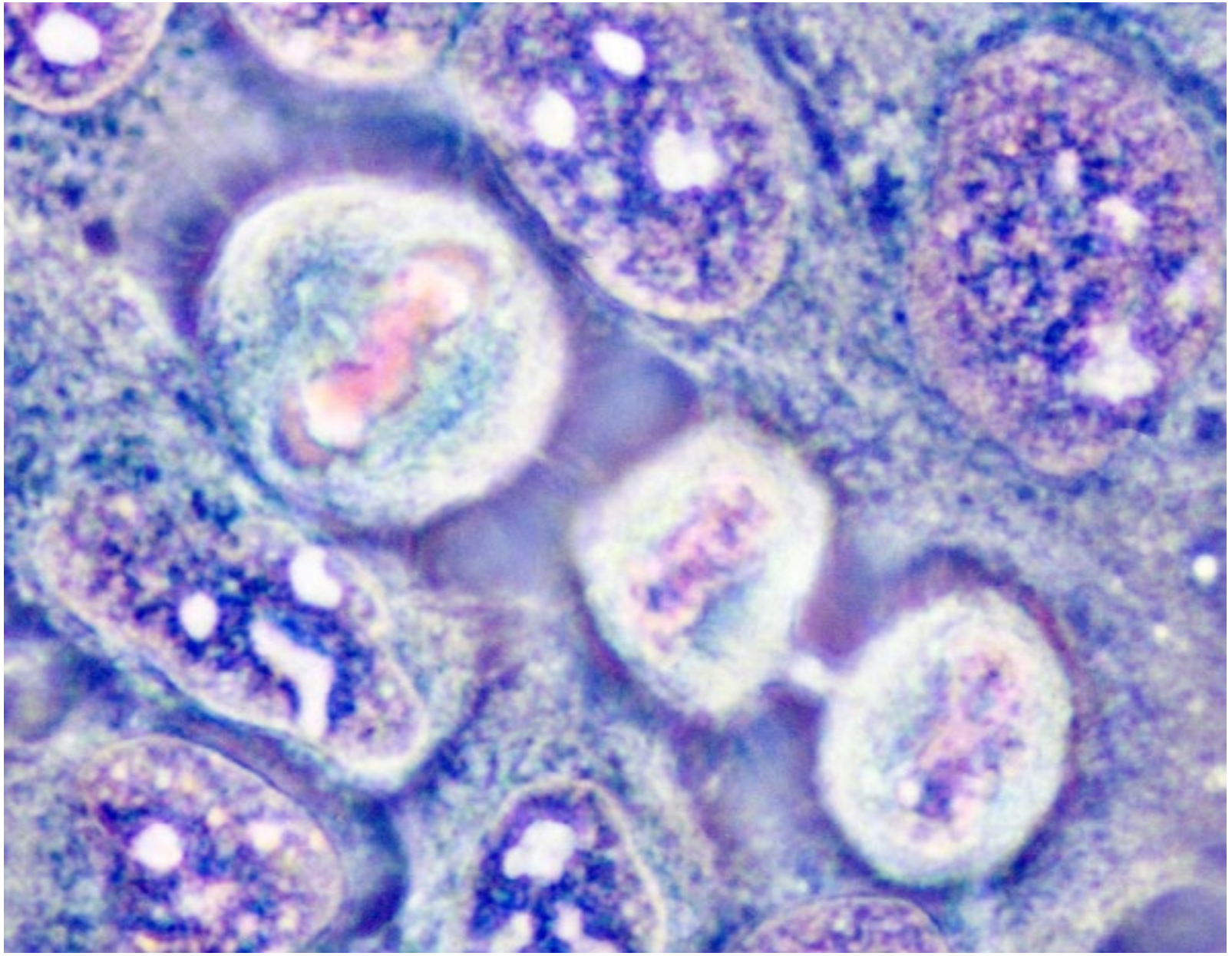

The Legal Implications of HeLa

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Overview:

Who is Henrietta Lacks?

What is HeLa?

The Two Main Legal Issues:

- Informed Consent
- Medical Records Privacy

Current Related Legal Concepts:

- The Informed Consent Requirement:
  - The Common Rule
  - FDA Requirements

Overview:

Current Related Legal Concepts:

- The HIPAA Privacy Rule:
  - Medical Research Application
  - Valid Authorization
  - Research Authorization
  - Waiving HIPAA Authorization
  - The Family Educational Rights and Privacy Act
  - Secondary Research
  - De-identified Data and Limited Data Sets
  - Other Research Accommodations
  - Certificates of Confidentiality

Resolutions

Who is Henrietta Lacks?

- She was a poor African-American woman needing medical diagnosis and treatment in 1951.
- She went to The Johns Hopkins Hospital.
  - This hospital was one of the only choices for treatment for poor African-Americans in 1951.
- She was diagnosed with cervical cancer and received radium treatment.
- Dr. George Gey, a virus and cancer researcher, kept a sample of Lack's cervical cells for medical research.
- Her cells differed from cells sampled from other patients by doubling daily instead of quickly dying.

