Bundesinstitut für Risikobewertung

Principles for safeguarding the Good Scientific Practice at the German Federal Institute for Risk Assessment

10.01.2023

Please note, this English translation is provided by BfR to allow an easier access to the principles for non-German speaking persons. However, only the German version (Grundsätze zur Sicherung der Guten Wissenschaftlichen Praxis am Bundesinstitut für Risikobewertung) is legally binding.

Preamble

The German Federal Institute for Risk Assessment (BfR) is a federal institution under public law with legal capacity in the portfolio of the Federal Ministry of Food and Agriculture (BMEL); its tasks include that of a federal departmental research institution.

In order to fulfil the responsibilities in research and the tasks directly associated with it, BfR has established regulations to ensure good scientific practice and how to deal with cases of scientific misconduct. The BfR thus ensures, among other things, the appropriate handling and use of public funds and other grants as well as compliance with scientific standards.

These principles follow the code "Guidelines for Safeguarding Good Scientific Practice" of the German Research Foundation (DFG) of 01 August 2019 and adapt them to the specific circumstances of BfR. BfR recognises this code as binding for all its staff. Notwithstanding this, BfR is also subject to the provisions of the BfR Act (BfRG) and other laws and regulations.

BfR is certified according to DIN EN ISO 9001 and carries out accredited test procedures according to DIN EN ISO/IEC 17025. Therefore, in addition to these principles further documents exist which are relevant to good scientific practice. Reference is made to these more detailed documents at the appropriate place.

1. Commitment to the principles

This text sets out the binding principles for "Good Scientific Practice" (GSP) at the German Federal Institute for Risk Assessment. All members of BfR staff (employees and officials) are informed of these principles in an appropriate manner and undertake to comply with them.

The standards of good scientific practice include, in particular, working according to the state of the art, maintaining strict honesty with regard to one's own and third parties' contributions, consistently question all results, and allowing and encouraging critical discourse in the scientific community. Further principles are set out in more detail below.

2. Professional ethics

The constitutionally guaranteed freedom of science and research is directly linked to a corresponding responsibility for diligence and honesty. It is the primary task of all scientists to comprehensively fulfil this responsibility.

Staff working scientifically have a responsibility to put the principles of good scientific work into practice.

Scientific work at BfR is strongly interdisciplinary. Cooperation requires appreciative behaviour across disciplinary boundaries. It is important for scientists to be aware of the limits of their own competences and to close gaps where necessary.

PhD students take a compulsory course on Good Scientific Practice at the BfR. This course is announced on the intranet and is open to all members of staff of the institute. The course materials are published on the intranet.

All members of staff working scientifically are expected to follow the principles of the Good Scientific Practice and keep themselves up-to-date.

3. Organisational responsibility of the Institute’s management

The Institute's management is responsible for communicating good scientific practice and creates the conditions for compliance with legal and ethical standards. BfR informs its scientific staff, i.e. scientific personnel, young scientists and its technical personnel - with reference to these principles - about the principles of scientific work and good scientific practice. New staff members are informed of these principles when signing their contracts. Within the BfR doctoral training programme, young scientists are introduced to the basic principles of scientific work.

BfR’s structure is presented in the Quality and Environmental Management Manual (QUMH), in the current organisation chart (“Organigramm”) and in the business distribution plan (“Geschäftsverteilungsplan”) and can be accessed on the intranet.

Transparent guidelines exist for staff selection and staff development. Furthermore, BfR is subject to the Federal Equal Opportunities Act (§ 3 No. 5 BGleiG) and pursues the actual equality of all genders. In this context, scientists in management positions familiarise themselves with the concept of *unconscious bias* and incorporate this into their decision-making.

4. Responsibility of the management of organisational units

The head of a scientific organisational unit shall bear responsibility for the entire unit. BfR’s rules of procedure (as amended, “Geschäftsordnung”) shall be followed.

