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_____

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 copy of this form.

Who is funding this study?

This study is being funded by Dexcom, Inc. Dexcom, Inc. is supplying all study devices for this study. This includes continuous glucose monitors, glucometers, test strips, and other study related supplies.

Key Information About This Research Study

Principal Investigator:	Meaghan Stumpf, MD UVA School of Medicine, Division of Endocrinology & Metabolism 1300 Jefferson Park Avenue, Charlottesville, VA 22908 Phone: (434) 982-4351
Sponsor:	Dexcom, Inc.

You are being asked to take part in a research study. You do not have to take part in this study. You should only agree to take part in this study after reading this consent form and discussing it with the study team. You may also discuss this with your family, friends, health care providers or others before you make a decision.

What problem is this study trying to solve?

Managing blood glucose in a patient with diabetes is an ongoing challenge and is complicated even further if the patient is on hemodialysis. Hemodialysis affects the amount of certain salts, sugars, and liquid in the blood throughout the day.

This study is trying to find out if a continuous glucose monitor (CGM) is accurate for patients with diabetes who are undergoing intermittent hemodialysis (iHD). The CGM used in this study

is approved by the FDA to measure glucose in patients with diabetes but is not approved for patients on dialysis.

You are being asked to take part in this study because:

- you have either Type 1 **OR**
- you require insulin to treat your Type 2 Diabetes **AND**
- you are on a hemodialysis regimen

Why would you want to take part in this study?
You will not be helped by being in this study, but the information gained by doing this study may help others in the future.

Why would you NOT want to take part in this study?
You might not want to take part in this study because we will ask you to wear a CGM and perform seven fingerstick blood glucose (FSBG) tests before meals, after meals, and at bedtime throughout the 10-day study. Your hemodialysis appointments may take an extra 30 minutes. The blood sampling during dialysis sessions will require about 4 tablespoons of blood.

What will I have to do if I take part in this study?
Full details of all the procedures are found later in this form.
If you take part in this study, you will:

- Wear a CGM during study (Neither you nor the study doctor will be able to see your blood glucose trends as measured by the CGM)
- Perform numerous fingerstick blood glucose tests at home on non-dialysis session days
- Record your weight every day
- During your regularly scheduled dialysis sessions, we will draw a small amount of blood from your existing IV line to test your blood glucose value as you undergo dialysis; the study team will collect about 12 blood samples (less than 1½ tablespoons) during each dialysis session
- The study team will collect information about you from your medical record.

By participating in this study, it may extend the time you spend in the dialysis center by 30 minutes.

What is the difference between being in this study and getting usual care?
If you take part in this study, the following things will be done differently than if you do not take part in this study.

- You will have more fingerstick blood glucose tests.
- You will weigh yourself daily and record the results on a diary.
- You will use a study glucometer and supplies for the duration of the study.
- You will wear a CGM.

- You will have blood drawn multiple times during your dialysis session, which may extend your dialysis time by 30 minutes.
- If you are a female who can get pregnant, you will have a blood pregnancy test.
- Information from your medical record will be recorded for research purposes.

What other treatments may I receive if I decide to not take part in this study?
You are being asked to be in this study because you have Type 1 or Type 2 Diabetes and are currently on hemodialysis.

The following alternative treatments are available to you if you decide not take part in this study:

- You may not participate in this study and still receive your standard medical care which consists of hemodialysis treatments and your current diabetes management plan.

Up to 50 people will be in this study at UVA.

How long will this study take?

Your participation in this study will require about 6 study visits over 10 days. These visits will be combined with your dialysis sessions. This study will add about 30 minutes over the procedure you are already having on some of the days.

What will happen if you are in the study?

If you agree to be in this study, you will sign this consent form before any study related procedures take place.

SCREENING VISIT (about 1 hour)

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. These are performed for research purposes and include the following:

- Review of your medical history
- Review of your medications
- Pregnancy test (blood)
- Results of the Hemoglobin A1c performed as part of your medical care will be collected from your medical record and used in this study.

The screening visit will be performed at the conclusion of your normal dialysis appointment. These tests and procedures may add about 30 minutes to your appointment in the dialysis center if they are not completed during your session.

If these items show you are eligible, you may begin your participation in the study on the same day or on a later date.

