CHARITÉ

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# Information for participants in the study

**Study title: Clinical evaluation of marker proteins in Alzheimer´s disease**

Dear Sir or Madam,

within the study of Dr. Jens Dernedde, a member of the Department of Clinical Chemistry and Pathobiochemistry (CharitéCentrum 5 für diagnostische und präventive Labormedizin - Zentralinstituts für Laboratoriumsmedizin und Pathobiochemie) at the Charité, we try to identify marker proteins indicative for Alzheimer´s disease. The study is conducted in close collaboration with Dr. Gerhard Jan Jungehuelsing from the Department of Neurology (CharitéCentrum 15 für Neurologie, Neurochirurgie und Psychiatrie - Klinik für Neurologie CBF). Complete addresses are mentioned below. Our study is part of an EU-financed project “NANOGNOSTICS” which aims at developing a novel and robust assay system to identify and quantify marker proteins of Alzheimer’s disease in blood or serum samples. Informations about this project can be directly received from Dr. Dernedde, from the project coordinator Dr. Niko Hildebrandt (address also mentioned below) or from the internet at www.nanognostics.org.

Neurodegenerative diseases are a varied assortment of central nervous system disorders characterised by the progressive loss of neural tissue. Among them, Alzheimer’s disease is the most prevalent cause for dementia in the elder population today. Alzheimer´s disease is a slowly progressive disorder with an insidious onset and duration of around 10 years, but it is estimated that neurodegeneration in Alzheimer´s disease starts 20-30 years before clinical onset, where men and women show first symptoms of mild cognitive impairment. Therefore, biomarkers are required to improve the diagnostic sensitivity and specificity and to monitor Alzheimer´s disease activity in terms of the dimension of neuronal involvement and the rate of disease progression.

Currently the diagnosis of Alzheimer´s disease is complicated and time consuming. Therefore, it is the aim of the study to establish a rapid, sensitive and specific immunoassay to identify marker proteins relevant to Alzheimer´s disease in whole blood or serum samples. Such an assay could largely improve early diagnosis as well as therapy- and disease progression-monitoring for the benefit of patients.

To conduct the study, we would appreciate your help to collect once an additional blood sample (EDTA-blood) of approximately 5 ml. There is only little additional time input required and a risk or burden for you to join the study is not to be expected. A separate insurance for the study participant will not be contracted. Malpractice by the study medical doctor is covered by the employer´s liability insurance.

It is the aim of the study to identify marker proteins indicative for Alzheimer´s disease and to quantify their abundance in blood or serum samples with a novel detection system. The sample will

be used solely in terms of the study. Research data, as well as the sample are not correlated with your personal data, but encoded (anonymised) handled and stored by receiving a code number. This means that a correlation between the participant and the respective code number is only possible by the study principal investigator. Research data are electronically stored in a secured database, samples are stored at a locked place for this comparative study. Access to data and sample is restricted to persons directly involved in the study. Data and sample will be destroyed latest by the end of 10 years. Please note that the results of the study can be published in an anonymous form.
During our research we do not expect to make incidental findings indicative for other diseases than Alzheimer. If in any case we should make incidental findings you will be immediately informed by the Charité in order to discuss these findings with you and to find a solution how to deal with them. You will get all necessary medical information about these findings by the Charité. The decision of how to proceed with these findings is solely yours.

At anytime you have the right to access the information on your personal data and test results, but according to the present state of knowledge no clinical relevant information for your health status can be deduced from this information.

Participation in the study is voluntary; a refusal to participate will involve no penalty or loss of benefits. You are entitled to withdraw your acceptance at any time, without giving reasons. The same applies to passing on your data and sample. In addition at any time you can call for deletion of your data and destruction of your sample.

**Study principal investigator:**

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**Study medical doctor:**

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