
Safe at School®: School Support for Students with Diabetes Participating in Clinical Trials

The mission of the American Diabetes Association® (ADA) is to prevent and cure diabetes and to improve the lives of all people affected by diabetes—this includes children and adolescents who spend many of their waking hours at school.

The ADA's **Safe at School®** campaign is devoted to keeping students with diabetes safe and healthy at school and making sure they are treated fairly. Safe at School® achieves this goal through the development of resources and guidelines aligning with federal and state legal protections for students with diabetes, offering assistance and self-advocacy tools to families, pursuing policy change when needed, and promoting best practices.

The Benefits of Student Participation in a Clinical Trial

A clinical trial is a type of research study that involves testing new drugs, medical devices, or treatments on human subjects to determine their safety and effectiveness. Clinical trials are conducted under strict ethical guidelines to protect the safety and well-being of the participants. Clinical studies can be sponsored by pharmaceutical companies, academic medical centers, device manufacturers, and other volunteer groups. They are facilitated by independent organizations and experts following protocols agreed upon by all parties.

The primary benefit of clinical trials is the advancement of medical knowledge regarding the safety and effectiveness of new treatment therapies. The results of clinical trials often form the framework for the development of emerging protocols to diagnose, prevent, treat, or cure diseases. Participation by children in a clinical trial allows children with diabetes access to innovative treatments that could improve blood glucose (blood sugar) management and reduce the risk of diabetes-related complications that are not yet available to the public.

As detailed in the National Institutes of Health (NIH) Children in Research standard operating procedure (SOP) inclusion of children in clinical trials is required for Food and Drug Association (FDA) approval of new therapies for children and "...must include children in all human subjects research conducted by NIH unless there are scientific or ethical reasons for excluding them."

In addition, clinical trials provide an opportunity for children with diabetes to receive closely monitored care from medical professionals who specialize in their condition. The FDA oversees clinical trials to ensure they are designed, conducted, analyzed, and reported according to federal law and good clinical practice regulations. **Learn more about regulations.**

The Legal Rights of Students Participating in Clinical Trials

Students with diabetes are protected by federal laws such as section 504 of the Rehabilitation Act, the Americans with Disabilities Act, the Individuals with Disabilities Education Act, and state laws.

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Diabetes meets the definition of a disability under these laws because it substantially limits the functioning of the endocrine system and major life activities. Schools must ensure there are trained and available staff to provide diabetes care to enable the student to safely access and participate in all school activities during the school day, after-school sports, field trips, and other school-sponsored events. This care and support include students with diabetes who are participating in clinical trials. More information about legal protections for children with diabetes is available at diabetes.org/FedLaw.

School's Role in Supporting Students Participating in Clinical Trials

When a school has a student participating in a clinical trial, it is important for the school nurse or designee to take certain steps to ensure the safety and well-being of the student while also respecting their privacy and confidentiality. The school should establish a clear path of communication with the student's parents/guardians, diabetes healthcare professional, and medical research team coordinator to obtain information about the parameters of the trial, impact on education, and the administration and use of the device or treatment. All accommodations needed for the student's participation in the clinical trial should be incorporated into the student's Diabetes Medical Management Plan and 504 plan as follows:

- The nature of the clinical trial, including the expected duration of the study, and any training and educational resources offered by the trial research team

- Potential risks and benefits to the student, including possible physical and mental side effects
- Specific accommodations needed to keep the student safe for the duration of the trial such as flexibility for appointments and/or procedures and additional academic support
- Contact information of the research team conducting the trial in case of questions or concerns

The ADA encourages all schools to take steps to educate and train staff and faculty about the clinical trial and how it may impact the student's education and daily school routine. The school nurse and non-clinical school staff should understand how to best support the student participating in the clinical trial. By taking these steps, the school can ensure the student participating in the clinical trial is able to receive the necessary care and support while continuing their education in a safe and supportive environment and help to foster productive trial outcomes.

Safe at School® resources and information are available at diabetes.org/SafeAtSchool.