



SACHSEN-ANHALT

Landesamt für Verbraucherschutz Sachsen-Anhalt
Ethik-Kommission des Landes Sachsen-Anhalt • Geschäftsstelle
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**Landesamt für
Verbraucherschutz**

**Ethik-Kommission
des Landes
Sachsen - Anhalt**

- Geschäftsstelle -

Ihr Zeichen, Ihre Nachricht vom:

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To whom it may concern,

the application process for clinical trials with medicinal products in Germany required two independent approvals, an authorisation from the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) or the Paul Ehrlich Institute (PEI) as the higher federal authority and a favourable opinion from the competent ethics committee.

According to German Medicinal Products Act (AMG), which implemented the Council Directive 2001/20/EC in national law in Germany, the competence of an ethics committee is regulated by the federal states law and depends on the residence of the German coordinating investigator ("Leiter der klinischen Prüfung").

The legal basis for the work of the three ethics committees for clinical trials with medicinal products in Saxonia-Anhalt is the Ethic Committees Regulation of Saxonia-Anhalt (Ethik-Kom-VO LSA). The three independent ethics committees for clinical trials with medicinal products in Saxonia-Anhalt are:

- Ethics committee of the Martin-Luther-University Halle-Wittenberg (responsible for clinical trials at the University Hospital Halle)
- Ethics committee of the Otto-von-Guericke-University Magdeburg (responsible for clinical trials at the University Hospital Magdeburg)
- Ethics committee of Saxonia-Anhalt attached to the LAV, a consumer's protection authority (responsible for sites and investigators outside the University Hospitals)

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According to the Ethik-Kom-VO LSA these ethics committees fulfil their tasks in accordance with:

- Declaration of Helsinki
- Council Directive 2001/20/EC
- Council Directive 2005/28/EC
- German Medicinal Products Act (AMG)
- German GCP Regulation (GCP-V)

Furthermore, according to the Ethik-Kom-VO LSA the ethics committees are multidisciplinary committees including physicians, lawyers, biometricians/statisticians, bioethicists or theologians and patient representatives. All members must be independent of the research project.

Henning Richter