

Checklist for research with humans Commented version

Version 2.1 from 14 March 2024

Introduction

This commented version of the checklist is meant to help researchers prepare their application to the Ethics Committee by providing you with some background information on the questions included in the checklist. Please keep in mind that not all issues addressed in this document will be relevant to your project, and similarly ethical issues not addressed here may be relevant to your project. Note that this commented version is also not intended to provide an overview of research ethics which is a much broader field than could possibly be covered here.

The Ethics Committee is aware that research involving humans is conducted in a range of settings, builds on a broad range of theoretical foundations, uses different qualitative and quantitative research methods, different sampling techniques, different options to ensure anonymity of participants, and different forms of interaction with research participants. This being the case, it is not really possible, nor appropriate, to prescribe a single set of ethical 'rules' to be followed when conducting research. There certainly are general ethical principles¹, but each researcher must decide what to do in each particular context.

Indeed, each researcher is individually responsible to ensure that their research is conducted ethically, from the development of a research idea, through planning and implementation, to publication and data management. As such, each researcher must make carefully considered ethical choices, addressing the dilemmas and trade-offs involved, and be able to justify their choices based on ethical principles. Based on the documents submitted, the Ethics Commission assess these choices and their justifications. The aim of this assessment is to ensure that researchers have anticipated ethical issues that might arise in their research with humans, that they have given them deliberate and thoughtful attention, and that they have addressed them in a way that is appropriate for their particular research endeavour. The Ethics Committee thus does not evaluate the relevance of your research topic nor the appropriateness of your study design or of your methods. This all falls under academic freedom, which is a fundamental right in Austria. The task of the Ethics Committee is solely to assess the ethical implications of your chosen design and methods based on the documents you submit.

Note that research ethics is closely linked to many issues related to scientific responsibility and integrity, as well as to legal obligations. This includes data protection (esp. the <u>GDPR</u>), contribution to professional development, transparency, fairness and respect when interacting with others, empowerment and inclusion, as well as equal opportunity and diversity agenda (see the <u>BOKU Ethics Charter</u> and the <u>Best practice guide for research integrity and ethics</u> of the BMBWF).

Please note that the application to the Ethics Committee needs to include all questions of the checklist. If a question is not relevant, please answer 'not applicable'. Your application must also include the numbering of the questions as indicated in the checklist.

¹ See e.g. EC (2021) 'Ethics in Social Science and Humanities'

1. General information about the research project

Please provide a short factual information about the research project:

- Name, e-mail, title, position (e.g. project leader, PhD student), and Institute of the person submitting the application to the Ethics Committee.
- Title of the research project
- If it is a project within doctoral studies: Name of the supervisor
- Funding agency to which the research project is (was) submitted for funding
- Reason for the application: what is the statement of the Ethics Committee needed for? (e.g. requirement of journals where the results will be published, request of a funding body, see GeschO §5 para. 2).
- Should the statement of the Ethics Committee be issued in German or in English? If in English, please make sure you provide an English project title
- Planned period of data collection (please note: contacting potential participants and data collection can only begin after the Ethics Committee has issued the final statement).

2. Research plan

Please provide a concise overview of the project, i.e. be as succinct as possible and as comprehensive as necessary (i.e. max. 1 page). This short description should give an overview of the project, focusing on the issues that are important to understand the overall design of the research. Please include the most relevant literature references for the 'state of knowledge'.

3. The general ethical aspects of the research project

3.1. What is the objective of the research project? What is the expected knowledge gain / benefits to society / to a group?

When considering the benefits for society, please be specific about which group is likely to benefit from your research. Consider principles such as inclusiveness in research and fair distribution of benefits. This means that particular individuals, groups or communities should neither bear an unfair share of the direct burdens of participating in research, nor be unfairly excluded from the potential benefits of research participation.

3.2. Will research findings be made available to study participants or relevant organisations? If yes, what format will this take?

Making research findings available should ensure that the groups who are expected to benefit from the research, actually do benefit. In the past social science research had a tendency to be extractive, characterised by the one-way flow of information (i.e. the researcher arrives, extracts relevant information, and leaves without any further contact). Collected data was almost only used for scientific publications, thus contributing to scientific knowledge and benefiting the academic advancement of researchers.

An ethical approach to research requires a more reciprocal and respectful engagement with participants. As such it has become good practice, and there is often a moral obligation, to provide research results to research participants. Thus, researchers should provide research findings or other products arising from the research to the individuals who were involved and/or to institutions or organisations that are best suited to act as disseminators within the participating communities. Researchers should ensure that participating individuals, groups and/or communities are informed how to access the results of the research (e.g. as part of the participant information sheet). Research findings should be made available to them in a culturally appropriate and meaningful form, i.e. should be written in plain language and focus on the results

relevant to them. Of course, if there are confidentiality provisions, e.g. as part of the funding agreement, these may limit which results can be shared.

