IRB Use Only
Approval Date: January 22, 2019
Expiration Date: January 22, 2020

Initiation of Continuous Glucose Monitoring at Diagnosis of Type 1 Diabetes

Please check one of the following:

_____ You are the parent or guardian of a child with type 1 diabetes providing consent for your own participation in the study as a parent or guardian

_____ You are the parent or guardian granting permission for a child in this study.

Print child's name here: _____

The following information applies to the parent participant or to the child or ward. If the participant is a child or ward, the use of "you" refers to "your child" or "your ward."

Are you participating in any other research studies? _____ Yes _____No

PURPOSE OF RESEARCH

You are invited to participate in a research study about the impact of continuous glucose monitoring (CGM) on families with newly diagnosed children with type 1 diabetes (T1D). We hope to learn about how continuous glucose monitoring affects glycemic variables and diabetes-related distress. This study involves the Dexcom G5 CGM System. This device is approved by the US Food and Drug Administration (FDA).

You were selected as a possible participant in this study because:

1. You were recently diagnosed with type 1 diabetes.
2. You are the parent or guardian of a child who was recently diagnosed with type 1 diabetes.

If you decide to terminate your participation in this study, you should notify Korey Hood, PhD at 650-497-6899.

This research study is looking for up to 75 participants with type 1 diabetes between 2.0 and 17.9 years of age and an equal number of parent participants. Enrollment in this study will occur at Stanford University and the University of Colorado. Stanford University will enroll up to 40 families.

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VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

DURATION OF STUDY INVOLVEMENT

Screening for this research study is expected to take 10 minutes. Active participation in this research study is expected to take approximately 2 years.

PROCEDURES

If you choose to participate, Dr. Hood and his research study staff will randomly assign you to one of two groups: the intervention group or the control group. Participants are assigned to the study groups at a 2:1 ratio, intervention to control. You will have a 67% chance of being assigned to the intervention group and a 33% chance of being assigned to the control group.

INTERVENTION GROUP

If you are assigned to the intervention group, you will receive education about continuous glucose monitoring, the Dexcom G5 Mobile Continuous Glucose Monitoring System, and how to use the system to make decisions about diabetes treatment. This session can take up to 120 minutes. A member of the research team will help insert the first sensor.

You will then use the Dexcom G5 system in conjunction with your blood glucose (BG) meter to make all diabetes decisions for two weeks once the system is started. After two weeks of using the Dexcom G5 CGM system in conjunction with your BG meter to make diabetes treatment decisions, you will receive additional education about the CGM system. This session can take up to 120 minutes. After the second education session, you may use the CGM system to make treatment decisions non-adjunctively; that is, without confirming sensor glucose values against a finger stick BG meter reading. You are free, however, to check and rely on blood glucose values via finger stick anytime a potential discrepancy between CGM and BG meter values is noticed or suspected. You will be asked to actively use CGM for 6 months. After six months, you may continue or discontinue use of CGM. If you decide to continue, the research team will work with your diabetes care team to assist in obtaining CGM supplies via standard clinic and insurance procedures.

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If you are between 11.0 and 17.9 years of age, we will ask you to complete questionnaires that ask about how you have been feeling and about your thoughts and experiences with managing diabetes. You have the right to refuse to answer particular questions.

There are seven study visits for the intervention group. Your first study visit will take approximately 2 hours. We expect each of the remaining study visits to take about 1 hour. The table below shows the study timeline and what will happen at each study visit.

Intervention Timeline

Visit Number	1	2			3			4	5	6	7
Study Time (weeks)	0	2	4	8	13	18	22	26	52	78	104
Consent	X[1]										
Medical and demographic history	X[1]										
Training on use of CGM	X	X									
Download CGM		X			X			X	X	X	X
Download BG meter and insulin pump (if applicable)		X			X			X	X	X	X
Finger stick HbA1c	X				X			X	X	X	X
Fasting C-peptide blood draw	X[2]				X				X		X
Questionnaire (parents and youth 11.0-17.9 years)	X				X			X	X	X	X
Online Survey (parents only)			X	X		X	X				

[1] Consent and History may occur prior to Visit 1, but still within 30 days of diagnosis.

[2] Fasting C-Peptide may occur up to 3 weeks after consent is obtained.

In total, you will have about 1 tablespoon of blood drawn for this study.

CONTROL GROUP

If you are assigned to the control group, you will receive usual care for your T1D and take part in blinded continuous glucose monitoring one week per month for

six months with the Dexcom G4 CGM system. A blinded continuous glucose monitor records CGM data, but the device will not show this data to you. “Usual care” refers to the treatment plan established by your diabetes care team. After six months, you will receive education about continuous glucose monitoring, the Dexcom G5 Mobile Continuous Glucose Monitoring System, and how to use the system to make decisions about diabetes treatment. This session can take up to 120 minutes. A member of the research team will help insert the first sensor.

