

**Biospecimen "Ownership": Point****Roberta B. Ness on behalf of the American College of Epidemiology Policy Committee**

Graduate School of Public Health, University of Pittsburgh, Pittsburgh, Pennsylvania

Biorepositories are rare and valuable resources, so it is perhaps not surprising that their "ownership" has been the focus of recent controversy and debate. From the vantage point of the epidemiologist, decisions about ownership or "custodianship" of biorepositories collected for research should be guided by a discrete set of principles (<http://www.acepidemiology2.org/policystmts>). First, custodianship should encourage openness of scientific inquiry and should maximize biospecimen use and sharing so as to exploit the full potential to promote health. Second, the privacy of participants must be protected and informed consent must provide provisions for unanticipated biospecimen use. Third, the intellectual investment of investigators involved in the creation of a biorepository is often substantial and should be respected. Finally, sharing of specimens needs to protect proprietary information and to address the concerns of third-party funders.

In March 2006, Judge Stephen N. Limbaugh, of the U.S. District Court in St. Louis ruled in the case of *The Washington University versus William J. Catalona et al.* that the University owned all biological materials in a prostate cancer research repository containing tissue and blood from >30,000 research participants. Dr. Catalona, a respected urologist who was instrumental in establishing the biorepository, was disallowed from taking specimens to Northwestern University, where he had assumed a new position.

The judicial decision clearly identifies three parties in the dispute: Dr. Catalona, patients with biospecimens in the bank, and The Washington University. This editorial focuses on the case of *The Washington University versus Catalona et al.* from the perspective of a clinical or population scientist. Specifically, we ask whether the Catalona decision best served the principles articulated by the American College of Epidemiology, above, for guiding decisions about control of the destiny of research biologic materials.

Did the Catalona decision encourage openness of scientific inquiry and maximize biospecimen use and sharing? The Court stated that, "Medical research can only advance if access to these materials to the scientific community is not thwarted by private agendas. If left unregulated to the whims of the research participants, these highly prized biological materials would become nothing more than chattel going to the highest bidder." Here, the Court envisioned the chaos that would ensue if individual research participants retained control over their specimens, a response colored by the specifics of Catalona's actions (who petitioned each patient to consent to having their specimens move with him). The Court cited legal precedent favoring the notion that subjects "donate" to a biobank and that donations cannot be rescinded for personal use or gain.

But is science best served when control rests in the hands of the researcher who establishes such a resource or in the hands of the University who employed the researcher and may have contributed material support? We argue that individuals with the greatest knowledge and intellectual interest are most likely to make informed decisions around biospecimen use and sharing. Particularly if the biobank adheres to the recent National Cancer Institute guidelines on biorepositories, which mandates maximizing specimen sharing, biorepositories are best held in the hands of scientists working in the particular field that the biobank supports. Let's work through how this would play out in three specific situations. First, consider investigators from multiple institutions researching disease X contribute to a biorepository. We believe that these experts on disease X would maximally exploit the rich resources held in the repository rather than, say, a research administrator at the institution wherein the freezers reside. Second, what about a single investigator who maintains a research biobank from his or her own patients? Again, that investigator is most likely to fully use and share the resource. Third, take a biobank wherein multiple investigators maintain the resource, as was true in the *Washington University versus Catalona et al.* case. Here, the loss of one investigator would little influence the full usage of the bank; in this particular situation, we agree with the Court that the legal precedents supporting the rights of universities to own employee-generated intellectual property surmounts the concern about fostering science.

The principle regarding the maintenance of research participant privacy and the use of biospecimens for previously unintended purposes, is more fully considered in the accompanying editorial by Dressler.

What about the intellectual investment of investigators involved in the creation of a biorepository? Does the Catalona decision respect their time, effort, and innovation? In the specific case of Catalona, many investigators contributed to the biobank, although it was generally accepted that Catalona established the infrastructure. The new National Cancer Institute *First Generation Guidelines for NCI-Supported Biorepositories* indicates that "The requestor (of specimens) should agree to group publication guidelines and to make assay data available to the biorepository according to agreed-upon rules." Perhaps a practical solution to protecting intellectual investment is for all biobanks to establish publication rules that specify inclusion in authorship and even in decision-making around specimen sharing independent of current institutional affiliation.

Finally, how do we consider the protection of proprietary arrangements in light of the Catalona decision? The Washington University biorepository was not established with funding from third-party funders and we do not believe this was relevant to this case. Moreover, case law cedes ownership of patents to institutions (universities generally establish policies involving profit sharing with employee inventors). When proprietary interests are involved, institutions and third parties are best served by negotiating expectations (with the help of legal council) upfront.

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**Requests for reprints:** Roberta B. Ness, University of Pittsburgh, Graduate School of Public Health, Room A548 Crabtree Hall, 130 DeSoto Street, Pittsburgh, PA 15261. Phone: 412-624-3045; Fax: 412-624-3737. E-mail: [repro@pitt.edu](mailto:repro@pitt.edu)

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Overall, then, we do not argue that there were major flaws in the Court's thinking in the Washington University versus Catalona et al. case. At the same time, the reasonableness of the decision resides within the context of its special characteristics. In other cases with different details, a decision supporting the investigator(s) over the university

might be more reasonable and in better keeping with the principles of open scientific inquiry, respect for intellectual investment, patient privacy, and proprietary considerations. These principles should be central to the reconciliation of other disputes over biorepository custodianship or ownership.