Making research findings available may take many forms, e.g.: interviewed experts may be given the opportunity to comment on a draft publication; a summary report may be written for the stakeholders, who have been involved; scientific publications may be offered for download from a website; a blog post may be published on the website of an organisation working on behalf of the community; an article published in a magazine for a broad audience or in a trade journal.

3.3. What are the possible effects on the groups or companies to which the participants belong? Can the project negatively affect the reputation of a specific group of people or businesses (e.g. reproduce stereotypes)?

An ethical approach to research is about the balance between benefits to society and the burden to participants. Thus, briefly state whether there are potential risks or negative effects for participants, and if yes which. Note that the risk of harm is multidimensional, and includes physical, mental, social, financial, and/or ecological dimensions. The risks to participants need to be necessary, justified, and minimised.

For example, social scientists are often interested in studying stereotypes and stereotyped reasoning and stereotypical behaviour, as related to e.g. gender, age, and racial stereotypes. While such research can make a valuable contribution to a more just and equal society, it may also reproduce and reinforce such stereotypes.

If a research topic involves vulnerable groups (e.g. refugees, irregular migrants, dissidents, people with cognitive impairments, children or elderly), there is a risk of stigmatisation, or a risk that the research may make participants vulnerable to physical or psychological abuse. Identify possible risks and take active steps to minimise them.

3.4. What possible risks are associated with the project? How will they be mitigated? Do the expected benefits (e.g. knowledge gain) outweigh the foreseeable risks associated with the research project?

Assessment of the risks and benefits is central to determining that a research study is ethically acceptable. For a study to be ethical, the (projected) benefits to society should outweigh the (projected) net burden to the participants. Clearly, assessing harms and benefits is associated with a high degree of uncertainty, and that balance point cannot usually be determined accurately. Yet, researchers should ensure that the balance tips in favour of societal benefit.

When considering risks and benefits, also take into account the principle of justice and fairness: who will receive the benefits of research and who bears the risks and burden of the research?

3.5. Study design: How has the sample size been determined? Which groups will be compared?

Especially in quantitative studies, sample size is often set based on methodological concerns (e.g. conceptual models, numerical guidelines derived from empirical studies, statistical formulae, rules of thumb) and practical concerns (availability of time and funds). In some qualitative approaches, the sample size cannot be set a priori, as it is determined in the course of the study, e.g. by saturation.

However, there is also an ethical dimension to choosing sample size, especially in quantitative studies. The question is the balance between the burden/inconvenience/discomfort put on participants and the scientific value that a study can be expected to produce. Thus, especially in quantitative studies, there is a trade-off between avoiding to burden more participants than necessary, and ensuring a large enough sample size to ensure sound statistical analysis (e.g. reaching p < 0.05). Thus please briefly state how the sample size has been set and the burden on participants considered.

3.6. Are there conflicts of interest (COI) on the part of the researchers involved? If yes: which?

There are various forms of conflict of interest that might arise in a research project. On the one hand, there is a conflict of interest if research objectivity is compromised, esp. in return for financial or non-financial benefits to any of the researchers involved, to their relatives or to their friends. Here some examples of COIs: using students to perform services for a company in which a researcher has a financial interest; accepting a research contract with a restrictive publication clause; imposing restrictions on the actions of students, including disclosure of research findings, at the request of a sponsor or financially interested company (see <u>Univ. of Pittsburg</u>). Such potential conflicts of interest should always be disclosed to ensure transparency.

On the other hand, there can also be a potential conflict of interest within the research team. This may include the nature and degree of collaboration, the roles, rights and obligations of team members, the division of labour, access to and rights in data and field notes, the contributions to publications, and how authorship will be assigned (e.g. see the <u>Committee On Publication Ethics</u> - COPE). It can thus be useful to clarify expectations within all relevant research partners, stakeholders, supervisors, and record them in writing, and possibly review them in the course of the research project.

3.7. What do researchers do, if they become aware of criminal acts by study participants, which they may have to disclose to authorities?

In the course of their data collection in the field, researchers may encounter problematic situations, e.g. witness infringement of animal welfare laws, indications of domestic abuse, or become aware of unlawful activities. Researchers are not legally required to notify relevant authorities. However, they may face an ethical dilemma between notifying authorities and risking the anonymity and/or trust of participants. It is useful for researchers to know in advance whom they can contact (e.g. in their team, or 'trusted advisors' at BOKU) to discuss the personal ethical dilemma, or the moral distress they may feel.

Moreover, researchers need to be aware that they have no special protection in a court of law, as e.g. lawyers or journalists do. Thus, while researchers may guarantee confidentiality to their participants, they need to consider whether or not they would breach this confidentiality if they are invited to testify in a court proceeding.

3.8. How will ethical aspects be reviewed in the course of the project? What procedures are in place to deal with unforeseen events that impact ethical aspects?

