RETT DATABASE NETWORK

Informed Consent Form

Updated: 08 March 2010

Title of the database network
"Rett syndrome Database Network"

Purpose of the database
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 Database Network for an easy access to quality human clinical resources for Rett syndrome that allow the development of specific research and diagnostic tools, as well as, new therapeutic methods for patients suffering from this rare disease.

However, we will not be able to reach this goal if patients and their relatives do not consent that their clinical records will be stored, preserved in appropriate conditions and used for further research.

Procedures
If you agree to participate in this project, clinical records concerning your family will be stored and information on it will be entered in a database available to all RETT DATABASE NETWORK 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 database.

Identification of the record
We will preserve the confidentiality of the records that will be marked with a code. The information will be stored, coded and anonymously handled by the researchers, but the participant could be identified through a code which access will be restricted to the database administrator and the person responsible for the local database. Thus the records will be anonymously handled by the researchers. De-codification will only be made by the database administrator *(prof. Alessandra Renieri)* or by a person expressly appointed by the researcher.

Length of storage
Clinical information will be kept for an indefinite period at http://www.rettdatabasenetwork.org under the responsibility of the person responsible for the local database.

Data use
Coded information will be used in other databases that count with the approval of an Ethical Committee. May we have your permission to keep your data and use it in other databases?

YES/NO

If YES, express your preference.

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

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.

Physical risks
No physical risks are expected.

Confidentiality
The creation of a database 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 policy (HBGRD Human Biobanks and Genetics Research Databases guidelines). Both the information gathered from you and research results will be confidentially treated. The information will be codified according to HBGRD Human Biobanks and Genetics Research Databases guidelines.

Data obtained will only be published in an anonymous and aggregated way, that is to say, as percentages or numerical 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 participant to rectify or withdraw. Should you wish to withdraw your data from the database you will be free to do so without further explanation. You should get in touch with the person responsible for the local database.

Resource persons
Should you need additional information regarding the database network or wish to communicate any change of address to us, you can contact the person responsible for the local database *(name, designation/position and availability*) at the following phone number:_____
_____

Final words
Dr (name) …… explained the nature and the progress of the Rett database. 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 database.

Signature, name, date

Name: _____

Surname: _____

Address: _____

_____

Telephone: _____

I will inform the person responsible for the local database of any change of address.

Signature of participant or his/her legal representative: _____

Date: _____