



INFORMATION SHEETS AND CONSENT CHECKLIST

This document aims to provide support for the preparation of the information sheets and consent form in research projects. More information on consent is available on [the DCC website](#).

The checklist includes the reference to the articles of the GDPR and the guidance documents on consent and transparency made by the Data Protection Working Party [WP259, WP260].

INFORMATION SHEETS

Information about the purpose(s), the data and the data processing:

- A clear statement of the purpose(s) of the research project and the purpose(s) of the processing the data.** [GDPR Art. 13(1)(c) and Rec. 42, 33]

Is the purpose(s) of the personal data processing presented in a non-technical language intelligible to the participants? For an answer to this question, take into consideration the different stages of the data lifecycle. Processing the data with the purpose of answering a research question(s) is different from the purpose of making the data available to other researchers. If at the end of your project you want to make the data open you need to ask the consent of the participants.

The GDPR contemplates some flexibility to the degree of specification of consent in the context of scientific research. Recital 33 states: "It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research". However, in case of special categories of personal data, the Data Protection Working Party gives a restricted interpretation of the Rec. 33 and, points at the need to ensure the essence of the consent requirements in other ways, such as in line with ethical standards in scientific research.

To compensate for the lack of purpose specification, you may provide to the participants a comprehensive version of your research plan. This research plan should specify the research questions and the working methods envisaged as clearly as possible. The research plan could also contribute to compliance with Article 7(1) GDPR. As controller, you need to show what information was available to data subjects at the time of consent to be able to demonstrate that consent is valid.

- What (type of) data will be collected and used.** [WP259 rev.01 pg. 13]

Will the project ensure that persons involved in the project give their informed consent, not only in relation to the aims of the project but also with regard to the process of the research, i.e. how data will be collected and by whom, where it will be collected, and how the results are to be used? [DW]

- How the data collected will be handled and protected (e.g. include detail/protocol on the pseudonymization technique)** [GDPR Rec. 33]

How has the methodology addressed ways in which sensitive information, data or sources will be handled (e.g. personal data, data protection, tracking of people)? [EC-FSS]



What arrangements have been made to preserve confidentiality for the participants or those potentially affected? [EC-FSS]

Please explain the mechanisms in place to ensure the confidentiality of private information and compliance with data protection law. [EC-FSS]

What concerns have been taken into account concerning the preparation and design of the research project? If agencies, communities or individuals are to be directly affected by the research (e.g. participants, service users, vulnerable communities or relations), what means have you devised to ensure that any harm or distress is minimized and/or that the research is sensitive to the particular needs and perspectives of those so affected? [EC-FSS]

The risks of the participation [GDPR Rec. 33]

Will the person be informed of the nature, significance, implications and risks of the project technology? [DW]

Will the person have an interview with a project representative in which he(s) will be informed of objectives, risks and inconveniences of the project or research activity and the conditions under which the project is to be conducted? [DW]

Particular attention must be paid to vulnerable categories of individuals such as children, patients, people subject to discrimination, minorities, people unable to give consent, people of dissenting opinion, immigrant or minority communities, sex workers, etc. If your research involves children or other individuals unable to make decisions for themselves, you must maintain an ongoing relationship with their legal guardians and/or careers; you must not only seek their consent but also allow them to monitor the research. [H2020]

If the individual is not able to give informed consent (for example, the person with dementia) to participate in a project or to use technology, will the project representatives consult with close relatives, a guardian with powers over the person's welfare or professional cares? Will written consent be obtained from the patient's legal representative and his doctor? [DW]

If the case, mention of possible commercial revenues from the research, especially when the revenues lead to the conclusion that the data is not processed solely for scientific research.

The rights of the participants

The existence of the rights of the data subjects (access, rectification, erasure). [GDPR Art. 13(2)(b)]

Does the consent outline the use for which data is to be collected, how the data are to be collected, instructions on how to obtain a copy of the data, a description of the mechanism to correct any erroneous data, and details of who will have access to the data? [Specific derogations may apply in research projects.](#) [GDPR Arts. 85, 89 and UAVG]

The right to lodge a complaint with a supervisory authority. [GDPR Art. 13(2)(b)]

A clear statement that participation is entirely voluntary and that participants can withdraw from the project at any time without prejudice, now or in future.

Is consent given truly voluntary? For example, does the person need to give consent in order to get a service to which there is no alternative? [DW]



- ❑ **A description of the easy procedures for withdrawal** [GDPR Art. 7(3) and WP259 rev.01 pg. 10-11]

Are people involved in or affected by the project able to withdraw from the project and to withdraw their data at any time right up until publication? [DW]

Plans at the end of the project

- ❑ **Plans for storage or archiving the data after the end of the project. The period for which the personal data will be stored, or if that is not possible, the criteria used to determine that period** [GDPR Art. 13(2)(a)]

Please take into consideration the institutional and discipline-specific guidelines and, if possible, add the URL. The period for which the personal data will be stored based on the discipline-specific guidelines.

