UNICAMP

University of Campinas
Department of Medical Genetics
RESEARCH CONSENT FORM

Project title: Molecular genetic studies in neuropsychiatric diseases - phase I
Main researcher: Dr. Iscia Lopes Cendes (phone: 19 3521 8907)

RESEARCH OBJECTIVE:

I understand that I was invited to participate in a research project involving patients and families of individuals presenting with

( ) Epilepsies
( ) Cortical malformations
( ) Choreas
( ) Ataxias
( ) Paraparesis
( ) Dystonias
( ) Bipolar affective disorder
( ) Schizophrenia
( ) Muscle diseases
( ) Mitochondrial diseases
( ) Parkinson
( ) Cerebrovascular disease/stroke
( ) Dementias
( ) Control group

This study aims to identify the genetic alteration that causes the disease. This can improve the disease diagnosis (if the alteration is found) and can lead to a better treatment in the future. However, I know that most likely my treatment will not be altered with my participation in this study.

PROCEDURE:

I understand that if I agree to participate in this study, the research participants will ask questions regarding my medical and family antecedents. I will be submitted to a neurological and/or to a psychiatric exam to establish my clinical state. In addition, I may be submitted to an electroencephalogram (EEG) or to an electromyography (EMG) and to a computed tomography (CT) or a cranial magnetic resonance imaging (MRI). A blood venous sample will be collected (20-30 ml, which is equivalent to two table spoons). Hospitalization will not be necessary. The procedures mentioned above, with the exception of the blood sample collection, include the routine medical care for a patient with neuropsychiatric disease.

POSSIBLE RISK AND DISCOMFORT:

The amount of 20-30 ml of venous blood will be collected. The risks associated with this procedure are minimal; such as pain and skin bruises may occur in the location of the blood collection, usually collected from the arm vein. This procedure will be performed by a trained professional with capacitation and licensing to perform this procedure.

CONFIDENTIALLITY:

I understand that all medical information, but not the genetic test results originated from this research project, will be part of my medical record and will be submitted to the rules and regulations of the University Teaching Hospital (HC) of the University of Campinas (UNICAMP), referring to confidentiality of medical information. No names or other personal identifiers will be used in publications of the results of this research.

Researcher initials	Initials of the research subject or their representative

ADVANTAGES:

I understand that I will not obtain any direct advantage with my participation in this study and that probably my diagnosis and treatment will not be modified. However, the study results may, in the long term, provide advantages for individuals with neuropsychiatric diseases and their families, allowing better diagnoses and a more adequate treatment.

It is important to note that presymptomatic diagnosis is not part of this research, but if I want to obtain genetic counseling, this will be provided in the Neurogenetics Clinic HC-Unicamp, phone (19) 3521-7754.

ADDITIONAL INFORMATION:

I understand that I can require additional information relative to the study at any time. Dr. Iscia Lopes Cendes, phone (19) 3521-7754, will be available to answer my questions and concerns about ethical aspects. In case of complaints, questions of any claims, I can contact the Research Ethical Committee directly; phone (19) 3521-8936.

REFUSAL OR DISCONTINUED PARTICIPATION:

I understand that my participation is voluntary and that I can refuse to participate or withdraw my consent (including removal of blood sample) without affecting the medical care that I receive currently or will receive in the future at HC-UNICAMP. I also recognize that Dr. Iscia Lopes Cendes may interrupt my participation in this study at any time that she deems appropriate.

I confirm that Dr._____ explained me about the aims of the study, the procedures to which I will be submitted, risks, discomforts and possible advantages from this research project. I read and understand (or it was explained to me) this consent form and I agree entirely to participate in this study. In addition, I inform that:

( ) I authorize the storage of the biological material and with no need for a new informed consent, in case of further use in other research projects.

( ) I authorize the storage of the biological material and wish to be consulted for a new consent in case of further use in other research projects.

( ) I DO NOT authorize the storage of biological material, which must be discarded after the end of my participation in the current research project.

PUBLIC SHARING OF GENOMIC DATA

With the advance of research in the genomic field, currently it is of great importance to share in public databases the results of some molecular tests. When sharing genomic data, it is always assured that there will not be any reference to sample identifiers (for example: name, parents names, address, registration number in the hospital); however, relevant information may be included for proper interpretation of genomic data in the research context, such as: sex, age, country and region of origin, diagnosis and other pertinent clinical information.

( ) I authorize that the genomic test results carried out under this research project are made available in public databases that shall be consulted by researchers of the medical field, provided that these data are not related to sample identifiers (see above identifier examples).

( ) I do not authorize the availability of results of the genetic tests performed in this research project.

Researcher initials	Initials of the research subject or their representative

University of Campinas
Department of Medical Genetics

_____
Participant and responsible person name

_____ _____
Participant or responsible person signature date

_____
Witness name

_____ _____
Witness signature date

RESPONSIBILITY OF THE RESEARCHER:

I explained to _____ about the objectives of the study, the required procedures and possible risks and benefits for participation, using the best of my knowledge. I agree to provide one original version of this consent form to the participant or responsible person. In case that a new research is carried out using the biological material collected and stored during this research, I agree to submit a request to the Research Ethics Committee.

_____
Researcher or associated name

_____ _____
Researcher or associate signature date