Informed consent form template for research with human participants

Originally created by the: BMS Ethics Committee with input from Human Research Ethics TU Delft

Adapted with extra information by the GEO Ethics Committee lead by ITC.

Last edited: Nov 8, 2022

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**Aspects for the researcher to consider:**

1. Note that this is a template to assist researchers in the design of their informed 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 informed consent form should be accompanied by an information sheet** that describes adequately (for the participants):
* Purpose of the research.
* Benefits and risks of participating (e.g. mention that your research project has been reviewed and approved by the GEO Ethics Committee).
* Procedures for withdrawal their participation (and their data, if applicable) 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.
	1. If the data will be aimed to be publish in a public trusted research repository in an open restricted manner, and if other researchers (outside the main research project) can access/use it. Please be explicit about this.
* Retention period for the research data, or if that is not possible, criteria used to determine that period.
* Contact details of the researcher (or their representative), contact details of the GEO Ethics Committee to file a complaint, and if applicable another institution than UT, or a funding source.
* Consent cannot be pressured in any way, so the researchers need to make everything within their possibilities to ensure this is the case.
1. Under the forthcoming General Data Protection Regulation (GDPR), consent needs to be:
* affirmative
* granular, seeking consent for different forms of data and for different use purposes.
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.

***NOTE TO RESEARCHER:*** *Separate ‘yes/no’ tick boxes allow you to make sure that the participant is actively affirming their consent. If the participant wants to tick the no box this allows you 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 […………………………………………………]

***NOTE TO RESEARCHER:*** *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: […..]

***NOTE TO RESEARCHER:*** *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, address, geolocation], will not be shared beyond the study team.  | □ | □ |  |
| (optional, when possible) I understand that I can withdraw my data from the study at the latest by [………] *Specify the last moment in time that a participant can withdraw their data and decide their participation even if they have consented.*  | □ | □ |  |
| 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 Recorded*I 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 and published 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, survey database, etc.; and if needed repeat the statement for each form of data you plan to deposit. 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.* | □ | □ |  |
| I understand that the [anonymized] information I will provide can be shared with, and potentially used by, [……………..] list all actors, organizations that are part of the project or intended to access the research data. For this please also think if you will put the final data in a repository as open access. | □ | □ |  |
| *Optional:*I agree that my information may be shared with other researchers for future research studies that may be 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.)  | □ | □ |  |
| 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/domain Geo-Information Sciences of the Faculty of Geo-Information Sciences and Earth Observation at the University of Twente by ethicscommittee-geo@utwente.nl  |  |  |  |