Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Participant's Name_____

Principal Investigator:	Daniel J. Cox, Box 800223, University of Virginia Health System, Charlottesville, VA 22908, (434) 924-8021
Sponsor:	Dexcom

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a signed copy of this form.

Who is funding this study?

This study is being funded by Dexcom Inc., a company that produces continuous glucose monitoring devices. Dexcom is also providing free continuous glucose monitors and related supplies.

Background:

Many people with type 2 diabetes monitor their blood glucose level before and after meals and also after exercise. This is called "systematic measurement of blood glucose", or SMBG. The use of continuous glucose monitoring (CGM) provides additional information about BG, so the use of CGM to improve the management of blood glucose (BG) is increasing in those with type 2 diabetes.

BG management can also be improved through changing behaviors or "behavioral modification." GEM refers to a program that includes behavioral modification and teaches patients about glucose control. It is short for "Glycemic load, Exercise and Monitoring blood glucose". The focus of the program is on reducing glucose levels, especially after meals, by teaching patients to choose low glycemic load foods, increase physical activity, and use BG monitoring to educate themselves about the impact of different food and activity choices on their blood glucose level.

Why is this research being done?

The purpose of this study is to find out if information provided by CGM and the use of the GEM program can work together to help individuals with type 2 diabetes (t2d) improve their BG

management and reduce the amount of diabetes medication they need compared to individuals who receive the routine care prescribed by their own doctor.

The devices used in this study (Fitbit activity monitor, Dexcom G4 & G5 CGMs, Bayer Contour Next blood glucose monitor, and all blood glucose testing materials) are approved by the Food and Drug Administration (FDA). All devices are being used in accordance with their labeling.

You are being asked to be in this study because you have t2d and your HbA1c is greater than 6.8%, suggesting that your current medication is not leading to adequate BG control.

Up to 33 people will be in this study at UVA.

How long will this study take?

Your participation in this study will require up to 8 study visits over 5 months. Each visit will last 1 to 2.5 hours. A 12-month assessment may be added depending on the results seen at the previous 8 visits. If so, the entire study will require up to 9 visits over 14 months.

What will happen if you are in the study?

Visit 1 *(Will take up to 2 hours)*

If you agree to participate, you will sign this consent form before any additional study related procedures take place. Before you can start in the study, there will be a screening period. You will have tests and procedures during this time to make sure you are eligible and it is safe for you to participate.

All of the procedures described below are being done as part of the research study.

These include the following:

- A blood test (1 tablespoon of blood to measure your BG control and your heart and kidney health)
- Questionnaires (These take about 30 minutes to do and ask about):
    - Diet
    - Knowledge about diabetes
    - Problems with your diabetes
    - Attitudes about BG monitoring
    - Depression
- A brief physical exam (to measure your height, weight, blood pressure, and heart rate)
- Having the study team review with you the medicines you are currently taking
- Asking you questions about your age, gender, race, ethnicity, and education.
- You will be given an activity monitor (Fitbit), a BG meter and supplies for BG monitoring, and a continuous glucose monitor (CGM) to be used during study assessments.
    - The use of these devices requires that you have a smartphone.

  - Data from your Fitbit and CGM will be automatically transmitted to the manufacturer's server, where the study team will access it. There is more about how this works in the HOW WILL YOUR INFORMATION BE SHARED SECTION of this document.
- You will be taught how to use each device.
- You will begin using these devices to record one week of exercise and blood glucose information.
- You will return in one week to share your data with the study team.

We will ask your primary care physician to attest to your eligibility to participate by sending him/her a letter with eligibility criteria and providing an overview of the study requirements.

Telephone Calls Between Visits 1 and 2 *(each call will take about 20 minutes)*
Between Visits 1 and 2 there will be 3 telephone calls. During these calls, the study team will ask questions about what you have eaten in the previous 24 hours.

Visit 2 (one week after Visit 1) *(will take about 2 hours)*
The following things will be done at Visit 2:

- A brief physical exam (to measure your height, weight, blood pressure, and heart rate)
- Urine samples: Right before you drink Boost for the Mixed Meal Glucose Tolerance Test, and again 60 and 120 minutes later, you will provide a urine sample. From the Urine sample we will measure your creatinine and c-peptide. This will allow us to know how much insulin your body produces after a standard meal. We will also use this information to measure your body's insulin resistance at the beginning and end of the study to see if it has changed.
- Questionnaires (These take about 30 minutes to do and ask about):
  - Diet
  - Knowledge about diabetes
  - Problems with your diabetes
  - Attitudes about BG monitoring
  - Depression
- A Mixed Meal Glucose Tolerance Test: You will be asked to drink an 8 oz. bottle of Boost original and sit quietly for 60 minutes. During this time you will complete the questionnaires described above. Six BG values will be collected by finger stick for this test – two at the beginning, two at the end, and two 60 minutes later.
- Exercise test: You will be asked to walk on a treadmill for 3 minutes at an easy pace for you, followed by three minutes of walking at a vigorous pace for you. You will do this pair of walking speeds 5 times until you have walked for 30 minutes.
- Data from your study devices will be downloaded. Then you will be placed into a study group by a process called randomization.

Randomization

You will be randomly assigned to 1 of 2 study groups. One third of the participants will be randomly selected to receive routine care as prescribed by their doctor. This group is called RC. Two thirds of the participants will be randomly selected to receive routine care plus a behavioral training program (GEM) and BG monitoring with CGM. This group is called GEM^{CGM}. Neither you nor your doctor or the study doctor can choose which treatment you are assigned to get.

GROUP 1: GEM^{CGM}
GROUP 2: RC

If you are randomized to the GEM^{CGM} group, you will keep the Fitbit and the other devices necessary to do the study. You will be trained to use these devices before you leave Visit 2. You will read Chapter 1 from the GEM manual prior to your next study visit. You will have 4 visits (Visits 3-6) and two CGM Refresher Periods over approximately the next 4 months. These are described below.

If you are randomized to the RC group, you will continue to follow the care prescribed by your doctor for approximately the next 4 months. You will return the Fitbit and the CGM device but you can continue to use the BG monitor. You will be asked to return at Visit 7, at which time you will be given back your FitBit, as described below.

VISITS 3-6 and Refresher Period: For GEM^{CGM} Participants ONLY:

VISIT 3 (GEM^{CGM} meeting 1): *(Will take about 1.5 hours)* In this group meeting, you will have the opportunity to discuss Chapter 1 with other participants. You will insert a sensor and use the CGM with SMBG for one week. You will receive Chapter 2 of the GEM Manual to read prior to your next study visit.

VISIT 4 (GEM^{CGM} meeting 2): *(Will take about 1.5 hours)* In this group meeting, you will have the opportunity to discuss Chapter 2 with other participants. You will insert a sensor and use the CGM with SMBG for one week. After the CGM period, you will monitor your BG for two more weeks using SMBG alone. You will receive Chapter 3 of the GEM Manual to read prior to your next study visit.

VISIT 5 (GEM^{CGM} meeting 3): *(Will take about 1.5 hours)*
You will discuss Chapter 3 in another group meeting. You will use your Fitbit so that you increase the amount of time you are active in the study. Following meeting 3, you will insert a sensor and use the CGM with SMBG for one week. After the CGM period, you will monitor your BG for two more weeks using SMBG alone. You will receive Chapter 4 of the GEM Manual to read prior to your next study visit.

VISIT 6 (GEM^{CGM} meeting 4): *(Will take about 1.5 hours)*
You will discuss Chapter 4 in a group meeting. Following meeting 4, you will insert a sensor and use the CGM with SMBG for one week. After the CGM period, you will monitor your BG for two more weeks using SMBG alone. After that, you will be encouraged to continue monitoring your BG using SMBG.

CGM Treatment Refresher:
In weeks 14 and 22, you will be instructed to insert a sensor and use the CGM with SMBG for 2 weeks. There is not a meeting associated with this refresher.

VISITS 7-8: All Participants – RC and GEM^{CGM} Groups

VISIT 7: *(Will take up to 2 hours)* This will be held at the Center for Behavioral Medicine Research. It will be similar to Visit 1. The following will be done:

- A blood test (1 tablespoon of blood to measure your BG control and your heart and kidney health).
- A brief physical exam (to measure your height, weight, blood pressure, and heart rate)
- Questionnaires (These take about 30 minutes to do) They ask about:
  - Diet
  - Knowledge about diabetes
  - Problems with your diabetes
  - Attitudes about BG monitoring
  - Depression
  - Importance of the program to you
- The study team will review with you the medicines you are currently taking
- You will begin using the study devices to record one week of exercise and blood glucose information. If you don't remember how to use these devices, the study team will remind you.