Not all ethical issues can be anticipated at the start of a research project. Indeed, ethical tensions are part of the practice of doing research. For example, during an interview, a seemingly anodyne question may trigger painful memory causing emotional distress in the participant. The researcher then needs to find a balance between maintaining a human connection and a non-exploitative stance, while at the same time being mindful of one's role as a researcher. The researcher thus faces a difficult choice: should they continue the interview as if nothing had happened, or should the researcher respond in some way? These are difficult, often subtle, usually unpredictable situations that may arise while doing research.

Depending on your research topic, there may also be a risk to re-traumatise people, e.g. by asking them about sensitive issues or asking them to talk about events they may have perceived as traumatic (e.g. people from conflict areas, witnesses of extreme weather events, victims of accidents, crime and/or violence), your team needs to know who has the necessary expertise and skills, and is thus able to provide advice on how to handle such emotionally charged situations.

Unforeseen events may also include more practical questions, such as a participant not wanting to be assigned a pseudonym but wanting their real name used when results are reported. Or the first few interviews revealing a flaw in the study design, which should be corrected before proceeding.

It may also be necessary to review aspects pertaining to maintaining the health, safety and well-being of the researchers themselves during the data collection period. The BOKU has the duty to care, i.e. to ensure the safety and welfare of its employees, and employees are responsible to take reasonable care of their own safety. If researchers are visiting a rural or isolated area for their field work and/or if researchers are collecting data in the participant's home, it is important to review potential risks to the researchers. For example, if a researcher works alone in the field they may be confronted with unexpected situations or be involved in an accident. It is important that someone knows where the researcher is, and what to do should they not return or check in at the expected time. Researchers need to know that they should walk away from any situation that they consider uncomfortable or threatening, e.g. because an interviewee seems to become angry, makes derogatory or inappropriate remarks towards the researchers. Even if such incidents are highly unlikely, it is better to have thought about potential situations, and about options to handle them in advance, so that they can be recalled quickly should the need arise.

The question is thus: what measures are taken to develop ethical competence during the project? Indeed, it is important to consider that unforeseen events that impact ethical aspects, are likely to arise, and to know how to handle such 'ethically important moments', not least as a part of the process of strengthening ethical competence. Ethical competence is about the willingness to acknowledge the ethical dimension of research, the ability to recognize the ethical dimension in a situation during data collection or processing, and the ability to respond appropriately. Thus: are there regular team meetings reviewing ethical aspects and risks? Should there have been an incident during data collection (e.g. an emotionally charged situation), is it clear with whom the researcher can discuss the issues and where they can get support and counselling (see e.g. 'trusted advisors' or occupational psychological consulting offered by the BOKU)? Will researchers document incidents in research notes? Will reflective review sessions be set up within the research team to discuss issues that have arisen and decide how to address them? Will these be documented in writing?

3.9. If students participate in a research project: how is the principle of voluntary participation taken into account?

In some research projects it may be purposeful for students to participate in data collection or analysis. It is important to acknowledge that the principle of voluntary participation applies to everyone, including students. Thus, participating in a research project should not be a precondition to complete a course. Especially if it is a compulsory course, a meaningful alternative must be offered.

3.10. Will the project contribute to Open Data (i.e. will anonymised, processed or unprocessed raw data be made available to other researchers?). If yes: which data? When? In which repository? If not, please briefly state why not.

To make the most of the data you have collected, it is desirable that the anonymized raw data be made available to other researchers. For more information, see the efforts at EU levels <u>OpenAIRE</u>, the guidelines for <u>FAIR data</u>, and repositories such as <u>Zenodo</u>.

4. Documentation of the ethical aspects specific to the participants

4.1. What criteria are used to select participants?

The principle of justice should be applied to the selection of participants. As such inclusiveness, non-discrimination and equitable treatment should guide the decision which individuals or groups to include. This means avoiding to inappropriately exclude some on the basis of attributes such as culture, language, gender, race, ethnicity, age or disability. As such you should state how you will take diversity and equality issues into account.

Historically many groups such as women, haven been inappropriately excluded from being participants in research projects. This has denied potential benefits to women, and exposed women to harm when research findings from male-only research projects were generalized inappropriately to women. Inclusivity is thus not just a question of research ethics, it also improves the generalizability of research findings.

Yet, we can never include everybody in our research. We thus must make choices: whom to include, and thus whom we exclude. What is important is to make the criteria for these choices transparent and to be aware of the implications of these choices. This avoids unconscious bias and inadvertently excluding certain groups. If you focus on certain groups of respondents, you might need to use screening to determine eligibility. If so, please explain what criteria will be used.

When you engage with and include the views of people from diverse backgrounds, particularly minority, under-represented or hard-to-reach groups, it may affect your research methods, e.g.: does your design ensure that people with caring responsibilities (timing), and people with physical impairment (accessibility) can take part in your workshops or focus group discussions? Do you exclude those from poorer economic background because you do not cover the costs incurred in taking part? Are you aiming at a fair representation of all genders (note that in Austria, since 2020, there are six legally recognized gender entries, so next to 'woman' and 'man', you should at least include 'non-binary or gender diverse', and possibly 'I prefer not to disclose')? If you want to include respondents who have difficulty reading or comprehending written materials, will you offer a choice between self-completion and interviewer-assisted interviewing?

