Instructions

Items in [ ] and {} are intended to be modified to fit your protocol's specific data processing. If the wording in [ ] and {} does not apply to your processing, please delete. Other wording is required as part of this template. If you have any questions about this template, do not hesitate to contact the JCHR Research Compliance Committee at rcc@jaeb.org.

When submitting to the RCC, make sure the document contains ALL newly added information as tracked from this template.

NOTE: When JCHR will only be receiving anonymized data, notice and consent are not required, and when JCHR will only be receiving pseudonymized data, then the other company should have already provided a privacy notice and/or obtained consent. In this instance, you would only need to receive confirmation in your contract that this has happened in accordance with GDPR requirements.

GDPR PARTICIPANT PRIVACY NOTICE AND CONSENT
(Subjects ≥ 16 years of age must sign for self)

STUDY TITLE: [***insert title of the study***]

Legally Authorized Representative (LAR)
In this form, when it says "you" it is referring to you as the participant if you are at least 16 years old, or to the person under your care that would be in the study if you are the legally authorized representative (LAR) in accordance with your local laws. Typically, a LAR would be a parent reviewing the information for their child to be in the study and for the processing of that child's personal data. In this case, when we say "you" in the form, we mean "your child."

Why are you getting this form?
The information in this form must be given to you because you are a person residing in the European Economic Area (EEA). There is a regulation called the Global Data Protection Regulation (GDPR) that says that we must give you this information, and that you have the right to consent to allow for the processing of your personal data. The Jaeb Center for Health Research (JCHR or Jaeb Center) is the company that says what data will be collected and how it will be used for this research study. For this reason, we are responsible for making sure you are informed and are called the "controller".

What is personal data?
Personal data is any information that is related to an identified, or identifiable person in the EEA. This means that personal data can be anything that ***could be*** used to find out who you are. Some common examples of "personal data" include:

- Names and Addresses (physical and virtual, such as IP Address)
- Identification Card Number and Phone Numbers (and other contact information)
- Location Data (e.g., GPS)
- ***Special Categories of data:***
  - Revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or
  - Relating to the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation

What is processing?
Processing can include just about anything that you can think to do with information. For example, the collection, analysis, sharing and storage of data and samples can all be thought of as processing.

What personal data will be collected about you?
{***If JCHR will not have contact information, then state:*** Your study doctor's office will collect information about you. This information includes things learned from study procedures as well as your name, address, date of birth, and health information from your medical records. Most of this personal data will not be shared outside of you study doctor's office.}

The following personal data will be processed by JCHR as it relates to this study {***modify accordingly***}:

- Contact information, like {***insert here***} ***– If JCHR will have contact information and you removed the paragraph above this***
- Demographics, like {***insert here***}
- Data concerning health, like {***insert here***}
- Biological samples, like {***insert here***}
- Lifestyle data, like {***insert here***}
- Psychosocial data, like {***insert here***}
- Physical characteristics, like vital signs, height and weight

[***If contact information was specified above, then explain why JCHR needs this information, example*** **-** Separately from your research data, the Jaeb Center for Health Research in Tampa, Florida will be provided with information on how to contact you for the phone calls specified in the main study consent form.]

[***Also as applicable:*** You will receive text messages from the Jaeb Center through [***explain: e.g., a third-party texting service***]. [***Describe how the information will be protected: e.g., The text messages will be sent automatically using a computer program from the Jaeb Center database. This database is designed with security protections. Your contact information will be saved in a different part of the database and will not be saved with your study information. The third-party texting service will only receive your phone number and has agreed to only use your phone number for the study texts.***]

How will that data be collected for this study?

Your personal data for this study will come from the following sources {***modify accordingly***}:

- Your {***state device type, like CGM***} data downloads
- The questionnaires that you complete online
- Your study doctor's office
- In reports from the Study Laboratory that analyzes your blood samples
- In reports from the Reading Center that reads the pictures of your eyes
- {***insert other ways as applicable***}

Why is this data needed for the study?

