*This is the EUR template (version 15 July 2021) for Informed consent forms, consisting of the information sheet and the Certificate of Consent.*

*When conducting ‘human research’ or research into data that represent ‘people’, the default option is to inform prospective participants and ask their consent. However, there are a few exceptions to this. More information can be found on the* [*EUR website*](https://www.eur.nl/en/research/research-services/research-quality-integrity/ethical-review/informed-consent)*.*

*This annotated template contains:*

* *instructions in grey and in italics*
* *examples in blue*
* *compulsory items are provided with an \*.*

*Please remove all instructions and examples before sharing this document with participants.*

*Please consider that this form refers to participants. If applicable, researchers can replace participants with data subjects.*

**Information sheet**

|  |  |
| --- | --- |
| Name of Principal Investigator\*: |  |
| Erasmus University Rotterdam/ specific School\*: |  |
| Name of Funding organisation\*: |  |
| Project Title and Version\*: |  |

**Introduction\***

*Briefly state who you are and that you are inviting the research participant to participate in your research. Assure the participant that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask additional questions at any time.*

[EXAMPLE TEXT] I am …., working for the Erasmus University Rotterdam. I am doing research on … . I am going to provide you information and invite you to be part of this research. This consent form may contain words that you do not understand. Please ask me for explanations when anything is unclear.

**Purpose of the research\***

*Explain the research question and purpose of the research in layman's terms. In your explanation, consider local beliefs and knowledge when deciding how best to provide the information.*

[EXAMPLE TEXT] Malaria is making many people sick in your community. We want to find ways to stop this from happening. We believe that you can help us by telling us what you know both about malaria and about local health practices in general. We want to learn … & … & …

**Type of research intervention\***

*Briefly state the type of intervention that will be undertaken. Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.*

[EXAMPLE TEXT] The research takes place over … days/ or … months in total. During that time, we will visit you … times for interviewing you at one-month intervals, and each interview will last for about one hour. The group discussion will be held once and will take about 1.5 hours.

**Participant selection\***

*Indicate why you have chosen the participant to participate in your research.*

[EXAMPLE TEXT] You are being invited to take part in this research because we feel that your experience as a social worker (or as a mother, or as a responsible citizen) can contribute much to our understanding and knowledge of … .

**Voluntary Participation\***

*Indicate clearly that participation is voluntary. Think of scenarios for your participant when he or she is placed in a situation where in a practical sense, the participant does not feel free to opt out, due to peer pressure or otherwise.*

[EXAMPLE TEXT] Your participation in this research is entirely voluntary. It is your choice whether to participate or not. The choice that you make will have no bearing on your job or on any work-related evaluations or reports. You may change your mind later and stop participating even if you agreed earlier.

**Right to Withdraw\***

*Inform participants on their right to withdraw their given consent. The text below is based on the GDPR. If you think your research does not allow this, please contact your privacy officer and inform your RERC/IRB.* ***(Please note, the text in this section cannot be filled in at will)***

[COMPULSORY TEXT] You have the right to withdraw your consent to use the personal data that you have provided at any time (unless the data has been anonymized). Data processed before the withdrawal of your consent is lawfully collected and can be used for the research. You do not have to justify your decision to withdraw your consent and there are no consequences for withdrawing your consent.

**Procedures\***

*Provide a brief introduction to the format of the research study. Explain the type of questions that the participants are likely to be asked and the setting [focus group / interviews / survey / etc.). If the research involves questions or discussion which may be* ***sensitive or potentially cause embarrassment****, inform the participant of this, and indicate which additional steps you have taken for the participant to ensure confidentiality of the data and trust you/ the researcher conducting the interview.* If the conversation takes place at a different location, don’t forget to include information on time and location.

[EXAMPLE TEXT]: We are inviting you to take part in this research project. If you accept, you will be asked to:

* [Focus groups] take part in a discussion with 7-8 other persons with similar experiences. This discussion will be guided by ….. You do not have to share anything that you are not comfortable sharing. The discussion will take place in …. The entire discussion will be tape-recorded, but no-one will be identified by name on the tape.
* [Interviews] participate in an interview with …. If you do not wish to answer any of the questions during the interview, you may say so and the interviewer will move on to the next question. The entire interview will be tape-recorded, but no-one will be identified by name on the tape.
* [questionnaire surveys] fill out a survey which will be provided by … and collected by …. OR You may answer the questionnaire yourself, or it can be read to you and you can tell the answer you want me to write down. The information recorded is confidential, your name is not being included on the forms.

***[OPTIONAL]*** *Participants should have an opportunity to review their remarks in individual interviews and erase part or all of the recording or note.*

[EXAMPLE TEXT] At the end of the interview/ discussion, I will give you an opportunity to review your responses. If you do not agree with my notes or if I did not understand you correctly, you may ask me to modify or remove parts of them.

