With more than 300 million human specimens currently in storage in the United States, human biological samples have become an integral component of the research infrastructure (1, 2). It is, however, a fragile component. Human “biobanking,” depends heavily on the public’s trust in the research enterprise and the willingness of individuals to contribute specimens. That cooperative spirit, in turn, will be significantly affected by the policies and practices we use in collecting, processing, maintaining, and distributing these specimens.

The recent legal battle over “ownership” of banked biological specimens in a Washington University prostate cancer repository shows how easily flawed policies can put the public trust, and thus biobanking, at risk. In Washington University v. Catalona, Washington University filed an action “seeking to establish ownership, and thereby, the destiny of human specimens as property” (2), that the Court assumed the legal, regulatory, and compliance risks. Nor is it maintained, administered, funded, and staffed and for which Washington University to protect its interest in a biorepository (3). It is not difficult to understand the desire of certain research biological materials currently stored at the cancer repository shows how easily flawed policies can put the public trust, and thus biobanking, at risk. In

From the participants’ point of view, ownership is rarely the issue. Volunteers entrust their samples to researchers and institutions under the assumption that they will be used in the best interests of the research participant and the public at large, who ultimately stand to benefit from the research (and often indirectly funds much of the research). A false trichotomy of ownership, which pits the Institution (Washington University) against the Researcher (Catalona) and the Research Participant(s) (~30,000 prostate cancer patients), ignores the principles that participants expect to be definitive in research decision making; respect for their considered choices as participants and loyalty to their interests. These foundational principles are echoed in every research ethics discussion, including the seminal works, which guide ethical research conduct internationally (Nuremberg Code, Helsinki Document) as well as nationally (Belmont Report, 45CFR46, including the Common Rule).

One illustrative example of the shortcomings of a purely legal analysis of the biorepository issues is its implications for the ethical imperative to allow research subjects to withdraw from studies at will. On this issue, Catalona confuses two different but related concepts: providing the research participant an option to terminate participation in a research study (or biobank) at any time and providing an option to withdraw samples from the biobank and transfer them elsewhere. Federal regulations, which mandate that a research subject be given the option to terminate participation in a research study, were written at a time when biobanking and repositories were not a part of the research plan. Consequently, the regulations do not address situations when a research participant decides to terminate participation in a biorepository. In Catalona, the following interpretation was made:

“The Court finds that the right to discontinue participation in a research project means nothing more than the RP [research participant] has chosen not to provide any more biological materials pursuant to one or more research protocols; i.e., not to make any more inter vivos gifts of donated biological materials to WU. Nothing more can or should be read into this right possessed by the RPs at all times (3).”

Viewing the issues in the case as a tug-of-war over who “owns” the stored biological materials as tangible property leads the Court to declare that a research participant with samples in a biorepository has made an irrevocable gift and has relinquished all further interest in those samples. As Ness points out in the companion commentary, the Court was concerned that, if research participants began routinely treating their samples as “chattel,” they might begin withdrawing or transferring samples from one repository to another, resulting in chaos for the research infrastructure (4). But this concern seems to be primarily an artifact created by the focus of the Court on property rights. As director of national and institutional tissue banks, housing thousands of specimens, it has not been my experience that research subjects expect to be able to withdraw, deposit, or transfer specimens at a moment’s notice from one repository to another as they would do in a financial bank. They do expect, however, that repository decision making will turn on their interests rather than the property interests of institutions. They expect these interests to be determined by their own preferences, outlined in the informed consent document, or, when informed consents lack this specificity, by a “best interest” standard similar to that taken on by stewards or trustees (5).

For example, under the “stewardship or trustee model” (5-7), common among many cancer specimen banks (2, 8), when a research participant requests that their participation in a biobank be terminated, the specimens remaining in the bank are either destroyed (for DNA or fluids) or returned to the treating institution that originally submitted the tissues (for surgical pathology paraffin-embedded tissue). In this way, the specimen(s) is no longer used in future research, a decision that respects the research participant’s request for termination of participation. Does this mean that the specimen(s) that has already been distributed to researchers must be returned...
and associated research results destroyed? No. This would be unrealistic and not be in the best interests of the researchers or the funding agencies or the public. The decision point would be determined by what remains in the repository at the time of the request for termination. For prospective specimen collections, these decisions, interpretations, and intent must be clearly described in the consent process and articulated in the informed consent document.

By contrast, the legal blinders of the Catalona court take it in just the opposite direction when an individual elects to discontinue participation in the biobank:

“If a RP chooses to discontinue participation, federal and state regulations govern the options WU has regarding the tissue/blood/DNA sample. The undisputed testimony was that 1) WU may destroy samples it no longer needs for research; 2) store the samples indefinitely; and/or 3) choose to “anonymize” the samples and continue to use them in certain areas of research. To “anonymize” a sample, all links to the RP’s personal identifying data is removed and the sample is no longer “linked” to a particular RP . . . (3).”

Aside from the issue of whether the specimens were indeed contributed by the research participants with the intent of making a gift of material property to Washington University, these statements and interpretations run counter to conventional research practice and, more importantly, do not honor the ethical principle of “respect for persons.” If we uphold the interpretation that to discontinue participation in a biorepository means that samples can continue to be used, we violate an individual’s right to self-determination, voluntariness, and autonomy. Furthermore, the decision to discontinue participation is in relation to continued use of the stored specimen, not the future use of a yet-to-be-collected specimen. Regardless of whether the sample(s) is coded or even anonymized to protect a research participant’s privacy, use of an individual’s sample in research following a specific request to terminate participation in a DNA biorepository by destroying DNA remaining in the repository, not by continuing to use the specimen. The stewardship model would also require that the implications of a request for termination be transparent so that the expectations of the research participant as well as the researcher and institution are met.

In summary, decisions about control of human specimens should turn on the ethical principle of respect for persons, which is embraced by a stewardship, not an ownership model. If we are to realize the promises of this most exciting time in biomedical and epidemiologic research, these decisions must have their foundations within an ethical, not legal framework, motivating all stakeholders in the scientific process.

References
Biospecimen "Ownership": Counterpoint

Lynn G. Dressler


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