

## **Research Ethics Applications to the KFE**

### **Guidelines for Researchers**

Version 29.09.2025 | Kommission für Forschungsethik KFE

The following guidelines provide researchers at the University of Basel with step-by-step information on the procedure for your application to the Research Ethics Committee of the University of Basel (Kommission für Forschungsethik KFE). Please reach out to the office of the KFE ([kfe@unibas.ch](mailto:kfe@unibas.ch)) if you have any questions or comments that help us improve the guidelines.

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### **1 Mandate of the KFE**

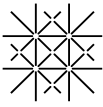
The Committee for Research Ethics (Kommission für Forschungsethik KFE) is a standing committee of the Senate (Regenz) of the University of Basel tasked with ensuring the implementation of the principles of research ethics at the University of Basel. It has 13 voting members representing all faculties, including experts in research ethics. The KFE is run by an office with a managing director in charge of daily operations.

The KFE's main task is to review and approve research projects from a research ethics point of view. Moreover, the KFE's role is to advise and support researchers in research ethics matters.

The KFE has new regulations since 1 October 2025, the guidelines for research ethics applications have been revised accordingly.

Regulations: Reglement der Kommission für Forschungsethik KFE ([DE/EN](#))

Office of the KFE: Dr. Isabelle Wienand (Managing Director); [kfe@unibas.ch](mailto:kfe@unibas.ch); [Website KFE](#)



## 2 Scope of the KFE

### 2.1 Research projects **out of the scope** of the KFE

The KFE does not review the following types of research projects (see KFE Regulations, § 3 Ziff. 3):

- Research projects falling within the jurisdiction of the Ethics Committee Northwest and Central Switzerland (EKNZ) according to the Human Research Act (HRA) and the Stem Cell Research Act (StRA)
  - > Please contact the [Regulatory Affairs of the Department of Clinical Research](#) and/or consult the website of the [EKNZ](#) and submit your research project via the portal [BASEC](#).
- Research projects involving animals that fall within the jurisdiction of the cantonal veterinary authority of Basel-Stadt according to the Animal Welfare Act (AniWA)
  - > Please contact the [Animal Welfare Office](#) ([tierschutz-animalwelfare@unibas.ch](mailto:tierschutz-animalwelfare@unibas.ch)).
- Research projects involving genetic resources that fall within the jurisdiction of the Federal Office for the Environment (FOEN) according to the Nagoya Protocol
  - > Please contact the Research Compliance Office ([research-compliance@unibas.ch](mailto:research-compliance@unibas.ch)).
- Research projects involving genetically modified organisms (GMOs) that fall within the jurisdiction of the Federal Office for the Environment (FOEN) according to the Containment Ordinance (ContainO), except for projects that fall under the Regulations on Particularly High-Risk Research
  - > Please contact the [Chief Safety Officer](#).
- Research projects which are under review, or entail revisions or have been rejected by other Ethics Committee(s).
- Research projects from the Faculty of Psychology
  - > Until the end of spring semester 2026, researchers of the Faculty of Psychology continue to submit their projects to the Ethics Committee of the Faculty of Psychology of the University of Basel (EKFP) (see KFE Regulations, § 10 Transitional provisions).
  - > Please consult the website of the [EKFP](#).

### 2.2 Research projects **in the scope** of the KFE

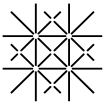
#### 2.2.1 Who is entitled to submit a research ethics application to the KFE?

- Project leaders («Projektverantwortliche») at the University of Basel and associated institutes are entitled to submit their projects to the KFE.
- The KFE can assess projects for which the University of Basel is not in the lead, but an official project partner (please contact the office of the KFE prior to submission).
- Researchers without an affiliation to the University of Basel are not entitled to submit their projects.
- BA and MA students are not entitled to submit research projects to the KFE. A research ethics assessment of BA and MA projects is in the responsibility of the supervisors. The KFE can advise and assess projects upon the supervisor's request (please contact the office of the KFE).

