Consent to Participate in a Research Study
CGM Intervention in Teens and Young Adults with T1D (CITY): A Randomized Clinical Trial to Assess the Efficacy and Safety of Continuous Glucose Monitoring in Young Adults 14-<25 with Type 1 Diabetes

Today, you are being asked to take part in this **research** study about continuous glucose (blood sugar) monitoring (CGM) because you have type 1 diabetes. The goal of this research is to get new knowledge that may help other people, but it is not the same as treatment of type 1 diabetes. We want to find what works best for treating you and others with this condition.

Your study doctor will be talking with you about this research and this document. Please take your time deciding whether you want to participate in this research and please carefully read this document.

Before you decide to take part in this research study, we encourage you to speak with friends and family members about it. If you do not understand all the information, please ask your study doctor or nurse to explain. If you are taking part in another study, please tell us right away.

NON-PARTICIPATION STATEMENT

Participation in this study is voluntary and you must agree to take part. If you decide to stop participation in this research, that will happen immediately. No penalty or loss of medical care will result from your decision. While the study is occurring you may continue to receive medical care not related to this study.

WHO IS DOING THE STUDY

Your study doctor(s) will carry out this study. Their names are listed on the Cover Page of this form. The Leona M. and Harry B. Helmsley Charitable Trust is paying for this research. This funding will be used by the Jaeb Center for Health Research to organize the study and pay your study doctor[s].

WHY ARE WE DOING THIS STUDY?

The purpose of this study is to find out how well CGM works in adolescents and young adults age 14 to 24 years.

A CGM measures the glucose level in the fluid under the skin. It consists of a sensor which is inserted into the skin, a transmitter attached to the sensor and a display device. Every 5 minutes, the transmitter sends glucose readings to the display device. The display device stores the readings. CGM can be used in a “real-time” mode where the numbers from the transmitter show on the display device. It can also be used in a “blinded” mode where the numbers do not show on the device.

HOW MANY PEOPLE ARE WE EXPECTING TAKE PART IN THIS STUDY?

We expect about 150 people will take part in this study at about 14 different medical locations.

WHO CAN PARTICIPATE IN THIS STUDY?

To take part in this study, you must be or have the following:

1) Clinical diagnosis of type 1 diabetes
2) Be at least 14 and not yet 25 years old
3) Diabetes duration of at least 1 year
4) Be using at least 0.4 units per kg of insulin per day
5) Have an HbA1c level between 7.5% to less than 11.0%
6) Be using an insulin pump or multiple daily injections of insulin (at least 3 shots per day)
   - How you take insulin must not have changed for at least the last three months and you must have no plans to switch how you take insulin during the next 6 months.
7) Perform at least 2 blood glucose meter checks per day.
8) Use CGM device for a minimum number of hours and calibrate the device appropriately during blinded CGM screening period.
9) Understand written and spoken English.

There are some exclusion criteria that may prevent you from being part of the study. Your study doctor will check if you have these or not.

1) Use of unblinded personal CGM and/or flash CGM as part of your diabetes management in the last 3 months
2) Skin reaction from adhesive
3) A significant medical disorder or use a medication that will affect wearing the sensor or completing the study
4) Have had more than 1 episode of diabetic ketoacidosis in the past 6 months
5) Pregnant or planning to become pregnant in the next 12 months.
6) Need to use acetaminophen (the ingredient in Tylenol) on a regular basis
7) You participated in a diabetes-related intervention study in past 6 weeks.

WHAT HAPPENS IF I AGREE TO TAKE PART IN THIS STUDY?

If you decide to take part in this study, a computer program will be used to select whether or not you will be in the group that continues to use your home blood glucose meter (BGM) without real-time CGM or be in the group that will use real-time CGM. The computer program is similar to flipping a coin to decide to what study group you will belong.

This study will include two phases. Each phase will last about 6 months.

