

# 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)

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#### **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

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- 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:**

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**Central German Competence Network**

**Rare Diseases**

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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

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Leiterin des KKS

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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**

