This form is written in the masculine gender for convenience only and is intended for all genders.

You are invited to participate in a medical research study. This form provides an explanation of the study you are being invited to join. Please read the information carefully. If you require further information about the study or have any questions, you may contact the Principal Investigator or their representatives.

Before deciding whether to join the research study, it is very important to understand the potential risks and benefits so that you can make an informed decision. This process is called “informed consent.”

Your participation in the research study is entirely voluntary, and you have the right to decline participation and not sign the consent form. You may also withdraw from the study at any time without needing to provide a reason. Your decision to decline to participate or withdraw will not affect your current or future medical care.

If you choose to participate in the study, you will be asked to sign this form. You will receive a signed copy for your records, and the original will be retained by the principal investigator.

|  |  |
| --- | --- |
| Name: | Surname: |
| ID No.: | |
| Address: | |

**1) Information about the research study**

Study number: 0405-24-TLV

1.1) Research study topic: **The Natural Course of Amyotrophic Lateral Sclerosis and Other Motor Neuron Diseases.**

1.2) The investigator, **Prof. Vivian Drory**, has received approval to conduct the research study from the Institute’s Helsinki Committee and from the Director of the **Tel Aviv Sourasky Medical Center**, in accordance with the Public Health (Medical Experiments on Human Subjects) Regulations, 1980.

1.3) Research objective: **This study aims to collect and store demographic and clinical data from patients with ALS and other motor neuron diseases over time using the NeuroBANK platform.**

1.4) The research study involves the collection of identifiable or encoded data: **The data from this study will be stored, for the benefit of the clinical research community and with the aim of advancing the understanding of neurological and other diseases, in a secure database on the NeuroBANK research platform, located at the Neurological Clinical Research Institute at Massachusetts General Hospital and under the oversight of the Mass General Brigham Enterprise Research Infrastructure and Services server farm.**

**The data collected in this study will include information from your medical records or from other clinical studies you have previously participated in that may be relevant to the current research, along with information specifically gathered for this study. This may include your ethnic background, gender, date of birth, medical details (such as medical history, symptom onset date, physical examinations, various functional assessments, medical procedures/events, medications you are taking, side effects, test results, diagnoses, treatments, surgery reports, and disease summaries), genetic mutations, and responses to research questionnaires.**

**This data will be stored in NeuroBANK and will not include any information that could directly identify you. Instead, your data will be encoded using NeuroGUID or NeuroSTAmP, and will be transferred and stored in this format within NeuroBANK. These unique identifiers are the only means of linking the data to your identity.**

**At the conclusion of the research study, all dates in your data stored in NeuroBANK will be removed and your data will be merged with other de-identified datasets. This data will be made available to other investigators and will be used for medical research purposes on various topics. The NeuroGUID/NeuroSTAmP numbers, along with any other codes that could link you to the data, will be removed prior to sharing the data with other investigators.**

**System-specific or Neurological Global Unique Identifier (NeuroGUID) or System-specific Transactional Anonymous PIN (NeuroSTAmP):**

**As part of your participation in the research study, you will be assigned a unique identifier – NeuroGUID or NeuroSTAmP. Your NeuroGUID is an alphanumeric identifier generated at the research center using your personal information, which will be encrypted. The personal information that will be encrypted to create your NeuroGUID include your first name at birth, surname, middle name (if applicable), gender assigned at birth, full date of birth (day, month, and year), city of birth, and country of birth. The personal details used to create your NeuroGUID will not be stored, transmitted to the secure server, or shared with NeuroBANK.**

**Although there is only one NeuroGUID uniquely associated with you, the NeuroSTAmP serves as your unique identifier for a specific research study.**

**Only the NeuroGUID server contains information that can link NeuroSTAmP identifiers to the NeuroGUID. Using NeuroSTAmP reduces the risk of participant identification, because it is different in each research project.**

**1.5)** What is your responsibility as a participant in complying with the research requirements? **The study will run for 5 years with the possibility of extension. You are required to agree to the transfer of your encoded demographic and clinical data to NeuroBANK.**