**Potential Risks and Discomforts** *(\*if applicable and not addressed under procedures)*

* *Explain and describe any risks and discomforts that you anticipate.*
* *Explain precautions to ensure participants’ safety.*
* *If relevant, pay attention to possible unintended/unexpected/incidental findings and how you deal with such findings.*

[EXAMPLE TEXT] During the focus group, we will be viewing and discussing clips taken from war-themed games, in which (violence against) unarmed civilians in a war context are shown in various ways. As a result, you might feel uncomfortable watching and discussing these topics. Please realize that you can stop participating in the research at any time. Might you experience feelings of discomfort opportunities will be given to talk about these feelings of discomfort after the focus group.

[EXAMPLE TEXT] During the interview, personal questions will be asked regarding some profound events that happened to you. This may evoke memories and emotions. Therefore, you may appreciate bringing someone who is close to you, such as a friend, to the interview.

In case you need emotional support and a listening ear, you can contact Victim Support Netherlands. They can also refer to further help. You can contact them on 0900-0101 or use the chat on the website: www.slachtofferhulp.nl.

**Potential Benefits** *(\*if applicable)*

*The benefits of answering the research question may be to the individual, to the community in which the individual resides, and/or to society. Mention only those activities that will be actual benefits and not those to which participants are entitled regardless of participation.*

[EXAMPLE TEXT] There will be no direct benefit to you, but your participation is likely to help us find out more about how to … [prevent/treat/…]…

**Reimbursements** *(\*If applicable)*

*State clearly what you will provide the participants with as a result of their participation.* *PLEASE NOTE, IF YOU ASK FOR AN IBAN-NR, ADDRESS THIS UNDER PRIVACY BELOW.*

[EXAMPLE TEXT] We will give you [provide a figure, if money is involved] for your time, and travel expense (if applicable).

**Privacy** *(\*when personal data*[[1]](#footnote-2) *or special categories of personal data*[[2]](#footnote-3) *are collected and processed)*

*Inform the participants that you will collect personal data or/and special categories of data.*

[EXAMPLE TEXT] During this research we will ask you to provide some personal data, which is information that can directly or indirectly identify you as an individual.

This research serves [amount] purpose(s) for which we collect and analyse the following categories of your personal data per purpose: *[DESCRIBE THE PURPOSE(S) OF YOUR RESEARCH AND HOW PERSONAL DATA IS GOING TO BE USED IN FOR THIS/THESE PURPOSE(S)].*

[EXAMPLE TEXT audio recordings] As indicated above, this research project involves making audio recordings of interviews with you for the purpose of *[PURPOSE]*. Transcribed, de-identified segments from the audio recordings may be used in published forms (e.g., journal articles and book chapters).

**Confidentiality** *(\* when personal or special categories of personal data involved)*

*Explain how the research team will maintain the confidentiality of data with respect to both information about the participant and information that the participant shares. Outline any limits to confidentiality.*

*Focus groups (or other group settings) provide a particular challenge to confidentiality because once something is said in the group it becomes common knowledge. Explain to the participant that you will encourage group participants to respect confidentiality, but that you cannot guarantee it.*

[EXAMPLE TEXT]

* We will only share your personal data with people who are directly involved in this research or who need access to maintain the IT systems used in this research.
* Unless you give your consent to be identifiable, we will make sure to de-identify your personal data during our research.
* [Please be aware that due to your specific position the answers you provide may lead to you, also when they have been de-identified.]

[Focus groups (or other group settings]: We will ask you and others in the group not to talk to people outside the group about what was said in the group. In other words, we will ask each of you to keep what was said in the group confidential. You should know, however, that we cannot stop or prevent participants who were in the group from sharing information.

**Retaining\* and Sharing *(recommended)* your data**

*Here you provide information on how long personal data will be stored and whether collected data will also be used or opened up for others to use for future research.*

*According to the EUR Research Data Policy, EUR researchers need to ensure that:*

* *all data, software codes and research materials, published or unpublished, are managed and securely stored for 10 years and that*
* *personal data are de-identified as soon as possible.*

*Additionally, according to The Netherlands Code of Conduct for Research Integrity 2018, researchers in the Netherlands need to ensure that, in accordance with the FAIR principles[[3]](#footnote-4), data is open and accessible to the extent as possible and remains confidential to the extent necessary.*

[EXAMPLE TEXT]

* Your personal data (e.g. audio or video recordings, forms, and other documents created or collected as part of this study) will be stored in a secure location for a minimum period of 10 years.***Contact your faculty data steward if you believe a different retention period applies in your case.***
* A selection of the data you provide us with may be useful for educational purposes and for future research, also in other areas of research. Therefore, we would like to re-use your personal data and will ask you to consent to this in the certificate of consent.

**Sharing the Results** *(Recommended)*

*Your plan for sharing the findings with the participants should be provided. If you have a plan and a timeline for the sharing of information, include the details. You may also inform the participant that the research findings will be shared more broadly, for example, through publications, data repositories and at conferences.*

***Please note****,* *when research leads to the creation of (possible) intellectual property, please fill out an Invention Disclosure Form (“IDF”) and submit the completed form to ERS [Erasmus Research Services]. ERS will support on any intellectual property right application for a patent, design right, trademark, domain name, etc. Do not share any information with participants or others until this process has been completed, and ERS has confirmed that the information can be disclosed.*

[EXAMPLE TEXT] The knowledge that we get from this research will be shared with you and your community before it is made widely available to the public. We will publish the results on a website *(include web address)* so that interested people may learn from the research.

**Your Privacy Rights and Contact Information\*** (The text below is compulsory\*)

You have the right to request access to your personal data and to request rectification, erasure, restriction, data portability, and to object to the processing of your personal data under certain circumstances.

If you want to invoke your rights or if you have a question concerning privacy about this study, you can contact Erasmus University’s DPO (Data Protection Officer) at fg@eur.nl. If you would like to lodge a complaint concerning privacy, you can do this with the national supervisory authority in the Netherlands on personal data (Autoriteit Persoonsgegevens).

**Who to Contact\***

*Provide the name and contact information of someone who is involved, informed and accessible - a local person who can actually be contacted.*

[EXAMPLE TEXT] If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact any of the following: *[name, address/telephone number/e-mail]*

*The text below can only be included when the RERC/IRB agrees:*

[EXAMPLE TEXT] This proposal has been reviewed and approved by *[name of the local RERC/ IRB]*, which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find out more about the RERC/IRB, contact *[Add contact details]* *[or refer to information on the website].*

Certificate of consent

*This section should be included with the informed consent form at the end. Each participant must give a form of consent before participating in the research. This written consent form is one of the options. The participant’s signed consent is only a reflection of their consent. Always make sure that the participant really understands the research by asking some targeted questions.*

*Participants don't or can't always give their written consent. They might be illiterate, or they are uncomfortable with signing any written form. There are other options for consent in these cases.*

*1. You can get a witness, whom the participant trusts, to sign the consent form.*

*2. You can get an oral consent recorded on audio/video. Make sure the participant is comfortable with this.*

*3. In the rare cases that it is impossible to ask for consent, make sure to discuss this with the Research Ethics Review Committee / Internal Review Board.*

I have read the Informed Consent Form and I understand what the purpose of the research is and data will be collected from me. The research has been explained to me clearly and I have been able to ask questions.

*Include what applies:*

By signing this Form, I

1. consent to participate in this research.
2. confirm that I am at least 18 years old[[4]](#footnote-5).
3. understand that participating in this research is completely voluntary; and
4. understand that my data will be de-identified for further research and publication, unless I give my explicit consent to the Quotes and Actual Name options below.

*Include elements that are necessary:*

**Explicit Consent**

I give my explicit consent to the collection, processing, use and storage of my personal data for the purposes of this research including [health/race/ethnic origin/political views/religious beliefs/ ideological convictions/trade-union membership/sexual behaviour/sexual orientation/genetic data/biometric data/audio through interviews/video through interviews]

**Audio/Video**

I hereby consent to having audio and/or video recordings made during the research and to have my answers transcribed.

**Data Sharing outside EEA**

I hereby consent to having my data shared with an organisation/institution based outside the European Economic Area (EEA), namely *[fill in organisation and country]*

**Quotes**

I hereby consent to having my answers quoted in research publications. When quotes are used, they will be de-identified.

**Actual Name**

I hereby consent to having my actual name stated with the Quotes referred to above.

**Further Research**

I hereby consent to having my data stored and used for educational purposes and for future research, also in other areas of research than this research.

**Name of the participant:**

**Signature of the participant: Date:**

*Optional:*

**You will be given a copy of the full Informed Consent Form.**

*It is recommended to at least provide information on where the results will be published and contact information (e.g., a website).*

1. Examples are: name, address, phone number, email address. [↑](#footnote-ref-2)
2. Personal data revealing racial or ethnic origin; Political opinions; Religious or philosophical beliefs; Trade union membership; Genetic data and biometric data processed for the purpose of uniquely identifying a natural person; Data concerning health; Data concerning a natural person’s sex life or sexual orientation. [↑](#footnote-ref-3)
3. *See the GoFair website:* [*https://www.go-fair.org/fair-principles/*](https://www.go-fair.org/fair-principles/) [↑](#footnote-ref-4)
4. GDPR permits 16 years old in the EEA to consent. From an ethics perspective, holding on to the age people become an adult may be preferable. Different countries may handle a different age for becoming an adult. [↑](#footnote-ref-5)