

What do Participants Understand?

{ Informed Consent and the Research Subject Advocate

Research Subject Advocate

- Liaison between:
 - Research participants
 - Investigators
 - Institutional review board (IRB) that approves a study

Address participant questions and concerns:

- Confidentiality
- Privacy
- Safety
- Research ethics
- Process of informed consent
- Rights of participants

Convey participant concerns to investigators and IRB

Outreach with current or potential participants

Research participant protections education

Available to monitor consents at the request of the IRB

Report non-compliance

1979 – Belmont Report & Informed Consent

- Principal of “Respect for Persons”

Informed consent or a waiver of consent is necessary for human subjects research

- Information presented
- Questions addressed
- Participant agrees to join a study

Recruitment	QUESTION
<ul style="list-style-type: none">• Methods<ul style="list-style-type: none">• A potential participant is approached to join a study• With proper training, anyone can recruit for a study (unless there are institutional restrictions).• Advertisements	<ul style="list-style-type: none">• Who approached you to ask if you were interested in a study?

Informed Consent	QUESTIONS
<ul style="list-style-type: none">• Done by key personnel familiar with a study• Potential participant receives adequate information to make a decision	<ul style="list-style-type: none">• How was the consent form presented?• Did you receive adequate information about the study?• Was the language in the consent understandable?

Informed Consent	QUESTIONS
<ul style="list-style-type: none">• During the consent process, a potential participant should have time to ask questions.• There should be a reasonable amount of time to consider joining a study.	<ul style="list-style-type: none">• Were you given enough time to ask questions?• How much time were you given to make the decision to join the study?

Volunteering	QUESTIONS
<ul style="list-style-type: none">• Joining a research study is completely voluntary.• A person should not feel pressured to join a study.	<ul style="list-style-type: none">• Did you feel pressured in any way to join the study?• Why did you join the study?

Research Experience	QUESTION
<ul style="list-style-type: none">• Researchers should make the research experience as positive as possible.• Benefits (individual or societal) should always outweigh risks.	<ul style="list-style-type: none">• Do you think joining a research study was a worthwhile experience?

Thank You!
