Informed consent form

Addressing future reuse of research data

This template can be used by researchers to gain informed consent to conduct research that collects data from people using questionnaires, observations, interviews, diaries, focus groups, video recordings, etc. It pays particular attention to ensure that research data can be curated and made available for future use, as well as addressing all standard requirements of a consent form. Also, this version of our template is consistent with our current knowledge of the requirements of the UK General Data Protection Regulation (GDPR) which comes into effect from 1 Jan 2021. These requirements are not new and currently aligns with the EU GDPR.

* This is a template to assist researchers in the design of their informed consent form. You must adapt this template to the requirements of your particular study, using the notes and suggestions provided.
* Before using this template, check whether your organisation provides a template consent form and if so, incorporate their requirements into the form (e.g. with regards to data protection).

# Information sheet

The informed consent form should be accompanied by an information sheet that describes:

## General information about the research and the collected research data

* Purpose of the research.
* Type of research intervention, e.g. questionnaire, interview, etc.
* Voluntary nature of participation.
* Benefits and risks of participating.
* Procedures for withdrawal from the study.
* Usage of the data during research, dissemination and storage, including how the information will be shared with participants and any access and benefits-sharing that may be applicable (e.g. traditional knowledge under the Nagoya protocol).
* Future publishing, archiving and reuse of the data, explaining to participants the benefits of data sharing and indicating whether research data will be deposited in a recognised repository, naming the organisation responsible for the repository (e.g. UK Data Service, your institutional repository, etc.).
* Contact details of the researcher, as well as their organisation, funding source, how to file a complaint.

## Additional information if personal information is collected from participants (for example their name, where they live, information that can disclose their identity)

* How personal information will be processed and stored and for how long (e.g. signed consent forms, names or email addresses in online surveys, people’s visuals in video recordings).
* Procedures for maintaining confidentiality of information about the participant and information that the participant shares.
* Procedures for ensuring ethical use of the data: procedures for safeguarding personal information, maintaining confidentiality and de-identifying (anonymising) data, especially in relation to data archiving and reuse.

## UK General Data Protection Regulation considerations

* Researchers undertaking research in the UK, and where personal data will be stored, need to comply with the requirements of the UK GDPR from 1 Jan 2021.
* Researchers will need to identify for which of the six lawful reasons [(Information Commissioner’s Office, ICO)](https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/lawful-basis-for-processing/) personal data will be processed; this will inform what the information sheet and the informed consent form should include.
* If the reason is consent, it needs to be freely given, informed, unambiguous, specific and affirmative; participants need to be able to withdraw their consent for the processing of personal data (this will not affect the lawfulness of the processing up to that point).
* The information sheet should also contain some specific information including:
* The contact details of the Data Controller (the entity that determines the reason for processing personal data, this can be a responsible person within the researcher’s organisation or the researcher), and the organisation’s dedicated Data Protection Officer.
* Who will receive or have access to the personal data, including information on any safeguards if the personal data is to be transferred outside the UK.
* A clear statement on the right of the participant to request access to their personal data and the correction (rectification) of removal (erasure) of such personal data.
* A reminder that the participants have the right to lodge a complaint with the Information Commissioner’s Office (ICO).
* The period of retention for holding the data or the criteria used to determine this. (If data are to be archived for re-use, then the retention period should be indefinite.)

**Notes**

1. The standard content of a consent form is provided.
2. Insert specific information in the highlighted square brackets [ ].
3. (Guidance) All text provided as guidance is to be replaced by the final version of text in the disseminated consent form.
4. (Optional) All text marked as optional can be used/removed as necessary.

# Informed consent for [name of study]

| **Please tick the appropriate boxes** | **Yes** | **No** |
| --- | --- | --- |
| 1. 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. | tick box | tick 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. | tick box | tick box |
| I understand that taking part in the study involves […………………………………………………](Guidance)* 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, an experiment, etc.].
* 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.
 | tick box | tick box |
| (Optional) If there is a potential risk of participating in the study, then provide an additional statement: I understand that taking part in the study has [………………………………….] as potential risk. | tick box | tick box |
| 1. Use of the information in the study.
 |  |  |
| I understand that information I provide will be used for […………………………………….……](Guidance)* List the planned outputs, e.g. reports, publications, website, video channel etc., using the same terms as you used in the study information sheet.
* Consider whether knowledge sharing and benefits sharing needs to be considered, e.g. for indigenous knowledge.
 | tick box | tick box |
| I understand that personal information collected about me that can identify me, such as my name or where I live, will not be shared beyond the study team. * At times this should be restricted to the researcher only.
 | tick box | tick box |
| (Optional) If you want to use quotes in research outputs, add: I agree that my information can be quoted in research outputs. | tick box | tick box |
| (Optional) If you want to use named quotes, add: I agree that my real name can be used for quotes. | tick box | tick box |
| (Optional) If written information is provided by the participant (e.g. diary), add: I agree to joint copyright of the [specify the data] to [name of researcher]. | tick box | tick box |
| 1. Future use and reuse of the information by others.
 |  |  |
| I give permission for the [specify the data] that I provide to be deposited in [name of data repository] so it can be used for future research and learning.(Guidance)* Specify in which form the data will be deposited, e.g. de-identified, 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 de-identified or 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.
 | tick box | tick box |

1. Signatures.

|  |  |  |
| --- | --- | --- |
| Name of participant [in capitals] |  | [DD/MM/YYYY] |

(Optional) For participants unable to sign their name, mark the box instead of signing: 

(Optional) 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 [in capitals] |  | [DD/MM/YYYY] |

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.

|  |  |  |
| --- | --- | --- |
| Name of researcher [in capitals] |  | [DD/MM/YYYY] |

1. Study contact details for further information.

[Name, phone number, email address]

[www.ukdataservice.ac.uk](http://www.ukdataservice.ac.uk)

datasharing@ukdataservice.ac.uk

+44 (0) 1206 872143

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