All responsible persons shall ensure that the tasks of management, supervision, conflict management and quality assurance are clearly assigned and guaranteed through appropriate organisation of their work area. The heads of the organisational units shall supervise junior researchers individually in a manner appropriate to the respective career phase and shall promote the careers of the scientific staff.

In order to prevent abuse of power, line managers are regularly trained with target group-specific advanced training. A supervision agreement between doctoral researcher and supervisor is mandatory for doctoral projects. It defines the rights and obligations of both parties and obliges both to comply with the principles of good scientific practice.

In cases of suspected abuse of power or exploitation of relationships of dependency, staff can contact their line managers, the Institute's management, the Human Resources Department, the Staff Council (“Personalrat”), the Equal Opportunities Officers (“Gleichstellungsbeauftragte”), the Social Counselling Service (“Sozialberatung”) and the Ombudspersons. Severely disabled staff and those with equal rights can also contact the representative of severely disabled people at the BfR.

5. Performance dimensions and evaluation criteria of scientific work

At BfR, a wide range of parameters are taken into account when assessing the performance of scientists. In addition to scientific publications, these also include the preparation of statements within BfR's legalremit. The evaluation of performance is primarily based on qualitative standards, i.e. besides of the quantity of the work results, the quality and originality of the work is particularly important. Further aspects may be taken into account, such as commitment to teaching and supervision of young scientists, acquisition of third-party funding, committee work and the effort required to comply with ethical and legal framework conditions.

6. Ombudspersons

The Institute's management appoints an ombudsperson to whom BfR staff can turn at any time with questions and complaints relating to good scientific practice. Alternatively, those seeking advice can turn to the "German Research Ombudsman ". The ombudspersons provide advice on questions of good scientific practice and in suspected cases of scientific misconduct, aiming as far as possible at solution-oriented mediation in conflicts.

The ombudsperson has a deputy who acts in the event of the ombudsperson's actual or legal prevention (e.g. in the case of conflict of interests). The deputy ombudsperson is also appointed by the Institute's management. Experienced scientists with management experience (e.g. of organisational units, project teams, laboratory units, etc.) who are scientifically active themselves and do not currently hold management positions at departmental level may be appointed. The aim of seeking gender equality, is taken into account when appointing the ombudspersons. The term of office is four years. A second term of office is possible. The names of the ombudsperson and the deputy ombudsperson are announced on the intranet. The ombudsperson acts independently in the exercise of his/her duties and is bound to secrecy, subject to obligations under service or labour law. In cases where initial suspicions are confirmed and in cases of serious breaches of duty, the ombudsperson may be obliged to inform the Institute's management on the basis of the procedure for dealing with scientific misconduct or on the basis of the contractual duty of

loyalty, especially if the breach of good scientific practice may also have criminal consequences.

The Institute's management facilitates further training for the ombudspersons in the areas of moderation, conflict resolution and Good Scientific Practice, if necessary.

The tasks of the BfR ombudspersons are described in more detail in Chapters 18 and 19 and in the Rules of Procedure for Dealing with Scientific Misconduct at BfR (VerfOwF).

7. Cross-phase quality assurance

The scientists at BfR carry out each step in the research process in accordance with the state of the art, consistently question their own results and ensure continuous research-accompanying quality assurance, particularly with regard to:

- compliance with subject-specific standards and established methods,
- processes, such as the calibration of devices,
- the collection, handling, analysis and documentation of research data,
- the selection and use of research software and its development and programming; and
- the keeping of laboratory records, documented in laboratory books.

Falsification of scientific hypothesis and/or experimental errors are a normal part of the research process. Against this background, scientists are encouraged to openly discuss errors. Such errors and misconceptions are not scientific misconduct as defined by the Good Scientific Practice.

When scientific findings are made publicly available, the applied quality assurance measures are always outlined. Materials and methods are described in sufficient detail and according to the rules of good scientific practice in a way that third parties can understand, replicate and verify the findings/results.

