



Guidelines for the Legally Sound Conduct of Members of Staff Anti-Corruption Guidelines

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In order to facilitate a better readability, the use of both male and female designations (in German) is avoided. In all cases, all personal designations are valid for both sexes.

Preamble

In many cases, a close cooperation between actors within the healthcare sector is desirable or even indispensable for the successful treatment of patients. There are, however, legal regulations as to how this should be carried out. With the Anti-Corruption Act, which entered into force on 4th June 2016, these regulations were streamlined and the criminal offence of bribery and corruption in the healthcare sector was anchored in the penal code. From that point onward, health care professionals who accept bribes have not only violated social and professional law, but have also committed a crime that is punishable by up to five years imprisonment.

The UKD and MFD expressly oppose all forms of corruption and bribery; they address these issues actively and openly. The aim is to fervently avoid the possibility of blackmail and to ensure the independence of members of staff at all times.

The Anti-Corruption Act has increased legal uncertainty as to which forms of conduct are permissible and which are not. However, these uncertainties should not compromise medically important measures that support patient welfare, such as the acquisition, administration and use of third-party funds and donations to the UKD and the MFD

within the framework of the applicable laws (see § 25 of the Higher Education Framework Act).

The aim of these guidelines is to provide all members of staff with a concrete plan in their everyday work life.

These guidelines are intended to help prevent any suspicion of corrupt conduct from arising and thus protect members of staff from possible consequences under employment law, labour law and/or criminal law. At the same time, the guidelines serve to protect the public perception of the company from a loss of confidence in both its working methods and in the integrity of its actions, altruism, objectivity and neutrality.

These guidelines also strive to educate and raise awareness.

I. General Regulations

§ 1 Scope of Application

These guidelines are addressed to all members of staff of UKD and MFD institutions with the aim of protecting them from situations, which could entail negative legal repercussions from not only a criminal perspective, but also from a professional perspective. The term “member of staff” also includes the managers and members of managerial bodies. These guidelines also apply (as of the date of the shareholder’s resolution) to subsidiaries of the UKD.

In the interest of every member of staff, it is their duty to internalise the contents of the individual guidelines and to comply with them at all costs and to the best of their ability in order to avoid the risk of criminal investigation. **Every member of staff is responsible for compliance with and the implementation of these guidelines. All managers must ensure that their members of staff are familiar with the contents of these guidelines and that the applicable regulations are observed. Members of staff should contact their manager if they have any queries regarding the application of these guidelines.**

The Board of Directors of the UKD and the Dean of the MFD reserve the right to spot checks to ensure compliance with the provisions stipulated in these guidelines.

§ 2 Legal Basis

These guidelines apply, inter alia, in addition to

- The Saxon Civil Servants Act of 18th December 2013, as amended,
- The Saxon Travel Expenses Act of 12th December 2008, as amended,
- The Administrative Regulation on the Enforcement of the Saxon Travel Expenses Act, as amended,
- The Saxon Secondary Employment Act of 16th September 2014, as amended,
- The Administrative Regulation on Third-Party Funding of the Saxon State Ministry of Higher Education, Research and the Arts (SMWK) of 4th April 2005,
- The Administrative Regulation of the Saxon State Government on Sponsoring in the State Administration of the Free State of Saxony of 16th October 2017,
- The Administrative Regulation of the Saxon State Government Prohibiting the Acceptance of Rewards, Gifts, and Other Benefits by Civil Servants of the Free State of Saxony (Administrative Regulation Rewards, Gifts and Other Benefits) of 12th October 2011, changed by the administrative regulation of 5th July 2013 as amended,
- The TUD Third-Party Funding Guideline of 20th August 1998, as amended,
- The UKD Travel Expenses Regulations, as of 1st April 2009,
- The Administrative Regulation for Anti-Corruption of the Saxon State Government of 11th December 2015, as amended,
- The relevant circular letters and any other relevant provisions, as amended, as soon as they enter into force.

Further special stipulations in laws, regulations, salary agreements, works agreements, other internal guidelines (in particular procedural instructions, safety and quality regulations, as well as the risk assessment), etc. remain unaffected. All members of staff are obliged to comply with the applicable legal and official regulations. Any involvement in dealings that clearly aim to circumvent any legal, official or internal guidelines is prohibited.