**1.6)** What are the known risks and/or potential discomforts from participating in this study? **There are no risks associated with your participation in the study.**

**1.7)** What are the potential benefits for you as a participant or for others with your condition as a result of this study? **You are not expected to receive direct benefits from participating in the study, only the knowledge that you are contributing to advancing research on the disease and ultimately supporting efforts to find a treatment.**

**2) General information**

**2.1)** For any questions related to the medical research, you may contact the investigator at the following numbers: **03-6973689, 052-4266723.**

**2.2)** The study sponsor, **Prof. Vivian Drory,** is funding the costs incurred by the medical institution to conduct the study. **The investigator has an affiliation with the study sponsor, as the principal investigator is also the study sponsor.**

**2.3)** The study results may hold value and could be used as part of a patent, publications, etc. Participants in the study will not have rights to any patents, publications, or other outcomes derived from the study they participated in.

**3) Data privacy and confidentiality**

**3.1)** As part of the study you were invited to participate in, medical and personal information is collected for the purposes of the research.

**3.2)** By consenting to participate in the study, you also agree that the collected medical and personal information may be shared with an external entity for data processing. This information will be transferred in an encoded format only, and will **not** include your name, surname, ID number, home address, or any other identifier assigned by state authorities.

In general, encoded information is regarded as identifiable information. The link between the code and your identifying details will be securely stored by the principal investigator in Israel. In certain cases, the investigator may access the code.

**3.3)** The encoded data and information will be stored by the investigator for a period defined by law (at least 7 years after the completion of the study).

**3.4)** Authorization to view the data, for the purpose of verifying research methods and data, will be granted only to authorized parties (such as authorized representatives of the investigator, the Helsinki Committee, the auditing body at the medical institution, and inspectors from health authorities). Access to your medical information will be facilitated by the investigator, in accordance with confidentiality laws and procedures.

**3.5)** Your identifying information will not appear in any scientific or other publication.

**4) Withdrawal from the study**

You have the right to withdraw from the study at any stage by notifying the principal investigator or their representative. You are not obligated to provide a reason for your withdrawal. The investigator may only use the encoded data collected up until the point of withdrawal. Once you have notified the investigator of your withdrawal, no further information may be collected from you. However, if any medically significant information regarding you is obtained, you will be contacted. You have the right to refuse to receive this information.

5) **Consent Documentation:**

**The participant**: By signing, I confirm that I have read the contents of this document, the study has been explained to me, and I agree to participate.

Name (First and Surname): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_

**The investigator providing the explanation:** By signing, I confirm that I have explained the study to the participant as described in this form. I believe that the participant understood the information, has had sufficient time to read the form, and has expressed their willingness to participate in the study.

Name (First and Surname): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_

**[Additional Consent (Optional)]:**

The investigator requests to use the data collected in this study for additional research projects. This additional use is not part of the current study plan. **Your refusal to consent to this does not affect your participation in the study.**

**6. [Use of information for future studies.]**

a. What information will be collected and how will it be gathered: Demographic and clinical data will be collected as outlined in section 1.4.

b. Who will receive the information: It is not yet known which future studies will be conducted, so the recipients of the data are currently unspecified. However, your data in NeuroBANK will be accessible to other investigators and potentially to commercial entities, and may be used for medical research purposes in various areas (not only for ALS and other neurological diseases). All data shared will be anonymized for future investigators, meaning that it will not contain any identifying information.

c. Data retention period: Seven years.

By signing, you consent to the use of these **data** for future studies that are legally approved. You have the right to withdraw your consent at any time by informing the principal investigator or their representative, without the need to provide an explanation.

**Participant**:

Name (First and Surname): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_

**The investigator providing the explanation:**

By signing, I confirm that I have verbally explained to the participant the implications of providing the samples and/or information as stated in this form. I believe that the participant has understood the explanation, has had sufficient time to read the form, and has given their consent.

Name (First and Surname): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_