RESEARCH PARTICIPANT INFORMATION AND CONSENT DOCUMENT
AND
AUTHORIZATION TO DISCLOSE HEALTH INFORMATION
FOR ADULTS AND SUBJECTS REACHING AGE OF MAJORITY

Sponsor / Study Title:	**Dexcom Inc. / "Assessing Non-adjunctive CGM Safety at Home and in New markets (ANSHIN)"**
Protocol Number:	**PTL-903833**
Principal Investigator: (Study Doctor)	**Anuj Bhargava, M.D.**
Telephone:	**(515) 329-6800 (24 Hours)**
Address:	**Iowa Diabetes and Endocrinology Research Center** **1031 Office Park Rd, Suite 2** **West Des Moines, IA 50265**

Participant Name: _____ Participant ID#: _____

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain words or information that you do not fully understand. You may take home an unsigned copy of this consent form to think about whether you would like to participate in the study. You should discuss your participation with family or friends before making your decision.

Warning:
You must be honest and complete in providing your medical history. Giving false, incomplete, or misleading information about your medical history, including past and present medication use, could have very serious health consequences.

Introduction:
You are being asked to participate in a research study of Dexcom's G6 Continuous Glucose Monitoring (CGM) systems because you have Type 1 or Type 2 Diabetes Mellitus. This study will enroll participants new to CGM. The CGM devices to be used in the study are Dexcom G6 CGM Systems. One of the commercially available devices, Dexcom G6, is approved by the Food and Drug Administration (FDA). The other is a commercial product which is already approved outside of the United States and in undergoing regulatory review with the U.S. Food and Drug Administration, Referred to as "Updated G6 Transmitter".

The purpose of the study is to examine whether non-adjunctive (without having to double check using another method) use of G6 CGM improves A1c in adults or children with diabetes managed by intensive insulin therapy. If you choose to participate, during one phase you will also be asked to use the G6 CGM in a "blinded" mode where you will need to do fingersticks to manage and treat your diabetes. During a different phase of the study, you will use the G6 CGM

system as currently approved by the FDA, which now allows you to use your CGM to treat your diabetes, without the need to do fingersticks. The Dexcom CGM Systems measure the amount of glucose (sugar) in the tissue underneath your skin.

Before you decide to take part in this study, you should read this form. This form, called a consent form, describes the purpose, procedures, benefits and risks involved in this study. It also describes your right to withdraw from the study at any time. Please ask as many questions as needed so that you can decide if you want to be in the study.

You do not have to take part in this study if you do not wish to. Also, you can stop participation in this study at any time. We ask that you read this consent form and ask any questions you have before agreeing to take part in this study.

Up to 80 individuals with diabetes will participate in the study at up to 8 research sites located in the United States. You will participate in both phases of the study. Phase 1 will be 20 weeks in duration. During which you will be doing fingersticks with a Blood Glucose Meter (BGM) and wearing 2 Dexcom G6 CGM systems. In Phase 2 you will be placed into either the commercial G6 Commercial Transmitter Group or into the Updated G6 Transmitter Group. Phase 2 will last for 12 weeks.

Background Information
It is important for people with diabetes to control their blood sugar. Scientific studies have shown that good control of blood sugar delays the long-term complications of diabetes. Examples of complications from diabetes include heart disease, kidney failure, amputations, skin ulcers (sores) and blindness. Today, most people with diabetes monitor their blood sugar by sticking their fingertips or forearms to get a sample of blood. They apply the blood onto test strips and use a glucose meter to read their blood sugar level.

The purpose of this study is to collect further information regarding the safety of using the CGM system as currently approved by the FDA, which now allows you to use your CGM to treat your diabetes, without the need to use fingersticks for treatment decisions. This study will enroll participants new to CGM (who have not used real-time or intermittently scanned continuous glucose monitoring (CGM) in the 6 months prior to enrollment).

Both Dexcom Systems consist of a transmitter, a sensor and needle, and receiver/display device. The transmitter is about the size of a thumbprint. The sensor probe is about twice the thickness of a human hair and is about a ½ inch long. The needle is slightly thicker and the same length as most needles used in a syringe to inject insulin. The needle is inserted into the skin just like a needle is used to inject insulin. The sensor probe is inside the needle. Once the needle is inserted, the needle is pulled out and the sensor probe stays under your skin for up to 10 days. The sensor continuously measures your glucose (sugar) levels. The transmitter is attached to the sensor pod and sends the glucose information using radio waves to the receiver/display device.

