Consent issues in data sharing

Dr Hina Zahid
Senior Research Data Officer
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Overview

• Why, how and when to seek consent?

• Special considerations and challenges.

• Consent in practice: wording used in real example consent forms/information sheet and in UKDS model consent form.

• Further resources & future training events.
Why to seek consent?
Why to seek consent?

To ensure:

• Participants understand what they’re signing up to making participation and research more effective.

• Research conducted is ethical.

• Compliance with data protection regulation.
Consent in research

- Consent for research ethics.
- Consent for processing of personal data.
Duty of confidentiality and data sharing

• Exists in UK common law and may apply to research data.

• Disclosure of confidential information is lawful when:
  • The individual to whom the information relates has consented.
  • Disclosure is necessary to safeguard the individual, or others, or is in the public interest.
  • There is a legal duty to do so, for example a court order.

• Best practice is to avoid very specific promises in consent forms.
Data protection considerations

• If personal information about people is collected or used in research, then the data protection regulations applies.

• **Personal information or data** is any information relating to an identified or identifiable natural person.

• Anonymised data is NOT personal data so the GDPR does NOT apply.
cont…Data protection considerations

• Data protection act 2018 (DPA), General data protection regulation 2018 (GDPR) & the UK GDPR 2021.

• DPA (2018) & the UK GDPR (2021) applies when
  ✓ a researcher based in the UK collects personal data about people anywhere in the world.
  ✓ a researcher outside the UK collects personal data on UK citizens.

• DPA (2018), EU GDPR (2018) & the UK GDPR (2021) applies when
  ✓ a researcher based in the UK collects personal data about people across Europe.
Principles of processing personal data

All data must be:

• be processed **lawfully, fairly and transparently**
• be kept to the **original purpose**
• be **minimised** (only the personal data that is necessary is collected)
• be **removed** if they are not necessary
• have the **accuracy upheld**
• be **kept confidential** and their **integrity maintained**.
Legal basis to process personal data (UK GDPR)

• consent
• public interest
• legitimate interest
• protect vital interest
• legal obligation
• performance of a contract.
Conditions of consent when used as a legal base for processing personal data

• Must be freely given, informed, unambiguous, specific (granular).

• A clear affirmative action.

• Cannot be inferred from silence, pre-ticked boxes or inactivity.

• Participants can withdraw consent to process their personal data at any time.

• Must be documented, i.e. recorded, written or oral.

• An explicit consent is required to process special categories data (e.g. a person’s race, ethnic origin, politics, religion, genetics, sex life, health).

  explicit = express statement of consent, e.g. written statement
## European diversity in informed consent

<table>
<thead>
<tr>
<th>Country</th>
<th>Consent required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Czech Republic</td>
<td>Yes, if personal data are collected</td>
</tr>
<tr>
<td>Croatia</td>
<td>Yes, if personal data are collected</td>
</tr>
<tr>
<td>Germany</td>
<td>Yes, if personal data are collected, processed and stored</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Yes, if personal data are collected, processed and stored</td>
</tr>
<tr>
<td>Norway</td>
<td>Yes, but exceptions for research</td>
</tr>
<tr>
<td>North Macedonia</td>
<td>Yes</td>
</tr>
<tr>
<td>Serbia</td>
<td>Yes</td>
</tr>
<tr>
<td>Sweden</td>
<td>Yes, if research is carried out on humans, biological material, or sensitive personal data</td>
</tr>
<tr>
<td>Switzerland</td>
<td>Yes, for any processing of personal data</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>No</td>
</tr>
</tbody>
</table>
How to seek consent?
Format of consent

• Consent can be gained in **written** or **oral** form.

• Format depends on the kind of research.

• Important to document how it has been gained, what information has been provided to the participants and what they have agreed to.
## Forms of consent

<table>
<thead>
<tr>
<th>Forms of Consent</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
</table>
| Written consent   | • More solid legal ground  
                    • Often required by Ethics Committees  
                    • Offers more protection for researcher | • Not possible for some cases: infirm  
                    • May scare people from participating |
| Verbal consent    | Best if recorded                                                            | • Can be difficult to make all issues clear verbally  
                    • Possibly greater risks for researcher |
Consent documentation: Information sheet

An information sheet should cover the following topics:

- **Purpose** of the research.
- What is **involved** in participating.
- **Benefits** and **risks** of participating.
- Procedures for **withdrawal**.
- **Usage of the data** during research, dissemination, storage, publishing and archiving.
- **Details of the research**: funding source, sponsoring institution, name of project, contact details for researchers, how to file a complaint.