Phase 1: For the first 6 months:

- One group will continue to use BGM without real-time CGM. This group will also wear a blinded CGM at certain time points.
- One group will use real-time CGM and be trained on how to use the device.

Phase 2: During the second 6 months all participants will use real-time CGM.

If you were a CGM group participant in Phase 1, you will have the choice to continue using a real-time CGM in Phase 2 with alarms for low and high blood glucose levels turned on or turned off. Your study doctor may help guide you with this decision.

If you were a BGM group participant in Phase 1, you may have a computer program decide whether or not you will be in a group that uses real-time CGM with alarms for low and high blood glucose levels turned on or in a group with most alarms and alerts turned off. If you have concerns with turning CGM alarms off you can continue in the study and start using CGM with alarms turned on.

The total time in the study for Phase 1 and Phase 2 is about 12 months.

The CGM system to be used in the study is made by Dexcom, Inc. The CGM kit has a sensor, transmitter and display device. The sensor has a plastic body and contains a thin, small needle and sensor wire the size of a human hair. Once inserted, the needle is removed and the sensor wire remains. The transmitter snaps on top of the sensor and tape is used to keep the sensor in place. The sensor wire measures the sugar level in the fluid beneath the skin every 5 minutes. This information is sent by the transmitter to the display device. The sensor works for up to 7 days and then needs to be replaced. Newer sensor versions that may be used in the study may last up to 10 days. The first insertion will be done by the study team at a study visit. The removal and next insertions will be done by you at home.

The blinded CGM that will be used in this study is the Dexcom G4 Platinum Professional. The Dexcom G4 Platinum Professional is approved by the FDA for people 18 years of age or older. Since the blinded glucose data will not be used for diabetes management the use of the blinded sensor should not carry any risk.

The real-time CGM that will be used in this study during the 1st 6 months is the Dexcom G5 Mobile. The Dexcom G5 Mobile is approved by the FDA for use in children 2 years of age and older. The Dexcom G5 Mobile uses a web program called Clarity. The study team will help you set up an account in Clarity to use the device. To set up the account you will need to provide an

email address and your date of birth. Dexcom will have access to your CGM data and the information used to create the account including your email address. This information will be stored in a secured database. If you are not comfortable using your personal information a different email address and birthdate can be created for you to use.
The Dexcom G4 Platinum Professional and Dexcom G5 Mobile use the same software and sensors.

The Dexcom G4/G5 sensor will cause false high sensor readings (blood glucose is not affected) if acetaminophen (the ingredient in Tylenol) is used. Therefore, if possible you should not use acetaminophen and medications containing acetaminophen for at least 24 hours before sensor insertion and while the sensor is being used. You may take Motrin/ibuprofen instead of Tylenol when possible as these medications are okay. You will be asked to contact your study team before taking acetaminophen-containing medicine.

During Phase 2 of the study you may be given a newer version of the Dexcom CGM if one becomes available. The newer CGM sensor may last up to 10 days before needing to be changed and may not need to be calibrated with a blood glucose meter in certain circumstances.

Initial Study Visit
The following will be done at the initial study visit:

- *Physical Examination* – similar to what would be done at usual office visit
- *Questionnaires* – to determine your attitudes and thoughts about your diabetes and health. You will be asked to create a user ID and password when completing the questionnaires so that, if needed, you can finish the questionnaire from home.
- *HbA1c* - a finger stick will be done to measure HbA1c

If you are eligible, we will place a CGM sensor on you. This CGM is set up so that it will record the glucose values but you will not be able to see them. This is referred to as "blinded CGM." We will teach you how to care for the CGM. You will need to place a new sensor after 7 days or sooner if needed.

To be eligible for the main study, you will need to wear the blinded CGM for 200 hours. Also, you will need to check your blood sugar with a personal home blood glucose meter at least 2 times per day and calibrate the CGM about every 12 hours (an average of 1.8 times per day).

