Position Statement 26: Participant Protections in Psychiatric Research

Policy Position

Mental Health America is dedicated to promoting mental health, preventing mental disorders and achieving victory over mental illnesses through advocacy, education, research and service. One of MHA's goals is to ensure the development of a broad-based national research agenda that includes basic research, diagnostic and treatment research, services research and prevention research.

MHA strongly supports continued and expanded research into the causes, progression and treatment of a range of mental health problems and mental disorders. Research is necessary to enhance existing treatment and service methods, and to advance the discovery and use of evidence-based, effective interventions. To accomplish this, it is clear that research technology will need to include testing with humans. While the participation of human subjects is an essential aspect of medical research, MHA believes that balance is needed to protect individuals with mental health conditions. The federal regulations concerning the "Protection of Human Subjects"[1], strike a good balance in providing that protection.

When provided with accurate and complete information, individuals with mental health conditions can make thoughtful and informed decisions about participation in psychiatric research, as well as provide valuable input to the research process. It is extremely challenging to provide information about research studies that is both complete and understandable to individuals without specialty medical training, but every effort should be made to do so. In all cases, a number of measures must be taken to ensure the health, safety, and rights of participants. Such protective measures (described under Background) include (but are not necessarily limited to) ensuring:

- A thorough Institutional Review Board (IRB) assessment
- Access to an independent advisor
- Informed consent
- Access to reasonably clear and complete information
- The opportunity to create research advance directives
- The right to withdraw from the study at any time
- Protection of confidentiality
- Receipt of any new information as the study is conducted; and
- Arrangements for post-study care.

Where there is the potential for acute psychotic episodes or other cognitive impairment, these issues must be raised during the consent process and advanced directives.

Background

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

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) guidance2.

Access to an Independent Advisor

OHRP guidance makes provisions for an Ombudsman to advise potential participants on the risks and benefits of participation in the proposed research project. Before giving initial consent, participants should always have access to an Ombudsman or other healthcare advisor who is independent from the interests of the research project or institution, and who will advocate for the safety of research participants. Mental Health America believes that the Ombudsman or other health care advisor should be approved by the IRB and should be sufficiently trained to be able to effectively advise research participants about the risk and benefits of the research. (Possible addition of citation to federal regulations describing the appointment of Ombudsman) If a potential participant does not already have such an advisor, the study organizers must make one available. In addition, the independent healthcare advisor should be available to advocate for research participants whenever their continued ability to provide informed consent is uncertain, or when continued participation will produce deleterious effects on the participant.

Informed Consent3

Persons with mental health conditions must be able to render informed consent to participate in medical research. 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. Children who are capable of understanding their role in proposed research should be required to give their assent4 before parents can give authorized consent to their participation.

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)5.

Advance Directives>

MHA supports the use of advance directives concerning participation in medical research as a means of encouraging people with serious mental illness to participate in advancing the effectiveness of treatment6. All research participants should have the right to provide advance directives for treatment or research prior to participation in the study, which are to be followed by the research staff. MHA supports the inclusion of advance directives as part of the informed consent process for all research studies.

Right to Withdraw at Any Time
All participants must 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.

Confidentiality
All research participants must have the right to confidentiality of their medical records, unless otherwise specified in the consent form.

Provision of New Information
All research participants should 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).

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 March 3, 2007. It is reviewed as required by the Mental Health America Public Policy Committee.

Expiration: December 31, 2012

1. 45 C.F.R. Part 46
2. US Department of Health and Human Services, Office of Human Research Protections. Title 45: Public Welfare, Part 46: Protection of Human Subjects. Effective June 23, 2005 - http://www.hhs.gov/ohrp
3. For more details on information necessary to informed consent, please see "What should you ask before agreeing to participate in a research study?," prepared by Mental Health America in partnership with the National Institute of Mental Health, June 2001. http://www.nmha.org/go/information/get-info/research-studies/what-should-you-ask-before-agreeing-to-participate-in-a-research-study
4. Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. US Department of Health and Human Services, Office of Human Research Protections. Title 4: Public Welfare, Part 46: Protection of Human Subjects.http://www.hhs.gov/ohrp
5. Paul P. Christopher, M.D., Mary Ellen Foti, M.D., Kristen Roy-Bujnowski, M.A. and Paul S. Appelbaum, M.D. Consent Form Readability and Educational Levels of Potential Participants in Mental Health Research. Psychiatric Services. Arlington, VA. Volume 58 (2007): 227-232.