***Instructions***

***If your study is no greater than minimal risk, consider using the “MR-ICF” consent template. Please do not adjust the document’s margins. The header may only be updated to reflect a site’s logo as required. The footer should only be edited to reflect the protocol’s short name and/or number (e.g., ABC123), and the version of the protocol under which this ICF is being submitted, as well as the version of this ICF. Your informed consent should be no higher than an 8th grade reading level and should be kept as concise as possible. In accordance with the Associated Press Style Manual, numbers below 10 should be spelled out, unless they are:***

***1. in a series of numbers i.e., 2, 4, 6, 7, 12***

***2. in an address***

***3. as an expression of money i.e., $3, but three dollars would be spelled out***

***4. as a statement of time i.e., 7 p.m.***

***5. part of a logo or other trademark i.e., 7-11 markets***

***6. part of a list or paragraph markers***

***7. part of an outline***

***For further Associated Press Style guidelines, please see*** [***https://owl.english.purdue.edu/owl/resource/735/02/***](https://owl.english.purdue.edu/owl/resource/735/02/)

***Items in [ ] are intended to be modified to fit your protocol. If the wording in [ ] does not apply to your study, please delete. Other wording is required as part of this ICF template. If you have any questions about this ICF template, do not hesitate to contact the JCHR IRB office at*** [***irb@jaeb.org***](mailto:irb@jaeb.org).

***When submitting an ICF and/or Assent to the IRB, make sure the document contains ALL newly added information as tracked AND a clean copy.*** ***This can be accomplished by taking your finalized clean document and utilizing the Compare function within Word, whereas the ICF template would be considered the Original and your finalized clean document would be considered the Revised. The JCHR IRB conducts document compares upon submission to ensure all changes from the template were tracked and to ensure clean and tracked documents match exactly in content.***

***NOTE: For research that is not greater than minimal risk (e.g., online survey), check first to see if it is exempt. If it is not exempt, you may submit waivers/alterations to some sections of this ICF template language. You can only do this when you have requested to make alterations to the ICF in your application. The waiver/alteration requirements must still be met as stated in the application (e.g., alteration does not affect rights). Also, for studies that are no greater than minimal risk, you can contact*** [***IRB@jaeb.org***](mailto:IRB@jaeb.org) ***to request the current eConsent Templates.***

***Before finalizing your ICF, please delete instructions, examples, and brackets [ ].***

**CONSENT TO TAKE PART IN A RESEARCH STUDY**

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

**STUDY DOCTOR’S INFORMATION**

Name:

Contact Number:

Site Name:

Mailing Address:

Emergency (24-hour) Number:

Study Coordinator Name/Phone:

**SUMMARY**

**[*This paragraph can be modified if only adults will be enrolled, or only children will be enrolled that do not have a chance of turning 18 before completing the study*]** In this form, when it says “you” it is referring to you as the participant if you are an adult, or to the person under your care that would be in the study if you are a legally authorized representative (LAR). This would be like a parent reviewing the information for their child, a minor, to be in the study. In this case, “you” would mean “your child.” A “minor” is generally a person under the age of 18. An LAR for a minor is a natural or adoptive parent, a legal custodian, or a legal guardian. An LAR for an adult that lacks capacity to consent can be an attorney in fact, a court appointed guardian, a participant’s spouse, a participant’s adult child, a participant’s parent, a participants domestic partner, a participants brother or sister or a close friend of the participant (in that order). This means that if the adult that lacks capacity to consent and has a court appointed guardian, then the spouse would not be permitted to serve as the LAR.

**This consent form will give you important information about this study. It will help you decide if you would like to take part in the study. You do not have to be in this study. You can stop the study at any time. You should read and discuss all the information in this consent form with the study doctor.**

**[If applicable]: The University receives compensation from the sponsor of this study for the conduct of this study. If you have any questions, please discuss this with your study doctor.**

* **The study is being done to [*briefly state*].**
* **The [insert which drugs, devices, and/or procedures are investigational for purposes of this study] [is/are] not approved by the Food and Drug Administration (FDA) for [insert condition, or state if not approved by the FDA for use at all]. For this reason, [it is/they are] called experimental in this study. [*or state as applicable:* This is a data collection study. There are no experimental study procedures. ]**
* **You will be asked to be in this research study for about [*briefly state duration*]. The study will involve [*give a general idea of the study procedures*]**
* **The most likely risks to you are [*briefly state*]. Also, the most serious risks are [*briefly state*], but these risks are unlikely [*or some such brief explanation of likelihood*].**
* **The possible benefits are [*briefly state if the subject may have benefit and add* but that is what the study is trying to find out *or state if it is not likely that the subject will have direct benefit*] *[state if others may benefit*].**
* **If you do not participate, you may [*briefly describe other treatment options available*].**

***SUMMARY EXAMPLE***

* ***The study is being done to find out if a new investigational drug helps you sleep better than a drug that is currently available.***
* ***The drug used in this study is approved by the Food and Drug Administration (FDA) for depression. It is not approved by the FDA for sleep problems. For this reason, it is called experimental.***
* ***You will be asked to be in the study for about 12 weeks. The study will involve taking a pill every evening and completing questionnaires about your sleep. It will also involve four office visits. At the visits you will have physical exams, blood draws, and driving simulator tests.***
* ***The most likely risks to you are doing things at night without you knowing (e.g., sleepwalking), mild headache, tiredness, and nausea.***
* ***The possible benefits are that you may have help with your sleep, but that is what the study is trying to find out. This research may help people sleep better in the future.***
* ***If you do not participate, you may still seek care to treat your sleep problems***

**WHAT IS INFORMED CONSENT?**

**Informed consent** is the process that tells you about what is involved in a research study. It tells you about the study, study procedures, and study treatments. It tells you about how study treatments are given and what side effects could happen. This process usually involves reading a form like this one, someone on the study team talking to you about the study, and getting answers to your questions and concerns. The goal is that you have all of the information you need so that you can decide if you want to participate in the study.

