

# Position Statement 26: Participant Protections in Psychiatric Research

## Policy

Mental Health America (MHA) is dedicated to addressing the needs of those living with mental health and substance use conditions and to promoting the overall mental health of all Americans. Our work is driven by our commitment to promote mental health as a critical part of overall wellness, including prevention services for all; early identification and intervention for those at risk; integrated care, services, and supports for those who need them; with recovery as the goal. One of MHA's goals is the development of a broad-based national research agenda that includes prevention, screening and diagnosis, and treatment and services. MHA strongly supports continued and expanded research into the causes, progression and treatment of the full range of mental health and substance use disorders.

## Background

Research is necessary to explore innovations in treatment and service methods in order to develop safer, more effective, evidence-based interventions.<sup>1</sup> To accomplish this, the inclusion of individuals with mental health and substance use problems in the design and implementation of research is essential. A balance can then be struck to promote innovation and research while also protecting individuals with mental health and substance use conditions participating in such research. The federal regulations concerning "Human Subjects Protection and Inclusion of Women, Minorities, and Children"<sup>2</sup> strike a good balance. When provided with accurate and complete information, people with mental health and substance use conditions can make thoughtful and informed decisions about participation in psychiatric research, adhere faithfully to research protocols, and provide valuable, randomized evidence to improve treatment. It is extremely challenging to provide information about research studies that is both complete and understandable to individuals without specialized medical training. However, every effort should be made to do so. No legally competent individual should ever be denied the opportunity to make an informed decision about his or her participation in psychiatric research because a third party wishes to protect that individual, however well-intentioned that third party's concern may be.

## Recommendations

In all cases, measures must be taken to ensure protection of the health, safety, and rights of participants. Such protective measures should include:

- Respect for people living with mental illness;
- A thorough Institutional Review Board (IRB) assessment;
- Inclusion of individuals with mental health and substance use conditions in research design and implementation;
- Participant access to an independent advisor;

- Participant access to reasonably clear and complete information;
- Informed consent for all participation;
- The opportunity to create and enforce advance directives;
- Acknowledgement that the individual's participation in research is voluntary, and that he or she has right to withdraw from the study at any time;
- Protection of participant privacy and confidentiality, in accordance with all applicable federal and state laws;
- Participant receipt of new and updated information as the study proceeds;
- Welcoming participant feedback during the study period; and
- Arrangements for post-study care.

MHA believes that partnerships between mental health consumers and researchers are essential to continually improving our understanding and treatment of mental health and substance use disorders. MHA believes that the following measures are essential to protecting the health and rights of research participants, while also facilitating scientific advances:

### Respect for the Individual

All legally competent adults can reasonably expect to be treated as such, and should therefore be expected to act in their own best interests in making a decision about whether or not to participate in research. Only in extraordinary circumstances should it be necessary to involve a third party (such as the parent of a young child, a conservator, or another legally-designated representative, who at all times should be acting in the best interest of the participant) in this decision-making.

### IRB

Prior to implementation, proposed research projects must be reviewed by an Institutional Review Board (IRB) in accordance with federal regulations and Office of Human Research Protections (OHRP) guidance.<sup>3</sup>

### Inclusion in Research Design

Persons with mental health and substance use conditions and their caregivers should be included in the entire process of research – including research design. Bringing people in recovery and caregivers into the design of research, including goals, outreach, and implementation, ensures that each project remains person –centered and allows for identification of protection needs by community members best able to identify problem areas. Inclusion of people in recovery and caregivers in research design also promotes diversity that will support the translation of science into practice. Diversity analysis should include consideration of the following factors: various types and severity of mental illnesses and addictions, socioeconomic background, race, national origin, culture, gender, sexual orientation, and geography.<sup>4</sup>

### Access to an Independent Advisor

Each IRB must include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. OHRP guidance also makes provision for an independent advisor<sup>5</sup> (Ombudsman) to advise potential participants on the risks and benefits of participation in the proposed research project,

as required. MHA believes that, before giving initial consent, participants should have access to an Ombudsman or other healthcare advisor upon request who is independent from the interests of the research project or institution and who will advocate for the safety of research participants. The Ombudsman should be approved by the IRB and should be sufficiently trained to be able to effectively advise research participants about the risks and benefits of the research. In addition, the Ombudsman should be available to advocate for research participants whenever their continued ability to provide informed consent is uncertain, or when there is a significant risk that continued participation could produce deleterious effects on a participant. This is particularly important if the participant is incarcerated or civilly committed.<sup>6</sup>