Your personal data is needed so that the researchers can meet the scientific intent of the study as explained in the study consent form. In other words, the study could not be done without this data. Specifically, this data will be used to help the researchers {***state purpose – like, to study diabetes (it is recommended that you focus your purpose on the disease and not the product, as any secondary research must be in line with this purpose)***}.

Also, as we explained in the study consent form, your personal data is used to make automated study decisions. For example, you must meet certain health criteria to be in the study. {***Add if applicable:*** Another example is that people in the study will be randomly assigned to their treatment group.} {***Add if applicable:*** Further, the way that each person is assigned to a group, or the dose that they are given, etc… is based on {***state health information, like HbA1c value, or what have you***.} {***If automated processing, then add:*** It is possible that one group might do better than another group, but that is what

we are trying to find out. We don't know how well you will do in the group to which you are assigned.} For more information about how this is done, and what the risks are, please see the study informed consent form. No one will be able to influence these automated decisions as they support the integrity of the data analyses.

Who can see your personal data?
The study doctor's office and JCHR ***will not*** share your personal data except as explained in this form or when required by law. The Jaeb Center and your study doctor's office will guard your privacy, and the confidentiality of your personal data as required.

It is possible that people outside of the study doctor's office and the Jaeb Center may need to ***see*** your personal data from this study. Some examples include government or state agencies, people that monitor safety, and companies that are providing either funding or supplies for the study. There are some situations where the personal data ***will not*** be coded, and may include your name, address, telephone number, or identification numbers, like when the records at the study doctor's office are checked. Everyone who needs to see your personal data will be told it is confidential, and they are required to follow the law too.

Will your personal data be shared for the study?
The following people or companies (e.g., study vendors) may receive your personal data because they would have to in order to do their work on the study:

- Your study doctor's office
- Jaeb Center for Health Research (United States)
- [***insert any additional vendors that may see this information (i.e., Bob's Laboratory, Reggie's Reading Center). Be specific, use actual company names, and note the country of origin" like we did with JCHR above.***]

It is important to note that your personal data will be shared with companies and people outside of the EEA, and specifically in the United States. The United States does not protect personal data in the same way as the EEA protects personal data.

How will your personal data be stored and for how long?
Your personal data will be stored at your study doctor's office {***state methods and duration***}.

Your personal data will be stored at JCHR in our secure database. This database has limited access and has security features to keep people from seeing your personal data that are not supposed to. For this study, all personal data will have to be stored for at least {***insert years***}, but no longer than twenty five (25) years, to comply with the laws that we have to follow in the United States and the GDPR. {If storing samples, then there must be and end date: The samples collected as part of the study will be stored {***state location***}. The samples will be destroyed {***state when, must have an end date for samples***}.}

Certificate of Confidentiality (*for applicable federally funded Studies – if not in main consent*)
[***Insert Agency Name***] has given us a Certificate of Confidentiality for this study [***The NIH considers the award to encompass the certification and does not issue one separately anymore, but other***

agencies will issue as applicable]. This adds special protection for study information that identifies you and allows us, in some cases, to refuse to give out information that could identify you without your consent. This could be done when the information is requested by a federal, state, local court or public agency. If you need medical help, we may still share your identifiable information. As described in this form or in other cases, we may share identifiable information. For example, if the government inspects us, they may see your identifiable information. Your study doctor and research team will follow local laws and will tell the local or state authorities:

- if certain diseases are present;
- if they suspect neglect, abandonment, or abuse of you; and
- if your study doctor or research team learn that you plan to harm yourself or someone else

Will your personal data be used outside of this study?
Your stored personal data will have a code number with it and will be held in JCHR's secure, limited access database to safeguard your data. It is possible that someone could still access this data that is not supposed to, but it is unlikely. Your permission for the use and sharing of this coded personal data will only be used for JCHR research that relates to the purposes of the study. This coded data does not have information like your name, address, email, telephone number, or identification numbers. This coded personal data may be used by JCHR researchers indefinitely. In addition, JCHR may share some of the coded personal data that could not readily identify you with other researchers, but only as it relates to {***insert, like diabetes***} research.

