

## **Procedures/Risks: sample\_storage**

### **Storage of blood, tissue and/or genetic material**

Some of the blood that you provided for the study will be stored (labeled only with coded identifiers to protect your privacy) and used for testing that has been described to you. Some of your blood that is left over after all research study testing is done, may be stored (labeled only with coded identifiers to protect your privacy) and used for future research. If you agree to the storage of these leftover samples, you will sign a separate consent document.

The samples that you are being asked to consent to storage are blood samples that have been taken during the course of a study visit. If any of that blood is left over after all required tests are completed, then you are being asked to consent to the storage of that blood for future research.

Before you sign this consent, it is important for you to know the following:

- Allowing your samples to be stored is completely voluntary. You may decide not to have left over samples stored but can still be in this research study or any future study. If you do decide that your samples are not to be stored for future research, you may change your mind at any time and withdraw consent from this portion of the study. In order for your stored blood sample to be withdrawn from any future use, you must contact your study doctor or nurse and let them know that you no longer want your samples used for future research. Your samples will not be used and will be destroyed to the extent possible. It is possible that your samples may not be able to be identified as yours and therefore not be able to be destroyed, nor be able to be connected to you (that they are yours) should they be used for future research purposes.
- Your samples will be stored at special facilities that are designed to store samples safely and securely. The storage facilities are designed so that only approved researchers will have access to the samples. Some employees of the storage facilities will need to have some access to your samples in order to store them and to keep track of where they are, but these people will not have information that directly identifies you. An Institutional Review Board (IRB) will oversee any research studies using these samples to protect you, and other research volunteers, from harm. [An Institutional Review Board (IRB) is a special committee at the researcher's institution that reviews and oversees research.]

If you decide to allow your genetic and blood samples to be shared with other researchers [at private or non-profit organizations], then you will not be required to do anything other than to give your permission for it to be shared with and used by these other researchers. Your samples have already been collected and stored, so you will not be asked to give new blood or tissue samples.

From the samples that you have already provided, your white blood cells were obtained and frozen. The white blood cells are not alive and cannot be reproduced. In genetic studies, DNA is taken from the white blood cells and differences in health conditions are examined. In the future, the DNA samples may be copied to produce DNA samples for other types of research studies.

Blood, genetic samples, tissue samples and/or other materials taken from you for this research study will be considered donated by you to medical research and will be under the control of [entity]. This research center provides these samples to [the entity] without personal identifying

information such as your name, address, and/or Social Security number. The [name of entity] may share your data and samples with other scientists who meet their requirements. All research on your samples will be done only by individuals and organizations that meet the [name of entities] standards and procedures. This means that research proposals will undergo careful review by the [name of entity], and by Institutional Review Boards. Organizations will be required to treat the data or samples as strictly confidential, and agree not to share data or samples with other parties.

Your blood and DNA samples will be stored at a central site (often called a “repository”) and labeled and identified with a unique code number. The samples will be stored for as long as they are useful for research. Your DNA may be copied, so that an unlimited supply can be available for future use without the need to obtain more blood from you.

By signing this consent form, your DNA and blood may be used by other scientists for research. Researchers may use the blood for approved specified purposes. They may not keep any leftover samples for other purposes but return it, or properly dispose of it.

Your consent to share your samples is completely voluntary. You may withdraw your consent for the use of your blood samples [and DNA] at any time. This will not affect your participation for any other part of the study. If you later decide that you do not want your blood or DNA to be used for future research at private or non-profit organizations, you may notify any of the researchers for this study at this center. The researchers will make every effort to stop any additional use of your sample(s). It is however possible that in some cases where the samples have already been shared or your DNA has been copied, it may not be possible to stop ongoing studies.

*Procedure:* Stored biological materials (e.g. tissues, blood, body fluids, urine, hair, skin) from research activities are periodically used by investigators to make important new measurements that were not possible at the time that the original research was conducted.

You are being asked to allow storage of your biological materials that remain from the current research. At the end of the current research, all the information that could link the data and samples back to you individually will be destroyed. Since the samples will be stored without identifiers, you would not be able to request removal of the samples from storage after that time. Your choice about sharing your samples for future use will *not* affect your ability to participate in the current study.

Do you wish to allow storage of your remaining biological materials (check one)?

\_\_\_\_\_ Yes

\_\_\_\_\_ No

*Risk:* Risks associated with giving your permission for use of your samples are thought to be minimal. There is a small risk of breach of confidentiality, but every effort is made to ensure that this does not happen. All information collected during this research will be kept confidential and results will not be given to [you or to] anyone without your permission, except as described below. Data may be given to other researchers for scientific purposes, but only after your name and all other personal identifiers have been removed. To ensure confidentiality, a study code number has been assigned to you. Samples provided to laboratories are labeled with a different code number.

Only a small number of scientists and staff [name participating sites/entities] will be able to link the study code number with the laboratory code number. The link will be kept in a secure location.

Any publication or presentation of the data will not identify you by name or by any other means. Your information will be grouped with that of all other persons taking part in the study and will only be used for statistical analysis to further medical knowledge. When results of this study are published or presented at medical or research meetings, only group findings will be presented.

No results of genetic or blood studies done on your samples will be provided to you, your family, or your doctor. These samples are being used for research purposes only. You will not be able to obtain your samples or information about them. The results of research studies apply only to groups as a whole and it will be unknown what they mean to you as an individual and to your personal health.

Participation in a genetic study does not mean that you have had genetic testing. Genetic testing means having a specific type of test performed and the results provided to you and your healthcare provider. If you are interested in having genetic testing performed, you should consult your healthcare provider.

There are few risks related to storing your samples. When tests are done on the stored samples, the greatest risk is to your privacy. In order to keep your information private, your samples will be labeled with a code [that can only be traced back to your research site. Your personal information (name, address, and phone number) will be protected by the research site.]

When researchers use your stored samples, they will not be given information that would identify you to them. The results of future tests will not be included in your medical records. Your name will not be in any publications or reports about this research. Every effort will be made to keep your personal information confidential, but researchers cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law [but may be protected under a Certificate of Confidentiality (see Certificate of Confidentiality)].

*Benefits:* You will not benefit directly from these genetic [and blood] studies. These studies may, one day, result in new tests and treatments, or may help to prevent or cure disease. Scientific knowledge often advances slowly, but it may benefit future generations. Neither you nor your family will benefit financially from any studies that use your sample(s) that have been collected as part of this study. Neither your blood nor DNA will be sold to anyone.

If you agree for your samples to be used by other researchers, then these samples may be shared with other researchers in the future. There is value in bringing together different scientists. Working together makes the best possible use of the samples that you have given. It may also lead to the development of new medicines. The scientists from outside organizations will be given the blood or DNA only after the [entity/sponsor] and the appropriate Institutional Review Board[s] have carefully reviewed their research proposals, and only after your name and all identifying information have been removed.

There are no costs to you or your insurance carrier for any of the blood or genetic research studies.