

## **Regulations for the Commission for Research Impact Assessment and Ethics at the University of Oldenburg**

**dated 17/03/2017**

On 7 December 2016, the Senate of the University of Oldenburg adopted the following regulations for the working procedures of the Commission for Research Impact Assessment and Ethics ("Commission" for short), which was established in accordance with Section 5 of the university charter, pursuant to Section 41.1.1 of the Lower Saxony Higher Education Act (NHG).

### **1**

#### **Scope**

- 1) The Commission for Research Impact Assessment and Ethics provides assistance in the form of consultation and evaluation of ethical aspects and impact assessment with regard to research projects, striking the balance between academic freedom and responsibility. This assistance does not relieve researchers of their own responsibility for the research project and its execution. Research projects in the medical field, in particular those that fall within the scope of the Drugs Law (AMG), the Medical Devices Act (MPG) and the Radiation Protection and X-Ray Ordinance are assessed by the competent Ethics Committee for the School of Medicine and Health Sciences.
- 2) The Commission works on the basis of the applicable law and academic standards as well as the relevant professional rules. It takes into account relevant national and international recommendations. In doing so, it uses the current state of science and technology as its basis.
- 3) The Commission deliberates on ethical conflicts that arise in the course of study, teaching and research activities.

### **2**

### **Members, term of office and chair**

- 1) The Commission is made up of seven members from the University of Oldenburg. Four members of the Commission must be professors or university lecturers, with the remaining members composed of a student representative, an academic staff member and a member of technical/administrative staff. They are elected by the members of their respective group in the Senate.
- 2) The Commission's term of office is two years (one year for student representatives).
- 3) The Commission shall elect a Chair and a Deputy Chair from its members.

### **3**

### **Applications and enquiries**

- 1) Members and associates of the university should seek advice from the Commission before carrying out a research project if the project in question involves humans or if it entails considerable safety-related risks. This applies in particular to the endangerment or violation of human dignity, life, health, freedom, property, the environment or peaceful coexistence. Safety-related risks exist in particular in research work that can be assumed to produce knowledge, products or technologies that may clearly be misused by third parties. The same shall apply if safety-related risks become apparent during the execution of a research project.
- 2) The Commission shall act upon request.
- 3) Researchers from the University of Oldenburg and from universities and institutions linked via cooperation agreements are eligible to apply to have their research project assessed in accordance with Section 1.1 of these regulations. In the case of theses and projects as part of the degree programme, the person responsible for the examination is also responsible for submitting the application to the Commission.
- 4) All members and associates of the University of Oldenburg are entitled to make enquiries within the meaning of Section 1.
- 5) Applications to assess research projects involving humans must be completed in accordance with the Commission's instructions for drafting applications and must be submitted to the joint administration office of the Ethics Committees. Applications concerning safety-related research must be submitted in writing to the Chair of the Commission for Research Impact Assessment and Ethics following an initial consultation with the Commission. The application should include a brief summary of the project in easy-to-understand language as well as a precise explanation of the safety-related aspects.
- 6) The Commission shall be informed about the research project by the applicant of the research project with regard to the following points:
  - Substantial changes before or during execution,
  - Failure to carry out the project or its abandonment,
  - Results or conditions that lead, could lead or have led to considerable risks or call into question the execution of the research project.

**4****Transparency and decision-making**

- 1) The Commission's meetings are not public. The members of the Commission, as well as those involved in an advisory capacity, are obliged to maintain secrecy about the deliberations and decision-making and to treat the consultation documents confidentially.
- 2) As a rule, the Commission shall discuss and decide on its matters for deliberation in meetings. This is always the case if a member of the commission so desires. In all other respects, the current version of the General Rules of Procedure of the University of Oldenburg shall apply.
- 3) The Commission and its members shall be independent when discharging their duties and shall not be bound by instructions.
- 4) Members of the Commission involved in the research project pending a decision shall usually be excluded from the debate and shall always be excluded from the decision-making process.
- 5) The Commission may ask the applicants of the research project to provide additional documents, information or explanations on the concept and execution of the research project. The Chair shall inform the applicants of the research project in writing of the Commission's reservations about the research project or the explanations. The applicants of the research project shall be given the opportunity to make a statement to the Commission.
- 6) The Commission may seek expert opinions in consultation with the applicants of a research project. Experts who are consulted in an advisory capacity shall be bound to confidentiality and secrecy.
- 7) Minutes shall be taken of each meeting of the Commission, showing the main results of the proceedings.

**5****Time period and decision-making**

- 1) The Commission must respond to an application according to Section 3.3 or an enquiry according to Section 3.4 within 12 weeks. It shall take decisions on the basis of a majority of its members. The applicant or party making an enquiry shall be informed of the Commission's decision in writing.
- 2) If the Commission deems the execution of a research project unacceptable on ethical grounds or only acceptable subject to conditions or recommendations, such a decision shall be justified in writing.
- 3) Any member of the Commission may express their divergent views in a dissenting opinion, which shall be attached to the decision.

**6****Entry into force**

These regulations shall enter into force following their publication in the official notices of the University of Oldenburg. At the same time, the previous regulations for the Commission for Research Impact Assessment and Ethics at the University of Oldenburg dated 21/03/2013 (Official Notices 1/2013, p. 19 f.) shall cease to apply.