

What to Know About Conducting Research with HeLa Cells

Session: 12 p.m. to 1:15 p.m. EDT

Part I

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June 24, 2024



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Disclaimer

The opinions expressed are those of the presenter and do not necessarily reflect the policy of the U.S. Department of Health and Human Services.

For a complete and accurate description of the regulatory requirements, please refer to the text of the regulations available on [OHRP's website](#).



Learning Objectives

Part I: Secondary research under the Common Rule (CR) – (OHRP)

- Describe the options for secondary research under CR
- Explain the ethical considerations for conducting research

Part II: Research involving HeLa Cell Whole Genome Sequence Data Sharing – (NIH)

- Understand the establishment of the NIH-Lacks Family Agreement
- Understand the submission and access process for HeLa cell data under the Agreement
- Learn about NIH actions to reinvigorate the Agreement

Part I: Conducting Secondary Research under the Common Rule (OHRP)



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What Is Secondary Research?

- The research use of information or biospecimens *originally* acquired for:
 - **Non-research purposes**
 - (e.g., information collected for routine clinical care; leftover blood from routine clinical tests; information collected for Medicaid billing), **OR**
 - **Research studies other than the proposed one**
 - (e.g., information collected for a drug study on Alzheimer's now being used to study if early-onset diabetes predisposes an individual to Alzheimer's development).
- Research use of HeLa cells is secondary research



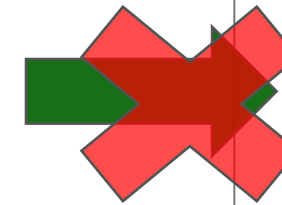
The Concept of Secondary Research and the Regulatory Definition of *Human Subject* at §46.102(e)(1)

Regulatory definition for ***Human Subject***: a living **individual** about whom an investigator conducting research

1) Obtains information or biospecimens ***through intervention or interaction*** with the individual...

OR

2) Obtains, uses, studies, analyzes, or generates ***identifiable*** private information or identifiable biospecimens



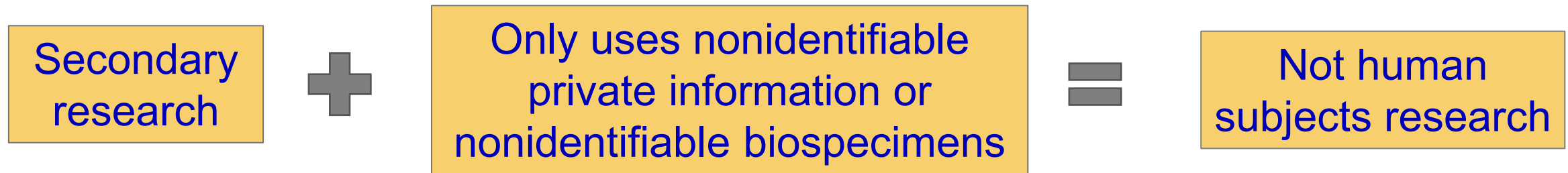
Primary Human
Subjects Research



Secondary Human
Subjects Research

In secondary research, there is no intervention or interaction done with individuals specifically for the purpose of this research.

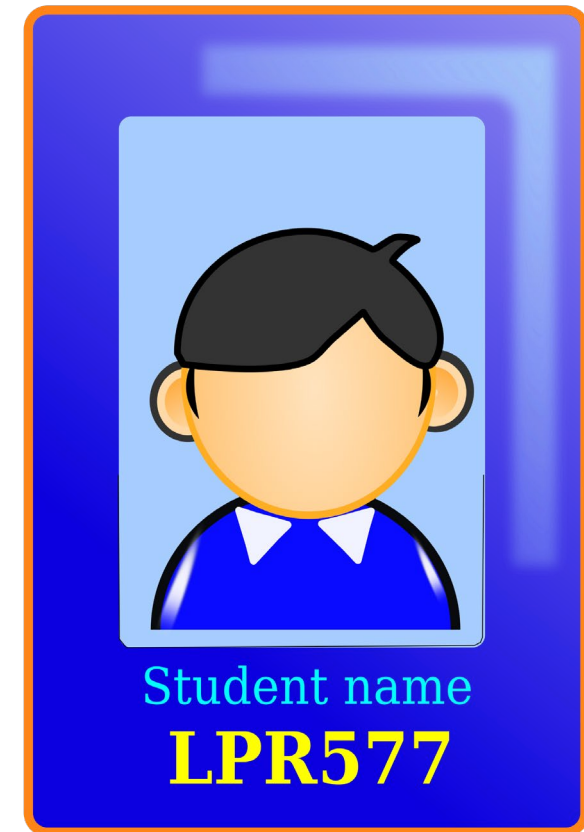
When Is Secondary Research Not *Human Subjects Research*?



