

13. Appendix

A. Patient/Companions Information and Patient Informed Consent

Participant Information

Name of study: Registration for participation in the European Huntington's Disease Network ('REGISTRY').

Dear Participant

You are either suffering from Huntington's disease (HD) or belong to a family at risk for HD. The clinician treating you has asked you whether you are willing to participate in a study which aims to recruit people with HD across Europe. This will enable you to enrol in studies relating to the natural progression of HD and interventional studies aimed at delaying this progression. Therefore, it is important that you are interviewed and examined by experienced clinicians in order to record how much, or how little, you are affected or impaired by HD. The results of the examinations will be entered onto an electronic database which is available to the network. Your name, address or any other information which could allow personal identification will not be recorded in the database. Your data will be 'pseudonymised', i.e. recorded under a 'code name', which is a series of 9 digits. Therefore, nobody but the clinicians treating you know your identity (for a detailed explanation see page 3: 'Information regarding data processing, data protection and data safety').

The European Huntington's Disease Network (Euro-HD Network) is a network supported by an American charity ('High-Q') and is in the process to build up an electronic database of patients with HD and their relatives. The aim of the network is to carry out clinical research into HD, to improve knowledge of the natural course of the disease, and facilitate the recruitment of suitable candidates for future pharmacological studies. Your consent relates solely to the electronic registration of your data; any further research requires the provision of subsequent details and your explicit written consent.

At each clinic examination, your physical and mental ability will be assessed by clinicians; these examinations are no different from those you are already familiar with from previous consultations. In addition, you will be asked to complete questionnaires assessing your wellbeing. Relatives or individuals involved in the care of HD patients will be asked to complete questionnaires relating to both the possible economic consequences of HD and their estimation of the level of care needed for HD patients.

There are no specific risks arising from your participation in the study given that it is an observational study. If you are willing to participate it is important that you (and a person accompanying you) attend a follow-up examination at least once a year.

Data entry and the use of this database will be carried out using the internet. The database is held at Central Coordination, Ulm University, Ulm, Germany. To ensure that nobody other than the clinician treating you can trace back your identity, any details which could identify you are not saved on the database.

To enable the clinician treating you to separate your data from your identity, a pseudonym will be given during study registration under which your data will be recorded ('pseudonymised') (see section 'EURO-HD Network: information regarding data processing, data protection and data safety' below for issues relating to data security, for example, the reassurance that only

authorised persons have access to the data and that there can be no mishandling of data during communication via the internet).

In addition to the use of the website for data storage, there are chat rooms that enable patients and relatives to contact other people affected by HD (anonymously if you wish).

Evaluation and publication of study results will be carried out anonymously and in the form of statistics. As a result, none of your personal data will ever be made public.

VOLUNTEERING

Your participation in this research project is voluntary. You are free to withdraw from the study at any time and without giving reason. This potential withdrawal does not affect your continuing medical treatment.

INSURANCE

Because `REGISTRY` is neither a pharmacological study nor a study to test new diagnostic procedures, there are no additional health risks and the participants therefore do not need insurance.

CLINICIAN CONTACT

Should you have any questions at anytime during the course of the research project you can reach (*local investigator*) on telephone number (*telephone number of local investigator*) at any time during working hours. For emergencies out of hours, ring (*local emergency number*).

CONFIDENTIALITY/DATA PROTECTION

All clinicians and related medical staff involved in looking after you during this clinical study abide by medical confidentiality and are obliged to comply with data protection.

Research results relating to this study are intended for use in an anonymous form in scientific publications.

As far as is necessary for ensuring correct data entry, authorized individuals (e.g. the sponsor, the university) are permitted to review your medical records.

If individuals authorized to view records are not bound by medical confidentiality as mentioned above, personal data that come to their attention during checks are confidential under the Data Protection Act.

Place; date

Name of the consenting clinician

EURO-HD-Network:

Information regarding data processing, data protection and data security.

An essential safety aspect of the project is the processing of my data in an exclusively pseudonymised manner. What does that mean and how is it carried out?

