Patient information Radboud Biobank Ophthalmology

Dear Sir / Madam,

With this letter, we would kindly invite you to participate in the Ophthalmology sub-biobank by making your medical data and bodily material available for research. We are contacting you as you are, or have been, treated at our eye clinic or are known to us as a healthy volunteer. Participation in the sub-biobank is wholly voluntary. You are advised to read this letter carefully to learn about the sub-biobank. You may discuss any aspects or questions with your own doctor. We also advise speaking to your partner, family and/or friends about possible participation. It is also possible to consult an independent doctor who is able to answer questions (see last page).

You are or you have been treated at Radboudumc for your eye disease, or you are a healthy volunteer. We kindly ask you to participate in the sub-biobank Ophthalmology by making your body material and medical data available. It is up to you to decide whether you want to participate or not. Before you make the decision, it is important to know more about the sub-biobank Ophthalmology. Please read this information letter carefully. Discuss it with your partner, friends or family. You can discuss any questions you may have with your doctor. There is also an independent doctor who can answer any questions if you prefer not to ask your own doctor. You will find their contact information on the last page.

What is the purpose of the sub-biobank Ophthalmology?
The goal of the sub-biobank Ophthalmology is to improve the diagnosis, treatment and prognosis of patients with eye diseases. The Ophthalmology biobank contains bodily material and specific data from the medical records of participating patients. We use this for scientific research into various eye disorders. The Biobank Ophthalmology is not about one specific research topic, but about several future studies into eye disorders, for which we would like to use your body material and medical data.

This makes it possible to answer different scientific research questions now and in the future from different perspectives and by different specialists conducting scientific research on eye disorders. To conduct the research properly, we also need healthy volunteers. Strict privacy rules apply during storage and subsequent use of data and materials. Your data will be stored encrypted so that the researcher conducting the study will not know which patients are involved.

What do I consent to?
<u>1. Consent to request and use your medical information.</u>
In order to better study eye disorders, we need data from your medical record, such as data about your treatment, now and in the future. Your data are always encrypted before they may be given to the person who wants to use the data for a scientific study. In this way we ensure that the researcher does not find out your identity.

<u>2. Consent for use of residual tissue.</u>
During your visit to the hospital, blood, biopsies and tissue may also be taken from you for diagnosis or during treatment. For example, the material may come from an operation that has already been performed or will be performed on you. Part of this material is used for diagnosis. Usually there is

some material left over. We call the remaining material residual tissue. With your permission, we would like to keep this remaining material and use it for future research. This includes eye tissue, aqueous humor or vitreous fluid that would be removed during a possible operation and could be useful for the research.

3. Permission to take additional body material from you and to take additional photographs (medical imaging) of the eye and the rest of the visual system

Blood. For proper diagnosis and/or treatment, blood is usually drawn from you. We would like to ask you to donate extra blood. During the blood collection, a few extra tubes of blood of about 10 ml, with a maximum of 8 tubes, will be taken for the Ophthalmology sub-biobank. This is a small amount from which you will not experience any physical symptoms. In order to burden you as little as possible, we try to take extra blood when a blood test has already been scheduled, during an operation or via an intravenous drip.

Non-invasive medical imaging of the eye. Extensive imaging of the eye is often performed as part of the regular care of your condition. Research may sometimes require additional medical imaging of the eye outside of regular eye care. The imaging techniques used are non-invasive and do not pose any additional risk.

In subjects where imaging is not done as part of routine care, it may be necessary to use eye drops to dilate your pupils.

Non-invasive medical imaging of the visual system. Not only the eyes play a role in being able to properly perceive images (visual information). Visual information is transmitted through the eye to certain areas of the brain and processed there. The path that visual information follows from the eyes to the brain is called the visual system. Sometimes imaging of the visual system is done as part of the regular care of your condition. Scientific research may require additional imaging of the visual system, outside of regular care. An example of such research is functional MRI. The imaging techniques used are noninvasive and of negligible risk and minimal burden.

