

Consenting Vulnerable Populations

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Agenda

1. Break it down:

- “Consenting”
- “Vulnerable”
- “Populations”

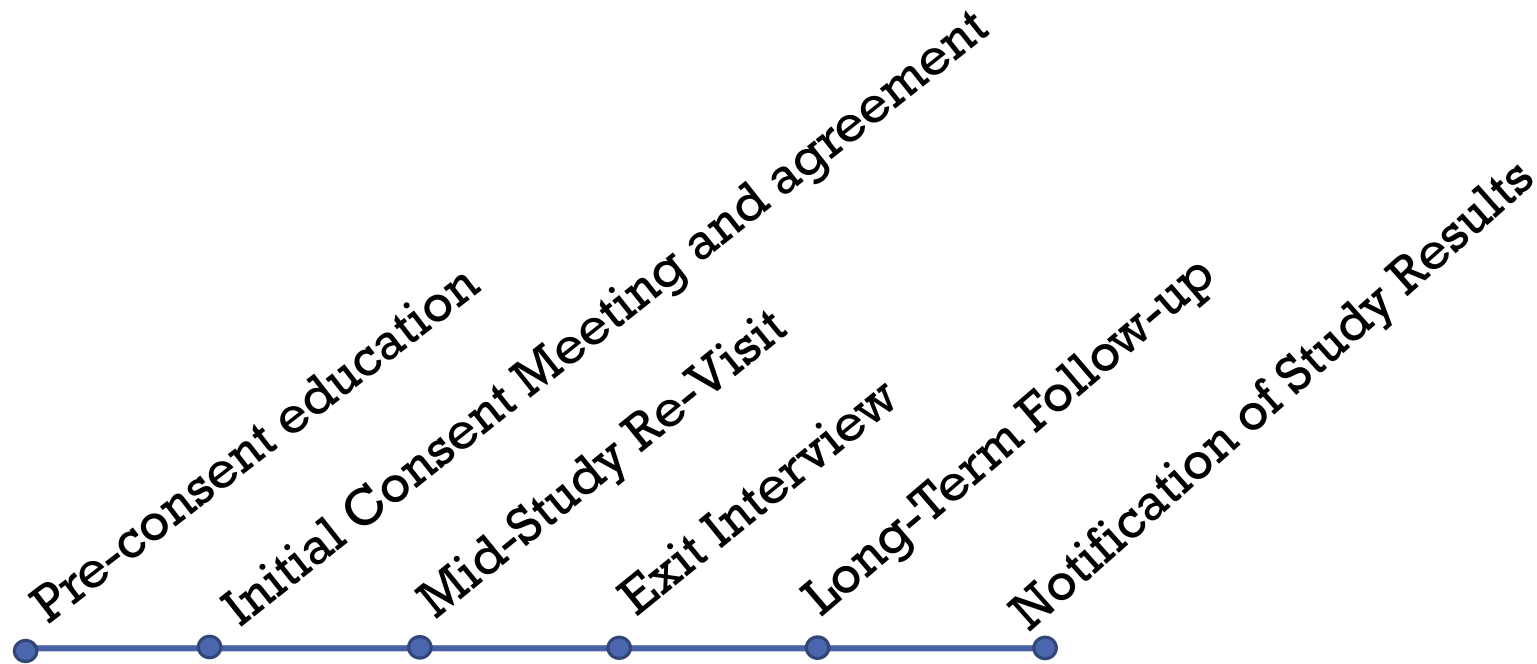
2. Put it back together

- What does it mean for me?
- What does it mean for them?

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“Consenting”

Consent as a process



Review: Elements of Consent

“The Eight Elements”


1. Research purpose and procedures
2. Foreseeable risks
3. Benefits
4. Alternative procedures
5. Confidentiality of records and subject identity
6. Compensation, treatment upon injury
7. Whom to contact with questions
8. Participation is voluntary

“The 6 Additional Elements”

1. Risk to fetus
2. Termination of participation by investigator
3. Additional costs to subject
4. Consequences if Subject chooses to withdraw
5. New findings that might affect subject willingness to participate
6. Number of subjects involved in study

