MEDIZINISCHE FAKULTÄTUNIVERSITÄTSKLINIKUM MAGDEBURG A. ö. R.

COORDINATION CENTER FOR CLINICAL STUDIES

Initial Consultation

The KKS Magdeburg offers its support in principle already in the preparatory phase of planned research projects/studies of any kind or clinical trials according to AMG/MPDG.

If the physicians and scientists of the University Medical Center (UMMD) are interested in conducting a clinical study/clinical trial, the KKS Magdeburg will provide an initial consultation.

It serves to ensure/increase the quality of any kind of **self-initiated clinical research projects/studies (IIS**) by physicians/scientists of the UMMD as well as from other faculties of the OvGU, who plan research with/on humans/data/biomaterials and according to the Declaration of Helsinki and the Model Professional Code of Conduct for Physicians §15 have to be advised by a competent EC (ethics application).

To this end, the KKS works closely with other UMMD institutions (including the Ethics Committee, the Institute of Biometry and Medical Informatics, the Department of Research (Refo), the Department of Third-Party Funding Management (DMV), the Legal Staff Office, the Central Pharmacy, the Institute of Clinical Chemistry and Pathobiochemistry, Board Division 2 Information Security, the Radiation Protection Staff Office, the IT and Medical Technology Business Unit). http://kks.med.ovgu.de/%C3%9Cber+uns/Interne+Kooperation.html

We are happy to assist with study conception including review of study-relevant documents, also for applications for public funding (IIS), contract review and cost calculations together with Refo and DMV.

To increase transparency in accordance with the Declaration of Helsinki 2013, we also offer the entry of research projects/clinical studies into the German Clinical Trials Registry (DRKS) as a primary registry for the WHO upon request.

http://kks.med.ovgu.de/Deutsches+Register+Klinischer+Studien+%28DRKS%29.html

Please use the following to arrange a consultation (by phone, on-site, by email) *Formular.*

If possible, existing study documents/draft documents should be provided (synopsis or draft protocol, draft patient/proband information/consent).

Additional forms and sample templates - if not already available - that are helpful in conducting the appropriate clinical trial may be provided.

If the trial is an Investigator-initiated clinical trial (IIT), the KKS takes over the further support as sponsor representative of the OvGU/Med. Faculty. http://kks.med.ovgu.de/Profil.html

During the mandatory initial consultation, a questionnaire is worked through together with the (principal) investigator and possible discussion points that have come to light during the review of the initial study documents are discussed. Additional forms and sample templates - if not already available - that are helpful for conducting the clinical trial will be provided.

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