When, Why, and How to Conduct Research in Child and Adolescent Psychiatry: Practical and Ethical Considerations

Donna T. Chen, MD, MPH[a,b,c,*], Lois L. Shepherd, JD[a,b,d]

KEYWORDS

• Research ethics • Children and adolescents • Mental health
• Practice-based research • Practical clinical trials

Consider the following: A psychiatrist is asked to join a research network and wonders if she should. Another psychiatrist tries to untangle research rules about parental permission, consent, and assent for an adolescent patient who is receiving psychotherapy without her parents' knowledge. How should these psychiatrists approach the ethical challenges of the rapidly changing world of research in child and adolescent psychiatry?

Psychiatrists have, as a profession, endorsed evidence-based medicine,[1,2] and much needed research can only be done with the participation of psychiatrists practicing in real-world settings.[3] Indeed, the Child and Adolescent Psychiatry Trials Network (CAPTN) was set up primarily to facilitate large trials in real-world settings.[4] Accordingly, psychiatrists and other clinicians who treat mental health problems of children and adolescents will increasingly encounter opportunities to conduct research in their clinical practices.[5] Even if they are not directly involved in research, treating psychiatrists will be asked for advice by parents considering whether to enroll their children in a study they

[a] Center for Biomedical Ethics and Humanities, University of Virginia School of Medicine, Box 800758, Hospital Drive, Barringer 5th Floor, Charlottesville, VA 22908, USA
[b] Department of Public Health Sciences, University of Virginia School of Medicine, Charlottesville, VA, USA
[c] Department of Psychiatry and Neurobehavioral Sciences, University of Virginia School of Medicine, Charlottesville, VA, USA
[d] School of Law, University of Virginia, Charlottesville, VA, USA
* Corresponding author. Center for Biomedical Ethics and Humanities, University of Virginia School of Medicine, Box 800758, Hospital Drive, Barringer 5th Floor, Charlottesville, VA 22908.
E-mail address: dtc6k@virginia.edu (D.T. Chen).

Psychiatr Clin N Am 32 (2009) 361–380
doi:10.1016/j.psc.2009.03.003 psych.theclinics.com
0193-953X/09/$ – see front matter

have found or have been asked to participate in.[6] Finally, in determining how much confidence to give published research results, psychiatrists need to understand how research studies are conducted. For all of these reasons, it is becoming essential that all practicing psychiatrists understand the basics of research ethics.

Several excellent overviews of the ethical issues that arise in child and adolescent psychiatric research have been published in recent years and serve to focus attention on the many ethical and practical challenges inherent in this work.[7,8] This article extends these discussions by focusing on some important decision points through case discussions. Because much future research will occur in the offices of private–practice psychiatrists,[1,3,9] the following cases emphasize some of the unique ethical concerns that arise in this setting. Most of the concerns discussed, however, are also present in research conducted in other settings.

Practice-based research networks (PBRNs) create a research infrastructure across multiple real-world practice settings and exist in multiple specialties.[10–12] The CAPTN is an important example of a PBRN in psychiatry.[4] These networks generally allow physicians to participate in the creation, design, and conduct of large practical clinical trials aimed at answering questions relevant to practicing physicians and their patients. Often, these large trials compare the effectiveness of two or more common interventions or test for a response from adjunctive treatments. Generally, they are not early phase studies of safety; many do not involve a placebo control group; and frequently, they allow for open assignment of patients to treatment arms, rather than randomization or double-masking.

Other studies conducted in private practices are sponsored by pharmaceutical and device companies and performed with the help of for-profit companies called clinical research organizations (CROs) and site management organizations (SMOs), which organize and manage clinical trials involving hundreds of community-based practices.[13–16] Rather than aiming to improve clinical decision-making, industry-sponsored studies are generally designed to gain regulatory approvals from the Food and Drug Administration (FDA), which are related to marketing their products. There are a number of excellent overviews of the ethical, legal, and regulatory aspects of research conducted in practice-based research networks[17–21] or for CROs.[22–24]

The first two cases that follow (A and B) present some of the general ethical concerns (and their practical consequences) involved in decisions about whether to participate in research and if so, in what kind of research. The remaining cases provide a brief analysis of particular examples of some ethical concerns in psychiatric research with child or adolescent participants. The particular issues highlighted in each case are listed in **Box 1**.

Box 1
Issues highlighted in cases

Case A: Deciding Whether to Conduct Research
Differences between research and medical care
Conflicts of interest
Relationship of trust with patients and community
Financial incentives (including finder's fees)
Conflicts of commitment
Risk-benefit assessments
Considerations involving staff
Operational challenges of research
Separation of medical and research records

Case B: Deciding Which Studies To Conduct and Communicating with Patients About Them
Scientific, social or clinical value of research study
Scientific validity of research study