

## Vitiligo BioBank Consent Form

Researchers are trying to learn more about vitiligo, diabetes, and other health problems. Much of this research is done using human tissue, such as blood. Through these studies, researchers hope to find new ways to detect, treat, and maybe prevent or cure health problems. Some of these studies may be about how genes affect health and disease, or how genes affect response to treatment. Some of them may lead to new products, such as drugs or diagnostic tools.

We are asking you to let us store some of your blood (10-15 ml) and health information so they might be used in vitiligo and other skin disease studies.

You can take part in this project or not. This Consent Form gives information to help you decide. Please read it carefully and take all the time you need to make your choice. Be sure to ask us as many questions as you want.

Everyone who takes part in research should know that:

- Taking part may involve some risks.
- Taking part is voluntary. If you choose to take part, you can quit at any time.
- No matter what you decide, now or in the future, it will not affect your medical care.

**WHAT IS THE PURPOSE OF THIS RESEARCH PROJECT?** The purpose of the Vitiligo Biobank is to collect and store blood and/or its derivatives such as serum and purified genomic DNA and health information so researchers can use them in future studies.

**WHAT IS INVOLVED?** If you agree to take part, we will ask you to sign this form. We will give you a signed copy to keep. Here is what will happen next:

1. We will direct you to a certified laboratory to get a blood sample from you using a disposable set for blood sampling from the cubital vein in compliance with all safety regulations.
2. We will get some information about you and your health.
  - Ensuring confidentiality of your data (see below), we will ask you to provide basic personal information (name, age, gender, and ethnicity), as well as family medical history, current data on vitiligo, its features and related factors in your case. We may contact you only with your consent (no more than once per year) in order to update the information.
  - We will get and keep in our database some health information from your medical record. Examples include test results, medical procedures, images (such as white skin spots), and medicines you take. We will use your medical record from time to time to update this information.
  - We will get and save research data from any studies done using your sample and information.
3. We will store your sample and information in the Biobank, along with those from all the other people who take part. There is no limit on the length of time we will keep it.
4. We will let researchers use the materials stored in the Biobank for approved studies. Researchers from Vitiligo Research Foundation, universities, the government, and drug- or health-related companies can apply to use the materials. A Scientific Review Committee of the VR Foundation and external experts if required will review each request. There will also be an ethics review. We will NOT give researchers your name or any other information that could directly identify you.

5. We may contact you in the future with offers to take part in other research, for example, in clinical trials of new methods or drugs for the treatment of vitiligo. There will be a new consent process just for those studies. We will contact you on this issue no more than two such studies per year.

**WHAT ARE THE POSSIBLE RISKS?** The most common risks related to drawing blood from your arm are brief pain and/or bruising.

There is a risk that someone could get access to the data we have stored about you. Even without your name or other identifiers, your genetic information is unique to you. There are laws against the misuse of genetic information, but they may not give full protection. We believe the chance these things will happen is very small, but we cannot make guarantees.

**HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?** Your privacy is very important to us and we will make every effort to protect it. Here are just a few of the steps we will take:

- We will remove your name and other identifiers from your sample and information, and replace them with a code number. Only a few of the Biobank staff will have access to the list and they sign an agreement to keep your identity a secret.
- Your genetic data and information will be submitted to a research database after removing any information that could identify you. Your genetic data and information may be made available to other researchers who apply and are approved to use this information for scientific research.
- Researchers who study your sample and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.
- We will not give information that identifies you to anyone, except if required by law.

**WHAT ARE THE POSSIBLE BENEFITS?** You will not get direct benefit from taking part. The main reason you may want to take part is to help researchers make discoveries that might help people in the future.

**ARE THERE ANY COSTS OR PAYMENTS?** There are no costs to you or your insurance. You will not be paid for taking part. If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

**WILL I FIND OUT THE RESULTS OF THE RESEARCH?** You should not expect to get individual results from research done using your sample. We will offer to tell you something we discover only if it is about a disease that is likely to cause early death if not treated. You can get general news about the kinds of studies being done through the Vitiligo Biobank at [www.vitinomics.net](http://www.vitinomics.net).

**WHAT ARE MY OPTIONS?** Taking part in Vitiligo Biobank is your choice. You can choose to take part or not take part. If you choose to take part, you can change your mind at any time.

**WHAT IF I CHANGE MY MIND?** Just call [*ENTER APPROPRIATE DETAILS*] and let us know. We will send you a form so you can tell us in writing what you would like us to do with any of your blood that we have not already given out for study.

**WHAT IF I HAVE MORE QUESTIONS?** Please send your questions about this project to e-mail address [biobank@vrfoundation.org](mailto:biobank@vrfoundation.org).

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**BIOBANK CODE**

**CONSENT STATEMENT**

The project staff has explained to me the purpose of the Vitiligo Biobank, the procedures involved, and the risks and benefits. I have asked all the questions I have now, and I know who to contact if I have more questions.

I voluntarily agree that my biosample(s) (blood and/or its derivatives such as serum and purified genomic DNA) and information can be stored at the Vitiligo Biobank. I understand it may be used in future research to learn about, prevent, or treat health problems.

In addition, I have made the optional choices marked below. I know that I can still take part in the Vitiligo Biobank, even if I answer 'no' to any of these options.

- Someone from the Vitiligo Biobank can contact me once a year to update my personal information.

YES \_\_\_\_\_ NO \_\_\_\_\_  
(initials) (initials)

- Someone from the Vitiligo Biobank can use my medical record from time to time to get updated information about my health.

YES \_\_\_\_\_ NO \_\_\_\_\_  
(initials) (initials)

- Someone from the Vitiligo Biobank can contact me with offers to take part in up to two other studies per year.

YES \_\_\_\_\_ NO \_\_\_\_\_  
(initials) (initials)

- My genetic and health information can be released, with no direct identifiers, into scientific databases.

YES \_\_\_\_\_ NO \_\_\_\_\_  
(initials) (initials)

\_\_\_\_\_  
Signature of Subject

\_\_\_\_\_  
Date

\_\_\_\_\_  
Contacts of Subject

E-mail \_\_\_\_\_ @ \_\_\_\_\_

Postal address (in the absence of e-mail) \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date