Scholar calls for a new legal, ethical framework for research with human tissue specimens

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A lawyer and researcher at the Johns Hopkins Berman Institute of Bioethics says a new legal and ethical framework needs to be placed around the donation and banking of human biological material, one that would more clearly define the terms of the material's use — and address donor expectations before research begins.

In a new law review article, "Why Not Take All of Me? Reflections on The Immortal Life of Henrietta Lacks and the Status of Participants in Research Using Human Specimens," Gail Javitt, J.D., M.P.H., uses the story of a woman whose cancerous cells revolutionized medical research as the launching point for an exploration of the flaws in the current legal approach to the use of human specimens in research.

The Immortal Life of Henrietta Lacks, by science journalist Rebecca Skloot, has stoked public interest in the ethical obligations owed to tissue contributors. Javitt says the "story is a powerful reminder that, behind every tissue sample in a laboratory, is the person it came from."

Recently, Skloot announced that her book will be adapted and turned into a cable-television movie. Javitt applauds moving the discussion of these issues into the public forum. As she writes, "by telling the Lacks family's story in such an engaging, accessible way, Skloot has moved the discussion beyond the narrow confines of courtrooms and academia and into the public domain, where all those with a stake in the answers can

participate."

Published in the *Minnesota Journal of Law, Science and Technology,* Javitt's article reports that human tissue and DNA are increasingly being collected and used in research. Yet they are obtained and stored under a patchwork of policies — some broad, some specific — that dictate how they may or may not be used in the future.

Many in the legal and scientific arenas say this is because federal and case law have fallen behind modern research demands and techniques.

The federal human subject protection law known as the "Common Rule" requires informed consent be obtained from participants in all federally funded research, and that includes tissue research. However, if identifying information has been removed, the law doesn't apply.

Even where informed consent is required, Javitt says, the human subject paradigm is not an adequate one for this type of research. She points out that informed consent is a mechanism aimed at protecting subjects from the type of harm and abuse that unwitting participants experienced in past research — such as the Tuskegee studies — and was never meant to be the process by which researchers negotiate to engage in a legal transaction.

"Informed consent was not conceptualized as a contract between two individuals with equal bargaining power," says Javitt, who has closely examined some of the best-known court cases involving the rights and expectations of human tissue contributors. "Rather, informed consent is an ethical duty that the researcher owes the human subject under conditions that historically have involved unequal power."

In contrast, the concept of donation "presumes an individual who understands that he is giving away something of value and the

consequences of making that choice."

Javitt's article cites legal cases that she says show the courts' failure to appreciate that those who contribute tissue for research are owed duties as research subjects to be informed that their tissue will be used for research. For instance, in Moore v. Regents of the University of California, the court ruled that a physician violated informed consent obligations to his patient (Moore) by performing surgery and ordering follow-up blood draws without disclosing that he was also developing a potentially lucrative cell line from the patient's specimens.

"The court's reasoning with respect to informed consent is flawed," Javitt says, because "the court failed to distinguish between Moore as patient and Moore as research subject."

The cases also show a failure to appreciate the dual role of the tissue contributor as both research subject and participant in the legal transaction of donation, according to Javitt. So, she argues for a bifurcation of the process: As research subjects, participants must be informed of the risks and benefits of the research, and consent to participation. As donors of tissue, participants also must be informed that they are entering into a legal transaction — donation — and made aware of the terms of that transaction.

"Although requiring separation ... may seem like a proposal for adding yet another piece of paper to an arguably already cumbersome process, the small piece of paper is performing a huge ethical and legal task," Javitt writes in her article.

Javitt also says she was troubled by what she sees as the courts' consistent preference for the needs of the research enterprise over the claims of the tissue contributors. Although the public generally is supportive of research, Javitt says, this may change if prospective

contributors of tissue samples feel deceived.

For example, in February, angry parents in Texas sued over the state's use of their babies' blood samples for research. Just two months later, the Havasupai tribe in Arizona succeeded in reclaiming their DNA samples from researchers at the state university system. Meanwhile, the book about Henrietta Lacks has amplified the frustration of her descendants in Baltimore over the use of her cells without their knowledge.

Across the board, mistrust was fueled by a lack of transparency and the discovery of details only after samples were used.

"How fitting it would be," Javitt's article concludes, "if the development of a new, transparency-based framework for tissue donation, one that is premised on the simple notion that tissue contributors should be asked—within a context that allows a meaningful answer—was Henrietta Lacks's true legacy."

More information: Gail Javitt, J.D., M.P.H. - www.bioethicsinstitute.org/mshome/?id=92

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