

Appendix E.7 Frequently Asked Questions about Biologic Sampling

FREQUENTLY ASKED QUESTIONS ABOUT BIOLOGIC SAMPLING

As part of this study we are asking to collect three types of biologic samples: cheek cells, blood, and hair. We are asking for cheek cells and blood from the child and both biologic parents. We are asking for a hair sample from the child only.

Biologic samples may provide clues that will help us learn more about autism and other developmental disabilities. These clues may be more useful if we can get back in touch with you after the study is over to ask more questions. We can only get back in touch with you if you give us permission to store your samples and call you at a later date. This form describes your options about storing samples. It also describes your options for having the study team contact you for future studies. Please tell us your choices about storing samples and contacting you on the last page of the overall consent form and cheek swab consent form.

Why are you collecting biologic samples?

Many children have developmental disabilities. Some people think these disabilities are related to genes. Some people also think these disabilities are related to other biological factors that can be looked at through blood (such as immune response and hormone levels). In addition, there are some people that think substances better measured in hair (such as metals) may be related to child development. We are collecting cheek cell, blood, and hair samples to explore these ideas. Having samples from parents as well as children will help us find genes related to autism and child development. The samples will also help us understand if certain substances found your child's blood are there just because they run in the family.

How will you collect biologic samples?

Cheek Cell Samples

We are asking you to provide cheek swabs by using a cheek swab sampling kit. The kit includes a separate consent form giving you more detailed information on how to collect these samples. An instruction sheet is also provided.

Blood Samples

A trained and experienced member of the study team will put a short needle in your arm to get the blood sample. We will draw a little less than four teaspoons of blood. We will offer children cream that will numb the part of the arm where the needle goes in. The entire process will take between 10 minutes and 40 minutes. It will take an extra 30 minutes if the child is given the cream. Sometimes blood can not be drawn the first time the needle is put in. If this happens the needle will need to be taken out and put in again. You can decide to stop at any point during the blood draw.

The same basic approach will be followed to get a blood sample on your child. You will be present the whole time blood is drawn from your child. Before we schedule the blood draw we will talk with you about how you think your child will react and get your ideas. We will do the blood draw in a child-friendly setting with toys available. We may ask you to bring some of your child's favorite things from home to help provide distraction.

A trained, experienced team member will insert the needle. This person will work with trained assistants who can help keep your child as calm and still as possible during the blood draw. The team will discuss different options with you for keeping your child calm and still. You can decide whether we first put on some cream that will numb the part of your child's arm where the needle goes in. If we put the cream on it is best to leave it on for 20-30 minutes covered by a band-aid. If your child will not keep a band aid on we can put it on without the band aid but we will watch your child to make sure he/she leaves that part of the arm alone. Decisions about whether and how the child will be held will be made based on your feelings as well as the blood draw team's thoughts on what approach would be best. Sometimes blood can not be drawn the first time the needle is put in. If this happens, the needle will need to be taken out and put in again. We will get your permission before we put the needle in another time.

Hair Samples

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The same team doing the blood draw will also attempt to take a small hair sample from your child. The goal is to cut a sample of hair about ½ inches wide from the back of the head, close to the scalp, just above the nape of the neck. If your child's hair is too short or thin to get a ½ inch sample we will take smaller groups from a few areas around the head. Before doing this, we will ask you whether you think the hair sampling process will upset your child and how upset you think he or she will get. We will not attempt to get the sample if you and the team decide that your child would be too upset by the hair sampling process. We can also stop the process of trying to take the sample at any point in time.

What will happen to the samples after we collect them?

All samples will be sent to a central study laboratory and repository. DNA will be taken from cheek cell samples and blood samples. DNA will be tested for genes possibly related to autism and other developmental disabilities. We will also look at blood for types and amounts of certain substances. These substances may help us find clues to biologic pathways possibly related to child development. We will measure levels of metals in the hair sample.

After the study is completed, we would like to store any samples that are left over. There are two ways that we can store samples.

1. The first way of storing the samples would keep them linked to personal information (through a study ID). This will allow study investigators or other researchers approved by the study team to contact you again in the future. We will only contact you to see if you would be willing to provide extra information that could help with new analyses of the stored samples. By agreeing to have your sample and your child's sample stored with identifiers you are not promising now to do these other studies. You are only agreeing to be contacted at a later date. Any future studies we contact you about will have to be approved by an Institutional Review Board (an institutional review board is a special committee that helps to protect people who decide to be in research studies). Your personal information will be kept private (as described in the section below) while your samples are stored. If you ever want us to break the link with your stored samples and your personal information (so you can not be recontacted) you will only need to tell study investigators to do so.
2. The second way samples can be stored is to keep them without a link to your personal identifiers. Under this approach the link between your study ID and your biologic samples will be destroyed at the end of the study. This way your samples and the information you gave for other parts of the study could be used for future analyses of child development, but researchers would not be able to add any new information.

Of course, if you do not want your samples stored for future use at all, you can choose to have us destroy your samples at the close of this study.

How will information about me be kept private?

Only people working on the study will have access to your samples. We will use a study ID to identify the sample instead of putting your name on the samples. A link between this code number and your name and other identifying information will be kept by investigators at the study manager's office in a locked drawer. This link will be maintained on a database that is kept on a secure computer (password protected) in the study manager's office. If a hardcopy list is printed linking your code number and identifiers this will be maintained in a locked file cabinet in the study manager's office.

We may share some study data with other outside researchers who are approved by our team. However, we will not give other researchers any information that could identify you. Other researchers will not have access to the list that links your study ID with your name.

You or your child will not be identified in any reports or papers written by study investigators or those involved with the study. We will report results only for groups of participants together, not for individuals.

Because sensitive information is collected in this study, <site> received a ‘Certificate of Confidentiality.’ This means that any information that <site> has that identifies you or your child will be used only for this project and cannot be given to anyone else unless you give your written consent.

What are the risks of giving biologic samples?

There are few risks involved with giving a blood sample. You and your child may feel a little discomfort when blood is drawn. We will offer a numbing cream that can be applied before the sample is taken. Rarely this cream can cause temporary redness or rash on the skin. Bruising and infection may occur at the puncture site. Study staff will do everything they can to reduce these risks. You or your child may feel some worry about having blood drawn. Again, study staff will do everything they can to reduce worry. For children, study staff will talk with parents before the visit about what happened other times the child had blood drawn. Study staff and parents will decide together what can be done to reduce the child’s worry.

What are the benefits of giving a blood sample?

You and your child are not expected to get any direct benefits from giving a blood sample. However, your sample and your child’s sample may help us learn more about risk factors for autism and other developmental disabilities. Results may help us learn more about autism and other developmental disabilities. Results may also help develop better services and treatments for children with developmental disabilities.

Are any costs involved?

No costs are involved with giving a blood sample. You will not be charged for any of the tests that we do.

Do my child and I have to give a blood sample?

You and your child do not have to provide a blood sample in order to be in the study. The decisions are up to you. Your participation is voluntary. There is no penalty if you do not want to be in this part of the study.