Start of Phase 1 Study Visit
You will have an office visit for this study after 14-21 days from the initial visit.
The following will be done at this visit:

- A finger stick will be done to measure HbA1c.
- Download of your blinded CGM and home blood glucose meter
- Skin assessment of where the blinded sensor was placed

We will check the CGM and blood glucose meter to see how much they have been used. If you are eligible, you will be ready to start the main study and will be assigned to one of the 2 groups.

If you are in the group continuing to use your BGM, we will give you advice on how to best manage your blood sugars.

If you are in the CGM group you will receive training on how to use the real-time CGM. A new sensor will be inserted and you will be able to see the glucose values on the display device (or on your smartphone if you choose to use the smartphone application).

The first real-time CGM training will take about 30 minutes. Additional training on using the CGM will take place as needed at each study visit.

Phase 1 Study Visits

You will have 3 to 4 additional office visits at 2 and 6 weeks and around 3 and 6 months after starting Phase 1 of the study. These office visits will replace your usual diabetes care visits while you are in the study. If you are in the CGM group the 2 week visit may take place via telemedicine instead of in the study clinic. You may need to go to the clinic for this visit if you are having issues with the CGM device. If you are in the BGM group the 2 week visit will be a phone call or audio/video communication. You will also have a phone call or audio/video communication with a study nurse at 1, 4, and 19 weeks. If you are in the BGM group you will have an additional visit at 24 weeks to place a blinded sensor.

In total, each study visit may take about 1 hour for the BGM group and 1-2 hours for the CGM groups. The phone calls or audio/video communications should take less than 30 minutes but may be longer for the CGM group.

The following will be done at visits for all groups:

- Review of diabetes management and download of blood glucose meter
- Physical exam – at the 3 and 6 months visits
- Finger stick to measure HbA1c – 3 and 6 months visits
- Questionnaire completion – 3 and 6 months visits

BGM Group

If you are assigned to the BGM group a blinded CGM sensor will be placed by study staff at the 13 and 24 week visits.

You will need to wear the blinded CGM sensor for 7 days after the 13 week visit. You will need to calibrate the CGM device with your home blood glucose meter at least 2 times per day. The clinic staff will make arrangements with you on how to return the blinded CGM back to the clinic. Two weeks before the 6 month visit you will have an extra visit to have the sensor placed. At the 26 week visit your study team will review the amount of sensor data. You may be asked to wear the sensor again if you do not have enough hours of sensor data.

CGM Group

If you are assigned to the real-time CGM group you will spend about 30 minutes at the start of main study visit learning about CGM. You will learn how it can be used to improve glucose readings. We also will give you instructions on how to make changes in the insulin dose. We will give you goals for glucose levels before and after meals and before bedtime. At certain times, you will be able to use the CGM blood sugar readings instead of a blood glucose meter for dosing insulin. We will give you instructions for when to use a blood glucose meter to confirm the CGM glucose reading.

About every 7 days you will need to insert a new sensor or earlier if the sensor is no longer working. You will need to calibrate the CGM device by checking your blood glucose with a home blood glucose meter 2 times per day. You also will need to check your blood glucose with a home blood glucose meter when your symptoms or the expected blood sugar value does not match the CGM reading.

You should try to use the CGM every day. You will be asked to contact the study team if you lose or damage the CGM and you will be provided with a new device. The damaged CGM should be returned to your study team.

The study team will help you create an account on the Dexcom Clarity website. You will need an email address to create an account. Once you have an account, you will be able to view your glucose data in reports on your computer or mobile phone. The study team will teach you how to review the glucose data.
If you stop using CGM we still want you to stay in the study. You may be asked to complete a questionnaire about reasons why you stopped using CGM.

In the table on the next two pages you will find what will happen at each visit.