4.2. How will participants be recruited?

Participants may be recruited using a variety of measures, e.g. adverts, personal contacts, email, a third party (e.g. employer), snowball, a search on the internet, an existing mailing list.

What is important in the recruitment process, is that the information provided is transparent. Thus, if you use an advert, please include the advertisement. If you get support from an employer, please provide the approval letter. If recruitment is conducted by a third party (e.g. association), do you have a letter requesting their assistance and/or a letter confirming their willingness to assist? Moreover, the provisions of the GDPR need to be considered, e.g. if you use an existing mailing list, have those on the list consented to have their address used for this purpose?

4.3. What benefits will participants gain from participating in the research project? Will there be any remuneration for participation?

Participating in your research will put a burden on the participants, not least because they need to take time to participate in the interview, or will incur costs to travel to a workshop. It should not be taken as granted that people take time and disrupt their day to take part in a research project. From an ethical perspective, you might want to consider how participants may benefit from participating in the research, to outweigh the burden they incur.

Benefits from research participation can be direct, e.g. when an individual participant learns new information about social issues as a result of participation in a research focus group. Or benefits may be indirect, if the research serves to advance knowledge that may lead to improved conditions for a group to which the participant belongs. It is important to be clear with prospective participants about the (indirect) benefits of participating in your research, to avoid raising unfounded expectations.

You may also choose to offer a token of appreciation to acknowledge their participation in the research project. Indeed, incentives and monetary compensation can be an important aspect of enabling participation and increase representation in a study, esp. if you want to include hard-to-reach groups. At the same time, if you offer direct financial benefits, you will need to consider whether the payment is appropriate to the local context; and you need to consider whether the payment/material benefit can become an inappropriate inducement to participate, which may

interfere with the free consent of participants. Note that if payment is offered and if a participant decides to withdraw at any time, the payment/material benefit still needs to be paid, or the compensation would in effect be coercive. Should payments be offered, please also include information on how the personal data you may collect as part of the payment process will be handled to comply with the GDPR.

4.4. Will personal or sensitive issues be addressed? If so, what measures are taken to minimize the risks of causing distress?

Privacy is a fundamental human right. The right to privacy encompasses among other things, information about diseases and health, political and religious views, and sexual orientation. However, researchers should be aware that there are variations in what people regard as sensitive and private, thus it is not possible to know in advance which questions individual participants might perceive as intrusive. This may include questions about health-related issues or questions about possibly illegal behaviour, e.g. related to the use of protected resources. Thus, while taking part in research can be a positive experience, it can also be disturbing. Participants might perceive it as an intrusion into their private lives find themselves uncomfortable due to introspection and increased self-knowledge, or build false hopes and expectations.

Researchers thus need to consider whether their research could induce psychological stress or discomfort and appropriate measures to mitigate them. Note that stress may also be caused by participants not being used to be in a research setting, interviewing people in a language they are not fluent in, presenting written information to someone who has difficulty reading and/or comprehending printed material.

Generally, researchers need to be sensitive during an interview, and should avoid asking questions that might be perceived as stressful, especially if they are only incidental to the research project. This also requires researchers to be aware of the cultural norms and local social practices so that they can avoid violating them inadvertently. If questions will be asked, that can be perceived as intrusive, stressful or may retraumatise participants, they need to be justified. If sensitive issues are a core part of the research topic, consider mentioning it in the informed consent form. It may also be purposeful to remind participants during the interview, that they do not have to answer all questions.

It is important to ensure that researchers are able to handle difficult, emotionally charged situations during interactions with participants, e.g. interviews or workshops. Appropriate awareness training might be needed, especially if students or field assistants (such as guides, translators) are involved in the data collection.

4.5. What risks or potential harms (in psychological, physical, social, legal, or economic terms) might the participants face as a result of the research project (during data collection or through the analysis, publication, use, and archiving of the results)? What measures are taken to minimize these risks?

It is possible that your research findings can adversely affect participants or affect other actors indirectly (e.g. cause conflicts, reinforce harmful stereotypes). This is particularly important when involving vulnerable or marginalised groups. Yet, sometimes this cannot be avoided, e.g. when a conflictual issue is the core of the research project. You should then identify measures to prevent, mitigate or minimise potential problems.

In social sciences the most common risks are those tied to privacy violations, i.e. the risk of being identified as someone who participated in a research project. This is why the pseudonymisation process is a crucial aspect of ethics in research with humans. Note that even if you pseudonymise transcripts, there is always a residual risk for re-identification.

