

# Informed Consent Workshop

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Part 2: The consent process

## The Belmont Principles

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Respect for Persons

Justice

Beneficence

The Nuremberg code (1949; emphasis added):

1. **The voluntary consent of the human subject is absolutely essential.**

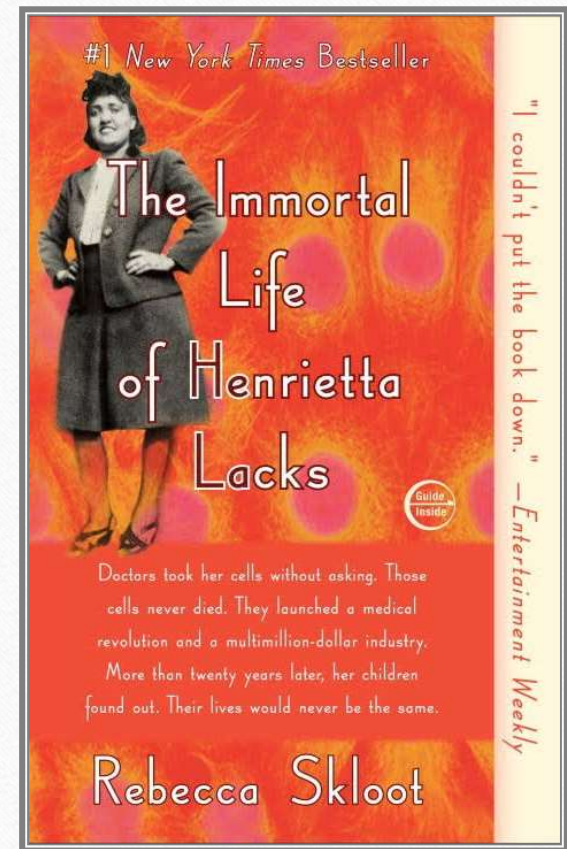
This means that the person involved should have legal capacity to give consent; should be so situated as to **be able to exercise free power of choice**, without the intervention of any element of force, fraud, deceit, duress, over-reaching or other ulterior form of constraint or coercion; **and should have sufficient knowledge and comprehension** of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, **there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person**, which may possibly come from his participation in the experiment.

The duty and **responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment**. It is a personal duty and responsibility which may not be delegated to another with impunity.



# Why is informed consent important?

Lessons from Henrietta Lacks



# Lessons from Henrietta Lacks

Example from *The Immortal Life of Henrietta Lacks* (pp 182-90):

- Researcher Susan Hsu: “We come to draw blood to get HLA antigen, we do genetic marker profile because we can deduce a lot of Henrietta Lacks genotype from the children and the husband.”
- Day Lacks: “They said they got my wife and she part alive [...] They said they been doin experiments on her and they wanted to come test my children see if they got that cancer killed their mother.”



# Lessons from Henrietta Lacks

Example from *The Immortal Life of Henrietta Lacks* (pp 182-90):

- Hsu: “They are very receptive [sic] to us when I made phone call. They are pretty intelligent. I think Mr. Lacks pretty much already knew that his wife made a contribution and are very aware of the value of HeLa cells. They probably heard people talking that the cell line is such important thing. Everybody talking about HeLa back then. They are a very nice family, so they very nicely let us draw blood.”
- “[Day] did what he’d always done when he didn’t understand something a doctor said: he nodded and said yes.”