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Visit – weeks from Randomization Visit or Contact	Screening V	Rand V	1w C	[a]2w V or C	4w C	6w V	13w V	19w C	24w V BGM Only	26w V
Visit Window			**±3d**	**±7d**		**±7d**	**±7d**	**±7d**	**±7d**	**±7d**
Blinded CGM Placement and training on placing sensor*	**X**						**X***		**X***	
Real Time CGM Initiated (CGM Group)		**X**								
Review diabetes management (CGM training for CGM group as needed)	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**		**X**
Pre-randomization compliance assessment		**X**								

*For BGM group and for participants in CGM group who have discontinued real-time CGM use (if willing)
[a]BGM group will have a phone call. CGM group will have option for either phone call/audio-visual contact or visit.
[b]CGM group asked to download CGM at home if possible

Visit – weeks from Randomization **Visit or Contact**	**Screening** **V**	**Rand** **V**	**1w** **C**	**[a]2w** **V or C**	**4w** **C**	**6w** **V**	**13w** **V**	**19w** **C**	**24w** **V BGM Only**	**26w** **V**
Visit Window			**±3d**	**±7d**		**±7d**	**±7d**	**±7d**	**±7d**	**±7d**
Blood draw or finger stick for HbA1c sample and C-peptide + glucose at rand only	**X**	**X**				**X**	**X**			**X**
Physical Exam including height, weight and blood pressure	**X**						**X**			**X**
Skin Assessment		**X**		**X**		**X**	**X**			**X**
CGM download		**X**	**X[b]**	**X[b]**	**X[b]**	**X**	**X**	**X[b]**		**X**
Questionnaires	**X**						**X**			**X**
Medical history, medications and/or adverse events ascertainment	**X**	**X**	**X**	**X**		**X**	**X**	**X**	**X**	**X**

*For BGM group and for participants in CGM group who have discontinued real-time CGM use (if willing)
[a]BGM group will have a phone call. CGM group will have option for either phone call/audiovisual contact or visit.
[b]CGM group asked to download CGM at home if possible

Phase 2

Both groups for Phase 1 will use real-time CGM during Phase 2.

Phase 1 CGM Group

If you were a CGM group participant in Phase 1, you will choose whether or not to have alarms turned on or off in Phase 2.

Phase 1 BGM Group

If you were a BGM group participant in Phase 1, you may be randomly assigned to one of two groups:

- **CGM with Alarms**

If you are in the CGM with alarms group, you will use CGM with alarms for low and high blood glucose turned on. These alarms will be set for you by the study team. You may change the alarm settings at any time after discussing with your study team.

- **CGM without Alarms Group**

If you are in the CGM without alarms group your study team will turn the alarms for low and high blood glucose off. The low glucose alarm of <55 mg/dl will remain on for safety. Your study doctor may decide to turn the alarms on in certain circumstances.

If you do not feel comfortable having the low or high alarms turned off you may still start using real-time CGM with alarms and continue in the study.

To start Phase 2 of the study, you must:

- Wear the CGM during the 14 day blinded wear for at least 200 hours prior to the 26 week visit

You will be instructed on use of the CGM and how to use CGM and BGM data to adjust diabetes management.

Phase 2 Visits and Schedule for Both Groups

If you did not use real-time CGM during phase 1, you will have a telephone or video telehealth contact at 1 week (27 weeks from study start) and a visit 2 weeks (28 weeks from study start) after CGM initiation for CGM training.

All participants will have visits at 39 weeks and 52 weeks, about 3 and 6 months from the start of phase 2. Additional visits and phone contacts can be made as indicated.

Visit procedures will be similar as those in the first six months. In the table on the next page you will find what will happen at each visit in the extension phase.

