

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")

1 Applicant: Name, Address, Tel./Fax-No.:	<p>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: monika.empl@med.uni-muenchen.de</p> <p>Univ.-Prof. Dr. med. Andreas Straube Senior Physician Department of Neurology Ludwig-Maximilians University Munich University Hospital Munich-Großhadern Marchioninistraße 15 D- 81377 Munich Telephone: +49 89-4400-73900 E-Mail: Andreas.Straube@med.uni-muenchen.de</p> <p>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: Angelika.Wagner@uni-hamburg.de</p>
2 Title of the research project:	Introvision in migraines and headaches-IntroMig
3 Training data and research experience:	See enclosed application, page 2f
4 Monocentric or multicenter study: <u>In multicenter studies:</u> Head of the clinical trial of other test centres, central evaluation point Votes of other ECs	<p>Monocentric study ⊗ <u>multicenter study</u> ○</p> <p>- n.a. -</p>

5 Declaration that the principles of the Helsinki Declaration are taken into account in their current version.	<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>
6 Study-related burdens: <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"/></p> <p>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"/></p> <p>No <input checked="" type="radio"/></p> <p>Yes <input type="radio"/></p> <p>No <input checked="" type="radio"/></p>
7 Wissenschaftliche Angaben zum Forschungsvorhaben:	<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</p> <p>Yes <input checked="" type="radio"/></p> <p>No <input type="radio"/></p> <p>With healthy volunteers</p> <p>Yes <input type="radio"/></p> <p>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</p> <p>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
8 Discussion of ethical-legal issues	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	Provided <input type="radio"/> Not provided <input checked="" type="radio"/>
<u>If provided:</u>	Indication of reasons
8.3. Research on minors	Provided <input type="radio"/> Not provided <input checked="" type="radio"/>
<u>If provided:</u>	Indication of reasons
9 Data protection	Irreversible anonymised use of samples/data (without reference to persons) <input type="radio"/> pseudonymised use of samples/ persons) <input checked="" type="radio"/> 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
10 Insurance:	Declaration that an insurance policy is / was completed <input type="radio"/> Why insurance is not necessary <input checked="" type="radio"/> See enclosed application, page 9 A road insurance has been completed

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