If discrepancies or errors are discovered after a publication, they shall be corrected. If the discrepancies or errors are the reason for the retraction/corrigendum of a publication, the researchers shall work with any collaboration partners as well as the publisher or infrastructure provider etc. as quickly as possible to ensure that the correction or retraction takes place and the publication is marked accordingly. The same applies if the researchers are informed of such discrepancies or errors by third parties and this criticism proves to be justified.

The origin of data, organisms, materials and software used in the research process is identified and the further use is documented; the original sources are cited. The type and scope of research data generated in the research process are described. Such data shall be handled in accordance with the requirements of the subject concerned. The source code of publicly accessible software shall be available in a persistent, citable and documented manner.

8. Actors, responsibilities and roles

The roles and responsibilities of all persons involved in a research project (including technical staff) are clearly defined at all times during a research project subject to the

requirements. Roles and tasks are documented in the respective project description. The persons involved in a research project are in regular contact with each other. In the case of cooperations with other institutions, the interests as well as the rights and obligations of the participants are laid down as far as possible and reasonable within the framework of cooperation agreements.

9. Research design

Investigations must be conducted according to the state of the art; knowledge of the current state of research and the appropriate methods is mandatory. The Institute shall make resources available to search for publicly accessible research results.

The validity of the results is determined by the research design, adequate, statistical experimental planning and evaluation, and planned, comprehensible documentation of the research data and findings. Animal studies, even those that do not fall under the legal obligation to notify, must be pre-registered in the Animal Study Registry before they are conducted. The choice of the research approach is central to the significance of the findings obtained, but also to their applicability and generalisability. The choice of methodology and model system should be carefully considered and the advantages and disadvantages openly stated; they should be reflected upon when evaluating projects. Models should be valid and the research design robust. The study design takes into account the extent to which gender and diversity are relevant to the research project. The influence of possible *unconscious bi*as is mitigated as far as possible through appropriate methods.

For the management of the research data, appropriate steps must already be taken in the planning phase of the project to ensure that the documentation is comprehensible for third parties and that the subsequent use of research data is possible, latest after completion of the project.

10. Legal and ethical framework, rights of use

Scientists shall comply with rights and obligations arising from laws, regulations and contracts, obtain official licences and ethics votes where necessary and submit them to BfR. The Institute's management is responsible for ensuring that the actions of its staff conform to the rules and promotes this through appropriate organisational structures and information.

The right to use research data belongs primarily to those who collected/generated the data; the regulations under labour or civil service law apply. In the case of collaborations between BfR researchers and third parties, a cooperation agreement shall be agreed on, if possible and reasonable, in which the rights and obligations of all parties involved are described. International rules and agreements are taken into account appropriately. The cooperation agreement also includes agreements on the rights of use of results developed within the joint project. In case no third parties are involved in the project, the relevant labour and civil service laws or other agreements reached shall apply.

If BfR employees are granted access to data of third parties, they shall comply with all obligations associated with access to the data. Third parties shall only be granted access to BfR data on the basis of agreements on access and the scope of use.

Scientists are responsible for assessing the consequences of their research. They are aware of the danger of misuse of research results (*dual use*). BfR appointed a contact person for safety-relevant research.

11. Methods and standards

To answer research questions, BfR uses scientifically sound, comprehensible and quality-assured methods based on the standards in the respective discipline. The specific competences required for the development and application of a method (for example, for the use of equipment) are ensured through documented training and, where necessary, the granting of authority. If necessary, competencies are covered through appropriately close collaborations.

To ensure the comparability and transferability of research results, researchers observe standards for:

- the development and application of new methods and software,
- the collection of research data and
- the description of research results.

The selection of materials, methods, controls and data analyses to be used shall be made according to subject-specific standards or, if these do not yet exist, according to good scientific practice.

The review and evaluation of results is carried out according to specific professional recommendations or standards, where these exist. If there is a deviation from these, the reasons are explained in a comprehensible manner.