Visit or Phone-weeks	26w (same visit as 26 week for Phase 1)	27 week phone call/ video chat Phase 1 BGM Only	28w Visit (Phase 1 BGM Group only)	39w Visit	52w Visit
Visit Window		**±3d**	**±7d**	**±7d**	**±14 d**
CGM Real-time Placement & Training	**X**	**X**	**X**		
Skin Assessment	**X**		**X**	**X**	**X**
Review Diabetes Management	**X**	**X**	**X**	**X**	**X**
HbA1c finger-stick	**X**			**X**	**X**
Physical Exam including height, weight and BP	**X**			**X**	**X**
Skin assessment	**X**		**X**	**X**	**X**
Data download	**X**		**X**	**X**	**X**
Questionnaires	**X**				**X**
Medical history, medications and/or adverse events ascertainment	**X**	**X**	**X**	**X**	**X**

ARE THERE RISKS IN THIS STUDY?

If you decide to take part in the study, you will be at risk for the side effects listed below. Risks related to your normal medical care are not listed in this form. There is a possible risk of unsecured communication during the telephone or video telehealth contacts. There may be additional risks that are not known at this time.

CGM

The CGM sensor may produce pain when it is inserted into the skin, similar to a pump site insertion or insulin injection. Rarely, a skin infection can occur at the site of insertion of the sensor. Itchiness, redness, bleeding, and bruising at the insertion site may occur. A reaction to the tape that holds the sensor to the skin is possible. The risk of skin problems could be greater if you use a sensor for longer than it should be used. Study staff will check your skin during the study visits, and will give information for skin treatments if needed. There is a chance that the sensor or needle may break under your skin. This is not expected to occur; but, if it does, you should ask your study doctor what to do.

The readings from the CGM may not be as correct as testing your blood glucose with a home blood glucose meter. It is important that you check your blood glucose with a home blood glucose meter when your symptoms or the expected blood sugar does not match the CGM reading. Use of acetaminophen-containing products may reduce the correctness of the CGM glucose readings, so we urge study participants not use acetaminophen while using blinded or unblinded CGM in this study. Newer versions of the CGM may not be affected by acetaminophen.

Fingerstick Blood Glucose Measurements

During the study, blood glucose measurements need to be made with a finger stick at certain times.

The finger-stick blood glucose measurements may produce pain or bruising.

Questionnaires

You will be asked questions about your private attitudes, feelings, and behavior related to diabetes and your health. You can decide not to answer questions, take a break, or stop taking part in the study at any time. There are no physical risks present. Many protections will be made to keep your information private, but this is not a guarantee. Your questionnaire responses will be sent electronically to the study coordinating center.

Risks may include psychological stress or loss of confidentiality.

We encourage you to discuss the risks with your study doctor or any other health care professional who may understand our process.

WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY?

It may be possible that the blood glucose information from the CGM along with the instructions provided for management decisions will be useful for your diabetes management if you decide to

take part in the study, but it is not a guarantee. You may receive no direct benefit from being in the study. Those who take part in this research study will add to new knowledge about the role of CGM in managing diabetes that may help others with diabetes.

WHAT ALTERNATIVE PROCEDURES OR TREATMENT ARE AVAILABLE IF I DO NOT TAKE PART IN THIS STUDY?

You may continue to use your home BGM or decide you want to use CGM but not be part of this study. We encourage you to discuss your options with your study doctor or another health care professional.

WHAT IF I WANT TO WITHDRAW FROM THE STUDY, OR I AM ASKED TO WITHDRAW FROM THE STUDY?

You can stop participating in this study at any time. You may continue to receive medical care not related to this study. However, we encourage you to talk to a member of the research group so they know why you are stopping the study.

If there are any new findings during the study that may affect whether your participation, you will be told about them so you can decide if you want to continue.

No penalty or loss of medical care will result from your decision. You may continue to receive medical care not related to this study.

The investigators, physicians or funding source may stop the study or take you out of the study at any time. They may remove you from the study for various administrative and/or medical reasons. They can do this without your consent.

Some reasons why you may be removed from include:

- The doctors judge that it is in your best interest
- The doctors think that being in the study may cause you harm
- If you experience a study-related injury
- If you become pregnant

If you are removed from the study or the study is stopped, you may continue to receive medical care not related to this study.

