Ethical Importance of Assent in Adults with Decisional Incapacity

The views expressed are my own.
They do not represent the position or policy
of the NIH or DHHS.

David Wendler, PhD
Department of Bioethics
NIH Clinical Center

Decisional Incapacity

- Informed consent is one of the primary safeguards for research participants.
- Participation of adults who cannot consent thus raises ethical concern: they might not receive appropriate protection.

Protect by Excluding

- To address this possibility, some guidelines prohibit research with adults who cannot consent.
- Nuremberg Code: Subject consent is “absolutely essential” to ethical research.
- This approach provides clear protection for adults who are unable to consent.

Problems with Exclusion

- But: blanket exclusion also blocks valuable research, and excludes individuals from studies that may benefit them clinically.

- Can we protect adults who cannot consent, while still allowing valuable research on conditions that affect them?

US Regulations

- Mandate consent of the participant or their legally authorized representative.
- US regulations do not place additional conditions on research with adults who cannot consent.
- As a result, there is no regulatory mandate to obtain their assent, or respect their dissent.

Possible Assumption

- One might support this approach on the grounds that adults who cannot consent are not able to understand or make their own decisions.

- Hence, it does not make sense to try to explain the study to them or to solicit their agreement to participate.

Tarlow v DC

- Suit by 3 DC residents with intellectual disabilities who were subjected to elective surgery without their input or agreement.

- Court of Appeals: Soliciting the views of patients who lack decisional capacity: “does not make logical sense”.

Decisional Capacity

- This view assumes decisional capacity is all or nothing.
- If an individual does not have decisional capacity, their input is irrelevant to how they ought to be treated.
- Treatment decisions should be based on what is in the individual's best interests.

Matter of Degrees

- The capacity to consent depends on a number of underlying capacities, which come in degrees.
- It depends on sufficient: understanding, appreciation, reasoning, voluntariness, decision-making, communication.
- And these capacities themselves are multi-faceted.

Understanding

study involves research, purpose, expected duration, procedures, procedures that are experimental, reasonably foreseeable risks or discomforts, any benefits, appropriate alternatives, confidentiality, compensation, voluntary, right to refuse, identifiers might be removed, future research studies, unforeseeable risks, termination, additional costs, consequences of withdrawal, new findings, number of subjects, whole genome sequencing

Risks

- Finally, some of these elements are themselves complex and multifaceted.

- To understand the reasonably foreseeable risks, individuals might have to understand 10 risks, including short-term and long-term ones; likely and unlikely ones.

Implications

- An individual who does not sufficiently understand even one of the “essential” elements of consent (e.g. long-term risks) is not able to give consent.
- Yet, this individual may understand a good deal.
- For example, an individual who does not understand the long-term risks might understand research and their own values and preferences.

‘Supported’ Decision-Making

- Moreover, no one’s decisional capacity is perfect.
- On this basis, some commentators argue that drawing a threshold on who has the capacity to consent and who doesn’t is arbitrary.
- They conclude that everyone should be able to consent for themselves.

Respect for Others

- Respect for others involves more than just permitting them to make their own decisions.
- It also involves protecting and promoting their values and interests.

Challenge

- This raises the need to recognize both individuals' decisional capacities and their decisional limitations.

- Can we involve individuals in the decision-making process while also protecting their values and interests?

5 Safeguards

- Necessity requirement
- Appropriate risk/benefit profile
- Surrogate permission
- Sufficient evidence of patient's wishes
- **Assent/dissent**

Wendler, Prasad. *Ann Intern Med* 2001;135(7):514-523

SACHRP

When consent will be provided by an LAR, the assent of the research participant should be sought at the outset and, as appropriate, throughout the course of research involvement, unless the participant is incapable of providing assent.

Declaration of Helsinki

When a potential research subject who is deemed incapable of giving informed consent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorised representative. The potential subject's dissent should be respected.

CIOMS

The consent of each subject should be obtained to the extent of that person’s capabilities, and a prospective subject's refusal to participate in research should always be respected, unless, in exceptional circumstances, there is no reasonable medical alternative and local law permits overriding the objection.

