EUROBIOBANK

European Network of DNA, Cell and Tissue Banks for Rare Diseases

Informed Consent Form

Updated: 11 may 2007

Title of the research project
"Setting up of a Rare Diseases biological samples bank for research"

Purpose of the research
The scientific advances on human genome developed in the last years are leading to substantial changes on how to approach treatments in many diseases and, at the same time, they are opening new perspectives in the field of scientific research.

Likewise, current techniques and those to be developed in the future might help us understand these diseases better and consequently improve treatments that allow healing of the ill.

This is why our intention leads to the creation of a biological samples bank for an easy access to quality human biological resources for rare diseases that allow the development of specific research and diagnostic tools, as well as, new therapeutic methods for patients suffering from rare diseases.

However, we will not be able to reach this goal if patients and their relatives do not donate blood, tissue samples to be stored, preserved in appropriate conditions and used for further research.

Procedures
If you agree to participate in this project, a sample of: *(specify: Blood, tissue...)* will be stored and information on it will be entered in a database available to all EUROBIOBANK researchers.

It is our aim to develop this activity with the respect due to individual rights in accordance with the internationally accepted ethical rules, ensuring you that all the research to be carried out will be under the supervision of an Ethical Committee, that will ensure the observance of the mentioned regulations.

For the above reasons we request your voluntary collaboration.

Access to your medical record
The research team might require for the development of the research to have access to your medical records to get information necessary for the execution of the project.

Identification of the sample
We will preserve the confidentiality of the samples that will be marked with a code. The samples will be stored, coded in……..and anonymously handled by the researchers, but the donor could be identified through a code which access will be restricted to the person in charge of the bank, thus the samples will be anonymously handled by the researchers. De-codification will only be made by the

principal investigator *(specify: Name)* or by a person expressly appointed by the researcher.

Length of storage
Samples will be kept for an indefinite period at *(specify: institute, research institute, center or biobank)* under the responsibility of (researcher or person(s) responsible for the bank).

Samples use
Coded samples will be used in other research projects that count with the approval of an Ethical Committee. May we have your permission to keep your sample and use it in other research projects?

YES/NO

If YES, express your preference.

A new consent will be necessary for the use of your coded sample in other research where main objective is other different for which the consent was originally sought.

YES/NO

Could your sample be used in those investigations that involve delivery of samples to other researchers, including those outside this institution?

YES/NO

Benefits
This is an altruistic donation, therefore no economic compensation should be obtained by the donor. However, we expect that results obtained from its use will enable us to improve the knowledge on this kind of disorders and finally may result in useful benefits for society as a whole.

OR

This is an altruistic donation, thence no economic benefit should be obtained by the person who donates his/her blood sample.
Information gathered may be useful for you or your relatives. On the other hand, we hope that the results obtained from its use will enable us to improve the knowledge on this kind of disorders and finally may result in useful benefits for society as a whole.

Physical risks
(*Possible physical damage related to sample extractions should be described).*
For example, in blood extractions:

Although the taking of the blood sample causes no serious problems for most people, it can cause some bleeding, bruising, and/or discomfort at the injection site.

Confidentiality
The creation of a biobank means the existence of a file containing his/her personal and medical data and this file will be governed by the regulations on data protection (*specify local law*). Both the information gathered from you and research results will be confidentially treated. The information will be *(describe*

safety systems to be applied according to the local legislation, if any: codified, clustered, locked…).

Data obtained will only be published in an anonymous and aggregated way, that is to say, as percentages or numeric al data without identification of the participant, never in an individualized way to prevent his/her identification.

Third-party access to the results. Unless you have provided specific authorization your personal results will not be made available to third parties such as employers, governmental organizations, insurance companies or educational institutions. This also applies to your spouse, other members of your family and your physician.

Communication of the results
In the case of scientifically validated results with possible impact for your health and where preventive measures or treatment are available, would you like to be informed through a physician?

- ☐ NO
- ☐ YES, in all cases even if no further treatments or preventive measures are required
- ☐ YES, but only if the results allow the application of a treatment or preventive measure.

Freedom of participation and right of withdrawal
Participation in this project is voluntary. Law of Data Protection grants the right of access, the donor's right to rectify or withdraw. Should you wish to withdraw your data or your samples from the laboratory you will be free to do so without further explanation. You should get in touch with the operator in charge of the laboratory.

Resource persons
Should you need additional information regarding the progress of the research project or wish to communicate any change of address to us, you can contact *(name, designation/position and availability*) at the following phone number: ……..……

Final words
Dr (name) …… explained the nature and the progress of the research project. I have fully understood the consent form and have received a copy. I have had the opportunity to ask questions that have been answered. Upon reflection, I agree to participate in this research project.

Signature of Principal Investigator:
Name:
Surname:
Address:
Telephone:

I will inform the principal researcher of any change of address.

Signature of participant or his/her legal representative:

Date: