Recommendations for interpreting Peru's Clinical Trial Regulation in light of the CRPD and the CIOMS guidelines

Sarah Carracedo

LEGAL BACKGROUND

Peru's framework on legal capacity

Civil Code, 1984 (Legislative Decree Nº 295)

Article 43: *They are absolutely incapable:*

2. Those who for any reason are deprived of discernment.

Article 44: *They are relatively incapable:*

2. The mentally retarded.

3. Those who suffer from mental deterioration that prevents them from expressing their free will.

Article 45: *The legal representatives of the incapable exercise their civil rights.*

Civil Code Reform (2018)

Legislative Decree Nº1384 that recognizes and regulates the legal capacity of people with disabilities on equal conditions

Article 42: *Every person over the age of eighteen has full legal capacity to exercise their rights.* ***This includes all people with disabilities****, on an equal basis with others and in all aspects of life, regardless of whether they use or require any reasonable accommodation or support to express their will.*

- It also repeals the articles related to the declaration of interdiction. **"Interdiction" is a process in which a court appoints a legal representative to a person with mental impairments after a capacity assessment that determines if she *can* decide by herself, and *to what extent.***

2017
CLINICAL TRIALS REGULATION

2017 Clinical Trials Regulation

Article 37: *The legal representative decides on whether a person with mental disabilities should participate in a clinical trial.*

CRPD

vs.

CIOMS

CRPD Committee: *"States parties' obligation to replace substitute decision-making regimes (…) requires the abolition of substitute decision-making regimes and the development of supported decision-making alternatives".*

Guideline 16: LAR + assent

How should the clinical trials regulation be interpreted in light of the CRPD, the Peruvian legal framework and the CIOMS guidelines?

3 KEY POINTS

1: *From the substitute decision-making to the supported decision-making approach.*

- Supporters voluntarily designated.
- Other mechanisms of support:
  - Special training for researchers.
  - Participation of psychologists, psychiatrists or experts in mental health in research teams.
  - Members with knowledge and expertise on mental health research, disability rights advocates or people with disabilities in ERCs.

2: *Capacity assessments should be allowed.*

- The development of supported decision-making mechanisms could include an assessment of their decision-making skills.

    1) We need to know *what* and *the extent* to which a person with disabilities understands to give them the best support.
    2) The assessment of the decision-making skills is not grounded in the disability and its purpose is not to deny legal capacity but to strengthen its exercise. As it could occur with *anyone* willing to participate in research, this assessment helps to adapt the process of informed consent to their specific circumstances.

3: *Decisions based on the "best interests" could be taken on a case-by-case basis.*

- When a person with mental disabilities is unable to understand the situation AND no advance directives exist:
  a) Exclusion
  b) Allow the supporter to decide in accordance with "the best interpretation of her will and preferences".
- If b) is unknown, the decision about her participation could be taken, exceptionally, in her best interests, when the research intervention is the best available medical option.

Conclusions

- The 3 key points try to balance the competing considerations established by the CRPD and the CIOMS guidelines in order to interpret the Peruvian clinical trials regulation in ways that are both ethically acceptable and legally valid.
- Capacity assessments and decisions based on the best interests are not a discriminatory denial of legal capacity, but a valid option that ensure a fair inclusion of people with mental disabilities in clinical trials while protecting their rights.