**INFORMATION AND CONSENT FORM**

Target audience: adult volunteers

Legal ground for the processing of personal data: (necessary in the) public interest

Language: English

Text marked in orange provides explanation for the researcher and should be replaced or deleted in the document submitted to the participant.

Example texts are always preceded by "E.g.". These are for illustrative purposes only and may therefore be replaced, deleted or modified.

**SECTION 1 - INFORMATION LETTER FOR PARTICIPANTS IN RESEARCH**

Title of the study: [Enter the (simplified) title of the study here]

This is a study conducted by Ghent University in collaboration with <name external institution/company>. The responsible researchers are:

|  |  |
| --- | --- |
| NAME RESEARCHERNAME RESEARCH GROUPGhent UniversityEmail: <name>@ugent.bePhone no.: <phone number> | NAME PROMOTORNAME RESEARCH GROUPGhent UniversityEmail: <name>@ugent.bePhone no.: <phone number> |

1. **Information about the study**

[Briefly explain who you are. Invite the participants to participate in the research you are doing. Explain to them that they may take their time in deciding whether to participate. Also explain to them that if they do not understand words or concepts, you will explain and they may always ask additional questions].

E.g.

Dear,

You are invited to participate in a study of Ghent University. Please take the time to read this information letter carefully before you decide to participate in this study. Do not hesitate to ask questions to the researcher if there are any ambiguities or if you would like additional information. Make sure you understand everything. Once you have decided to participate in the study you will be asked to sign the consent form on the last page.

***What is the purpose of the research?***

[Give a brief description of the research and its objectives. When doing so, try to use language that is understandable for the target audience and avoid jargon].

***Ethical Approval***

[If applicable, state that this study was approved by an ethics committee. Clarify which ethics committee specifically is involved and when the study was approved by the ethics committee].

[Indicate codes of conduct, protocols under which this study may fall and to which researchers must adhere].

E.g. This study was approved by the Ethics Committee of the Faculty [name faculty] of Ghent University on February 1, 2021. Under no circumstances should you consider the approval by the Ethics Committee as an inducement to participate in this study.

The study is conducted according to the guidelines in the General Ethical Protocol of the Faculty [name faculty] (Ghent University)[[1]](#footnote-1). The researchers will conduct this study in accordance with accepted standards of scientific and ethical conduct. In doing so, they adhere to the principles of research integrity as described in "The European Code of Conduct for Research Integrity" (2017, revised edition, ALLEA)[[2]](#footnote-2) and adopt good research practices.

1. **Information about participation**

***What does participating in this study entail?***

[Explain the practical course, expected duration, procedures used, and research intervention used].

[Explain how a participant can discontinue participation and the consequences of doing so].

[If a person participates in this study as part of an educational programme, and certain criteria are used to determine whether a study participation is 'completed' (e.g. min. 50% of a task must be completed), then you should explain these here. An 'early' discontinuation should not have a negative impact on the grading of the educational programme. This means that the participant must complete an alternative task or can participate in another study if the examiner considers it possible].

E.g. Participation in this study is completely voluntary and there can be no coercion in any way. You may refuse to participate in the study and you may withdraw from the study at any time without having to provide a reason. If you refuse to participate, or if you decide to withdraw from an ongoing study, this will in no way affect your continued relationship with the investigator, your evaluation and/or study supervision (if you are a student), or your treatment (if you have a therapeutic relationship with the investigator).

[Explain (the possibility of) feedback afterwards].

E.g. If you wish, you can get a summary of the research findings after the study is completed and the results are known. To get a summary, you can request it from the researcher you are in contact with.

***What are the risks and benefits of participating in this study?***

[Explain any risks to the participant as a result of his/her participation in this study. Describe the potential harm or adverse effects and then estimate the likelihood that this would occur. This could include physical risks, side effects, pain, long-term effects, emotional effects, effects on integrity, socioeconomic risks, ... . Also state if no risks or harms are expected].

E.g. There is no known ongoing risk associated with this study.

[Explain what benefits participating in the study will have for the participant, his/her family, knowledge within the field, society as a whole, as a result of his/her participation in this study. Also state if no benefits are expected].

***Is there any compensation or reward provided when participating in this study?***

[Discuss any rewards or allowances (e.g., travel expenses) and the conditions for receiving them].

1. **Information about Privacy and Personal Data**

[Only applicable if personal data will be collected or processed during or as part of the research. See <https://onderzoektips.ugent.be/nl/tips/00001761/> for a definition.]

[Sometimes UGent is not the "data controller’. If so, state who it is and what the UGent's role is. It is also always the controller who determines the legal ground of the data processing. For more info on the different roles and responsibilities see <https://onderzoektips.ugent.be/en/tips/00001789/> ]

The legal framework for the processing of personal data and confidential information in the context of this study is defined by:

* The European General Data Protection Regulation 2016/679 of April 27, 2016, in force since May 25, 2018 (the GDPR);
* The Belgian Law on the Protection of Natural Persons with regard to the Processing of Personal Data of 30 July 2018.

Researchers from Ghent University have to comply with the generic code of conduct for the processing of personal data of Ghent University[[3]](#footnote-3).

***What personal data are collected?***

[Provide a (general) overview of the personal data or types of personal data that will be collected. Try to be as complete as possible.

For the definition of personal data, see <https://onderzoektips.ugent.be/en/tips/00001781/>

If you process special categories of personal data (see <https://onderzoektips.ugent.be/en/tips/00001840/>) you must clearly state this along with an overview of the special categories of personal data that will be processed.

Also indicate how the personal data are collected].

E.g.

The following personal data will be processed:

* Surname and first name, postal code, occupation, gender, education, email address
* Response times to computer tasks.

The following *special categories of personal* data will be processed:

* Data relating to the personality of the participant
* Data relating to the participant's cognitive ability.