4. Non-invasive navigation test of a subject's functioning in a maze

Through medical imaging of the eye, much information is obtained about the functioning of the eye. However, this information does not say everything about the functioning of a test subject in the daily situation, such as, for example, a low-light environment. A subject's daily functioning and mobility can be observed in a so-called visual function navigation test. This test is carried out in a room where a kind of maze is created using mats and obstacles made of foam. The test subject then walks through this, at different light intensities. The speed with which a test subject can complete the maze under a certain light intensity says something about the test subject's visual functioning. For example, a test subject may not cross the edge of the mats in this process. The subject's route through the maze is recorded using cameras, so that afterwards objective measurements can be taken of the subject's functioning in the maze. Each subject will be informed about the duration and purpose of the particular study prior to the navigation test. At any time during the investigations, the subject may indicate his or her wish to stop.

A limited number of subjects participating in the Biobank will be asked to participate in the navigation test. If you are not asked, or do not wish to participate in the navigation test, you may continue to participate in the Biobank as usual.

5. Consent to ask you additional questions through questionnaires

Epidemiological research that deals with the genesis of eye disease takes into account a variety of factors, including those from the environment. Certain behaviors or lifestyles, as well as certain dietary choices and other habits such as smoking, can affect the onset of disease or how the disease responds to treatment. Therefore, we would also like to ask you additional questions that may not be found directly in your medical records. We have submitted the questions we are asking you to an ethics committee prior to this. You are not required to answer certain questions, nor do you have to give reasons for not completing questions.

6. Permission to contact you in the future as well

There may be reason in the future, for purposes of scientific research, to conduct additional or supplementary research that requires more data than we have from you. It may also happen that the body material kept from you runs out and you are no longer a patient at this hospital. Therefore, we ask your permission to continue to contact you in the future to collect additional data or body material. If you consent, you can always refuse to provide additional data and/or body material if we approach you to do so.

7. Permission for linking to existing Dutch public health registration systems

In order to gain more insight into the origin and course of certain eye disorders, we may want to use more data from you in the future. This data may already be available in an existing Dutch health registration system. Examples include pharmacy and GP registrations, the Dutch Cancer Registry (NKR), the Pathological Anatomical National Automated Archive (PALGA) and the Central Bureau of Statistics (CBS; requesting cause of death data). We ask for your permission to request your data from one or more of these existing registration systems. Requesting such data or making the aforementioned link requires a positive opinion from the medical ethics review committee, who will monitor the need for it.

What are possible advantages and disadvantages of participating in the sub-biobank Ophthalmology?

You will have no immediate benefit from participating in the sub-biobank Ophthalmology. Since this is scientific research, no individual conclusions can be drawn from, for example, certain markers in your blood. Any findings only say something about the group and not about you as an individual. Therefore, you will not receive a personal result. However, future research may provide useful data for people suffering from the same condition. You will not be informed about the nature of the research for which your body material and medical data will be used.

Taking pictures of the retina requires the administration of eye drops that make your pupils large. This lasts for about 3-4 hours, and during this period your vision will be somewhat blurred and you will be less able to tolerate bright light. Driving a car is not allowed during this period.

When walking through the maze, there is a risk of falling on a soft surface. You also risk running into soft objects. In addition, you may become frustrated while trying to walk through the maze.

Some scientific research techniques may find something in your genetic material or on the imaging taken that has nothing to do with your condition. Genes that we currently know are linked to a serious

condition, such as cancer, are "covered" during genetic testing. In other words, these are not looked at and therefore these genes cannot be found during genetic testing. There is a chance that in the future, by chance (because we are not looking for them), we may discover new genes related to a serious condition. We call this a collateral finding. The chance is very small that we will find such a finding but we cannot completely rule it out.

Medical imaging is used for scientific research and is not routinely reviewed by an ophthalmologist or radiologist. Therefore, participants should not trust that all is well in the event that no side findings are returned as a result of the imaging taken.

If you or your children, brothers or sisters have a real chance of developing a serious condition (for example, cancer) against which meaningful medical measures are possible, you will be contacted by the Radboudumc.

Knowledge of a secondary finding has the following advantage. Timely medical measures can be taken. This may prevent the condition from occurring or reduce the chance of it occurring. Or it may ensure that the disorder will occur later or to a less severe degree.

However, there may also be disadvantages to knowing about a secondary finding. It can be psychologically stressful to know what health problems one may face in the future**.**

Knowledge of a secondary finding further means that your relatives may find out through you that they may also have an inherited predisposition to the disorder in question. This may have the same advantages and disadvantages for your family members.

