rijksuniversiteit groningen / faculteit rechtsgeleerdheid

Application form

Ethical assessment of research by the CETOR (Research Ethics Review Committee Faculty of Law)

Please first read the instructions in the attached reading guide to save yourself possible work.

Do not hesitate to contact the secretary of the CETOR if you have any questions.
You can also discuss your application with him before submitting it.

1. Date of submission

Day-Month-Year

2. Title of your research

Complete (working) title

3. Date of commencement and duration of study

Intended start date of the study and total duration (Day-Month-Year - Day-Month-Year).

4. Applicant and any other investigators

Your name and email address and the names of any other investigators. *Are you the responsible investigator (or Primary Investigator/P.I.)?* *If not please state who is.*

5. Department/section

Department or section where the research is conducted

6. Description of the Study

Brief description of the study, including at least information on:
a. The research question;
b. Previous studies in the same field;
c. The participant's potential burden (physical and mental), when applicable;
d. A reflection on the balance between the burden of and risks to respondents or data subjects) and researchers on the one hand, and the importance of the research on the other.
Is this the optimal balance, is there an alternative that creates less burden and/or risk?

See also the explanation of this question, page 6

7. Funding and principal

Who funds your research? The UG (1st flow of funds), research funders such as NWO or the EU (2nd flow of funds) or other institutions or companies (3rd flow of funds).
In case of external funding, has your research already been reviewed by the funding agency on the aspects of ethics and data management?

See also the explanation of this question, page 6

8. Previously conducted similar research

Has similar research been conducted at the RUG before?
If so, has that research been reviewed by an ethics committee at the RUG or research funder?

9. Methodology

What is the nature of the research, what will be your research methods. More specifically the question:
a. Are any subjects involved in your research?
b. Will interviews be conducted?
c. Will you be working with surveys?
d. Will you be working with secondary data?
e. What type of data will be collected?
f. Will you use software to analyse data, if so, what software?

See also the explanation of this question, page 6

10. Participants

If you will be working exclusively with secondary data and/or there is no interaction with individuals you can skip this question.
a. Describe the research population (students, citizens, experts, etc.).
b. Are there any underage participants?
c. Are there participants from vulnerable groups (e.g., children, disabled, patients, prisoners, or persons in a hierarchical relationship (e.g., employees)?
d. Is there a dependency relationship between the researcher and the participants? If so describe.
e. Describe the method of recruiting respondents.
f. Are participants rewarded (if any)?
g. What information is reported back to participants?
h. How is the safety of both participants and researchers ensured?

See also the explanation of this question, page 6

11. Permission

Are there agencies outside the RUG that need to give permission for the research and if so, to what extent has this permission already been obtained?

See also the explanation of this question, page 6

12. Protection of Personal Data

Because of the General Data Protection Regulation (GDPR), a number of things need to be recorded. Among other things, it must be demonstrated that there is a basis for processing personal data and that the researcher is taking appropriate "technical and organizational measures" to protect the personal data processed in the research.

A. Categories of research subjects *People whose personal data will be processed*	○ Adults (not vulnerable) >18 years ○ Minors < 16 jaar ○ Minors < 18 jaar ○ Patients ○ Vulnerable people ○ Other (describe below) Explanation: research subjects may be "vulnerable people" depending on circumstances regarding the project and or the research subject. People are vulnerable within the context of the GDPR when: - they cannot give their consent freely or object freely to participating in the research (e.g. students who have to take participate in a research project in order

	to receive study credits); - they are not able to establish an opinion on the processing of their personal data (e.g. mentally ill people); - the processing of personal data processed about them could harm them (e.g. processing political opinions of people in countries with suppressive governments)
B. Categories of personal data that will be processed Please select (more than one answer is possible)	O General personal data (see explanation on page 9 for examples*)* O Special personal data o Nationality o BSN (Citizen's service number) or V-number (alien registration number) o Information revealing racial or ethnic origin o Information revealing a person's political views o Information on a person's physical health o Information on a person's mental health o Information on a person's sex life or sexual orientation o Information revealing religious or philosophical beliefs o Information revealing membership in a trade union o Biometric information o Genetic information o Criminal record o Other (please explain below)
C. Providers of personal data Who will provide the personal data that will be used in the research? If the personal data are to be provided by an external party (not being the research subject or the UG), describe which party or parties this concerns and for each party, indicate whether an agreement has been signed.	o Data is provided by the research subject o Data is provided by the University of Groningen o Data is provided by an external party (explain below) Explanation: In the case of interviews or surveys, the researcher provides the data him- or herself. In the case of external parties, these are agreements that include provisions for handling the personal data used in your research.

