Aim and requirements of the Participant Information Letter (PIF)

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

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

Note:

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

The information letter requires the following elements:

What does the research entail?

- Title (if necessary simplified, abbreviated or translated)
- Purpose (specify if the research is conducted by students as part of their Master or Bachelor education at the OU)

What does participation in the research entail?

- What is expected of participants
- Duration of the participation
- Advantages and disadvantages/consequences/risks for participants and how they will be minimized (if necessary, add contact information in case participants can experience negative emotions).

Information about the participation

- Voluntariness Deliberation time
- Right to decline and to withdraw from the research at any moment without any negative consequences, and without providing any explanation
- Traceability and confidentiality protection
- How and what kind of data will be collected and how it will be used and 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 questions or additional information requests (name, telephone number and email address of researchers, including the supervisor in case of students). 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 provide their consent

In case of personal data:

- A full description of personal data to be collected and how it will be used and reported
- Where, how and for how long the data will be stored, and who will have access to the raw dataset
- Right to request access to and rectification, erasure, restriction of or object to the processing of the personal data. The right to erasure does not apply if the data is processed for archiving purposes in scientific research, where erasure is likely to render impossible or seriously impair the achievement of that processing. More information about the rights: HYPERLINK "https://www.autoriteitpersoonsgegevens.nl/"Autoriteit Persoonsgegevens
- Add the contact information of the data protection officer of the OU.

If applicable:

- Applicable insurance guarantees (in case of an 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, per hour)
- Clarity about other parties involved in the research, including their role and responsibilities
- Period of time to which participant's consent applies, e.g. if the study includes follow-ups at a later time point