

Informed Consent & Assent for Pediatric Psychopharmacology: A Refresher

The entity of legally effective informed consent has been clarified in detail in the research arena, and includes familiar elements of: disclosure of all information needed to make a decision; facilitation of comprehension of said information; and that the individual in question had the capacity to reach that decision without undue influence or coercion.¹

General medical practice has adopted these elements. The American Medical Association provides the following guidance: *“Informed consent is more than simply getting a patient to sign a written consent form. It is a process of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention. In the communications process, you, as the physician providing or performing the treatment and/or procedure (not a delegated representative), should disclose and discuss with your patient:*

- *The patient's diagnosis, if known;*
- *The nature and purpose of a proposed treatment or procedure;*
- *The risks and benefits of a proposed treatment or procedure;*
- *Alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance);*
- *The risks and benefits of the alternative treatment or procedure; and*
- *The risks and benefits of not receiving or undergoing a treatment or procedure.*

In turn, your patient should have an opportunity to ask questions to elicit a better understanding of the treatment or procedure, so that he or she can make an informed decision to proceed or to refuse a particular course of medical intervention. This communications process, or a variation thereof, is both an ethical obligation and a legal requirement spelled out in statutes and case law in all 50 states.”²

For pediatric psychiatric practitioners, the American Academy of Child and Adolescent Psychiatry recommends a comprehensive and ethical approach. As with most areas of psychiatric practice, the relationship between the practitioner, the child and the family is foundational. Psychoeducation in all areas of diagnosis, treatment recommendations and duration build upon this. Specific discussions on informed consent for medication or any other intervention should occur prior to initiation of any trial, at the transition to the maintenance phase and before discontinuation. Items to deliberate include indications, benefits and risks for proposed intervention or medication as well as those for alternative treatments; prognosis of condition with and without treatment; the timing for assessing outcomes or side effects; and subsequent steps should the child not respond as expected to proposed medication or intervention. Throughout this process, the practitioner should take into account the psychosocial, cultural, spiritual, medical, and environmental factors of the child and family that could potentially influence the outcome or response to the intervention or medication. It is also strongly suggested that these conversations are documented in as much detail as necessary; and indicate whether the child and guardian were allowed to have any questions or concerns addressed and acknowledged full understanding.³

Assent (a child's affirmative agreement to participate, not just failure to object)⁴ should also be obtained in the manner outlined previously, and ideally, simultaneously. In July 2015, the Arizona Health Care Cost Containment System (AHCCCS) issued Policy 108.1⁵ which outlines the minimum requirements for informed assent and consent for psychotropic treatment should occur for their enrolled members.

References

¹ U.S. Department of Health and Human Services . Informed Consent FAQs. <http://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/> Last accessed August 11, 2016

² American Medical Association. Informed Consent. <http://www.ama-assn.org/ama/pub/physician-resources/legal-topics/patient-physician-relationship-topics/informed-consent.page>. As noted from "What is Informed Consent" The Institute for Health Quality and Ethics. http://instituteforhealthqualityandethics.com/Informed_Consent.html Last accessed August 11, 2016

³ American Academy of Child and Adolescent Psychiatry. Practice Parameter on the Use of Psychotropic Medication in Children and Adolescents. *J. Am. Child Adolesc. Psychiatry.* 2009; (48(9):961-973

⁴ National Institutes of Health. Research Involving Children. https://humansubjects.nih.gov/children1#Requirements_Child_Assent Last accessed August 11, 2016

⁵ Arizona Health Care Cost Containment System. Policy Form 108.1 Informed Consent/Assent for Psychotropic Medication Treatment https://www.azahcccs.gov/PlansProviders/Downloads/GM/BHSPolicy/bhs-policy-form-108_1.pdf Last accessed August 11, 2016