Patient information Radboud Biobank Rare Diseases (Adult)

(version 2 / January 2019)

Dear Sir/Madam,

You have had, or will shortly attend an appointment with the Department of Genetics at the Radboudumc. Your appointment is related to a question you have regarding the hereditary nature of a specific disease/disorder.

We kindly ask you if you would consider supporting the Radboud Biobank 'rare diseases' by participating in our research. In the Biobank we will be saving biological samples and patient details for an indefinite period. Participation is completely of your own choice.
Before being able to make a decision on whether to take part or not, it is important to know more about the Biobank. Please take the time to read this information carefully and discuss this with your partner, friends or family. If you should have any further questions your case doctor will be happy to help. There is also an independent doctor available to answer any questions if you would prefer not to ask the case doctor. The appropriate information can be found on the last page.

What is the objective of the Radboud Biobank Rare Diseases?

We often see that hereditary factors play a role in rare diseases. The department of Genetics at the Radboudumc has considerable experience in the field of genetic research and are determined to shed more light on the causes of hereditary diseases and disorders. In order to perform high quality and trustworthy research, we aim to collect as biological samples and medical details from as many patients as possible, all of which, will be carefully saved in the Biobank. The researchers at the department of genetics and other scientists in The Netherlands and over the whole world, will be able to conduct research with the help of the Biobank.

The Biobank will enable research into the cause of diseases, insight into the natural course of diseases and the effects of treatment. When dealing with rare diseases, it is of the utmost importance that researchers can save and share biological samples, background information and patient details. The greater the quantity of biological data we have at our disposal, the higher the quality of the research we can do. This is not just about one singular research project, but many future research projects that will also require biological samples and patient data.

What does participation in the Radboud Biobank 'Rare Diseases' involve?

<u>Giving permission for us to have access to your medical records</u>
To better understand the hereditary factors involved in disease, we require not just now, but also future access to your medical treatment records. Your personal information such as name, address and telephone number are not part of the Biobank, they remain in sole possession of the doctors that are treating you, and the hospital administration department. The personal details of Biobank patients are specially encoded.

Giving permission for the use of residual tissue

During an appointment at the hospital, blood, urine, biopsies and tissue samples could be extracted to provide a diagnosis or for treatment, for instance during an operation you might undergo. Part of this tissue is used to help provide a diagnosis. The remaining tissue is something we (with your permission) would like to store in the Biobank.

Giving permission for a one-off blood sample to be taken

For the purposes of diagnosis and treatment, a blood sample will be taken from you. We would like you to provide some extra blood;. During a standard blood extraction that would have already be planned for you, for blood research or genetic research, we would like to extract some extra blood samples for the Radboud Biobank Rare Diseases. The amount of blood is minimal and will be of no cause for any discomfort.

Giving permission to contact you in the future

It might be, that in the future, we require extra data than we already have been able to obtain from your records, in order to perform more in-depth research. This might also be the case in a situation where you no longer receive treatment at our hospital, or that your biological samples are elsewhere.. For these reasons we would like to ask you for your permission to contact you in the future about possible extra medical information and biological samples. Even if you have given us your permission to contact you, our request can still always be declined(for medical information and biological samples) and/or you can decline permission for future contact.

Giving permission for the use of patient photos

During treatment at the hospital, it is common practice to take photos in support of a possible (genetic) diagnosis. The pictures could typically be profile photos but also, for example, photos of hands or feet. When diagnosing rare disorders, it is particularly helpful to compare photos of other patients with rare disorders, enabling the establishment of common denominators or distinct differences. It is for these reasons that we would like your permission to use such photos. We would like to make it clear, that these photos will be handled with the utmost discretion and without any kind of personal details. Such photos will also never be identifiably used in any scientific publications. Should the use of identifiable photos be of value in a scientific publication, you will always first be re-contacted and asked for permission via a separate ‘publication consent form’.

Giving permission for a link with existing Dutch registration systems

To gain more insight into the origin and development of rare diseases, we might need extra medical details in the future. These details could be made available by existing Dutch registration systems for National Health, such as the Dutch Cancer Register (NKR), the Dutch National Pathological Anatomic Automated Archive (PALGA) and the Central Bureau for Statistics (CBS). Any and every link with existing registration systems, must first be approved by the Medical Ethics Commission. It might also be necessary that we ask you or your GP for some extra information about the mental and physical state of your dependent. In these situations, a link to the Base Register for Persons (BRP) might be needed. Any and every link would, once again, first be approved by the Medical Ethics Commission.

What are the possible advantages and disadvantages of participation in the Radboud Biobank for Rare Diseases?

