Informed Consent in Child and Adolescent Psychiatry Research

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Overview

• Backdrop: Scope of Psychiatry research at UMN
• Description of informed consent/assent process
• Special considerations for Psychiatry: capacity to consent
• Risks related to dual roles
### Scope of Current Research in Psychiatry

#### Health Issues
- Mood Disorders
- Anxiety Disorders
- Eating Disorders
- Autism
- Schizophrenia
- Addiction
- Fetal Alcohol Syndrome

#### Measurements
- Clinical information
- Neuroimaging
- Genetics

#### Interventions
- Psychotherapy
- Neuromodulation
- Pharmacotherapy
- Cognitive Training
Scope of my research

• Overarching goals: To advance understanding of neurobiology and treatment of mood disorders in adolescents

• General description of research activities:
  – Clinical evaluation
  – MRI scanning
  – Neurocognitive Tests
  – Saliva samples
  – Blood tests
  – Novel interventions
Informed Consent Process

• In-person meeting with parent(s) or guardian(s) and child
• Detailed review of study activities and the risks of each aspect of the research
• Complete consent form with parent, assent form with child
• Assessment of capacity for consent
Key issues in determining capacity for consent

- Understanding
- Appreciation
- Reasoning
- Expressing a Choice
Special challenges for conducting consent in psychiatric research

• Potential impact of psychiatric illness on capacity to consent
  – Mental illness can sometimes cause impaired attention, confusion, reality distortion, and other problems that can negatively impact decision-making

• Mental exhaustion could impair a person’s thorough consideration of the risks

• Patients who are suffering may be motivated to try experimental treatments
Capacity to consent in patients with mental illness

- MacArthur Competence Assessment Tool-Clinical Research
  - Developed in mid-90’s
  - Initial study found deficits in understanding, appreciation, reasoning, in patients with mental illness (schizophrenia and major depression) versus medical illness and community controls¹
  - Deficits were more pronounced in patients with schizophrenia, in particular a subgroup who had greater levels of thought disturbance.¹
  - Subsequent studies found similar results (few decision-making impairments found in hospitalized depressed patients, more pronounced deficits in patients with schizophrenia²,³)

1. Appelbaum & Grisso, Human Behavior and Law, 1995
2. Appelbaum et al, AM J Psychiatry 1999 156(9): 1380-4
Assessment of Capacity to Consent

• IRB-mandated tools
  – Studies of minimal risk: University of California San Diego Brief Assessment of Capacity to Consent
    • Jeste DV et al. (2007). Arch Gen Psychiatry 64(8):966-74
  – Studies of greater than minimal risk: MacArthur Competence Assessment Tool for Clinical Research
    • Appelbaum, PS, and Grisso, T: Professional Resource Press, Law and Psychiatry Program, University of Massachusetts Medical School, Worcester, MA, 2001
Important risks to be considered for research in clinical settings

- Risk of dual (clinical and research) roles:
  - Therapeutic misconception—patient does not understand that this is research and not treatment
  - Coercion—patient wants to please the doctor, and does not want to be viewed negatively by their doctor
  - Conflict of interest (when PI wears two hats)
Management of Risks

• Use clear language distinguishing the purpose of research versus the purpose of clinical treatment

• Detailed assessment of understanding, appreciation, reasoning, expressing choice

• Create clear separation between clinical activities and research activities
Who should conduct the consent process?

• Department of Psychiatry’s policy now prohibits principal investigators from consenting their own patients

• Solution: co-investigators, trained research staff
Training

• HIPAA www.ulearn.umn.edu
• CITI training www.citiprogram.org
• Good Clinical Practice www.citiprogram.org
• Capacity for Consent Training https://umn.qualtrics.com/jfe/formSV_2bn1nKdS0VO0vN
• Observation, supervision
Conclusions

• Ethics of research in psychiatry are dynamic, and best-practices are evolving

• Recent changes in the department of Psychiatry have been made to mitigate potential risks and ensure ethical research conduct