If you use data collected from the internet, note that in this context, privacy issues are an open topic of debate, not least because personal data is proliferating on the web, in a way that

challenges traditional assumptions about privacy. Thus, if your research uses Big Data, i.e. collects and analyses data on individuals from the web, you need to make a thorough assessment of issues tied to privacy and gaining informed consent (for additional information see e.g. EC (2021) 'Ethics in Social Science and Humanities').

4.6. Could material harm (up to and including criminal penalties) result from the information collected? What measures are taken to minimize harm for participants?

Researchers need to be aware that data given to them in confidence does not enjoy legal privilege and may be liable to subpoena by a court. Thus, consider whether participants might be put at risk, e.g. if there are questions about illegal activity, where retribution might be anticipated.

4.7. Is participation planned for people from vulnerable groups (e.g., children, refugees, the elderly, those in need of care, or who are cognitively impaired)? What steps are taken to protect them from exploitation or stigmatisation?

If you work with children or vulnerable groups of any age, you need to take a number of protective measures. For example, if children participate in a research project at school, it is important to ensure not only consent from their parents, but also that time for the project does not reduce their break time, and that they know that it will not impact their grades.

You need to be aware that protecting vulnerable groups is a complicated and evolving area, so make sure you get the appropriate legal and ethical provisions to ensure that children and vulnerable people have a safe and positive research experience, as well as protecting them and yourself from harm, including accusation of inappropriate behaviour.

4.8. Is intentional deception of participants planned? If yes, how do you justify it? Will participants be informed about this after data collection or analysis? If yes, how?

Using deceptive techniques is usually understood as incompatible with the standard of informed consent and the autonomy principle, i.e. the right of individuals to make their own decisions. Since it can be seen as an instrumentalization of human beings, it not only violates the rights of persons involved in research, it can also undermine social trust in research.

However, in some cases, it can be justified to intentionally withhold essential information during the consent process, e.g. to avoid bias in an experimental setting (as e.g. in the case of the classical bystander apathy experiment), or obtain more accurate information, i.e. avoid answers that are skewed towards socially desired behaviours. However, the use of deception, misleading information, or misrepresentation needs to be justified.

If you use deception, it is usually required that, at the latest when the study is completed, there is a debriefing by the researcher to explain any deception or incomplete disclosure. This debriefing should also help the participants to deal with any distress or discomfort they might have experienced during the research.

5. Documentation of participant information and declaration of consent

The principle of autonomy and self-determination acknowledges the right of individuals to make their own decisions, and serves to ensure that respondents participate voluntarily. Before being able to provide informed consent, they need to be informed what the study is about (i.e. its goals, methods, possible risks and benefits) and what is expected of them. This information should be provided in a way that they can easily understand, i.e. the information sheet and consent form should be in plain language and must be in a language that the prospective participant is fluent in. This ensures that consent is truly informed and voluntary, i.e. participants are not misled or coerced into participating.

5.1. Have you prepared a Plain Language Statement (PLS) that explains the nature of the research, the aim of the data collection, their rights (e.g. voluntariness, possibility to withdraw at any time), and possible risks?

All participants should receive a verbal or written briefing before participating in research. What is essential, is that the information is easy to understand, i.e. provided in <u>plain language</u>, avoiding technical jargon and complicated sentence structure, so that it can be understood at first reading.

Researchers also need to exercise judgement how much details are provided, deciding what is most adequate in a particular context, carefully considering pros and cons, in particular the rights of the prospective participants. Indeed, informed consent can never be complete, as it would be unethical to burden the potential participant with too much irrelevant information (e.g. the background scientific discourse, theoretical concepts, or details of the data analysis). Also, it is practical to avoid spending too much time on the consent part of the interaction with participants. So while on the one hand researchers need to provide all relevant information, on the other hand it is generally useful to be concise and to focus on the information that it is relevant to the potential participants.

The participant information sheet (which needs to be included in your submission to the Ethics Committee) should include following information:

- Affiliation: Institution (BOKU), department, institute / research unit
- Details of the researcher and how to contact them (email, possibly phone number)
- Project tile
- The source of funding
- Purpose and objectives of the research
- Intended use of the research findings and information on how research findings may be accessed
- Details of what the participation might require (interview, questionnaire, audio/film recording, photographs), the estimated time commitment and risks involved (if any)
- Information on anonymity and confidentiality, as well as potential limitations
- Advice that participation is voluntary and that they can withdraw consent at any time (which will not affect the payment of any compensation, if any)
- The arrangements made to protect the confidentiality of data, and its limitations (i.e. how any data will be recorded, managed, and stored)
- Their rights regarding their personal data (see point 6, GDPR)
- Information about whether/what data will be destroyed and when
- Whom the participant might contact if they have any concern or complaint about the conduct of the interview or the research in general

5.2. How will you ensure informed consent for participation in the project?

Once you have informed prospective participants, you must ask for their consent to participate in the research. This consent might be given in oral or written form. If oral consent is sought, please explain why and how it will be documented. If written consent is sought from participants, please include the written consent form in the application to the Ethics Committee. Please note that the will of the participant must be clearly visible, thus it is often helpful to offer two boxes to tick ('yes, I agree' and 'no, I do not agree'), especially if participants are given the option to opt out of some of the options.

The consent form should include:

- Affiliation: Institution (BOKU), department, institute / research unit
- Project tile
- Confirmation for various aspects of the research (you might want to seek separate consent for each confirmation item), e.g.:
 - Confirmation that the involvement is voluntary and that the participant is free to withdraw at any time
 - Confirmation that they have been made aware of any potential risks associated with the research (if applicable)
 - Confirmation that the participant has been provided with the participant information sheet, and that the participant has had the opportunity to ask questions and that these have been answered satisfactorily
 - Confirmation to consenting that the interview will be recorded
 - Consenting to having the data being stored and analysed, that it will be used for research purposes, and that it may be used by the larger research team (as applicable)
- Printed full name of the participant, date and signature

5.3. How is the principle of free and voluntary participation implemented?

Briefly describe how the participant information sheet and the consent form will be handled. While the participant information sheet usually remains with the participant, the signed informed consent sheet is usually collected and archived by the researcher.

Regarding the participant information sheet, you might for example, have different categories of participants (e.g. experts and general public) and thus might need somewhat different participant information sheets. Briefly describe how you will provide the participant information sheet to the potential participants (e.g. will it be sent out beforehand (e.g. by email), will it be handed over at the beginning of the interaction, will it be read out; if the project involves children, how will you request consent from the parents/guardians/proxies). State whether the sheet will remain with the participants, so that they can refer to it at any time (e.g. if they want to revoke their consent). If data is collected in a face-to-face setting, clarify whether research participants will be given the opportunity to ask any questions prior to starting.

If you have decided to withhold information at the beginning of the interaction (use of deception or withholding information to avoid biasing answers), will you have a debrief session?

How will you handle asking for consent? Consent may be given orally (recorded) or written (signature on a form). How do you take into consideration whether participants have any difficulty in reading and/or understanding printed material that you might give them? Will the participants get a copy of the signed consent form?

If you use secondary data, you should ensure that informed consent was given to the original data collector, that they have provided consent for the scientific use of their data and included the right to share data with third parties. In case you use Big Data or collect data on individuals from the web, you need to be aware that the discourse on research ethics with Big Data (not least given the challenges to traditional assumptions of privacy) is still on-going, and that there are major challenges in ensuring informed consent.

6. Documentation of aspects related to anonymity and data protection

When engaging in research with humans, they entrust us with personal data and information and it is the ethical (and legal) duty of researchers to protect this data and ensure – as far as possible – that participants are protected from any negative fallout from the information they have given us in confidence, by protecting their anonymity. The <u>General Data Protection Regulation</u> (GDPR) establishes the main principles in relation to the processing (i.e. collection and management) of

personal data (see definition in <u>GDPR Art 4(1)</u>). Personal data refers to that through which the research participant is identifiable, i.e. it includes names, address(es), location data (e.g. on mobile phones), IP address. Note that following the principle of 'data minimisation' (<u>GDPR Art 5(1)(c)</u>), you should limit collection of personal data to what is directly relevant and necessary to accomplish the specified purpose of your research.

Since the GDPR is a legal requirement, please consult the <u>BOKU Legal Department</u> if you have any questions (including questions regarding the requirements to keep raw data or the list of names of participants to document the integrity of the research). The concern of the Ethics Commission is with the ethical dimension of how the provisions of the GDPR are implemented to adequately protect the privacy of participants.

6.1. Please briefly explain how you implement the provisions of the GDPR. In particular: How will personal data be protected? This includes digital data, but also e.g. signed consent forms which carry the names of the participants.

Personal data must be kept confidential. Thus, please provide a brief outline of your data management plan (DMP), which allows you to clarify how you handle the data in such a way as to maintain the anonymity and confidentiality of your participants. This needs to cover all the media that are generated in the course of the research and which might carry the names of the participants, i.e. consent sheets, files with the list of names of your participants, and audio recording of the interviews (starting e.g. on your mobile phone, external hard drive, laptop, BOKUdrive).

You might need to keep the list of names of people who participated in your research to document the integrity of the research. You might also want to use the addresses/contact to inform the participants that the research results are available or share/send them to them. These files must be stored in a secure system to protect personal data from access by unauthorized persons at all times (i.e. while in the field and back at BOKU), i.e. all computer hard drives, memory sticks should be password protected, or better, encrypted. You need to specify how you will control access to the data (e.g. when it will be stored on BOKUdrive), and who has access to it (usually at least yourself and your supervisor/the project leader).

If you have audio files or film footage, these are likely to include personal data also (e.g. names of people or places). Clarify how this raw data will be stored.