STUDY PROCEDURES

Day 1 (about 30 minutes)

This visit will take place at your regularly scheduled dialysis session. You will complete your dialysis run as you normally would. After it is complete, the study team will insert a CGM on your abdomen. The CGM contains a small needle that inserts a catheter, or small tube, under your skin to measure the glucose in that area. Neither you nor the physician will be able to see the CGM readings during the study.

We will provide you with a study glucometer and testing supplies. You will be instructed on how to use the study glucometer.

You will also be asked to weigh yourself every morning (Days 1-10) with the study-supplied scale and record it in a study record.

Days 2, 3, 5, 7, 9, 10 (Home procedures)

On non-dialysis days, you will be asked to perform 7 fingerstick blood glucose tests before meals, after meals, and at bedtime. You will use the study glucometer to perform these tests. You can use the study glucometer to test your blood glucose at any time. You will be asked to weigh yourself each morning after voiding. You will be asked to record your weight in a study record.

Days 4, 6, 8 (Dialysis treatment procedures)

On dialysis days, you will attend your regularly scheduled dialysis session and with no change from standard care. Your appointment may take 30 minutes longer than normal. During the session, 10-12 samples of blood will be drawn from the hemodialysis (HD) IV line. These 12 samples will require about 1 teaspoon of blood. The study team will record these blood glucose results. These samples will be collected at about the following time points:

Beginning at the start of your dialysis treatment:

- every 15 minutes for 90 minutes (7 samples)
- then every 30 minutes for 60 minutes (3 samples)
- then every hour until the end of your HD session (about 0-2 more samples)

You will be asked to weigh yourself each morning after voiding. You will be asked to record your weight in a study record.

Vital signs including height and weight, and other clinically important medical information will be collected from you and your medical chart (e.g. a copy of your Basic Metabolic Panel lab work that is collected weekly as part of your usual care.)

Day 11 (Return study equipment)

At the final study visit, you will remove the CGM sensor and transmitter from your abdomen. You will discard the sensor. You will return the CGM transmitter to the study team. You will discontinue use of study equipment and return all study supplies to the study team (e.g. CGM, glucometer, scale, etc…). You will continue with your standard care for your end-stage renal disease and diabetes management.

The CGM transmitter has been collecting blood glucose values during the 10 days that you have been wearing it.

Fingerstick Schedule for Monday, Wednesday, Friday dialysis patients (Example)

Sensor placement will occur at the end of the Friday dialysis appointment with the following fingerstick schedule:

Friday (Day 1)	**Saturday (Day 2)**	**Sunday (Day 3)**	**Monday (Day 4)**	**Tuesday (Day 5)**	**Wednesday (Day 6)**	**Thursday (Day 7)**	**Friday (Day 8)**	**Saturday (Day 9)**	**Sunday (Day 10)**	**Monday (Day 11)**
Dialysis day. Place CGM sensor. Check FSBG before meals and at bedtime.	7 FSBG readings: before & after meals & at bedtime.	7 FSBG readings: before & after meals & at bedtime.	Dialysis day. Obtain 10-12 glucose values during HD session: q15m x 90min, q30m x 60min, q60m until end of HD session	7 FSBG readings: before & after meals & at bedtime.	Dialysis day. Obtain 10-12 glucose values during HD session: q15m x 90min, q30m x 60min, q60m until end of HD session	7 FSBG readings: before & after meals & at bedtime.	Dialysis day. Obtain 10-12 glucose values during HD session: q15m x 90min, q30m x 60min, q60m until end of HD session	7 FSBG readings: before & after meals & at bedtime.	7 FSBG readings: before & after meals & at bedtime.	Dialysis day. Final study visit to return study supplies. No FSBGs.