You can take as much time as you need to think about whether or not you want to be in this study. You can also take a copy of this form with you to discuss with friends, family, or other doctors to help you decide. Please read this document carefully. Do not agree to be in this study unless all of your questions have been answered.

You do not have to be in this study. If you decide not to be in this study, you will not be treated differently as a person just because you did not want to be in this study. Also, your regular care will not be impacted.

**WHO IS DOING THE STUDY?**

This research study is being done by [***name of team***]. It is being paid for by [***name of funder***]. The Jaeb Center for Health Research will use the funding to organize the study. Your study doctor and clinic staff will use the funding to carry out this study. The name of the study doctor, the doctor’s contact information, and the mailing address are listed on the first page of this form. If one of the study doctors gets money or benefits from a company that makes the [***drugs or devices***] in this study, then they have to tell the Jaeb Center.

**WHY IS THIS STUDY BEING DONE?**

You are being asked to take part in this research study [***explain why, including*** ***name of condition and a short definition if relevant, such as ‘because you are a child with type 1 diabetes and use an insulin pump’.***]. The goal of this study is to learn things that may help people with [***condition***].

The purpose of this study is to [***insert purpose. Be clear and concise – shouldn’t take more than one paragraph***].

**WHO CAN PARTICIPATE IN THIS STUDY?**

[***Insert approximate # of subjects over approximate # of sites in the US and then outside of the US, and expected duration. Be clear and concise – shouldn’t take more than one or two sentences***].

In general, to take part in this study, you must: [***insert general inclusion criteria in lay terms, be sure to say if you must reside in the US to participate***]

Also, you must not: [***insert general exclusion criteria in lay terms – If explicitly excluding pregnant women, specifically address this here, otherwise you will need to address certain pregnancy provisions at a minimum.***]

Your study doctor and staff will review more health-related requirements with you.

**WHAT WILL HAPPEN IN THIS STUDY?**

[***Please do not cut and paste from your protocol. Using lay terms, give a concise yet complete description of the study procedures that the subjects will be expected to follow (i.e. blood tests, surgical procedures, dosage amounts of medications, how dosage will be administered and how often, or if it is a survey, how it will be answered, what the survey entails, etc.). Explain the research and how it is experimental (i.e. new drug, extra tests, or what is being looked at, etc.). Describe the overall experience that will be encountered. If there are multiple steps, use headers, bullets, tables and/or pictures as appropriate.*]**

***Be sure to describe Randomization as applicable using the following:*** If you decide to take part in this study, a computer program will be used to select whether you will be given[***insert drug***]or [***insert drug***]at [***insert when drug provided to participant***].This is like flipping a coin to decide which group you will be in.

***Be sure to explain Placebo as applicable using the following:*** A placebo does not have any medicine in it, but it looks like the study drug.

***Be sure to explain if the study is Blinded/Masked using the following:*** Neither you [***include*** nor your study doctor ***as applicable***] will know which treatment you are receiving. This information is available in the event of an emergency.

The table below shows what will happen at each visit:

[***Insert table – Note: if there is too much information and the table is very small or overly-complicated, then please break out tables where possible. For example, if there are two phases, then have one table for the first phase, and one table for the second phase. Each study table must be able to fit on one page with 12 pt font, including table key information.***]

***Be sure to explain any optional procedures (de-identified only as applicable):***

**{*EXAMPLE*} Optional Blood Draw**

If you agree, extra blood samples will be collected at Randomization, Week 13, and Week 26 visits. These samples will be used for future research by the research team at the Jaeb Center for Health Research. The types of research that may be conducted with these samples include studying different antibodies people may develop against insulin, and ways to measure the antibody level in blood.

The samples will not identify you. There is no end date to the use of these samples. Your samples from this study will not be shared with other researchers.

If you decide not to let your samples be used, you will not be treated differently as a person, and you can still be in this study. Your regular care outside of the study will not be impacted. If you change your mind later we will not be able to get your samples back.

**WHAT ARE THE RISKS OF THIS STUDY?**

If you choose to take part in this study, you need to know that there are some side effects or risks of being in this study. [***or for applicable studies, replace the entire*** ***WHAT ARE THE RISKS OF THIS STUDY? Section (except text/email sections as applicable) with the following paragraph –*** It is not expected that there would be any risks from being in this data collection study other than a possible risk to confidentiality or possibly getting upset from questions asked. This study will be capturing some information about you that includes identifiable, personal information, like your date of birth. The study has procedures in place to protect that information. There is a chance that a loss of that protection could occur. This would be a loss of confidentiality. Please see the “How will my information be protected and kept confidential” section below for more information. Also, if any questions make you uncomfortable, you can refuse to answer. You can decide to take a break or stop taking part in the study at any time.]