Please note: if you have printed out the consent forms and had them signed, these do not formally fall under the GDPR (which only applies to data being processed by automated means). However, to protect the privacy of the participants, these paper documents also need to be protected, e.g. by storing them in a locked cabinet. Such signed consent forms may be kept five years after the end of the study and should then be destroyed.

Please note: pseudonymized transcripts of audio recordings do not fall under the GDPR, since they do not contain personal data. These research data should be archived. This archiving, esp. of the raw data such as pseudonymised interview transcripts, is required to maintain scientific integrity and the verification of the research process (i.e. prove that you have not invented/falsified data). Following the FOG §2f(3) the minimum archive duration for research data and records is 10 years after original publication. These transcripts might be used in other research projects at the BOKU. You may also consider making pseudonymised transcript available open access to other researchers (e.g. on platforms such as the Austrian Social Science Data Archive (AUSSDA or Zenodo) thus contributing to Open Science.

6.2. Will personal data be erased? If yes, when?

As noted above it is likely that various files (excel, word, audio, video, etc.) which contain personal information will be generated during the course of the research project. The personal data should be stored "no longer than is necessary" given the purposes for which it was collected (<u>DSGVO</u>

<u>Art. 5 (1e)</u>). In Point 6.1 you state for what purpose the data is collected, allowing to assess when that purpose has been fulfilled. Thus, please state the date (month, year) when the data will be destroyed and who will do it (as this may be after the end of the contract of e.g. PhD students).

6.3. Will the data be anonymized/pseudonymized? If yes, how?

While anonymisation (or in many cases pseudonymisation, as it is referred to in the GDPR) of data might be straightforward in some research setting, it can be very challenging in others. In practice, there is a continuum from inherently anonymous to fully identifiable.

Please briefly explain how you will maintain the anonymity of the participants when reporting your research results. How will you identify participants: will you use pseudonyms? Will you identify people's role or organisation? Will you identify the specific place where the interviews/research took place? You need to keep in mind that in a small-area geographic context, it may be possible to identify an individual even if you use pseudonyms, e.g. through a combination of postcode, small-scale geography data, age and gender.

Especially in qualitative research, there are limits to anonymisation. The whole point of qualitative research is to generate rich descriptions of people's experiences and views, so that this data will always contain information that might be attributable to a person, even if the names, addresses, etc. are withheld. Thus, if participants belong to a small community, neighbours or other members of the community or organisation are likely to be able to identify a respondent based on quotes from the interview. As such, just using a pseudonym may not be sufficient protect the anonymity of your respondents. This may be unavoidable, but if it is the case, it needs to be communicated in the consent form.

6.4. Will the participants be informed of their rights? Is this in easy-to-read, plain language (PLS)?

Art. 13 GDPR includes a list of the rights that participants need to be informed about. This includes: contact of the project leader and the data protection officer, purposes of the processing of personal data, period for which the data will be stored, right to erasure of personal data, right to restrict processing, right to withdraw consent, right to lodge a complaint with a supervisory authority.

While providing the rights in detailed legal language would fulfill the provisions of the GDPR, it is not conducive for an ethical engagement with participants. It is thus useful to ensure that participants are informed of their rights in plain language. Plain language is about writing in a clear, concise and well-organised way, so that your intended audience can understand it the first time they read or hear it.

This information might be included in the information sheet.

7. Ethical aspects in case of interventions in an ecosystem²

This topic only applies if your research involves environmental field work, e.g. work that involves sampling or directly monitoring a site, or involves movement in an environmentally sensitive area.

If so, please clarify if you have taken appropriate steps to gain permission to access field sites. Do you have permission to access privately held land? Have you made arrangements with the

² If your research does not affect the environment or does not take place in the Global South, just list Question 7 and/or Question 8 and write 'not applicable'. No need to list the sub-questions 7.1 till 7.3 and/or 8.1 till 8.6

landowner/responsible bodies? Does the fieldwork involve sampling rare/endangered or harmful taxa/species? If yes, have you acquired the appropriate permits?

7.1. What are the expected impacts on animals covered by the Animal Protection Act?

If the fieldwork will be carried out on agricultural land or farmland, could it cause distress to livestock? Is there sensitive, rare or endangered birdlife or wildlife in the area? If so, how might your work impact these animals?

7.2. Which measures are being taken to minimise suffering of vertebrates?

Will the fieldwork significantly disrupt the site and/or its environment and/or rare/endangered species? How will you minimise the impact of your work on vertebrates?

How will you keep sample/specimen collection to a minimum?

7.3. What are the expected impacts on the ecosystem?

If the field work will be carried out in an environmentally sensitive area, are there sensitive, rare or endangered flora in the area? Will your fieldwork involve sampling rare/endangered species? If so, how might your work impact these rare/endangered species?

If you collect samples, will you remove sufficient quantities to have a negative physical / environmental impact on the site or the ecosystem? Will your field work significantly disrupt the site and/or its environment?