12. Documentation

The documentation of research results is a main component of good scientific practice. All the information relevant to a research result is documented in such a comprehensible manner as is necessary and appropriate in the subject area concerned in order to be able to double-check and evaluate the result. All individual results are documented, including those that do not support the research hypothesis. Any exclusion of results or observations must be fully documented and justified. An interest-driven selection of research results is not permissible. Documentation and research results must not be manipulated and must be protected against manipulation as best as possible.

In order to be able to guarantee the traceability and comparability of data, information about the software used for data processing should also be deposited in the description of measurement data. Whenever possible, freely available software solutions should be used.

13. Establishing public access to research results

Scientific results should be communicated to the scientific public in the form of publications and scientific assessments; the publications are thus - like the scientific observation or experiment - an integral part of the research process. Scientists decide on the publication of results in compliance with BfR’s rules on scientific publications. In principle, all results are included in the scientific discourse unless there are reasons to the contrary in specific cases,

e.g. in connection with security-relevant research, data protection concerns, patent applications, or if interests of the federal government result in restrictions on publication. Inappropriately small publications are to be avoided and self-citations should be limited to an appropriate extent as required for understanding the publication.

When planning research projects, evaluating and interpreting results and drafting publications, the focus is on careful description and validity as well as the complete publication of results and the quality of the publication. BfR supports and encourages staff to make research data from publicly funded research publicly available.

In order to ensure the comprehensibility and subsequent use of results, the following should be made available: Research data, materials and information, the methods used as well as the software used, if applicable also self-programmed software, including the source code. The data shall be made available insofar as this is actually possible and reasonable unless there are exceptional circumstances according to paragraph 1. Wherever possible, this shall be done in recognised archives and repositories, taking into account the FAIR principles (*Findable, Accessible, Interoperable, Re-Usable*). Scientists shall provide complete and correct reference of their own and others' previous work; scientists shall explicitly identify previous work to allow for subsequent use. If research software developed in-house shall be made available to third parties, it shall be provided with an appropriate licence.

14. Authorship

Authorship requires a creative contribution of one's own. Author of a scientific publication is someone, who has made own contributions

- to the design of the studies or experiments or
- to elaborate, analyse and interpret the data or
- to the formulation of the content of the manuscript

and which has become a part of the publication. Authorship is based on objective criteria and is not subject to discretion. The legal provisions of copyright law must be observed.

Other contributions like

- the acquisition of funding,
- the provision of examination materials,
- the instruction, supervision and approval in the supervisor position,
- the instruction of authors in methods,
- editorial corrections or linguistic adaptations without substantial contribution to the content,
- participation in data collection and compilation / technical assistance in data collection and material collection,
- mere transfer of data records,
- mere ideas, suggestions or formulation of questions,

do not in themselves constitute authorship. Honorary authorship must not be granted. Persons whose contribution to the publication does not justify authorship shall be named by way of acknowledgement.

All authors of the same scientific publication are jointly responsible for its content and for compliance with the provisions of these principles. Scientists whose views dissent from those

stated in the publication may refuse to be named as authors. Their dissenting views will not be taken into account in the publication.

Scientists agree on authorship. Agreement on the order of authors shall be reached at the latest when the manuscript is being drafted, on the basis of transparent criteria taking into account the conventions of the discipline.

15. Organ of publication

Researchers shall check, whether the results and findings obtained in the course of scientific research and assessment can be published. Depending on the quality of the data and the target audience, suitable journals, books, conferences, etc. are selected for publication (text, language, images). The choice of the publication medium depends on the quality, quantity and focus of the data, aiming to achieve the highest possible degree of dissemination to the target group. Publication in *open access journals* should be aimed for if the journals are equally suitable in terms of scope andimpact. The quality of a scientific paper is determined solely by its content, not by the type and reputation of the publication medium. BfR publications are deposited in the Open Agrar repository.