[***Include in this section all foreseeable potential side effects of drugs used, the discomforts associated with any procedures and tests that are done because of the study, and any psychological or socioeconomic harm that might result.***

***Clearly itemize types of adverse experiences when possible, the relative severities and the expected frequencies. For consistency, side effects are categorized as:***

* ***mild - those that do not require a therapeutic intervention***
* ***moderate - require an intervention***
* ***severe - potentially fatal or life-threatening, disabling, or require prolonged hospitalization*]**

**The more common side effects that are known:**

* [***list***]

***EXAMPLE OF MORE COMMON:***

***The more common side effects that are known:***

* about half of the people that took these drugs did things at night without knowing, like sleep walking and eating
* about 3 out of every 4 people that took these drugs had mild nausea
* about 1 out of every 10 people that took these drugs had mild headaches

***(please be consistent with the format that you choose, and note that the JCHR IRB prefers the “about 1 out of every 10 people” format)***

**Other Important Risks**

[***Explain, such as applicable, like:*** Although it is very rare, some people taking this drug has a partial or total loss of vision. Their vision returned a few weeks after the drug was stopped.]

It is always possible that anyone [***taking a drug or using a device***] for the first time may have an allergic reaction. Also, there may be additional risks from the [***drug or device***] or the study procedures that are not known. If we find out that there are any new risks, you will be told about them. You will be able to decide if you want to continue in the study based on this new information.

**Other less common side effects that are known:**

* [***list***]
* **Washout Period** [***if applicable***]

This study will involve a washout period of [***insert time***]. A washout period is the time that you go without medicine for [***condition***] to get all of the medicine out of your body. This is done to make sure your old medicine does not interact with the new drugs in the study. The time without medicine may make your [***condition***] or symptoms worse for a period of time.

* **Blood Draw Risks** [***insert if applicable***]

Anytime you have your blood drawn you may have bruising, discomfort, bleeding, infection, or fainting. These risks are possible but unlikely, and usually mild.

**Genetic Information [*if applicable*]**

The study may collect and use your blood and/or tissue samples to learn more about how diseases occur more in some families than in other families. They may also be used to learn about why some medicines work better or have more side effects in some people than in other people. It is possible that others could misuse this information.

A federal law called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination if you have already been diagnosed with the genetic disease being tested.

***[You must also describe if the research will or might perform whole genome sequencing and include risks as applicable. If not, then state:*** Whole genome sequencing, like identifying your DNA, will not be done as part of this genetic research.***]***

**Risks for Unborn Babies**

The risks of the [***drugs or devices***]in this study on an unborn baby or breastfeeding baby are unknown. For this reason, anyone who is pregnant or breastfeeding cannot be in this study. Anyone who becomes pregnant during the study will [***state:*** have to stop being in the study***, or*** be asked to stay in the study but will no longer receive the drugs or devices ***(as applicable***)]. Urine pregnancy tests are done as part of this study for anyone that is considered to be able to get pregnant. For example, anyone that has started having menstrual periods, or is still having menstrual periods, will have pregnancy tests no matter how young or old they are. They will also be asked about how they plan to make sure that they do not become pregnant while in the study (like if they use birth control). The study doctors are required to do this even if someone thinks there is no possibility of pregnancy.

For minors, the results of a pregnancy test will only be told to the LAR if the minor has given permission by signing an Assent form. Minors will be told about the pregnancy tests in the Assent form. If you are not comfortable with any of the following, then you should not allow the minor to participate:

* The minor getting information about pregnancy
* The minor discussing pregnancy with you and the study doctor
* The minor having pregnancy tests
* The minor giving permission to share results of pregnancy tests

[***Add information about nursing if there is a risk and it is exclusionary***].

**Risks to Confidentiality [*if applicable]***

This study will be capturing some information about you that includes identifiable, personal information, like your date of birth. The study has procedures in place to protect that information. There is a chance that a loss of that protection could occur. This would be a loss of confidentiality. Please see the “How will my information be protected and kept confidential” section below for more information.

[***Device Companies/Other Service Providers/Other Disclosures, if applicable. EXAMPLES:***

**Focus Groups**

It is possible that someone could recognize you from the focus group. We are asking that everyone who participates in the focus group keeps the information of other people private. These meetings will not be recorded but notes will be taken by the study team. The notes will not identify anyone. If you become uncomfortable sharing information in the focus group, can decide to take a break or stop taking part in the study at any time.

**Data Entry/Uploads**

The ABC app will be used to upload your device data. The XYZ app will be used to enter your meal tracking. These apps may collect some information like your email address and health information. The companies that own these apps have policies in place to protect your information. They use this information to provide the services of the apps and for internal purposes, like training and making the apps work better. For more information on their privacy policies, please visit their websites or ask the study team for copies.

**Interviews/Transcription**

You will be asked to have sessions with a {***specify, like: diabetes educator, study coordinator, etc.***}. These sessions will be recorded but will not be shared with anyone outside of the study. The recordings will then be transcribed. The transcriptions will not identify you.]

**Text or Email Messaging**

[***Secure text messaging -*** ***if applicable add:*** You will be receiving secure text messages in this study [***to/for/because - state reason]***. The text messages are called secure, because there are steps in place to help keep people from seeing these messages that are not supposed to. It is possible that someone else may see the text messages on your phone. If they do, they might know that you are in a study or see a detail about the study. You will receive text messages [***state frequency***]. The company that manages the system that sends the texts will see your phone number. They use this information to send the texts. They are not allowed to send your phone number to other people or companies. Please ask the study team if you would like a copy of the company’s privacy policy. ]

[***Unsecure text or email messaging when necessary -*** ***if applicable add:*** The study doctor and staff may use your contact information to call, text or email you during the study. They may do this to send you things like appointment reminders. They are not allowed to send you private information by text or regular email because it is unsecure. This means that there is a risk that a message may be seen by someone that is not supposed to see it, like when an email gets hacked. Your email, phone number and [***your/your child’s***] name will likely be in the text or email. If you think that the study doctor’s office has texted or emailed information that they should not have please contact JCHR at 813-975-8690 and ask to speak to the IRB Administrator. If you text or send a regular email to the study doctor’s office, it is unsecure and what you put in the text or email is not protected. You will receive text messages [***state frequency***].]

