WAGENINGEN
UNIVERSITY & RESEARCH

WUR – REC Non-Medical Research Informed Consent Template

In almost all cases, research with human participants needs to be based on informed consent, to be given prior to the participation, with an active and demonstrable action. For more information about informed consent, please consult the Nethics code, sections D and E.

You are not obligated to use this template but your information sheet/consent form is required to cover the different areas listed in this template, unless indicated as optional. Bear in mind that whether information is optional will depend on the circumstances.

Please note that this template and instructions should apply to non-vulnerable and vulnerable groups. However, for vulnerable groups, the REC may require additional information to be provided on the consent form.

This template may be subject to change. Therefore do not save or distribute it, but always download the latest version from the REC intranet site.

Study Background

- Describe to the participant in lay terms (not like you are writing to other researchers) the goals of the research study and the participating organisations.
- Best practice involves informing the participant of the research funding agencies involved and that the study has been approved by the WUR-Research Ethics Committee for non-medical research as meeting the Netherlands Code of ethics for research in the social and behavioural sciences involving human participants. If there is a justifiable reason for not informing participants of this information, please inform us.

What is being asked of you as a participant?

- Describe what you are asking from the participant with regard to the ways in which they will be participating (e.g., interviews, focus groups, etc.).
- Also provide the participant with an estimation of how much time it will take them to participate in the way that you are asking.
- Inform the participant that their participation is voluntary. If applicable in the context of the research, add that they will not be denied or restricted from any services if they choose not to participate.
- Inform the participant that they can skip answers (and such) and stop participating without having to provide any reasons and without any negative consequences. Inform them how they can stop, if this is not obvious.

Are there any benefits for participating?

- If applicable, inform the participant if they will receive any financial or other forms of compensation as a result of their participation.
- You may also tell the participant of the social benefits that might come from their participation in the study (for example, helping researchers to better understand consumer attitudes about protein diets).

Are there any risks in participating?

- the REC asks researchers to think carefully about possible discomfort and risks (e.g. reexperiencing a traumatic event) and in case of risk, we ask you to address how you as researchers will address that risk among your participants (for example, linking them to specific services).
- If applicable, name any reasonably foreseeable factors regarding the nature, purpose and duration of the research that may influence participants' willingness to participate (such as discomfort or other potential risks)

How will your information be handled?

Describe the nature of the data collection and management. In order to determine how, you need to verify: will you process any personal data?

What are personal data and when are they processed?
Personal data is: any information relating to an identified or identifiable human being. A person is identified when the person is actually known, or identifiable when it is possible to find out their identity. Participants can be identified or identifiable by their (almost unique) identifiers such as names, voices, (audiorecordings) or (e-mail) addresses. They can also be identified or identifiable by information that that first needs to be combined with other information, such as a zip code in combination with household composition and philosophical beliefs. The latter is called "indirect identifiability". The other information may be findable within your research project but also outside of it. It concerns information that is either already known, by any person, or that can be found, within a reasonable time-frame and effort, by any person who is committed to find it.
Note that identifiability often depends on context. For example, in a more specific population it may be easier to identify participants. Or, even in a less specific population, a participant may be singled out due to their special (combination of) features.
Once the participant is identified/identifiable, any information about them that can be derived from your study counts as personal data. In addition to the more obvious identifiers such as contact data, these include personal or professional opinions, behaviour, experiences, (illegal) activities, income, characteristics, health, possessions, family life, preferences, etc. etc.
Processing is: any act with regard to personal data. This includes for example: collecting, storing, analyzing, sharing, and the act of anonymizing.

So if you work[1] with participants' identifying information in any form in the context of your research, even if it's just to later provide a participation fee, you will process their personal data.

Option 1: No personal data /Anonymous: Anonymous is reserved only for those cases where you don't ask for or otherwise have at your disposal any information that may identify participants. As a general principle, you may assume that in research with human participants, anonymity is hardly ever feasible. Also note that if you've recruited anonymous participants from third parties, or if participation is through an online application with anonymous mode, anonymity will be removed when answers to questions in your survey may identify participants.

