

### Declaration of Use of Patient Information

Dear Patient,

Your physician has determined that you and/or your family members may suffer from an inheritable deficiency in your blood clotting system. This form details specific information concerning available diagnostic tests that can be used to verify the specific type and cause of your blood clotting deficiency disease. After you read this form, your physician will meet with you to personally review the detailed information printed here that is applicable to you and answer any questions you may have. The results of the tests suggested by your physician will help him to make the best decisions about how to treat your medical condition.

Many blood clotting deficiencies in individuals can often be traced to inherited genetic abnormalities (mutations) that result in changes to their DNA – the genetic material contained in each cell. Such changes to the DNA can be found by performing laboratory tests on a small sample of blood – usually 5 to 10 milliliters volume collected in a glass tube by a medical laboratory technician. For most patients, taking such a blood sample presents no risk to their health. For prematurely born babies, as well as for infants and small children, a pediatrician can explain any possible risks involved in taking a blood sample, and a sample of smaller volume than for adults can be taken.

If laboratory tests confirm a mutation of one of the genes of the blood clotting system, your physician will schedule a follow-up appointment with you to discuss possible treatment options.

In the event that a genetic mutation is not found, it is still possible that you may have a mutation that was not detected by the specific laboratory tests used. It is also possible that a mutation in a gene that was not tested could be responsible for the blood clotting problem. In this case, the negative test results for the genes tested are called „false negative“ results. In this case your physician will advise you if further tests should be made.

If a number of family members are tested at the same time for an inheritable blood clotting disease, it could be possible that one of the individuals is found to be not genetically related to the other family members – for example, if a child does not have the same father as its other siblings. Information concerning genetic related-

ness between family members will only be made available to the patient and family members if there is urgent or compelling medical need to do so.

There is always a remote possibility that patient samples could be mixed up during the testing procedures conducted in a medical laboratory. However, many safety measures are taken and cross checks performed to avoid such mistakes.

If you decide you do not want your blood sample to be saved for future use as a laboratory control for samples to be tested from other family members, or for other future use in medical research investigations, your sample will be destroyed immediately after the physician-ordered tests are performed. In this case, it would not be possible to repeat the test at a later date on the same sample, if requested, to reconfirm the original results. Otherwise, samples are typically kept in the medical laboratory until the legal storage time has been reached. The legal storage time depends on the laws of the country where the samples are stored – for our laboratories in Germany, this time limit is 10 years.

Currently, scientific knowledge about the genetic basis of inheritable diseases of the blood clotting system is limited, although we are constantly discovering and learning more about such diseases. State-of-the-art clinical testing sometimes does not lead to finding a concrete cause for blood clotting problems. With your permission, we would like to perform a scientific investigation of the genetic material – the DNA – in your blood sample

in order to learn more about inheritance of blood clotting diseases. It is possible that, in the coming years, we will discover new genes that play roles in clotting diseases and want to further investigate these genes from the sample you are currently providing us. If you wish, we can keep you informed in the event that we discover new genetic factors from your stored blood samples that you and/or your family members may carry and that play a role in blood coagulation diseases. You may also wish to exercise your right to not be personally notified in the event of such findings, even though you may wish that the results from your blood sample be used for continuing scientific investigations and that your actual identity be permanently removed from all further scientific investigations and resulting scientific publications. In this case, all of the data indicating your identity will be permanently removed from your samples – in other words, your samples can continue to be used for scientific investigations, while your identity remains forever anonymous. Should you choose this option, we will follow strict, legal guidelines for insuring your anonymity. You may revoke your decision to allow the use of your blood sample for research purposes at any time and without having to give a reason for your decision. You may inform us that you wish us to destroy your sample either immediately or after the maximum, legally defined storage time has passed.

Your blood sample, and those of your family members, will be used exclusively for investigating and diagnosing only inheritable blood clotting disease genes and their protein products. We are not allowed to perform other laboratory tests on your blood sample that reveal other illnesses, diseases, infectious or other substances that may be in your blood.

Your personal data may be stored in both written and digital (computer) form only for purposes of medical diagnostics. Access to data from your blood sample by investigators and employees working in our laboratory is kept separate from your personal identity (name or other specific identifying information) – no person working with your blood sample will know your identity. In summary, both the physician's sworn oath to patient confidentiality and governmental laws for the protection of stored patient data are in effect to insure that your identity remains confidential at all times after you donate a blood sample.

You may ask for a clarification of your results at any time. You have a right to request a clinical counseling session concerning the results of tests made on your blood samples, and you further have a right to request and receive genetic and/or psychological counseling as a follow-up to receiving your test results.

At any time in the future, you may change your response to any of the questions asked you on the form you sign and date declaring your wishes concerning the use of your blood sample and any information resulting from genetic testing of that sample.

For this purpose, please send your request in writing and signed by you to:

**Prof. Dr. med. J. Oldenburg, Director**

Institute of Experimental Hematology  
& Transfusion Medicine  
University Clinic Bonn  
Sigmund-Freud-Str. 25  
53127 Bonn  
Germany

\_\_\_\_\_  
Patient's Last Name, First Name (printed)

\_\_\_\_\_  
Patient Signature

\_\_\_\_\_  
Date, Location (City, Country)

This Declaration is to be retained by the primary physician to document that proper counseling and notification have taken place and to document the patient's wishes concerning future use of blood samples and data resulting from them.

A copy of this document should be given to the patient, but should not be forwarded to the clinical diagnostic laboratory.