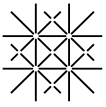
#### 2.2.2 Research projects that must be submitted to the KFE for review

- If your research project fulfills **at least one of the following five criteria**, it is **mandatory** to submit an ethics application to the KFE (Mandatory review criteria, KFE Regulations § 3 Ziff. 2):

Regulations KFE (Criteria)	Specifications and Comments
<p><b>1. SPECIAL CATEGORIES OF HUMAN PARTICIPANTS</b> § 3 Ziff. 2 lit. a (Research involving minors, vulnerable persons, or persons lacking capacity to consent)</p>	<p>Within the framework of research ethics, <a href="#">vulnerable</a> individuals or groups are identified as requiring special protection because of limited capacity to give consent and/or liability to exploitation for various reasons. Non-exhaustive list of population groups with a heightened potential to experience negative consequences from their participation:</p> <ul style="list-style-type: none"> <li>– children;</li> <li>– refugees;</li> <li>– irregular migrants;</li> <li>– persons in captivity;</li> <li>– sex workers;</li> <li>– persons with cognitive impairments;</li> <li>– dissidents;</li> <li>– traumatized people at risk of re-traumatization (e.g. people from conflict areas, victims of crime and/or violence).</li> </ul> <p>Please note: this criterion applies to projects involving living participants. It does not apply to retrospective studies, for instance archival research involving (deceased) participants. Access authorizations and further legal regulations (e.g. copyright) may apply. For more information, please contact the Data Protection Officer (<a href="#">DPO</a>).</p> <p>Sources: EU-Guideline <a href="#">Ethics in Social Science and Humanities 2021</a> / <a href="#">UKRI Guidance 2025</a></p>
<p><b>2. SENSITIVE PERSONAL DATA</b> § 3 Ziff. 2 lit. b (Research processing «sensitive personal data»)</p> <p><b>«Besondere Personendaten»</b> Art. 3 Informations- und Datenschutzgesetz des Kantons Basel-Stadt (IDG)</p> <p><b>«Besonders schützenswerte Personendaten»</b> Art. 4 Bundesgesetz über den Datenschutz (DSG)</p> <p><b>«Special categories of personal data»</b> Art. 4, 9 EU General Data Protection Regulation (GDPR)</p>	<p>«Sensitive personal data» is a subcategory of <a href="#">personal data</a> whose <a href="#">processing</a> poses a particular risk of violating fundamental rights.</p> <p>Non-exhaustive list of sensitive personal data: Personal data that contains information concerning</p> <ul style="list-style-type: none"> <li>– racial or ethnic origin;</li> <li>– political opinions;</li> <li>– religious or philosophical beliefs;</li> <li>– trade union membership;</li> <li>– genetic data, biometric data for the purpose of uniquely identifying a natural person;</li> <li>– health-related data;</li> <li>– a natural person's sex life or sexual orientation;</li> <li>– Geolocation data (Ortungsdaten).</li> </ul> <p>Sources: EU-Guideline <a href="#">Ethics and Data Protection 2021</a> / CH-Guideline <a href="#">Research and Data Protection</a></p> <p>&gt; <u>Please note</u>: Depending on the context/country you work in, specific legal definitions apply (for more information consult the <a href="#">Research Ethics Glossary</a> and the website of the DPO). For further guidance on how to process/work with personal data (and in particular sensitive personal data) consult the <a href="#">Data and Information Classification</a> of the University of Basel and the website of the <a href="#">DPO</a>.</p>