To take part in this study the participant must:

- Be at least 2 years of age or older.

- Have a diagnosis of type 1 diabetes (T1D) or type 2 diabetes (T2D) and use intensive insulin therapy (IIT).
- Have not used real-time or intermittently scanned continuous glucose monitoring (CGM) in the 6 months prior to enrollment into the study.
- Have an A1c value ≥ 7.5% (≥ 58 mmol/mol) measured by local lab or point of care within prior 30-days before enrollment.
- Be currently performing 2 or more SMBG (self-monitoring blood glucose) fingersticks a day by historical average and willing to continue this during the blinded CGM wear.
- Be willing to use the study-provided SMBG meter for the duration of the study
- Have a BMI< 45
- Have no anticipated changes to insulin delivery method or insulin formulation(s).
- Not be pregnant (as demonstrated by a negative pregnancy test at study entry) or planning to become pregnant during the study.
- Have no planned or current use of weight reduction medications, programs or surgery.
- Not have a disease or condition that may compromise your safety including and not limited to severe mental illness, a diagnosed or suspected eating disorder or any uncontrolled long-term medical condition that would interfere with study related tasks or visits, or ongoing treatment for a significant malignancy.
- Not have a known severe allergy to medical grade adhesive.
- Not have Renal (kidney) disease defined as estimated glomerular filtration rate (eGFR) ≤30 reported via local lab within the last 30-days
- Not have any condition, per investigator assessment, that could impact the stability of the A1c measurement, for example:
    - Acute or chronic blood loss or bleeding disorder,
    - Red blood cell transfusion or erythropoietin administration in the 3 months prior to enrollment,
    - Or red blood cell transfusion or erythropoietin administration anticipated during the course of the study.
- Not have anticipated acute use of oral or injectable glucocorticoids that could affect glycemic control and impact A1c, for example:
    - Frequent steroid bursts used for inflammatory arthritis or inflammatory bowel disease,
    - Or recurrent lumbar epidural steroid injections (injections of steroids into the space between the vertebrae of the lower back).
    - **NOTE**: Stable maintenance use of glucocorticoids, such as for treatment of rheumatoid arthritis or Addison's disease, is not an exclusion criterion.
- Not currently being treated with hydroxyurea
- You must not be currently participating in another study of a device or drug at time of enrollment or during the study.
- Be able to participate in the study for 8 months.

Please tell us if any of the above does not apply to you or if you are not willing to do what is asked above. Please ask questions if there is something you do not understand.

How the Dexcom CGM System works:

- The sensor and all of the parts (including the needle) that touch your skin are sterilized (free from bacteria) before use.
- The sensor is inserted through a small needle into the fat of your belly, just under the skin. It is inserted with an applicator that works similar to a syringe. The sensor is secured to your skin with an adhesive patch. The sensor will stay under your skin for up to 10 days.
- To begin sensing glucose, the transmitter must be attached to the sensor pod that is attached to the adhesive patch. The receiver/display device is then turned on and "paired" with the transmitter to start a sensor session.
- The G6 CGM receiver/display once started will provide sensor glucose values, trend graphs, and high/low glucose alerts for up to ten days.

What is involved in the study?

Phase I and Phase II: You will participate in both phases of the study.

In Phase I you will have 4 clinic visits where you will be trained on the use of the G6 CGM system; Have blood drawn for laboratory testing; Wear 2 "blinded" (you receive no glucose readings, notifications, alerts or alarms) G6 CGM systems for two 10-day periods; Complete study questionnaires; Continue current diabetes management and treatment plan. You will then be trained on the use of G6 CGM systems for use without having to double check using another method, along with insertion and removal procedures that will allow you to insert and remove the G6 CGM systems at home over the next 17 weeks.

Phase II you will be randomly placed into 1 of two groups: Updated G6 Transmitters or the G6 Commercial Transmitter Group. During this phase of the study you will be wearing G6 CGM systems for 12 weeks. If you are in the Updated G6 Transmitter Group, you will wear 2 "blinded" CGMs for the first 10 days of Phase II. You will have blood drawn for laboratory testing and will complete study questionnaires. There will be 2 clinic visits during this phase.