Cont...
Consent documentation: Consent form

Consent form should:

• Use simple language and free from jargon.
• Allow the participant to clearly respond to points such as:
  • The participant has read and understood information about the project.
  • The participant has been given the opportunity to ask questions.
  • The participant voluntarily agrees to participate in the project.
  • The participant understands that they can withdraw at any time without giving reasons and without penalty.
  • Future uses (e.g. publications, share and reuse).
  • Signatures and dates of signing for the participant and the researcher.
cont…Consent documentation

If **personal information** is collected:

- How personal information will be processed and stored and for how long.
- Procedures for maintaining confidentiality.
- Procedures for ensuring ethical use of the data.

If the **GDPR applies**:

- The contact details of the data controller (DPO, REO, Researcher).
- Who will receive or have access to the personal data.
- A clear statement on the right of the participant (right to access, correction or removal).
Methods used to obtain consent

• **Signing** a consent statement on a paper form.
• **Ticking** an opt-in box on paper or electronically.
• **Clicking** an opt-in button or link online.
• **Selecting** from equally prominent yes/no options.
• **Choosing** technical settings or preference dashboard settings.
• **Responding** to an email requesting consent.
• **Answering** yes to a clear oral consent request.
Record keeping when processing personal data

Good record keeping should include the following:

• **Who consented**: name or other identifier.
• **When they consented**: dated document for written or oral consent and a time stamp for online records.
• **What they were told at the time**: for written consent, a copy of the consent form used to demonstrate the consent statement and for an oral consent a document with the script that was used at the time of data collection.
• **How they consented**: written, online, oral.
• **Have the consent withdrawn**: if so, when?
When consent becomes invalid

- If there are **doubts** over whether someone has consented.
- If a **person doesn’t realise** they have consented.
- There are **no clear records** to demonstrate participants had consented.
- **No genuine free choice** over whether to opt in was given.
- There was a clear **imbalance of power** between a researcher and the individual.

cont…
cont...When consent becomes invalid

• The consent request was **vague or unclear**.
• **Pre-ticked opt-in boxes** or other **methods of default consent** were used.
• The researcher’s organisation was not specifically **named**.
• Subjects were not informed about their **right to withdraw**.
• Subjects cannot **easily withdraw consent**.
• The **research purposes or activities have evolved** since the original consent.
When to seek consent?
One-off consent or process consent?

<table>
<thead>
<tr>
<th>One-off consent</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Simple lease hassle to the participants</td>
<td>Research outputs not known in advance</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Participants may not know all info they contribute to</td>
</tr>
<tr>
<td>Process consent</td>
<td>Ensures active consent</td>
<td>May not get all consent needed before losing contact,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>repetitive, may annoy participants</td>
</tr>
</tbody>
</table>
Special considerations when seeking consent

• medical research
• internet research
• twitter
• consent for linking to administrative data
• children and young adults
• people with learning difficulties
• research within organisations or in the workplace
• crime.

Further information: consent in special cases.
Challenges

• Retrospective consent - could be obtained when consent was not sought at the point of data collection.
• Right to withdraw – what to do with already collected data?
• Research without consent (Further details: Research without consent).
• Participant perception and expectations.
• Children & vulnerable people.
• Participant’s poor awareness of their rights.
• Failure to provide adequate information.
• Absence of consideration of participant’s background such education, culture.
• Use of jargon.
• Skeptical of confidentiality issues.
UKDS Model Consent Form & examples from real research
Three key areas to be addressed

Wording in consent forms and information sheets could be broken down in three key areas:

• taking part in the study

• use of the information in the study

• future use and reuse of the information by other.
Informed Consent for [name of study]

Please tick the appropriate boxes

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.

If you want to use quotes in research outputs, add: I agree that my information can be quoted in research outputs.
If you want to use named quotes, add: I agree that my real name can be used for quotes.
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].
UKDS Model Consent Form template: Section on future use and reuse of the information

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. 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 (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.
In practise: wording in consent form/information sheet 1

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.
In practise: wording in consent form/information sheet 2

<table>
<thead>
<tr>
<th>Use of information I provide beyond this project</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>I agree for the data I provide to be archived at UK Data Archive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I understand that other genuine researchers will have access to the data only if they agree to preserve the confidentiality of the information as requested in this form</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I understand that other genuine researchers may use my words in publications, reports, web pages, research outputs only if they agree to preserve the confidentiality of the information as requested in this form</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
We ask you to consider the following points before agreeing to participate.