§ 3 Description of Corruption and General Principles of Cooperation with Third Parties

Corruption has many faces. There is no all-encompassing definition of corruption, not even in criminal law. In general usage, the term corruption stands for both punishable acts such as “Accepting Benefits” or “Bribery” (cf. §§ 331, 332 and §§ 299a, b German Penal Code), as well as for certain ethically and morally reprehensible conduct.

From the perspective of criminal law, corruption amongst civil servants or health care professionals can be described as an action or an omission,

- Which is prohibited by criminal law,
- During which an official role or the status of a health care professional is misused,
- Where and individual acts on their own initiative,
- By which the individual aims to elicit material or immaterial benefits for themselves or third parties.

The risk of criminal liability in cooperation with businesses or other third parties can largely be reduced by adhering to the following four principles:

1. Separation Principle

Contributions are to be clearly separated from turnover.

a) Separation of medical services and contributions

Paid or unpaid contributions to doctors must not be linked to the allocation of patients or to a specific therapeutic behaviour or prescriptions. These are prohibited under social, professional and criminal law if they are intended to influence the doctor’s medical or therapeutic decision.

b) Separation of procurement decision and contribution

Paid or unpaid contributions may not be made in relation to turnover with the UKD or MFD or have any influence on the procurement decisions. This means that no contributions (payment in kind, services, cash benefits or other pecuniary or immaterial gains) may be accepted that could have a direct or indirect influence on the performance of the service or on procurement decisions, or even those that create this impression.

Even if the receiving party in no way intends to be influenced in their decisions by the contribution, merely accepting the contribution can be considered bribery and can lead to it being treated as criminal activity. This applies equally to influencing the prescription of medication in connection with the conducting of clinical or observational studies.

On this occasion, it is noted that procurement decisions are made on the basis of statutory provisions and the applicable procurement regulations. In accordance with the Commission's rules of procedure, matters pertaining to the Equipment Commission are discussed by its members and submitted to the Board of Directors for approval. Minutes shall be kept, which detail the recommendations of the Commission. The participation of other members of staff of the UKD/MFD, in particular the respective applicant, is limited exclusively for the purpose of clarification of technical and subject-specific requirements.

The UKD's statutory Medicine Commission (of which one member from each clinic is a member) decides on the UKD's list of medicines via an open vote. The minutes of the meetings are recorded. The attending healthcare professional has the freedom to decide on therapy and on the procurement of medication after consulting with the patient and in compliance with the legal requirements. This is carried out using a special application signed by said healthcare professional and processed by the clinic's pharmacy.

c) Dealing with patients, clients, business partners, officials

Patients, clients and business partners must not be offered, promised or granted, whether directly or indirectly, any contributions that are likely to influence the taking of objective and fair decisions. Civil servants, politicians and other representatives of public

institutions may not receive any benefits or contributions, which call their neutrality into question.

2. Principle of Transparency

According to the principle of transparency, contributions to members of staff that benefit or could potentially benefit them are to be reported in detail to the Board of Directors/ Dean. This also includes the disclosure of agreements, such as activities involving consulting or inspection, which potentially influence members of staff and create dependency relationships e.g. with businesses. All relationships to any businesses providing these contributions must therefore be described in detail. Upon announcing the contributions and other potential advantages, the secrecy, which is an essential characteristic of corruption, is removed. Contributions that serve private purposes or contributions to third parties, such as relatives of the member of staff, are not permitted. Announcing the contribution can lead to it being approved according to § 331 para. 3 German Penal Code (*StGB*).

Contributions can be both monetary and non-monetary, as well as financial or immaterial advantages, which benefit the UKD, the MFD or their members of staff as a result of cooperations with third parties. Conversely, these monetary and non-monetary contributions also include those granted by the UKD, the MFD or their members of staff to a medical professional in private practice or another healthcare professional for the allocation of examination materials or patients. According to § 24 of the Saxon Professional Code, doctors shall submit all contracts concerning their medical activities to the Medical Association before signing them, so that these contracts can be checked to decide whether the professional interests are being safeguarded.