(Biographics, 2018) (Chattopadhyay, 2020) (*Johns Hopkins Medicine*, n.d.a)

What is HeLa?

- The cells sampled from Henrietta Lacks' cervix are called HeLa.
  - The nickname originates from the two letters at the beginning of her first and last names.
- HeLa were the first cells capable of easily being multiplied and shared in a lab.
- HeLa was used for medical research without human experimentation.
- HeLa continues to be used for medical research after Henrietta Lacks died in 1951.
  - HeLa was critical in polio and COVID-19 vaccine development.

(Biographics, 2018) (Chattopadhyay, 2020) (*Johns Hopkins Medicine*, n.d.a)

Informed Consent:

The Johns Hopkins Hospital retrieved and used HeLa for medical research without Henrietta Lacks' consent.

- During the 1950s:
  - Collecting and using HeLa for medical research was legal and acceptable.
- However, today:
  - This would not be legal or acceptable because informed consent is required by law.

(*Johns Hopkins Medicine*, n.d.a) (*Johns Hopkins Medicine*, n.d.b)

Informed Consent:

The Johns Hopkins Hospital retrieved and used HeLa for medical research without Henrietta Lacks' consent.

- During her cancer treatments, a healthy sample and a cancerous sample from Henrietta's cervix were retrieved without her consent.
- The tissue samples were given to Dr. George Gey for medical research, and the cells have been multiplied for decades and since used for many various medical research purposes.
- Richard TeLinde, a doctor at Hopkins and the leading cervical cancer expert in the world at the time, had the opinion that the samples and research were compensation for medical services received for free.

(Biographics, 2018) (Chattopadhyay, 2020) (*Johns Hopkins Medicine*, n.d.a)

Medical Records Privacy:

The Johns Hopkins Hospital shared Henrietta Lacks' medical information without her consent.

- During the 1950s:
  - Patients did not have the right to access or keep a copy of their medical records.
  - No laws restricted the sharing of medical information related to medical research.
- However, today:
  - Patients have the right to access and keep a copy of their medical records.
  - Federal and state laws restrict the sharing of medical information related to medical research.

(*Johns Hopkins Medicine*, n.d.b)

Medical Records Privacy:

The Johns Hopkins Hospital shared Henrietta Lacks' medical information without her consent.

- In 1971 after Dr. George Gey died, Johns Hopkins University first publicly disclosed that Henrietta Lacks was HeLa's origin.
  - Her family discovered that her cells were still living.
- During 2013, researchers posted the entire genome sequence online for a strain of HeLa without the Lacks family permission.
  - Despite drastically mutating over decades, the data disclosed some data about Henrietta Lacks and possibly her descendants.

(Chattopadhyay, 2020) (*NCBI*, 2013) (*ProQuest*, 2020)

The Informed Consent Requirement:

The Common Rule:

- All medical research receiving federal funding and using human subjects must act in compliance with the federal Policy for the Protection of Human Subjects, generally known as the Common Rule.
- The Common Rule mandates that researchers collect and document sufficient informed consent for all human subjects used in the research.
  - An Institutional Review Board (IRB) may waive this requirement under certain circumstances.

(Hammaker, 2020, p. 368-71)

The Informed Consent Requirement:

FDA Regulations:

- The federal Policy for the Protection of Human Subjects regulates research controlled by the FDA.
- The FDA regulations differ from the Common Rule in that they apply regardless of federal funding.
- FDA regulations mandate that clinical researchers acquire a patient's informed consent or consent from a patient's personal representative by giving understandable information under noncoercive circumstances.
- Exceptions could apply in some circumstances.

(Hammaker, 2020, p. 371)

The HIPAA Privacy Rule:

- The Privacy Rule sets a federal minimum baseline for PHI privacy protection.
  - Applicable state laws may be broader and stricter and need to be followed in addition to federal regulation.
- The Privacy Rule only applies to HIPAA-covered entities collecting or using PHI:
  - Care Providers, Insurance Plans, and Clearinghouses
- HIPAA generally forbids a covered entity from using or disclosing PHI without a participant's written authorization.

(Hammaker, 2020, p. 372, 377-78)

The HIPAA Privacy Rule:

Medical Research Application:

- To comply with the Privacy Rule, a covered entity may access, use, or disclose PHI related to research if:
  - The entity acquired a valid patient authorization
  - The entity acquired a valid IRB or privacy board waiver to the requirement for authorization
  - An exception applies.

(Hammaker, 2020, p. 372-73)

The HIPAA Privacy Rule:

Medical Research Application:

- HIPAA does not directly apply to medical researchers since it does not directly apply to anything other than covered entities. However, HIPAA has some indirect application.
  - A covered entity will require a researcher to record written documentation of securing valid HIPAA authorization or qualifying for a waiver or an applicable exception to the authorization requirement before sharing the requested health record with the researcher.
  - Many researchers are also HIPAA-covered providers.