The risks are negligible because participation only involves using residual material/tissue and extra blood samples being taken during standard blood sampling during routine care. You as an individual,

have no immediate advantage by participating in the Radboud Biobank for Rare Diseases. It is however a distinct possibility that your participation will provide invaluable information for other people who suffer from the same disease or disorder. You will receive no information as to the nature of the research involving your biological samples or medical information. The staff, who perform the research, have no access to your personal details. It remains a possibility that during research with your biological samples or medical details, that something is detected that we feel is of importance to your health or that of your family members. Below we have provided a description of this procedure.

Incidental Findings

There is always a possibility that during research, that by coincidence, something is detected that we feel is of importance to someone's health, or to that of their family members. We call these situations 'Incidental Findings'. An incidental finding could for instance point to an increased chance of cancer or heart disease. In the case of an incidental finding, the researchers notify the Biobank. If there is a distinct possibility that you, or one of your family members, are at risk of a serious medical condition, that can be treated by taking medical measures, then the clinical geneticist, who is treating you, will be in contact with you.

Within scientific genetic research into your condition, there are many different research techniques that can be used. Some techniques make it possible to detect incidental findings whereas other techniques do not. You get to choose if you would like to make your medical samples available for scientific research with the possibility of incidental findings or only for those projects that do not. You can mark your choice on the consent form. As it is important to weigh-up the advantages and disadvantages of eventual incidental findings, they are explained below.

The Pros and Cons of Incidental Findings

In order for you to make a well-considered choice, it is important to weigh-up the advantages and disadvantages of having the extra insight provided by incidental findings. The knowledge gained by Incidental Findings has the advantage of enabling timely medical treatments. This might result in the prevention of, or increased chance of prevention of, being afflicted by a serious medical condition. Another possibility is that due to timely medical treatment, a disease is significantly delayed in its effects or the effects could be significantly reduced.

The knowledge gained by Incidental Findings can also have some disadvantages. It can be worrying to know which medical ailments you, or others in your family, are likely to experience in the future. This is especially the case if the current medical treatments only partially help, or have a dramatic effect. Being aware of Incidental Findings entails you informing your family members of the possibility that they can hereditarily have the predisposition for a certain disease or disorder too. This puts your family members in more or less the same position regarding pros and cons.

Information about Incidental Findings in the event of you passing away

Your biological samples will be saved for an indefinite period. That is why it is possible that Incidental Findings can occur even after you are deceased. Incidental Findings in these circumstances could be of great importance for your family members such as brothers and sisters. In the event that we find

a higher risk of a serious condition in your biological samples, it can mean that your family members also carry this risk. This is the reason that Incidental Findings are shared with other family members if you should pass away. The consent form has a section where you can state if you have a preference for which family members should be informed. We assume that you will have informed the family members of them being listed as our contact on the consent form.

Supervision of processes

Scientific research with biological samples is something that is carried out with the greatest care and attention. All existing European and Dutch rules and regulations are abided by and subject to approval by the Medical Ethics Commission of the Radboudumc on a project-by-project basis.

How is privacy protected?

All the records and personal details belonging to you are subject to medical ethics and bound by the laws of confidentiality. The medical records and biological samples that might be used for research are saved using an unique code making it impossible to confuse or switch files. The code makes it equally impossible for any of the medical institutions or medical professionals who we do research with, to see any of your personal details. The results of our research could be published in medical journals but cannot be connected to any and every link to your personal details.

Costs, ownership and corporate collaboration

It goes without saying that your participation in the Biobank involves no extra costs. In some fields of research it is imperative that we work together with private companies. A good example of such collaborations is the development of new medicines. The results that arise from these collaborations could become the property of the private company. All results from our research will benefit the healthcare system. There are no circumstance that you could make a claim to financial reward for future developments. Just as we have described in this information, your rights and utmost privacy are protected in line with European and Dutch legislation.

Sharing Information with third parties

Your biological samples and coded medical details might also be shared with researchers in countries outside the European Union. The countries outside the EU do not have the same data protection laws as the EU. In these cases we facilitate a written contract that clearly states that any researcher/research institute in a non-EU country will guarantee your rights and level of privacy protection as previously explained in this brochure. As previously stated, every piece of scientific research using biological samples and personal details, must first be approved by the Medical Ethics Commission.

The Radboudumc has a data protection administrator who can be contacted for any questions you might have (gegevensbescherming@radboudumc.nl or Radboudumc, GDRP officer, internal post number 624, postbus 9101, 6500 HB Nijmegen). In the event of complaints, you can contact the Dutch Personal data authority.

Freedom to participate

It is completely your own choice to decide on your participation in the Radboud Biobank Rare Diseases. If you decide you would not like to participate, then you do not need to take any further action. Obviously, a refusal of participation will never impact your treatment and care: You will receive diagnostic opportunities, treatment and care as normal. You can always reconsider a decision and withdraw consent after initially agreeing to participate.

What is the importance of the consent form?

