

Template for the study information and informed consent in scientific research projects

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RDC Qualiservice (ed.)

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Background

The Research Data Center (RDC) Qualiservice, together with the law firm MLS LEGAL GmbH - Rechtsanwalts- und Fachanwaltsgesellschaft, has drawn up legally compliant declarations of consent to safeguard your data processing, which covers both the collection and processing of data in the research process as well as the transmission to Qualiservice for further secondary scientific use and archiving. These are available for download on our website. With these declarations of consent, we would like to support you in the preparation of the various phases of data processing in your research project, but also in the preparation of preparation of a planned archiving and provision of the research data for secondary scientific use.

Information and Declaration of Consent¹

For the scientific research project *[insert the complete title of the scientific research project]* -
[insert the abbreviation of the scientific research project] -

Information about the scientific research project

Dear participants of the scientific research project,

we ask for your consent to participate in the scientific research project *[insert the abbreviation of the scientific research project]* and the involved processing of your personal data. For this reason you receive the following information about the content and the sequence of the scientific research project as well as the intended use of your data:

What is the issue of the scientific research project?

The scientific research project is conducted to *[insert and explain: What is the reason for the scientific research project and will personal data be processed? For what purpose or rather what is the goal of conducting the scientific research project? If necessary to mention: Who is the funding authorities? If necessary to mention: What is the term of the scientific research project?]*.

What is the exact procedure for the scientific research project and how will my data be used?

Your participation in the scientific research project will probably go for [If it is possible insert the extent and period: for example period of time: 1 hour, 1 day, 8 weeks etc. or for example one or two scheduled interviews etc.].

During the scientific research project you will *[insert and explain: Procedure of the scientific research project and the measures conducted, for example: ...“participating in an interview. The interviews will be recorded. In addition you will be asked to complete a questionnaire.”]*.

What costs are incurred by the participation in the scientific research project and will an expense allowance be paid?

By participating in the scientific research project no additional costs are incurred.

No remuneration/expense will be paid for your participation in the scientific research project *[note: if necessary only within the framework of a justifiable expense allowance, for example: „As an expense allowance you will receive once EUR 10,- for accruing travel cost.“]*.

Claims for further remuneration, royalties or other participations in financial benefits and profits, that may be achieved on the basis of the research results, are excluded.

¹ This is an english translation of the german version which is the only legally binding version.

Am I insured during the execution of the scientific research project?

[For all research projects, it must be examined on a case-by-case basis whether a special insurance need to be taken out. If no insurance has been taken out, this must also be mentioned.]

Alternative A:

Your participation in the scientific research project is covered by an insurance with *[insert: name and address of the insurance company, telephone, fax, policy number]*. The maximum benefit per insured person is *[insert xx Euro]*. The insurance covers all possible damages that you may incur as a result of measures taken in the research project.

We would also like to point out that you are not insured by us against accidents on the way to and from the location of the research project taking place.

Alternative B:

Please note that no special insurance has been taken out for the implementation of this scientific research project.

Who decides whether I should withdraw from the scientific research project prematurely?

Participation in this scientific research project is voluntary. You may terminate your participation at any time without giving reason and without incurring disadvantages.

Under certain circumstances, however, it is possible that a scientific research project is terminated prematurely, for example for organisational reasons.

If, during the course of the scientific research project, important new information comes to light which could affect your decision to continue your participation in this scientific research project, you will be informed.

Data protection information: What happens with my data?

What data is collected in the scientific research project?

In the context of the scientific research project the following data will be collected from you:

- data of contact *[insert: name all personal data, for example: name, address, telephone number, e-mail]*
- project data, which means the information about you produced in the context of the scientific research project, in particular: *[insert, for example:*
 - *audio recordings of an interview,*
 - *video recordings,*
 - *written version of an interview,*
 - *questionnaire data about your person.].*

Project data may include special categories of personal data such as personal data revealing racial or ethnic origin², political opinions, religious or philosophical beliefs or trade union membership, genetic data, biometric data, health data or data concerning a natural person's sexual life or sexual orientation *[please delete from this list those not applicable].*

How is the data processing in the scientific research project carried out?

The produced project data, i.e. the *[insert and describe: the method of data processing, e.g.: „... Original texts of your interview OR original audio recordings of you interview OR original video recordings are evaluated by project members. Within the scope of the evaluation, copies are also made in which all information that could lead to an identification of you person (e.g. names) and other references, are changed, abstracted or removed from the transcripts“].*

The original data or -records are kept for at least 10 years in accordance with the guidelines for handling research data of the German Research Foundation for safeguarding good research practice and are deleted afterwards, unless legal requirements stipulate longer archiving obligations *[If this section is not applicable, because the data e.g. should be archived for an unlimited period of time, please delete this section completely].*

In scientific research publications, such as in papers or at meetings and conferences, no personal data of yours will be mentioned, i.e. the research results are published without reference to you personally. Interviews are only quoted in excerpts to ensure to third parties that the resulting overall context of events cannot lead to an identification of your person.