Telephone Calls After Visit 7 *(each call will take about 20 minutes)*
In the week after Visit 7, there will be 3 telephone calls. During these calls, the study team will ask questions about what you have eaten in the previous 24 hours.

VISIT 8: *(Will take up to 2 hours)* This will be held at the Center for Behavioral Medicine Research. It will be similar to Visit 2. The following will be done:

- Urine samples: Right before you drink Boost for the Mixed Meal Glucose Tolerance Test, and again 60 and 120 minutes later, you will provide a urine sample so we can measure your creatinine and c-peptide levels. This will allow us to know how much insulin your body produces after a standard meal. We will also use this information to measure your body's insulin resistance at the beginning and end of the study to see if it has changed.

- A Mixed Meal Glucose Tolerance Test: You will be asked to drink an 8 oz. bottle of Boost original and sit quietly for 60 minutes. During this time you will complete the questionnaires described above. Five BG values will be collected by finger stick for this test – one at the beginning, two at the end, and two 60 minutes later.
- Exercise test: You will be asked to walk on a treadmill for 3 minutes at an easy pace for you, followed by three minutes of walking at a vigorous pace for you. You will do this pair of walking speeds 5 times until you have walked for 30 minutes.
- Data from your study devices will be downloaded.
- Payment: You will be paid $100 for completing Visit 8.

POSSIBLE VISIT 9: *(Will take about 3 hours)* All Participants – RC and GEM^{CGM} Groups
Depending on the results of the previous 8 visits, you may be asked to return for Visit 9. This will be held at the Center for Behavioral Medicine Research. At this visit, the procedures done in Visits 7 and 8 will be repeated. You also will have an opportunity to leave anonymous comments about the study if you want to. If you participate in Visit 9, your data from this study will be combined with data from another study (HSR #19370) so we can compare your results to people who completed a weight loss program. You will be paid $200 for completing Visit 9.

Telephone Calls After Visit 9 *(each call will take about 20 minutes)*
In the week after Visit 9, there will be 3 telephone calls. During these calls, the study team will ask questions about what you have eaten in the previous 24 hours.

Invitation to Re-enter this Study: After completing the study, if you still meet the enrollment requirements you will be invited to participate again, but you will be assigned to a different study group than you originally received. You can only re-enroll once.
- If you were originally in the GEM^{CGM} group, you will be assigned to the RC group.
- If you were originally in the RC group, you will be assigned to the GEM^{CGM} group.

Opportunity to be in a Related Study: After you finish this study, you will receive an email invitation to enter a second study (HSR 19370) if you meet the participation requirements. You do not have to be in HSR 19370 if you don't want to. If you decide to participate, you would be assigned to a different treatment group than you receive in this study: If you complete the GEM group in the current study, you will be assigned to the WL group in the next study. If you complete the WL group in the current study, you will be randomly assigned to one of 3 GEM groups in the next study. You can only participate in the second study one time.

During the research, you will complete questionnaires about how you are feeling. If we learn you are having thoughts about suicide or hurting yourself or others, the research staff will ask you more questions about your thoughts. Based on your response, the staff may provide you with help to get treatment. This may include: working with you to contact your doctor or therapist, referral to a therapist to discuss your thoughts, contacting a trusted family member, significant other or clergy or working with you on a plan that may include getting you to a hospital for safety and treatment.

Study Schedule

TABLE 1	Pre-Tx Assess. (ALL SUBS)			Treatment (GEM^{CGM} SUBS ONLY)					3 mo. Post-Tx Assess. (ALL SUBS)			POSSIBLE 12 mo. Post-Tx Assess. (ALL SUBS)	
Visit #:	1	phone	2	3	4	5	6		7	phone	8	9	phone
Visit Name:	Wk 0 Assess	ASA24	Wk 1 Assess	GEM^{CGM} training 1	GEM^{CGM} training 2	GEM^{CGM} training 3	GEM^{CGM} training 4	CGM refresh	Wk 22 Assess	ASA24	Wk 23 Assess	Wk 61 Assess	ASA24
Study Week:	0	0-1	1	1	2	5	9	14, 22	22	22-23	23	61	61-62
STUDY PROCEDURES:													
Informed Consent	x												
Review Study Eligibility	x												
Blood Draw	x								x			x	
Blood sample (finger stick)			6								6	6	
Urine sample			3								3	3	
Physical Exam	x		x						x			x	
Questionnaires	x	3 calls	x						x	3 calls		x	3 calls
Mixed Meal Glucose Tolerance Test			x (fast)								x (fast)	x (fast)	
Exercise Test			x								x	x	
Medication Review	x										x	x	
Demographics questions	x												
Randomization			x										
Receive Devices & Training	x								x				
Receive CGM Sensors	x		GEM^{CGM}			GEM^{CGM}	GEM^{CGM}		x				
Begin/continue using devices	v				GEM^{CGM}	GEM^{CGM}	GEM^{CGM}	GEM^{CGM}	v				
Download device data			x								x	x	
Receive GEM chapter			GEM^{CGM}	GEM^{CGM}	GEM^{CGM}	GEM^{CGM}							
GEM training				GEM^{CGM}	GEM^{CGM}	GEM^{CGM}	GEM^{CGM}						

