

Leiden University
Faculty of Humanities
Ethical considerations for research involving human subjects

HOW TO USE THIS FORM

This form is to be used by students who, in the course of their thesis research, will be collecting personal data about participants. [Personal data](#) means any information relating to an identified or identifiable natural person. [Sensitive personal data](#) refer to, among others, data regarding racial or ethnic origin; religious, political and philosophical beliefs; sexuality orientation and gender identity; genetic and biometric data. Please consult the [GDPR](#) for further information. The form should be used during the preparatory stage of the research and its contents discussed between the student and their supervisor. Ideally, it should be filled out after the research topic has been determined but before data collection begins. This form is provided for guidance only and is not intended to be submitted to a committee or board for approval. We do, however, recommend, that a copy of the completed form be attached as an appendix to the thesis (not counting toward the total number of words).

If, after using it, you have feedback about this form, please send it to:
ethics4studentresearch@hum.leidenuniv.nl using "Feedback" in the subject line.

1. RESPONSIBLE PROJECT INVESTIGATOR (RPI) Include all persons who will be directly responsible for 1) the project's design or implementation, 2) recruitment of participants, 3) obtaining informed consent, 4) data collection, data analysis, or follow-up.

Last Name:	First Name:	Academic Degree(s):
Dept. or Unit:		
Phone:	E-mail:	

2. PROJECT TITLE

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3. Research Summary: Please summarize, in no more than 150-200 words and in lay language, the objectives and significance of the research.

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4. Participants:

4A. What is the estimated total number of participants?

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4B. Briefly describe the population(s) from which participants will be recruited. Do they include vulnerable populations (e.g., children under 18, pregnant women, incarcerated individuals)?

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4C-1. Describe how participants will be recruited.

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4C-2. Attach copies of all recruiting materials that you will use for this study. This includes text that will be used for online recruitment (via social media), final copy of printed advertisements and/or the final version of any audio/taped advertisements.

4D-1. Are you reimbursing participants financially? If not, are there other ways in which you recognize/remunerate participation in your project?

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4D-2. In case you are reimbursing participants financially, will reimbursements be made by Leiden University directly or by a third party?

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NB: If reimbursements are made by Leiden University, you may be obliged to collect personal information (see <https://www.staff.universiteitleiden.nl/finance-and-procurement/financial-services/payments-to-research-participants> for more information). If you need to collect personal information for payments, please explain how you will keep this information separate from other information that you collect. If you prefer to make anonymous (cash) payments, please explain why doing so is important (as opposed to a different type of non-financial recognition).

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5. Research Procedure:

5A. What will participants do and where will research activities take place?

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5B. What is the estimated length of time participants will spend on research activities and in how many visits/meetings?

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5C. What are the approximate study dates?

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5D. What research tools (questionnaires, interviews, surveys etc.) do you use? Please list them below and attach complete copies as an Appendix to your thesis (include translations, if applicable).

Tool 1:	
Tool 2:	
Tool 3:	

List additional tools on an attachment and check here: ☐

6. Confidentiality:

Please explain how confidentiality will be maintained during and after data collection. Issues to consider after data collection include risk mitigation strategies (how will you minimize risk of e.g. data leaks, theft?), storage (how and where will you store your data, who will have access to it?), and retention of data (what happens to the data once your project is over?). For more information, please consult [Privacy policy and procedures - Leiden University](#).

7. Consent Process:

7A. Describe when and where voluntary consent will be obtained, how often, by whom, and from whom.

7B. Please indicate all that apply for the consent process and provide all consent documents (including translations, if applicable).

- ☐ Written informed consent
- ☐ Online consent
- ☐ Oral consent
- ☐ Unsigned Information Sheet Provided
- ☐ Waiver of Informed Consent (if informed consent will not be sought, please explain briefly why this is not necessary in the box below)

8. Publication plans:

8A. What is (are) the proposed form(s) of dissemination (e.g., journal article, thesis, academic paper, conference presentation, sharing with the industry or profession, etc.)? If you are planning to publish, please contact a [data steward](#) or [CDS librarian](#) for help on FAIR archiving

8B. Could your presentations and/or publications be potentially harmful to the participants in your study? If so, what safeguards will you take during the presentation and publication of your data to minimize this risk?

8C. If you work with publicly available (e.g. internet) data: how will you ensure that your dissemination of the results demonstrates respect for the interests and concerns of the persons behind the data?

9. Individually identifiable information: Will any individually identifiable information, including images of participants, be published, shared, or otherwise disseminated?

☐ No

☐ Yes

If yes, participants must provide explicit consent for such dissemination. Provide appropriate options on the relevant consent documents.

10. Expected Completion Date:

Supervisor

Date

Additional information: You can find more information about Privacy Policy and Procedures on the site [Privacy policy and procedures - Leiden University](#). For any remaining questions regarding privacy and data protection only, please contact your unit's [privacy officer](#).