Clinic Visit 1

Study staff will:

- Assess eligibility
- Assess participant's comfort in remote (telehealth) clinic visits
- Use electronic data capture (EDC) for remote screening and data capture
- Obtain demographic data (including date of birth), clinical history, and current medication list
- Record height and weight
- Obtain blood samples for A1c
- As applicable, confirm negative pregnancy test
- Obtain diabetes management information
- Survey completion of participant-reported outcomes
- Place and activate 2 blinded G6 Pro CGMs
    - Place and document one on the posterior upper arm
    - Place and document one on the abdomen

- Provide a SMBG meter, compatible test strips, and a lancing (blood sampling) device if needed, and instructions to conduct SMBG testing per routine
- Schedule Clinic Visit 2

Participants will be instructed to call the clinic with questions or issues.

Clinic Visit 2

Clinic Visit 2 should occur within ±2-days of the 10-day anniversary of Clinic Visit 1. The following should occur during this visit:

- Removal of the first two G6 Pro CGM sensor and collection of their data
    - **NOTE**: Data from these CGM systems are NOT to be shared with participants or study staff at the research site.
- Placement and activation of a second pair of blinded G6 Pro CGM systems
    - Place and document one on the posterior upper arm
    - Place and document one on the abdomen
- Downloading data from the study-provided SMBG meter
- Provision of instructions to perform SMBG testing per routine
- Participants respond to questions from clinic study staff regarding severe hypoglycemia (low blood sugar), diabetic ketoacidosis (when blood sugar is very high and acidic substances called ketones build up to dangerous levels in your body. This can lead to a diabetic coma), and sensor wear
- Will schedule Clinic Visit 3

Participants will be instructed to call the clinic with questions or issues.

Clinic Visit 3

Clinic Visit 3 should occur within ±2-days of the 10-day anniversary of Clinic Visit 2. The following should occur during this visit:

- Removal of the two G6 Pro CGM systems and collection of their data.
    - **NOTE**: Data from these CGM systems are NOT to be shared with participants or study staff at the research site.
- Download data from the study-provided SMBG meter
- Changes to diabetes therapies should be based on the SMBG data and discussion with the participant.
- Fasting Lab draw for A1c, serum glucose and C-peptide to be run at local lab within ± 2 days of Clinic Visit.
- Provide instructions on deploying and using the G6 CGM system.
- Setup CLARITY and G6 Apps on Study phone with participant using participant assigned account information.
- Provision of simple instructions for using CGM data.
- Supply participant with two transmitters, study phone and sensors sufficient for 4 months.

- Participants will respond to questions from clinic study staff regarding severe hypoglycemia, diabetic ketoacidosis, and sensor wear.

Participants will be instructed to call the clinic with questions or issues.

By the end of Clinic Visit 3, participants should be prepared to start using devices without having to double check the results with another method. They should also be prepared to remove and replace sensors at home and understand how to remove the transmitter from the sensor pod and install it in another sensor after sensor insertion.

Clinic Visit 4

(Virtual/Remote visit is optional at investigator discretion)

Clinic Visit 4 should occur within ±4 days of the 4-week [28-day] anniversary of Study Clinic Visit 3. The following should occur during this visit:

- CGM data from the Dexcom CLARITY account will be reviewed by the participant and the study staff.
- Study staff may suggest adjustments to therapy based on the CGM data
- The study staff will review with participant; alerts settings and adjust as needed and review the impact of alerts.
- Participants will be trained on the remote monitoring and Share/Follow features.
    - All participants will be encouraged to have at least one active follower.
- Study staff will review and offer assistance and education on the use of the CLARITY Phone App including weekly notifications
- Participants will respond to questions from clinic study staff regarding severe hypoglycemia, diabetic ketoacidosis, SMBG testing frequency, and sensor wear.
- Study staff will review current supplies and provide additional equipment if needed.

Participants will be instructed to call the clinic with questions or issues.

Clinic Visit 5 – End of Phase 1 Beginning of Phase 2

Clinic Visit 5 should occur within ± 4 days of the 12-week [84-day] anniversary of Clinic Visit 4.

