Consent form template for research with human participants

Authors: Ethics Committee CIS (based on template by BMS EC)

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1. Note that this is a template to assist researchers in the design of their consent forms. It is important to adapt this template to the outline and requirements of your particular study, using the notes and suggestions provided.
2. The consent form should be accompanied by an information letter that describes adequately and comprehensibly for the participants:
* Purpose of the research
* What will happen during the session, how long it will take, what will be asked of the participant, etc
* Benefits and risks of participating (e.g. mention that your research project has been reviewed by the Ethics Committee Information and Computer Science)
* Procedures for withdrawal from the study
* Whether any personal information about the participant will be collected, processed and how and for what purpose; the right of the participant to request access to and rectification or erasure of personal data
* Usage of the data during research, safeguarding personal information, maintaining confidentiality and de-identifying (anonymising) data, controlled access to data, especially in relation to data archiving and reuse, ways of dissemination, data archiving and possible publishing
* Retention period for the research data, or if that is not possible, criteria used to determine that period
* Contact details of the researcher (or his/her representative), contact details of the Ethics Committee Computer and Information Science to file a complaint, and if applicable another institution than UT, or a funding source.
1. Under General Data Protection Regulation (GDPR), consent needs to be:
* affirmative
* granular, seeking consent for different forms of data and for different use purposes
* more information on the appropriate use of personal data in scientific research according to the GDPR can be found [here](https://www.utwente.nl/.uc/f3eda9ef2010222e8db0078d23f031a77411fe019972a00/Appropriate%20use%20of%20personal%20data%20in%20scientific%20research%20-%20V1.pdf)
1. In this template:
* square brackets indicate where specific information is to be inserted
* black text forms the standard content of a consent form
* red text is notes to help the researcher finalise the form, not to be included in the consent form.
* grey text indicates extra optional questions

**Consent Form for [*name of study*]
YOU WILL BE GIVEN A COPY OF THIS INFORMED CONSENT FORM**

|  |  |  |  |
| --- | --- | --- | --- |
| ***Please tick the appropriate boxes*** | **Yes** | **No** |  |
| **Taking part in the study** |  |  |  |
| I have read and understood the study information dated [DD/MM/YYYY], or it has been read to me. I have been able to ask questions about the study and my questions have been answered to my satisfaction.*Separate ‘yes/no’ tick boxes allow the researcher to make sure that the participant is actively affirming their consent. If the participant wants to tick the no box this allows the researcher to clarify any points the participant is unsure about. If this is not applicable for your study, then remove the ‘no’ box.*  | □ | □ |  |
| I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason.  | □ | □ |  |
| I understand that taking part in the study involves […………………………………………………]*Describe in a few words how information is captured, using the same terms as you used in the information sheet, for example: an audio-recorded interview, a video-recorded focus group, a survey questionnaire completed by the enumerator, ….]**For interviews, focus groups and observations, specify how the information is recorded (audio, video, written notes)**For questionnaires, specify whether participant or enumerator completes the form.**For audio or video recordings, indicate whether these will be transcribed as text, and whether the recording will be destroyed.*OPTIONAL (delete if not needed):**Risks associated with participating in the study** | □ | □ |  |
| I understand that taking part in the study involves the following risks: […..]*Describe in a few words risks associated with participating in the study, for example: physical or mental discomfort, risk of the participant identity being revealed to close relatives etc.* | □  | □ |  |
| **Use of the information in the study** |  |  |  |
| I understand that information I provide will be used for [………………………………………………]*List the planned outputs, e.g. reports, publications, website, video channel, …… , using the same terms as you used in the study information sheet. Consider any secondary use and whether knowledge sharing and benefits sharing needs to be considered, e.g. for indigenous knowledge.* | □ | □ |  |
| I understand that personal information collected about me that can identify me, such as [e.g. my name or where I live], will not be shared beyond the study team.  | □ | □ |  |
| Possible extra questions:*If you want to use quotes in research outputs then add extra question:* I agree that my information can be quoted in research outputs*If you want to use named quotes, then add extra question:* I agree that my real name can be used for quotes*If written information is provided by the participant (e.g. diary) then add extra question:* I agree to joint copyright of the [*specify data*] to [*name of researcher*] | □□□ | □□□ |  |
|  |  |  |  |
| *You may also need to obtain dated consent for specific activities when those activities are optional. Whether an activity is required or optional must be clearly described in the main body of the information sheet. Some common optional research activities are included below:* |  |  |  |
| Consent to be Audio/video RecordedI agree to be audio/video recorded. Yes/no | □ | □ |  |
| **Future use and reuse of the information by others** |  |  |  |
| I give permission for the [*specify the data*] that I provide to be archived in [*name of data repository*] so it can be used for future research and learning.*Specify in which form the data will be deposited, e.g. anonymised transcripts, audio recording, survey database, etc.; and if needed repeat the statement for each form of data you plan to deposit.**Specify whether deposited data will be anonymised, and how. Make sure to describe this in detail in the information sheet.* *Specify whether use or access restrictions will apply to the data in future, e.g. exclude commercial use, apply safeguarded access, etc.; and discuss these restrictions with the repository in advance.**Optional:* | □ | □ |  |
| I agree that my information may be shared with other researchers for future research studies that are similar to this study. The information shared with other researchers will not include any information that can directly identify me. Researchers will not contact me for additional permission to use this information. (Note: This separate consent is not necessary if you will only store and share deidentified data. That means not just pseudonymised, but completely anonymised.)  | □ | □ |  |
| I give the researchers permission to keep my contact information and to contact me for future research projects.  | □ | □ |  |
|  |  |  |  |
| **Signatures** |  |  |  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_ Name of participant [printed]and legal representative If applicable) Signature Date |  |  |  |
| *For participants unable to sign their name, mark the box instead of sign*I have witnessed the accurate reading of the consent form with the potential participant and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_Name of witness [printed] Signature Date |  |  |  |
| I have accurately read out the information sheet to the potential participant and, to the best of my ability, ensured that the participant understands to what they are freely consenting.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_ Researcher name [printed] Signature Date |  |  |  |
| **Study contact details for further information: [*Name, email address*]****Contact Information for Questions about Your Rights as a Research Participant** (or put this in your information sheet)If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the Secretary of the Ethics Committee Information & Computer Science: ethicscommittee-CIS@utwente.nl  |  |  |  |