

**Ethics Committee of the DGfS** Questionnaire for the Performance of Investigations with Human Subjects[[1]](#footnote-1)

**1.** **Name of the** **applicant:**

Click or type here to enter text.

**2.** **Are you a member of the DGfS?**

[ ]  yes [ ]  no

**3.** **Name of the participating scientists:**

Click or type here to enter text.

**4.** **Name of the project:**

Click or type here to enter text.

**5.** **Type of application:**

[ ]  student thesis

[ ]  lab application

[ ]  neither student thesis nor lab application

**6.** **Name of the investigation:**

Click or type here to enter text.

**7. I confirm all persons listed under 1 and 2 of the current** **application are aware of it and consent to its submission.**

Date: Click or type here to enter text.

Signature of the project management: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**8. A statement with regard to data-protection law by my institution's data protection will be gained.**

 [ ]  yes

The Ethics committee does not request a statement regarding data protection. Please note that the ethics vote does not release you from the obligation to obtain a statement from the responsible data protection officer that confirms the conformity of data collection and management with the data protection regularities. The obligations to ensure that the data management is handled in compliance with the data protection regularities lies in the responsibility of the applicant.

**9. Planned beginning of the investigation:** Click or type to enter a date.

**10. (Expected) supporter/sponsor of the project:**

Click or type here to enter text.

**11. Brief description of the investigation (goals, hypotheses, design, method, devices used):**

Note on item 11: Provide details about special features during the selection of the methods and devices here. Alternatively, you can attach the third-party funding application and refer to the corresponding pages.

Click or type here to enter text.

**12. Is this a follow-up application for an already approved investigation?**

 [ ]  yes [ ]  no

If yes: Provide the application number and describe the changes compared to the previous application.

Click or type here to enter text.

**13. Has an application for the current investigation already been submitted to another** **ethics committee?**

 [ ]  yes [ ]  no

 Note on item 13: If yes, please attach the application and the statement by the other ethics committee.

**14. How will you recruit the** **participants (e.g., via the internet, using a register or an organization)? If you recruit via the internet, please also indicate who your addressees are or how you “find” your investigation participants.**

 Click or type here to enter text.

**15. Information about the participants (e.g., number, age ranges):**

Note on item 15: One aspect of the appraisal of ethics applications lies in the assessment of the risk-benefit profile of the study being applied for. For this purpose, for qualitative studies an explanation is required of how the study design can ensure that the gain of knowledge outweighs the risks and consequences of the observation. For quantitative studies, the applicants must provide a sample size estimation to justify the number of subjects being requested. This is done both to prevent studies with samples sizes that are too low and to prevent unnecessary investigations. The calculated sample size estimation here is based on pre-published effect sizes of comparable studies. A direct reference to the sample size of comparable studies is only permitted if pre-published effect sizes are not available. Therefore, the ethics committee insists that effect sizes should always be indicated for the publication of quantitative studies.

 Click or type here to enter text.

**16. Special selection criteria of the investigation participants (e.g., social background, diseases, disabilities, services) and exclusion criteria:**

 Click or type here to enter text.

**17. Which actions should be implemented to take the special needs of vulnerable groups into account?**

Click or type here to enter text.

**18. How will it be explained to (potential) participants that they have the option of withdrawing from participation at any time and without providing reasons?**

 Click or type here to enter text.

**19. How will the purpose of the research, the expected duration of the investigation and the procedure be explained to the (potential) participants?**

 Click or type here to enter text.

**20. How will it be explained to (potential) participants that they have the right to demand the deletion of their personal data at any time (even after the investigation has ended)?**

 Click or type here to enter text.

**21. How will (potential) participants be informed who they should contact in the event of questions about the research project and about their rights?**

 Click or type here to enter text.

**22. How will the (potential) participants be given the opportunity to obtain answers to their questions about the research project?**

 Click or type here to enter text.

**23. How will the explanation with the necessary contact addresses of the study management, your organization’s data protection officer and the official complaint office be handed out?**

 Click or type here to enter text.

 Note on item 23: Please attach the written summary of the explanation(s) and informed consent(s).

**24. Will the investigation participants be physically or mentally stressed (e.g. by the duration of the investigation, aversive stimuli, negative experiences)?**

 [ ]  yes [ ]  no

 If yes: By which measures?

 Click or type here to enter text.

If no: Please explain briefly why this is not the case.

Click or type here to enter text.

**25. The investigation will include:**

 manipulative questions [ ]  yes [ ]  no

covert observation [ ]  yes [ ]  no

deceptions [ ]  yes [ ]  no

no manipulation or deception [ ]  yes [ ]  no

no risks [ ]  yes [ ]  no

Note on item 25: Deception means that the goals of the study make it necessary that the contents and goals of the study are not explained to the participants in a truthful way.