D. Technical and organizational measures Select which of the following security measures are used to protect the personal data:	○ Pseudonomyzation ○ Anonymization ○ Encryption of storage ○ Encryption of transport ○ None of the previous answers ○ Other (describe below)
E. Personal data forwarded outside EU Will any personal data be transferred to countries outside the European Economic Area (EU, Norway, Iceland and Liechtenstein)? Please note: After May 1, 2021, the United Kingdom is also a non-EU country.	○ No ○ Yes (please explain below to which country/countries)

13. Anonymity (identity protection)

Describe the ways in which you will protect the identity of participants or data subjects throughout the study. In doing so, pay attention to the different phases of the research. These phases are:

- Recruitment of participants (if applicable);
- Data collection and transfer of data;
- Storage and archiving. Sharing and publishing of research data;
- Reports and publications.

Are there conceivable situations in which anonymity is breached? If so, what are they? How are these risks taken into account and what technical and organizational measures are taken to minimize these risks?

14. Withholding information or using deception

Describe whether, and if so, how information is withheld or deception is used in the study.
Indicate how participants are informed about this after the event (debriefing).

15. Risks for data subjects

Describe whether there are any risks to data subjects such as profiling or discrimination.
If so, what measures will you take to eliminate or reduce these risks?
In doing so, consider whether it is necessary to refer participants to agencies that can provide help/aftercare.

16. Risks to the executive researcher

Describe whether there are any risks to the researcher and, if so, what measures you are taking to eliminate or reduce these risks.
In doing so, weigh up whether it is necessary to provide investigators with special support.

17. Risk to image of the UG as a university that should meet ethical standards for research

Describe whether there are any risks for the image of the RUG or for your own reputation; for example, socially controversial research and/or funding from controversial companies or interest groups.
If so, what measures are you taking to eliminate or reduce these risks?

18. Risk of malicious use

Explain if there is a risk of third parties using the research maliciously

Attachments to this application

- Research Data Management Plan (mandatory)
- Form information about the study (mandatory)
- Form Informed consent (when applicable)
- Form Debriefing (when applicable)
- Recruitment materials respondents (when applicable)
- Questionnaires or topics list semi structured interview (when applicable)

Please submit this form and attachments by email to the CETOR Secretary:

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Secretary of the Ethical Committee (CETOR)
Faculty of Law - Research Office
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If you have any questions about the forms or procedure or would like to discuss your application before submitting it, you are also welcome to contact the CETOR Secretary.

Explanation on questions

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.

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.

8. Previously conducted similar research
If you or someone else has conducted similar research (in a similar way) you can indicate this here, including whether that research has been reviewed by an ethics committee and about the decision of that committee

9. Methodology
Answering this question is necessary for the committee to assess:
a. Whether the investigative methods and techniques used pose a risk to the protection of personal data;
b. Whether they are in accordance with the VSNU and UG code of conduct for researchers and the legal requirements (GDPR).

10. Participants
The answer to this question, 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. Note: if you only process data from external sources (secondary data) you do not have to answer questions about the composition of your study population. This still needs to be answered under question 12 in connection with the AVG.
By "secondary data" we mean data collected in another study or data obtained from another party.
See the DCC website: www.rug.nl/research/research-data-management/data_protection-gdpr/re-use/

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.

12. 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.

12A *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.

12B. 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.

12B. What is Sensitive personal data?

According to the GDPR (art. 9), the following personal data should be considered as special category (sensitive) 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 category (sensitive) personal data explained by the "Autoriteit Persoonsgegevens" (in Dutch)

Special category (sensitive) 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.
See also the DCC website:
www.rug.nl/research/research-data-management/data_protection-gdpr/consent

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.

12C. 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.

12D. 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/

www.rug.nl/research/research-data-management/data_protection-gdpr/consent

12E. 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. For example, by working together on the data in a virtual workspace (Virtual Research Workspace)