.
[2]45 C.F.R. § 46.101(b)(4).
[3]45 C.F.R. § 164.508(c)(1)(v).