(Hammaker, 2020, p. 372-73)

The HIPAA Privacy Rule:

Valid Authorization:

- HIPAA sets authorization requirements.
  An authorization is valid if it:
  - Is dated and signed by the authorizing patient
  - Is written in language that is easy to understand
  - Provides details about information being collected and what the uses and disclosures will be
  - Includes an event or date of expiration (could be *end of research* or *none* for research)
  - Explains any effect to treatment or payments
  - Alerts the patient about risks of redisclosure
  - Explains the right of the patient to retract authorization
  - Includes a waiver of information access when applicable

(Hammaker, 2020, p. 373)

The HIPAA Privacy Rule:

Research Authorization:

- HIPAA authorization for disclosing or using PHI for research differs from informed consent required by the Common Rule and FDA requirements for research participation.
  - HIPAA authorization concentrates on privacy risks and explains details about disclosing or using PHI related to research.
  - Informed consent describes the study, its risks and benefits, and the extent of confidentiality protection, but the confidentiality provisions typically are more vague than HIPAA provisions.

(Hammaker, 2020, p. 373-74)

The HIPAA Privacy Rule:

Waiving HIPAA Authorization:

- HIPAA authorization can be waived:
  - If only a minimal risk exists to the privacy of participants
  - If the research could not be accomplished without the waiver
  - If the review is for research preparation
  - If the research incorporates deceased individuals
  - If the research involves reporting requirements of the FDA or public health
- Only a minimum of information can be used or shared, and protection safeguards must be used.

(Hammaker, 2020, p. 374-75, 383)

The HIPAA Privacy Rule:

The Family Educational Rights and Privacy Act:

- HIPAA does not apply to student health records or educational records under the Family Educational Rights and Privacy Act. These records can be disclosed or used for medical research purposes without acquiring authorization or IRB waiver.

(Hammaker, 2020, p. 375)

The HIPAA Privacy Rule:

Secondary Research:

- Researchers must acquire a new authorization or IRB waiver before using previously collected PHI in secondary research. The study will be a new study unless the new research was adequately explained in the primary study authorization.

De-identified Data and Limited Data Sets:

- Two methods exist for secondary use of participants' PHI originating from primary research.
  - De-identified patient data
  - Limited data set
    - Limited data sets are an essential alternative to using de-identified data because de-identified data often does not include enough data to be successful

(Hammaker, 2020, p. 375-76)

The HIPAA Privacy Rule:

Other Research Accommodations:

- The Privacy Rule grants the right of research participants to acquire an accounting of their PHI disclosures.
- Participants will not be allowed to access their records or trial results during medical research.

Certificates of Confidentiality:

- Researchers can acquire a Certificate of Confidentiality in situations when releasing collected PHI could lead to negative consequences for the participants. The certificate allows researchers to refuse disclosing identifying information in legal proceedings.

(Hammaker, 2020, p. 376-77)

Resolutions:

- Act in compliance with all current federal, state, and applicable international regulations for new research and secondary research.
- Alter or update current regulations considered to be outdated (*ProQuest*, 2020) (*Gronowski*, 2011, p. 543).
  - The considered revision would require authorization before specimens are used for research, even if the specimens are deidentified (*ProQuest*, 2020).
- Authorized consent forms should be more specific, tiered, and standardized (*Gronowski*, 2011, p. 541-43).
  - Experts agree that deidentification helps maintain privacy but that no sample is truly deidentified due to genome sequencing. Sample donors must be informed of the risk of reidentification (*Gronowski*, 2011, p. 542-43).

Resolutions:

- Attempt to make amends (*ProQuest*, 2020).
  - Make agreements with participants or descendants of participants before such laws existed (*NCBI*, 2013).
    - Henrietta Lacks' many descendants want a celebration of her legacy (*ProQuest*, 2020).
  - Offer monetary compensation when cells have been used without authorization (*ProQuest*, 2020).
    - Current research should inform participants of the potential for financial gain. However, regularly distributing revenue to donors may be too complicated to facilitate (*Gronowski*, 2011, p. 541-42).

The Legal Implications of HeLa

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The Legal Implications of HeLa

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The Legal Implications of HeLa

IMAGES:

- Cell culture (HeLa cells) (261 18) Cell culture (HeLa cells) - metaphase, telophase. Photograph. *Wikimedia Commons*. Web. 4 December 2021. https://commons.wikimedia.org/wiki/File:Cell_culture_(HeLa_cells)_(261_18)_Cell_culture_(HeLa_cells)_-_metaphase,_telophase.jpg

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- Henrietta Lacks statue, Bristol, RHS. Photograph. *Wikimedia Commons*. Web. 4 December 2021. https://commons.wikimedia.org/wiki/File:Henrietta_Lacks_statue,_Bristol,_RHS.jpg

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