

## Application form for non-AMG/non-MPG studies

**(in addition, a separate study protocol must be submitted)**

(See also "explanations of the application for non-AMG/non-MPG studies)

<b>1 Applicant: Name, Address, Tel./Fax-No.:</b>	Dr. med. Monika Empl Neurology Consultant Department of Neurology Department of Neurology Ludwig-Maximilians University Munich University Hospital Munich-Großhadern Marchioninistraße 15 D- 81377 Munich Tel.: +49 89-4400-73906 E-mail: <a href="mailto:monika.empl@med.uni-muenchen.de">monika.empl@med.uni-muenchen.de</a>
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	Univ.-Prof. Dr. Angelika C. Wagner Pedagogic Psychology Department of educational science Research Group Introvision, University of Hamburg Bogenallee 11 D - 20144 Hamburg Telephone: + 49 40-42838-7990 E-Mail: <a href="mailto:Angelika.Wagner@uni-hamburg.de">Angelika.Wagner@uni-hamburg.de</a>
<b>2 Title of the research project:</b>	Introvision in migraines and headaches- IntroMic
<b>3 Training data and research experience:</b>	See enclosed application, page 2f
<b>4 Monocentric or multicenter study:</b>  <u>In multicenter studies:</u>  Head of the clinical trial of other test centres, central evaluation point Votes of other ECs	Monocentric study <input checked="" type="checkbox"/> multicenter study <input type="checkbox"/>  - n.a. -

<p><b>5 Declaration that the principles of the Helsinki Declaration are taken into account in their current version.</b></p>	<p>I/we declare that the principles of the Helsinki Declaration are taken into account in the current version</p> <p>Munich, 22.10.2015</p> <p>(Dr. med. Monika Empl, On behalf of all applicants)</p>
<p><b>6 Study-related burdens:</b></p> <p>a) Radiation exposure</p> <p><u>If yes:</u></p> <p>b) Diagnostic investigations</p> <p>c) Blood/Tissue Collection</p>	<p>Yes <input type="radio"/> No <input checked="" type="radio"/></p> <p>I/we declare that prior to the study the approval of the BFS is obtained.</p> <p>Yes <input type="radio"/> No <input checked="" type="radio"/></p> <p>Yes <input type="radio"/> No <input checked="" type="radio"/></p>
<p><b>7 Wissenschaftliche Angaben zum Forschungsvorhaben:</b></p>	<p>See enclosed application, page 3ff</p>
<p>7.1 Study Objective</p>	<p>See enclosed application, page 5f</p>
<p>7.2 Study Design</p>	<p>With control group Yes <input checked="" type="radio"/> No <input type="radio"/></p> <p>With healthy volunteers Yes <input type="radio"/> No <input checked="" type="radio"/></p>
<p>7.3 Case number estimation and evaluation concept</p>	<p>Yes <input checked="" type="radio"/></p> <p>Mrs. Dr. Hoster, Institute for Biometry and Epidemiology (IBE), LMU See enclosed application, page 7f</p>

	No <input type="radio"/> Please explain
7.4 Statistical advice by	Mrs Dr. Hoster, IBE, LMU Munich
7.5 Study duration	Expected Start Date: 01.12.2015 Expected End: 31.12.2016
<b>8 Discussion of ethical-legal issues</b>	See enclosed application, page 8
8.1. Discussion of the disadvantages, risks, burdens and potential benefits of the study	
8.2. Inclusion of persons not able to consent  <u>If provided:</u>	Provided <input type="radio"/> Not provided <input checked="" type="checkbox"/>  Indication of reasons
8.3. Research on minors  <u>If provided:</u>	Provided <input type="radio"/> Not provided <input checked="" type="checkbox"/>  Indication of reasons
<b>9 Data protection</b>  <u>If pseudonymised use</u>	Irreversible anonymised use of samples/data (without reference to persons) <input type="radio"/>  pseudonymised use of samples/ persons) <input checked="" type="checkbox"/> Encryption)  Information on how the encryption code is formed, who has access to the encryption code, reasons for decryption and how long the data/samples be kept  See enclosed application, page 8f
<b>10 Insurance:</b>	Declaration that an insurance policy is / was completed <input type="radio"/>  Why insurance is not necessary <input checked="" type="checkbox"/>  See enclosed application, page 9  A road insurance has been completed

	Yes <input type="radio"/> No <input checked="" type="radio"/>
<b>11 Financing:</b> A) Financing of the research project B) rewarding doctors/patients/volunteers	See enclosed application, page 9
<b>12 Expenditure compensation for the EC:</b>	The costs of expenditure compensation are taken over <input checked="" type="checkbox"/>  Application for reduction of expenditure compensation (explanation to attach) <input checked="" type="checkbox"/>  Billing address (if different from the address of the applicant):
Date, Signature	22.10.2015