3. Documentation Principle

Agreements with third parties, including calculating the flow of finances, should be fully documented in writing. In this way, business relationships that have been duly carried out and are not legally objectionable are verifiable at any time. This also applies to cooperations that stipulate the provision of equipment, renting of rooms, etc.

All paid and unpaid services provided by third parties to the UKD/MFD, their members of staff or to the business must be recorded in writing, must be verifiable and must be fully outlined for third parties at all times (e.g. payment flow, contractual provisions on the type and purpose of the contribution, research results, etc.).

In doing so, subsequent suspicion of criminal activity can be avoided or eliminated. Under no circumstances may price reductions, discounts, etc. be accepted or granted via cooperation agreements or funding associations that exist outside the scope of this service agreement.

4. Principle of Equivalence

In any contractual relationship between a third party and the UKD/MFD or its members of staff, a service and its reciprocation must be in reasonable proportion to one another.

It must always be guaranteed that payments to external doctors in private practices serve to exclusively remunerate the fulfilment of the contracts, which relate solely to medical services and do not influence decisions on prescriptions or therapy, as this is also prohibited under social, professional and penal law. The patient's freedom to choose a doctor or clinic must always be observed.

The remuneration of advisors and intermediaries must also be commensurate with the services they provide. It must not be used to offer businesses or third parties unlawful advantages.

Especially the question as to whether the remuneration is appropriate can give rise to delineation issues. In cases of doubt, it is advisable to obtain a recommendation from an external lawyer or to involve the responsible medical or hospital association.

Compliance with this principle is intended to ensure that payments are made exclusively for the fulfilment of a contract and not for the purchasing of administrative and procurement decisions or for the referral of patients, etc., and that there is goodwill associated with this.

§ 4 Notification Obligation, Secondary Employment, Competition

(1) In principle, all activities carried out for the UKD/MFD require a notification obligation and a contractual agreement between the UKD/MFD and the third party.

(2) Secondary employment is defined as all activities carried out in addition to official duties, either on a freelance basis or on the basis of a separate contractual relationship. Official duties are all actions carried out that have an official quality and fulfil an official obligation. The contractual relationship may also be based on an oral agreement. For the purpose of these guidelines, secondary employment includes, in particular, advising, lecturing, presenting, reviewing and organising. There is no insurance cover provided by the employer in the case of secondary employment. In addition, the member of staff in secondary employment must pay the taxes on income and expenses themselves, as this is not managed by the UKD or the MFD. A concurrent approval of a business trip is excluded. Details can be found in § 17 para. 1 of these guidelines.

(3) No member of staff may enter into agreements with business partners, which intend to impair competition. It is not permitted to treat business partners unlawfully (§§ 299 a, 299 b German Penal Code (*StGB*)).

§ 5 Contributions to Third Parties

The corruptions regulations also cover contributions to third parties (or related persons) which do not benefit the member of staff or the UKD/MFD themselves or the medical professional in private practice/healthcare professional cooperating with the UKD/MFD themselves.

These related persons include, for example, persons within the meaning of § 6 para. 4 sentence 2 of the Public Procurement Regulation (*Vergabeverordnung*) as well as third parties who have a connection with the member of staff under company law, obligation law or actual personal relationships. Such contributions are not permissible.

§ 6 Conduct in the Event of Suspicion of Corruption

All members of staff are required to inform their supervisor as soon as they become aware of any violation of these guidelines. In addition, the details must be reported to the Anti-Corruption Officer. Any information received will be treated as strictly confidential and will be protected by appropriate organisational and technical measures.

§ 7 Consequences of Corruption Offences

Violations of legal and official regulations can result in a number of consequences, ranging from the implementation of employment law measures up to the termination of employment. Criminal repercussions may also be pursued.

II. Contractual Cooperation between UKD/MFD and Third Parties

§ 8 General Framework Conditions for Contractual Cooperation

(1) The UKD/MFD may only provide services for companies or third parties on the basis of a written contract, which explicitly quantifies the service and reciprocation. All agreements and subsidiary agreements must be contained in the relevant contract. No services may be rendered outside the scope of the signed and disclosed contract, and no contracts extending beyond this may be signed for the benefit of the member of staff in question.