<p>§ 3 Ziff. 2 lit. b fn. 6 (Research involving participant observation – covert, open)</p>	<p>«Participant observation is a method in the social sciences with which researchers intend to gain a holistic overview of the studied context through engagement in, and observation of, the setting to describe its population, social environments, processes and relationships» (KFE <a href="#">Guide to Participant Observation</a>, p.1).</p> <p>&gt; <u>Please note</u>: Consult the KFE Guide to Participant Observation for further information and guidance.</p>
<p><b>3. HIGH-RISK SETTINGS</b> § 3 Ziff. 2 lit. c (Research taking place in settings with high risks for the research team, participants and third persons)</p>	<p>Non-exhaustive list of high-risk settings:</p> <ul style="list-style-type: none"><li>– conflict regions;</li><li>– authoritarian or fragile settings;</li><li>– sites with high levels of criminal activity;</li><li>– environments with a high exposition to health hazards (e.g. natural disaster settings).</li></ul> <p>Sources: EU-Guideline <a href="#">Ethics in Social Science and Humanities 2021</a> SCNAT <a href="#">Guidelines to conflict Sensitive Research 2020</a> SNSF <a href="#">Research in Crisis Area</a></p>
<p><b>4. ENVIRONMENT</b> § 3 Ziff. 2 lit. d (Research entailing potentially high risks for the environment)</p>	<p>Non-exhaustive list of high-risk research for the environment:</p> <ul style="list-style-type: none"><li>– Release of chemicals, substances or biological material that may cause harm to the environment during or after the research activity;</li><li>– Use of processes (technologies) that may cause harm to the environment during or after research activity;</li><li>– Involving endangered fauna and/or flora /protected areas;</li><li>– Permanent leaving of detrimental or uncommon materials in an environment;</li><li>– Actions that have a potential to raise public concern, aesthetic damage, including visual, noise, and odor pollution.</li></ul> <p>Sources: EU-Guidance <a href="#">Ethics Self-Assessment 2021 pp.36-37</a> / SNSF <a href="#">Sustainability in Research</a></p>



<p><b>5. PARTICULARLY RISKY RESEARCH («Risikoforschung»)</b> § 3 Ziff. 2 lit. e (Research falling under the competence of the «Regulation concerning particularly risky research»)</p>	<p>List of particularly risky research projects:</p> <ul style="list-style-type: none"> <li>– Financed by funding programs or agencies with a military connection, military relevance and/or a potential military purpose;</li> <li>– <a href="#">Dual Use Research of Concern (DURC)</a>;</li> <li>– <a href="#">Gain-of-Function Research (GoF)</a>;</li> <li>– <a href="#">Potential Pandemic Pathogens Research (PPP Research)</a>.</li> </ul> <p>Source: Reglement betreffend besonders risikobehafteter Forschung (<a href="#">DE/EN</a>)</p> <p>&gt; Please note: projects that fall under the «Reglement betreffend besonders risikobehafteter Forschung» need to be authorized by the Rectorate. For applications to military or military associated funding agencies, the project proposal and related documents have to be sent to the Grants Office at least 8 weeks before submission to the funding agency. For the submission of projects that qualify as particularly risky research, you have to send the project proposal and the full documentation for an ethics assessment (as outlined in chapter 3) to the mail-address <a href="mailto:risikoforschung@unibas.ch">risikoforschung@unibas.ch</a>. In case your project is in an earlier stage of development, please contact the Research Compliance Office for further guidance.</p> <p>With any questions concerning particularly risky research please contact the Research Compliance Office (<a href="mailto:research-compliance@unibas.ch">research-compliance@unibas.ch</a>).</p>
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- If your project falls under the mandatory review criteria outlined above, but is embedded in a bigger research project that has already received an ethics approval through the lead institution, submit the confirmation letter to the office of the KFE ([kfe@unibas.ch](mailto:kfe@unibas.ch)).

### 3 Submission Procedure for research ethics assessments

#### 3.1 Research ethics self-assessment tool

The [research ethics self-assessment tool](#) helps you determine whether your project can or must undergo a research ethics review procedure. In case you have questions concerning your project, or if you encounter problems with the tool, please reach out to the office of the KFE ([kfe@unibas.ch](mailto:kfe@unibas.ch)).

#### 3.2 When and how to submit your research ethics application to the KFE

- Ideally, projects should be submitted to the KFE as soon as possible and at the latest immediately after the funding institution has given its approval and in any case before the start of data collection.
- The KFE can advise and review research projects earlier in the process (e.g. during the funding review phase, contact the KFE office for further inquiry prior to submission).
- Applications to military or military associated funding agencies have to be assessed and approved prior to submission of the application to the funding agency.
- To submit an application, please download and complete the documents listed below, and send them as word-documents in one e-mail specifying your full name and the project title in the header of the mail.