**26. The data collected from the individuals will contain information about:**

[ ]  gender [ ]  address

[ ]  age [ ]  telephone number

[ ]  cultural background [ ]  other variables

[ ]  linguistic background

[ ]  income

[ ]  educational background/duration of schooling

**27. When is the deletion of all personal data planned?**

 Click or type here to enter text.

**28. Is the deletion of all scientific data planned after the 10-year retention obligation?**

 [ ]  yes [ ]  no

**29. The data storage will be carried out by:**

 Note on item 29: Before the beginning of the investigation, the participants or their legal representatives must be informed of the type and duration of the saving and further processing of personal audiovisual recordings and must confirm with their signature that they agree with the conditions of the investigation. Please attach the relevant explanatory text and the informed consent.

[ ]  Recordings on paper

 [ ]  Recordings on electronic data carriers

 [ ]  Recordings by means of audiovisual media

**30. Will data – in whole or in part – be collected, saved or processed by an external service provider?**

 [ ]  yes [ ]  no

 Note on item 30: If yes, attach the agreement on the commissioning for data processing to the ethics application.

**31. Will all employees who have access to the data submit a confidentiality agreement?**

 [ ]  yes

 [ ]  no, because no sensitive data will be collected

 Note on item 31: If yes, attach the confidentiality agreement to the ethics application.

**32**. **Will the data you work with...**

 [ ]  be anonymized?

 [ ]  be pseudonymized?

 If yes: When and how?

 Click or type here to enter text.

Note on item 32: Anonymization is the alteration of personal data in such a way that the individual data about personal or material circumstances can no longer be assigned to a specific or identifiable natural person, or that this can only be done with a disproportionately large expenditure of time, costs and labor. Pseudonymization is the replacement of the name and other identification characteristics by an identifier (pseudonym, code) for the purpose of excluding the identification of the person in question or to make this considerably more difficult, (German Federal Data Protection Act, Section 3(6)). An unblinding list contains the link of pseudonyms with personal data.

**33. How will the original data of the participants (e.g., filled out questionnaires, test booklets, addresses, informed consent forms, bank details) and the data for the decryption of codes be stored?**

 Click or type here to enter text.

**34. Which precautions will be taken to protect the data, in particular personal data, against access by third parties?**

Note on item 34: Please provide the rules for the handling, access authorization and securing of this data. If necessary, specify the separate storage of personal data, pseudonymized data and unblinding data. Indicate to whom (e.g., all project employees) and in what form (e.g., written instruction with signature) these rules will be handed out.

 Click or type here to enter text.

**35. Instruments:**

[ ]  published investigation instruments/standard investigation instruments

 [ ]  instruments developed for the investigation

 Please describe your data collection procedure.

 Click or type here to enter text.

**36. Will your participants receive an expense allowance?**

 Note on item 36: Before the beginning of the investigation, the investigation participants must be informed about the amount of the expense allowance and, if applicable, told that not all participants will be paid the same amount of money and the reasons for this.

 [ ]  yes [ ]  no

 If yes: Is the anonymity of the participants guaranteed in the process? Please describe how this is done.

 Click or type here to enter text.

 If yes: How will the expense allowance be regulated in the event that participation in the investigation is terminated prematurely?

 Click or type here to enter text.

**37. Can incidental findings occur?**

 [ ]  yes [ ]  no

 If yes: Please explain in what form incidental findings could occur and how you intend to inform the investigation participants. Please also keep in mind the right to remain uninformed.

 Click or type here to enter text.

**38. Designate one individual who will be responsible for compliance with the following data protection guidelines for the study being applied for:**

 *General data protection guidelines*

* *Any documents with personal information will be protected against access by unauthorized persons. “Physical” documents (e.g., informed consent forms, video cassettes, storage media) will be kept under lock and key. Electronic data will be password protected.*
* *Data sets that are used for everyday work will be factually anonymized, i.e., they will not allow for direct identification of the individuals investigated. Investigation participants will only be recorded in the test subject databases with their consent. At the request of those affected, such entries will be deleted immediately and irrevocably.*
* *Access to personal data and unblinding lists (i.e., lists that allow for the assignment of personal information and results) is limited to one or a few individuals. Individuals authorized for access have been informed of the data protection guidelines.*

Responsible for compliance with the above-mentioned data protection guidelines in the investigation being applied for:

 Click or type here to enter text.

**39. I attest to the accuracy of the statements I have made under items 1 to 38.**

Date: Click or type to enter a date.

Applicant’s signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. This questionnaire is based on the questionnaire of the Ethics Committee of the DIPF/Research Center IDeA in Frankfurt. We thank our colleagues for their cooperation. [↑](#footnote-ref-1)