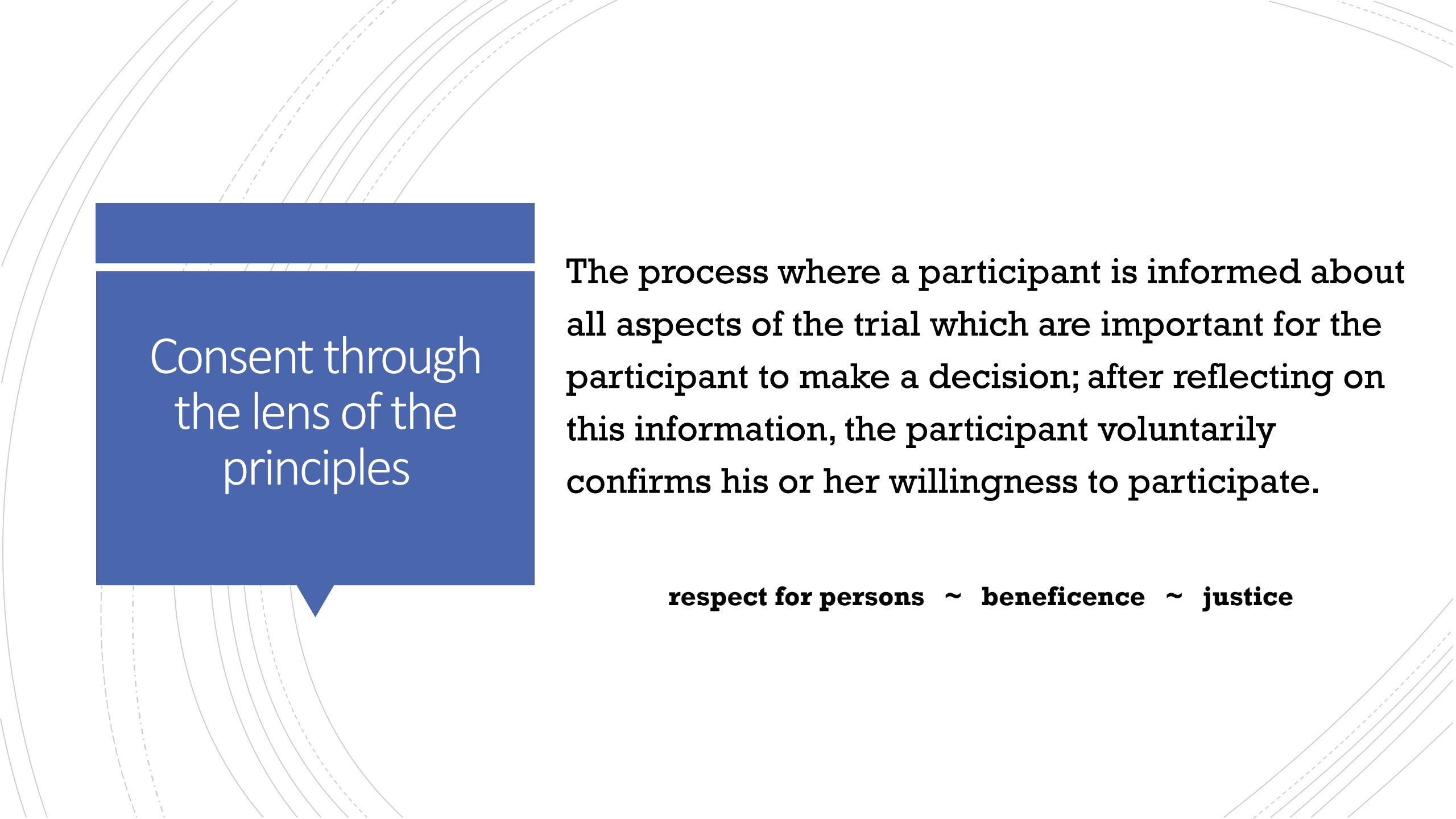
Definition of Consent

The process where a participant is informed about all aspects of the trial, which are important for the participant, to make a decision; after reflecting on this information, the participant voluntarily confirms his or her willingness to participate. *

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Review: The Belmont Principles

- **Respect for persons**
- **Beneficence**
- **Justice**

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Consent through the lens of the principles

The process where a participant is informed about all aspects of the trial which are important for the participant to make a decision; after reflecting on this information, the participant voluntarily confirms his or her willingness to participate.

respect for persons ~ beneficence ~ justice

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“Vulnerable”

Definition

To be vulnerable means to face a significant probability of incurring an identifiable harm while substantially lacking ability and/or means to protect oneself.*

From Henk ten Have's Book: *Vulnerability: Challenging bioethics*

Reframe the perspective

- Persons can be vulnerable, in and of themselves, but are can also be *made* vulnerable by circumstances.
- *All* subjects are made vulnerable by the nature of being a participant in research, but they may also be made vulnerable by *other* factors.
- Examples:
 - teenagers
 - pregnant women
 - non-English speakers
 - cancer patient

Addressing vulnerability

- Identify the vulnerable-making factors
- Address them
- Document the process

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“Populations”

Personal Bias

- Each person is a unique entity with their own personal set of concerns and goals that are affected by circumstances singular to them at this moment in time.
- Examples:
 - teenagers (wise/snarky)
 - pregnant woman (physician/religious)
 - non-English speakers (educated/illiterate)
 - cancer patient (remittent/terminal)

What does this mean?

- For the professional:
 - What do I need to do my job?
 - Instructions?
 - Information?
 - Tools?
 - Support?
- For the research subject:
 - What do they need to do their job?
 - Instructions?
 - Information?
 - Tools?
 - Support?

Consenting Vulnerable Populations

- Identify the elements of consent, and reflect on the bioethical implications of each
- Identify how the subject might be made vulnerable
- Address the vulnerable-making factor
- Have the tools to do your job
- Check in with subject and self
- Document



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