**Study Questionnaires/Surveys [*if applicable*]**

***If the study in question involves a minimal risk questionnaire or survey, include the following wording:***This study will involve asking you some questions about {***state what, like your diabetes***}.If any questions makeyou uncomfortable, you can refuse to answer. You can decide to take a break or stop taking part in the study at any time. ***If any sensitive questions will be asked, include:*** You will be asked about [***insert any sensitive questions***]. The [***risk/risks***] of [***this/these***] [***question is/questions are***] that you may feel [***uncomfortable, upset, etc.***] [***Add additional information regarding questions that could have legal consequences for adults (e.g., drug use, abuse, etc.). Also, add additional information regarding questions for minors that could “get them in trouble,” including drug use, smoking, alcohol use, sexual activity, abuse, etc. Be sure to include how this information will be protected (e.g., we will not report responses, or “these responses from minors will not be shared with the LAR unless there is a safety concern for the minor, etc.***]

[**Other Sensitive Data*:*** *Further, it is important to consider and describe instances of safety concerns that would warrant data disclosures for the health and safety of participants in addition to the sensitive data noted above. For example, if your study will be collecting data about or testing for infectious diseases like COVID or HIV, or if certain health data is not immediately available to the investigators (e.g., certain continuous glucose monitor data downloads) may need to be disclosed, be clear about when and how this data will be disclosed, remembering that certain data will require mandatory reporting to state or local authorities*.]

Please discuss the risks with your study doctor or any other health care provider.

**WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY?**

The possible benefits are [***briefly state if the subject may have any benefit and add*** but that is what the study is trying to find out ***or state*** it is not likely that you will have any direct benefit]. People who take part in this research study will add to new knowledge that may help other people with [***condition***].

**ARE THERE OTHER OPTIONS THAN BEING IN THIS STUDY?**

If you do not take part in this study, your options include standard treatments like [***give examples***], other research studies, or you may choose not to do anything. Your study doctor will discuss these choices and the risks and benefits of each with you. [***or the following as applicable –*** Since this is a data collection study you can get care like you normally would.]

**CAN I STOP BEING IN THE STUDY?**

You can stop being in the study at any time. If you decide to stop being in this study, you will not be treated differently as a person. Also, your regular care will not be impacted. [***If interventional study*** - Please talk to your study doctor or staff so they know why you are stopping the study and can help you do so safely.] Also, if you want to stop study treatment but want to stay in follow-up or allow ongoing data collection during the study, you will need to tell the study team. Information can only keep being collected this way if you say that it is okay in writing, like with a letter or an email. You can also use the JCHR IRB Withdraw Letter on our website at [www.jaeb.org/research-participants](http://www.jaeb.org/research-participants).

[***If applicable:*** You can decide to stop getting text messages or email contacts at any time. You will need to tell your study doctor if you would like to stop receiving text messages or emails. You [***can/cannot***] still be in the study if you do not want to get text messages [***or emails***] anymore.]

If we find out that there is any important new information about the study, you will be told about it. You will be able to decide if you want to continue in the study based on this new information.

The study may stop or the study doctor may decide to take you out of the study at any time. You do not have to give permission for the study to stop or for the study doctor to remove you from the study. You will be told if this happens. Some reasons why you may be removed from the study include:

* The doctors feel that it is in your best interest
* If you do not follow the study instructions

[***if interventional add the following:]***

* The doctors think that being in the study may cause you harm
* If you experience an injury related to the study
* If you need additional or different medication

If you withdraw, are removed from the study, or the study is stopped, you may continue to receive care like you normally would if you were not in this study. [***Add a sentence about what will be the impact of this. For example: Also, you will no longer be able to use the device. [or] Also, you may still have the drug in your system for up to three days.***]

**ARE THERE COSTS RELATED TO TAKING PART IN THE STUDY?**

***[Using language below, state whether there will be additional cost to the subject because of taking part in the research, and, if so, what the cost will be (i.e. professional fees, hospital charges, diagnostic and laboratory studies, drugs, devices, transportation). State any drug, device, test, examination, etc. that may be free of charge. Elaborate where needed.]***

The study will pay for [***insert what the study will pay for***]. The study [***state the*** ***drugs or devices***] will be provided to you at no cost. [At the end of the study, or if you decide to withdraw from the study, you must return [***state the drugs or devices***] to [***state who needs to receive them, e.g., PI’s name***]]. Any additional tests and procedures will be billed to you or your insurance company like they normally would.

The costs of routine treatment, office visits, and tests that are part of your regular care will be billed to you or your insurance company like they normally would if you were not in a study. **Please ask to speak to someone at your study doctor’s office if you want more information about what you or your insurance will be expected to pay.**

[***or, if this is a data collection only study:*** This is a data collection study so it is not expected that there will be any costs related to being in this study.]

[***Be sure to consider other aspects of the study that may incur cost for the participants, such as possible data charges from text messaging or data uploads, cost of app usage, etc***.]

