CENTER FOR BIOETHICS & SOCIAL SCIENCES IN MEDICINE
UNIVERSITY OF MICHIGAN

Best practices from the field

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MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN

Funding

- National Human Genome Research Institute (K01HG010496)
- National Cancer Institute (R01CA21482901A1)
- National Center for Advancing Translational Sciences (UL1TR002240)
- AAOHNS & AHNS Young Investigator Award

Argument:

1. Biospecimens and health data are governed by method of procurement
2. What contributors care about is use
3. Biospecimens and health data that are procured differently end up being used similarly
4. Regulatory mechanisms and market forces have failed to reconcile this tension
5. Other governance forces are necessary to protect contributor autonomy and life-saving medical research

Governance by method of procurement:

HIPAA: (Identified) clinical

Common Rule: (Some identified) research

(Maybe) FDA/FTC/CMS: Commercial

What contributors care about is use

- Expectation for formal opt-in consent (Jagsi 2017)
  - 35% think its necessary to obtain specific research consent even for secondary research (48% among blacks/Hispanics)
- Access to deidentified medical information (Jagsi 2017)
  - 9% uncomfortable for university research
  - 16% uncomfortable for drug companies
  - 48% uncomfortable for insurance companies
- "Non-welfare interests" (De Vries 2016)
  - 68% agreed to blanket consent
  - But 70.4% unwilling when presented with a specific controversial research scenario

Jagsi R et al. Perspectives of Patients With Cancer on the Ethics of Rapid-Learning Health Systems. *J Clin Oncol.* 2017; De Vries RG et al., The moral concerns of biobank donors: the effect of non-welfare interests on willingness to donate. Life Sciences Society and Policy 2016, 12(1): 1-15 DOI: 10.1186/s40504-016-0036-4;

ETHICS

By Kayte Spector-Bagdady, Raymond G. De Vries, Michele G. Gornick, Andrew G. Shuman, Sharon Kardia, and Jodyn Platt

Encouraging Participation And Transparency In Biobank Research

DOI: 10.1377/hlthaff.2018.0159
HEALTH AFFAIRS 37,
NO. 8 (2018): 1313–1320

- 67% believe notification about commercial use of biospecimens is important
- 77% uncomfortable with university hospital use to generate income
- 62% believed that profits should be used only to support future research

Spector-Bagdady K, De Vries RG, Gornick MG, Shuman AG, Kardia S, Platt J.Encouraging Participation And Transparency In Biobank Research. *Health Aff* (Millwood). 2018;37(8):1313-1320.

How specimens and data become mixed

Commercialization of specimens and data collected from patients and participants

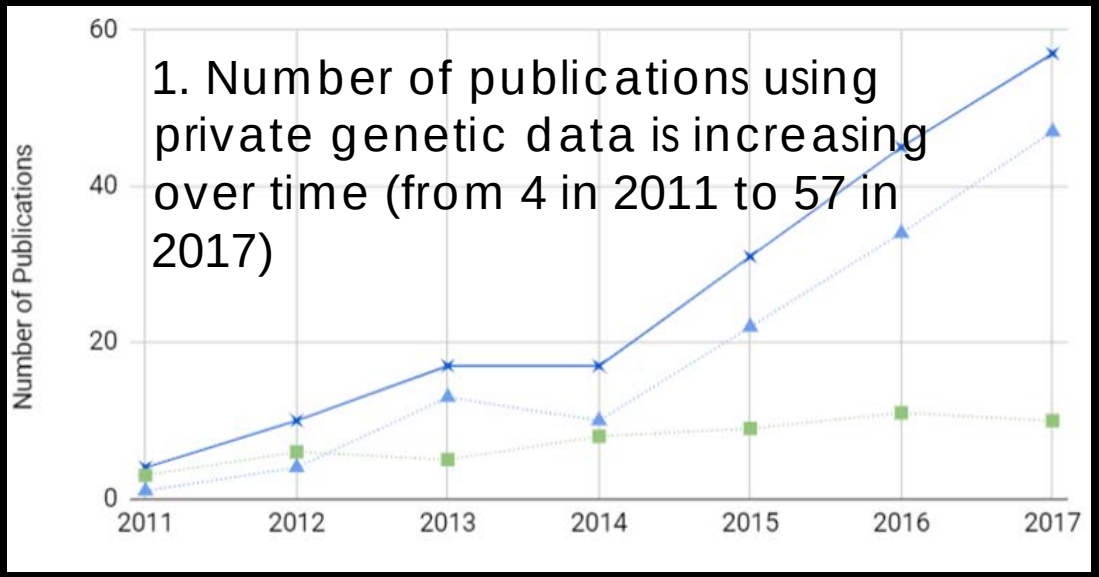
Steinsbekk KS, Ursin LO, Skolbekken AJ, Solberg B. We're not in it for the money—lay people's moral intuitions on commercial use of 'their' biobank, 2013. Med Health Care and Philos; 16:151-62; Cardigan RJ, Lassiter D, Haldeman K, Conlon I, Reavely E. Neglected ethical issues in biobank management: results from a U.S. study, 2013. Life Sci Soc Policy; 9(1):1-13.

