

Ethical Principles and Practices for Research Involving Human Participants With Mental Illness

American Psychiatric Association's Task Force on Research Ethics

This report of the American Psychiatric Association's task force on research ethics addresses ethical issues related to the conduct of research involving human participants with mental illness. The report includes discussion of recruitment and ongoing participation of persons whose decisional capacity may be impaired and the ethical costs of categorically excluding persons with serious mental illness. Investigators should receive education in research ethics that addresses rules and norms governing research; sensitivity to ethical implications of decisions and actions; and skills in ethical problem solving, including ascertainment and disclosure of conflicts of interest. Ethical research design must ensure that a study has scientific merit, methods used should yield knowledge of value, and procedures must minimize risks to participants and optimize benefits. When risks are anticipated, plans should be developed to ensure participants' safety. The task force concludes with 12 recommendations for researchers, ethical review bodies, and advocacy groups to promote research and ensure ethical conduct of research. (*Psychiatric Services* 57:552–557, 2006)

Research to understand the causes and consequences of mental illness and to improve health care for individuals with mental disorders is of great importance. One in five individuals develops a serious mental illness during his or her lifetime, leading to substantial suffering by these individuals and their families and creating an immense social burden (1). In the United States, mental disorders are linked to direct and indirect socioeconomic costs in excess of \$150 billion annually (2).

Despite the importance of scientific research to advance care for individuals with mental illness, society has no moral warrant or legal authority to require individuals to participate in such research. On the contrary, conducting

research with human participants is a privilege grounded in trust. Individuals who participate in research entrust investigators with personal information and at times assume significant personal risk. They do this with the hope that their participation will lead to improved understanding of mental illness and treatments for themselves and for others. In addition, they seek to contribute to the advancement of science for the benefit of society. Society trusts researchers to conduct methodologically rigorous scientific studies in a manner that aims to serve the public good as well as to protect individual volunteers.

The ethical context of research involving human participants with mental illness is also affected by the strong

social stigma still associated with mental illness (1). Stigma, together with unwarranted generalizations and assumptions, can lead people to exaggerate the deficits and vulnerabilities of individuals with mental illness and to overlook or discount their strengths.

For all these reasons, research involving participants with mental illness raises complex ethical issues and concerns. The task force on research ethics was established in 2001 by the American Psychiatric Association (APA) to clarify the ethical parameters of psychiatric research and to make recommendations to ensure that such research embodies the highest ethical and scientific standards and is conducted with the utmost professional integrity.

Ethical foundation of research with human participants

The ethical conduct of human research depends on the professional integrity of investigators and the leaders of health care organizations and other institutions that sponsor and conduct research. The 1978 Report of the National Commission on the Protection of Human Subjects of Biomedical and Behavioral Research (the Belmont Report) (3) articulates three principles for guiding ethical research with human participants: respect for persons, beneficence, and justice. These principles form the basis of the federal regulations governing human research.

Over the past three decades, regulatory requirements and ethical standards governing human research have continually evolved. These standards

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include federally mandated oversight of informed consent procedures and documentation, scientific and ethical review, formal confidentiality protections, and data and safety monitoring for clinical trials and treatment studies. In addition, all researchers have an obligation to ensure the professional integrity of their work and to insulate themselves from extraneous pressures and influences that could compromise or distort the objectivity and ethical merit of their research.

Safeguards to protect the dignity and well-being of human research participants are especially important when research involves persons whose capacities for autonomy and informed consent may be compromised by the nature of their illnesses (for example, terminal illness and serious physical or mental illness), by their life circumstances (for example, institutionalization), or by other characteristics (for example, research with children).

In recent years, the enthusiasm and hope generated by extraordinary advances in basic and clinical science have been dampened by disheartening examples of unethical practices in human research. Such infractions, although relatively rare in relation to the overall scope of clinical research, prompt substantial concern. In response to concerns about the adequacy of the current system of participant protection, many experts and authoritative bodies have recommended changes.

Increasingly, it is recognized that protection of human research participants requires an integrated approach among the various stakeholders in research, including research sponsors, institutions, investigators, and research participants. In *Responsible Research: A Systems Approach to Protecting Research Participants* (4), the Institute of Medicine identified four conditions to ensure an adequate system of human research participant protection: accountability for providing participant protection; adequate resources (financial and nonfinancial) to sustain robust protections activities; ethics education programs for persons who conduct and oversee research; and transparency, meaning open communication between the research institution, investigators, research par-

ticipants, the local community, and other stakeholders. Each research organization is expected to satisfy these prerequisite conditions in a manner that is consistent with its mission, the breadth and substance of its program, and the context of its community.

