Consulting and Evaluation

Dear Professor Driessen,

for the above-mentioned research project, you have applied for advice from the Ethics Commission of the Ärztekammer Westfalen-Lippe and the Westfälische Wilhelms Universität Münster (“Ethics Commission”) in your letter of 15.11.2016. At its meeting on 13.01.2017, the Ethics Commission discussed your application, examined and decided on the additional documents submitted in a committee in accordance with § 5 para. 1 sentence 3 of its statutes:

The Ethics Committee has no fundamental ethical or legal concerns for the implementation of the research project.

The present assessment applies to the research project as presented on the basis of the documents referred to in Annex 1.

The Ärztekammer Westfalen-Lippe charges fees for the decision of the Ethics Committee in accordance with its administrative fee schedule. You will receive a separate notification of the fees from the Ärztekammer.

General information:

With the present statement, the Ethics Committee advises the physicians belonging to the Ärztekammer Westfalen-Lippe on the ethical and legal issues associated with the research project in accordance with § 15 para. 1 of the ÄKWL professional code of conduct. The Commission's assessment is not binding for the applicant as an open-ended consultation. The Ethics Committee points out that, irrespective of the present statement, the medical, ethical and legal responsibility for the implementation of the research project remains with its director and all physicians or researchers participating in the project.
The members of the Ethics Committee listed in Appendix 2 took part in the deliberations and decision-making process. No members participated who were themselves involved in the research project or whose interests were affected by it.

In accordance with the Declaration of Helsinki, the Ethics Committee strongly recommends that clinical trials be registered before the start of studies in a publicly accessible register that meets the requirements of the World Health Organization (WHO), in particular the minimum information required. Detailed information on the International Clinical Trials Registry Platform (ICTRP) is available on the WHO website: [http://www.who.int/ictrp/about/en/](http://www.who.int/ictrp/about/en/)

For the criteria of the International Committee of Medical Journal Editors (ICMJE), for example, reference is made to the information below: [http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html](http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html)

The WHO Primary Registry for Germany is the German Registry for Clinical Trials (DRKS) in Freiburg. It meets the requirements of the scientific journals: [http://www.drks.de/index.html](http://www.drks.de/index.html)

The Ethics Commission of the Westphalia-Lippe Medical Association and the Westphalian Wilhelms University of Münster is organised and operates in accordance with the national regulations and the GCP guidelines of the ICH.

The Commission wishes your research project every success and assumes that you will report on the results once the project has been completed.

Yours sincerely

Univ.-Prof. Dr. med Hans-Werner Bothe M.A.
Vorsitzender der Ethik-Kommission
### Anhang 1

**The following documents were available at the time the resolution was adopted:**

In the case of several versions of a document, our evaluation always refers to the latest version of the document version.

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Anhang 2

The following members of the leading ethics committee took part in the final consultation and resolution in the meeting of 13.01.2017:

Prof. Dr. med. Peter Baumgart
Universitätsklinikum Münster, Experimentelle Neurochirurgie

Dr. med. M.A., LL.M. Doris Dorsel
Ärztekammer Westfalen-Lippe

Univ.-Prof. Dr. med. M.A. phil. Hans-Werner Bothe
Universitätsklinikum Münster, Experimentelle Neurochirurgie

Univ.-Prof. Dr. med. Wolfgang Köpcke
Westfälische Wilhelms-Universität Münster, Institut für Biometrie und klinische Forschung

Univ.-Prof. Dr. med. Prof. Dr. med. Frank Ulrich Müller
Universitätsklinikum Münster, Institut für Pharmakologie und Toxikologie

Prof. Dr. med. Heinrich Schulze-Mönking
St. Rochus-Hospital Telgte GmbH, Abt. für Psychiatrie und Psychotherapie

Univ.-Prof. Dr. jur. Heinz-Dietrich Steinmeyer
Westfälische Wilhelms-Universität Münster, Institut für Arbeits-, Sozial- und Wirtschaftsrecht II

Alfred Storck
Sonderschulrektor i.E., St. Elisabeth Schule, Steinfurt

Prof. Dr. med. Constantin Uhlig
Universitätsklinikum Münster
Klinik für Augenheilkunde

Dr. rer. nat. Dorothea Voß
Apothekerin für klinische Pharmazie und Apothekerin für praktische und theoretische Ausbildung i.R., Münster