BRIEF COMMUNICATION | Genetics inMedicine

Genetic data partnerships: academic publications with privately owned or generated genetic data

Kayte Spector-Bagdady, JD, MBE[1], Amanda Fakih, MHSA[2], Chris Krenz, BA[3], Erica E. Marsh, MD[4] and J. Scott Roberts, PhD[5]

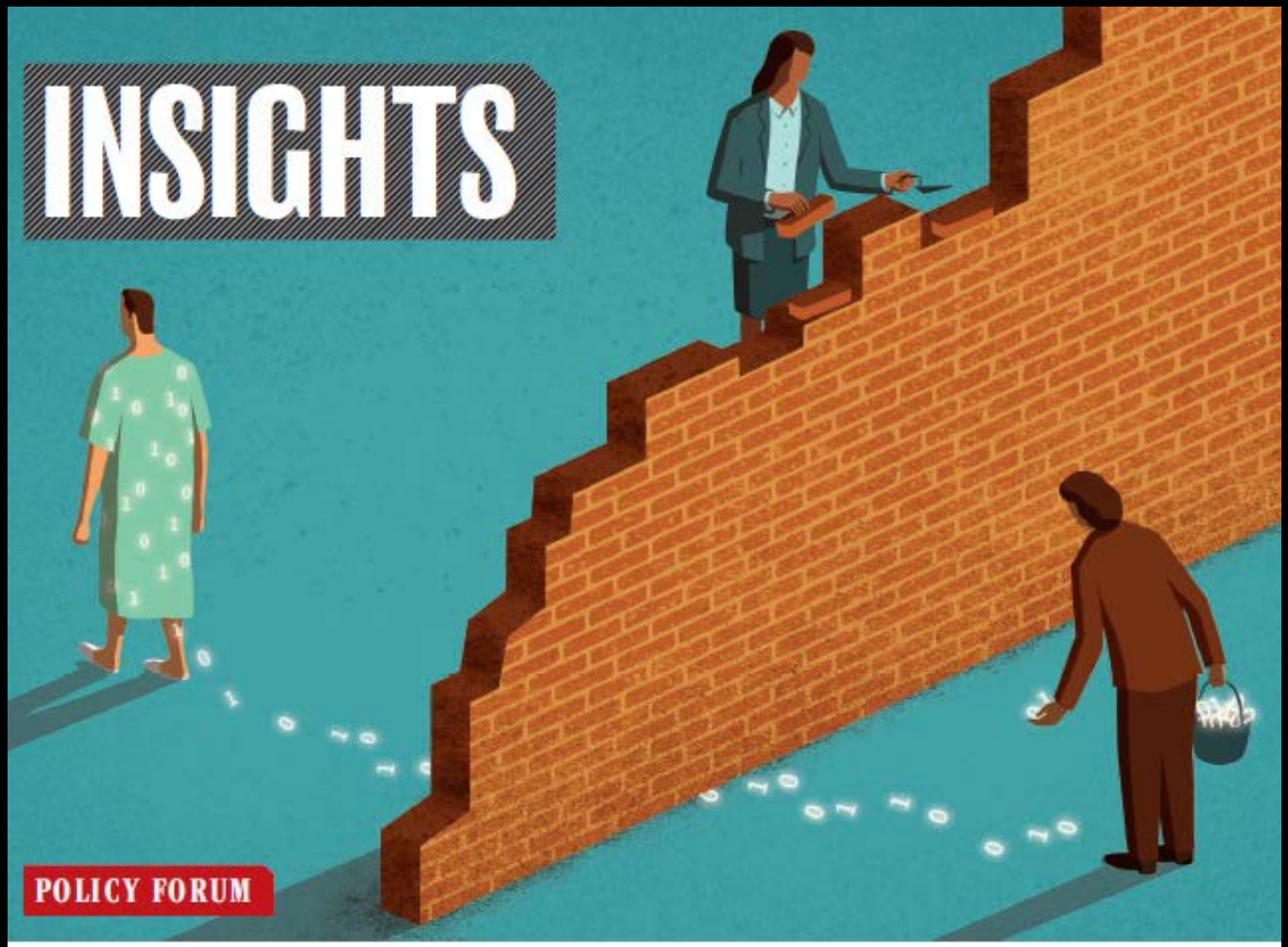
1. Number of publications using private genetic data is increasing over time (from 4 in 2011 to 57 in 2017)