What are your responsibilities in the study?

You have certain responsibilities to help ensure your safety. These responsibilities are listed below:

- You must come to each study visit.
- You must be completely truthful about your health history.
- Follow all instructions given.

- You should tell the study doctor or study staff about any changes in your health or the way you feel.
- Answer all of the study-related questions honestly and completely.

Specimens

Blood testing

We will take (or "draw") up to 1 tablespoon of blood by venipuncture on 3 separate visits that are at least one month apart. In addition, 6 finger sticks will be required on 3 different visits for the self-measurement of blood glucose. The total amount of blood we will take during the study will be **3 tablespoons**.

The blood we take will be tested to measure your diabetes control and how well your pancreas is working. When these tests are done, any left-over sample will be thrown away or they will be de-identified. This means there is no information that could be used by anyone to determine who the sample came from.

Urine testing

You will provide 3 urine samples on 3 separate visits, for a total of 9 samples.

If you want to know about the results before the study is done:

During the study your study leader will let you know of any test results that may be important to your health. In addition, as the research moves forward, your study leader will keep you informed of any new findings that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time you can ask for more information about the study results.

What are the risks of being in this study?

Risks and side effects related to the study procedures include:

Risks of completing questionnaires:

Some of the questions asked may be upsetting or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question.

Risks of having your blood drawn:

Having blood drawn may cause:

- pain (common)
- bruising (sometimes)
- fainting or passing out (not very often)
- infection (rare)

If the people doing the study are exposed to your blood or body fluids in a way that could give them a disease, your blood may be tested. The tests might check for:

- hepatitis
- HIV (Human Immunodeficiency Virus)
- other infections

You and the person exposed would be told the test results. However, your name would be kept private. If your test is positive for hepatitis or HIV, we will tell you the results and help you understand what the results mean for you.

Risks of CGM use:

Wearing a CGM involves inserting a small thread-like sensor under your skin and sticking a small transmitter (about the size of the tip of your little finger) to your stomach with something like a band aid.

- Some people find the sensor uncomfortable to wear or painful upon insertion.
- A small number of CGM users get a rash, skin blistering, irritation, or infection at the location where the CGM is placed.
- Wearing the CGM may cause some people to feel embarrassed or different from others.
- The CGM or the sensor could malfunction so that you receive an incorrect BG reading or no reading at all. Procedures to manage occasional CGM or sensor malfunction will be provided during the CGM training and in the CGM manual.

Risks of the exercise test:

This test involves walking on a treadmill for 30 minutes, continuously alternating between 3 minutes of easy walking and 3 minutes of vigorous walking.

- Vigorous exercise could lead to distress of the heart or hypoglycemia (abnormally low blood sugar).

Risks to privacy:

There is a small chance that your private information could be viewed by an individual who is not on the research study team. We will take every precaution to protect your private information. Please refer to the section entitled "How will your personal information be shared.

Other unexpected risks:

You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Could you be helped by being in this study?

You may or may not benefit from being in this study. Possible benefits include:

- Having an activity monitor may encourage more physical activity.
- Having free BG monitoring supplies may encourage measuring BG more often.
- Results from the blood tests and brief physical may be of use to you and your doctor.

- Using a CGM may teach you how your BG responds to different foods and types of physical activity.

Although you may not benefit from being in this study, the information researchers get from this study may eventually help others with their diabetes management.

What are your other choices if you do not join this study?

You do not have to be in this study to be treated for your illness or condition. You can continue receiving your usual care from your doctor or health care provider. You can purchase and use an activity monitor whenever you want. You are free to discuss the use of CGM with your healthcare provider.