- Explain that you will not collect or use any information that is retraceable to the participant
- Explain how and for how long the research data will be stored
- If applicable, explain that the research data will be used in publication(s)
- If applicable, explain whether the research data will be made available for re-use in future research, including (if applicable) research by other researchers

Option 2: Personal data:

A. Use of data

- Point out that you will collect/use participant's personal data and give (at least) some examples. Be aware of special categories of personal data or other sensitive data[2]. You must be extra critical with respect to the necessity of collecting them and protect them very well.

B. Protection and storage of data

- You will furthermore need to describe to the participant and the REC how you will keep the personal data confidential.
    - For example, you will assign a unique ID to each participant's identifying information and keep this identification sheet as a separate file.[3] Explain this to the participant in lay terms.

[1] Even if you work with publicly available personal data, you process personal data. Also working with personal data that you did not collect yourself, or that you collected earlier for a different research, is processing.
[2] Special categories of personal data reveal information about: racial or ethnic origin/political opinions/religious or philosophical beliefs/trade union membership/genetic data/biometric data for the purpose of uniquely identifying a natural person/a person's health/a person's sex life or sexual orientation. Other sensitive personal data are: (possible) illegal activities and any other personal data that may be sensitive or high-risk to the participant, also in view of any circumstances.
[3] In privacy terms, this is called pseudonymization. Pseudonymization is a good method to protect data. But it is not anonymization. Only when (re)identification will no longer be possible, e.g. when the key to encoded identifying information would no longer be available (and of course provided that there are no personal data in

- If applicable: when you separate the identifying information from the research data, explain who still has access to the identifying information. Also, if applicable, explain that the (other) researchers who will work with the data will not be able to link the research data to participants.
- Explain who has access to the (non-pseudonymized) personal data and to the other research data.[4]
- Explain how you will store the personal data and other research data and for how long. If applicable, make a distinction per type of data and phase of the research.

C. Recordings

- If applicable, you should specifically mention that audio- or video recordings will be made and why. Specify whether and how long recordings will be kept, and whether they will be used in publications or shared with other scientists.

D. Disclosure

- You should also indicate if and how participant's information will be used in scientific publications. Only if it is certain that the data will be published in a way that participants are not identifiable[5], you can state that in publications it will not be possible to trace the information back to them. Otherwise you could say for example that participants' names will not be included in any publication but that you cannot guarantee that they will not be recognized due to …
- If applicable, mention that you may use quotes in publications and point out either that you will only use quotes that will not make participants recognizable, or point out the possibility that they may make them recognizable.
- If applicable, explain that the (personal and or other) data will be possibly be made available for re-use in future research and if applicable, add: in other research areas and/or by other scientists. Only if applicable, limit this to anonymous data. In that case you could add for example: When we share the data / make the data available for this purpose, we will do this in a way that no information can be traced back to you.

E. Various

- When names, recordings, recognizable photo's or quotes will be used in any way, ask for separate consent (e.g. by using a separate check mark) at the time of signing the consent
- When in online surveys it is not possible for participants to receive a copy of the informed consent, point out the possibility of making a screenshot.

What if I have questions about the study, or change my mind?

- In this section, you should list the contact information for any questions after reading this information or at any other time. This will include the study's lead investigator and the contact information for the WUR-REC .
- Indicate as well that participants can withdraw from the study during or after their participation. Add that they can ask for their information to be removed from the study if they choose. Explain how they can do this. You may add that removal may not be (totally) possible, when this would severely harm the research. if applicable, the second argument can be replaced by: would not be possible when the participant is not recognizable due to anonymity.

I consent in participating in this research and to the use of my personal data as described.

(Ask participant's name and signature in written consent. In online surveys, use tick boxes)

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the remaining research data), the data can be considered anonymous data. However, also due to ever advancing techniques, e.g. for merging data with other data, it is difficult to speak of anonymous data when personal information is involved

[4] The REC considers access to be limited to only those specific persons who have been listed/included on the ethics application, and, if applicable, indicated research partners. If you wish for anyone else to have access to the data during the course of the research, you will need to file an addendum for ethics approval for this additional person to have access (including PhD candidate, MSc student).

[5] It is possible that data will appear as anonymous data in publications. To prevent privacy jargon, description is chosen in this example. Another suggestion is to state that the information will not be retraceable to the participant.