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Consortium of European Social Science Data Archives
European Research Infrastructure Consortium

Gaining Informed Consent for Data Sharing

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Disclaimer

- The information on the GDPR in this presentation is based on our current interpretation of the legislation and its implications for research and the archiving of research data

- This is a very fluid area and thus changes are still possible

- This presentation **does not constitute, or should not be construed as, legal advice and / or guidance**

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Overview

- Informed consent is the process by which a researcher discloses appropriate information about the research so that a participant may make a voluntary, informed choice to accept or refuse to cooperate

- Normally informed consent is given before the start of the research

- Gaining informed consent is crucial to meet your legal and ethical obligations towards participants whilst simultaneously enhancing the value of your research data

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Consent is Needed Across the Data Lifecycle

- Engagement in the research process
  - What activities are involved in participating in the project?

- Dissemination in presentations, publications, the web
  - Consent for use of quotes for articles and video publicity

- Data sharing and archiving
  - Consider future uses of data

* Consent is always dependent on the research context – special cases of covert research and verbal consent

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Informed Consent (Broadly)

- Consent needs to be **freely given**, **informed**, **unambiguous**, **specific** and by a **clear affirmative action** that signifies agreement to the processing of personal data

- When special categories data are processed – and the processing grounds for this is consent – there is a further requirement to the above that this must be based on **explicit consent**

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‘Explicit’ Consent

- The term explicit refers to the way consent is expressed by the data subject
- It means that the data subject must give an express statement of consent
- An obvious way to make sure consent is explicit would be to expressly confirm consent in a written statement
- In theory, the use of oral statements can also be sufficiently express to obtain valid explicit consent, however, it may be difficult to prove for the controller that all conditions for valid explicit consent were met when the statement was recorded
- Two stage verification of consent can also be a way to make sure explicit consent is valid

Working Party 29 Guidance on Consent (18/19)

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Informed Consent – Research (1)

- To obtain informed consent in practice, researchers should:
  - Inform participants about the purpose of the research
  - Discuss what will happen to their contribution (including the future archiving and sharing of their data)
  - Indicate the steps that will be taken to safeguard their anonymity and confidentiality
  - Outline their right to withdraw from the research, and how to do this

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Informed Consent – Research (2)

- When seeking to obtain informed consent from participants, it is important for researchers to also consider the specific circumstances and needs of the participants

- This may mean, for example: pictures or diagrams are used on the consent form instead of using a lot of text or the consent form is translated into another language

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Informed Consent – Research (3)

» The GDPR recognises that it is often not possible to fully identify the purpose of the personal data processing in research at the time of data collection and, therefore, data subjects should be able to give their consent to certain areas of the research (in keeping with recognised ethical standards for research)

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Informed Consent – Data Sharing (1)

- Gaining informed consent for data sharing is seen as '**one more small step**' to gaining consent from participants to partake in a research project

- Adding the discussion of data sharing and archiving permits the participant to make an informed decision. This empowers them and puts them in charge of choosing whether they wish for their contribution to the research project – and their data – to be available for use in future research projects

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Informed Consent – Data Sharing (2)

- The best way to achieve informed consent for data sharing is to **identify** and **explain** the p**ossible future uses of their data** and offer the participant the option to consent on a **granular level**

- For example, in a qualitative study, this may involve allowing the participant to consent to data sharing of the anonymised transcripts, the non-anonymised audio recordings and the photographs

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In Practice: Wording in Consent Forms / Information Sheets

The interviews will be archived at ……. and disseminated so other researchers can reuse this information for research and learning purposes:

- ❑ I agree for the audio recording of my interview to be archived and disseminated for reuse
- ❑ I agree for the transcript of my interview to be archived and disseminated for reuse
- ❑ I agree for any photographs of me taken during interview to be archived and disseminated for reuse

We expect to use your contributed information in various outputs, including a report and content for a website. Extracts of interviews and some photographs may both be used. We will get your permission before using a quote from you or a photograph of you.

