

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

PHACE SYNDROME PATIENT DATABASE

H-19026- PHACE SYNDROME PATIENT DATABASE

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**Background**

PHACE syndrome is the association between large infantile hemangiomas, usually of the face, and birth defects of the brain, heart, eyes or skin. The diagnosis is generally made from the physical examination, along with imaging of the head and chest, and an eye examination. PHACE is most common among female infants. The cause is unknown, and there is currently no means of treatment or prevention.

This research study is sponsored by Glaser Pediatric Research Network and Texas Children's Hospital Auxillary Board.

**Purpose**

This research registry is designed to help clinicians and basic scientists understand the cause of PHACE syndrome, which may help lead to treatment and prevention. The registry is a central database of patient information, that provides blood samples (kept anonymous) to scientists studying PHACE syndrome, and tracks important information among patients. The registry also serves as an educational resource for families who are interested in learning more about this syndrome.

**Procedures**

You will be one of approximately 250 subjects to be asked to participate in this study.

The research will be conducted at the following location(s): Baylor College of Medicine, TCH: Texas Children's Hospital.

You/your child will be one of at least 250 patients included in this database. The research will be conducted at Texas Children's Hospital/Baylor College of Medicine. All information on your child is kept confidential, and only non-identifying information will be provided to researchers. You will be asked to fill out a medical questionnaire which will provide investigators with important family and medical history. The questionnaire will take approximately 15 to 30 minutes to complete. We are also asking that you provide permission for the release of medical information to the researchers, permission for photographs in order to document our findings, permission to allow us to contact you if an update in your/your child's medical information is needed. We are also asking for a small donation of blood (about 1 teaspoon) from you, if you are the patient with PHACE syndrome, or your child. Collection of blood will involve sticking a vein with a needle. You may give permission to all or some of these requests below. You will also be contacted by phone at which time the study coordinator will review this consent form with you.

1. Medical information regarding my child (or myself) \_\_\_\_\_, may be released by any physician, clinic, hospital, school or institution, to the PHACE registry located at Texas Children's Hospital (Houston, Texas). This information is to be used for professional/research purposes only and will be regarded as confidential. The PHACE registry staff may contact any persons or institutions to obtain any additional information regarding my child (or myself), when necessary.

Initials: \_\_\_\_\_ Date: / /

My/my child's photograph(s) may be used for the purposes of study, research and teaching and may be

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published in scientific publications or on the intranet or internet, in which case my child's or family's name will not be used without my/my child's permission. Photograph(s) sent by mail will not be returned.

Initials: \_\_\_\_\_ Date: / /

The PHACE registry staff may contact me about my/my child's participation in future studies, but there is no obligation to do so.

Initials: \_\_\_\_\_ Date: / /

A small blood sample (about 1 teaspoon) from myself (if I am the patient with PHACE syndrome) or my child may be donated for research purposes.

Initials: \_\_\_\_\_ Date: / /

Although investigators will have a record that this information/specimen was obtained from you/your child, your/your child's identity will be kept strictly confidential. Every effort will be made to maintain the confidentiality of your study records. Research specimens may be stored for a long time at Texas Children's Hospital. Portions of the samples will be used for research studies, and the remaining portions will continue to be stored for future research studies related to this project. We anticipate that these samples will be kept indefinitely. They will not be available to you for other clinical testing, and they will not be sold to any third parties. These specimens and information about subjects may be shared with other researchers studying PHACE or related conditions under an approved protocol. In all cases, you/your child's name will not be released. If you decide to withdraw from the study, you may request that the sample be destroyed. Otherwise, they will be kept in laboratories at Texas Children's Hospital.

The purpose of this project is to develop new knowledge about the cause of PHACE syndrome. Because the studies we plan to do are research procedures for which the clinical relevance has not yet been proven, we will in general not be able to provide clinical information or any test results resulting from this research to you. Conclusive results of future studies can become available to the public when they are published in professional journals. Even then, you/your child will not be identified by name in such publications.