Ethical context for participants with mental illness

Unique ethical considerations in research involving individuals with mental illness derive from the nature and heterogeneity of mental disorders. These unique considerations include the varying impact mental disorders can have on behavior and cognitive function, the possible effects of mental illness on decisional capacity, the stigma associated with mental illness, and the diminished social opportunities and political voice of many individuals with mental illness in our society.

Mental illnesses can disrupt the thoughts, feelings, experiences, and relationships of affected individuals and their families and loved ones. Although some mental illnesses are brief and relatively less severe, many are chronic and serious and can become a defining feature of the lives of individuals who suffer from them. Stigma associated with mental illness can lead to discrimination and diminished opportunities for productive lives and, unfortunately, can also impede access to optimal treatment and psychosocial support. Many people with severe and chronic mental illnesses undergo a profound loss of social function and have few resources. Moreover, research participants with mental illness may have less social support and fewer sources of advocacy than other human study participants.

Notwithstanding these vulnerabilities, it would be a profound ethical mistake to assume that people with mental illness are categorically incapable of directing their own lives or making their own decisions about participation in research. On the contrary, recent research has shown that people with serious mental illnesses retain substantial decisional capacities and that in many cases of impaired capacity, targeted intensive educational interventions can improve the ability to make an informed decision (5–8). An

important challenge for researchers is to develop valid and reliable methods of assessing the relevant decision-making abilities of people with mental illnesses and other disorders that may impair decisional capacity and to integrate interventions to improve these abilities into the research process (9).

Given the current sociolegal research environment, it is difficult to know whether, in practice, researchers and research review bodies err in overestimating or underestimating the decisional capacities of persons with mental illness. Either type of systematic error can be costly. Allowing persons with mental illness to participate on the basis of defective consent would violate the most basic ethical tenets governing human research and can amount to exploitation. Yet, by erring too much in the other direction—that is, by overemphasizing the vulnerabilities of persons with mental illness—researchers and review bodies could unfairly exclude competent individuals with mental illness from opportunities to participate in research.

The ethical costs of excluding willing individuals with mental illness from participating in research are not sufficiently emphasized. Unjustified exclusion from research, however well intended, is a form of discrimination. Moreover, in the absence of adequate research on the most severe forms of mental illness, individuals with these illnesses are relegated to receiving treatments for which there is only inferential evidence of efficacy. For these reasons, a major ethical challenge for psychiatrists and other professionals engaged in mental illness research is to develop ethical principles and practices for selecting research participants that ensure proper respect and protection without reinforcing incorrect assumptions about individuals with mental disorders.

Preparing investigators for research with human participants

Psychiatric investigators must be adequately prepared for the ethical responsibilities of their research to help ensure that it is conducted with integrity, embodies the highest ethical and scientific standards, and provides appropriate protections for research

participants. The obligation to conduct research ethically extends throughout the research process, beginning with the choice of the study question, and entails a continuing duty to minimize risks and enhance the benefits of the research for society and the participants. Respect for research participants should be evident in the care given to the procedures for recruiting and selecting participants and in the safeguards used to ensure informed consent and to protect the confidentiality of private information.

A critical component in the process of becoming a scientific investigator is learning how to conduct research responsibly. Preparation of psychiatric investigators involves training in the biomedical sciences, research methods, professional and research ethics, and human research regulations. Being prepared to address ethical dimensions of research with human subjects requires knowledge about the rules, regulations, and norms governing research; sensitivity to ethical implications of various decisions and actions; and skills in ethical problem solving (the abilities to identify ethical conflicts, reason about the various alternatives, and resolve questions and conflicts through an ethically adequate process). Investigators should be aware that financial arrangements supporting the research infrastructure have the potential to create conflicts of interest that could compromise the integrity of their research as well as the rights and welfare of the research participants. Investigators in training who are physicians have the additional challenge of developing professional identities as physician-investigators that at times conflict with their roles as physicians. Formal education in research ethics for psychiatric researchers is essential to address these complex issues.

Ideally, education in research ethics should be introduced early in research training and continue throughout an investigator's career. Investigators must keep abreast of the evolving strategies and norms of responsible conduct in research. In addition, psychiatric investigators must pay special attention to evolving scientific and ethical considerations inherent to psychiatric research studies. Thus life-

long learning for psychiatric investigators includes specific attention to maintaining the knowledge, sensitivities, and skills required for the responsible conduct of research involving human participants. Competency can be assessed, for example, through peer review, by formal testing of knowledge and skills, or by direct observation in research settings.

