

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

Marisha Wickremsinhe

Ethox Centre and Wellcome Centre for Ethics and Humanities

# 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



UNITED NATIONS

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

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

## International Ethical Guidelines for Health-related Research Involving Humans

Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO)



Geneva 2016

# 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 decision-making

## 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 is 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

1. 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 decision-making should not be accepted, in line with the CRPD