(2) Payment transactions shall be carried out exclusively by bank transfer or cheque to the accounts of UKD or MFD.

If the payment is made by cheque, the cheque must contain the following information:
the recipient named as UKD or MFD, the name of the institute or clinic, and the name of the member of staff (project manager).

(3) When carrying out projects financed by third-party funding and signing contracts with the UKD, it must be ensured that these are not misused by the contractual partner for the purpose of influencing decisions regarding therapy or procurement, or for mere advertising purposes.

(4) The signing and allocation of contracts for the UKD and MFD must take into account competitive market criteria. Every member of staff is obliged to act in the interest of MFD or UKD respectively. Situations, in which the member of staff's own interest or those of persons closely associated with the member of staff conflicts with the interests of the UKD or MFD, should be avoided.

§ 9 Contracts for Third-Party Funded Projects

(1) Contracts for third-party funded projects (such as research and development projects, clinical studies, equipment testing, cf. § 16 etc.) serve to promote medical-scientific research and development, as well as the teaching and promotion of early-career researchers. Third-party funds are made available for the implementation of any projects on the basis of contracts with a company. These contracts are drawn up in conjunction with the Department for Third-Party Funding Management.

(2) The contractual partner is Technische Universität Dresden (TUD), represented by the Chancellor. The executive body is the MFD of TUD and the corresponding institute or clinic including the name of the responsible member of staff.

(3) Each project shall be reported to the Department for Third-Party Funding Management in good time, i.e. as soon as it becomes known. For this purpose, the form "Notification of a Third-Party Funded Project" must be completed and, if necessary, the cost estimate must be attached. After review by the Department for Third-Party Funding Management, the contracts of the MFD, including the notification of external funding for the project, must be submitted to the Dean for approval.

(4) If participation in symposia, further education and informational events etc. is necessary for the proper execution of a project financed by third-party funds, the resulting travel costs may be covered by the third-party sponsor, provided that a corresponding regulation has been stipulated in the contract.

(5) The Department for Third-Party Funding Management must be informed immediately of any foreseeable obstacle in the fulfilment of the contractual duties, regardless of which contractual party is involved and the type of obstacle.

§ 10 Application Studies

(1) Application studies refer to a non-interventional, observational study in the field of medical research, designed to gather knowledge on the use of marketable medicinal products, in particular on their efficacy and tolerability. By conducting application studies, pharmaceutical companies chiefly pursue marketing-related goals, which means that the scientific value is often lost. For this reason, contracts for application studies at the UKD and the MFD are generally not welcomed.

(2) Exceptions include the collection of application data for new drugs as stipulated by lawmakers, as well as legally ordered application studies. In order to clarify the background of the planned application study and to ensure guaranteed transparency, the planned observation must be reported to both the Board of Directors and the hospital pharmacy before any contract is signed. The hospital pharmacy checks the application study for permissibility before approving it.

If there is no basis that supports its permissibility, the signing of the contract shall generally be rejected. The Board of Directors or the Dean decide on exceptions.

Details can be found in the circular letters from the Anti-Corruption Officer dated 19th February 2009 and 23rd February 2016.

§ 11 Sponsorship of Continued Education

(1) The acceptance of contributions from third parties (sponsors), which are used for company-related advertising and public objectives in the context of scientific symposia, conferences and workshops, is permissible to a reasonable extent if the nature, content and presentation of the continued education events are determined exclusively by a medical organiser or by a scientific institution.

(2) Sponsorship contracts must always be drawn up in writing between the company and the organiser (MFD or UKD, usually represented by Carl Gustav Carus Management GmbH), specifically stating the service and the reciprocation. Sponsorship contracts cannot be arranged as private secondary employment.

(3) All sponsored events require approval. When announcing and carrying out continued education events, all relationships with the sponsor must be disclosed to the Board of Directors or Dean using the form (cf. Attachment 1).

(4) In this context, it should be noted that such events should not be carried out by the sponsor themselves, but that the Carl Gustav Carus Management GmbH or other event providers should be commissioned to carry out the organisational, contractual and financial proceedings.