### Informed Consent

Persons with mental health conditions must give informed consent to participate in medical research.<sup>7</sup> MHA does not support enabling authorization by another person as a legal representative for the purpose of the initial consent to participate in medical research. The inclusion of children as research participants is important to identify safe, early mental health intervention options for youth. Children and youth who are capable of understanding their role in proposed research should be required to give their assent before parents can give consent to their participation.<sup>8</sup>

### Accessible Information

Steps should be taken to ensure that participants comprehend the information they receive not only before they agree to study participation, but throughout each phase of the study. All written and verbal information provided to a participant (or potential participant) must be linguistically appropriate, and written using language that is appropriate for the potential participants' reading level. Any necessary accommodations must be made for people with disabilities or with low literacy levels. (e.g., by providing information in sign language or Braille).<sup>9</sup>

### Advance Directives

MHA supports the use of advance directives concerning participation in medical research as a means of encouraging people with severe mental illness to participate in advancing the effectiveness of treatment. All research participants should have the right to provide advance directives for treatment or research prior to participation in the study, which are followed by the research staff. MHA supports the inclusion of advance directives as part of the informed consent process for all research studies.<sup>10</sup>

Where there is a significant risk of acute psychotic episodes or other cognitive impairment, potential treatment issues should also be raised during the consent process, and advance directives should be offered to assure that the treatment dialogue takes place prior to any loss of capacity.

### Right to Withdraw at Any Time

All participants have the right to withdraw from a research study at any time without consequence. In those cases where abrupt discontinuation of treatment could harm the participant (e.g., sudden discontinuation of a medication), the research team must work with the participant to ensure that the withdrawal process is monitored and conducted as safely as possible, and that substitute treatment is provided.

### Privacy and Confidentiality

All research participants have the right to privacy and to confidentiality of their medical records and the information included in them, in accordance with applicable state and federal law.

### Provision of New Information

All research participants must be informed of any new information that becomes available

during the course of the study that might affect continued study participation (e.g., changes in the risk associated with the research).<sup>11</sup>

### Post-Study Care

All medical research designs should ensure continuity of care for participants following the conclusion of the research project. Participants should be followed for a minimum of six months post-research to ensure that they are medically stabilized and reconnected with essential services.

### Effective Period

This policy was approved by the Mental Health America Board of Directors on September 9, 2017. It is reviewed as required by the Mental Health America Public Policy Committee.

**Expiration:** December 31, 2022

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1. See, generally, [MHA Position Statement 12](#), Evidence-based Healthcare
  2. 45 CFR, Part 46, <https://www.nih.gov/grants-funding>
  3. 45 CFR §§46.301-46.306.
  4. Brownson, R. C., Colditz, G.A. & Proctor, E.K., eds. *Dissemination and Implementation Research in Health: Translating Science to Practice*. Oxford University Press (2012).
  5. OHRP QA Self Assessment Tool includes the following question: Does your institution/IRB organization have an advocacy program or ombudsman accessible to potential or enrolled research participants? <https://www.hhs.gov/ohrp/sites/default/files/ohrp/education/qip/ohrpqatool.pdf.pdf>
  6. 45 CFR §§46.301-46.306.
  7. 45 CFR §46.116. For more guidance read: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3275995/> Gupta UC, Kharawala S. Informed consent in psychiatry clinical research: A conceptual review of issues, challenges, and recommendations. *Perspectives in Clinical Research* 3(1):8 (2012),  
*Or: Informed Consent in Clinical Mental Health Research NIH Guide*, , Volume 24, Number 27, July 28, 1995 <https://grants.nih.gov/grants/guide/pa-files/PA-95-080.html>
  8. Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. 45 CFR §§46.401-46.409.
  9. Christopher, P.P., Foti, M.E., Roy-Bujnowski, K. & Appelbaum, P.S., "Consent Form Readability and Educational Levels of Potential Participants in Mental Health Research," *Psychiatric Services* 58:227-232 (2007).
  10. See, generally, [MHA Position Statement 23](#), Advance Directives
  11. 45 CFR §46.116(b)(5)