Should you grant consent, then we ask you to complete and sign the consent form in duplicate. One copy is for your own administration, this way you can always re-read what you have consented to. Your participation in the Biobank is indefinite, but you may withdraw consent at any moment of your choice, without consequences. Should you choose to withdraw consent, then you only have to sign a 'withdrawal of consent' form.

The Medical Ethics Commission of the Radboudumc has given its approval to the Biobank Rare Diseases. Every time that biological samples or medical data are requested, the Medical Ethics Commission must first give its seal of approval.

Submitting your consent

The consent form that you have filled-out, can be handed over to your case doctor or send by mail, using the enclosed envelope.

Withdrawing your consent

The biological samples used for scientific research will be saved indefinitely. You are free to withdraw your consent at any time. You can do this by filling out the withdrawal of consent form and sending it to 'Datasteward Biobank Genetica, afdeling Genetica (836), Radboudumc, Postbus 9101, 6500 HB Nijmegen'. You will receive conformation of your withdrawal of consent. Following withdrawal of consent, your biological samples present in the Biobank will be destroyed and will never again be used for new scientific research projects. Any medical information that has been gathered up to your withdrawal of consent, will, however, be saved.

Extra Information

In the event that you might have any extra questions or enquiries about the Biobank then feel free to get in touch with your doctor via this telephone number: +31 (0)24-3613946. In the event you would like independent advice on participation in this research we can bring you into contact with and independent doctor. You can contact Prof. Dr. M.A.A.P. Willemsen (professor of Child Neurology) via phone number +31 (0)24 3614430, or Prof. Dr. M.G. Netea (professor of Experimental Internal Medicine) via phone number +31 (0)24 3614763.

Finally, we would like to sincerely thank you for taking the time and effort to read this information. We hope that it helps you in making a careful and well-considered choice regarding your participation in scientific research into rare diseases.

Prof. Dr. H.G. Brunner
Head of Department of Human Genetics

☐ ID ☐ Onco ☐ Cardio ☐ Other, being…

Consent form Radboud Biobank Rare Diseases (Adult)

I am satisfied with the explanation and background information given to me regarding the aims of Radboud Biobank Rare Diseases and my making available of my biological samples and medical records. I have received and read the information letter about the Radboud Biobank Rare Diseases (version 2 / January 2019) and I have *been* given ample opportunity to ask any questions I might have. I have had enough time to carefully consider my decision to participate in the Biobank.

I give my consent to the extraction of, and provision of, biological samples and coded medical records to the Radboud Biobank Rare Diseases in the ways, and for the aims as described in the information letter.
O yes O no

I give my consent to research with the possibility of Incidental Findings, and the results and feedback provided by Incidental Findings.
O yes O no

In the event of my passing away, any Incidental Findings deemed of medical relevance may be conveyed to following person / persons.

Name : . . . . . .
Relation: child / partner / brother / sister (please encircle which is applicable)

Contact details:
. . . . . .

. . . . . .

Name : . . . . . .

Relation: child / partner / brother / sister (please encircle which is applicable)

Contact details:
. . . . . .

. . . . . .

I give my consent to extra biological samples / medical records being made available in the event that it is deemed necessary for extra research.
O yes O no

I give my consent to the use of patient photos during the research.
O yes O no

☐ ID ☐ Onco ☐ Cardio ☐ Other, being…

I give my consent to the linking of existing Dutch registration systems as described in the information letter.
O yes O no

I give my consent to request my eventual cause of death by contacting the Central Bureau for Statistics.
O yes O no

Signature and Date

Surname and Initials patient:

Date of Birth:

Signature: Date: __ / __ / ____

I hereby declare that I have fully informed the patient of all the details of the research.

Name doctor/nurse:

Signature: Date: __ / __ / ____

Form for withdrawal of consent for participation in the Radboud Biobank Rare Diseases

I hereby declare my withdrawal of consent for participation the Radboud Biobank Rare Diseases.

After receiving and processing the signed and completed withdrawal of consent form, no new scientific research may be performed with the use my biological samples and/or medical records. Any collected biological samples and medical records will be saved for as long as it is necessary for research that is currently using them or has used them.

I fully understand that after the withdrawal of my consent for participation, that I can still be informed of any Incidental Findings by the case doctor. This is the case if I have previously provided consent for research with a possibility of Incidental Findings and in research that has already been performed and where Incidental Findings* were found.

* I understand that Incidental Findings refer to the risk of a serious medical condition, that can be intervened by taking medical measures.

Name: _____

Date of Birth: _____

Date: _____

Signature: _____

You are by no way compelled to give any reason for the withdrawal of your consent, but we would appreciate any and every sort of feedback. With your information and feedback regarding withdrawal of consent we can improve our processes regarding the Biobank.

Reason for withdrawal of consent:

_____