**IS THERE PAYMENT FOR TAKING PART IN THIS STUDY?**

***[If payment will be given to the subject for taking part in the study, let the subject know that it will be prorated if he/she withdraws from the study. It is a violation of FDA standards to make the entire payment contingent upon completion of the study. State a variation of the following or state if they will not be paid. Be sure to specify who will receive payment as applicable (e.g., research with minors).***

If you take part in the study, you will receive up to [$ ***state total max amount, e.g., $200***] for your participation. These payments will be paid as follows: [***briefly break down the payment schedule, e.g., $50 for each completed visit (up to 4 visits)***]. [***State in what form they will receive and who will receive, e.g., “These payments will be made by sending gift cards to your home. They will be addressed to the LAR.”***]. If you withdraw from the study, you will still be paid for the visits that you have completed. You will not receive extra payments for visits that are required as part of your normal care or for visits that are for treating an illness or injury. ***[(If applicable)* *You may be asked to repeat a testing procedure if the study staff cannot use your data. If repeating the procedure requires you to schedule a doctor’s visit outside of normal care, you will be provided an additional [$ state dollar amount***]].

***[If there will be additional payments made for travel, then add the following so as to not need additional JCHR IRB approval:*** “If you would like reimbursement for your travel expenses, then please tell the study doctor’s office. Direct and reasonable travel expenses for study required visits will be reimbursed. You will be asked to provide receipts or proof of mileage. Direct and reasonable travel expenses are the actual cost of the most sensible travel option to get you to and from required study visits. ***[Specify any minimum and/or maximum thresholds for your study, like ‘if you are traveling more than X miles round trip’ or ‘up to $200 per visit…’.]*** Parking validation or reimbursement for parking is also available.”]

[***If specimens are being collected, you must add the following:*** The use of your samples may result in commercial profit. You will not be compensated for the use of your samples other than what is described in this consent form. The samples collected will not be used for whole genome sequencing or other genetic research {*unless it will as described in the Genetic Risks section*}.]

[*If subjects will receive compensation, include the following text]:* Compensation for participation in a research study is considered taxable income for you. If your compensation for this research study or a combination of research studies is $600 or more in a calendar year (January to December), you will receive an IRS Form 1099 to report on your taxes.

[*If subjects will receive compensation and/or reimbursement, include the following text*]: For any compensation or reimbursement you receive, we are required to obtain identifiable information such as your name, address, and [for amounts >$50] Social Security number for financial compliance purposes.

Travel reimbursement is not taxable income per the IRS.

**WHAT HAPPENS IF I HAVE AN ILLNESS OR INJURY FROM BEING IN THE STUDY?**

***[If your study involves treatment with a drug or device, you will need to include a statement that addresses injury and emergency care. Also state whether there will be financial compensation for time missed from work or injury. Exculpatory language is prohibited.]***

If you have an illness or injury that is related to your participation in the study, then you can get care like you normally would. If you have an emergency, please seek emergency care as soon as possible. Please tell the emergency doctor that you are in a research study. Please also tell your study doctor about the emergency as soon as you can. Care will be billed to you or your insurance like it normally would. The study [does/does not] have funds set aside for care or other expenses relating to illnesses or injuries. [***If the study will provide costs, specify which costs are covered***]. The University of Arizona and Banner-University Medical Center have no funds set aside for the payment of treatment expenses for this study.

[***or if this is a data collection or minimal risk only study:*** {This is a data collection study and all procedures are part of your regular care. ***OR*** This study does not have any more risk than you would have if you were not in the study.} It is not expected that there would be any study related illness or injury. If you have an illness or injury that is related to your participation in the study, then you can get care like you normally would.]

**CONTACT INFORMATION FOR QUESTIONS OR PROBLEMS**

If you have questions about this study; a research illness or injury; or have concerns, suggestions or questions about the study, then contact your study doctor using the contact information on the first page of this form.

Contact the Jaeb Center for Health Research Institutional Review Board (IRB) Office at 813-975-8690 or [irb@jaeb.org](mailto:irb@jaeb.org) if you have questions, comments or suggestions about the research. You can also contact the IRB if you want more information about your rights, injury reimbursement, or the future use of your information or samples.

**HOW WILL MY INFORMATION BE PROTECTED AND KEPT CONFIDENTIAL?**

This section tells you about how your personal Protected Health Information (PHI) will be protected and kept confidential if you decide to participate in this study.

You are being asked to not only be in this study, but also to give your permission for your PHI to be released from your doctors, clinics, and hospitals to the researchers doing this study. This is called giving your Authorization. Please see the “Authorization for Use and Disclosure of PHI” section below for more information.

The “Authorization for Use and Disclosure of PHI” section below will describe how you can cancel your Authorization for the use and disclosure of your PHI. If you cancel your Authorization, you will no longer be part of the study and no new PHI will be shared for the study, except if there is a safety concern. If there is a safety concern, your entire medical record may need to be reviewed. The researchers will receive all the information that was collected for the study up to the time that you canceled your Authorization or are no longer in the study. Any information that has been received will remain in the study database after you withdraw.

The researchers will use a code that may have your initials or date of birth to keep your study information (study results) together at the Jaeb Center for Health Research in Tampa, Florida.

Sometimes people not directly working on the study need to see your PHI. For example, the Food and Drug Administration (FDA), other federal agencies, and committees that monitor safety may inspect health and study records. In most cases, the information will be coded instead of having your PHI, but not always.

You have the right to see your records. During the study, you may not be able to see or get copies of everything. For example, if you are not supposed to know which study group you are in, then we wouldn’t want to tell you before the study ends. The study doctor will be able to tell you if you will have to wait to get some information. When the study is over, you have the right to see the full records.

**AUTHORIZATION FOR USE AND DISCLOSURE OF PHI**

**Will my study-related information be shared, disclosed, and kept confidential?**

It is anticipated that there will be circumstances where your study related information and Protected Health Information (PHI) will be released to persons and organizations described in this form. If you sign this form, you give permission to the research team to use and/or disclose your PHI for this study. Your information may be shared or disclosed with others to conduct the study, for regulatory purposes, and to help ensure that the study has been done correctly. These other groups may include:

• Banner University Medical Group and Banner Health

•Your primary care physician or a specialist taking care of your health.

