



Sample text

for the donation, storage and use of biomaterials as well as the collection, processing and use of data in biobanks recommended by the German Working Group on Medical Ethics Committees according to decision of 11.09.2013

Letterhead (contact person / address) of EEBB:

Professor Ingmar Blümcke
Director of the Institute of Neuropathology
University Hospital Erlangen
App. no. 26031
E-mail: bluemcke@uk-erlangen.de

Letterhead (contact person / address) of Epilepsy Center Erlangen:

Patient information

Dear patient !

You are currently treated at the (please specify name of hospital, city and state). The hospital supports the European Epilepsy Brain Bank, hereinafter referred as EEBB, which is a biobank at the University Hospital Erlangen in Germany. The EEBB is a collection of human biomaterials, such as blood, cerebrospinal fluid and brain tissue linked to selected medical data about the patient's epileptic disorder, in order to support and promote scientific research.

Scientific analysis using stored human biomaterials is becoming increasingly important in medical research. Therefore, we ask our patients whether they are willing to donate tissue and data for this research study. Your participation will be voluntary. You will have no disadvantage if you do not want to participate or withdraw your consent at any time.

With the following paragraphs, we will inform you about the goals of EEBB, the procedures and measures for the protection of your privacy. This will allow you to build your own opinion and to take your own decision.

Please do not hesitate to ask us any questions about the research or about this form. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a copy of this form to keep.

For further information, you can also contact Prof. Dr. Ingmar Blümcke, director of the Neuropathological Institute of the University Hospital Erlangen and director of EEBB at any later time point (phone +49-9131-8526031; fax +49-9131-8526033; Email: bluemcke@uk-erlangen.de).

1. Why is this research study being done (objectives of the EEBB)

The European Epilepsy Brain Bank (EEBB) is a consortium of European epilepsy centers and supported by the European Union aiming to better diagnose and understand the structural and molecular cause of epilepsies. For this purpose, standardized diagnostic procedures will be applied for the analysis of surgically resected brain samples by means of light, laser scanning or electron microscopy to detect cellular changes by using antibody stainings, electrophysiological measurements or cell culture experiments and to identify causally involved molecules and genes. We will also apply genetic and epigenetic research technology to study DNA or other components of brain and blood samples, including the entire human genome. This information will help us to understand which genes are involved and how they interact with environmental factors during development and progression of epilepsy. Research findings will be correlated with your medical data stored in a controlled-access database with a double-encoded pseudonym to protect your privacy. The information in this database will be available only to researchers from the EEBB, in order to gain insights into the cause and the course of your epileptic disorder. This knowledge will open new strategies for the development of better therapies in the future.

2. What kind of biomaterial and data will be stored?

Biomaterial refers to any tissue, blood and cerebrospinal fluid taken during your hospital stay for the purpose of disease examination and/or treatment, if such tissue probes will be no longer needed and otherwise destroyed. We will also ask for additional 10 ml of venous blood. Your clinical data collection will include selected information about your person (age, sex) and medical history such as age at epilepsy onset, duration of disease, diagnostic procedures and current as well as previous treatment regimens. In addition, we will collect information about structural abnormalities histopathologically identified in brain (if tissue from surgical resection is available), and whether similar changes/disease histories have been recognized in your family.

3. Use of biomaterials and data?

Available biomaterial and data will be used exclusively for the study of epilepsy or other diseases related to the central nervous system. However, it is not possible to consider all medical and research questions at present time. We will apply, therefore, under certain circumstances also genetic investigations including your entire genome from brain tissue and blood specimens. Biomaterial and data will be stored for unlimited time at the EEBB for medical research purpose only. You have the right to specify individual limitations (eg the exclusion of certain research procedures, or distribution of biomaterial to third parties).

4. What are risks and possible discomforts from being in this research study?

a) Health risks:

Since we use only biomaterial that is removed anyway during your diagnostic examination or treatment and will be normally destroyed thereafter, your donation is not related to any additional health risk.

We want to additionally draw 10 ml of venous blood (equivalent to about 1 tablespoon), which is not linked to any additional health risk.

b) Other risks :

A possible risk is the loss of confidentiality about your medical information (e.g. the possibility to identify you). This may especially apply to your genetic information, and such risks cannot be completely ruled out. The risk may even increase with more data becoming available or linked together, e.g. if you will publish genetic data yourself at the internet (e.g. for family research). The EEBB assures to provide as much protection as possible of your privacy, and share samples and data only with projects that can demonstrate a suitable data protection strategy (see point 8: "Who has access to your biomaterials and data ?").

The following steps will be taken to protect your privacy:

a) DNA samples will not be labeled with your name or other easily identified numbers.

b) Your sample will be coded (assigned a unique number) which will allow the researchers to link your sample to other information that you provide through questionnaires or other study activities.

c) The key to the code linking you to your DNA sample will be maintained in confidential files with standard security precautions. The key is used only to connect other information you provide to your DNA sample. The key to the code will never leave EEBB at the University Hospital Erlangen, Germany.

d) Some of the tests performed on your samples may be done by affiliated researchers or laboratories outside of EEBB at the University Hospital Erlangen, Germany, but they will never know who you are or have access to the code linking samples to you.

5. What are the possible benefits from being in this research study?

For your health, you should not expect any immediate advantage or benefit from the donation of your samples and data. The results are intended solely for research purpose, and your participation will contribute to a better understanding of the factors that influence health.

A return message may occur when we believe that any new information will have significant importance for your health. This is the case when outbreak of a (possibly life-threatening) disease can be avoided or a previously unrecognized disease can be treated. However, you may need to disclose this information then at other organizations (e.g. at an insurance policy). If you do not want to be informed, please deny the possibility of getting re-contacted (see below, point 10).

