



MEDIZINISCHE FAKULTÄTUNIVERSITÄTSKLINIKUM MAGDEBURG A. Ö. R.

COORDINATION CENTER FOR CLINICAL STUDIES

Internal Cooperation

Due to European directives as well as national laws and resulting national guidelines, the KKS Magdeburg as the quality assurance unit of the sponsor is obliged to monitor the conduct of non-commercial clinical trials (IITs) at all times.

Therefore, KKS Magdeburg works closely with the following institutions:

Lead Ethics Committee of the University of Magdeburg

Dr. Norbert Beck (Managing Director)

Tel.: 0391-67-14344

norbert.beck@med.ovgu.de

**Clinical trials with medicinal
products according to EU
Regulation 536/2014 (CTR) and
AMG**

The documents are no longer sent separately to the Ethics Committee. The complete submission process is carried out electronically via the EMA's Clinical Trial Information System (CTIS) by the sponsor of the clinical trial. The responsible ethics committee is assigned via a defined business allocation plan of all participating ethics committees in Germany.

**Clinical trials with medical devices
according to EU Regulation
745/2017 (MDR) and MPDG**

The documents are no longer sent separately to the Ethics Committee. The complete submission process is carried out electronically by the sponsor of the clinical trial via the German Medical Devices Information and Database System (DMIDS) of the BfArM. Currently, the ethics committee of the principal investigator is still responsible for this..

Other Clinical Studies

1 x paper version, 1 x digital on USB,
email or via DocShare

- Cover letter requesting consultation of the study according to MBOÄ § 15
- Form Consultation Overview EK ? Beratungsformular
- Study protocol incl. contact details
- Informed consent incl. data protection
- Any questionnaires or other documents relevant to your studies

Unit for Research (REFO) and Third-Party Funding Management

Dipl.-Kff. Melanie Thurow

Tel.: 0391-67-25130

melanie.thuro@med.ovgu.de

- The acquisition of public third-party funds,
- Research availability areas and other research resources,
- Contractual arrangements for research collaborations and material/data transfer,
- Announcements of junior researcher awards and scholarships,
- The registration of patents and utility models in cooperation with the TUGZ.
- Administration and control of research-related third-party funds incl. preparation of numerical proofs
- Processing of contracts in the context of contract research
- Calculation of costs of contract research
- Preparation of statistics and reports

Institute of Biometry and Medical Informatics (IBMI) ? Consultation Request Form

Director:

Prof. Dr. rer. nat. Dr. med. Johannes Bernarding (Manager)

Tel.: 0391-67-13535, -15537

johannes.bernarding@med.ovgu.de

Deputy Director:

Dr. rer. nat. Markus Plaumann

Tel.: 0391-67-13508, -17859

markus.plaumann@med.ovgu.de

Creation e-CRF:

Dipl.-Ing. Sebastian Baecke

Tel.: 0391-67-13546
sebastian.baecke@med.ovgu.de

Statistic Consultaton / Biometry:
Dipl.-Math. Anke Lux

Tel.: 0391-67-13530
anke.lux@med.ovgu.de

Stabsstelle Recht

Attorney Ute Klanten (Manager/Data Protection Officer)

Tel.: 0391-67-15753
ute.klanten@med.ovgu.de

Data Protection Management:
Susan Rönnebeck

Tel.: 0391-67-15192
susan.roennebeck@med.ovgu.de

For Insurance:
Christina Knappe
christina.knappe@med.ovgu.de

Tel.: 0391-67-15082

Central Pharmacy (ZAP)

Dr. rer. nat. Stefanie Zibolka
(Manager)

Tel.: 0391-67-15941
stefanie.zibolka@med.ovgu.de

Dr. rer. nat. Denise Kramer

Tel.: 0391-67-13543
denise.kramer@med.ovgu.de

Institute for Clinical Chemistry and Pathobiochemistry (KCP) ?

Formblatt

OÄ Dr. med. Katrin Borucki (Deputy Director)

Tel.: 0391-67-13928
katrin.borucki@med.ovgu.de

Mandy Schulze

Tel.: 0391-67-13901
mandy.schulze@med.ovgu.de

Radiation Protection Unit

M.Sc. Nicole Fröhlich (Radiation Safety Officer)

Tel.: 0391-67-25177
nicole.froehlich@med.ovgu.de

Board of Management Area 2 - Information Security (V2)

Dr.-Ing. Jana Fruth (Manager)
Information Security Officer (ISB)

Tel.: 0391-67-25142
jana.fruth@med.ovgu.de

Dipl.-Ing. André Helm (Deputy
Information Security Officer)

Tel.: 0391-67-25162
andre.helm@med.ovgu.de

**Business Unit IT and Medicine
Technic**

Dr. Robert Waschipky (Manager)

Tel.: 0391-67-15710
robert.waschipky@med.ovgu.de

Medicine Technic Department(G6.1)

M.Sc. Sabine Deux

Tel.: 0391-67-15700
sabine.deux@med.ovgu.de

Purchasing Business Unit(G3)

Dipl.-Ing. Christian Zander (Manager)

Tel.: 0391-67-15152
christian.zander@med.ovgu.de

**Central German Competence Network
Rare Diseases**

Prof. Dr. med. Klaus Mohnike

Tel.: 0391-67-24016
klaus.mohnike@med.ovgu.de

Dr. med. Katja Palm

Tel.: 0391-67-24000
katja.palm@med.ovgu.de

Susann Empting

Tel.: 0391-67-24031
susann.empting@med.ovgu.de

The Central German Competence
Network for Rare Diseases (MKSE) is
a central institution of the Medical
Faculty of Otto von Guericke
University and as such directly
assigned to the Dean. The
management has been assigned to
Prof. Dr. Klaus Mohnike.

Kontakt & Anschrift

Dr. rer. nat. Antje Wiede

Leiterin des KKS

Tel.: 0391/67-21 838
Fax: 0391/67-15 898
kks@med.ovgu.de

Otto-von-Guericke-Universität
Medizinische Fakultät,
KKS Magdeburg
Leipziger Str. 44

39120 Magdeburg
Haus 1, Ebene 4, rechts

Anfahrt und Lageplan

KKS-Nutzungsordnung_ZMF

KKS Beratungsanfrage

Hinweisblatt Studienplanung

Kurzleitfaden Eine Studie-Ein Votum

Schulungsangebote intern NEU

Regularien

Links

KKS-Netzwerk

BfArM

BfS

Paul-Ehrlich-Institut **PEI**

Bundesministerium für Gesundheit

European Medicines Agency **EMA**

Registrierung **DRKS**

Ethikkommission **AKEK**

ICH