Given the nature and heterogeneity of mental illnesses, it is important for researchers who conduct research involving individuals with mental illness to understand the important features of the disorders they wish to study and the contexts in which individuals with these disorders generally receive care. Researchers interested in studying mental illness (or other conditions) that may affect decisional capacity must keep abreast of ethical guidance and specific regulations developed to safeguard individuals who lack decisional capacity. In addition, researchers working with individuals with severe and persistent mental illness must recognize that individuals participating in their research may not be able to advocate for themselves or to protect their own interests. Therefore, researchers should develop and implement efficient and effective safeguards for filling this gap in studies involving significant risk. Finally, researchers should aim to minimize the effects of stigma in the research environment.

Designing and implementing ethically sound studies

The Belmont principles highlight several ethically sensitive features of psychiatric research. Respect for persons in the context of psychiatric research means that research participants must be regarded with dignity and an appreciation for their full personhood, life experiences, autonomy, privacy, values, and capacities. Respect for persons also requires suitable safeguards to protect the rights and interests of vulnerable individuals enrolled in research. Beneficence in the context of psychiatric research refers to the duty of clinician-investigators to apply their professional expertise and skills to diminish the suffering and enhance the lives of persons with mental illness. Justice requires that

the burdens and benefits of human investigation be distributed equitably. In psychiatric research, justice requires that studies focus on scientific questions of importance to people with mental illness and that studies include the least vulnerable individuals necessary to answer these scientific questions adequately.

In order to be ethically sound, research protocols must meet several requirements. First, they must have scientific merit and use methods likely to yield new knowledge of value to the population under study. This helps ensure that the contributions of study participants are meaningful and justify their effort and risk. Investigators and other members of the research team must have sufficient clinical and research expertise to undertake the proposed research. Possible threats to research integrity stemming from inadequate institutional and investigator resources (such as lack of adequate support for the institutional review board [IRB] and its membership) should be anticipated and avoided. The research design and research procedures should be selected to minimize risks to participants and optimize benefits. Research strategies that involve study conditions that are expected to have less efficacy than standard treatment methods (for example, placebo) or that utilize techniques that are likely to result in symptom emergence or exacerbation—for example, medication-free intervals and provocative or challenge tests—should have an explicit scientific rationale that is peer reviewed for appropriateness, scientific justification, and the lack of safer scientific alternatives.

The inclusion of perspectives from individuals who have the disorder under study or from their families or significant others should be considered whenever possible in designing research, particularly with regard to informed consent and assessment of acceptable and appropriate risk. This basic obligation is already incorporated into the norms for IRB review of protocols. Under some circumstances, stronger participant involvement should be considered. For example, a process of prospective participant consultation, employing the principles of participatory research,

should be considered when investigators are considering a novel research strategy or one that poses significant risk to potential participants. Current or past participants may be well suited to suggest how best to describe research procedures in a manner that is understandable to future potential participants.

When risks are anticipated, clear plans should be developed to minimize the negative effects of these risks and to ensure the safety of research participants. For example, when emergence or exacerbation of preexisting symptoms is anticipated, it is important to monitor participants closely, track symptom severity and timing, make other treatments available as needed, define appropriate criteria for withdrawal from the study, and build in “back-up” clinical care options for participants who must leave the study.

The sample selection and recruitment of participants should ensure that individuals enrolled in research are those who would be least disadvantaged by study participation but sufficiently representative of the patient population of interest to answer the scientific question. For example, the properties of a medication should not be examined in a hospitalized cohort solely for the sake of convenience. However, if the scientific question relates to determining the effectiveness of a medication in reducing the symptoms of people with treatment-resistant chronic psychosis, it may be necessary to select, recruit, and enroll severely ill, hospitalized individuals. Similarly, in developing interventions to prevent and minimize suicidal behavior, it may be necessary to design studies that include individuals who are very ill and at high risk of suicidal behavior.

The invitation to participate in the study and the informed consent processes should provide information of appropriate depth, scope, and accuracy to promote an authentic, voluntary choice about participation. Researchers should not set levels of incentives so high as to unduly influence an individual to participate in a study with a risk level he or she would not otherwise accept. Some individuals may seek to participate in research as a method of obtaining treatment. In

these situations, investigators need to take extra care to ensure that these individuals understand that participation in research may not be the same as receiving standard medical treatment and that they may or may not receive personal medical benefit from participation in research.

