Clinical trial information is critical to ensuring that your research is conducted correctly from a scientific and legal point of view. It needs to be drawn up conscientiously and carefully by an expert. It must be redrafted for each project so that it reflects the specific requirements in each case.

Information document about the re-use of unencoded biological material and genetic data for a research project (Art. 28 HRO)

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Title of the clinical trial
= concise title or abbreviation in the participants' language and official full version of the title of the clinical trial.

Sponsor (without logo): …

Dear reader

- **Who we are:**
  We are (employees of the hospital, institute ... / my name is ..... I am in charge of the .... project)

- **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 our research project, 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 our research project in unencoded form. "Unencoded" means that you can be identified by this data.

- **General information on the research project**
  This section should contain a summary of the most important information: Nature, purpose, duration and practical details:
  - Background information, national/international project, purpose of the project,
  - project design, in particular reference to the fact that data will be used in unencoded form;
  - State the total duration of the project (weeks/months) and the approximate number of donors, both locally and in total,
- **Donors’ rights**
  - You should only release your data and physical material for re-use 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 this decision.
  - [Consequences of withdrawing consent]
  - You can ask any questions you like about the research project at any time. To do this, please contact the person named at the end of this information document. You can also contact other people working on the project.

- **Research results**
  We will be happy to give you all the results from the research project that relate to you and your health if this is possible*. However, if you do not want to know the results you can instruct us not to tell you. Alternatively, you can ask for the results to be given to a person of your choice.

  So we would like to ask you to decide beforehand:
  - Do you want to know the results?
  - Do you not want to know the results?
  - Do you want us to give the results to a person of your choice? (for instance, relatives, friends, your GP, etc.).

  *There are also results that are of no significance to individual patients or that do not allow any conclusions to be drawn with regard to health or treatment. In these cases we cannot give you any information.

- **Confidentiality**
  We will treat your data and physical material in strictest confidence. They will be handled only by people working on the project who really need your data and physical material for their work. We will not pass on your data or physical material to anyone else without your consent. In particular …

  (explanation of specific measures, storage location, access rules etc.)

- **Research project funding**
  Most / three quarters of the project funding is provided by:
  Institution
  Address

- **Contact(s)**
  If you have any further questions about our project, please contact
  Xy

  You can also contact any other person working on the project.

  Advice centre: (if applicable)
  If you would like to contact an independent body not involved in the project, you can contact:
  ………
  This body is not connected with us researchers in any way. It will treat your questions in the strictest confidence.
Declaration of consent for the re-use of unencoded biological material and genetic data for a research project
(Art. 28 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 unencoded form for research purposes.

I understand that as a donor, I have the right to be informed about research results concerning the state of my health.
My choice: (PLEASE CHECK ONE)

☐ I would like to be informed. ☐ I would prefer not to be informed.

☐ I would like the following person to be informed. (NAME, CONTACT INFORMATION)

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