§ 12 Cooperations with Medical Professionals in Private Practice

Cooperation between the UKD/MFD and medical professionals in private practice to promote optimised patient care is both sensible and appropriate. However, they must be permissible and comply with the legal and internal regulations, cf. in particular § 2. Proper accounting and invoicing of the services of doctors and consultants requiring remunerations is of the utmost importance.

Services carried out based on authorisations by one's personal health insurance or by community health centres may only be provided by doctors, who are authorised to do so.

III. Unilateral Miscellaneous Services Provided by Third Parties

§ 13 Remunerations and Reimbursements from Third Parties to Employees

(1) The reimbursement or covering of travel expenses, accommodation costs, participation fees at events – such as further training, courses, symposia and seminars – etc. of members of staff by third parties (e.g. industry, professional societies, associations) for the purpose of conducting business outside the place of work is not permitted. The same shall apply to in-depth and continued education events arranged for official purposes.

In exceptional circumstances, such reimbursements or covering of costs may be permissible if a corresponding contractual agreement exists between the third party and the UKD/MFD (e.g. within the framework of a contract for the carrying out of clinical studies, in which a reimbursement of costs is expressly stipulated and the activities agreed upon in this contract are carried out by members of staff in the context of their employment relationship). The Saxon Travel Expenses Act defines whether the reimbursement is appropriate.

(2) If the prerequisite of paragraph 1 is not met, the reimbursement of costs by third parties to members of staff can only take place within the framework of a secondary employment. A permit for secondary employment must be applied for in good time before embarking on the trip, cf. § 17 para 2.

(3) If the member of staff of the UKD/MFD provides services (e.g. lecturing, consulting) within the scope of the events mentioned in para. 1, which are financed through a reimbursement of costs or remuneration, it is only considered a service if a contract between the UKD/MFD and the company forms the basis. The remuneration must be transferred to the UKD/MFD account and may not be collected privately. Otherwise, it is considered secondary employment.

§ 14 Training Courses

Training courses (e.g. plaster cast courses, therapeutic apheresis, etc.) conducted by third parties (pharmaceutical companies, equipment manufacturers, medical device manufacturers, etc.) may not be carried out at the UKD/MFD without a contractual basis as stipulated by anti-corruption and liability law.

If an appropriate training course is necessary for subject-specific reasons, it must be based on a corresponding contract (e.g. consulting contract).

§ 15 Donations

(1) Donations must always be made to the Stiftung Hochschulmedizin Dresden (*University Medicine Foundation Dresden*). The contact person is the Chairperson of the Board of the foundation, who can be reached via the foundation's office, tel. 458 – 3715.

(2) If the sponsor expressly wishes to make a donation to the UKD/MFD for a specific purpose, a case-by-case examination will be carried out. In order to decide whether a donation will be accepted, a letter of contribution must be submitted to the Finance Division, Revenue Planning/General Issues in each case, stating the reason for the donation and the intended purpose. If necessary, the existing relationships with the donating party must be described in more detail in a memorandum.

§ 16 Funding Associations

(1) A particular legal problem are contributions to funding associations, in which UKD or MFD staff are members or even serve on the Board of Directors. Legally, this can be done with so-called circumvention financing, i.e. a company does not directly donate the money to the UKD/MFD, but via a funding association. In this case, even though the grant is not acquired or accepted for carrying out the service, the acceptance of the contribution can be deemed to have an actual or possible effect on the service itself. This constitutes a criminal action i.e. the acceptance of an advantage or bribery and is not permissible.

(2) In order to prevent conflicts of interest, UKD/MFD staff should not be associated with or be members of sponsoring associations. The contributing associations are obliged to disclose the income of companies or institutions with which the UKD/MFD has business dealings of supplying goods and services upon request by the Board of Directors or Dean and must disclose donations decisions.

(3) With regard to the acceptance of contributions, the same procedure must be followed as for donations (§ 15).

§ 17 Gifts

(1) The acceptance of any rewards, gifts or other benefits offered to members of staff in connection with their employment by any third party having or seeking a business relationship with the UKD or MFD is prohibited.