# Barriers to Informed Consent

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# Barriers to Informed Consent

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- Language
- Education
- Backgrounds
- Follow-through and Contact information
- Lack of cultural / interpersonal empathy and understanding

# Lessons from Henrietta Lacks

Example from *The Immortal Life of Henrietta Lacks* (pp 182-90):

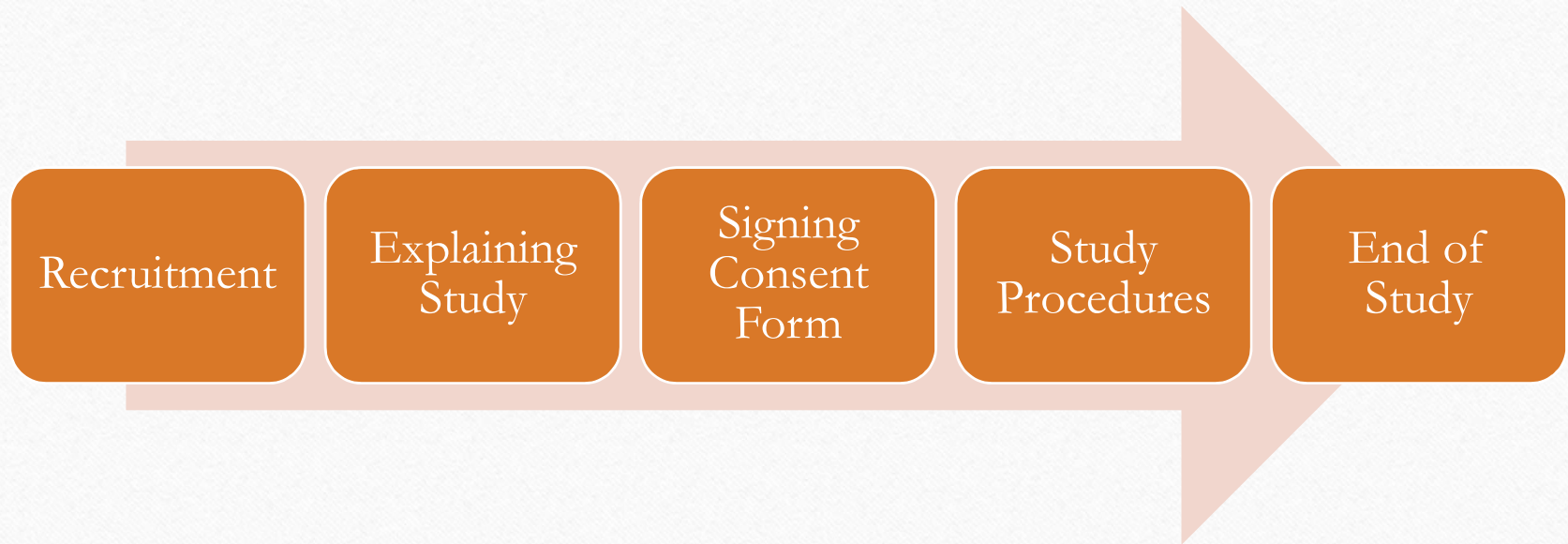
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“I feel very bad,” she said. “**People should have told them.** You know, we never thought at that time they did not understand. [...] Just tell them I’m really grateful [...] **They should be very proud** of the mother or the wife – I think that **if they are angry probably they didn’t realize** how famous the cells are now in the world. It’s unfortunate thing what happened, **they still should be very proud**, their mother will never die as long as the medical science is around, she will always be such a famous thing. [...] **If they are willing, I wouldn’t mind to go back and get some more blood.**” (emphasis added)



# The Consent Process

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# Tips – Recruitment

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- Make it clear that this is research
- Include:
  - What you're studying
  - Basic eligibility criteria
  - Time commitment
  - Contact information and/or study location
- Don't overemphasize payment/compensation
- Don't promise benefits
- Submit fully formatted version (font size, color, bolding, etc.)



# Tips – Initial consent



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- Choose a private location
  - Allow time for the participant to:
    - Read
    - Digest
    - Ask
    - Decide
  - Explain the study, don't read the consent document
  - Verify understanding (“teach-back” method)
  - Give participant a copy to keep

# Tips – Ongoing consent



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- Reminder: this is research; participation is voluntary
  - Ask if they still want to continue
  - Respect the decision if they say no
    - It's ok to ask why they decide to stop.
    - It's NOT ok to pressure them for a reason.
  - Allow participants to review results of the study before publication



Your turn ...

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