As noted above, some, but not all, psychiatric disorders may impair an individual's ability to provide informed consent for research. This impairment can be transient, fluctuating, or enduring. Therefore, appropriate provisions must be made to evaluate an individual's capacity to consent and to enhance his or her ability to provide informed consent when necessary. Because decision-making capacity may deteriorate or change during the course of research participation, procedures should be in place to protect the rights and welfare of consenting participants during the course of the study. A process for active ongoing monitoring of decisional capacity is recommended. When it is likely that individuals will experience diminished decisional capacity during the course of a research protocol, supplemental safeguards should be considered to ensure continuing consent. For example, it might be possible to use a research advance directive describing different scenarios, documenting the participant's preferences, or designating a surrogate decision maker. Specific procedures should be included to ensure that individuals are withdrawn from research when genuine concerns arise about their desire for continued participation.

Confidentiality safeguards should be developed for all aspects of a study, including staff confidentiality training, procedures for securing data during collection and analysis, and use of nonidentifying data in publications.

Financial arrangements between institutions or investigators and corporate entities (such as pharmaceutical companies) create potential conflicts of interest. Conflicts of interests can alter or compromise investigators' objectivity, distort the ethical and scientific aims of research studies, and adversely affect the rights and welfare of research participants. Perceived conflicts of interest may undermine public trust in the research enterprise. Fi-

nancial arrangements, such as obtaining fees or institutional overhead for provision of research services, have the potential to create individual or institutional conflicts of interest. All apparent institutional and individual conflicts of interest should be carefully assessed by the appropriate entities within the research organization, including the institution's conflict of interest or ethics review committee and IRB. Investigators should be aware of and adhere to all applicable policies governing conflicts of interest that are prescribed by their institutions and by research sponsors and regulatory agencies (such as the National Institutes of Health and the Food and Drug Administration).

Genuine conflicts of interest should be avoided and, if unavoidable, should be managed to ensure that they do not compromise the rights and welfare of research participants or the research itself. Management of such conflicts of interest should include full disclosure of pertinent information to the institutional oversight bodies to enable them to assess the effect of any particular conflict of interest on the study, the need for safeguards or other measures to manage or mitigate the conflict, and the appropriate manner of disclosing the possible conflicts to research participants and potential participants. The guiding principles for these practices should be openness and transparency. Upon completion of the research, efforts should be made to ensure appropriate and accurate dissemination of both positive and negative research results with disclosure of sources of potential conflicts of interest as consistent with the reporting policies of scientific journals.

Conclusions and recommendations

Concerted and systematic efforts are needed to promote research by fostering societal understanding of mental illness; highlighting the positive role of psychiatric research in understanding, preventing, and treating these conditions; and identifying priorities for scientific investigation.

Recommendation 1

The task force recommends that APA works to increase public understanding of mental illness and of the im-

Additional Resources

U.S. Department of Energy: Advisory Committee on Human Radiation Experiments: Final Report, 1995. Available at <http://tis.eh.doe.gov/ohre/roadmap/achre/report.htm>

Preserving the Public Trust: Accreditation and Human Research Participant Programs. Washington, D.C., Institute of Medicine, 2001. Available at www.nap.edu/books/0309073286/html

Research Involving Persons With Mental Disorders That May Affect Decision-Making Capacity. Washington, D.C., National Bioethics Advisory Commission, 1998. Available at www.georgetown.edu/research/nrcbl/nbac/capacity/toc.htm

Institutional Review Boards: Promising Approaches. Washington, D.C., Department of Health and Human Services, Office of the Inspector General, 1998. Available at www.oig.hhs.gov/oei/reports/oei-01-97-00191.pdf

Harold Alan Pincus, Jeffrey A. Lieberman, and Sandy Ferris (eds.): *Ethics in Psychiatric Research: A Resource Manual for Human Subjects Protection*. Washington, D.C., American Psychiatric Publishing, 1999

Laura W. Roberts: Ethical dimensions of psychiatric research: a constructive, criterion-based approach to protocol preparation: the Research Protocol Ethics Assessment Tool (RePEAT). *Biological Psychiatry* 46:1106–1119, 1999

importance of conducting psychiatric research in a scientifically and ethically rigorous fashion. These efforts must be collaborative with governmental agencies, advocacy groups, educational institutions, the media, pharmaceutical companies, and other relevant organizations.

Recommendation 2

The task force recommends that APA promote scientific research on mental illnesses and assist in setting priorities for research on mental illness. In this effort, APA should collaborate with the American Psychiatric Institute for Research and Education (APIRE), the National Institute of Mental Health, and other professional psychiatric research organizations, as well as patient and family advocacy groups.

It is both necessary and feasible to provide ethically appropriate safeguards for the autonomy and well-being of research participants while avoiding undue impediments to advancing scientific understanding of mental illness and its treatment.

