

Research ethics and data confidentiality: informed consent

Managing and sharing social science research data
UK Data Archive, 18 June 2010

Informed consent: critical for legal and ethical research

Inform research participants about:

- 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...

Foundations for consent

- Historical – Nuremberg Code, Geneva Convention, Universal Declaration of Human Rights, Declaration of Helsinki 1964
- Philosophical theories
 - Consequentialist (e.g. utilitarianism)
 - Deontological (e.g. rights or duties)
 - Situational (e.g. contextual)
- Need to balance...
 - Benefits of research
 - Best interests of participants
 - Obligations to wider audiences

Diverse views of IC in social research

- Society-wide growth of regulation; 'risk society'
- Attempt to respect autonomy of individuals
- Based on modern/rational individual, primacy of 'choice'
- Constraint on researcher autonomy
- Simplifies compliance with DPA
- Enables authentic collaboration with participants

Is 'fully' informed consent possible?

- Active and legitimate debate about this
 - Not possible for emergent research
 - “if there were full information, there would be no reason to conduct the research” (Reynolds, 1979; 95)
- Is IC the right model for social research?
- Even some medical research is using other approaches
 - Fully IC not possible for using DNA in stem cell research
- Real purpose of IC – to avoid deception or coercion (O’Neill)

What types of consent are needed?

- Engagement in the research process
Who approves transcripts?
- Use of their data/materials in various outputs, presentations, publications
Who approves research outputs?
- Data sharing and archiving
What about unknowable future uses of data?

A good consent form...

- Meets requirements of DP 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,....) where this is relevant
- Simple
- Avoids excessive warnings
- Complete for all purposes: use, publishing, sharing

Issue 1: When to ask for consent

	Pros	Cons
One-off	<ul style="list-style-type: none">• Simple• Least hassle of participant	<ul style="list-style-type: none">• Research outputs (even questions, not known in advance)• Participants will not know all content they will contribute
Process	<ul style="list-style-type: none">• Most complete for assuring active consent	<ul style="list-style-type: none">• Might not get consent needed before losing contact• Repetitive, can annoy participant

Issue 2: Right to withdraw

- Right to withdraw – one of key features of consent
 - Extensible information
 - Free to discontinue
- What about already collected data?
 - Not usually allowed (at least in most surveys)
 - But most likely would be discussed
- What if project is longitudinal?
 - Timescapes solution

Issue 3: Format for consent

- Written
 - More solid legal ground (participant agreed to disclose confidential info)
 - Not possible for some cases: infirm, illegal activities
 - Can be perceived to be off-putting
 - Can help (or even be 'required') by RECs
 - May offer more protection for researcher
- Verbal - with or without recording
 - Can be difficult to make all issues clear verbally
 - Possibly greater risks for researcher
 - Best if recorded
- Law is not specific
 - Written consent not used on large surveys-implicit by taking part
 - Need to match format of consent with research content

Issue 4: Types of material

- Ranging from less sensitive (survey) to highly sensitive (NHS protocols for medical)
- Most qual 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 useless by anonymising (blurring)
 - Gaining consent or limiting access are better alternatives

Issue 5: Special cases of participation

- Children
 - under 16s not presumed competent
 - But if they ‘understand’, then parental consent not necessary, but...
- Employees
- Vulnerable - need to balance
 - Protection from harm with
 - Right to participate