If you are an employee of UVa, your job will not be affected if you decide not to participate in this study. If you are a student at UVa, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?

You will be paid $100 for finishing Visit 8, the follow-up assessment done 5 months after starting this study. If you do not finish the follow-up assessment, you will not be paid $100. If the study leader says you cannot continue, you will still be paid the full amount for the study.

If Visit 9 is done, you will be paid an additional $200 for finishing that visit.

You should get your payment about one month after completing Visits 8 and 9. The payment may be reported to the IRS as income.

If you owe money to the University of Virginia or the University of Virginia Medical Center, the money to be paid to you in this study can be withheld to pay what you owe. If a court has issued a judgment against you, the money may be withheld to pay the judgment creditor for such things as taxes, fines, or child support that you owe.

By agreeing to be in this study, you are donating your blood and urine samples for research and giving up any property rights you may have in them. The results of this research using your donated materials may have commercial value. However, you will not receive any payments.

Will being in this study cost you any money?

The following procedures/tests, which are being done for research purposes, will be provided at no cost to you or your health insurance:

- Blood and urine tests
- Brief physical exam
- Psychological tests

All participants will be provided with an activity monitor, a BG meter and 6 months of BG monitoring supplies to be used during the study. In addition, those in the GEM^{CGM} group will receive the CGM and supplies free of charge.

You and/or your insurance company must pay for any tests or care given beyond what is required in this study. You will have to pay for any costs not covered by your health plan. You may be responsible for co-payments or deductibles. You may wish to ask for an estimate of your financial costs. You may also wish to check with your insurance company before the study starts. Ask what they will cover and if they require you to get their permission before you decide to be in the study.

You will be responsible for the cost of travel to come to the study visits and for any parking costs.

What if you are hurt in this study?

If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover. You do not give up any legal rights, such as seeking compensation for injury, by signing this form.

What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader can take you out of the study. Some of the reasons for doing so may include:

a) Your study physician is concerned about your health
b) Your disease gets worse
c) New information shows the treatment will not work or is not safe for you
d) You do not follow your doctor's instructions
e) The study sponsor closes the study for safety, administrative or other reasons

How will your personal information be shared?

The UVa researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVa.

Fitbit: Once registered, data from your Fitbit will be transmitted automatically to Fitbit servers for access and storage. The study team will access your study data on the manufacturer's server.

CGM and Dexcom: This information is exactly the same for anyone using Dexcom CGM as part of their clinical care even if not involved in research. This is the way Dexcom CGM works.

For the study, you will be using the Dexcom G5 CGM. In order to use this device you will have to download an application to your smartphone. Information about you blood glucose is then automatically sent to servers at Dexcom. Dexcom has two sharing services; Share and Clarity. Both require the CGM user to transmit their readings to their server. Share is geared towards friends and family, sending alerts to their mobile device whenever you are having an episode. Clarity is their web-based analytics software that produces graphs and reports.

UVA will register as a health care provider, and you can provide the study team with a code that will give us access to your readings through the Clarity gateway.

Any data Dexcom receives (glucose readings) will be subject to the requirements of HIPAA and the HITECH Act, but they also state that they intend to de-identify your data for their own research and development purposes.

This is a link to the Dexcom privacy policy:
http://www.dexcom.com/linked/documentservice/PrivacyPolicy
The above process is exactly the same for anyone using CGM as part of their clinical care, even if not involved in research.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address and date of birth
- Social Security number because you are being paid to be in this study
- Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers. This may include mental health care records, substance abuse records, and HIV/AIDS records.

Who will see your private information?

- The researchers, to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- The sponsor of this study, and the people or groups it hires to help perform or review this research
- Insurance companies or other organizations that may need the information in order to pay your medical bills or other costs of your participation in the study
- Tax reporting offices (if you are paid for being in the study)
- People who evaluate study results, which can include sponsors and other companies that make the drug or device being studied, researchers at other sites conducting the same

study, and government agencies that provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.

Some of the people outside of UVa who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

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

What if you sign the form but then decide you don't want your private information shared?
You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

Please contact the researcher listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Dr. Daniel J. Cox
University of Virginia Health System
Box 800223
Charlottesville, VA 22908
Telephone: (434) 924-8021

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22908
Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult (18 years of age or older)

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

Person Obtaining Consent from an Adult

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE