

Information document about

the re-use of encoded biological material and medical data for a research project (Art. 29 HRO)

Dear reader

- **Who we are:**

We are [employees of the hospital, institute ... /...]

- **Why we are contacting you:**

We are writing to invite you to help medical research.

As part of your medical treatment, you might give physical material such as blood or urine, or your doctor might take a small piece of skin or other tissue from you. You might also have an examination that produces genetic data (for example, whether you have a genetic predisposition for a certain disease). We would like to re-use this physical material and genetic data for medical research once it is no longer needed for your treatment.

We are therefore asking you to allow your doctor to send us this physical material and genetic data for research purposes in encoded form.

- **Donors' rights**

You should only release your physical material and data for re-use in research if you wish to do so. Nobody may force you to do so in any way, or attempt to persuade you. You do not have to give reasons for refusing.

If you decide to release material and data, you can change your mind at any time. You do not have to give reasons for withdrawing your consent.

- **Confidentiality**

We will use your physical material and genetic data in encoded form. That means that the material and data will be labelled with a number. We will not be given your name, address, exact date of birth or similar details. The key – i.e. the list linking the number to your name – is kept securely at

...

Only [name of the individual(s), the custodian]

...

is/are permitted to see this list. It is therefore impossible for third parties to connect the physical material and data to you. We ourselves are only permitted to de-encode the material and data in clearly defined cases:

- if it is necessary to protect your health or your rights (for instance, because you want to withdraw your consent), or

- if required by law, for example in the context of the investigation of a crime.

If any such request is made, we will pass on your material and data to third parties in this encoded form. However, the key will continue to be held by [the designated body / the persons named]. The recipients of your material and your data are also only permitted to know that they come from you in the aforementioned cases.

**Declaration of consent for the
re-use of encoded biological material and medical data for research purposes (Art. 29
HRO)**

Surname and first name of the patient/person concerned:

Date of birth:

I hereby consent to biological material taken from me and genetic data about me that have been obtained as a result of medical treatment or otherwise being re-used in encoded form for research purposes.

I confirm that

- I have received the information document relating to this declaration of consent.
- I have been told that my consent is voluntary.
- I know that I can withdraw this consent at any time without giving reasons.
- I know how my material and data are protected.
- I know that my material and data can be passed on to third parties for research purposes.

Place, date, legally valid signature of the patient / person concerned or his / her authorised representative.

Place, date, legally valid signature of the person giving the information