At this visit, the following should occur:

- Record height and weight.
- CGM data from the Dexcom CLARITY account will be reviewed by the participant and the study staff.
- Study staff may suggest adjustments to therapy based on the CGM data

- Download data from the SMBG meter.
- Collection of A1c measurement at local lab ±2 day Clinic Visit 5
- Participants will respond to questions from clinic study staff regarding severe hypoglycemia, diabetic ketoacidosis, SMBG testing frequency, and sensor wear.
- PRO Surveys will be administered
- Participants will be provided with a 12 week supply of CGM System Transmitters and Sensors
- Participants will be randomized to either Updated G6 Transmitters or current G6 Commercial Transmitter groups.

- **Participants randomized to continue G6 Commercial transmitters**:
    - Will continue normal user experience with commercial G6 wearing one transmitter and sensor and use of the provided study smart phone.

- **Participants randomized to Updated G6 Transmitters** will wear two sensors for the initial 10-day period.
    - One sensor will be placed on the back of the arm and one on the Abdomen.
    - You will carry a receiver which is blinded (you will not be able to see the glucose data) for 10 days.

- After the initial 10 days:
    - Participants will continue normal user experience with Updated G6 Transmitter wearing one transmitter and sensor and use of the provided study smart phone.

All participants will be instructed to call the clinic with questions or issues

- **Phone Call 1** (10 days ± 2 days after Clinic Visit 5)
    - Following 10-days of wear, the receiver, transmitter and sensor pod from the arm location and the sensor and transmitter pod from the abdomen will be placed in the provided container and returned to the research site by participant.
    - This may be returned by UPS/FedEx/equivalent with tracking information.
    - You will then continue normal use of the provided G6 system with supplied transmitters, sensors and study phone.

Clinic Visit 6

(12 weeks [84-days] ± 4 days after Visit 5)

- Lab draw for A1c at local lab ±2-days
- Download and review all data from CLARITY
- Return all used study products

WHAT HAPPENS AT THE END OF THE STUDY PERIOD?

You have completed participation in the study once you complete the Clinic Visit 6, final study visit.

WHAT ARE THE POSSIBLE DISCOMFORTS OR RISKS?

Risks of Wearing the CGM System

When the needle and sensor is inserted, you should expect to experience a sensation similar to an insulin injection or the insertion of a pump infusion set. After insertion, you may or may not experience the following:

- Pain,
- Inflammation or redness
- Swelling
- Minor infection
- Minor bleeding at the sensor insertion site,

Significant or serious health risks with the study device are not anticipated.

Minor irritation may occur where the adhesive pad is placed. This will occur in most research participants and should clear up within hours to not more than a week after removal. You may experience some itching in the area during the healing process, which is normal.

You may develop an allergic reaction to one or more parts of the sensor and transmitter. This is similar to allergies that occur due to medical tape or jewelry. Allergic reactions will usually be mild and require only a skin cream to make them better. Severe allergic reactions are rare. Some symptoms of allergic reactions are:

- Rash
- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat or eyes
- A fast pulse or sweating.

If you have or think you are having an allergic reaction you should seek treatment immediately and notify the study staff.

There is a chance that the sensor or needle may break during use of the device. This is not expected to occur; but, if it does, you should consult the study doctor about what to do. They will see if you have symptoms of infection or inflammation, swelling, redness, or pain at the insertion site. Treatment will be provided if needed. If a sensor breaks, it may be left under the skin indefinitely as long as no portion of the wire sensor fragment is visible above the skin and there are no symptoms of infection, redness, and/or swelling.

The radio waves that the transmitter puts out will not hurt you, nor will you be aware of them.

Risks of Having Low or High Blood Sugar
As with any person having diabetes, there is always a risk of having a low blood sugar (hypoglycemia) or high blood sugar (hyperglycemia) which may occur with usual treatment of diabetes. Symptoms of hypoglycemia can include:

- Sweating
- Jitteriness
- Not feeling well

If you use rapid acting insulin as part of treatment, mild low blood sugars are expected to occur during the study. Severe low blood sugar could result in loss of consciousness or a seizure.