Exceptions require the prior consent of the Board of Directors of the UKD or the Dean of the MFD. Personal gifts on special occasions, e.g. anniversaries of service, promotions, awards, nominations, special birthdays may be accepted in exceptional cases, provided that they are within an appropriate framework in accordance with the regulations of the Free State of Saxony and provided that acceptance is approved by the Dean or the Board of Directors. The unauthorised acceptance of such benefits constitutes a breach of official duty, which may result in disciplinary, labour law and criminal consequences.

(2) The approval is generally granted if it concerns:

1. low-value gifts and/or promotional items of a value of up to approx. 20 euros per gift and a total of approx. 60 euros per year,
2. personal recognition of ward and support staff in the form of benefits in kind of low value (e.g. coffee, flowers, etc.).

The generally given consent can be revoked by the Board of Directors / Dean if the acceptance could give the impression of preferential treatment of individuals or of bias.

(3) The acceptance of social contributions (so-called social donations) which serve to support company events such as Christmas parties, company outings, birthday parties or the like is prohibited.

(4) In the case of an advantage, the acceptance of which is not generally to be granted, the approval of the Board of Directors / Dean must be obtained. The following procedure applies:

- the agreement must be obtained before acceptance of the advantage and is to be obtained immediately in writing via the Anti-Corruption Officer.
- The application must be accompanied by the circumstances relevant to the decision, the nature of the benefit, its estimated value, the reason for granting the benefit, by whom the benefit was granted and the relationship of the applicant to the grantor of the benefit.

If the approval is not given, the advantage - if already illicitly received - is to be returned to the grantor.

§ 18 Hospitality Costs Using Acquired Third-Party Funds

Hospitality costs are generally only permitted to an appropriate and socially adequate extent. For the settlement of MFD-funded working lunches or catering services within the scope of research and teaching, the relevant event must be documented in a suitable, verifiable manner with a concrete indication of the group of participants. Hospitality costs for accompanying persons cannot be claimed. It should be noted that the costs for hospitality, in which predominantly UKD/MFD employees participate, are not refundable.

§ 19 Equipment

(1) The acceptance and use of equipment as a third-party contribution (loan agreement) requires the prior written approval of the Logistics and Purchasing Department.

(2) The testing of devices (testing contract) may only take place after prior approval by the Medical Technology Department of the Logistics and Purchasing Department.

(3) With regard to the inclusion of equipment in the UKD or MFD inventory, the procurement regulations of the UKD shall apply.

(4) As a rule, a loan contract for equipment is to be drawn up for a period of up to one year; a test contract may be drawn up for a maximum of six months. At the end of this period, it must be checked whether the equipment is being purchased in accordance with public procurement law.

IV. Part - Cooperation between UKD/ MFD Members of Staff and Third Parties in Secondary Employment

§ 20 Secondary Employment and Employer's Authorisation

(1) Before a secondary employment (§ 4 para. 2) may be carried out, a notification or application, depending on the nature of the employment relationship and in accordance with the attachment (template) in the Personnel Department, must be submitted to the responsible person in charge of the Personnel and Legal Affairs Department, Section Travel Expenses/ secondary employment, disclosing all facts relevant to the decision. Members of staff are obliged to notify the employer of any secondary employment or to obtain approval prior to commencing such secondary employment. An employer's authorisation can only be granted on this basis.

A prerequisite for the granting of a secondary employment permit and an employer's permit is the sending of the following documents and information, or the sending of the contract concluded as a private individual:

1. the amount of the travel and accommodation expenses covered
2. programme of event
3. information as to whether and, if so, in what form a personal contribution is to be made
4. presentation of the interest of the service

5. presentation of the business relations of the UKD/ MFD with the respective companies.

The employer's authorisation is not covered by a secondary employment authorisation.

(2) There is no review or co-signing of contracts carried out by members of staff in secondary employment.

V. Part - Miscellaneous Provisions

§ 21 Entry into Force

These Guidelines will enter into force after their approval by the UKD Board of Directors and by the Dean of the MFD and at the same time replace the provisions of the Guidelines for Cooperation with Industry in relation to the Anti-Corruption Act of 1st March 2012 and its amendments.

For the UKD Institution under Public Law, Dresden,

Prof. Dr. med. D. Michael Albrecht

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