• Jaeb Center for Health Research

• The University of Arizona (UA) and the UA Institutional Review Board

If you agree to take part in this study a copy of this signed informed consent form will be saved into your electronic medical record (EMR) at Banner Health. As a result, healthcare providers and staff who are not working on this study, but who may provide you medical treatment in the future, will know that you are taking part or took part in this study.

Your PHI may no longer be protected under the HIPAA privacy rule once it is disclosed by the research team.

**What study-related information and PHI will be obtained, used or disclosed from my medical record at Banner?**

Information related to this research study that identifies you and your PHI will be collected from your past, present, and future hospital and/or other health care provider medical records.

The PHI you are authorizing to be used and/or disclosed in connection with this research study is:

•***Specify what PHI, including specific data elements that will be used.***

Demographic information to be disclosed may include, but is not limited to, your name, address, phone number, or social security number. If you receive compensation for participating in this research study, information identifying you may be used or disclosed as necessary to provide that compensation.

Your existing health records may include information related to the diagnosis or treatment of sexually transmitted disease (STD), acquired immunodeficiency syndrome (AIDS), human immunodeficiency virus (HIV), other communicable diseases, genetic information (e.g., genetic testing), and/or alcohol and/or drug abuse. The study staff and study sponsor’s monitor may see this information while reviewing your regular health records for this study, but they WILL NOT create, collect, or disclose this type of information for the purposes of this research study.

**When will my authorization expire?**

There is no expiration date or event for your authorization. Therefore, unless you cancel this authorization (as instructed below) this authorization will continue to be effective.

**Do I have to sign this authorization form?**

You do not have to sign this authorization. However, if you decide not to sign, you will not be able to participate in this research study; and it will not affect any non-study Banner Health medical treatment or health care, payment, enrollment in any health plans, or benefits.

**What do I need to know if I decide to cancel my authorization?**

After signing the authorization, you may decide to cancel your previous authorization for the research team to use your PHI. If you cancel the authorization, you will no longer be able to stay in the research study. Please note that any PHI collected before you cancel the authorization may still be used. You may revoke the authorization by contacting the Principal Investigator in writing. Contact information is under “Who can answer my questions about the study” below.

**Will access be limited to your research study record during this study?**

You **[may or may not]** have access to the research information developed as part of this study until it is completed ***[Describe]*.**

**Who can answer my questions about this study?**

If at any time you feel you have had a research-related injury, or for questions, concerns, or complaints about the study you may contact [***Enter Name and Number]***.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Protection Program Director at 520-626-8630 or online at https://research.arizona.edu/compliance/human-subjects-protection-program

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact ***[Enter Name and Number]***.

If you have questions, concerns, or complaints about the use or sharing of your health information or would like a copy of the Banner Notice of Privacy Practices, you may contact the Banner Research HIPAA Liaison at [BannerResearchCompliance@bannerhealth.com](mailto:BannerResearchCompliance@bannerhealth.com).

To cancel your authorization for access to PHI you must notify the Principal Investigator and/or Research Team in writing at the following address:

***Insert address for Investigator***

**Certificate of Confidentiality** (*for applicable federally funded Studies*)

[***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

**Clinical Trial Reporting *(if applicable)***

***[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*](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. A copy of one of the study consent form templates will also have to be posted on a federal Web site.

**Other Considerations**

***[Per JCHR IRB, you must state if de-identified data or samples may be shared, or made public]*** The information [***and/or samples***] collected in the study may be used in future studies without additional permission from you. This may include research done by other researchers. The information that may be shared will not contain any PHI that could identify you. There may still be a chance that someone could identify you, but this is not likely. [***And if applicable -*** A copy of the information 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 PHI. The study results will also be made public. These results will not have any PHI either.] Study results without PHI may be shared in medical journals and at scientific meetings.

[***And if applicable -*** A limited dataset that contains some PHI may be provided to certain researchers. This PHI will not include things like your name, address, identifying pictures, or medical record numbers. Any researcher would need to sign an agreement to protect your PHI before getting this dataset as required by law.]

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

**Social Media** ***(if applicable)***

We would like to ask you not to share any of the specific details of this study public, like in social media posts. This is one way we can help protect confidentiality. This is also important because the products being used in this study are not available outside of this study. You do have the right to discuss the study with others to help you decide if you want to be in the study or stay in the study at any time.

**Contact from the Jaeb Center (*if applicable*)**

[***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 described earlier. Also, if your study doctor’s office is not able to locate you when they try to schedule your follow-up visit, a third-party search service may be used to try to contact you.]

[***Also as applicable:*** You may also have communication with the study doctor’s office by phone, text, or by video (like FaceTime or Skype). There is a chance that someone could see or hear the conversation like they could if you were speaking or texting with anyone.]

[***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.*** ***These messages are secure, but you will not be able to respond to them.***]

***[For studies that will be including the provision for expanded use of information that were collected as part of the main study that are IDENTIFIABLE, that could be used for future research, they must include the following (NOTE:*** ***A separate biobank protocol and consent will be required for the future use of potentially IDENTIFIABLE samples (e.g., genetic samples):***

**Study Information for Future Use**

Some of your identifiable study information may be stored or used for future research by [***state - most likely your study doctor’s office and the Jaeb Center, but specify***]. This information includes [***provide a general description***]. The types of research that may be done with this information includes [***provide a general description***]. If someone got this information, then they might be able to figure out that it is your information. [***explain what/how, example: The pictures of your eyes show your retinas. Your retinas are unique to you, like a fingerprint. This means that retinas are identifiable information. It is not likely that someone could identify you by looking at a picture of your retina, but it is possible.*** There are plans to protect your information by [***state your plan***]. There is still a risk that a loss of that protection could occur. This would be a loss of confidentiality.]

