

Ethical issues arising in research with people with mental health conditions

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Governance paper: Equity-based research ethics governance model for the inclusion of people with mental health conditions in research

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Brief description

This proposal aims to address the shortcomings of the risk-based research ethics governance model adopted by the Research Ethics Committees (RECs) in Malaysia. To date, there are 14 registered RECs in Malaysia established by medical research centers, institutions of higher learning and jointly between institutions. All RECs developed their own policies, guidelines, and procedures as their governance tools. The policies of most RECs made general reference to the CIOMS Guidelines that require benefits and risks evaluation for the inclusion of people incapable of giving informed consent.¹ However, analysis of the policies, guidelines and procedures published by the RECs found that the risk-based governance model does not specifically address the inclusion of vulnerable population or people with mental health conditions in research. The risk-based governance model is inadequate to promote and support the inclusion of people with mental health conditions in research for the following reasons: i) the policies do not impose a positive obligation on the RECs to promote and support the inclusion of people with mental health conditions in the research that has the potential to benefit them; ii) the guidelines do not impose a negative obligation on the researchers to refrain from arbitrarily excluding people with mental health conditions either at proposal or recruitment stage; and iii) the procedures do not impose a positive obligation on the reviewers to ensure people with mental health conditions are not unfairly excluded from participating in the research that has the potential to benefit them. To fill in the gaps, this proposal provides recommendation for an equity-based research ethics governance to be integrated into the risk-based research ethics governance of the RECs in Malaysia.

Commentary

Under the existing governance model, a research project that involves people with mental health conditions will be classified as beyond minimal risk research, that entails specific protections. The specific protections include presentation for review before a full board, obtaining informed consent and assent, and taking extra precautionary measures not to cause physical and emotional harms against people with mental health conditions. These specific protections inadvertently prompted researchers to exclude people with mental health conditions from their population of study.² They may also adopt evasive strategy, by excluding people with mental health conditions during recruitment process.³ The motives for exclusion are to avoid legal risks, or due to additional costs, efforts and time required to comply with the RECs approval conditions.⁴ As a result, people with mental health conditions are often under-represented, and are denied an equal opportunity to voice their opinions, and to provide valuable inputs in the research that has the potential to benefit them.⁵ While the inclusion of people with mental health conditions may raise unique ethical and legal risks, they should not be used as the sole justification for their exclusion as research participants.⁶ People with mental health conditions may be willing, or motivated by altruism, or interested to participate in research,⁷ as having a mental illness is not synonymous with being incompetent to make decisions.⁸

Advocates of human rights and mental health called for a governance model that could overcome further exclusion of people with mental health conditions in research.⁹ The risk-based research ethics governance model is non-optimal since the researchers may end up excluding people with mental health conditions who are willing to participate but assumed as not fit or risky in the

exclusion criteria. The risk-based governance model also enables the researchers to exclude people with mental health conditions since this group of people may have little or no practical value to the research.¹⁰ In contrast, an equity-based research ethics governance model promotes inclusiveness, whereby its ethical governance is guided by the principles of justice, diversity and fair equality of opportunity.¹¹ An equity-based research ethics governance model upholds the right to life, procedural fairness, equal treatment, and freedom of expressions as envisaged in Article 5, Article 8 and Article 10 of the Malaysian Federal Constitution. An equity-based governance model empowers policy intervention to address inequality and asymmetry in the participation of people with mental health conditions.¹² It is also equipped with a check and balance mechanism to prevent deliberate and out of convenience exclusionary practices.¹³ The principles of fairness and proportionality entrenched in the governance model require a risk management plan proportional to the degree of risks arising from the inclusion of people with mental health conditions.¹⁴

Recommendation

The proposed equity-based governance model consists of substantive component (policy, guidelines) and procedural component (standard operating procedure (SOP) and review protocol) as its governance tools. The governance model could be introduced as a stand-alone model or integrated into the existing risk-based governance model. The model adopts a broad-based approach covering basic, applied, and experimental research. It caters for all categories of people with mental health conditions classified by the Malaysian Institute of Mental Health.¹⁵

The policy statement should provide that people with mental health conditions are entitled to participate in research. The policy should have the following objectives: i) to promote and support fair, diverse and equitable inclusion of people with mental health conditions in the research that has the potential to benefit them; and ii) to protect people with mental health conditions from being unfairly or arbitrarily excluded from participation in the research that has the potential to benefit them.

The guideline should provide the RECs ethical judgement is guided by the principles of non-discrimination, justice, and fair opportunity. In addition to the CIOMS Guidelines, the RECs guideline should refer to the following documents: i) the UN Sustainable Development Goals that envisage inclusivity and non-discrimination to improve the lives of the people; ii) the UN Convention on the Rights of Persons with Disabilities that unlinks the notion of incapacity from the notion of mental disability; and iii) Article 5, Article 8 and Article 10 of the Malaysian Federal Constitution that guarantee the right to equal treatment and freedom of expression.

The main responsibilities of the RECs under the proposed governance model is to ensure: i) researchers do not unfairly exclude people with mental health conditions; ii) involvement in research activities is more representative particularly by increasing inclusion of people with mental health conditions; and iii) the participation of people with mental health conditions is promoted by using social media.¹⁶

The SOP should provide an equity-based assessment criterion before allowing the exclusion of people with mental health conditions. The criteria that should be taken into consideration are: i) the potential increase in knowledge that is directly or indirectly relevant to people with mental health conditions; ii) the necessity to include people with mental health conditions as it is not possible that the same increase in knowledge could be achieved other than by recruiting them as research subjects; and iii) the potential benefits to people with mental health conditions are sufficient and important to outweigh any risks of harm inherent in the research.

The review protocol of the RECs should provide reviewers must ensure: i) the researchers do not conveniently assume that people with mental illness are categorically incapable of making their own decisions about participation in research;¹⁷ ii) the researchers who exclude the involvement of people with mental health conditions, must provide compelling rationale and justification that inclusion is inappropriate with respect to the welfare of the participants or the purpose of the research; iii) the decision to exclude must not be generalized and their exclusion must be

individualized, according to the context, on a 'case-by-case' basis; and iv) the reviewers disapprove or modify research proposal that unfairly exclude people with mental health conditions.

Conclusion

This proposal identifies the gaps in the governance tool of the risk-based governance model and provides justification for an equity-based research ethics governance model to promote and support the inclusion of people with mental health conditions in research. While the proposal focuses on people with mental health conditions, it can be applied to other vulnerable people or groups who have been unfairly excluded from participation in research that has the potential to benefit them. The proposed equity-based governance model is in line with the UN Sustainable Development Goals to reduce inequality, and the Malaysian Mental Health Policy that envisages inclusivity and non-discrimination to improve the lives of all groups of people in Malaysia by 2030.

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