- Your contribution to the research will take the form of a focus group participant. This will be digitally video recorded and transcribed.

- Your name and any information which may directly or indirectly identify you will be altered to protect your anonymity.

- Any recordings of the discussions will be kept securely, and only authorised to other researchers on the condition they preserve your anonymity.

- The transcriptions (excluding names and other identifying details) will be retained by the researcher and analysed as part of the study. They will also be deposited with the UK Data Archive which has strict regulations about accessing data for research and protecting participant confidentiality.

Any personal information that could identify you will be removed or changed before files are shared with other researchers or results are made public.
Example information sheet outline

- What is the purpose of the study?
- Why have I been invited to take part in the study?
- Do I have to take part?
- What will happen if I take part?
- What will I have to do?
  - Walking interview and questionnaire
  - Living with sensors
  - Time use diary
  - Final interview and questionnaire
- What are the possible disadvantages or risks of taking part?
- What are the possible benefits of taking part?
- What happens when the research study stops?
- What if there is a problem?
- Will my taking part in the study be kept confidential?
- Who is organising and funding the research?
- Who has reviewed the project?
Example from Health Research Authority (HRA)
Example from Health Research Authority (HRA): 1
Example from Health Research Authority (HRA): 2
Example from Health Research Authority (HRA): 3
Example from Health Research Authority (HRA): 4
Example from Health Research Authority (HRA): 5
Example from Health Research Authority (HRA): 6
Consent checklist (ICO)

Checklist

Asking for consent

☐ We have checked that consent is the most appropriate lawful basis for processing.
☐ We have made the request for consent prominent and separate from our terms and conditions.
☐ We ask people to positively opt in.
☐ We don’t use pre-ticked boxes, or any other type of consent by default.
☐ We use clear, plain language that is easy to understand.
☐ We specify why we want the data and what we’re going to do with it.
☐ We give granular options to consent to independent processing operations.
☐ We have named our organisation and any third parties.
☐ We tell individuals they can withdraw their consent.
☐ We ensure that the individual can refuse to consent without detriment.
☐ We don’t make consent a precondition of a service.
☐ If we offer online services directly to children, we only seek consent if we have age-verification and parental-consent measures in place.
## Informed consent checklist (ICO)

<table>
<thead>
<tr>
<th>Informed consent</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Request for consent is independent of other obligations or any other terms and conditions</td>
<td></td>
</tr>
<tr>
<td>Pre-ticked boxes or any other type of consent by default is not used</td>
<td></td>
</tr>
<tr>
<td>Language used is easy and clear to understand</td>
<td></td>
</tr>
<tr>
<td>Data subjects are being informed why the data is being collected and how it will be processed</td>
<td></td>
</tr>
<tr>
<td>Named organisation and any third parties</td>
<td></td>
</tr>
<tr>
<td>Included an affirmative statement indicating the right to voluntary participation</td>
<td></td>
</tr>
<tr>
<td>Included an affirmative statement indicating the right to withdraw</td>
<td></td>
</tr>
<tr>
<td>Included an affirmative statement indicating any potential risks</td>
<td></td>
</tr>
<tr>
<td>Included an affirmative statement indicating any potential benefits</td>
<td></td>
</tr>
<tr>
<td>Included an affirmative statement indicating information about data sharing and archiving</td>
<td></td>
</tr>
</tbody>
</table>
Take away message

• Do not collect personal data if it is not essential.

• Indicate clearly in a consent form where the participant’s consent is being asked for processing their personal data and where consent is being asked for taking part in the research.

• Keep consent forms under constant review.

• Different forms of consent for different materials, e.g. audio recordings vs transcripts.
• As simple as possible and in easy language.
• Avoid excessive warnings.
• Indicate the future uses of data (publishing, archiving).
• Indicate the steps that will be taken to safeguard anonymity and confidentiality.
• Remember, consent is NOT the only ground to process personal data.
• GDPR does not apply if data is anonymised.
• Different data sharing consent agreements for different types of research data, e.g. less sensitive (survey) vs. highly sensitive (medical).
Further resources

- UK Data Service
- UKDS Model Consent Form
- Example Information Sheet
- Consent for data sharing
- DARIAH ELDAH Consent Form Wizard | CFW
- HRA Example Consent Form
- Regulating access to data
- Managing and sharing research data: A guide to good practise
Thank you.

Dr Hina Zahid
UK Data Service
Email: hzahid@essex.ac.uk
Twitter: UKDataService
Twitter: hinaz2016