Your body material and medical imaging are stored indefinitely. Therefore, it is possible that your body material may reveal a secondary finding after you have died. We will inform your family members about any incidental findings if there is a compelling reason to do so. You can indicate on the consent form if you would prefer that a particular family member will be informed. We assume that the person(s) you name on the consent form is/are aware of this.

Monitoring implementation

Scientific research with your body material will be conducted with care. The Medical Ethics Review Committee of the Radboudumc has approved the sub-biobank Ophthalmology. Any scientific use of material or data obtained specifically for the sub-biobank Ophthalmology requires the positive opinion of this committee.

How is privacy ensured?

All your data are covered by medical confidentiality. Your personal data, such as your name, address and other personal information that can be traced back to you as an individual, will be kept in the hospital where you are or were undergoing treatment, subject to legal regulations. Your personal data will remain known only to your attending physician and hospital administration and will not be given to others. The medical data and bodily materials that may be used for research will be kept under a unique code, in order to prevent any mix-up of data, but also so that whoever is conducting the research or collaborating with you will not have access to your personal data. In some cases, research

may be conducted by universities or commercial companies within or outside Europe. In these cases, Radboudumc will draw up a contract with these parties in which privacy of your data is guaranteed with a security level in accordance with European legislation. The results of the research will be published, for example in scientific journals. Your personal data will never be found therein.

Costs, ownership and collaboration with commercial parties

Your participation in this project involves no additional costs to you. The sub-biobank Ophthalmology is a non-commercial scientific initiative. The owner is the Radboudumc. However, for some research it is important to cooperate with commercial companies.

In some cases, Radboudumc may make body materials (for example, blood samples), or products derived from body materials and non-reducible medical data (such as diagnosis, age and gender) available to commercial companies, for example, to test new drugs. For example, blood cells can be extracted from your blood, and these cells can then be grown in the laboratory under special conditions so that these cells develop into cells that occur in the retina. These cells then possess the properties of cells found in your retina, and these retinal cells can be used to test the effect of new drugs. This is a preliminary stage in research that is very important to further develop new drugs and eventually test them in patients. Commercial companies are also interested in these cells to test their new drugs on. The Radboudumc may receive financial compensation for this, which will be used as compensation for costs incurred and to conduct scientific research. The results from such research can become the property of the company. The results may also be used by the company for further commercial developments, such as patents. All research results benefit health care. You will not obtain ownership rights to the results and you will not be entitled to any future financial benefit. Of course, your rights, which are described in this information, are also guaranteed in the event of commercial collaboration.

Voluntariness of participation

You decide whether or not you participate in the sub-biobank Ophthalmology. Participation is voluntary. If you decide not to participate, you do not have to do anything else. You do not have to sign anything. Nor do you have to say why you do not want to participate. If you are a patient, you will simply receive the treatment you would otherwise receive. If you do join, you can always change your mind and then stop.

What is the importance of the consent form?

We will ask you to sign a consent form. You will sign the consent form in duplicate. This means that you can keep one copy and you can always see what you consented to. You will give the other copy to your doctor at the next outpatient visit. Your body material will be kept indefinitely for the purpose of scientific research.

Contact

If you have any questions about the project after reading this information letter, please contact us at the e-mail address research.ohk@radboudumc.nl. You can also find information about the sub-biobank ophthalmology on the website http://www.radboudumc.nl/deelbiobankoogheelkunde. Would you like independent advice on participating in this study? Then please contact independent

physician: drs. N. Crama, consultant ophthalmologist, Department of Ophthalmology, tel. 024-3614448.

Do you want to withdraw your consent?

Your bodily material and coded medical data are stored indefinitely in the Ophthalmology biobank. Withdrawal from the biobank is possible at any time, without further consequences. You can withdraw your consent by completing a form for withdrawing a previously granted consent and sending it to the Department of Ophthalmology, route 696, Radboudumc, Postbus 9101, 6500 HB Nijmegen. You will also receive this form. You will receive confirmation of receipt of your withdrawal. After receipt and processing of the completed and signed withdrawal form, no new scientific research will be carried out with your bodily material and data. The collected body material and the collected data will be retained for as long as this is necessary for the research for which your body material and data are or have been used.