Personal data will be collected using computer tasks, paper questionnaires, audio and video recording of interviews, and audio recordings of focus groups.

***Why are these personal data collected?***

[Describe why you need the personal data for the purposes of your research. These may include practical considerations in addition to scientific ones, such as collecting an email address to contact participants in a longitudinal study].

***Who has access to my (personal) data?***

[The following information should be provided:

Describe which persons (e.g. researchers or employees) have access to the data within UGent and for what purpose? Indicate how long the data will be kept in this context and which technical and organizational measures (e.g. pseudonymisation, anonymisation, encryption, ...) will be taken to guarantee the confidentiality of the personal data.

Describe which persons (e.g. external collaborators) will have access to the data outside UGent and for what purpose? Indicate how long the data will be kept in this context and which technical and organizational measures (such as pseudonymising, anonymising, encrypting, ...) will be taken to guarantee the confidentiality of the personal data. Describe whether agreements have been made with the external parties in the context of confidentiality. Please note: if personal data is transferred, shared or accessed by external parties outside the EU, this should be communicated to the participants.]

**Reuse of data**

[Explain whether the collected research data will be re-used by researchers within UGent (including re-use by yourself) or externally for scientific research with purposes other than the current study.

For reuse by researchers outside UGent, explain the modalities under which this reuse will take place and the platform or channel through which the research data will be shared].

E.g., the research data collected in this study may also be useful in answering other research questions. Therefore, there is a possibility that the research data will be reused at a later date for other research. The reuse of the research data can be done both within the own research team and by external researchers within and outside the European Union. To this end, the research data will be made available in a controlled manner via a dedicated research data sharing platform. All necessary measures will be taken to guarantee the confidentiality of your personal data as prescribed in the UGent Generic Code of Conduct for handling personal data and confidential information.

***What rights do you have as a participant with regard to the processing of your personal data?***

[Explain that the legal basis used is 'public interest' and inform data subjects of their rights]

In accordance with European and Belgian privacy legislation[[4]](#footnote-4), your personal privacy is respected. As already indicated, you may withdraw your consent at any time without giving any reason. This means that your data will not be processed any further from the moment of withdrawal.

You have the right to consult the data which have been collected about you and you may also request a copy, as long as this does not violate the rights and freedoms of others, including Ghent University. Any incorrect data about you can be corrected at your request. Moreover, you have the right to be forgotten: this means that, after withdrawing your permission, you can ask to have your personal data removed.

To exercise any of the above rights, please contact the relevant researchers at <name of the researcher@ugent.be>.

[In the context of research, exceptions to these rights are possible, e.g., if the exercise of a right makes the achievement of the research objectives impossible or seriously impedes them. These exceptions must then be justified in the AVG register. See also <https://onderzoektips.ugent.be/en/tips/00001790/> for more information.]

***How can I file a complaint?***

If you want to file a complaint about the way your personal data are handled or if you have any questions regarding your personal data in the context of this research, you can contact the Data Protection Officer of Ghent University at privacy@ugent.be or T +32 (0)9 264 95 17.

You can also file a complaint with the Data Protection Authority, Drukpersstraat 35, 1000 Brussels (email: contact@apd-gba.bep) and/or the Flemish Supervision Commission (email: contact@toezichtscommissie.be).

**SECTION 2 – CONSENT FORM**

1. **Consent for participation in the research**

|  |  |  |
| --- | --- | --- |
| **Please check the appropriate box** | **yes** | **no** |
| I voluntarily participate in this scientific study. | o | o |
| I know that I may withdraw from the study at any time without giving a reason for this decision and without it affecting in any way my continued relationship with the researcher.*[if applicable*]If I am participating in this study as part of my degree program, I understand that discontinuing my participation early will not negatively impact my evaluation and/or coursework.*[if applicable]*I understand that discontinuing my participation will not negatively impact my treatment or support. | o | o |
| I have read the information sheet and have received sufficient explanation of the nature, purpose, duration, and anticipated effects of the study. I was given the opportunity to ask questions and I received satisfactory answers to all my questions. | o | o |
| *[In case of a particular high risk]*I know that participating in this study may have as a possible consequence that ... | o | o |

1. **Consent for the processing of personal data**

|  |  |  |
| --- | --- | --- |
| **Please check the appropriate box** | **yes** | **no** |
| I have read the information form and I know that I have rights to safeguard my privacy (including access, correction, deletion) and to whom I should turn to exercise these rights. | o | o |

1. **Consent about the reuse and sharing of data**

[Note: if you do not include this clause, you cannot share or reuse (pseudonymized) data for other purposes].

|  |  |  |
| --- | --- | --- |
| **Please check the appropriate box** | **yes** | **no** |
| I give permission for my data to be reused for further scientific research beyond the scope of the current study. | o | o |
| I give permission to share my data for further scientific research, and to do so with researchers within and outside the EEA. In doing so, all necessary measures will be taken to protect the confidentiality of my personal data. | o | o |

|  |  |
| --- | --- |
| Name participant | Name researcher |
|  |  |
| Date:  | Date: |
| Signature | Signature |

1. [link to ethical protocol of the faculty] [↑](#footnote-ref-1)
2. <https://allea.org/code-of-conduct/> [↑](#footnote-ref-2)
3. <https://www.ugent.be/en/ghentuniv/privacy/code-of-conduct-personal-data.htm> [↑](#footnote-ref-3)
4. These are: the European General Data Protection Regulation 2016/679 of April 27, 2016, in force since May 25, 2018 (this is the GDPR); the Belgian Law on the Protection of Natural Persons with regard to the Processing of Personal Data of July 30, 2018; the Belgian Law of August 22, 2002 on the Rights of the Patient. [↑](#footnote-ref-4)