Mental Health Clinical Research

Part 3

So you have been asked to take part in a research study. This can be a very satisfying experience, allowing you to help yourself now and to help others in the future. After all, without research, treatment cannot improve, and without those who take part, there would be no research!

Involvement of Family Members and Others

You may wish to involve family members in some parts of a research study. For example, you might consult with a family member about taking part in the study, or you may wish to review the information with a family member or close friend and discuss being a research subject with that person. If you are a parent or the legally authorized representative of someone who might be a research subject, you may wish to involve other concerned family members in any decision you make.

Many family members welcome the chance to make sure, along with the research team, that no one will take advantage of you during the study. This role is clear if a family member is a patient's formal legally authorized representative; but even lacking such legal status, families usually do all they can to protect a family member who is ill.

Remember that Federal regulations protect your right to privacy in the handling of your records throughout (and following) a study. You must give clear permission if you wish the researcher to share personal information about you with family members. Still, you should be aware that, with your consent, your family members or other friends may have several opportunities to provide information during the study.

Will You Have Access to Those Drugs That Work After a Trial Is Complete?

Understandably, if an investigational drug helps you, you may wish to continue taking it after the trial has been completed. In some instances, a medication that is being investigated for use in treating your illness may have been approved by the Food and Drug Administration (FDA) for other uses. If you find that you benefit from such a medication, your own doctor can prescribe it for you.

Often, the company developing a new drug may try to see that you can continue to get it, even before the FDA has approved it for sale. You may be able to do this under what is termed a compassionate plea basis. This means that because the new drug has been so helpful, the manufacturer can give it to a physician, who may then prescribe it for you.

While companies often make such a new drug available, there may also be good reasons why a company cannot. Perhaps only a very small portion of a drug was prepared for the research project, and no more is available for use afterwards. Then again, a manufac-turer may want to further test the drug under certain conditions, or to examine the results of a research study more fully before releasing it for compassionate plea use. A company would be especially careful if a new medication required that the doctor who prescribed it have some special knowledge or skill to monitor its safe use.

You and any family members interested in your well-being should discuss with the director

of the research your questions about compassionate plea use. Each case is different, so the agreement has to be between the drug manufacturer and your own doctor.

Obtaining Care After a Research Project Has Ended

If you decide to take part in a research study—and, especially one that takes place in a hospital—you may find that you will have to stop, or interrupt, the care you now are getting for a mental disorder. Doing that, even temporarily, may result in your losing access to a program of personal care that had been expensive and hard to access. The director of research on your study will often help you to get back into a program of care when the study is finished. The investigator's institution may assist in arranging for follow-up care.

Learning About the Results of Research

In most informed consent forms, the researcher promises to share what is learned from the study with you. These results will sum up the responses of everyone who took part in the study. In addition, the researcher will discuss with you any results that relate to your diagnosis or that may be useful in deciding on the best treatment for your disorder.

Be sure to ask the director of research when you can expect to hear about the results. Ask how you will get this information. Will the researcher write an article describing the study, or will those who took part be invited to a meeting with the study director when all the results are in? If you have questions about the results when you receive them, ask the researcher who can help you to understand what they mean.

A frustrating thing about research is that it often takes years before the results of a study are available. This is because of the time it takes to conduct the study, including getting enough people in the study to make the results meaningful. Be patient, but remember to ask for the results if you have not received them when you expected them.

Checklist of Questions

So you have been asked to take part in a research study! This can be a very satisfying experience, allowing you to help yourself now and to help others in the future. After all, without research, treatment cannot improve, and without those who take part, there would be no research! You are the one who makes research possible.

But how you do know if you want to take part? What questions should you ask? The researcher should answer these basic questions clearly for you. Others undoubtedly will arise during the discussion.

- Q. Why do you want me in your study?
- Q. What is the research about? How will this research help in treating or understanding my disorder?
- Q. What do I need to do and how much time will this take?
- Q. How might this study help me, my relatives, or other people with my disorder?
- Q. How will this be different from the care I am getting now, and do I have other options or choices?
- Q. Could my illness become worse during the study? What will happen if it does?
- Q. What will happen to me at the end of the study?
- Q. What should I do if I want to drop out of the study?
- Q. May I get back to you after I discuss this with my family/friend/case manager/doctor?

Remember to ask again if you do not understand the explanation to any question you have.

And, if you forget the answers to these questions during the study, just ask them again.

Editor's Note
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1 National Institute of Mental Health. (2000). A participant's guide to mental health clinical research (NIH publication #00-4379). Bethesda, MD.