This information [***may/will not***] be shared with researchers outside of [***state company from above***]. [***If others may use, then*** ***add*** “The researchers may include” ***and then specify the types of researchers***]. This information from this study may be stored for up to [***state duration of storage***]. Your information may be used for up to [***state duration – this can be indefinite***]. You will not be told about the specific purposes of the future research. If there is a certain kind of research study that you would not normally want to do, you will not know if a future study is like that. Also, the results from the future studies will not be shared with you.

It is not expected that you will have any benefit by allowing this information to be used for these future research purposes. The information may help people in the future. You do not have to allow [***state company listed above***] the use of this information for future purposes if you don’t want to.

[***Select one of the following future use options as applicable:***

1. ***If the future use is not directly related to the main study (i.e., not required as part of the study), then state the following and note additional consent boxes to be included below (see signature page for additional specifications):*** If you decide not to let your informationbe used, you will not be treated differently as a person, and you can still be in the study. Also, if you decide in the future that you no longer want to allow your information from the study to be used for future research, then you can withdraw your permission. If you decide that you want to withdraw your permission for this future use, you can contact the JCHR IRB Office at 813-975-8690 or [irb@jaeb.org](mailto:irb@jaeb.org).] [***OR***]
2. ***If the future use is directly related to or required from the main study (e.g., future use limited to the network, limited to the compound under investigation, required by the funder), then state the following:*** If you decide that you do not want to allow the future use of your study information, then you cannot be in the main study either. This is because the future use is an important part of the research for the **[*insert here*]** group doing the current research **[*and/or*** it is required by [***state here***].] Your regular care outside of the study will not be impacted. Also, if you change your mind in the future, we will not be able to remove the information or samples once shared.]

{***If obtaining eConsent, then add the following statement and delete the remaining sections of this form as they will be incorporated into the attestation page(s) by development:*** If you agree to be in the study at this time, you will be asked to electronically sign with your unique password, called eConsent. You will be able to save or print copies of this form. You can also ask the study doctor’s office for a paper copy at any time at no cost. The Jaeb Center will have your eConsent information, like your name. This information will be kept separate from your study results. It will be kept confidential and private.}

**Complete this section when the participant is an Adult. If the participant is a Minor, check “N/A” here and skip this section \_\_\_\_\_\_N/A**

**Adult Participant’s Full Name (printed): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |
| --- |
| **When the Participant Lacks Capacity to Consent Participation in the Study \_\_\_\_\_N/A**  I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (print name of legally authorized representative (“LAR”)) attest that I am authorized to provide consent and authorize the use and disclosure of the participant’s protected health information on behalf of the participant named above as I am one of the following LARs (checkbox), and there is not a LAR that has higher authority (see following order):  Attorney in Fact,  Judicially Appointed Guardian,  Participant’s Spouse,  Participant’s Adult Child, then  Participant’s Parent  Participant’s Domestic Partner  Participant’s Brother or Sister  Participant’s Close Friend    LAR Signature Date  **I certify that the participant lacks capacity to consent and that the LAR named above is in fact the person authorized to consent on behalf of the participant.**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Investigator’s Printed Name Investigator’s Signature Date**  **[*if study is no greater than minimal risk, then the signature line can be changed to the following:***  **Investigator or Designee’s Printed Name / Investigator or Designee’s Signature / Date]** |

**Adult Study Participation**

|  |
| --- |
| By signing below, you/the participant agree to take part in this study. Your signature means that:   * you have read this informed consent form * you have been given the chance to discuss the study and to ask questions to your satisfaction * you freely choose (or you freely choose to allow the participant) to participate and you/the participant can withdraw at any time * [***if expanded consent for future use required to be in main study, add***] you allow the future use of your/the participant’s identifiable study information * you are authorizing and permitting uses and/or disclosures of your de-identified data for future research purposes (e.g., future studies) as described in this document. * you will receive a copy of this consent form * you authorize the use and disclosure of your protected health information. This information is collected as part of participation in this study. You/the participant cannot be in this study if you do not provide this permission.     Participant or LAR’s Signature Date |

**Complete this section when the participant is a Minor. If the participant is an Adult, check “N/A” and skip this section \_\_\_\_\_\_N/A**

**Minor’s Full Name** (printed)**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Minor’s Legally Authorized Representatives (LARs) Permission**

