Region Hovedstaden

Informational letter to former and current patients in Region Hovedstaden

We are contacting you because you have had a blood sample taken in relation to treatment at one of the hospitals in Region Hovedstaden within the last eight months.

After analysis, the rest of your blood sample has been stored in Copenhagen Hospital Biobank (Region Hovedstadens Biobank). The purpose of the biobank is to use the blood samples for research in diseases in the population, and thereby contribute to new medical knowledge and develop better treatment for patients. You were informed that residual blood samples may be kept for research purposes in your hospital appointment letter, along with additional information on your patient rights.

Your blood sample has *not yet* been used in a specific research project, but it is likely to happen in the future. With this letter, we wish to inform you about your options regarding the storage and use of your respective blood sample.

Research on blood samples from Copenhagen Hospital Biobank

- The blood samples in Copenhagen Hospital Biobank are used for genetic research in e.g., cardiovascular diseases, arthritis diseases, infertility, osteoporosis and pain conditions.
- The research is carried out in collaboration with the company deCODE genetics in Iceland.
- In very rare cases, genetic research leads to the discovery of gene variants with a high risk of disease. If this happens, we will contact you. We will only contact you if the gene variant is very serious and the disease can be prevented or treated (read more below under incidental findings).

The Danish Health Act allows samples taken in connection with examination and treatments to be stored in a biobank. All research projects that use biobank samples must be approved by the National Scientific Ethics Committee and comply with the Danish Act on Data Protection (Databeskyttelsesloven) as well as the EU data protection regulation, which is set in place to protect personal data. On the next page you can read more about genetic research and how we safely take care of your data. On our website www.regionh.dk/biobank (in Danish) you can read more about our research and watch videos about selected research projects. You can also find answers to 'frequently asked questions'.

- ***If you <u>agree</u> to our use of your blood sample for research, you do not have to take any action.***
- ***If you <u>do not</u> wish that we use your blood sample for research, you can at any time contact us and have your sample destroyed.***

If you have questions or wish to have your blood sample destroyed, you can write to us via secure digital mail
Click here to send a Digital Post to Copenhagen Hospital Biobank via borger.dk (login with MitID)
or find the link at www.regionh.dk/biobank
You are also welcome to contact us by telephone (+45) 35 45 35 55 on weekdays between 10am-2pm

Tissue Utilisation Register (Vævsanvendelsesregistret)

As a patient, you have the right to decide that your blood samples *in general* only can be used for medical treatment of yourself and never be used in research, neither in Copenhagen Hospital Biobank nor other studies. If you choose this, you must register such a decision in the 'Tissue Utilisation Register' which is administrated by The Danish Health Data Authority. Registration to the Tissue Utilisation Register can be done at https://www.sundhed.dk/borger/sygdom-og-behandling/donation/brug-af-vaevsproever/ or the form can be requested by calling (+45) 33 32 60 06 (Wednesday and Friday from 10 a.m. to 12 p.m). Your decision has no consequences for your current or future medical treatment.

Sincerely,

Erik Sørensen, Biobank leader

Sisse Rye Ostrowski, Professor

Genetic studies

In research projects that use blood samples from Copenhagen Hospital Biobank, we are particularly interested in differences in the human genetic makeup (genes, DNA) which may explain some of the causes for disease. The human DNA contains approximately 20,000 genes. We carry the genes with us our whole lives, and therefore information about our genes are different from most other health data as these typically explain only the current health state of a person. There are variations in the genes of all humans. Sometimes these variations cause disease or elevated risk of disease. A genetic disease occurs if one or several genes do not operate normally. Changes in a gene, also referred to as a variation or mutation, can either be newly emerged in an individual or genetically inherited from one or both parents.

Previously it was only possible to study one or a few genes at a time. It could therefore take many years to detect the genetic cause for a hereditary disease. It is now possible to examine all the human genes at the same time, with the so-called 'extensive genetic testing'. This kind of research is expected to result in new knowledge that can enable a more targeted treatment for the individual patient, which is beneficial for the overall public health.

In the research projects that use samples from Copenhagen Hospital Biobank, the National Scientific Ethics Committee has granted permission to perform this kind of 'extensive genetic testing', where the genetic make-up is examined for genetic variations. This research is carried out in collaboration with the Icelandic company deCODE genetics and follows Danish and EU legislation.

Incidental findings

It is important to emphasize that the studies are research projects and not patient studies as part of ordinary medical treatment. In principle, we do not expect the included patients to benefit personally from the study, and they will therefore not receive feedback on findings in the genetic studies. If your blood sample is selected for extensive genetic testing, unforeseen knowledge may emerge. Thus, in very rare cases, we can find a genetic variant that are associated with severe hereditary disease. Genetic findings that researchers have not looked for are called 'incidental findings'.

If we in a research project make an incidental finding, we will handle it according to the guidelines from the National Scientific Ethics Committee. This means that in such rare cases we will contact you and inform you of the incidental finding if the found gene variant can cause serious illness that can be prevented or treated. Because of the heredity, such a finding could also have an impact on your family members. If necessary, we will also help in the screening of your relatives - but only after it has been thoroughly discussed with you.

Please note that we do not offer a systematic genetic review of your genes for all known diseases. We will *only* contact you if we during our research incidentally find serious genetic changes in your genes.

Your data security -confidentiality and professional secrecy

We are handling your personal data with complete confidentiality and your data is only used for scientific research purposes. There are very strict security demands for handling your data and to our duty of confidentiality. This ensures that scientists can only gain access to data on a level where it is it impossible to identify the unique patient (pseudonymized data), and patients are unidentifiable in the scientific reports that are published.
The specific genetic testing is done in Iceland. Data is treated in compliance with Danish and EU legislations.
Data is stored in accordance with the Danish Act on Data Protection and EU's General Data Protection Regulation.

We thank you for taking the time to read this letter. We hope that you are now informed about Copenhagen Hospital Biobank and the research based on it. If not, you are welcome to contact us, by using the contact information found at the beginning of the letter.