

***When is Open-Ended Consent
Adequately Informed?***

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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.

“Give it to me, and let me use it for anything.”

Pearl O’Rourke at PRIM&R

- **A person can certainly say “yes” to a vague statement that they are allowing any future research of whatever nature.**

- **Example: “We will let the researchers use the materials in the Biobank for approved studies.”**
- **No details are provided, in the several pages of the consent form, about what such research might involve.**

- Is it ethical to not provide any information about what the research might involve?
- Is the consent in this instance *informed* consent?

- **Why might there be special concerns regarding whether broad open-ended consent is adequately informed?**
- **Perhaps looking at an example from *clinical care* can be helpful.**

What should Leah be told?

John Lantos—18 *Second Opinion* 81 (1993)

- Leah, age 18, is from Israel

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- She has adenocarcinoma of the cervix

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- She has adenocarcinoma of the cervix
- With hysterectomy and other treatment she has a 60-70% chance of 2 year survival

- **She hasn't been told any of this**

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- **Her father has brought her to the University of Chicago for treatment**

- **She is engaged to be married**

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- **After a hysterectomy, since she would be infertile, she could not marry**
- **Her father believes that if she learns about this, she might kill herself**

- **So he wants her to undergo the hysterectomy without being told what it means for her fertility**

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- **And she is agreeing to this**

- **Should the doctors agree to this?**

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- **Would her consent be informed?**

The bottom line:

- Saying “yes” to something open-ended—
“do whatever you want”—can be *uninformed* if the person doesn’t fully appreciate what “whatever” can include

- **What might someone consenting to open-ended use of their specimens not know about—and that they might object to if they did know about it?**

- **Cloning (the real thing)**

- **Cloning (early stages, part of reproductive research)**

- **Genome wide association studies, or whole genome sequencing**

- **Creating a cell line (Henrietta Lacks revisited--having your cells live in perhaps thousands of labs, creating tons of your tissues, living long after you are dead)**

- **When a consent form that is pages long, has one sentence about what will be done with the specimen— “We will let the researchers use the materials”—what do we know about what the subjects who say “yes” understand about what they have agreed to?**

- **Perhaps some empirical research might help—asking someone presented with that open-ended language whether they knew they were consenting to x, y, and z, and if any of that bothers them**

And there are multiple ways to deal with these issues:

- **Recognizing that certain types of research are not covered by open-ended consent**
- **Add specific discussions of those issues (once we figure out how to identify them—which may not be easy) so subjects will know they are agreeing to this**
- **Add specific discussions and options to opt in to those types of research**