We will ask you to have a pregnancy test before you start this study. Only you will be told the results. If you are pregnant, we will also advise you to get care for your pregnancy. You will be asked not to be in the study or you will be removed from the study if your pregnancy test is positive.

If there is any chance that you are pregnant or you might become pregnant during the time of this study, we would recommend that you think really carefully about whether you should be in the study. It is okay if you decide that you do not want to be in the study or to stay in this study. You do not need to give a reason for not being in the study.

ARE THERE COSTS RELATED TO TAKING PART IN THE STUDY?

Testing that is specifically for this study will be paid for by the study. The costs of treatment, office visits, and tests that are part of your usual standard diabetes care and are not specifically part of this study will be your insurance company's responsibility. The study will pay for all procedures and tests done specifically for this study. All other tests and procedures are your insurance company's responsibility.

At no cost to you, the study will be providing the CGM device and sensors for you to use during the study. If you complete the study, you will be able to keep the CGM devices. Sensors for the CGM and replacing the CGM transmitter will be your responsibility after the study and if needed study staff will assist you with obtaining insurance coverage to the degree possible.

You may be provided with a study BGM and test strips if your current BGM is not able to be downloaded.

IS THERE COMPENSATION FOR TAKING PART IN THIS STUDY?

If you take part in the study, you will receive $50 for each completed visit required for the study. This $50 payment is to help compensate for the money spent on travel and other visit-related expenses.

You will receive $25 each for the 19 week phone call. If you are in the BGM group, you will receive an extra $25 for the 24 week blinded CGM placement visit.

You will receive each payment within a week from completing the visit/contact. You will not receive payment for extra visits your doctor believes are needed for your usual care. There will be no payment for completing study required phone calls or audio/video contacts except for the 2 week visit (if not done in the office) and the 19 week contact.

Study Participant Reimbursement Schedule:

Visit		Total Amount
Blinded Run-in Phase	Screening	$50
Phase 1 Randomized Trial	Randomization Visit	$50
	1 week telephone or video telehealth contact	No payment
	2 week follow-up visit/contact (CGM Group only)	$50
	4 week telephone or video telehealth contact	No payment
	6 week follow-up visit	$50
	13 week follow-up visit	$50
	19 week telephone or video telehealth contact	$25
	24 week blinded sensor placement (BGM Group only)	$25
	26 week follow-up visit	$50
Phase 2 Extension	27 week telephone or video telehealth contact (Phase 1 BGM Group)	No payment
	28 week CGM training visit (Phase 1 BGM Group)	$50
	39 week follow-up visit	$50
	52 week follow-up visit	$50

WHAT HAPPENS IF I EXPERIENCE A RESEARCH RELATED INJURY?

Medical care is available if you have a research-related injury. If you have an emergency, you can get emergency care. If possible, you should tell the emergency care medical staff that you are in a research study. You should also tell your study doctor about the emergency as soon as possible.

The study will not provide costs for medical expenses or any other costs for research-related injuries. Money for lost wages or direct or indirect losses is not available.

CONTACT INFORMATION FOR QUESTIONS OR PROBLEMS

If you have questions about this study, a research-related injury, have concerns, suggestions or questions about the study, contact your study team using the provided contact information on the Cover Page.

If you have unanswered questions about your rights as a research participant, wish to talk about your concerns or suggestions linked to the research study, want additional information about the research, or want to provide comments about the research, contact the Jaeb Center for Health Research Institutional Review (IRB) Office at 813-975-8690 or irb@jaeb.org.

HOW WILL MY INFORMATION BE PROTECTED AND KEPT CONFIDENTIAL?

As required by law, study-related records with identifying information will be kept confidential. Safeguards for authorized access, security, and privacy of your information have been put in place by the Federal Privacy Regulations. Unless the law requires it, your name, address, social security number, telephone number, or any other direct identifying information will not be used to identify you.