Recommendation 3

The task force recommends that in formulating protections for adults with impaired decisional capacity, ethical review bodies utilize three categories of risk levels analogous to the categorization employed in the U.S.

federal regulations governing research with children (minimal risk, minor increase over minimal risk, and more than minor increase over minimal risk). The task force further recommends that analysis of the benefits of research use the two categories that are in the U.S. federal regulations governing research with children (prospect of direct benefit to research participants and no prospect of direct benefit). As described in the APA “Principles of Informed Consent in Psychiatry” (10), “prospect of direct benefit” means that, on the basis of scientific evidence, it is reasonably expected that some participants’ physical, medical, or mental conditions and related functioning might be improved as a direct result of participation in research, including ameliorating symptoms or avoiding side effects of standard therapy.

Recommendation 4

The task force recommends support for the conduct of research entailing various levels of risk, including the cautious application of research strategies that may prolong or exacerbate symptoms (for example, placebo controls, medication-free intervals, and symptom provocation). The task force further recommends that investigators considering these research strategies be en-

couraged to discuss them with patient and family representatives from the community and consider these perspectives in the design of such studies. Research strategies that may prolong or exacerbate symptoms can be justified when practicable alternative research strategies have been carefully considered and found scientifically inadequate and when clear plans are developed to minimize negative effects and to ensure the safety of the research participants.

Recommendation 5

The task force recommends that investigators and research review bodies use a range of options for assessing and documenting decisional capacity in the research context, as described in the APA “Principles of Informed Consent in Psychiatry” (10). The task force further recommends that, regardless of the option chosen, the plan for assessing decisional capacity should be described in detail in the research protocol and explicitly discussed and approved by the research review body.

Recommendation 6

The task force recommends that states facilitate the use of proxy decision makers in research involving adults with impaired decisional capacity by authorizing the person empowered under state law to make surrogate treatment decisions to also make research decisions, as long as this authority is exercised within ethical and regulatory boundaries analogous to those defined in U.S. federal regulations governing research involving children.

Recommendation 7

The task force recommends intensified research on the capacities and experiences of individuals with mental illness as research participants, including their contributions and insights as well as deficits, and on the impact of the research process on patient outcomes. Research on the impact of stigma on the current policies and practices governing research participation by persons with severe mental illnesses is also needed.

Recommendation 8

The task force recommends that APA review and monitor proposed human research guidelines, regulations, and practices for their impact on, and appropriate application to, mental illness research.

Recommendation 9

The task force recommends that APA work to assemble and disseminate evidence-based “best practices” for designing ethically sound research and for ensuring that safeguards for human research are effective in protecting the well-being and rights of research participants with mental illness. To accomplish this recommendation, collaborative efforts with APIRE, other professional psychiatric research organizations, patient and family advocacy groups, public and private research sponsors, regulatory agencies, and accreditation bodies are recommended.

Recommendation 10

The task force recommends that all apparent institutional and individual conflicts of interest be carefully assessed by the appropriate institutional oversight bodies. Genuine conflicts of interest should be avoided and, if unavoidable, should be managed to ensure that they do not compromise the interests of research participants or the research itself. Possible strategies for mitigating conflicts include divestment of questionable holdings and use of independent entities to monitor aspects of the research that could be adversely affected by the conflict, including participant recruitment, the consent process, data collection, data review, or data analysis and interpretation. Information bearing on conflicts of interest should be disclosed to research participants in the manner prescribed by ethics review bodies.

Leaders of research institutions, organizations, and sponsors must commit sufficient resources to protection of human research participants to ensure adequate infrastructure; to provide ethical training for researchers, research staff, and members of review bodies; and to ensure adequate oversight and continuous improvement of research practices.

Recommendation 11

The task force recommends that APA develop and support educational programs for psychiatric investigators and other investigators who conduct research involving individuals with mental illness. The task force further recommends that APA take effective and continuing educational measures to ensure that investigators remain aware of current ethical and regulatory requirements pertaining to human studies. The task force recommends collaborative efforts with APIRE, other professional psychiatric research organizations, patient and family advocacy groups, public and private research sponsors, and accreditation bodies to accomplish this goal.

Recommendation 12

The task force recommends that APA work with the Association of American Medical Colleges, the Accreditation Council for Graduate Medical Education, the American Board of Psychiatry and Neurology, and other partners to encourage academic medical centers, research institutions, and clinical training programs to develop, implement, and evaluate innovative ethics education to provide necessary knowledge and skill to prepare tomorrow's psychiatric researchers for the emerging, increasingly complex ethical issues that they will encounter.

Acknowledgments

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