² Original wording of the legal text according to article 9 paragraph 1 GDPR.

Your contact data will be marked with a project data identifier and stored separately from the project data in different locations to which only authorised employees of the scientific research project and authorised scientists have access.

After the completion of the scientific research project, your contact data will be automatically deleted, unless you expressly agree to the further storage of your contact data for future topic related scientific research projects. In this case, scientists would be provided with the data on request so that they can contact you and ask whether you are available to participate in a scientific research project.

Such participation is of course voluntary and you can refuse it without giving reasons. You can of course object to a longer storage at any time; your contact data will then be deleted.

Who has knowledge of the data and which persons and institutions have access to the data?

Access to your data is restricted to employees of the scientific research project as well as authorised scientists. These persons are obliged to observe the data protection requirements. The data is protected against unauthorised access.

What rights do those persons have affected by the data processing?

Participation in the scientific research project is voluntary; if you do not participate, you will not suffer any disadvantages. You have the possibility to assert the following rights at any time:

- **Right of access** about the personal data processed concerning you (art. 15 GDPR),
- **Right to rectification** of inaccurate personal data concerning you (art. 16 GDPR),
- **Right to erasure** of personal data concerning you (art. 17 GDPR),
- **Right to restriction** of processing of personal data concerning you (art. 18 GDPR),
- **Right to object** the processing of personal data concerning you (art. 21 GDPR),
- You also have the right to lodge a **complaint** with a **data protection supervisory authority** about the processing of personal data by us concerning you (art. 77 GDPR),
- If you have consented to the processing of your data, you have the right to **withdraw** this consent at any time for the future (art. 7 paragraph 3 GDPR). In this case, all personal data must either be deleted or made anonymous.

Your rights must always be asserted in writing to the person responsible for data processing.

Who is responsible for the scientific research project and the associated data processing?

Who can I contact if I have further questions?

The scientific research project will be carried out by *[insert: implementing institution with name, address]*. Responsible for the data processing is *[insert: the person responsible for the data processing to mention with name, job title, institution, address, e.g. N.N., Head of the research project, University XY.]*.

If you have any questions regarding data protection law, please contact the data protection officer at the *[insert: name of the institution, name of the data protection officer, address, telephone, e-mail]*.

If you have further questions regarding the scientific research project, please contact the following contact point/project management.

If you wish to participate in the scientific research project, please read and sign the enclosed declaration of consent.

The original of the declaration of consent remains with *[insert: institution with which the original declaration of consent is deposited]*. You will receive a copy of the declaration of consent. The information letter on the scientific research project also remains with you.

Kind regards

[insert: N.N.]

Head of the scientific research project

[insert institution]

Information and Declaration of Consent

For the scientific research project *[include the complete title of the scientific research project]* -
[include the abbreviation of the scientific research project] -

Declaration of consent to participation

I have received the written information about the scientific research project *[insert: abbreviation of the scientific research project]*.

I was given a copy of my signed declaration of consent for participation and data protection. I have read and understood both documents. I was informed in detail - orally and in writing - about the aim and the course of the research project, my rights and obligations, the insurance cover I am entitled to and my data protection rights. I had a chance to ask questions. These were answered satisfactorily and completely.

I hereby declare my participation in the scientific research project *[insert: abbreviation of the scientific research project]*. It has been pointed out to me that my participation in the research project is voluntary and that I have the right to terminate it at any time without giving reasons, without any disadvantages for me.

Yes **No**

I hereby declare my consent that I may be contacted by scientists for future topic-related scientific research projects at their requests.

Yes **No**

Data protection declaration of consent

I hereby consent to the process of my collected personal project data, namely *[insert: e.g. audio recordings of my interview OR video recordings OR written versions of my interview OR questionnaire data about my person etc.]* within the framework of the scientific research project *[insert: abbreviation of the scientific research project]*, *[please delete from this list those not applicable: „.....in particular also with the processing of special categories of my personal data such as personal data revealing racial or ethnic origin³, political opinions, religious or philosophical beliefs or trade union membership, genetic data, biometric data, health data or data concerning a natural person's sexual life or sexual orientation]*.

Yes **No**

Furthermore I hereby declare my consent that even after completion of the scientific research project *[insert: abbreviation of the scientific research project]* my collected personal contact data will be

³ Original wording of the legal text according to article 9 paragraph 1 GDPR.

stored and processed for future topic related scientific research projects as well as transmitted to scientists on their request.

Yes

No

first and last name

address

place and date

signature

As the scientist in charge [*alternatively: project manager*] I have explained the aim, purpose, significance, scope and possible risks of the scientific research project [*insert: abbreviation of the scientific research project*].

place and date

signature