A. Purpose of Authorization

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your information. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

You must sign the **Protected Health Information Authorization** at the end of this form if you want to be in the study. When you sign the form, you give permission for the use and disclosure of your Protected Health Information (PHI) for the study. PHI is health information that identifies you. Your authorization is beneficial and important for the study. Without your authorization, you will not be able to be in this research study.

B. Use and Disclosure of the PHI

Your study doctor will collect information about you. This information includes things learned from procedures listed and described in this form as well as your name, address, date of birth, and information from your medical records. Your name, address, telephone number, and social security number are examples of identifiable information.

A code number will replace your name, address, telephone number, or social security number in the results given to the study coordinating center which is the Jaeb Center for Health Research in Tampa, Florida.

The study doctor's office will not disclose study results that have your identifiable information except as explained in Section C, or when required by law. The Jaeb Center and this doctor's office will guard the privacy of your study PHI.

Study results without the protected information may be shared in medical journals and at scientific meetings. Your records will be confidential. No one will disclose your identity in a medical journal or at a scientific meeting.

C. Authorized Recipients and Users

It is possible that people outside of this doctor's office and the Jaeb Center may need to see or receive your information from this study. Some examples include: government agencies (such as the Food and Drug Administration), committees that monitor safety, other sites in the study, the laboratory testing your blood samples, and companies that sponsor the study. Dexcom, Inc. will have access to CGM data and the information used to create your Dexcom Clarity account.

In most cases the information will have a code number with it instead of your name, address, telephone number, or social security number.

There are some situations where the information will not have a code number but may include your name, address, telephone number, or social security number (PHI). If so, people outside this doctor's office who assist in your care may see your study PHI. They may not be covered by the federal Privacy Rule. Everyone who needs to see your information will be told it is confidential – but we cannot guarantee full confidentiality.

Other Considerations

The data collected in the study may be provided to other researchers to use; however, the data that are provided will not contain any information that could identify you.
When the results are made public, all of the study data collected may also be made public. However, there will be no identifying information included.

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.

D. Cancellation of HIPAA Authorization

You may cancel your permission for the use and disclosure of your study PHI at any time. You need to contact your study doctor and give him/her a notice of cancellation in writing. When you cancel your permission or when you withdraw from the study directly, you are no longer part of

the study. No new information about you will be gathered for the study except when there is an adverse (unfavorable) event that is related or potentially related to the study. If an adverse event happens, your entire medical record may need to be reviewed.

The Jaeb Center will receive all the information that was collected for the study up to the time of cancellation or withdrawal. The Jaeb Center will receive any new information about any adverse (unfavorable) event that is related or potentially related to the study.

E. 50 Year Expiration Date and Indefinite Expiration Date

Some of your study PHI does not have a code number with it. Your permission for the use and disclosure of this PHI lasts 50 years from the date of your signature or until the end of the study, whichever is sooner.

The rest of your study PHI does have a code number with it. When it is collected, it becomes a research report. Your permission for the use and disclosure of these coded data will never end. These coded data do not have your name, address, telephone number, or social security number.

The above supports the HIPAA Privacy Rule – 45 CFR 164.508

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Your Full Name (printed) _____

Description of Representative's Authority to Act for the Subject
_____ (if applicable)

Protected Health Information Authorization

By signing, you authorize the use and disclosure of your protected health information. This information is collected as part of your participation in this study.

_____ _____
Signature Date

Study Enrollment

By signing, you agree to take part in this study. Your signature means that:
- ***you have read this informed consent form about the study named below;***
- ***you have been given the chance to discuss the study and to ask questions;***
- ***you have verbally summarized your understanding of the study to the person who is explaining it to you; and***
- ***you freely choose to participate.***

Name of Study: CITY

_____ _____
Signature Date

I certify that to the best of my knowledge the participant understands the nature, demands, risks, and benefits involved in his/her participation in this study.

_____ _____ _____
Investigator's Printed Name Investigator's Signature Date

You will be given a signed copy of this document in case you want to read it again.