Aim and requirements of the Participant Information Letter (PIF)

Participation in research requires informed consent. The written information is part of this process. Oral information, exchange of views and asking questions can also be part of this. Participants, or their legal representatives, must be given ample opportunity to understand the nature and anticipated consequences of research participation. They need to be informed in written about the purpose, procedures and means of the study before they provide their written consent. The information must be unambiguous, upright and sufficient to ensure participants can make a proper informed decision about their participation (or not) in the study.

If you collect personal data, the GDPR states that participants must also be fully informed about what personal data will be collected, how the data will be stored and what the rights of the participants are.

Note:

- Provide sufficient time for participants to consider participation, which is dependent on the nature of the research. General rule: higher impact or burden, means more time.
- The provided information must be comprehensible for the participants, in consideration of factors like age, cultural differences, economic and linguistic barriers, and levels of education and literacy. The starting point is that the letter is written on VMBO level.
  Tip: ask expertise of a professional editor, information officer or communication officer. Also have your text proofread by someone who is not a content expert and preferably with a VMBO (preparatory secondary vocational education) education level.
- Use subtitles in your information letter to make it more readable

The information letter requires the following elements:

What does the study entail?

- Title (Title of the study, if necessary simplified, abbreviated or translated)
- Purpose
- Nature of the study

What does participation in the study entail?

- Procedures
- Disadvantages/consequences/risks or advantages for the participant and how they will be minimized

Information about the participation

- Voluntariness of participation
- Deliberation time
- Right to decline to participate and (how to) withdraw from the research once participation has begun, without any negative consequences, and without providing any explanation
- Traceability and confidentiality protection

- How the data will be collected, used, reported
- Where, how and for how long the data will be stored, and who will have access to the raw dataset.
- Contact in case of question or additional information requested (name and telephone number/ email address researchers, including the supervisor if applicable). Please make sure to use OU contact information.
- Possibility to ask questions before, during and after participation
- Reference to OU privacy disclaimer: www.ou.nl/privacy
- Indicate how participants can sign consent

In case of personal data:

- A full description of personal data to be collected and why.
- Who has access to the data, how data will be stored and for how long.
- Right, in principle, to request access to and rectification, erasure, restriction of or object to the processing of the personal data. Data already collected can be used for analyses. You can use the OU privacy disclaimer: www.ou.nl/privacy. More information about the rights: Autoriteit Persoonsgegevens
- Add the contact information of the data protection officer.

if applicable:

- Applicable insurance guarantees (only if there is additional insurance to the standard insurance)
- Procedure for incidental findings
- Re-use of specified data in current, future or other research (like Open Science)
- Incentives for participation (traveling expense, pp hours)