2. Two main models of data-sharing, including researchers using existing private data held by industry (n = 172) or researchers sending in new samples for analysis (n = 6)

3. 45% of the publications were supported at least in part by the NIH

4. Type of contributor consent is not disclosed/unclear in the publication almost half (43%) the time



DATA AND REGULATION

Shadow health records meet new data privacy laws

How will research respond to a changing regulatory space?

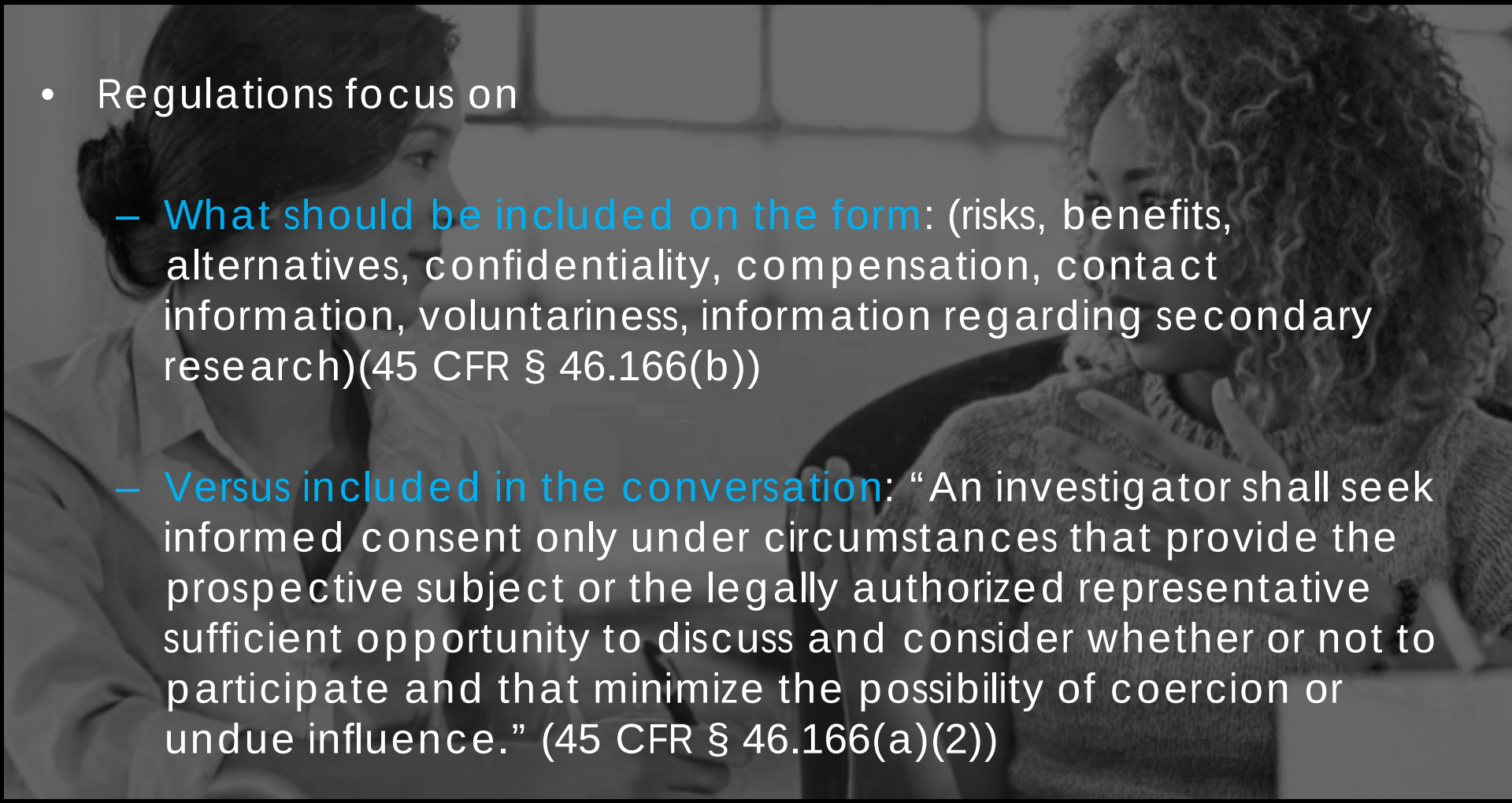
By **W. Nicholson Price II[1,2], Margot E. Kaminski[3,4], Timo Minssen[2,5], Kayte Spector-Bagdady[6,7]**

spite data privacy rules. Now that space for regulatory arbitrage is changing. The long arms of Europe's new General Data Protec-

regulatory structure in the United States, however, was built neither to protect nor to enable such uses of big data to drive research and improve health. Although the United States does not have a general-purpose federal data privacy law, its most sweeping data privacy regulations—the Privacy and Security Rules of the Health Insurance Portability and Accountability Act (HIPAA)—target personal health information and aim to protect health data privacy (*1*). The Privacy Rule governs when protected health information (PHI) may be used or disclosed by health care pro-

Failure of current regulations

- Only intervention found to consistently improve participant comprehension is a conversation (Beskow 2016)



- Regulations focus on
  - What should be included on the form: (risks, benefits, alternatives, confidentiality, compensation, contact information, voluntariness, information regarding secondary research)(45 CFR § 46.166(b))
  - Versus included in the conversation: "An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence." (45 CFR § 46.166(a)(2))

Beskow LM. Lessons from HeLa Cells: The ethics and policy of biospecimens. *Annu. Rev. Genom. Hum. Genet.* 2016. 17:409.

Patients do not understand

- "Turning patients into participants in a precision medicine protocol"
- Empirical ELSI protocol nested within a prospective precision oncology genomic sequencing study in an NCI-designated cancer center
- Goal: Further understand the decision-making process of both the clinician who refers a patient to a precision medicine trial and the patient who agrees to transition to participant

Spector-Bagdady K et al. "My research is their business, but I'm not their business": Patient and Clinician Perspectives on Commercialization of Precision Oncology Data *Oncologist* (forthcoming).

Comprehension re commercialization

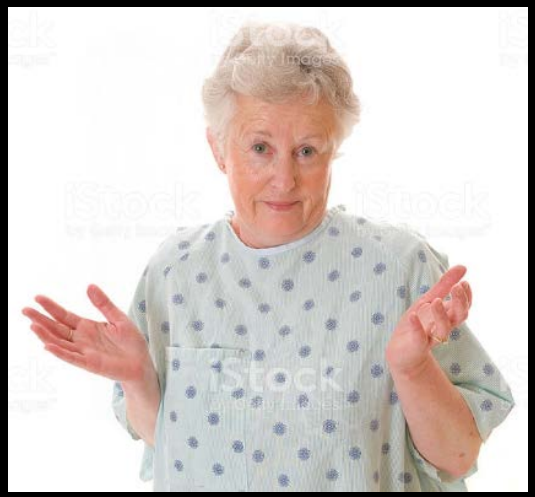
- "…the following elements of information, when appropriate shall also be provided to each subject… A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit" §46.1169(c)(7)

Comprehension re commercialization

- "All of the information collected about you will be preserved and made available to others for research…This information may ultimately have significant therapeutic or commercial value. By agreeing to participate in this study, you consent to such uses…If a new discovery, diagnostic test, or treatment results [UM] and collaborators including commercial entities could profit by filing a patent. Should any product developed from participant samples, participants will not be responsible for any costs of development, nor will they obtain any profit from the commercial use."

Comprehension re commercialization

"…I hope you don't, because I don't think you said you would, or did you? I don't remember the consent form…I'd get my lawyer because you promised that none of my personal information would be given to anyone outside the university!" (Patient 04)



"I hope we aren't selling it to 23 and Me! …[P]atients trusted in us, that we have a trial where we are the sole people in charge of their information, and…to then after the fact sell it…I would have a problem with that. I would think that we would need to have a secondary approval from patients." (Clinician 04)

Spector-Bagdady K et al. "My research is their business, but I'm not their business": Patient and Clinician Perspectives on Commercialization of Precision Oncology Data *Oncologist* (forthcoming).