During your first visit, your clinicians will enter certain data about you into the computer. From these personal data a unique code name ('pseudonym') is calculated, consisting of a series of 9 digits. The following personal data are used: first name, birth name (surname), date of birth, place of birth and mother's maiden name.

Example:

Maria, Miller nee Mustermann, born 10.11.1964 in Ulm, mother's maiden name Schmidt.

This information generates the code ('pseudonym'): 425-491-326.

Importantly, the pseudonym is created on the basis of a hash-algorithm. This is where a unique value is assigned during a complicated procedure. The mathematical algorithm ensures that this can only take place in one direction, i.e. the resulting value (the 'pseudonym') cannot be traced back to your person by anybody (not even the system programmer).

The personal data transmitted during the registration process are held only for the calculation of the pseudonym for a short time in the memory of a large computer ('server'). Viewing personal data during this time is impossible. These data are then erased so that no identification details remain. Following this, all data entry and use of data is exclusively carried out under the assigned pseudonym.

Which data do I have to reveal apart from the registration data in the course of the Registry study and subsequent studies?

During the course of the Registry study, some health and/or medical data will be recorded as well as your personal details (see Participant Information Sheet for further details). If you are participating in any subsequent studies, your clinician will give you detailed information about the study and the data required for it accordingly. Each subsequent study requires separate patient consent.

Who can see and use my data?

1.You

if you wish, you can gain access rights with which you can call up your data. If you don't have access to your stored data, you can view the data stored about you through the clinician treating you.

2. The clinician treating you

As your contact with the EURO-HD Network, the clinician treating you locally is the only person apart from you who can link your pseudonym and personal details. After the initial registration, however, data entry and viewing by your treating clinicians is carried out via the pseudonym assigned to your person.

Your clinician can use your personal information to contact you as and when future studies arise for which you are a suitable candidate.

3. EURO-HD staff

EURO-HD staff analyse your stored data in order to: 1) contact the treating clinician and 2) to co-ordinate projects with the data. EURO-HD investigators can only view and use pseudonymised data entered on the EURO-HD network.

For the purpose of data control, investigators of the EURO-HD-Network ('monitors' and 'auditors') are allowed to check with clinicians treating you that the data entered onto the network matches with the data found in your medical records. Naturally, monitors/auditors are bound by confidentiality during this, and no personal data will be recorded outside the documentation belonging to clinicians treating you.

4. Scientists

This only includes scientists who are involved in Huntington's disease research. The scientists have to apply to the Board of Directors (a group of eight experienced clinicians and scientists) for authorisation to use the data. These scientists can only view and use the pseudonymised data. They are also required to ensure that any further use of the data and any publications are carried out in an anonymised form (i.e. not even using the pseudonym).

5. System Administrators

In order to safeguard the EURO-HD-Network central database, a small number of authorised system administrators can view pseudonymised data.

6. Other groups and Individuals

No-one other than the groups and individuals mentioned above can gain access to or receive the data stored about you.

What reassurance do I have that unauthorised individuals cannot gain access to my data via the Internet?*

During data entry, the data processing is encrypted. The server where the database is stored is located behind a 'firewall'. This sophisticated security system ensures that only authorised computers and individuals can access the database. Furthermore, the central database holds no record of your personal identity as it is pseudonymised).

How long is my data stored for?

All data will remain stored for the foreseeable future. A complete deletion of data is impossible because the data is likely to have become part of a scientific study. The reason for this is because the researchers responsible have to be able to prove that the relevant study was carried out in accordance with regulations, even years after the research was completed. Alternatively, complete anonymisation can be carried out in the following cases:

- If you withdraw your consent for participation in the entire project and request that your data is anonymised.
- If you withdraw from participation in a particular study and request complete anonymisation of past data relating to that study.
- If you did not participate in any study for at least 10 years (excluding Registry).
- 10 years after your death

Following anonymisation, data can never ever be linked to your person.

Location, date

Name of the informing clinician