#### Documents:

- [KFE Ethics Application Form](#).
  - KFE Template Information Sheet and Informed Consent ([DE/EN](#))
  - [KFE Risk Assessment Plan](#)

Contact and submission of applications: Office of the KFE [kfe@unibas.ch](mailto:kfe@unibas.ch)

## 4 Review and Outcome of research ethics assessments

### 4.1 Review timeline

- The whole review procedure – i.e. from the complete ethics application to the approval – will take a maximum of eight weeks (provided no revisions are needed). See [KFE Regulations § 4 Ziff. 5](#).
- The KFE works with a risk based approach ([DE/EN](#)) and triages the projects into three categories, in order to ensure a faster treatment of less risky projects.

### 4.2 Review outcome

The office of the KFE will inform you via e-mail about the outcome of the review process. The following scenarios may apply (KFE Regulations: § 4 Ziff. 4):

- **Approval with no revisions:** You will receive a confirmation letter that your project underwent a review by the KFE and was fully approved.
- **Approval with minor or major revisions:** You are asked to undertake minor, respectively major revisions to your project. Please send the revised documents as soon as possible to the office of the KFE in two versions (clean and track-changes-mode). The KFE will assess your revisions. The KFE office will inform you whether the project has been fully approved and send the confirmation letter.
- **Rejected research ethics applications:** The KFE does not consider the project to be ethically acceptable. Rejected applications can be resubmitted one more time to the KFE, on the condition that the resubmitted project has adequately addressed the KFE's objections and concerns and undergone the requested revisions.
- **Dismissed research ethics applications** may not be resubmitted to the KFE for reasons of incompatibility with the regulations and scope of the KFE.

### 4.3 Your responsibilities

- **Start of your project:** If your project needs an ethics approval, you may not start your project without the KFE approval. The KFE does not issue retrospective ethical reviews, i.e. after data collection has already started.
- **The decisions of the KFE are binding:** Compliance with the decisions of the KFE is part of the Good Scientific Practice according to the Code for Scientific Integrity (KFE Regulations § 4 Ziff. 6).
- **Notification of changes relevant to research ethics:** Changes (e.g. in the research design or research settings) and unexpected incidents relevant to research ethics must be reported without delay to the office of the KFE (KFE Regulations § 4 Ziff. 7).
- **Research authorization and ethics approval abroad:** You need to ensure that you respect legal obligations abroad and gain the relevant permits to conduct research. Contact the relevant local authority or ethics committee and apply for an approval to conduct your research abroad.

- **Further considerations:** Your research might raise further questions and challenges relating to
  - Data protection (e.g. data management, anonymization and pseudonymization, data transfer or use agreements, use of IT tools, etc.); contact the [Data Protection Office](#) for further guidance and advice
  - Export control issues; contact the [Research Compliance Office](#) for further guidance and advice
  - Nagoya Protocol; contact the [Research Compliance Office](#) for further guidance and advice

#### 4.4 Points of contact

- [Office of the Research Ethics Committee KFE](#):  
Please contact the office of the KFE for all your questions that concern research ethics, the research ethics committee and the research ethics application procedure.
- [Research Compliance Office](#):  
Please contact the Research Compliance Office for your projects that fall under the [Reglement betreffend besonders risikobehafteter Forschung](#), e.g. research relating to PPP, GOF and DURC, to the Nagoya Protocol and to export controls and sanctions.
- [Data Protection Officer of the University \(DPO Office\)](#):  
Please contact the DPO office for advice regarding questions relating to the processing of personal data, data protection regulations, data transfer or use agreements, and the data classification of the University.
- [Research Data Management Network \(RDM\)](#):  
Please contact the Research Data Management Network of the University of Basel for information on research data management (data analysis, data storage, data sharing, etc.). Here you also find the contact details of the [data stewards](#) of the faculties and departments.
- [Research & Infrastructure Support \(RISE\)](#):  
Please contact RISE if your research is in the humanities and social sciences. They will assist you in the conception of computer-based research, and help you choose the adequate tools for the creation, analysis and user-oriented presentation of digital data, as well as in sustainable and open methods of data dissemination.
- [Chief Information Security Officer \(CISO\)](#):  
Please contact the CISO for information and advice on information security matters.
- [Grants Office](#)  
Please contact the Grants Office for advice and questions regarding funding agency applications.
- [sciCore](#):  
Please contact Scicore if you need powerful and secure compute and storage systems. sciCORE provides advanced infrastructure, secure environments, and expert guidance.