Clinical Trials Unit at Kennedy Krieger Institute

Who We Are

The Clinical Trials Unit (CTU) at Kennedy Krieger Institute facilitates research to improve quality of life for individuals with life-altering medical and psychological diagnoses. Its researcher-initiated, pharmaceuticalsponsored clinical trials are designed to better understand and treat genetic, developmental, behavioral and psychiatric disorders.

The CTU also brings together clinical trial participants and their families with clinicians and pharmaceutical sponsors to study how currently available, newly developed treatments may improve the lives of people with a wide variety of conditions. These treatments could include new drugs, new combinations of drugs, new surgical procedures or devices, and new ways of using existing treatments.

Who We Serve

We offer clinical trials for children, adolescents and adults with a wide range of conditions, including psychiatric disorders, musculoskeletal disorders, neurological conditions and rare genetic diseases. Examples of diagnoses we investigate include:

- Anxiety
- Attention-deficit/hyperactivity disorder (ADHD)
- Cerebral palsy
- Down syndrome
- FMR1-related disorders, including fragile X syndrome (FXS)
- Leukodystrophy
- Osteogenesis imperfecta
- Rett syndrome
- And many more

Our Team

Our interdisciplinary team consists of physicians, psychiatrists and research coordinators who are experts, collectively, in the fields of genetics, psychiatry and mental health for children, adolescents and adults. Physicians and researchers from Kennedy Krieger and Johns Hopkins Medicine bring expertise from a wide range of disciplines to conduct our trials. Research coordinators oversee all trials and are available to answer participants' questions throughout each trial.



Our Approach

All research is undertaken with the utmost care and concern for the safety, health, confidentiality and privacy of each participant. Every clinical trial is approved and monitored by the Johns Hopkins Medicine Institutional Review Boards (IRB), independent committees that ensure trials are ethical and the rights of participants are protected. Each individual participating in a Kennedy Krieger clinical trial receives expert assessment, careful screening and diligent monitoring throughout the entire course of the trial. In a process known as "informed consent," all participants, or their parent(s) or legal guardians, are informed about the details of a clinical trial and any known risks or potential benefits before they may agree to participate in it.

Why Participate in a Clinical Trial?

For many, participating in clinical trials offers access to new treatments not available anywhere else—treatments that might make a difference in quality of life—while receiving extra care and monitoring from doctors and researchers. For others, there is a larger purpose: a chance to help others by advancing research that will lead to medical breakthroughs and improved care for the next generation.

Visit nih.gov/health-information/ nih-clinical-research-trials-you/ why-should-i-participate-clinicaltrial for more information.



What to Expect

If you're interested in participating in a trial, or in having your child participate, your first step will be to complete a pre-screening interview via telephone or in person. During the interview, you'll receive more information about the trial.

Following the pre-screening, if you remain interested in participating, you'll be invited to Kennedy Krieger for an in-person screening visit. During this visit, you will meet with a board-certified physician and the research coordinator assigned to the trial. You will have an opportunity to ask questions, receive comprehensive answers, and decide whether you would like to consent to participate. If you choose to participate, we will begin the screening process, which may involve assessments, questionnaires, exams and blood draws. Completing these procedures will help ensure that it is safe for you or your child to join the trial.

At each visit, you'll meet with the research coordinator and the physician working on the trial. The research team will be very accessible to you and will provide regular updates about your or your child's status in the trial.

Many of your visits may involve physical exams, questions from the physician and providing blood and/or urine samples. There will also most likely be testing and/ or questionnaires to be filled out by you or—if your child is the participant—by both you and your child.

Research and Collaboration

Expanding our knowledge is one of the main goals of the CTU. We are constantly working to find new studies that may benefit patients. Our collaboration with Johns Hopkins Medicine, and its Institutional Review Boards, allows us to access the vast Johns Hopkins knowledge and research base. All physicians working in the Institute's CTU also hold faculty appointments at Johns Hopkins. We work with many departments throughout Kennedy Krieger, including the Center for Developmental Behavioral Health; the Neurology and Developmental Medicine Program; the Center for Autism Services, Science and Innovation; and the Child Life and Recreation Therapies Department.

"Clinical trials represent the final leap from the lab into the real world. I'm passionate about these studies because each one represents an opportunity to identify a safer, more effective intervention. Our patients and their families deserve that. They are truly our partners in this journey. We could not do it without them."

> – Bradley Grant, DO, Clinical Trials Unit principal investigator

CONTACT US

Clinical Trials Unit at Kennedy Krieger Institute

For more information about active clinical trials: Email: **ResearchTrials@KennedyKrieger.org** Phone: **443-923-3850** Visit: **KennedyKrieger.org/Participate**

Location 1741 Ashland Avenue Baltimore, MD 21205

The photograph used is for illustrative purposes only, and any person shown is a model.

Kennedy Krieger Institute recognizes and respects the rights of employees, trainees, and patients and students, and their families. At Kennedy Krieger, we ground our care, services, training and research in treating others with respect and civility. We respect the cultural identity of every person. Kennedy Krieger does not discriminate against people based on, but not limited to, perceived or actual race, color, culture, ethnicity, national origin, age, language spoken, accent, marital status, veteran or military status, immigration status, socioeconomic status [i.e., access to resources], physical or mental disability, religion, pregnancy status, sex, sexual orientation, or gender identity or expression. We strive for equitable care for all individuals for whom we provide services, training, education and research participation. We encourage employees, trainees, and patients and students, and their families, to become active partners in the services provided by asking questions, seeking resources and advocating for their needs. Our culture of care is extended to our patients' family members and other people served. Here, "family" refers to parents, other family members, guardians, surrogate decision-makers and healthcare agents. ©2024 Kennedy Krieger Institute 10/2024



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