|  |
| --- |
| I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (print name of LAR) attest that I am one of the following individuals authorized to provide consent for the child named above as I am one of the following LARs (checkbox):  Natural or Adoptive Parent;  Legal Custodian; or  Legal Guardian  By signing below, you agree to allow your child to take part in this study. Your signature means that:   * you have read this informed consent form * you have been given the chance to discuss the study and to ask questions to your satisfaction * [***if expanded consent for future use required to be in main study, add***] you allow the future use of your child’s identifiable study information * you freely choose to allow your child to participate, you and your child can withdraw your child at any time, and you will receive a copy of this consent form * you authorize the use and disclosure of your child’s protected health information. This information is collected as part of participation in this study. Your child cannot be in this study if you do not provide this permission.     LAR Signature Date  *[****If the study is greater than minimal risk, AND there is no prospect of direct benefit to the child (e.g., healthy kids), then both parents will need to sign this consent form unless there is only one parent/LAR reasonably available, or unless otherwise granted by the JCHR IRB with a waiver/alteration request. If the study is no greater than minimal risk, or there is a minor increase over minimal risk and a prospect of direct benefit to the child (e.g., kids with disease related to investigation), then you can remove the second signature requirement.]***  **N/A - Second LAR signature not required because: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Or** I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (print name of second LAR) attest that I am one of the following individuals authorized to provide consent for the child named above as I am one of the following LARs (check box):  Natural or Adoptive Parent;  Legal Custodian; or  Legal Guardian  By signing below, you agree to allow your child to take part in this study. Your signature means that:   * you have read this informed consent form * you have been given the chance to discuss the study and to ask questions to your satisfaction * [***if expanded consent for future use required to be in main study, add***] you allow the future use of your child’s identifiable study information * you freely choose to allow your child to participate, you and your child can withdraw your child at any time, and you will receive a copy of this consent form * you authorize the use and disclosure of your child’s protected health information. This information is collected as part of participation in this study. Your child cannot be in this study if you do not provide this permission.     Second LAR Signature Date |

**Complete all remaining sections for all participants.**

**Permission to Notify Primary Provider About Participation *[If appropriate for study, e.g., interventional study]***

|  |
| --- |
| It might be a good idea for {***your/your child’s***} regular provider or doctor’s office to know that {***you are/your child is***} in this study. With your permission, we can contact {***your/your child’s***} regular provider or doctor’s office for you and give them information about the study and {***your/your child’s***} health.    I ***do*** give my permission for the study team to contact {***my/my child’s***} regular provider or doctor’s office to tell them about {***my/my child’s***} participation in this study. This may include some health information about {***me/my child***} too. I understand that I will be asked to provide the contact information of {***my/my child’s***} regular provider or doctor’s office. I may need to sign a release of information form at the study doctor’s office too.  I ***do not*** give my permission for the study team to contact my primary physician to inform them about my participation in this study  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Participant or LAR Signature Date |

**Permission for Future Use of Study Collected Information *[only if applicable under expanded use where separate consent is required (i.e., not required as part of main research)]***

|  |
| --- |
| Identifiable information is information that may be related to your/the participant’s identity (PHI). This would be like a picture of an eye because the patterns in your eye are unique to you. We are asking to use this information for future research, but would not be giving information like your name, address, or health record number. ***[Use this language when future research is optional]*** A future research activity is part of this project. If you choose to participate in the future research activity your PHI will be included in this future research activity. By initialing the line below you agree to allow your information to be used and/or disclosed for the optional future research referenced above.    \_\_\_\_\_ \_\_\_\_\_(initials) I/we ***do*** give my permission to allow for the storage, maintenance, and use of the participant’s information as described above, or  \_\_\_\_\_ \_\_\_\_\_(initials) I/we ***do not*** give my permission to allow for the storage, maintenance, and use of the participant’s information as described above    Participant or LAR Signature Date    Second LAR Signature Date  Or  N/A – second LAR signature not applicable |

**{*EXAMPLE for De-identified*} Optional Blood Samples for Future Use**

|  |
| --- |
| **The extra blood samples MGH will be using for future use would not include any identifiable information about you. Please choose only one of the options below:**  ***[Use this language when there is additional optional research that includes PHI]***  **Optional Research Activity**  An optional research activity is part of this project. If you choose to participate in this optional activity your PHI shall be included for this optional activity. By initialing the line below, you agree to allow your PHI to be used and/or disclosed for the optional Study activity referenced above.  **Please choose only one of the options below:**    \_\_\_\_\_ \_\_\_\_\_(initials) **I *do* give my permission to allow for the collection of extra blood samples for future research as described above, or**  \_\_\_\_\_ \_\_\_\_\_(initials) **I *do not* give my permission to allow for the collection of extra blood samples for future research**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Participant or LAR Signature Date** |

**Permission of Father of the Unborn Child {*this section is required when the study is greater than minimal risk, and the prospect of benefit is ONLY for the fetus – i.e., no benefit to the pregnant woman*}**

|  |
| --- |
| I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (print name of father) attest that I am the father of the unborn child.  By signing below, you agree to allow the participation in this study to take place. Your signature means that:   * you have read this informed consent form * you have been given the chance to discuss the study and to ask questions to your satisfaction * you understand what the known risks to the unborn child are * you understand that there may be risks that we don’t know about yet * you freely choose to allow this participation, you or the participant can withdraw permission at any time * you will receive a copy of this consent form     Father’s Signature Date  **N/A - Father’s signature is not able to be obtained**  **I certify that the person named above either (1) did confirm that he was the father of the unborn child, or (2) that the signature of the father of the unborn child could not be obtained for a qualifying reason in accordance with 45 CFR 46.204(e).**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Investigator’s Printed Name Investigator’s Signature Date** |

**Investigator’s Certification [*if study is no greater than minimal risk, then this can be changed to* “Designated Person Obtaining Consent”]**

|  |
| --- |
| **I certify that to the best of my knowledge the participant and/or LAR(s) are who they say they are, and understand(s) the nature, demands, risks, and benefits involved in the participation of this study. {If research does not explicitly exclude pregnant women, then add: Further, I certify that researchers have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; nor will the researchers have any part in determining the viability of a neonate; nor will there be any inducements (monetary or otherwise) offered to terminate a pregnancy.}**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Investigator’s Printed Name Investigator’s Signature Date**  **[*if study is no greater than minimal risk, then the signature line can be changed to the following:***  **Investigator or Designee’s Printed Name / Investigator or Designee’s Signature / Date]** |