High blood sugar usually does not cause many symptoms, but you may:

- Become thirsty
- Have an increased amount of urine
- Experience blurring of vision

High blood sugar may be severe and result in Diabetic Ketoacidosis (DKA), requiring you to seek medical attention

Pregnancy (While Wearing a CGM System)
If you suspect that you have become pregnant while being in the study, you must contact the study staff immediately. It is unknown whether the use of the study device and the intensive testing performed during the study pose a risk during pregnancy. As a precaution, female volunteers of child-bearing potential will undergo a pregnancy testing before entering the study and will not be allowed to be in the study if they are pregnant.

This study may include risks or side effects that are unknown at this time.

Removal from Study
Your participation may be discontinued before you complete the study, if certain situations arise:

- Failure to comply with study plan or procedures
- Change in your medical condition (for example, pregnancy, fever/acutely ill, etc.)
- Discontinuation of the study for any reason by the sponsor, study doctor/research site, or government agencies
- Opinion of the study doctor
- Other reasons including new information available to the study doctor or harmful unforeseen reactions experienced by research participants in the study

New Findings
You will be told about any new information that might change your decision to be in this study.

RESULTS OF THE STUDY

The results of the study will be used to evaluate long-term safety of using CGM for diabetes management. Although we may publish the results of this study, your results will not be identified to you.

What are the possible benefits of the study?

The use of CGM technology in this study may or may not help you to better understand your diabetes, positively impact your ability to manage your diabetes, or even discover glucose patterns you may not have been aware of. The information gained from the study may or may not help people with diabetes in the future.

Alternatives:

You do not have to be in this study to treat your diabetes. Rather than participate, you may choose to continue your current glucose monitoring and diabetes management routine. The CGM devices are also available outside of this study if prescribed by a health care provider.

Will I have to pay anything?

You will not be charged for the CGM device or any of the study procedures or clinic visits. You will get to keep the CGM device after the study if you want to continue to use the CGM and if the study doctor determines it is in your best interest.

Compensation:

You will receive compensation for study participation.

- Clinic visit 1 (screening) $120
- clinic visit 2 $120
- Clinic visit 3 $120
- Clinic visit 4 $120
- Clinic visit 5 $120
- Phone call $25
- Clinic Visit 6 $120

You will be paid following each completed visit.

If you leave the study early, you will only be paid for completed visits.

Because payments for your participation in this study may be reported to the IRS as income, you may be required to provide your Social Security number.

The study doctor is being paid by the sponsor to conduct this study.

Compensation for Injury

If you feel you are hurt because of the activities of the study, treatment will be available, including first aid, emergency treatment, and follow-up care as needed. Dexcom Inc. will pay for any care needed for injuries related to your participation in the study. If an injury you have is caused by the study, please contact your study doctor immediately (see "Questions" section below).

To pay these medical expenses, the sponsor will need to know some information about you like your name, date of birth, and social security number or Medicare Health Insurance Claim Number. This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

AGREEMENT TO NOT DISCLOSE STUDY DETAILS

By signing and dating this consent form, you agree not to disclose, share or use any information gathered during the course of the research study. All information about the study, including the study product and study procedures, is confidential. Any publication about the products or the study by print or electronic format (such as blogging, online chat forums or discussion boards) is strictly prohibited.

Legal Rights

You do not lose any legal rights by signing and dating this consent document. The above statement, "Compensation for Injury," does not stop you from getting legal help in case of negligence.

Who is paying for this study?

This research is being paid for by Dexcom, Inc., the manufacturer of the study devices.

Confidentiality

Study records that identify you will be kept confidential as required by law. Except when required by law, you will not be identified by name, social security number, address, phone number, or any other direct personal identifier in study records disclosed to outside individuals or institutions. When such disclosures do occur, you will be assigned a unique code number. The key to the code will be kept under secure conditions by local study personnel. Study-related information will be included in your regular medical record.

All records and documents pertaining to this study will be retained for a minimum of 2 years by Dexcom and will be available for inspection by FDA or other regulatory agencies. All records containing personal identification or information that identifies you will be handled confidentially within the law. These records will be maintained in Dexcom's secure electronic server. Your identity will not be used in any reports or publications from this study.