- ❑ **Plan for making the data reusable after the end of the project** [GDPR Art. 13(3), Rec. 32 and WP259 rev.01 pg. 10]

The participant needs to give explicit consent to make his/her data reusable at the end of the project.

Information on the person that will have access to the data

- ❑ **In the case of joint-controllers the names of all the controllers and clarification of responsibilities in a transparent way** [WP259 rev.01 pg. 13]

Controller means the natural or legal person, public authority, agency or other bodies which, alone or jointly with others, determines the purposes and means of the processing of personal data. An organization is a joint controller when together with one or more organizations it jointly determines 'why' and 'how' personal data should be processed.

An alternative measure would be an elaborated annex to the Data Management Plan available to the participants.

Take into account that in case of joint controllers the University of Groningen may have to sign, with the other controller, a cooperation agreement on processing the data (in Dutch "Samenwerkingsovereenkomst verwerking persoonsgegevens").

- ❑ **If the case, a full list (no names) of recipients or categories of recipients and processors** [GDPR Art.13(1)(e) WP259 rev.01 pg 13]

Recipients or categories of recipients means internal and external people who will have access to the data.

The data processor means a third party which processes personal data on behalf of the controller. The duties of the processor towards the controller must be specified in a contract or another legal act. A typical activity of processors is offering IT solutions, including cloud storage. In research, a processor could be a company or a person that processes the data during the project: such as, collect the data, transcribe interviews, analyze the data, etc.



- ❑ **Where applicable, the fact that the controller intends to transfer personal data to a third country or international organization and the existence or absence of an adequacy decision by the Commission.** [WP259 rev.01 pg. 18, GDPR Art 46, 47, 49(1)(a)]

The participant needs to give explicit consent to transfer his/her data.

- ❑ **Where applicable, the fact that the controller intends to use of automated individual decision-making, including profiling.** [GDPR Art. 22(1)]

“The data subject shall have the right not to be subject to a decision based solely on automated processing, including profiling, which produces legal effects concerning him or her or similarly significantly affects him or her.” (GDPR Art. 22(1)). The participant needs to give explicit consent to be subject to this process (GDPR Art. 22(2)(c)).

Contact details

- ❑ **Contact details of the University of Groningen and, where applicable, of the controller's representative.** [GDPR Art. 13(1)(a)]

- ❑ **Details of who to contact for further information and complaints**

This information should allow for easy identification of the controller and preferably allow for different forms of communications with the data controller (e.g. phone number, email, postal address etc.). As a further measure on transparency for scientific purposes: while full information cannot be provided at the outset, it could designate a specific contact person for data subjects to address with questions. Data Protection Working Party suggests the use of a single point of contact.

- ❑ **The contact details of the Data Protection Officer (Functionaris Gegevensbescherming) and right to complain with the officer.** [GDPR Art. 13(1)(b)]

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University of Groningen

Postal address: P.O. Box 72 9700 AB Groningen

An. Central Privacy Desk

E-mail: privacy@rug.nl

CONSENT FORM

The consent form should be a short document that concisely covers the core statements to which the participant is being asked to agree.

Separate 'yes/no' check boxes allow the researcher to make sure that the participant is actively affirming their consent. If the participant wants to check the no box this allows the researcher to clarify any points the participant is unsure about.

The consent should at least cover the following statements:

- The participant has read and understood the information about the research project and the purpose of the data processing.
- The participant had the opportunity to ask questions.
- The participant voluntarily agrees to participate.
- The participant has been informed of his/her rights.
- The participant understands that he/she can withdraw at any time without giving a reason.
- The participant understands how his/her data will be processed and protected.

The controller may need to obtain from the participant the explicit consent to some specific processes (here are some examples):

- Whether the participant agrees or not with the reuse of his/her data at the end of the research project.
- Whether the participant agrees or not with the transfer of personal data to a third country or international organization and the existence or absence of an adequacy decision by the Commission.
- Whether the participant agrees or not with the use of automated individual decision-making, including profiling.

The form should include the signatures of the participant and dates. Good practice: add the signature of the person that collects the form.

The participant should receive a copy of the form and the researcher should retain the signed original.

Reference documents

[WP259] Article 29 Data Protection Working Party, WP259 "Guidelines on Consent under Regulation 2016/679".

[WP260] Article 29 Data Protection Working Party, WP260 rev 0.1 "Guidelines on transparency under Regulation 2016/679".

[WP248] Article 29 Data Protection Working Party, WP248 "Guidelines on Data Protection Impact Assessment (DPIA) and determining whether processing is "likely to result in a high risk" for the purposes of Regulation 2016/679"

[DW] David Wright and Emilio Mordini "Privacy and Ethical Impact Assessment" in Privacy Impact Assessment, Editors David Wright and Paul De Hert, Pages 397-418, Springer 2012.

[H2020] European Commission "Horizon 2020 Programme Guidance How to complete your ethics self-assessment", Version 6.0, July 2018

[EC-FSS] Ethics guidelines Faculty of Spatial Sciences, University of Groningen.