

Participant ID:

Protocol Title: A feasibility CGM trial for patients with type 1 diabetes followed at a rural, first-level hospital in a low-income country
Principal Investigator: Alma Adler
Description of Participant Population: Patients and families of people with type 1 diabetes
Version Date: June 25, 2021

My name is Todd Ruderman. I am a clinician at Neno District Hospital. I am trying to learn whether your daily life with type 1 diabetes would be improved with Continuous Glucose Monitoring (CGM) or home glucometer technology.

I am asking you and other children to take part in my research study. A research study is a way to learn more about something. You are being asked to join this research study because you have type 1 diabetes.

If you agree to join this study, during your routine medical appointments you will be asked to be interviewed by our staff about your experiences with diabetes, as well as your experiences with doctors and nurses. We expect this to take about an hour, but you can leave at any time. You will also be able to use some helpful new devices that will help you know your blood sugar levels throughout your day. These devices are called continuous glucose monitors, and they have never been used in Malawi or other similar contexts before.

You might feel a little discomfort with using this new technology so you are able to stop participating in the study at any time, and we will have nurses who can help you get back to your usual care. We will do everything that we can to make sure that anything you say will be kept confidential between us. We do think that these new devices could help you manage your diabetes and also help your doctor do their job better by understanding what you need throughout your normal daily life.

You do not have to join this study. It is up to you. You can say okay now and change your mind later. All you have to do is tell us you want to stop. No one will be mad at you if you don't want to be in the study or if you join the study and change your mind later and stop. You may talk to your mom or dad if you want. Before you say **yes or no** to being in this study, we will answer any questions you have. If you join the study, you can ask questions at any time. Just tell the researcher when you see them or contact [me](#), Todd Ruderman, at Neno District Hospital.

If you sign your name below, it means that you agree to take part in this research study.

Child/Adolescent Assent

Signature of Study Participant

Date

Signature of Researcher

Date

Harvard Human Research Protection Program

Consent Form Title: **Assent Form, CGM Feasibility Trial Malawi, updated June 2021_clean**
IRB Protocol No: **2019P003554**

Consent Form Valid Date: **8/5/2021**

Consent Form Expiration Date: **5/25/2023**

Sponsor Protocol No: **Two**

IRB Amendment No: **AME4**

IRB Amendment Approval Date: **8/5/2021**

Sponsor Amendment No: **N/A**

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