Fingerstick Schedule for Tuesday, Thursday, Saturday dialysis patients

Sensor placement will occur at the conclusion of the patient's Saturday dialysis appointment with the following fingerstick schedule:

Saturday (Day 1)	Sunday (Day 2)	Monday (Day 3)	Tuesday (Day 4)	Wednesday (Day 5)	Thursday (Day 6)	Friday (Day 7)	Saturday (Day 8)	Sunday (Day 9)	Monday (Day 10)	Tuesday (Day 11)
Dialysis day. Place CGM sensor. Check FSBG before meals and at bedtime.	7 FSBG readings: before & after meals & at bedtime.	7 FSBG readings: before & after meals & at bedtime.	Dialysis day. Obtain 10-12 glucose values during HD session: q15m x 90min, q30m x 60min, q60m until end of HD session	7 FSBG readings: before & after meals & at bedtime.	Dialysis day. Obtain 10-12 glucose values during HD session: q15m x 90min, q30m x 60min, q60m until end of HD session	7 FSBG readings: before & after meals & at bedtime.	Dialysis day. Obtain 10-12 glucose values during HD session: q15m x 90min, q30m x 60min, q60m until end of HD session	7 FSBG readings: before & after meals & at bedtime.	7 FSBG readings: before & after meals & at bedtime.	Dialysis day. Final study visit to return study supplies. No FSBGs.

q means 'every' (for example, "every 15 minutes")

Study Schedule

	Screening	Home	Dialysis Treatment Day
Study Day	**1**	**2,3 5,7,9,10**	**4,6,8,11**
Informed Consent	X		
Review study eligibility	X		
Medical History	X		
Pregnancy Test (blood)	X		
Insert CGM	X		
Fingerstick Blood Glucose Testing		X	
Glucose Collection			X
Record weight	X	X	X
Record lab results	X		X
Remove CGM; Return study equipment			X

What are your responsibilities in the study?

You have certain responsibilities to help ensure your safety.

These responsibilities are listed below:

- 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 completely.
- Inform the study doctor or study staff as soon as possible if you have to take any new medications, including anything prescribed by a doctor or those that you can buy without a prescription (over the counter), including herbal supplements and vitamins. The study doctor will let you know if you can take these medications.

Blood Testing

We will perform testing on drops of blood obtained by fingerstick during the Home Study. These blood drops will be used to measure your blood sugar. This blood sampling will require less than a tablespoon of blood during the study.

We will collect blood samples during the Hemodialysis Treatment. These blood drops will also be used to measure your blood sugar and to see if you are pregnant (females of childbearing potential). This blood sampling will require about 4 tablespoon of blood during the study.

When these tests are done any left-over sample will be thrown away. This means there is no information that could be used by anyone to determine who the sample came from.

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 related to treating type 1 diabetes (with or without using study equipment)

Likely

- Risk of possible mild to moderate low blood sugar and possible symptoms of low blood sugar, such as sweating, trembling, difficulty thinking, dizziness, and feeling uncoordinated.
- Risk of possible mild to moderate high blood sugars and possible symptoms of high blood sugars such as thirst and frequent urination. You may have a higher level of sugar in your urine.

Rare but serious

- Risk of severe temporary low blood sugar (hypoglycemia) that can lead to unconsciousness, hypoglycemic seizure, hospitalization or even death.
- Risk of prolonged high blood sugar leading to diabetic ketoacidosis, hospitalization, and coma. DKA can lead to renal failure (kidney failure), cardiac arrhythmia (irregular heartbeat), myocardial infarction (heart attack), rhabdomyolysis (muscle breakdown), and even death.

Risks and side effects related to continuous glucose monitor sensor use include:

Likely

- Failure of CGM to stay on skin, requiring insertion of a new sensor
- Discomfort from insertion of sensor

Less Likely

- Bruising less than ½ inch
- Bleeding less than ¼ teaspoon

- Sensitivity to adhesives with use of the CGM resulting in skin irritation, redness, blistering, scarring, systemic allergic reaction, or secondary skin infection

Rare but serious

- Swelling or redness at insertion site
- Breakage of the CGM sensor under the skin with possible symptoms of skin irritation and inflammation. If a sensor breaks and no portion of it is visible above the skin, do not attempt to remove it. Please call the study team or seek immediate medical assistance. Seek professional medical help if you have symptoms of infection or inflammation – redness, swelling, or pain – at the insertion site.
- Bloodborne pathogen, such as Hepatitis B, if the shared CGM transmitter is not cleaned thoroughly with a diluted mixture of bleach or another appropriate cleaner after use per hospital approved cleaning procedure.

