Data Sharing and Privacy and Consent Implications for the Collaboratory:

Ethics

Overview:

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. What are the implications for the Collaboratory?

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Problems with governance

Limited scope of current regulations

Only readily identifiable research

- “Human subject” is a living person with whom the investigator “obtains information through intervention or interaction” or which involves “identifiable private information or identifiable biospecimens”

- Regulators recently considered expanding the definition to include identifiable data or any human biospecimen
  - 1,520/2,000 comments submitted to the 2015 NPRM discussed this proposal – with about 1,480 in opposition
  - Rule proposed a new committee to re-consider whether biospecimens should be considered inherently identifiable

Waiver of informed consent

Even if research falls within the scope of federal regulation and *even if* participants fall within the definition of “human subjects,” researchers may still apply for a waiver of informed consent if the research meets the following criteria:

1. Involves no more than minimal risk to the subjects
2. Could not practicably be carried out without the requested waiver
3. The waiver will not adversely affect the rights and welfare of the subjects; and
4. Whenever appropriate, additional pertinent information will be provided after participation.

Lack of responsiveness to risk/ benefit profiles of secondary research

Foundation of human subjects research regulations

Individual, physical, and profound

New risks

- Dignitary harms: privacy breaches, non-welfare interests, or algorithmic biases
- Negative externality: while the *risks* of secondary research remain individual, the *benefits* redound to either the entity holding the data or the common good

C. Grady et al., "Informed Consent," New England Journal of Medicine 376 (2017): 856-67; https://www.cnet.com/news/tmi-some-fitbit-users-sex-stats-on-google-search/; De Vries RG, Tomlinson T, Kim HM, Krenz CD, Ryan KA, Lehpamer N, Kim SY6. The moral concerns of biobank donors: the effect of non-welfare interests on willingness to donate. *Life Sci Soc Policy*. 2016;12:3;I Price WN 2nd, Kaminski ME, Minssen T, Spector-Bagdady K. Shadow health records meet new data privacy laws. Science. 2019;363(6426):448-450.

Dinerstein v. Google & UChicago

- UChicago shared de-identified EMR data of all adult UChicago patients over a five year period
  - Goal of generating machine learning techniques
- Dinerstein sued for breach of HIPAA (among other things) because only allowed to share PHI for research in exchange for a reasonable cost based fee
  - "Whatever a perpetual license for 'Trained Models and Predictions' actually means, it appears to qualify as direct or indirect remuneration."
- But dismissed for failure to state a claim upon which relief can be granted

Dinerstein v. Google, LLC, No. 19 C 4311, 2020 WL 5296920, 1079-1124 (N.D. Ill. Sept. 4, 2020).

Governance by method of collection no longer makes sense

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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 Black/Hispanic participants)

- 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;

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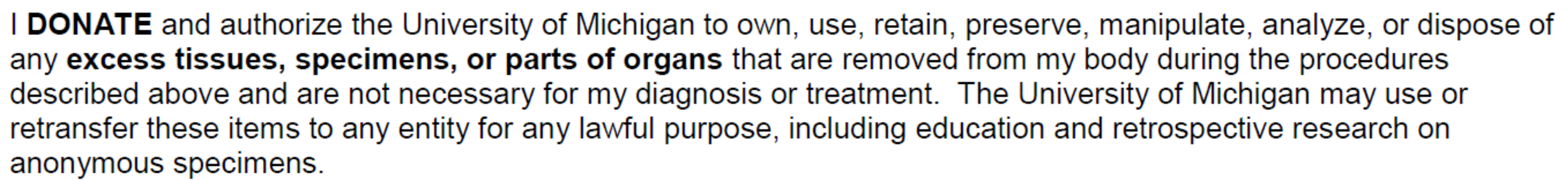
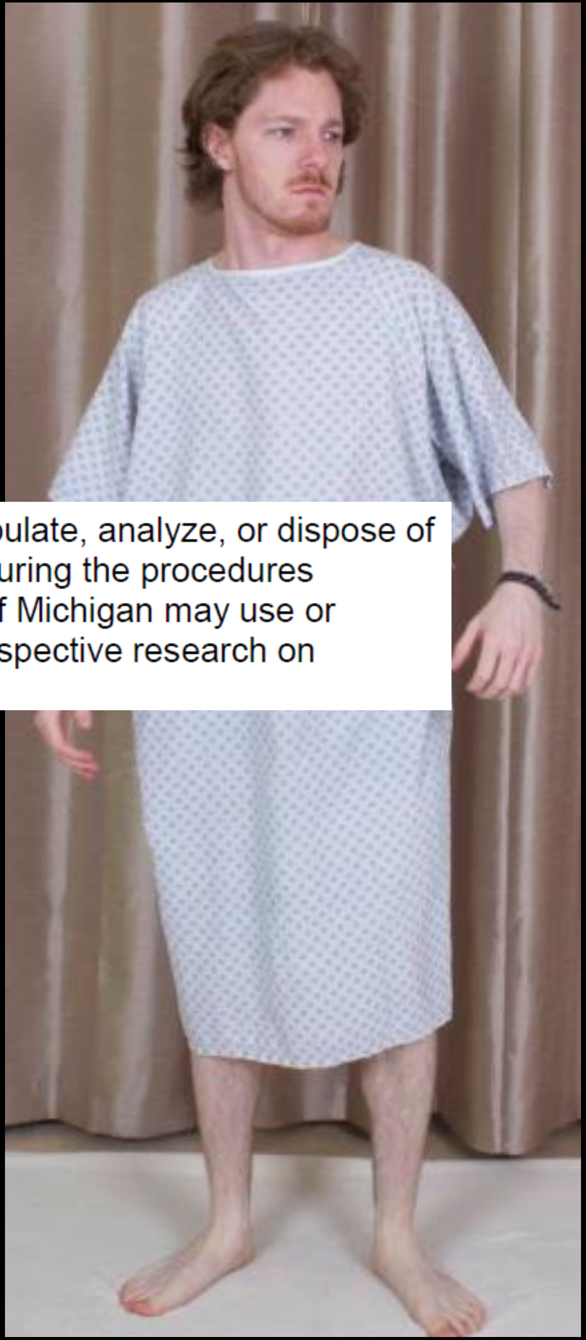
Patient informed consent



I **DONATE** and authorize the University of Michigan to own, use, retain, preserve, manipulate, analyze, or dispose of any **excess tissues, specimens, or parts of organs** that are removed from my body during the procedures described above and are not necessary for my diagnosis or treatment. The University of Michigan may use or retransfer these items to any entity for any lawful purpose, including education and retrospective research on anonymous specimens.



Participant informed consent

"We would also like your permission to keep some of your biospecimen and medical information collected in the main study, so that we may study it in future research.

The future research may be similar to this study or may be completely different… We may share your biospecimen and medical information with other researchers, so that they can use it in their research…With appropriate permissions, your samples and collected information may also be shared with other researchers here, around the world, and with companies.

Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent…Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them."

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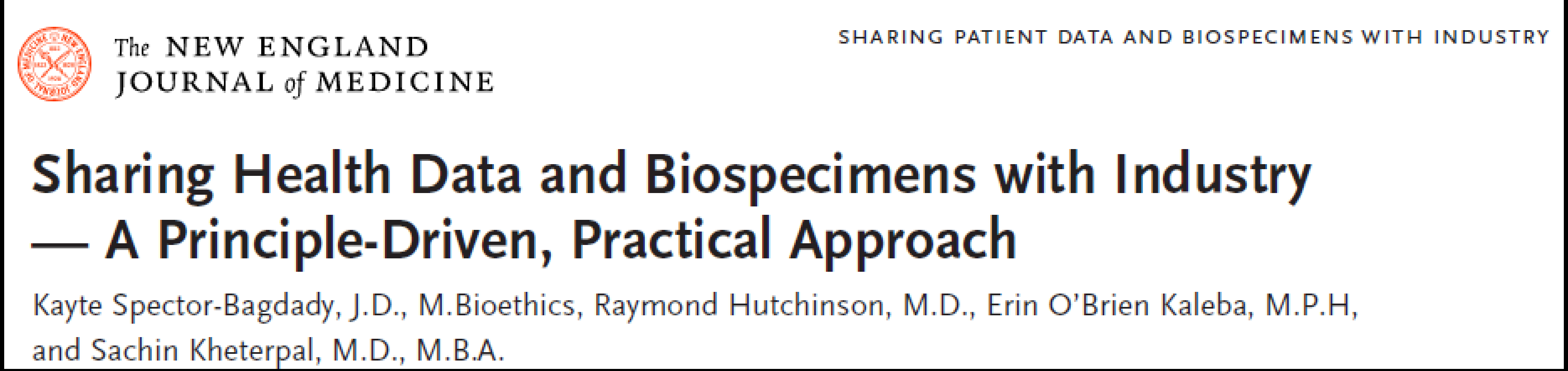

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SHARING PATIENT DATA AND BIOSPECIMENS WITH INDUSTRY

Sharing Health Data and Biospecimens with Industry — A Principle-Driven, Practical Approach

Kayte Spector-Bagdady, J.D., M.Bioethics, Raymond Hutchinson, M.D., Erin O'Brien Kaleba, M.P.H, and Sachin Kheterpal, M.D., M.B.A.