You will then use the Dexcom G5 system in conjunction with your blood glucose (BG) meter to make all diabetes decisions for two weeks once the system is started. After two weeks of using the Dexcom G5 CGM system in conjunction with your BG meter to make diabetes treatment decisions, you will receive additional education about the CGM system. This session can take up to 120 minutes. After the second education session, you may use the CGM system to make treatment decisions non-adjunctively; that is, without confirming sensor glucose values against a finger stick BG meter reading. You are free, however, to check and rely on blood glucose values via finger stick anytime a potential discrepancy between CGM and BG meter values is noticed or suspected. You will be asked to actively use CGM for 6 months. After six months, you may continue or discontinue use of CGM. If you decide to continue, the research team will work with your diabetes care team to assist in obtaining CGM supplies via standard clinic and insurance procedures.

If you are between 11.0 and 17.9 years of age, we will ask you to complete questionnaires that ask about how you have been feeling and about your thoughts and experiences with managing diabetes. You have the right to refuse to answer particular questions.

There are seven study visits for the control group. We expect each study visit will take approximately 1 hour, except for visits 1, 3, and 4. These visits will take around 2 hours. The table below shows the study timeline and what will happen at each study visit.

Control Timeline

Visit Number	1			2			3	4	5	6	7
Study Time (weeks)	0	4	8	13	18	22	26	28	52	78	104
Consent	X[1]										
Medical and demographic history	X[1]										
Training on use of CGM							X	X			
Download CGM				X			X	X	X	X	X
Download BG meter and insulin pump (if applicable)				X			X	X	X	X	X
Finger stick HbA1c	X			X			X		X	X	X
Fasting C-peptide blood draw	X[2]			X					X		X
Questionnaire (parents and youth 11.0-17.9 years)	X			X			X		X	X	X
Online Survey (parents only)		X	X		X	X					

[1] Consent and History may occur prior to Visit 1, but still within 30 days of diagnosis.

[2] Fasting C-Peptide may occur up to 3 weeks after consent is obtained.

In total, you will have about 1 tablespoon of blood drawn for this study.

PARENTS/GUARDIANS

If you are a parent or guardian participating in this study, you will be asked to complete questionnaires on the schedule listed in the timeline table for the study group your child is assigned to. Additionally, you will be asked to complete 4 brief, online surveys in between your child's study visits. The schedule for these surveys can also be found on the timeline table for the study group your child is assigned to. Each online survey will take 20-30 minutes to complete. You have the right to refuse to answer particular questions.

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DEVICES

The Dexcom G5 CGM System is an FDA approved glucose monitoring system indicated for detecting trends and tracking patterns in persons (age 2 years and older) with diabetes.

The Dexcom G4 CGM System is an FDA approved glucose monitoring system indicated for detecting trends and tracking patterns in persons (age 2 to 17 years) with diabetes.

TISSUE SAMPLING

Research using tissues is an important way to try to understand human disease. You have been given this information because the investigators want to include your tissues in a research project.

Your tissues (blood) will be used to obtain the test results and will be destroyed upon completion. No samples will be saved for future research.

Your blood sample for the C-peptide measurement will be sent outside of Stanford for analysis.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Use the study device as instructed.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Protocol Director or research staff if you believe you might be pregnant or gotten your partner pregnant.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for type 1 diabetes and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify Korey Hood, PhD at 650-497-6899.

If you withdraw from the study, you must:

- Stop using the Dexcom G5 CGM system provided as part of the study.
- Immediately resume usual care of your diabetes.
- Return all study-related devices to the research staff immediately upon your withdrawal from the study.

The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- Pregnancy
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

You may feel some pain (like a pinprick) when the glucose sensors are placed under your skin. In very rare cases, the skin at the sensor locations can become irritated or infected. Sensor tips may break off under the skin on very rare occasions.

Incorrect sensor glucose readings can result in incorrect diabetes management. Taking medications with acetaminophen (such as Tylenol or Excedrin Extra Strength) while wearing a Dexcom sensor may falsely raise sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person.

The adhesives used to secure the CGM can sometimes cause skin irritation or allergic reactions.

A small drop of blood will be obtained by fingerstick to measure your blood glucose and HbA1c. Pain is common at the time of lancing. In some cases, a small amount of bleeding under the skin will produce a bruise. A small scar may persist for several weeks.

Having your blood drawn may cause a small amount of pain. A temporary bruise may develop. Rarely, some people faint after having their blood drawn. In total, you will have about 1 tablespoon of blood drawn for this study.

