Informed consent for data sharing and reuse under GDPR

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Managing and sharing research data: best practice for data protection

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Consent in research, along data lifecycle

In research with people, informed consent is used for many reasons:

- Voluntary participation in the study
- Research information you will collect
- Personal information you will collect
- Maintaining confidentiality of information or not
- Use of the collected information
- Future data sharing and reuse of personal information and/or de-identified information

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General Data Protection Regulation (GDPR)

Six grounds for processing ‘Personal Data’ and one must be present to process a person’s personal data:

- Consent of the data subject
- Necessary for the performance of a contract
- Legal obligation placed upon controller
- Necessary to protect the vital interests of the data subject
- Carried out in the public interest or is in the exercise of official authority
- Legitimate interest pursued by controller

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Consent for personal data - GDPR

- When consent is the legal basis for collecting and processing personal data in accordance with the GDPR, this consent for the use of personal data should be distinguished from other consent requirements (ethics, procedural obligation)
- Consent for collecting and processing personal data needs to be freely given, informed, unambiguous, specific (granular) and a clear affirmative action
- Consent cannot be inferred from silence, pre-ticked boxes or inactivity
- Participants can withdraw consent to process their personal data at any time
- Consent must be documented
  - Recorded, written or oral
  - Required proof of process

Consent form / information sheet when collecting - processing personal data under GDPR

If consent is processing ground, then provide as information:

- Contact details of the researcher, data controller (the entity that determines the reason for processing personal data), 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
- Right of the participant to request access to their personal data and the correction (rectification) of removal (erasure) of such personal data
- Reminder that the participants have the right to lodge a complaint with the information Commissioner's Office (ICO)
- 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)

GDPR and consent

- When special categories data are processed (e.g. a person's race, ethnic origin, politics, religion, genetics, sex life, health,…) – and the processing grounds for this is consent – then this must be based on explicit consent
- Explicit = express statement of consent, e.g. written statement, two-stage verification of consent

- GDPR =
  - TRANSPARENCY
  - EASY LANGUAGE
  - PARTICIPANTS DECIDE

Promising ‘anonymity’

- Once ‘anonymised’, data falls out of data protection legislation
- But, bear in mind that not all research data can be fully or easily anonymised/de-identified
  - Combinations of unique key attributes
  - Rich textual data
  - Combining data from different sources

Consent and data sharing

- The best way to achieve informed consent for data sharing is to identify and explain the possible future uses of their data and offer the participant the option to consent on a granular level
- Discussion data sharing and archiving with participants permits them to make an informed decision, 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
- Across the research lifecycle e.g. for each new data collection in a longitudinal study
- Examples:
  - In a multi-modal study, allow the participant to consent (or not) separately to data sharing for various data collection events, e.g. survey, clinical assessment,…
  - In a qualitative study, allow the participant to consent (or not) separately to data sharing of anonymised transcripts, non-anonymised audio recordings, photographs,…

Consent in practice

- 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 anonymity and confidentiality
- Outline the right to withdraw from the research
- Need to balance
  - As simple as possible
  - Complete for all purposes: use, publishing and sharing
  - Avoid excessive warnings
  - Easy language

Timing and form of 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

	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)

Types of material and consent

Different data sharing consent agreements may be applied to different types of research data, e.g. less sensitive (survey) vs. highly sensitive (medical)

- Text and transcripts:
  - Can be anonymised
- Images, audio/video recordings:
  - Data more likely to reveal identities
  - Less usable after anonymising (distortion or blurring)
  - Anonymising costly
  - Consent or access control may be better alternatives than anonymisation

Aspects to consider

- Right to withdraw – what to do with already collected data?
- Informed consent for ‘unknown future data uses’ ?
- Provide maximum information about reuse
  - Who can access the data – authenticated researchers
  - Purposes – research, teaching, both
  - Confidentiality protections; agreement by future users

Discussion

- How easy / difficult is consent for data sharing in your research ?
- Which wording would you use?
- UK Data Service model consent form
- Example consent forms:

  https://www.ukdataservice.ac.uk/manage-data/legal-ethical/consent-data-sharing/consent-forms

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Questions

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