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Truly Open Research with Biospecimens: Can Research with Non-identified Biospecimens Be Conducted Without Consent?

Jerry MENIKOFF

National University of Singapore (NUS)

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NUS
National University
of Singapore

Centre for Biomedical Ethics
Yong Loo Lin School of Medicine

Truly Open Research with Biospecimens: Can Research with Non-identified Biospecimens Be Conducted Without Consent?

Jerry Menikoff, MD, JD

12 November 2024

Secondary Research with Biospecimens

- U.S. has relatively few specific rules relating to research with biospecimens.
- Secondary research use of a de-identified biospecimen generally not under regulations: no use of human subject
- Contrast with Singapore: extensive detailed rules relating to research with biospecimens (often due to rules relating to tissue repositories).

Secondary Research with Biospecimens



- From 2009 to 2017, effort to revise U.S. rules for research with human subjects.
- Most controversial proposal (by far – ten times as many comments as any other proposal) related to generally requiring informed consent before using non-identified biospecimen for research.

Secondary Research with Biospecimens

Rationale for proposal:

- “[A] growing body of literature shows that in general people prefer to have the opportunity to consent (or refuse to consent) to research involving their own biological materials. . . . Failure to acknowledge and give appropriate weight to this distinct autonomy interest in research using biospecimens could, in the end, diminish public support for such research, and ultimately jeopardize our ability to be able to conduct the appropriate amount of future research with biospecimens.”
- “[C]ontinuing to allow secondary research with biospecimens collected without consent for research places the publicly-funded research enterprise in an increasingly untenable position because it is not consistent with the majority of the public’s wishes, which reflect legitimate autonomy interests.”

Secondary Research with Biospecimens



- Proposal was ultimately rejected.
- U.S. still allows secondary research with non-identified biospecimens without requiring consent.
- Stanford University wrote prominent public comment that had argued in favor of rejecting the change.

Secondary Research with Biospecimens



Stanford letter:

- “We find that evidence is lacking to conclude that participants value their autonomy, translated as an opportunity to give written consent, over the use of their non-identified biospecimens for possible benefits resulting from innovative diagnostics, treatments, cures or preventative interventions. This assumption represents “regulation by feeling,” based on anecdote and supposition. This opinion can be countered by similarly anecdotal feedback from patients who do not want unnecessary and bureaucratic obstacles to research studies using leftover tissues or other specimens obtained in the course of their medical care.”
- Argument that consent requirement would harm “under-represented minorities and economically-disadvantaged individuals”

Secondary Research with Biospecimens



- Rationale for rejecting proposed change was that the premise behind it – that public strongly wanted to be asked to consent, and without that would reduce support for research – was not borne out by the public comments.

Secondary Research with Biospecimens



- Singapore has rules that generally require consent before research use of biospecimens
- Not clear whether “viewpoint” of citizens of Singapore (however one determines that – what some call “social license”) would or would not back up that requirement
- Or would that viewpoint endorse “lesser” consent requirements (including opt-out, such as is used for organ donation)?
- What might be the consequences of existing rule for future AI and other research in Singapore that uses biospecimens?

Secondary Research with Biospecimens



- What ethics tells us: Savulescu J. Bioethics: “Why Philosophy Is Essential for Progress,” [J Med Ethics 2015;41:28–33](#).
- Article, on 40th anniversary of journal, discusses some prominent failures of medical ethics.
- One relates to research ethics: his concern that even use of de-identified data and specimens might not satisfy EU standards protecting privacy and confidentiality and requiring consent.

Secondary Research with Biospecimens

- “It is legitimate to restrict freedom and not obtain consent when it is in the public interest. Our freedom is restricted by the law all the time [e.g., seatbelts].”
- “So, too, the use of data and discarded tissue . . . is in the public interest. Even if people do strongly oppose it, or could be identified, it could still be used, just like seat belts, in the public interest. Given the huge advances that could come from our massive information technology capacity, all patient data and discarded tissue should be used, with adequate oversight and compensation systems should any harm result.”