After the project has ended, we intend to archive the interviews at …. Then the interview data can be disseminated for reuse by other researchers, for research and learning purposes.

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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. ☐ ☐

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, 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.

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. ☐ ☐

2. 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 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.

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.

Potential additional statements

i) If you want to use quotes in research outputs: I agree that my information can be quoted in research outputs. ☐ ☐

ii) If you want to use named quotes: I agree that my real name can be used for quotes. ☐ ☐

iii) If written information is provided by the participant (e.g. diary): I agree to joint copyright of the [DD/MM/YYYY] to [name of researcher]. ☐ ☐

3. 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. ☐ ☐

> 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.

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Consent Form Content

- Break down into 3 key areas:
  - 1. Taking part in the study
  - 2. Use of the information in the study
  - 3. Future use and reuse of the information by others

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I understand that taking part in the study involves [.....]. ☐ ☐

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For questionnaires, specify whether participant or enumerator completes the form.
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List the planned outputs, e.g. reports, publications, website, video channel etc., using the same terms as you used in the study information sheet.
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Documenting Consent

- Under the GDPR, consent needs to be documented, which means (in the context of research) it will be important for researchers to maintain documented and accurate records of the consent obtained from their participants

- This could, for example, be written consent or audio recorded oral consent

- Though the GDPR does not require this consent to be in a written form, many UK research ethics committees and professional bodies do require this or recommend it as best practice

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Special Cases of Consent

Children

- Aged 16 and above can give their own consent
- If minor is competent, need consent from child, and parent / guardian
- Gillick principle – even children under 16 can consent to medical treatment, without parental consent

Employees

- Employee may owe duty of confidentiality to employer

Vulnerable participants, disabilities of any kind

- Need to balance protection from harm with right to participate

Criminal activities

- Usually no obligation to disclose, unless investigation is active

Retrospective consent; covert research, observational experiment

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Timing and Form of Consent

	Advantage	Disadvantage
Written consent	More solid legal ground, e.g. participant has agreed to disclose confidential info Often required by Ethics Committees Offers more protection for researcher (as they have written documentation of consent)	Not possible for some cases: infirm, illegal activities May scare people from participating (or have them think that they cannot withdraw their consent)
Verbal consent	Best if recorded	Can be difficult to make all issues clear verbally Possibly greater risks for researcher (in regards to adequately proving participant consent)

	Advantage	Disadvantage
One-off consent: participant is asked to consent to taking part in the research project only once.	Simple Least hassle to participants	Research outputs not known in advance Participants will not know all info they will contribute
Process consent : participant's consent is requested continuously throughout the research project	Ensures 'active' consent	May not get all consent needed before losing contact Repetitive, can annoy participants

Information Sheet

- **A/ 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 data repository, naming the organisation responsible for the repository (e.g. UK Data Service, your institutional repository)
  - Contact details of the researcher, with institution, funding source, how to file a complaint

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Information Sheet

- **B/ 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

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Information Sheet

- ***C/* GDPR Considerations**
  - The starting point for this should be identifying the grounds on which the personal data are being processed. There are 6 possible grounds for this and depending on which ground is chosen this will impact on the what the information sheet and the informed consent form should include
  - If consent is chosen as the process grounds then it needs to be freely given, informed, unambiguous, specific and by a clear affirmative action, and the participant needs to be made aware that they can withdraw their consent at any time, and that will not affect the lawfulness of the processing up to that point

- The information sheet and the informed consent form will need to address a variety of other considerations including:
  - The contact details of the researcher, the data controller (which will likely not be the researcher), and the 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 EU
  - The period of retention for holding the data or the criteria used to determine this
  - 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 Supervisory Authority

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Questions

- Dr Scott Summers
- Collections Development and Producer Relations team
- UK Data Service
- University of Essex
- ukdataservice.ac.uk/help/get-in-touch

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