Risks and side effects related to performing fingersticks include:

Likely

- Pain at site of lancet (finger-pricking needle) use
- Bleeding at site of lancet use

Less Likely

- Incorrect information from a false low or a false high fingerstick value

Rare but serious

- Infection at site of lancet use

Risks and side effects related to performing a blood pregnancy test (for females who are able to become pregnant) include:

Less Likely

- False positive or false negative results

Risks of having your blood drawn:

Having blood drawn may cause:

- ✓ pain (common),
- ✓ a bruise (sometimes),
- ✓ fainting or passing out (not very often), and
- ✓ 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), or
- ✓ 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 or any other infection that may affect your clinical care, we will tell you the results and help you understand what the results mean for you.

Risks for women:
Being in this study might hurt your unborn baby, so you will not be able to join or stay in the study if you are pregnant. You must use an effective method of birth control during the study. If you have questions about birth control, please ask the study leader. If you are pregnant now, or get pregnant during the study, please tell us right away.

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 will not benefit from being in this study. However the information researchers get from this study may help others in the future.

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 get the usual treatment even if you choose not to be in this study. The usual treatment would include:

- Continuing your current diabetes management plan and hemodialysis treatments. You may also discuss with your primary doctor if there are other options available for you

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 $150 for completing the study by check. If you do not complete the study, you will be paid for the visits completed as outlined here:

- Screening: $25
- Day 4 Visit: $25
- Day 6 Visit: $25
- Day 8 Visit: $25
- Day 11 Visit: $50

You should get your payment about 4 weeks after finishing the study. The income may be reported to the IRS as income.

If you do not finish the study, you will be paid for the visits you completed as outlined above. If the study leader says you cannot continue, you will be paid the full amount for the study.

If you owe money to any Virginia state agency, the state can use the money you earn in this study to pay those debts. These state agencies include the UVa Medical Center, VCU Medical Center or a college or university. The money may be withheld to pay back debt for such things as unpaid medical bills, taxes, fines, child support. Even if this happens, the money you earn may be reported to the IRS as taxable income.

By agreeing to be in this study, you are donating your blood and bodily fluids 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 sampling from the HD line during dialysis, blood pregnancy testing, use of the CGM sensor and transmitter, glucometer, lancets, test strips, and study-supplied scale.

You and/or your insurance company must pay for any tests or care given beyond what is required in this study. In addition, you and/or your health insurance may also have to pay for other drugs or treatments that are given to help you control any side effects. You will have to pay for any costs not covered by your health plan. You may be responsible for any co-payments or deductibles. You may wish to ask your insurance company for an estimate of what these costs might be or if pre-approval is required.

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

What if you are hurt in this study?

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). 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.

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) You do not follow your doctor's instructions

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.

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 ONLY IF 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/or 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(s) 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.

Information about you and/or samples from you may be given to other researchers outside of the University of Virginia after all identifiers, such as name, address, phone number, have been removed.

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.

Information and samples obtained from you during this study will not be used in future research.

A description of this clinical trial will be available on 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 or complete the "Leaving the Study Early" part of this form and return it to the researchers. 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 Principal Investigator listed earlier in this form 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

Principal Investigator: Meaghan Stumpf, MD
1300 Jefferson Park Avenue
Charlottesville, VA 22908
Telephone: (434) 982-4351

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

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

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

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

Notification of My Health Care Provider

Please indicate below whether you want us to notify your health care provider that you have agreed to take part in this study.

_____ Yes, I want the study doctor to notify my health care provider that I have agreed to take part in this study.

Health Care Provider Name: _____

Health Care Provider Address: _____

Study team will send a copy of the consent form to the health care provider.

_____ No, I do not want the study doctor to notify my health care provider that I have agreed to take part in this study or I do not have a health care provider.

Leaving the Study Early

Signatures should be obtained in this section if the subject decides to leave the study early.

If you leave the study early the study leader will keep the data collected about you up until the time you leave the study to help determine the results of the study.

Check one option below:

____ I am withdrawing my consent from the intervention or treatment part of this study but agree to continue to have follow up information about me collected by the study team.
The follow up information will be collected by:

- Obtaining information from my medical records
- Phone call one time
- In person follow up visit to collect study equipment

____ I am withdrawing my consent for this study. No additional information may be collected about me including follow up information from my medical records.

Consent From Adult

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

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below you confirm that you have fully explained the implications of withdrawing from the study to the subject and have answered all their questions.

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