Reminder: Consider the research project as a whole; it's purpose, what it's doing to answer the questions. Don't just look at the activities in isolation of the reasons for why they are being carried out!

What Are the Options for Conducting Secondary Research? (1)

- 1) Entire research involves the use of identifiable data/biospecimens = human subjects research
 - Ask: Does the whole research meet the conditions for one or more exempt categories at 46.104(d)?
 - **Yes** - Exempt human subjects research; Exempt from the CR regulatory requirements.
 - **No** - Nonexempt human subjects research; follow CR regulatory requirements for IRB review, informed consent, Federalwide Assurance (FWA), etc.



What Are the Options for Conducting Secondary Research? (2)

- 2) Entire research *only* involves the use of ***nonidentifiable*** data/biospecimens = **not human subjects research**; no CR regulatory requirements.
- 3) Entire research *only* involves the use of data/biospecimens from ***deceased*** individuals = **not human subjects research**; no CR regulatory requirements.



Which of the Following Statements Best Describes the Use of HeLa Cells in Research?

Research use of HeLa cells is

- A. Primary human subjects research
- B. Secondary human subjects research
- C. Not human subjects research because the cells are nonidentifiable
- D. Not human subjects research because it doesn't involve living individuals
- E. Not research under CR



Reminder

- The CR regulatory framework provides a baseline standard for human research protections for federally funded research.
- Research that falls outside CR is:
 - Not necessarily of little or no risk to subjects
 - Not necessarily free of ethical concerns
- Similarly, for research that CR regulates, mere compliance does NOT mean that the research study is necessarily protective or free from ethical concerns!



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Ethical Concerns for Research Outside CR



<https://journalofethics.ama-assn.org/article/genetic-research-among-havasupai-cautionary-tale/2011-02>

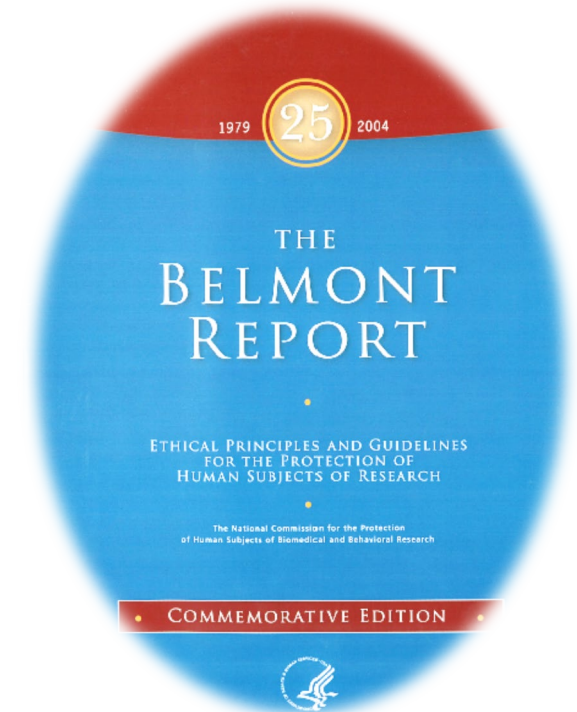


Recidivism Scores *mistakenly* giving higher scores to more black defendants than white counterparts.

<https://datasciencedojo.com/blog/big-data-ethics-10-experiments/>

The Belmont Report (1979) - Ethical Principles for Human Subjects Research

- Respect for persons
 - Promotes autonomy
- Beneficence
 - Maximizes benefits to all, minimizes harms to individuals
- Justice
 - Ensures equitable distribution of burden and benefits



Question: Does the Belmont principles provide an adequate ethical framework for research that implicate third parties in a significant manner?

Mark Your Calendars for OHRP's Events! No Registration Needed

50th Anniversary of the National Research Act - Commemoration

Watch *Live* on **Friday, July 12!**

www.hhs.gov/ohrp/education-and-outreach/national-research-act-50th-anniversary/index.html



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OHRP Exploratory Workshop on AI Research

Virtual on **September 19**

www.hhs.gov/ohrp/education-and-outreach/exploratory-workshop/index.html



Contacts

- Contact us or submit your questions to OHRP@hhs.gov
- Visit OHRP website at www.hhs.gov/ohrp
- Check out our [decision charts](#). For making exemption determinations!



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