

Title: Developing an Informed Assent/Consent Process for Youth with Intellectual and Developmental Disabilities

Authors: Iulia Mihaila, Kathleen Diviak, Rebecca Feinstein, Kristin Berg

Background: Youth with intellectual and developmental disabilities (IDD) experience disparities in mental health access/treatment. To optimize outcomes and develop evidence-based interventions, the inclusion of youth with IDD in research is key. Yet, challenges to obtaining informed assent/consent from individuals with IDD may dissuade researchers from including youth with IDD in research, despite the meaningful contributions they can provide. The aim of the present study was to describe the informed assent/consent process developed for recruiting youth with IDD into a randomized control trial seeking to examine the efficacy of a stratified behavioral health treatment in promoting mental health.

Methods: The 2-arm trial randomized youth with IDD into two groups – existing care coordination versus existing care coordination plus a mental health program. Eligibility criteria included being 13-20 years and having a caregiver/self-reported IDD diagnosis and 4th grade comprehension. If preliminarily eligible, an informed assent/consent meeting was scheduled and conducted on Zoom. During the meeting, an adapted assent/consent PowerPoint (written at a 4th-grade level) was shared. Questions from the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) were incorporated throughout the PowerPoint to support assessment of the youth with IDD's capacity to consent to study participation. This provided an opportunity for youth with IDD to describe their understanding of key study ideas and activities in their own words, to ask questions, and for staff to reframe study concepts as needed.

Findings: To date, 406 youth with IDD have been screened as preliminarily eligible, of whom 24 were deemed ineligible after screen and 255 were enrolled. Lessons learned from developing the assent/consent PowerPoint and conducting the informed assent/consent process will be shared.

Conclusions: Developing an accessible informed assent/consent process is key to engaging youth with IDD in research. Utilizing visual tools and questions to gauge understanding may be valuable tools for supporting informed assent/consent.