[***And if applicable -*** A copy of some of the personal data collected as part of the study will be made public in a dataset. This will be done after the study ends. This dataset will not contain any personal data that could readily identify you, but will contain health information. The study results will also be made public. These results will not have any personal data that could readily identify you, but will contain health information.]

Study results may be shared in medical journals and at scientific meetings. Your personal data will be confidential. No one will share your identity or any readily identifiable personal data in a medical journal or at a scientific meeting, but it may include health information.

Results from the study [***will/will not]*** be sent to you [***if they will, state when and how***].

Clinical Trial Reporting ***(if applicable and if not already in main consent)***
[If your study is a clinical trial, please add the following sentences. A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by US 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. A copy of one of the study consent form templates will also have to be posted on a federal Web site.]

Can you change your mind?
You may cancel your permission for the processing of your personal data at any time. You will need to contact your study doctors and give them a written notice of cancellation, and you will need to contact the Data Protection Representative (DPR) Group. When you cancel your permission or when you withdraw from the study, you are ***no longer*** part of the study. No new personal data will be gathered

about you, except when there is a public safety concern related to the study. The Jaeb Center for Health Research will still need to process the personal data that was collected for the study up to the time that you cancel or withdraw. This is important because that data is necessary to prove that we protected the people in the study and their rights and freedoms, and for the scientific merit of the study, but it will be coded.

Who can you contact with questions about your rights?
DPR Group is the company that has been hired by the Jaeb Center for Health Research to give data subjects a contact in their country. You can contact the DPR Group one of two ways:

- Send an email to jaeb@dpr.eu.com
- Fill out a webform at www.dpr.eu.com/jaeb

If you contact DPR Group, please be sure to reference "***Jaeb Center for Health Research***" and a study identifier, like the name of the study. You may be asked for more information so that DPR Group can make sure they are actually communicating with you, and not someone pretending to be you.

You also have the right to contact the Data Protection Officer at the Jaeb Center for Health Research directly with any questions or concerns, or to get copies of JCHR policies and procedures via email: DPO@jaeb.org or by mail:

Data Protection Officer
Jaeb Center for Health Research
15310 Amberly Drive, Suite 350
Tampa, Florida 33647
United States

You can visit the JCHR public website for more information at www.jaeb.org

What are your data protection rights?

- You have the right to request ***copies*** of your personal data from JCHR and/or your study doctor's office. Please know that some data may not be able to be shared until the study is over if sharing that data would impact the study. For example, telling you which treatment group you are in.

- You have the right to ask that JCHR and/or your study doctor's office ***correct*** any information that you believe is incorrect or incomplete.

- You generally have the right to ask that your personal data be ***erased***, but like we shared above, we will need to keep coded personal data that is necessary to maintain the scientific merit of the study.

- You generally have the right to ask that the processing of your personal data be ***restricted***, but like we shared above, we need to process the personal data as described in order to conduct the study.

- You have the right to ***object*** to the processing of your personal data, or the automated decision making. This would mean that you would choose not to be in the study, or that you would ***withdraw*** from the study.

- You have the right to request that your personal data be ***received*** by another company on your behalf.

- You have the right to file a ***complaint*** by contacting the DPR Group, and to lodge a complaint with a supervisory authority, if you think that any of the processing of your personal data is not following the GDPR requirements or if you believe there has been an infringement of your rights. You also have the right to take legal action.

You may exercise these rights without prejudice or penalty. If you would like to exercise these rights, please use the contact information provided above. If you make a request, we will have up to thirty (30) days to respond to you.

Participant's Study Identification (e.g., PtID): _____

Participant's Full Name (printed): _____

Participant/Legally Authorized Representative's (LAR's) Consent

(subjects ≥ 16 years old must sign for self)

By signing below, you are giving permission for the processing of your/the participant's personal data as part of this study. Your signature means that:

- you have read this form
- you understand that the United States does not protect personal data in the same way as the EEA protects personal data
- you have been given the chance to discuss the processing of personal data
- you understand data subject rights as it relates to the processing of personal data
- you know that you do not have to give permission, but if you don't, then you/ the participant cannot be in the study
- you know who to contact for questions and concerns about these rights
- you will receive a copy of this form

_____ _____

Participant/LAR's Signature Date