



**Consent to Participate in a Research Study**  
*(Insert protocol title here)*

**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.

*Below Sections A-E are required by the Jaeb Center IRB (JCHR IRB). Wording modification must be voted on and approved by the JCHR IRB.*

**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.



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

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40 **C. Authorized Recipients and Users**

41 It is possible that people outside of this doctor’s office and the Jaeb Center may need to see or  
42 receive your information from this study. Some examples include: government agencies (such as  
43 the Food and Drug Administration), committees that monitor safety, other sites in the study, and  
44 companies that sponsor the study.

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

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

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55 **Other Considerations**

56 The data collected in the study may be provided to other researchers to use; however, the data  
57 that are provided will not contain any information that could identify you.

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*Is there a possibility the study data will be made public? If so, please add the following two sentences.*

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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.

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*If applicable to your study, add the following information.*

Separately from your research data, the Jaeb Center for Health Research in Tampa, Florida will be provided with information on how to contact you.

- About every 6 months, you may receive a phone call from a staff member at the Jaeb Center to check on your condition and to see if you have any questions. You will be called at a time that you indicate is most convenient for you. If you are not available at the time of the call and prefer to call the coordinating center yourself, you can call the coordinating center toll-free at 1-866-372-7601
- If we are not able to locate you when we try to schedule your follow-up visit, the Jaeb Center may try to contact you through the alternative contact information you have given us. If this is not successful, the Jaeb Center may use a third-party search service.

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*If your study is a clinical trial, please add the following two sentences.*

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.

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**D. Cancellation of HIPAA Authorization**

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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.

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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.

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**E. 50 Year Expiration Date and Indefinite Expiration Date**

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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.

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93 The rest of your study PHI does have a code number with it. When it is collected, it becomes a  
94 research report. Your permission for the use and disclosure of these coded data will never end.  
95 These coded data do not have your name, address, telephone number, or social security number.  
96 *The above supports the HIPAA Privacy Rule – 45 CFR 164.508*  
97

*For “masked” studies, please use the below statement:*

98 Some of your information from this study may be stored separately from or added to your medical  
99 record. You will not be able to see this information until the study ends. If your non-study physician  
requires it for your care, *[they]* will be able to view it.



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100 **Your Full Name** (printed) \_\_\_\_\_

101

102 **Description of Representative’s Authority to Act for the Subject**

103 \_\_\_\_\_ (if applicable)

104

105 **Protected Health Information Authorization**

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*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

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108 **Study Enrollment**

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*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:** \_\_\_\_\_

\_\_\_\_\_  
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

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

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