16. Confidentiality and neutrality in reviews and consultations

All persons involved in the review of funding applications, project ideas and manuscripts are obliged to maintain strict confidentiality and neutrality. Knowledge gained from the review of other persons' work and applications may not be incorporated by the reviewing or advising person into his/her own activities, either intentionally or negligently, or passed on to third parties. Each person involved in the review shall immediately disclose to the respective requesting body any possible conflict of interests with regard to the subject or his or her own person. These rules also apply when participating in review, advisory and decision-making processes and in cases where individual BfR scientists are asked by a journal to review a manuscript.

17. Archiving

The Institute’s management shall ensure that the infrastructure required for archiving is made available. The scientists shall secure the research data or research results as well as the underlying data and, if applicable, the research software used in an adequate manner, considering the standards of the subject area concerned. They shall retain the data for at least ten years. The retention period begins with the date on which public access was established. If there are reasons for not retaining certain data or for retaining them for a shorter period, the researchers shall document these reasons. In case of differences, the legal requirements and the guideline for the processing and management of documents in federal ministries (“Registraturrichtlinie”) of the Federal Ministry of the Interior and Home Affairs (BMI) shall take precedence. If, due to these regulations, the data is not kept or only kept for a shorter period, this is documented.

18. Whistleblower and person affected by allegations

All BfR staff members who - in connection with their official duties - become aware of articulable suspicions of scientific misconduct must either seek clarification with the person concerned or contact the ombudsperson or his/her deputy.

The whistleblower must have specific evidence that standards of good scientific practice may have been violated. The whistleblower must make the allegation in good faith. Deliberately inaccurate or vexatious allegations may themselves constitute scientific misconduct. The ombudsperson does not investigate anonymous hints.

The ombudsperson is obliged to treat the whistleblower's information on the matter as well as the identity of the whistleblower as strictly confidential. In the course of proceedings, it may be necessary to disclose the identity of the person providing the information, for example if there is a legal obligation to do so or if the person affected by the allegations cannot otherwise defend themselves properly. The whistleblower has the option of withdrawing the complaint before disclosure in order to avoid the disclosure of his or her own identity. In agreement with the ombudsperson, the proceedings are then discontinued; however, in the case of a suspicion of serious scientific misconduct, the ombudsperson may decide to continue the proceedings even without the consent of the person providing the information. Serious scientific misconduct exists if its type and/or extent could potentially impair the scientific integrity of BfR. In such a case, the interests of BfR in clarifying potentially serious scientific misconduct take precedence over the individual interests of the person providing the information. A procedure is also continued - even without the consent of the whistleblower - if there is a legal obligation to do so, for example if there is a suspicion of a criminal offence.

The Institute's management shall ensure, if necessary after being informed by the ombudsperson, that the person making the report does not suffer any professional disadvantages as a result of the report of suspected scientific misconduct. The whistleblower shall also be protected in case the allegation of scientific misconduct could not be confirmed, provided that the report of the allegations was not made frivolously or against better knowledge.

The ombudsperson is also obliged to protect the interests of the person affected by allegations and to treat all information on the matter as well as the identity of the person affected by allegations as strictly confidential until possible opening of official proceedings. The presumption of innocence shall apply. Generally, the person affected by allegations shall not suffer any disadvantages from the investigation of the suspicion until scientific misconduct has been confirmed and formally established.

19. Proceedings in cases of alleged scientific misconduct

Compliance with the rules of good scientific practice is the basis of trustworthy science. The BfR therefore establishes a procedure for dealing with suspected cases of scientific misconduct. In this way, the BfR also assumes its responsibility for the money entrusted to it, stemming e.g. from taxes or third-party funding.

I. Scientific misconduct

(1) Scientific misconduct shall be deemed to have occurred if, in the course of scientific work, false statements are made in a deliberate or grossly negligent way, the intellectual property of others is infringed or their research activities are maliciously impaired.

