Tensions between the UN CRPD and CIOMS Guidelines: implications for fair inclusion of individuals living with psychosocial disabilities in research

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UN Convention on the Rights of Persons with Disabilities (UN CRPD)

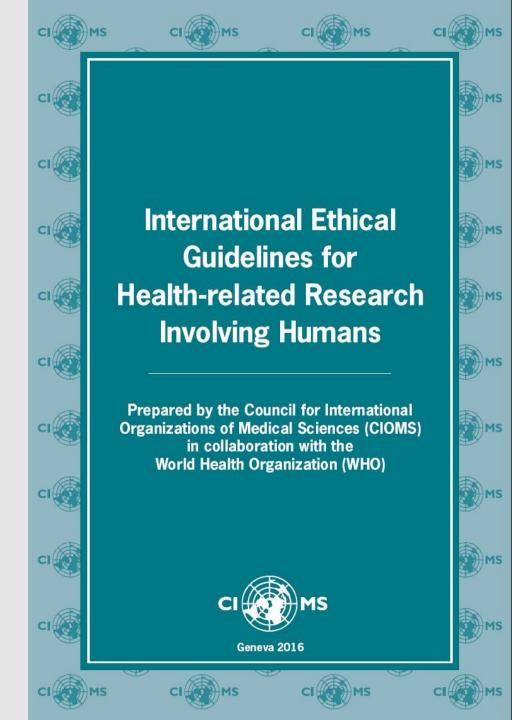
- International human rights treaty
- Entry into force in 2008
- Paradigm-shift toward a social model of disability

Convention on the Rights of Persons with Disabilities and Optional Protocol



International Ethical Guidelines for Health-related Research Involving Humans (CIOMS Guidelines)

- Influential guidelines for research
- Revised in 2016
- International scope/aim



Tensions between the UN CRPD and CIOMS

Surrogate decision-making and informed consent

Non-discrimination and participant selection

"Vulnerability" and psychosocial disability

Surrogate decision-making and informed consent

UN CRPD

 Universal legal capacity prohibits surrogate decisionmaking

CIOMS

 Surrogate decision-making is appropriate to include research participants who are unable to give consent

When the prospect of individual or community benefit outweighs potential risks, should surrogate decision-making be permissible to consent to participate, per CIOMS, even though it violates the CRPD?

Non-discrimination and participant selection

UN CRPD

 Discrimination on the basis of disability is unjustifiable in all cases

CIOMS

 Permits exclusion in some cases, on the basis of "sound ethical or scientific reason"

How do we ensure that "reasonably justified" exclusion criteria, per CIOMS, do not violate the CRPD's non-discrimination principle, while recognizing that the categorical exclusion of individuals living with psychosocial disabilities <u>is</u> discriminatory?

"Vulnerability" and psychosocial disability

UN CRPD

All individuals retain legal capacity at all times

CIOMS

 Suggests that capacity can be compromised by "mental or behavioural disorders"

How then should we understand which individuals living with psychosocial disabilities—if any—are "vulnerable" from a research participation perspective, even if such a designation contravenes the CRPD?

Resolving the tension

• "Fair research participation" as the right to benefit from research, but not necessarily the right to participate in research

Recommendations

- Presence of psychosocial disability does not imply incapacity (affirmed already by CIOMS)
- 2. For population-wide, generalizable research: psychosocial disability should not be an exclusion criteria
- 3. For research with individuals living with psychosocial disabilities, capacity should be assessed according to standard protocols for informed consent to respect the principles of non-discrimination
 - If an individual is found to not have the capacity to understand the research study with respect to informed consent principles, surrogate decisionmaking should not be accepted, in line with the CRPD