rijksuniversiteit groningen / faculteit rechtsgeleerdheid

CETOR Guide on ethical assessment

Guide to the application form and further steps in the review of your research by the CETOR (Committee on the Ethical Review of Research in Law).

Please note: in case your research falls under the "WMO: Wet medisch-wetenschappelijk onderzoek met mensen" (*Medical Research Involving Human Subjects Act;* [1]
or in case there is a high risk of misuse of personal data that could require a DPIA[2];
please consult the Secretary of the CETOR before proceeding.

The application form and accompanying documents

The application form contains (short) help texts. You can simply overwrite these with your own text. In this Guide you find extensive explanation of the questions asked in the application form.

Accompanying documents

You are required to submit a number of attachments to the application form. These are:

a) Information about the study for participants *or*
   Information about the study for 'data subjects';
b) A consent statement for the participants, if applicable in your research;
c) A 'debriefing' procedure, if applicable in your research;

For these documents a template is provided. You can adapt these templates to the intended group of participants; feel free to use your own words and/or other documents that fit the purpose of informing your participants and asking consent.

Procedure at the CETOR

You can submit your application form and attachments to the secretary of the CETOR, Christine Penninga. E-mail: c.penninga-lin@rug.nl

As a rule, you will receive a response within six weeks for regular assessments. In some situations, an abbreviated assessment is possible; the secretary will inform you if this is the case.

Please note: According to the CETOR regulations (link), you may only commence your research once CETOR has granted its approval. If this causes you to run out of time or if there are other reasons why you wish to commence your research earlier, please contact the CETOR secretary.

More information about the CETOR and ethical review (link)

[1] More information on WMO related medical ethical assessment in Appendix I of this Guide

[2] More information on a Data Processing Impact Assessment (DPIA) in Appendix II of this Guide

Explanation and help on the CETOR Application form

Q.6 Description of the Study

From the answer to this question, the committee should get a good idea of the way(s) in which individuals and/or personal data are involved in the study and, in a general sense, how the study population is composed and what personal data are processed by the researchers.

Q.7 Funding and principals

This question is important for the committee to be able to assess the independence of the research and whether the funding organization should also be consulted. If your research has already been ethically reviewed by the funding organization and/or you have had to make a data management plan, as for example in the case of NWO or EU funded research, this will speed up the procedure at the CETOR.

Q.8 Data collection

Empirical research collects both quantitative and qualitative data, which can be either

a. primary data gathered through direct observation or experimentation, or
b. secondary data from existing sources.

Quantitative data consists of numerical and measurable information, while qualitative data is non-numerical and focuses on descriptive insights like opinions or observations

Q.9 Participants

The answer to these questions , should enable the committee to understand the nature of the study population in order to determine whether there are any risks for the persons involved and/or the researcher

Q.11 Permission

It is important to know whether other agencies have had to grant permission and whether conditions have been imposed. You should also answer the question whether an ethical review has already been carried out and/or a data management plan has been drawn up.

Q15 Risk to the reputation of the University of Groningen

Meant is the reputation in an ethical sense, not reputation in research excellence.

Q.16 Processing and Protection of personal data

The GDPR has a number of legal grounds for processing personal data in scientific research. For example, the explicit consent of those involved if you want to process special personal data. You must be able to demonstrate that you meet the conditions.
NB These questions concern the processing of personal data, so you also need to answer them if you only use secondary data in your research.

What is meant by vulnerable participants?

Vulnerable participants are defined as those who have (or think they have) a dependency relationship with the sponsor or implementer of the research. This dependency may be psychological, social, economic, political, or other. A dependency relationship can result in participants feeling compelled to give consent or not daring to refuse the processing of their data. Examples include employees or students of the RUG, children vis-à-vis their parents/carers/school, but also other vulnerable persons, such as patients vis-à-vis their health care provider/insurer, people entitled to benefits vis-à-vis the municipality or UWV, prisoners vis-à-vis the judicial authorities, and so on.

What is general personal data?

The term "personal data" includes any information relating to an identified or identifiable natural person (or "data subject").
General personal data includes, for example, a home address, date of birth, telephone number.

Please note: as combinations of data could be used to identify a person, this data – which may at first not look like personal data – must be counted as such!

For example:

the combination ‘name X’ ‘man’ ‘owns a Toyota’ ‘in the Netherlands’	= directly identifiable (person X)
the combination ‘man’ ‘owns a Toyota’ ‘address’ ‘in the Netherlands’	= indirectly identifiable (address leads to person X)
the combination ‘man’ ‘owns a Toyota’ ‘in the Netherlands’	= truly anonymous
the combination ‘man’ ‘owns a Toyota’ ‘in Groningen’	= given the number of Toyota owners, probably still truly anonymous
the combination ‘man’ ‘owns a Lada’ ‘in the Netherlands’	= unclear, because how many people own a Lada in the Netherlands?
the combination ‘man’ ‘owns a Lada’ ‘in Groningen’	= probably indirectly identifiable (the combination leads to person Y)

As you can see, data that does not directly identify a person must still be considered to be personal data if it is reasonable to assume that the data could be combined, either now or in the future, with other data and lead to the identification of a person .

This includes datasets that use unique identification numbers, even if you as the researcher do not know who the numbers refer to, or datasets with unique combinations. This is pseudonymized data, and therefore personal data.