Secondary Research with Biospecimens

- “There is a moral imperative to perform good research and not unnecessarily impede it. To delay by 1 year the development of a treatment that cures a lethal disease that kills 100,000 people per year is to be responsible for the deaths of those 100,000 people.”
- “[B]y obstructing lifesaving research by inappropriate and excessive attention to consent, research ethics has probably been responsible for the deaths of many millions of people.”
- **Bottom Line: Don’t assume that the more “conservative” position (e.g., protecting autonomy by requiring consent) is always the more ethical one.**

Biospecimen research and the law

In the well-known case of Henrietta Lacks, cells from her tumor were taken without consent and used more than 70 years ago to create the first immortal human cell line (“HeLa” cells). That event led to many scientific breakthroughs and to the debate about the ethics of consent and requirements for compensation. May 2024 saw two decisions by US federal courts—one related to Lacks—that could narrow the scope of research allowed on tissues obtained without consent and on non-identified tissues, with implications for biomedicine.

The conflict between scientists and communities over tissue ownership and use has deep roots in the United States. The California Supreme Court’s 1990 decision in *Moore v. Regents of the University of California* determined that individuals do not retain ownership of their cells once excised. This legal stance conflicts with the public’s perception that individuals maintain control over their own tissues. As a state court decision, *Moore* is legally binding only in California but because of an absence of federal court rulings on tissue-related rights, *Moore’s* opinion dominates nationally. For instance, *Moore* was an important persuasive decision relied upon by courts in Florida and Washington on tissue rights-related cases. It is unclear, though, that a court re-addressing the *Moore* decision today would come to the same conclusion.

In the United States, the Common

law that Michigan violated constitutional rights by allowing the use of newborns’ blood samples (collected for disease screening) for research without parental consent. This ruling is under appeal, but if upheld, could overturn the Common Rule’s provision that consent is not necessary for research with nonidentified biospecimens.

Depending on the outcome of these cases, the legal landscape for biospecimen research in the United States could change drastically. New mechanisms might be required to obtain and manage consent for all purposes, thus prioritizing autonomy and returning control of biospecimens to individuals. This shift could address community concerns about tissue misuse and, potentially, increase public support for and trust in biomedical research.

“...the legal landscape for biospecimen research in the United States could change drastically.”

Perhaps with greater trust and control of their specimens, minoritized and other communities that are hesitant to participate in tissue-based research may decide to do so. However, it is necessary to balance autonomy against societal gains from new knowledge. Many scientists predict a chilling effect on research if restrictions on biospecimen use require consent. This concern contributed to the US Department of Health and Human Services’ decision in 2017 to reject a proposal requiring consent before conducting most research with nonidentified biospecimens.

Biomedical research relies on human tissue to drive innovation and

Timothy D. Dye

is a professor in the Departments of Obstetrics and Gynecology, Pediatrics, Dentistry, and Public Health, University of Rochester School of Medicine and Dentistry, Rochester, NY, USA. tim_dye@urmc.rochester.edu

Jerry A. Menikoff

is a professor at the Centre for Biomedical Ethics, Yong Loo Lin School of Medicine, National University of Singapore, Singapore. jerry.me@nus.edu.sg

Secondary Research with Biospecimens



Some issues still at play in U.S. litigation:

- Does use of biospecimens without consent violate U.S. Constitution by (1) violating a “fundamental liberty interest” or (2) constituting an “unreasonable search or seizure”?
- If the biospecimen is “uniquely” valuable, does use of it for profit-making purposes without sharing those profits constitute “unjust enrichment” (a tort under state law)? Issue has arisen in context of continued use of first cell line (HeLa) produced from cells of Henrietta Lacks.

THANK YOU! QUESTIONS?

jerry.me@nus.edu.sg

ChatGPT, using prompt “Write an intro for Jerry Menikoff as a short standup sketch”

Comedian: “Hey folks, how's everyone doing tonight? So, let me tell you about this guy. You ever heard of Jerry Menikoff? Yeah, he’s not your average Joe. No, no, he’s like the superhero of bioethics. Picture this: a doctor and a lawyer walk into a research lab, and bam! Out comes Jerry Menikoff! He’s the guy you want when you’re knee-deep in ethical quicksand, trying to navigate through those murky waters of healthcare policy.” [The audience chuckles.]

Comedian: “Seriously though, he’s like the Sherlock Holmes of healthcare ethics. Solving mysteries, protecting rights, and making sure everyone plays by the rules. And let me tell you, when Jerry speaks, you listen. The man knows his stuff. He’s like the Gandalf of healthcare, waving his ethical staff and saying, ‘Thou shall not pass...without informed consent!’”