6. What are the benefits for our society?

All activities currently carried out as well as future medical and scientific research projects aim at improving our understanding of the disease pathogenesis and diagnosis and on this basis to the new development of improved treatment approaches.

7. What conditions apply to the use of your data and biomaterial?

a) A prerequisite for research of your biomaterial and medical data is written consent. Your consent is voluntary and may be withdrawn at any time (see also item 11 " Your Privacy Rights ").

b) Biomaterial and data will be stored at the EEBB under standardized and state-of-the-art quality and security precautions and will be made available only to researchers from the EEBB for specific research purpose.

c) It is a prerequisite that the research project requesting biomaterial and data has been reviewed by their local ethics committee or institutional review board exploring the ethical and legal aspects of the research project.

8. Who has access to your data and biomaterial and how are they protected?

Identifying information (name, date of birth, address, etc.) will be replaced immediately with an encrypted pseudonym (unique code). Following submission to the EEBB at University Hospital Erlangen, Germany, all biomaterial and medical records will be stored with a second unique code. This dual coding protects your privacy and identification by unauthorized persons, according to current knowledge and best data-security practice. Biomaterial and data will be handled for research purposes only using double encoded labels.

b) The patient identifying data remain in the hospital where biomaterial and data were collected and were stored separately from biomaterial and medical data. Access to this information may be necessary if medical records are missing or incomplete and should be re-evaluated if you have consented to contact us (see below, point 10). Submission of personal data to researchers or other unauthorized third parties, such as insurance companies or employers, will not occur.

c) Double-coded biomaterial and medical data can be submitted, if necessary, on request for research purpose to other universities, research institutes and research companies abroad. Under certain circumstances, the data may be linked with medical records from other databases, considering that all legal requirements are met.

d) Biomaterial and data that has been passed on to third parties may be used only for the research and will not be disclosed by the recipient for other purposes. Any unused material is returned or destroyed at the biobank.

e) Scientific publications of research results are anonymous in a form that does not allow any conclusions about your person.

9. Is there any financial advantage from the use of your data and biomaterial?

You will receive no payment for your donation of biomaterial and data. If commercial benefit will be achieved from the research, you will not participate. After submission of your biomaterial to the EEBB, it will become property of the University Hospital Erlangen. You authorize the EEBB to use your data. You have the possibility to correct faulty stored or processed data at any time. EEBB may charge users for providing samples and data.

10. Will there be any additional contact?

To gain follow-up information of a specific treatment regimen, it may be necessary to contact you again at a later time point and to request additional information and / or biomaterial. New contact can be also used to obtain your consent to link with other databases or provide you / your doctor / investigator / your GP feedback on healthrelated issues (see above point 5).

If a contact is necessary, an employee from the University Hospital Erlangen will contact your physician from the attending hospital. This doctor will then contact you by mail or telephone.

If you do not want any new contacts, please mark the appropriate box on the consent form below.

11. Your privacy rights

You may withdraw your consent to donate biomaterial and data at any time without notice for any reason and without adverse effects for your further medical treatment.

If you are going to withdraw your consent, you can decide if your biomaterial should be destroyed and all associated data to be deleted, or whether they may be used in an anonymous form (no possibility to link with your person) for further research. Once the key to link your biomaterial and data with your personal information has been destroyed, biomaterial and data cannot be re-identified nor deleted anymore. In addition, data cannot be removed from previously performed studies. Despite your withdrawal, the possibility to recognize your genetic information from other sources cannot be completely ruled out.

Please submit your withdrawal to:

Prof. Dr. Ingmar Blümcke
Director Dept. of Neuropathology
University Hospital Erlangen
Schwabachanlage 6
91054 Erlangen
Phone +49 9131-8526031
Fax +49 9131-8526033

Declaration of informed consent

Patient: _____
(Name, first name)

Date of Birth : _____

I agree that my biomaterial and data will be submitted to the EEBB and used for medical research purpose, as described in the information document. This may apply also under circumstances, when research projects will be performed abroad and with potentially lower level of data protection.

I transfer ownership of biomaterial to the EEBB .

I have read the information sheet and have had the opportunity to ask questions.

I know that my participation is voluntary and I can withdraw my consent without notice for any reason at any time without any disadvantages for further treatment.

I agree that I will be eventually contacted at a later date (if not applicable, please mark "no")

- For the purpose of obtaining further information / biomaterial no
- For the purpose of consent to compare with other databases no
- For the purpose of feedback for health-related issues no

This feedback should be made / data obtained by the following doctor (if desired, *please specify*)

Name and address of the doctor:

Privacy Statement

I hereby agree that the (please specify name of hospital, city and state) as described in the above patient information

- Collect and store my personal data,
- Extract further details from my medical records,
- Provides pseudonymous data together with my encrypted biomaterial for medical research to the EEBB.

The biomaterial and data will be used for medical research for an unlimited period at the University Hospital Erlangen and EEBB.

The encrypted biomaterial and data may be transferred to other universities, research institutes and research companies, possibly even abroad, for the purposes of medical research.

I have been informed that I may withdraw my consent without notice for any reason at any time. Following withdrawal, the remaining biomaterial and collected data will be destroyed or erased or made anonymous. I understand, that data from previously performed studies cannot be deleted.

I have received a copy of the patient information and consent form. The original remains with the Epilepsy Center Erlangen, Department of Neurology, Universitätsklinikum Erlangen.

Patient Name in block letters

Place, date (to be entered by the patient) Signature of patient

I've conducted the discussion and obtained the patient's consent.

Doctor's name in block letters

Place, date Signature of physician