CMHSR
January 2006
Vol 3, Issue 1
Center for Mental Health Services Research
University of Massachusetts Medical School
Issue Brief

Can People with Mental Illness Consent to Research?

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For many professionals in health care, informed consent is a piece of paper that needs to be signed before a procedure can be started. For some researchers, it is a long description of their study that has the potential for discouraging participation in research. Even research subjects often view informed consent as a bureaucratic ritual. However a close look shows that informed consent is based on some of our most cherished values and its use with people with mental illness is an important recognition of their *inclusion* in the broader community.[1, 2]

What is "Informed Consent?"

The primary stimulus for the development of the doctrine of informed consent to research was the revelations of the atrocities committed by Nazi physicians, in the name of scientific research, on Jews, Gypsies and other detainees. This research included studies such as how long it took someone to freeze to death at different temperatures.[3] Subsequent investigations of American research also found dramatic examples of researchers exploiting subjects including a project that left poor African-American farmers with syphilis untreated in order to describe the natural course of the disease and a study injecting nursing home residents with cancer cells to see if they would develop cancer from them.[4]

Ethically, informed consent has been justified both as an essential feature of rational decision making (patients cannot make rational decisions without adequate information) and a grounding for patient autonomy (patients should be the final decision makers).

Common to both views are the basic elements of informed consent:

- Information needs to be provided to patients about the risks and benefits of, the alternatives to and the nature and purposes of the proposed treatment or research.
- Patients who are asked to make decisions need to be competent to do so
- Decisions must be made voluntarily without any coercion or undue influence of others.[5]

To these elements, federal regulations about research, the so-called "common rule" (45 C.F.R. 46), have added a number of other disclosures:

- The confidentiality of information gathered
- Potential compensation for injuries suffered
- Disclosure that participation is voluntary and that the subject can withdraw at any time
- A variety of other disclosures pertinent only to specific types of research.

Needless to say, there has been considerable discussion about whether, and under what circumstances, this applies to people with mental illness. Can an individual who is committed to a hospital, under an outpatient commitment order, or even strongly pressured to get treatment by family

members, truly be said to be making a voluntary decision? Can an individual who has psychotic delusions be thought of as competent to make treatment decisions?[6]

Research findings about informed consent

Perhaps because informed consent was such a radical change from previous practice, there have been a large number of research studies of the degree of understanding produced by informed consent disclosures. Although the details differ, there is broad agreement that, in most circumstances most patients and research subjects do not have an adequate understanding of the issues to make a completely rational decision.[7] This is true of people with mental illness and people who do not have a mental illness. What is not agreed about is whether this is because the issues are too difficult for most people to understand or because disclosures are rarely adequate.

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One major problem in informed consent to research is what is called the therapeutic misconception.[8] This is the belief on the part of research subjects that researchers can be expected to take the best interests of the subject as the primary basis for decisions as a health care practitioner would do. They expect that there is no substantial difference between the way in which they will receive care in a research project from the way it would happen in routine health care settings. This, of course, ignores such differences as double blind designs, the use of placebos, randomization to treatment arms and treatments specified by research protocols rather than the individual needs of a patient.

Systematic research suggests that, on average, people with mental illness are somewhat less competent to make decisions about their care than the population at large but it also shows that the distributions overlap.[9] That is, although the average score of people with mental illness on Grisso and Appelbaum's measure of competence is lower than that of the rest of the population, many people with mental illness score better than many people in the "normal" population. A similar pattern is true for therapeutic misconception. Recent studies have shown that 62% of subjects show some signs of therapeutic misconception.[10] The same data set shows that 74% of subjects in psychiatric studies show signs of therapeutic misconception. Although, on average, people with mental illness do not do as well as the general population, most people with mental illness perform about the same as most of the rest of the population.

Overall, these data suggest that professionals who are doing research with people with mental illness need to be especially careful in getting consent from their subjects. However it is clear that having a mental illness is not synonymous with being incompetent to make decisions about treatment for oneself. Indeed, the presumption should be that people with mental illness, like everyone else, have the right to make informed decisions about their treatment and their participation or non-participation in research.

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