Plain Language Informed Consent Rewrite Sample

Device-based diabetes research | participant-facing consent language

Sample Type: Plain-language informed consent editing and participant-facing risk communication

Scenario: A research team needs a clearer consent section for a public, device-based study comparing continuous versus periodic use of a continuous glucose monitor in adults with type 2 diabetes who are not using insulin. The sample below demonstrates how complex study information can be translated into participant-centered consent language while preserving accuracy, voluntariness, and regulatory tone.

Editorial Objectives

- Use direct address and plain language while avoiding oversimplification of key procedures.
- Separate research activities from usual diabetes care.
- Make random assignment, device expectations, privacy limits, and foreseeable discomforts clear.
- Preserve informed consent concepts required under federal consent standards, including voluntariness, alternatives, risks, and the right to stop.

Before and After Editing Demonstration

Original-style language	Portfolio rewrite
Subjects randomized to continuous or intermittent CGM will maintain current antihyperglycemic therapy and comply with protocol-specified device wear, app utilization, clinic visits, and metabolic assessments.	If you join, you will keep taking your usual diabetes medicines unless your regular doctor changes them. You will wear a glucose sensor, use a phone app connected to the sensor, come to study visits, and have blood tests so the study team can compare glucose patterns over time.
Participants may be assigned to continuous CGM or periodic CGM use following an initial run-in period.	For the first 3 months, everyone will wear the glucose sensor. After that, a computer will place you by chance into one of two groups. One group will keep wearing the sensor all the time. The other group will wear it for part of each month. You cannot choose your group.
Risks include skin reactions, data privacy risks, and inconvenience associated with study procedures.	You may have redness, itching, irritation, or discomfort where the sensor is placed. You may feel bothered by wearing the device or by checking the app. There is also a small risk that information collected by the app or study team could be seen by someone who should not see it, even though safeguards will be used.

Draft Participant-Facing Section: What Happens if I Say Yes?

If you decide to join this study, you will be asked to use a continuous glucose monitor, also called a CGM. A CGM is a small sensor placed on your skin that measures glucose levels throughout the day and night. The study team is trying to learn whether wearing the CGM for part of the time works about as well as wearing it all the time for adults with type 2 diabetes who do not use insulin.

Your participation would last about 6 months. During the first part of the study, everyone will wear the CGM so the study team can learn about your glucose patterns. You will also receive education about how food, activity, and daily routines may affect your glucose levels. After this first part, you will be assigned by chance to one of two groups. One group will continue wearing the CGM all the time. The other group will wear the CGM for part of each month. Assignment by chance is like flipping a coin. You and the study team cannot choose the group.

You will be asked to replace the sensor as instructed, use a smartphone app connected to the CGM, and come to study visits for checkups and blood tests. The study team may review CGM readings, weight, blood pressure, blood test results, and your feedback about using the device. The study does not replace your regular diabetes care. You should continue seeing your usual health care provider and taking your diabetes medicines unless your provider tells you to make a change.

Possible Risks and Discomforts

- Skin irritation: The sensor adhesive may cause redness, itching, rash, or discomfort. Tell the study team if you have a reaction.
- Device burden: Wearing a sensor, checking readings, replacing sensors, and using the app may feel inconvenient or frustrating.
- Glucose-related concern: Seeing glucose readings may make some people worried or may lead them to make changes without talking with a clinician. You should not change your medicines unless your health care provider tells you to do so.
- Privacy risk: The study team will protect your information, but there is a small risk that your health or device information could be seen by someone who should not see it.

Your Choice

Taking part is voluntary. You may choose not to join, and your regular medical care will not be affected. If you join, you may stop at any time. The study team may ask to collect final safety information or return study equipment, but you do not have to continue study procedures you no longer want to complete.

Quality Control Note

The rewrite avoids unsupported claims, keeps the study purpose and random assignment clear, distinguishes research from routine care, and presents risks in participant-centered language. It also avoids implying personal medical benefit from CGM use while still explaining why the study matters.

Selected Public Sources Used for Mock Sample

1. ClinicalTrials.gov. Continuous Glucose Monitoring in Non-Insulin Treated Type 2 Diabetes: Continuous vs. Periodic Use. NCT07336329. Accessed May 29, 2026.

5. 45 CFR 46.116. General requirements for informed consent.