

General Population Level Estimation for Type 1 Diabetes Risk in Children During Routine Care Delivery

NCT04477928

Status	RECRUITING
Sponsor	Sanford Health
Enrollment	33,000 participants

Plain Language Summary

This study aims to identify children at risk for Type 1 diabetes by testing blood sugar-related markers during routine doctor visits — without requiring any extra appointments. The goal is to catch Type 1 diabetes early, before serious complications develop.

****You may be eligible if...****

- You are a newborn (at least 36 weeks gestation) born at a Sanford Health hospital
- You are a child under 6 years old who receives routine care at a Sanford clinic
- You are a child aged 9–16 receiving routine care at a Sanford facility
- You are a sibling (ages 6–17) of a child known to have Type 1 diabetes-related antibodies
- You receive regular care at a Sanford facility

****You may NOT be eligible if...****

- You do not receive care at a Sanford Health facility
- A parent or guardian is unable to provide consent

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (5)

- Newborn Entry: Viable, term infants, defined as 36 weeks gestation by either dates or ultrasound who are born to pregnant women, 18 years or older, who are willing and able to provide informed consent (IC) prior to the onset of active labor. Who are born at a Sanford Health Hospital and plan to have routine well-child care at a Sanford Clinic
- Pediatric Entry: Children less than 6 years of age who receive their routine care at a Sanford facility and whose parents are able to provide IC.
- Adolescent Entry: Children, ages 9-16 years old, who receive their routine care at a Sanford facility and whose parents are able to provide IC.
- Siblings of children known to have T1D-relevant antibodies; ages 6 to 17 years old who receive care at a Sanford clinic
- Have an active MyChart account (with proxy access).

Exclusion (2)

- Subject is in the opinion of the investigator, unable to comply with the requirements of the study protocol.
- Children known to have T1D

Locations (4 total)

Sanford Bemidji Region Clinics, Bemidji, Minnesota, United States
Sanford Bismarck Region Clinics, Bismarck, North Dakota, United States
Sanford Fargo Region Clinics, Fargo, North Dakota, United States
... and 1 more locations

<https://clinicaltrials.gov/study/NCT04477928>

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