

NOTE TO IRB: This exact text of this consent will be presented on-line. The participant will be able to scroll through the content at their own pace to read and review. To provide their consent, participants will check a box which will appear on screen at the end of the consent document. A screen capture of how this will appear is shown below.

Participation in all parts of this study is voluntary. You are free not to take part in this study and are free to withdraw from any or all parts of the study without penalty or loss of benefits to you. If you wish to be in the study, please indicate this below.

WHO CONTROLS AND OWNS THE BIOLOGICAL SAMPLES?

Unless you ask to withdraw from the study, survey information and DNA samples will not be returned or destroyed, but will be kept under the control of the Principal Investigator after the study is finished. If you wish to have your specimens removed from storage and destroyed, please call Dr. Edward Lammer collect at (510) 428-3885.

The stored samples may be used for future research about genetic or environmental factors related to birth defects, and these results will not be reported to you or your doctors. If the investigators want to use the stored samples for other purposes, additional consent will be sought.

Selecting the "I agree" box below indicates that you agree, or give permission, for your child and yourself to be in this study.

I agree to participate in this web-based survey

I do **not** agree to participate in this web-based survey

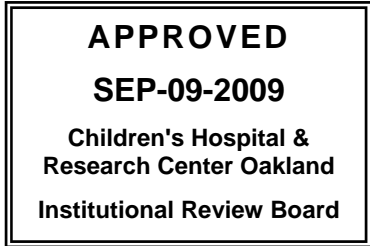
Next >>

A separate consent form for the saliva sample will be sent with collection kit.

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

NAME OF THE STUDY:

Factors Influencing Spina Bifida



WHAT IS THIS STUDY ABOUT?

Serious, medically significant birth defects occur in about 1 out of 33 babies. For most of these conditions, the cause is unknown. Birth defects can be prevented only if the causes are understood. We are doing a research study with children who have spina bifida and their parents. To help us understand more about the genetics of this birth defect, we are asking mothers of children with spina bifida to participate in a web-based survey providing relevant information about their pregnancy. At the conclusion of this phase of the study, all participants will be asked, under a separate consent agreement, to collect a saliva sample from you and, if possible, your child. This saliva sample will provide the genetic information. With this information, along with the information from the survey, we will be able to explore genetic and other factors, such as nutrition, as possible causes of spina bifida.



WHO PAYS FOR THIS STUDY?

This study is paid for by VitaPath Genetics, Inc.

HOW MANY PEOPLE WILL BE IN THIS STUDY?

Survey data from 1,000 mothers will be collected.

WILL THE INVESTIGATORS MAKE MONEY FROM THIS STUDY?

No, the investigator will not make money from this study. Dr. Edward Lammer is the Principal Investigator responsible for the study at Children's Hospital & Research Center Oakland. Dr. Lammer does not have any financial ties or interactions with the sponsor, VitaPath Genetics, Inc. that would influence the conduct of this study or the reporting of the results.

WHAT WILL HAPPEN IN THIS STUDY?

If you agree to be in this study, you will do two things: 1) complete a survey and 2) be asked to provide a saliva sample. For the survey, you will answer some questions about your medical history and other factors that may be linked to birth defects.

At this point, you are only being asked to take part in the survey. When you complete the survey, you and, if possible, your child will be asked for a saliva sample. To provide this sample, about 1/2 teaspoon (2 milliliters) of saliva is collected into a kit provided by us. These samples will provide DNA that will be used to study genes that may play a role in why some babies have birth defects. They will only be used to study birth defects and for no other purpose.

WHAT ARE THE RISKS OR POSSIBLE SIDE EFFECTS OF THIS STUDY?

You may find it emotionally difficult to discuss your pregnancy. Some questions are personal and sensitive.

HOW LONG WILL I BE IN THE STUDY?

Participation in the study will require about 10 minutes of your time to complete the survey.

ARE THERE BENEFITS TO BEING IN THE STUDY?

There is no personal benefit to you for taking part in the study. The major benefit is that this study may result in a better understanding of the causes of birth defects so that some day many may be prevented. This information will be helpful to all individuals who

may have children. We will share what we learn with other researchers and health professionals through medical publications. You or your child will not be identified in any of these publications.

The studies done on these samples will not tell us anything about your child's, your child's father's or your own current health or medical condition. The results of these studies will not be returned to you. Please consult your health care provider if you have questions about the usefulness of any genetic tests.

HOW WILL MY PRIVACY BE PROTECTED?

Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations protect your privacy, restrict who is allowed to look at your records, and require security to protect your records. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records shared outside of Children's Hospital & Research Center Oakland. For records shared outside of Children's Hospital & Research Center Oakland, you will be given a code number. The list that can match you to the code number will be kept in a locked file in the Principal Investigator's office.

Survey information will be stored on a computer that can only be accessed by the investigators. We will shred any paper surveys after information is entered in the computer. After the link between your DNA samples (if provided) and the survey is made, all information that could identify you will be removed. We will create a separate password-protected file that will only be accessible to the Principal Investigator. The DNA samples will be labeled only with a unique ID number that can be linked to the identifiers, but only the Principal Investigator will be able to make the link to you.

DO YOU HAVE TO PAY TO BE IN THE STUDY?

No, there will be no cost to you to be in this research study. There will be no charge to you or your insurance company for any of the costs related to this study.

WILL YOU BE PAID FOR BEING IN THE STUDY?

There is no payment for the survey itself. However, once you are accepted into the second phase of the study and if you agree to and return the saliva collection kit, you will receive your choice of a \$10 Target gift card or a \$10 donation to the Spina Bifida Association.

WHAT IF I HAVE QUESTIONS OR PROBLEMS?

If you have any questions about the research, either before deciding whether to participate or during this study, please contact the genetic counselor supporting this study either by phone at 866-575-0110 or by email at support@sbgenetics.org. The phone number will be staffed during normal Pacific Time business hours. Emails will be answered within 48 hours.

If you wish to speak to someone not associated with this study about complaints or your rights as a research participant, you may contact the Institutional Review Board (that reviews the research to protect your rights) at:

Children's Hospital & Research Center Oakland
IRB Office
747 52nd Street
Oakland, CA 94609
(510) 428-3754

WHAT ARE MY RIGHTS? DO I HAVE TO AGREE TO THIS STUDY?

Participation in all parts of this study is voluntary. You are free not to take part in this study and are free to withdraw from any or all parts of the study without penalty or loss of benefits to you. If you wish to be in the study, please indicate this below.

WHO CONTROLS AND OWNS THE BIOLOGICAL SAMPLES?

Unless you ask to withdraw from the study, survey information and DNA samples will not be returned or destroyed, but will be kept under the control of the Principal Investigator after the study is finished. If you wish to have your specimens removed from storage and destroyed, please call the study coordinator at 866-308-0031.

The stored samples may be used for future research about genetic or environmental factors related to birth defects, and these results will not be reported to you or your doctors. If the investigators want to use the stored samples for other purposes, additional consent will be sought.