8. For research projects that (partially) take place in the Global South²

When doing research in countries of the Global South, you need to take into account a range of international guidelines (esp. the 'Global code of conduct for research in resource-poor settings'), conventions (e.g. the Nagoya protocol), European Directives (e.g. Regulation (EU) 511/2014), as well as the national laws and guidelines of the country in which the research takes place.

8.1. Does the research project meet the needs of the country where the data will be collected?

To ensure the principle of fairness, local relevance of research is essential and should be determined in collaboration with local partners. Indeed, research that is not relevant in the location where it is undertaken imposes burdens without benefits (Global code of conduct, Art. 1). Thus please explain how the proposed research gives due consideration to the social, cultural, political, economic, ecological and technical needs and situation of the local stakeholders?

To achieve the aims of having an impact locally, it is necessary to ensure that the research findings are available on-site. Thus briefly explain how the research findings, associated publications and reports will be made available in the country where the research took place. Will the research findings be made available in the local language? What format will this take (leaflet, radio broadcast, oral debrief)?

8.2. Will local researchers be involved in the research project? Will the results be provided to local researchers? If yes: in what form and when?

Please state how you take into account the relevant provisions in the global code of conduct, especially:

Art. 4: Local researchers should be included, wherever possible, through the research
process, including the study design, its implementation, data ownership, intellectual
property and authorship of publications.

- Art. 7: It is essential to compensate local research support systems, for instance translators, interpreters or local coordinators, fairly for their contribution to research projects.
- Art. 20: A clear understanding should be reached among collaborators with regard to their roles, responsibilities and conduct throughout the research.

If you work with field assistants and/or translators: how were they recruited? Was the process transparent and non-discriminatory? Are they known and trusted by the local community, so as to ensure effective communication? Will they receive adequate training to further strengthen their skills and to be able to do their tasks effectively and responsibly?

8.3. How do you take into account local customs and social norms (e.g. how has it influenced the study design, access to the field, selection of participants)?

To comply with the principle of respect, potential cultural sensitivities should be explored in advance of the research with local communities, to avoid violating customary practices (Global code of conduct, Art. 8).

Please explain how your study design and field access takes into account the relevant local customs and social norms. How will relevant traditional, local and indigenous knowledge be considered?

8.4. How do you ensure informed consent if participants are illiterate or come from educationally poor backgrounds or belong to vulnerable groups? Is a written consent culturally appropriate? If not, how will you ensure oral consent? Do you also have to receive consent from a local authority? If yes: which?

In some contexts the provision of written participant information and consent sheet might be inappropriate or not meaningful; if so explain why it is inappropriate or problematic. Nonetheless such an information sheet should be provided with your application to the Ethics Committee, as it will form the basis of any verbal communication.

Informed consent procedures should be tailored to local requirements to achieve genuine understanding and well-founded decision-making (Global code of conduct, Art. 12). This includes a clear procedure for feedback, complaints and allegations of misconduct (Art. 13).

Note that lower educational standards, illiteracy or language barriers can never be an excuse for hiding information or providing it incompletely. Plain language and a non-patronizing style in the appropriate local languages should be adopted (see Global code of conduct, Art. 21). In some contexts it may also be appropriate to supplement verbal communication with an illustrated/visual equivalent of the Plain Language Statement (PLS).

In some cultures (e.g. hierarchical societies) you many need to obtain consent from a community leader or a senior family member before approaching a prospective participant. This does not substitute for individual consent, which must still be obtained from each prospective participant (see Global code of conduct, Art. 9). Please explain how informed consent will be implemented in your research.

In some contexts a written consent might not be appropriate. If verbal consent is sought, explain how it will be recorded or if you use a witness.

8.5. Have you followed the provisions of the BOKU Emergency Plan for Travel Abroad?

The BOKU has the duty to care, i.e. to ensure the safety and welfare of its employees, and employees are responsible to take reasonable care of their own safety. The BOKU provides information for researchers travelling abroad (see emergency checklist website). Please briefly indicate if you are aware the emergency checklist and state whatever other provisions are taken to ensure your health and safety.

Additionally, the BOKU offers relevant courses and trainings, e.g. 'Security training for studying and field research abroad – raising awareness for critical emergency situations'. It might be advisable to take part in such a course.

8.6. If your research (partly) takes place in a non-EU country, have you taken into account the relevant provisions of the European Commission (e.g. material transfer agreement, export authorization, benefit sharing).

In case your research involves the collection of biological material, there are a number of legal provisions to take into account. In particular this applies to the compliance with rules on access and benefit-sharing arising from the use of genetic resources and associated traditional knowledge (Regulation (EU) 511/2014). If you intend to transfer specimens and samples, please briefly state whether you have established written material transfer agreement, to allow legal certainty on the transfer of ownership and custodianship (see Art. 4 Regulation (EU) no 511/2014 and the Nagoya protocol).

For further information

Website of the Ethics Committee: https://short.boku.ac.at/ethics
Office of the Ethics Committee: ethikkommission@boku.ac.at