Who Owns Diagnostic Specimens in the Era of Personalized Medicine?

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The Canadian Chairs of Pathology and Laboratory Medicine read with great interest the article by Cheung and colleagues published earlier this year in the Canadian Medical Association Journal. In that opinion piece, the authors addressed the very important issue of ownership, stewardship, and accessibility of diagnostic specimens for research, teaching, and quality assurance purposes. We applaud the authors for tackling this complex and still unresolved issue, which for us stimulated a lively discussion with our academic colleagues from health law research groups. With this commentary, we would like to contribute to this important discussion by giving the academic perspective (i.e., a perspective with a major focus on maintaining and facilitating reasonable access to human diagnostic specimens for teaching and research).

As a general practice, the collection of specimens for diagnostic purposes usually does not require consent for research use. However, widespread current practice is that institutional research ethics boards permit "secondary" research use of archived or excess diagnostic specimens and derivatives without specific consent for such use, subject to rules that protect donor and patient privacy in accordance with health information protection legislation (specifically, if the specimens are de-identified).

Cheung and colleagues take a strong position that because diagnostic specimens and derivatives are a component of the patient record, they are owned by the institution that collects them. We think that this interpretation overstates the law by comparing tissue to a physical medical record. Questions regarding tissue ownership remain unsettled in both Canadian jurisprudence and elsewhere, and the case law discussed by Cheung and colleagues does not definitively address or decide the issue. A better view may be that the law is presently unclear on who owns excised tissue, whether classified as diagnostic tissue or as research tissue. One thing is clear: once a diagnostic specimen is excised, the donor has rights founded in consent (at least to the procedure of removing the tissue) and privacy law (and in some situations, fiduciary law), but it is not clear whether this extends to an ownership interest. In our opinion, it is not legally established that ownership of tissue specimens lies with the collecting institution. It is possible that derivatives from the specimens belong to the collecting institution or to the person who derived it. In any event, the ownership question should not be our priority because from a donor rights perspective, access to specimens for research and teaching (i.e., purposes other than rendering diagnoses) should not depend on ownership but primarily on consent rules and privacy protections. The ownership question is perhaps only important in determining who (between the collecting institution and researchers) should benefit financially from exploiting the specimens and derivatives.

Therefore, in our opinion the most relevant question is whether the academic community can use diagnostic tissue and derivatives for research and teaching without specific (prospective or retrospective) consent. Pathology archives across the world – and particularly in Canada – contain unprecedented amounts of human tissue specimens that were virtually all procured, stabilized, refined, and stored through public resources (i.e., a public health care system). Such public resources...
support indicates that it is in the public interest to facilitate widespread but regulated access to these specimens for use in research. We suggest that the term *ownership* does not properly describe the role of the institutions in which these tissue archives are housed and is inconsistent with this concept. Ownership of these specimens by an institution that may be private or become private in the future could imply that the institution has the legal right to sell these specimens to the highest bidder; they would cease to be a public resource for research, teaching, and quality assurance. We therefore recommend that the term *ownership* be abandoned in this context and replaced with the term *stewardship* to more accurately describe the role of the institution as custodian of these tissue archives.

If researchers are seeking to use a tissue specimen collected for diagnostic purposes, then current legal and ethical rules require specific consent for research use. It is possible that these rules do not apply to derivatives from the diagnostic specimens, particularly if the derivatives are classified as data or information. The reason for this is that health information legislation throughout Canada provides that one does not need consent to use or disclose health information if it has been de-identified or (if identifiable) a research ethics board has approved such use or disclosure. Therefore, the most important question to us is, at what stage does a human tissue specimen procured for diagnostic purposes become “data or information”? One can postulate that it becomes so once it is manipulated or altered to create a “research-specific” derivative (e.g., when fixation and tissue processing is applied to the otherwise unmodified specimen). This becomes even more obvious if true derivatives that fundamentally alter the original diagnostic specimen are generated, such as stained histological sections or extracted ribonucleic acid. Cheung and colleagues take the further step of characterizing the diagnostic tissue specimen as part of the health record and therefore “data/information.” To our knowledge, no legal clarity has been established in regard to this question in Canada. In the era of personalized diagnostics – with archived specimens becoming accessible to “omics” technologies even after formalin fixation and paraffin embedding – it is crucial to address this unmet need. To this end, a concerted response by health care providers, academia (medical, legal, and ethical), and legislative bodies is required.

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References

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