

Ethical issues arising in research with people with mental health conditions

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Governance paper

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

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Introduction

In 2018, Peru changed its legal framework on legal capacity and amended its Civil Code in accordance with the Article 12 of the Convention on the Rights of Persons with Disabilities (CRPD)^{1,2}. This new framework aims to recognize the legal capacity of people with disabilities on an equal basis by eliminating the figure of interdictionⁱ and providing them support to exercise their legal capacity to make their choices by themselves. Even though this is an important achievement towards equality in the country, in practice it generates some challenges, and requires several modifications of other laws and regulations, especially those related to the areas of health. The Peruvian regulation on the conduct of clinical trials is a good example of this situation³.

The clinical trials regulation was issued in 2017. Therefore, it establishes that for the inclusion of participants with mental impairments who cannot decide by themselves the informed consent of their legal representative is mandatory. Even though this provision adheres to CIOMS guideline 16⁴, it violates the CRPD. The Committee on the Rights of Persons with Disabilities (CRPD Committee) states that substitute decision-making regimes deprive people with disabilities of their rights and imply a discriminatory denial of their legal capacity⁵. Therefore, it calls for the provision of support in the exercise of the legal capacity of people with disabilities as the Peruvian Civil Code currently establishes¹.

In this paper I give three key recommendations for interpreting the Peruvian clinical trials regulation regarding the process of informed consent of potential participants with mental disabilitiesⁱⁱ. These suggestions aim to address the conflicts between the CIOMS guidelines and the CRPD, and more generally, the Peruvian legal framework on legal capacity.

Key points for interpreting Peru's clinical trials regulation

Given that the Peruvian clinical trials regulation has not yet been adapted to the Civil Code, two scenarios might be occurring in practice: people with mental disabilities are being systematically excluded from research or they are being allowed to participate in research in the terms they have always had (i.e., with the consent of their surrogate decision maker). Evidently, both ways are unjust. The first one deprives people with disabilities from the benefits of research; and the second, does not treat them on an equal basis with others in accordance with the CRPD. Moreover, not interpreting the clinical trials regulation considering the current framework on legal capacity goes against Peru's constitutional order. In this sense, the following three key points should be taken into account for interpreting Peru's clinical trials regulation.

1. *A shift from the substitute decision-making to the supported decision-making approach needs to be implemented*

Surrogate decision-makers must be replaced by supporters. Supporters voluntarily designated should therefore be involved in the decision-making process of people with mental disabilities to help them to decide whether to participate in a clinical trial. Besides this, other types of mechanisms of support should be considered when approaching potential participants with mental impairments. For instance, strategies to obtain informed consent should accommodate their specific needs and be sensitive to their contexts, on a case-by-case basis. These measures may also require special training for researchers in order to avoid paternalistic attitudes and stereotypes, as well as the participation of psychologists or experts in mental health in research teams. In the same sense, research ethics committees should also have members with knowledge and expertise on mental health research or disability rights advocates who represent the points of view and protect the interests of persons with mental disabilities.

2. *Capacity assessments during the process of informed consent should be allowed to promote autonomy*

The CRPD Committee establishes that a functional approach to mental capacity is a discriminatory denial of legal capacity of people with mental disabilities. CIOMS, by contrast, states that individuals' decisional capacity must be assessed, when there are good reasons to believe that they are incapable of giving consent.

The development of supported decision-making mechanisms imply to consider different types of support, in accordance with the diversity of persons with mental disabilities. These forms of support however could include an assessment of their decision-making skills aimed at tailoring the measures of support given to people with disabilities. Assessments of mental capacity in these contexts should not be considered discriminatory but compatible with the CRPD goals. Firstly, supporters, research teams and research ethics committees need to know *what* and *the extent* to which a person with disability understands to give them the best support in accordance with their own characteristics and preferences that ultimately, promote their autonomy to decide to participate in a clinical trial. Secondly, the assessment of the decision-making skills is not grounded in the disability and its purpose is not to deny legal capacity to people with mental impairments, 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. Thus, capacity assessments do not necessarily entail a discriminatory treatment but a safeguard that ensures that the process of informed consent is being conducted adequately.

3. *Decisions to participate in a clinical trial based on the "best interests" could be taken, on a case-by-case basis*

It may be the case that even though the supporter has tried everything in her power, a person with mental disabilities is unable to understand the situation. In this case - and if no advance directives exist - two things can be done: *a)* exclude her from research or *b)* allow the supporter to decide about her participation which should be done in accordance with "the best interpretation of her will and preferences". This option aligns with the CRPD. However, what happens if people's will and preferences are not known? Should people with mental disabilities be automatically excluded from research? If this is the case, the decision about their participation could be taken, exceptionally, in their best interests, when the research intervention is the best available medical option, as suggested by CIOMS. Decisions based on the best interests should not be always considered as a violation of the CRPD because they do not always constitute a discriminatory denial of legal capacity. In this scenario, these decisions carefully balance the potential individual benefits and risks of research, and other competing considerations – including those related to

the exercise of the legal capacity of people with disabilities – that ultimately protect their right to health.

Conclusions

The current framework on legal capacity in Peru represents a significant achievement. However, its lack of implementation in research is currently affecting the participation of people with disabilities in clinical trials. Regarding the process of informed consent, the three suggested key points for interpreting this regulation in the light of the CRPD and the CIOMS guidelines ensure a fair inclusion of people with mental disabilities in clinical trials while protecting their rights.

References

1. Civil Code, 1984
2. Legislative Decree N° 1384, September 2018
3. Supreme Decree N° 021-2017-SA, June 2017
4. CIOMS. International Ethical Guidelines for Health-related Research Involving Humans, 2016
5. UN Committee on the Rights of Persons with Disabilities. General comment N° 1, 2014

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ⁱ “Interdiction” is a process in which a court appoints a LAR to a person with mental impairments after a capacity assessment that determines if she *can* decide by herself, and *to what extent* (Art. 564, Peruvian Civil Code, 1984).

ⁱⁱ People with mental disabilities or people with mental impairments is used indistinctly to refer to people with cognitive or psychosocial disabilities.