However, in those cases where research testing methods have been shown to be sound through publication in a peer-reviewed scientific journal and in which the results may be clinically important, we will offer you the option of receiving results of research testing.

Initials: \_\_\_\_\_ Date: / /

You can see and get a copy of your research related health information. Your research doctor may be able to provide you with part of your information while the study is in progress and the rest of your information at the end of the study.

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**Potential Risks and Discomforts**

Risks of drawing blood are minimal and include pain, bleeding, bruising and rarely, infection, at the blood drawing site. The completion of the questionnaire may make you uncomfortable. You do not have to answer any questions that you feel uncomfortable with.

**Potential Benefits**

You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand the cause of PHACE syndrome, and possible treatment(s) or even prevention..

**Alternatives**

The following alternative procedures or treatments are available if you choose not to participate in this study: The only alternative to this study is non-participation..

**Subject Costs and Payments**

There are no costs to you to participate in this research study. You will not be paid to participate in this research study.

This institution does not plan to pay royalties to you if a commercial product is developed from blood or tissue obtained from you during this study.

**Subject's Rights**

Your signature on this consent form means that you have received the information about this study and that you agree to be a part of the study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

The investigator or sponsor may decide to stop you from taking part in this study at any time. You could be removed from the study for reasons related only to you (for example, if you move to another city, if you do not take your study medication, or if you have a serious reaction to your study medication) or because the entire study is stopped. The sponsor may stop the study at any time.

There may be unknown risks/discomforts involved. Study staff will update you in a timely way on any new information that may affect your health, welfare, or decision to stay in this study.

If you are injured because of this study, you will receive medical care that you or your insurance will have to pay for just like any other medical care. You will not be paid for the injury.

**Your Health Information**

We may be collecting health information that could be linked to you (protected health information). This protected health information might have your name, address, social security number or something else

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that identifies you attached to it. Federal law wants us to get your permission to use your protected health information for this study. Your signature on this form means that you give us permission to use your protected health information for this research study.

If you decide to take part in the study, your protected health information will not be given out except as allowed by law or as described in this form. Everyone working with your protected health information will work to keep this information private. The results of the data from the study may be published. However, you will not be identified by name.

People who give medical care and ensure quality from the institutions where the research is being done, the sponsor(s) listed in the sections above, representatives of the sponsor, and regulatory agencies such as the U.S. Department of Health and Human Services will be allowed to look at sections of your medical and research records related to this study. Because of the need for the investigator and study staff to release information to these parties, complete privacy cannot be guaranteed.

The people listed above will be able to access your information for as long as they need to, even after the study is completed.

If you decide to stop taking part in the study or if you are removed from the study, you may decide that you no longer allow protected health information that identifies you to be used in this research study. Contact the study staff to tell them of this decision, and they will give you an address so that you can inform the investigator in writing. The investigator will honor your decision unless not being able to use your identifiable health information would affect the safety or quality of the research study.

The investigator, DENISE W. METRY, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: DENISE W. METRY at 832-822-3718 during the day or through the Texas Children's Hospital page operator at 832-822-824-2099 during the day or after hours.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970.

If your child is the one asked to take part in this study you are signing to give your permission. Each child may agree to take part in a study at his or her own level of understanding. When you sign this, you also note that your child understands and agrees to take part in this study according to his or her understanding.

Please print your child's name here \_\_\_\_\_

**CONSENT FORM**

HIPAA Compliant

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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

\_\_\_\_\_  
Subject Date

\_\_\_\_\_  
Legally Authorized Representative Date Relationship to Subject

\_\_\_\_\_  
Legally Authorized Representative Date Relationship to Subject

\_\_\_\_\_  
Investigator or Designee Obtaining Consent Date

\_\_\_\_\_  
Witness (if applicable) Date

\_\_\_\_\_  
Translator (if applicable) Date