(2) Misconduct shall include in particular:

1. Misrepresentation:
   a) inventing or falsifying data,

b) inventing or falsifying evaluations/interpretations,
c) inventing or falsifying results,
d) the distorting manipulation of a representation or image,
e) the incongruent presentation of image and associated text,
f) incorrect information in a letter of application or a funding application,
g) fictitious information on publications or research reports.

2. Infringement of another's intellectual property
Another person's intellectual property is the copyrighted work created by another person or the essential scientific knowledge, hypotheses, teachings or research approaches originating from another person. An infringement is committed in particular by:

a) the unauthorised exploitation by claiming authorship (plagiarism),
b) the exploitation of research approaches and ideas, especially as a reviewer (idea theft),
c) presumption or unfounded assumption of scientific authorship or co-authorship,
d) falsification of the content,
e) maliciously delaying the publication of a scientific paper, in particular as an editor or reviewer, or
f) unauthorised publication and unauthorised making available to third parties as long as the work, finding, hypothesis, teaching or research approach has not yet been published.

3. Claiming the (co-)authorship of another person without that person's consent.

4. Maliciously interfering with research activity (including damaging or tampering with experimental set-ups, equipment, records, hardware, software, chemicals, cell and microorganism cultures or other property needed by another person to carry out their scientific activity).

5. The disposal of research data, research documents or their documentation, unless an obligation to do so arises from statutory provisions.

6. Conducting research without first obtaining obviously required ethics votes, and misrepresenting the existence of ethics votes in publications or to persons whose research projects depend on such votes.

7. The frivolous handling of accusations of scientific misconduct, in particular
a) making false accusations frivolously or against one's better knowledge, or
b) ignoring a suspicion that scientific misconduct may have occurred, e.g. if scientists do not investigate the suspicion of data falsification in their environment by asking questions or the like, or
c) discouraging another person from reporting suspected scientific misconduct.

(3) There is joint responsibility for misconduct, inter alia:

1. in the case of intentional participation (in the sense of instigation or aiding and abetting) in the misconduct of others,

2. in the event of intentional or grossly negligent co-authorship of publications that knowingly contain false data or information,

3. in the event of wilful or grossly negligent neglect of the duty of supervision, if the misconduct would have been prevented or made considerably more difficult by the necessary and reasonable supervision.

II. Procedure in cases of scientific misconduct

(1) In the event of suspected scientific misconduct, the procedure described in the Rules of Procedure for Dealing with Scientific Misconduct at BfR (VerfOwF) shall be followed. The procedure shall be conducted by the ombudsperson and - if the prerequisites are met - by the investigating commission. The entire procedure is confidential. In the event of misconduct, the Institute's management decides on the consequences. Further details can be found in the VerfOwF.

III. Procedure in cases of serious breaches of duty in connection with scientific misconduct

(1) If, in addition to scientific misconduct, there are indications of a serious breach of duty, the ombudsperson or the investigating commission shall submit the facts of the case to the Institute’s management. A submission to the Institute’s management is also made if the suspicion of scientific misconduct is not confirmed, but there are nevertheless indications of a serious breach of duty. A serious breach of duty is particularly given if there is a suspicion of a criminal offence.

(2) If the ombudsperson or the investigating commission come to the conclusion that the suspicion of scientific misconduct cannot be substantiated or that no such misconduct exists, but the specific case points to other serious problems or deficits (e.g. in leadership behaviour or in communication) or to violations of the prohibition of discrimination, they shall inform the Institute's management of this in an appropriate manner.

IV. Possible decisions and sanctions in cases of scientific misconduct

If scientific misconduct has been established, the Institute's management will determine the further course of action and take the necessary measures, taking into account the proposal of the investigative commission. Scientific misconduct may also have consequences under labour and employment law. Further details are regulated by the VerfOwF.

20. Final provisions

With the entry into force of these principles, the "Principles of Good Scientific Practice at the German Federal Institute for Risk Assessment (BfR)" of 14.02.2018 lose their validity.

Berlin, 26 January 2023

[signed]

Professor Dr. Dr. Andreas Hensel

President