Informed Consent

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Looking after and managing your research data:
an advanced training course
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UK Data Service

Informed consent for ethical research

- What does it mean for consent to be “informed”?
  - purpose of the research
  - what is involved in participation
  - benefits and risks
  - mechanism of withdrawal
  - data uses – primary research, storing, processing, re-use, sharing, archiving
  - strategies to ensure confidentiality of data where this is relevant – anonymisation, access restrictions…

- RCUK expects data to be accessible for other uses

  RCUK Common Principles on Data Policy

  www.rcuk.ac.uk/research/Pages/DataPolicy.aspx

- Now a requirement for ESRC awards:

  “Where research data are considered confidential or contain sensitive personal data, award holders must seek to secure consent for data sharing or alternatively anonymise the data in order to make sharing possible.” ESRC Research Data Policy 2010 2.4(32)

Do participants consent to share data?

- Foot and mouth disease in N. Cumbria
  - Sensitive community information
  - 40/54 interviews; 42/54 diaries; audio restricted
- Finnish research on consent
  - Re-contact project: life stores, gender, etc.
  - 165/169 (98%) agreed
- Timescapes
  - Longitudinal data on personal relationships
  - 95%+ consent rate
- Bereaved relatives want others to benefit from their data

Consent needed across the data life cycle

- Engagement in the research process
  - decide who approves final versions of transcripts
- Dissemination in presentations, publications, the web
  - decide who approves research outputs
- Data sharing and archiving
  - consider future uses of data

Always dependent on the research context – special cases for covert research, verbal consent, etc.

A good information sheet & consent form

- Meets requirements of Data Protection laws
  - purpose of the research
  - what is involved in participation
  - benefits and risks
  - mechanism of withdrawal
  - usage of data – for primary research and sharing
  - strategies to ensure confidentiality of data (anonymisation, access etc.) where this is relevant
- Need to balance
  - as simple as possible
  - complete for all purposes: use, publishing, sharing
  - avoid excessive warnings
- UK Data Archive model consent form
  www.data-archive.ac.uk/media/210661/ukdamodelconsent.doc

When to ask for consent

	Pros	Cons
One-off	Simple Least hassle of participant	Research outputs not known in advance Participants will not know all content they will contribute
Process	Most complete for assuring active consent	Might not get consent needed before losing contact Repetitive, can annoy participant

Right to withdraw

- Right to withdraw – one of key features of consent
- What about already collected data?
  - not usually allowed, at least in most surveys
- What if project is longitudinal?
  - permit withdrawal, but
  - explain to participants the cost to the project of data that would be lost

Format for consent

Written

- more solid legal ground, e.g. participant has agreed to disclose confidential info
- often required by Ethics Committees
- offers more protection for researcher
- not possible for some cases: infirm, illegal activities

Verbal - with or without recording

- can be difficult to make all issues clear verbally
- possibly greater risks for researcher
- best if recorded

Types of material and consent

Ranging from less sensitive (survey) to highly sensitive (medical)

Most qualitative research falls in-between

- Text and transcripts
- Audio recordings, still and moving images
  - data more likely to reveal identities
  - data more likely to be rendered unusable by anonymizing (distortion or blurring)
  - gaining consent or limiting access are better alternatives than anonymisation

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

Internet, blog, social media – “New social media, new social science?”

- nsmnss.blogspot.co.uk/2014/02/new-social-media-new-social-science-and.html
- aoir.org/reports/ethics2.pdf

Retrospective consent; covert research, observational experiments

Informed consent for unknown future uses

- It is possible to provide much information about reuse
  - who can access the data – only authenticated researchers
  - purposes – research or teaching or both
  - confidentiality protections, undertakings of future users
  - general consent - similar to consent with emergent research topics
- Medical research and biobank models – enduring, broad, open consent
  - no time limits; no recontact required
  - unspecified hypotheses and procedures
  - 99% consent rate (2500+ patients) – Wales Cancer Bank

ESRC expects that others will also use it [data], so consent should be obtained on this basis and the original researcher must take into account the long-term use and preservation of data. **(ESRC Framework for Research Ethics, 1.17.5.1)**

Questions

Contact details

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