- U-M policy more conservative than regulations:
    - Review both biospecimens and data
    - No grandfathering in of data & specimens collected before updated regs
    - Review even "de-identified" data

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Hospitals should act now to notify patients about research use of their data and biospecimens

Private industry is increasingly soliciting hospitals to sell or share health data and biospecimens, but current laws offer more disclosure and consent protections for research participants than for patients receiving clinical care. Hospitals can offer more protections than required by law, however, and should move toward greater transparency with their patients about the research use of clinical health data and biospecimens to respect patients and avoid distrust.

Kayte Spector-Bagdady

In November 2019, a whistleblower released information regarding an agreement between Ascension, a US non-profit health system, and Google Health to share up to 50 million fully identified medical records[1]. Google Health subsequently reported that the goal of the agreement was to conduct research into developing an "intelligent suite of tools" for clinicians to better leverage electronic medical record data to take care of their patients[2]. The ability to compare one sick patient with the treatment plans and outcomes of many patients with similar demographics and health issues would be an invaluable tool to be able to sell back to health systems. Unlike a previous agreement between the University of Chicago and Google, in which de-identified patient data were shared[3]. Ascension shared fully

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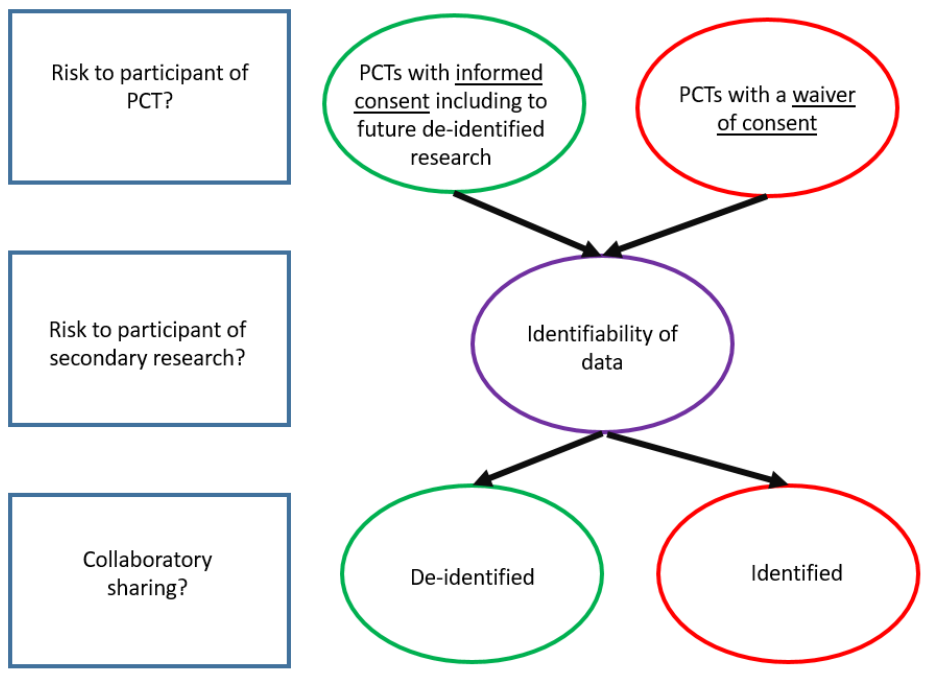
Special case of PCTs with waiver of consent

- Participants whose data was generated/used via a PCTs which went through the <u>informed consent</u> process consented to future de-identified research
- Participants whose data was generated/used via a PCTs with a <u>waiver of consent</u> did not consent to future de-identified research because the underlying PCT was considered minimal risk.
- HOWEVER, the risk of future datasharing is generally based on whether the data are de-identified or not
- Thus all data – whether the participants provided full consent and consented to future de-identified research or not consent at all – are treated the same.



Morain et al, Ethics and Collateral Findings in Pragmatic Clinical Trials, Am J Bioeth 2020 Jan;20(1):6-8; Roberts et al, Ethical and regulatory concerns in pragmatic clinical trial monitoring and oversight, Ethics Hum Res 2020 Sept;42(5):29-37.

Data enclaves?

- Therefore patients whose data are systematically collected and analyzed under the auspices of a PCT-AWC may simultaneously be:
    1. Unaware they are involved in a research protocol and
    2. Unconsented to share the underlying primary data generated in this research, some highly sensitive, for future research as IRBs require of other studies involving human subjects

Discussion

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Kayte Spector-Bagdady, "Governing Secondary Research Use of Health Data and Specimens: The Inequitable Distribution of Regulatory Burden Between Federally-Funded and Industry Research" (February 15, 2021). J Law Biosci (forthcoming). Available at SSRN: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3786853