What is Sensitive personal data?

According to the GDPR (art. 9), the following personal data should be considered as 'Special categories of personal data':

- personal data that reveals racial or ethnic origin;
- personal data that reveals political opinions;
- personal data that reveals religious or philosophical beliefs;
- personal data that reveals trade union membership;
- data about a person's health;
- data concerning sexual behaviour or sexual orientation;
- genetic data (data that provides unique information about physiology or health and/or the health of family members);
- biometric data that allows the unique identification of a person (data that provides unique information on physical, physiological or behavioural characteristics).

Special categories of personal data explained by the "Autoriteit Persoonsgegevens" (in Dutch)

Special categories of personal data by the "UK Information Commissioner's Office" (in English)

Conducting research with special personal data

To do scientific research with special personal data explicit permission must be requested from the participant for the processing of these data.
Of course, in addition, all GDPR conditions apply to be able to process ordinary personal data.
Note: If there is a high risk of misuse of personal data you should first perform a "Data Protection Impact Assessment (DPIA)". Please check, using the "DPIA scan" in the Appendix of the Readers Guide, whether this may be the case.

Why is the data provider asked?

If you do not collect the personal data yourself but receive it from another party, or if you have personal data that you have collected yourself is processed by a party outside the RUG, an agreement such as a 'data sharing agreement' or 'data processing agreement' must be drawn up for this purpose in order to comply with the requirements of the AVG.

What are technical and organizational measures?

Technical measures are, for example, pseudonymization and encryption. Organizational measures include not storing data on devices or keeping consent forms and transcripts separate.
More information on the website of the DCC:
www.rug.nl/research/research-data-management/data_protection-gdpr/measures/

Why is it asked if personal data is transferred to countries outside the European Economic Area?

The GDPR imposes restrictions on the transfer of personal data outside the European Union, to third countries or international organizations, to ensure that the level of protection of individuals provided by the GDPR is not undermined.
In this case, it must be demonstrated by the researcher that it is necessary for the research to transfer these data, for example because there is a research partner in those countries and what (additional) measures have been taken to achieve the same level of protection.

Appendix I: Medical or non-medical research

Research is covered by the Medical Research on Human Subjects Law (*Wet Medisch-wetenschappelijk Onderzoek met mensen, WMO*) if the following criteria are met:

1. It concerns medical/scientific research **and**
2. Participants are subject to procedures or are required to follow rules of behaviour.

In that case, the research proposal must be reviewed by an accredited Medical Research Ethics Committee (*Medisch Ethische Toetsingscommissie, METc*).

The WMO does not give a definition of the term *medical-scientific research*. As a result, it is not always clear if research must be submitted for review by a METc.

There are also cases where the participants are patients but the research is not medical in nature. In those cases, it is advisable that researchers contact the METc for advice.
The METc can issue a *Statement of Exemption*, which certifies that the study does not have to be reviewed by the METc.

There are academic journals that demand a Statement of Exemption as a prerequisite for publication.

Researchers of the UG can find more information on the website of the UMCG:
https://metcgroningen.nl/indienen/non-wmo-research/?lang=en

For more information, see also https://english.ccmo.nl/

Appendix II. Data Protection Impact Assessment (DPIA) Pre-scan DPIA

In some cases, the processing of personal data poses a risk to data subjects. In such a situation, the General Data Protection Regulation (GDPR) requires that a Data Protection Impact Assessment (DPIA) be carried out to ensure that major risks to the rights and freedoms of data subjects are prevented and that their rights and freedoms are safeguarded.

A DPIA is a systematic assessment of the impact of a particular system on the data protection of affected individuals. Such an assessment is required if the researcher intends to collect a large amount of data and/or highly sensitive data. Based on this assessment, recommendations can be made to minimize this impact as much as possible by applying technical and organizational measures. For example, by not asking for birth dates but birth years or by never storing data on a laptop or PC but always directly on a secure network storage.

The purpose of the DPIA is to identify the risks of data processing, before the start of a research project, and to name measures to limit those risks. What personal data will be processed? What will the researcher do with it? What measures does the researcher take to protect the rights and freedoms of data subjects?

Please use the pre-DPIA scan below to check whether a DPIA is necessary. If so, or if you are hesitating, please contact the Privacy & Security coordinator of the Faculty of Law Maarten Goldberg.

Pre-Scan DPIA

In a situation as listed below, it is advisable to perform a DPIA.

1. Processing sensitive personal data (e.g. criminal data, data on orientation, health data);
2. Processing personal data of vulnerable persons (e.g. children, mentally ill persons and patients);
3. Assessing people based on personal characteristics (i.e. profiling);
4. Making automated decisions based on personal data (making decisions without human intervention, for example providing a mortgage);
5. Systematic and large-scale monitoring (e.g. camera surveillance);
6. Large-scale data processing (e.g., because of numbers of people, duration, or amount of data);
7. Linking of collections of personal data (e.g., combining databases of multiple organizations);
8. Use of new technologies (e.g. mobile apps, new access control, smart camera systems);
9. Blocking a right, services or contract based on personal data (individuals lose control or a right).

More information: www.rug.nl/digital-competence-centre/privacy-and-data-protection/gdpr-research/dpia