"Informed consent" that does not inform

- Only 1/1,000 consumers click on a website's terms of service…only 1/10,000 if it requires two clicks (Bakos 2014)
- Median reading time is 29 seconds (Bakos 2014)
- People express "little concern about sharing health data with the companies that sold the devices or apps they used, and indicated that they rarely read the terms and conditions (Ostherr 2017)
- However, "significant resistance" from participants regarding sharing data for "scientific study" (Ostherr 2017)

Kirsten Ostherr, Svetlana Borodina, Rachel Conrad Bracken et al., *Trust and privacy in the context of user-generated health data*. BIG DATA & SOCIETY 2017;5(1):1-11; Bakos, Yannis and Marotta-Wurgler, Florencia and Trossen, David R., Does Anyone Read the Fine Print? Consumer Attention to Standard Form Contracts. *The Journal of Legal Studies* Vol. 43, No. 1 (January 2014), pp. 1-35; Neil Richards & Woodrow Hartzog. The Pathologies of Digital Consent. *Wash U L Rev* 2019 (forthcoming).

RESULT - PRIVATIZATION

- *All of Us* research program
- EMR data from 112,000 participants
- 80% “underrepresented in biomedical research”
- $2.16 billion through 2026

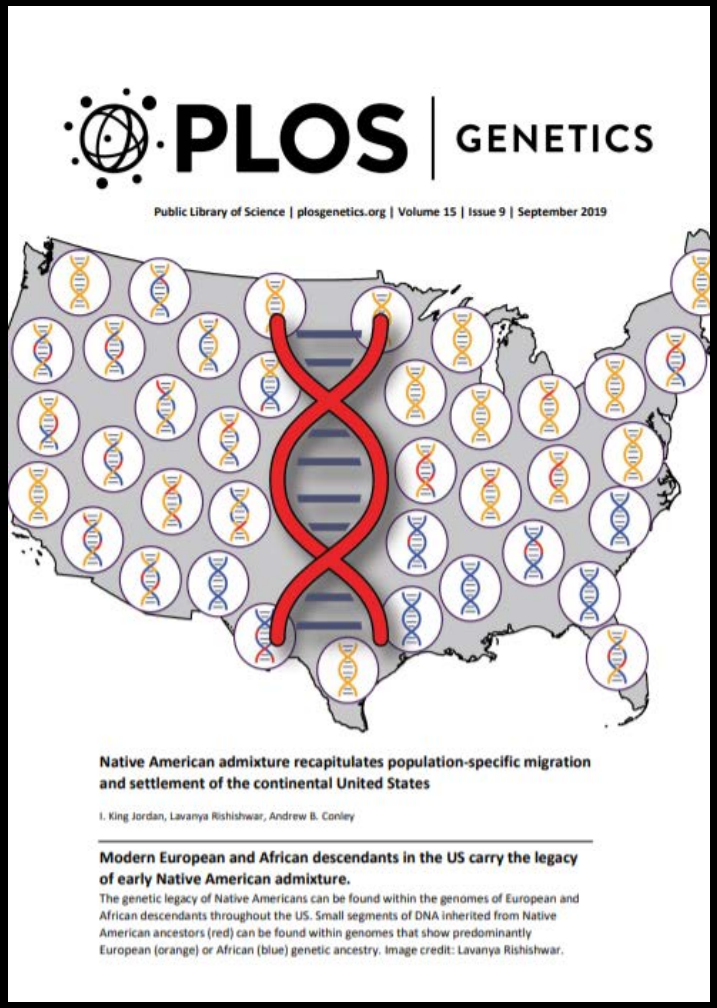
- 23andMe
- 10 million genetic & phenotypic participants
- 80% white & educated
- Valuation of $2.5 billion

Problem = Access

- Gives industry a gatekeeping function over what research is enabled
  - In 2011, 96.5% of published, industry-sponsored, head-to-head comparative effectiveness trials found favorable results (Flacco 2015)
- Limits ability to validate work or build derivative discoveries
- Decreased future access (e.g., price increases or change in leadership)
- Myriad

Flacco ME, Manzoli M, Boccia S et al. Head-to-head randomized trials are mostly industry sponsored and almost always favor the industry sponsor. *J Clin Epidemiol*. 2015;68(7):811-20.

Governance alternative: Journal standards



Governance alternative: Institutions

Human Data and Biospecimen Release Committee:

- **Applies to data in addition to specimens**
- **Applies to all data and specimens collected during research**
- **Does not grandfather in previously collected specimens**
- **Areas for future consideration:**
  - **Limitations of informed consent**
  - **Clinical data and specimens**

/fin

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