

# Rules of Procedure for Research Ethics

Adopted by the Executive Board's 4-2018 meeting on 29 November 2018.

Put into effect by the Board of the Leibniz Association on 27 February 2019. Amendments adopted by the Executive Board's 1-2022 meeting on 1 March 2022.

Version: 1 March 2022

## Disclaimer

This English translation of the Rules of Procedure for Research Ethics is provided for information purposes only. In the event that the English and German versions permit different interpretations, the German text shall prevail.

## Preamble

Within the sphere of activity of Leibniz Integrity, the Executive Board of the Leibniz Association adopts these Rules of Procedure for Research Ethics, based on the recommendations of the German Research Foundation (DFG) and the German National Academy of Sciences Leopoldina.<sup>1</sup> They govern the duties of the Executive Board Representative for Research Ethics and of the Leibniz Commission for Research Ethics, and define relevant principles and rules of procedure that reflect the importance of research ethics and the disciplinary breadth and organisational diversity of the institutes of the Leibniz Association.

## § 1 Duties of the Executive Board Representative for Research Ethics

- (1) The Executive Board Representative for Research Ethics is appointed by the Executive Board of the Leibniz Association in accordance with the Statutes § 11 (5) for a renewable term of four years. The representative chairs the Leibniz Commission for Research Ethics. They are also a member of the Leibniz Integrity Advisory Board and bring research ethics topics to the advisory board.
- (2) The Executive Board Representative for Research Ethics represents the Leibniz Association internally and externally in matters relating to research ethics and is the contact person for national and international cooperation partners. Another of their tasks, in collaboration with the Leibniz Integrity Advisory Board, is to contribute to raising

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<sup>1</sup> DFG/Leopoldina: Scientific Freedom and Scientific Responsibility. Recommendations for Handling Security-Relevant Research, 28 May 2014.

awareness of security-relevant and ethical aspects of research and, in addition, to contribute to knowledge transfer in the Leibniz Association and to networking activities, continuing professional development and training in this area.

- (3) The Executive Board Representative for Research Ethics reports to the Executive Board on an annual and event-driven basis on the latest developments in the area of research ethics.

## **§ 2 Duties and basic principles of the Leibniz Commission for Research Ethics**

- (1) The task of the Leibniz Commission for Research Ethics is to advise on and assess research projects in terms of any significant security-relevant and ethical risks to human dignity, life, health, liberty, property, the environment or peaceful coexistence. In particular, security-relevant risks exist in research work that is likely to make use of, or result in, knowledge, products or technologies that could be misused directly by third parties. Irrespective of the advice provided by the Leibniz Commission for Research Ethics, the researchers remain responsible for their own actions.
- (2) The Leibniz Commission for Research Ethics deals exclusively with requests relating to research and transfer projects for which there is no other established review process in place (see Annex to these Rules of Procedure). In addition, there is still a need at the level of the institutes to provide efficient processes to clarify security-relevant and ethical issues, according to requirements.
- (3) The work of the Leibniz Commission for Research Ethics is based on applicable legislation, professional standards and the relevant rules of professional conduct. It takes account of national and international recommendations and takes the current state of research and technology as its basis.

## **§ 3 Convening the Leibniz Commission for Research Ethics**

- (1) Requests intended for the Leibniz Commission for Research Ethics are to be addressed in writing to the chairperson or to Leibniz Headquarters.
- (2) A request must contain a summary in lay terms and an exact presentation of the security-relevant and ethical aspects of the project and, where relevant, the results of any assessments already conducted in this regard. In addition, in order for the Commission to deal with a case, the ethical or security-relevant issue in the research project must have a demonstrable relevance beyond the individual case in question for a key Leibniz Association field of research.
- (3) The chairperson of the Leibniz Commission for Research Ethics checks the formal and subject-matter competence and facts of incoming requests in consultation with the Secretary General. The chairperson is entitled to take decisions directly where requests concern clear, straightforward risks, and may call on expert opinions where appropriate.
- (4) The Leibniz Commission for Research Ethics is convened ad hoc by the chairperson, provided the case does not fall within the remit of a commission at the member institute

or, where relevant, at a collaborating university, or if no clear responsibility can be identified.

- (5) The Leibniz Commission for Research Ethics can also be convened on the basis of third-party evidence sent to the chairperson. Such evidence is to be treated in confidence. However, the Commission is not obliged to follow up anonymous tip-offs.

#### **§ 4 Composition of the Leibniz Commission for Research Ethics**

- (1) The Executive Board Representative for Research Ethics, in consultation with the Secretary General of the Leibniz Association, proposes the composition of the Leibniz Commission for Research Ethics and invites the members. This should usually take place within four weeks of receipt of a relevant request.
- (2) Besides the chairperson, voting members of the Leibniz Commission for Research Ethics are the Secretary General and at least two other suitable experts for assessing the case in question who have experience of research or research management and are familiar with the process of assessing issues relating to research ethics. In addition, membership of the Leibniz Commission for Research Ethics is open to the spokesperson of the Section affected by the case.
- (3) The Leibniz Commission for Research Ethics may call on other non-voting experts as required.
- (4) The Leibniz Commission for Research Ethics and its members are independent and not bound by instructions in the exercise of their duties. They are to act to the best of their knowledge and belief. Members cannot be held personally liable for work they carry out within a Leibniz Commission for Research Ethics and neither can the Executive Board Representative.

#### **§ 5 Proceedings of the Leibniz Commission for Research Ethics**

- (1) The Leibniz Commission for Research Ethics deals with requests within a reasonable timeframe and produces a final written statement that records its assessment of how legally and ethically justifiable it is to conduct the project in question, where relevant with modifications and restrictions, e.g. to minimise risks.
- (2) Those submitting requests are given the opportunity to present the project comprehensively in writing and, where appropriate, orally.
- (3) The Leibniz Commission for Research Ethics manages the other details of its working methods itself, based on the Model Statutes for Committees for Ethics in Security-Relevant Research produced by the German Research Foundation (DFG) and the German National Academy of Sciences Leopoldina, particularly sections 6 to 9 (Initiating proceedings, Proceedings, Decision-making procedure and Notification of unexpected risks and security-relevant aspects). In addition, the General Rules of Procedure of the Leibniz Association shall apply.
- (4) The chairperson of the Leibniz Commission for Research Ethics reports on its processing of requests to the Executive Board of the Leibniz Association and, where

appropriate, to the Joint Committee on the Handling of Security-Relevant Research established by the German Research Foundation (DFG) and the German National Academy of Sciences Leopoldina.

- (5) The work of the Executive Board Representative for Research Ethics and of the Leibniz Commission for Research Ethics is supported by Leibniz Headquarters.

## Annex to the Rules of Procedure for Research Ethics

The Leibniz Commissions for Research Ethics do not deal with requests relating to research and transfer projects for which other security-relevant and ethical assessment and control procedures are already established. This applies in particular to issues covered by the following legislation:

- Animal Protection Act (Tierschutzgesetz, TierSchG)
- Medicinal Products Act (Arzneimittelgesetz, AMG)
- Medical Devices Act (Medizinproduktegesetz, MPG)
- Stem Cell Act (Stammzellgesetz, StZG)
- Protection Against Infection Act (Infektionsschutzgesetz, IfSG)
- Labour Protection Act (Arbeitsschutzgesetz, ArbSchG)
- Biological Agents Regulation (Biostoffverordnung, BioStoffV)