Others

- New York State Advisory Work Group
- MD Attorney General's Working Group
- Canadian Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2022)
- Coming soon: Policy 403!

Respect

- Consensus on the importance of assent raises the need to determine who has the capacity to assent.
- The goal is to ensure proper respect for individuals who have intellectual or cognitive disabilities.
- When does obtaining their “affirmative agreement” to participate promote this goal?

Current Guidance

- It depends.
- Researchers should consider the adult's decisional abilities, psychological and emotional state, as well as their condition.
- Makes sense, but what are we looking for?

Capacity to Assent

- It is not respectful to ask individuals to agree to things they do not understand.
- Hence, whether an adult who cannot consent has the capacity to assent depends on whether they can understand the basic elements of the study.
- What are they?

Stanford

- Study: all procedures; which parts experimental
- Risks
- Potential benefits
- Any alternatives
- Participation secret, but information to sponsor
- Explain plan for compensation for injuries
- Contact information if questions

https://researchcompliance.stanford.edu/panels/hs/for-all-researchers/consent/assent-process

CHOP

"To have the capacity to assent, the subject must be able to understand the general purpose of the research and the nature of the procedures and must be able to understand the concept of voluntariness."

https://www.research.chop.edu/services/adults-with-diminished-capacity

Tentative Proposal

- Trying to learn things to help others
- What being asked to do
- Whether chance of personal benefit
- Whether could harm them
- Can say no (but participation requires LAR)

Practice

- If the person can understand the basic elements, solicit their assent.
- If they can't, don't try to solicit their assent.

Process

- Explain the basic elements in a way the individual can understand.

- AAHRPP: researchers should make reasonable efforts to offer information regarding the procedures that he or she will undergo and ensure that his or her participation is willing.

Form and Signature

- Provided it is meaningful to the individual: Include an assent form and ask them to sign it.
- [Assent forms are usually better than consent forms!]
- For longitudinal studies, solicit on-going assent at reasonable intervals.

Decision

- If the individual and the LAR give their affirmative agreement, the individual can participate.
- If the individual declines or dissents, they are not enrolled (or withdrawn).

Dissent

- Because dissent is a lack of assent, one might assume there is no need for a separate dissent requirement (see: US pediatric regulations).

- This approach ignores the dissent of individuals who are not able to assent.

Respecting Dissent

- Dissent, unlike assent, does not require understanding of even the basic elements, and can result from an individual *not* understanding.

- Respecting dissent, even in individuals who cannot assent, gives them some control over their lives and protects them from excessive stress/anxiety/harm.

Inability to Assent

- Information is typically provided to research participants as part of soliciting their consent or assent.

- This raises concern that adults who are not able to consent or assent will not be provided with any information regarding their participation.

Information

- Providing information can be valuable even when an individual is not being asked to assent.
- For example, providing information can give individuals a sense of what to expect and reduce stress.
- Provide basic information and ask if any questions.

Need for Interpretation

- In some cases, dissent is clear!
- In others, it can be unclear whether an action constitutes dissent: pulling away; frowning.
- “I want to go home”?
- Is the individual indicating they do want to proceed with the study or the study is causing them distress?

Assessment

- Is the individual indicating they do want to proceed with the study or the study is causing them distress?
- Input from individuals who know the participant can help to make this assessment.

Response

- It is not necessary to withdraw an individual at the first indication of dissent.
- Instead: stop, assess, address.
- If successful, the individual can participate.

Implications

- If an individual continues to dissent to a particular aspect of the protocol (e.g. MRI), can that aspect be skipped or dropped?

- If not, the individual should be withdrawn.

Summary

- Decisional capacity is a matter of degree.
- Obtaining the assent of adults who are capable of assent shows respect for their capacities.
- Individuals who can understand the “basic” elements of the study are capable of assent.
- Providing information and respecting the dissent of all individuals helps to protect them from significant distress.