Authorization to Use and Disclose Information for Research Purposes

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

In signing and dating this consent form, you are authorizing the use and disclosure of your health information collected in connection with your participation in this research study. Your information will only be used as outlined in this consent form and according to applicable law. This health information includes, but is not limited to:

- Your past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research about physical exams, laboratory test results and questionnaires

Representatives of the following groups are authorized to use and/or disclose your health information in connection with this research study:

- Study doctor and study personnel

The parties listed in the preceding paragraph may disclose your health information where required by law to do so or to the following individuals or organizations for their use in connection with this research study:

- Department of Health and Human Services (DHHS)
- Food and Drug Administration (FDA)
- Study sponsor and their designated representatives
- IRB (Institutional Review Board)
- Other State or Federal Regulatory Agencies

Representatives from other countries may join in the review of your research records, including research related medical reports and information, in conjunction with the FDA or the sponsor noted above.

The use and/or disclosure of your personal data/information is part of Dexcom's standard terms of use. During the course of this study you will be asked to disclose your first name, last name, date of birthday, home address, phone number, country, email address and gender with the use of Dexcom CGM software. We do not disclose to third parties any "Use Information" that can identify you (except as permitted by law). We may "de-identify" your personal information by removing information that could identify you, and we may use such de-identified information for any purpose, except where we are required to do otherwise under applicable law.

Reasonable effort will be made to protect your information against re-disclosure, except where such re-disclosure is permitted by law. As permitted by law and outlined in this consent form, your health information may be used and disclosed until all necessary study-related information has been collected, analyzed, and verified. It is not known how long this will take. After all necessary use and disclosure, the information will be destroyed in a confidential manner.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

By signing and dating this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research study. If you cancel your permission after you have joined

the study, you will be dropped from the study and the study staff and the study doctor will stop collecting your personal health information. Although they will stop collecting new information about you, they will need to use the information they have already collected to maintain the dependability of the study.

This permission to share your personal health information for this study does not have an expiration date. In California and any other state that requires an expiration date, the Authorization will expire 50 years after you sign and date this authorization document. If you no longer want to share your personal health information, you may cancel your permission at any time by writing to the study the study doctor listed on the first page of this form.

You have the right to review and copy your health information. However, if you decide to be in this study and sign and date this permission form, you will not be allowed to look at or copy your research information until after the research is completed. Your access to your records will not be limited by your participation in this study.

The study sponsor will make every effort to keep your personal health information private and will not give it to anyone except as explained above. However, after the study staff or the study doctor releases your personal health information, federal privacy laws may not apply, although there may be other laws that protect your privacy.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date

FOR CHILDREN WHO BECOME ADULTS

I have been told that my parents/legal guardian agreed to the use and disclosure of my Protected Health Information as outlined in this document. I have read and understand the information in this authorization. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I continue to authorize the use and disclosure of my Protected Health Information. I will receive a copy of this signed and dated authorization.

_____

Participant's Printed Name

_____ _____

Participant's Signature Date

Voluntary Participation/Withdrawal

Your participation is completely voluntary. You do not have to take part in this study. You can say "no" without any further explanation. No one will refuse you treatment at this clinical site or benefits to which you would otherwise be entitled because you do not want to take part in this study.

You may leave the study at any time. You may notify the study coordinator at any time if you do not want to continue in the study.

When you withdraw your permission, no new health information, which might identify you, will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

The sponsor, study doctor, FDA, or IRB may end your participation at any time without your consent if thought appropriate. In the event that you withdraw or are withdrawn from the study early you may be asked to perform study exit procedures.

Whom to contact about this study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046

- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00045988.

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.

Do not sign and date this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records. Participant's Statement of Consent:
I have read all the information in this consent form and I have been given enough time to make my decision. I have asked questions and I have received answers. I hereby voluntarily consent to participate in this study.

By signing and dating this consent form, I have not waived any of the legal rights, which I otherwise would have as a participant in a research study.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

FOR CHILDREN WHO BECOME ADULTS
I have been told that my parents/legal guardian agreed for me to participate in this research study as a minor. I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to continue to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

_____
Participant's Printed Name

_____ _____
Participant's Signature Date

I have explained the information to this participant. I believe that this participant has sufficient understanding of this clinical study to provide appropriate informed consent.

_____
Printed Name of Person Explaining Consent Discussion

_____ _____
Signature of Person Explaining Consent Discussion Date

Name of Study Doctor (Print)

(If different from Person Explaining Consent Discussion)

Signature of Study Doctor Date

(If different from Person Explaining Consent Discussion)