Some people may be uncomfortable with researchers having access to their diabetes data or knowing about their daily diabetes habits. Some of the questions you are asked may make you uncomfortable.

There may be other risks and side effects that are not known at this time.

POTENTIAL BENEFITS

You may or may not benefit from taking part in this study. It is possible that the glucose information from the CGM along with the instructions provided for treatment decisions will be useful for your diabetes management. The introduction of CGM at diagnosis of type 1 diabetes might reduce diabetes-related distress and impact glycemic variables during the first year of T1D.

We cannot and do not guarantee or promise that you will receive any benefits from this study.

ALTERNATIVES

The alternative to participating in this study is to not participate and continue with your usual care for type 1 diabetes.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

ClinicalTrials.gov

A description of this clinical trial will be available at http://www.clinicaltrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results of this study. You can search this website at any time.

CONFIDENTIALITY

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law. However, there is always some risk that even de-identified information might be re-identified.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to obtain data or information on the safety and effectiveness of non-adjunctive CGM use upon diagnosis of type 1 diabetes; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?
The purpose of this research study is to determine the impact of continuous glucose monitoring (CGM) on families with newly diagnosed children with type 1 diabetes (T1D). Your health information will be used to learn about how continuous glucose monitoring affects glycemic variables and diabetes-related distress.

Do I have to sign this authorization form?
You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study, including receiving any research-related treatment. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?
If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Korey Hood, PhD, 780 Welch Road, Room CJ320G, Palo Alto, CA 94304-5776.

What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to:

- Demographic data including but not limited to: name, date of birth, address, phone, email, social security number (needed for payment).
- Data downloaded from diabetes devices such as BG meter, ketone meter, insulin pump, CGM, and any other devices used.
- The results of medical history, review of past medical records and test results as needed to ensure participant meets eligibility criteria or to review any records relevant to medical issues that may arise during participation in the study.
- The results of physical exam, lab tests and questionnaires as well as lab results relevant to diabetes management or possible complications of diabetes.
- Results of logs, questionnaires, and interviews maintained for study
- Serial numbers of devices used (ex: BG meter, CGM, insulin pump, other devices used in the study).

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director, Korey Hood, PhD
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- Dexcom, Inc.
- The Food and Drug Administration

- The Data Safety Monitoring Board
- Investigators and research staff working on this study at the University of Colorado

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of your health information will end on December 31, 2045 or when the research project ends, whichever is earlier.

Will access to my medical record be limited during the study?
To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if included in your official medical record).

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Legally Authorized Representative Date
(e.g., parent, guardian, or conservator)

_____
Print Name if Legally Authorized Representative

_____
Legally Authorized Representative's Authority to Act for Participant
(e.g., parent, guardian, or conservator)

FINANCIAL CONSIDERATIONS

Payment
Youth 11-17 years of age will receive $25 for the completion of each of six assessments. Parents will receive $40 for the completion of each of six assessments. In total, a family can receive $390 and may keep the Dexcom G5 CGM system upon completion of the study.

Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa. You may need to provide your social security number to receive payment.

Costs
If you participate in this study, the study will pay for those services, supplies, procedures, and care associated with the study that are not a part of your routine medical care. However, there may be additional costs to you. These include basic expenses like transportation and the personal time it will take to come to the study visits. You and/or your health insurance must pay for services, supplies, procedures, and care that are required during this study for routine medical care. **You will also be responsible for any co-payments and/or deductibles as required by your insurance.** Participation in this study is not a substitute for health insurance.

Sponsor
Dexcom, Inc. is providing financial support and/or material for this study. The National Institutes of Health are providing some financial support for the facility and staff where part or all of the study is taking place.

Consultative or Financial Relationships
Dr. Bruce Buckingham is a paid consultant to Dexcom, the company sponsoring this study.

COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Korey Hood, PhD at 650-497-6899. You should also contact him at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

Alternate Contact: If you cannot reach the Protocol Director, please contact Sarah Hanes at 650-736-6661.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;

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- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

May we contact you about future studies that may be of interest to you? ☐ Yes ☐ No

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____ _____
Print Name of LAR LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

_____ _____
(If available) Signature of Other Parent or Guardian Date

_____ _____
Print Name of Other Parent or Guardian Authority to Act for Participant

The IRB determined that the permission of two parents is required in accordance with 21 CFR 50.55 unless one parent is deceased, unknown, incompetent, not reasonably available, or only one parent has legal responsibility for the care and custody of the child. *Not reasonably available* means that the other parent is not present during the consenting process, or will not be available prior to the start of research procedures.

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent