

Research ethics: Data protection, confidentiality and consent

Data Management and Sharing Workshop
Vienna, 14-15 April 2010 WISDOM

Session topics

- Legal and ethical aspects of protecting, managing and sharing confidential research data
- European, Austrian and British policy contexts
- Dealing with confidential research information and personal data
- Informed consent – interpretation, forms
- Developing agreements for obtaining informed consent from participants - including consent for data sharing

Focus

- Research with people as participants/studied subjects
- Confidential research data
 - Legal aspects
 - Ethical aspects
- Managing and sharing data:
 - Primary research data use
 - Data use in teams of researchers/institutions
 - Data re-use
 - Data publishing
 - Data archiving

Stakeholders in research

- Researchers
- Participants
- Funding agencies
- Research ethics committees
- Institutions
- Government bodies
- Archives/libraries
- Wider research community
- Public

All play a role in how we deal with confidential research data

Researchers' obligations

- a duty of confidentiality towards informants and participants
- a duty to protect participants from harm by not disclosing sensitive information
- a duty to treat participants as rational, autonomous beings, able to make their own decisions on how the information they provide can be used, shared and made public (through informed consent)
- a duty to inform participants how information and data obtained will be used, processed, shared, disposed of, prior to obtaining consent
- a duty to wider society to make available resources produced by researchers with public funds (e.g. data sharing required by research councils).

(based on guidelines from various professional bodies)

International policies - data sharing

- OECD, UNESCO, European Strategy Forum on Research Infrastructures (ESFRI) and the Committee on Data for Science and Technology (CODATA) have policies that promote or recommend data sharing (Ruusalepp 2008; http://www.jisc.ac.uk/media/documents/programmes/preservation/data_sharing_report_main_findings_final.pdf)
- European Research Council (requires data deposit)
- Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities 2003 (includes data)
- Austrian Science Fund/Fonds zur Förderung der wissenschaftlichen Forschung (requires data deposit; also a signatory to Berlin Declaration)
- Research funders' policies <http://www.sherpa.ac.uk/juliet/>

International policies- data protection

- Directive 95/46/EC of the European Parliament (Data Protection Directive)
 - Protects right to privacy in the processing of personal data, and
 - Enables data sharing across the EU
- European Convention on Human Rights (ECHR) – Article 8 - privacy in family life
- National laws drafted to interpret international agreements
 - UK Data Protection Act (1998)
 - Austrian Datenschutzgesetz 2000 - DSG 2000
 - <http://www.dsk.gv.at/site/6248/default.aspx>

Data Protection Acts

Apply only to personal data, not to all research data, not to all confidential data; but what are personal data?

UK DPA 1998

- relate to a living individual
- the individual can be identified from those data or from those data and other information
- include any expression of opinion about the individual

Austrian DSG 2000

- Data" ("Personal Data") [Daten" ("personenbezogene Daten")]: Information relating to data subjects (sub-para. 3) who are identified or identifiable

Confidential data are...

- Data that can be connected to the person providing them
Directly or indirectly identifying information: names, addresses, occupation, sensitive data that incriminate participant or third party, photograph, etc.
- Data or info given in confidence and data agreed to be kept confidential (secret) between 2 parties that are not in the public domain
Information on business, income, health, medical details, opinion, etc.

Sensitive data are...

Data regarding an individual's race or ethnic origin, political opinion, religious beliefs, trade union membership, physical or mental health, sex life, criminal proceedings or convictions, ...
(DPA1998 and DSG 2000)

DSG 2000 – Research uses of data

Permissible uses of data (if results not specific to data subjects) (Sec. 46)

- Already in public domain
- Lawfully collected for other purposes
- “Indirectly personal” (not identifiable by legal means)

And even if these conditions not met, use is permitted with participant consent

And even if consent can not be obtained, research may be permissible if

- It is in the public interest
- Professional aptitude of applicant is demonstrated

In sum: data protection is not intended to, and does not, inhibit ethical research

Data Protection Law

Personal data should be:

- processed fairly and lawfully
- obtained and processed for a specified purpose
- adequate, relevant and not excessive for the purpose
- accurate
- not kept longer than necessary
- processed in accordance with the rights of data subjects, e.g. right to be informed about how data will be used, stored, processed, transferred, destroyed, ...; right to access info and data held
- kept secure
- not transferred abroad without adequate protection

- only disclosed if consent has been given to do so (exception e.g. legal reasons)
- every individual has the right to access info and data held

If data are anonymised (personal identifiers removed) then DP laws will not apply as these no longer constitute 'personal data'

Data Sharing Review of the DPA

- Carried out in 2008 , requested by Prime Minister
- Concludes that greater use could be made of the ability to share personal data safely, particularly in the field of research and statistical analysis, e.g.:
 - allow important statistical and research analysis to proceed, while minimising the risk of identifying individuals from within datasets
 - ‘safe havens’ to be developed as an environment for population-based research and statistical analysis in which the risk of identifying individuals is minimised

<http://www.justice.gov.uk/reviews/datasharing-intro.htm>

Which ethical/legal aspects apply?

- Ethical guidelines – crucial
- Data Protection Acts – only for personal data
- UK: FoIA, SRSA, HRA, EIA – marginal (fears far greater than real effects)

Implications for research with confidential data

- Not all research data are personal data !
- Is there a need to collect personal data or confidential data in research?
- Levels of confidentiality needed are research related
e.g. oral history vs. community study
- Take reasonable steps to protect identities
- Avoid over-estimating confidentiality (no paranoia)

Data sharing and ethical concerns

- Most UK research with human participants requires ethical review by a Research Ethics Committee (REC)
- Potential tension between data sharing and data protection/research ethics
- RECs ensure ethical conduct in research and protection of safety, rights and well-being of research participants
 - guidelines/regulations on ethical aspects of data collection, dealing with participants, primary data uses
 - few guidelines on data sharing or re-use
- Data archives (UKDA/ESDS) ensure ethical re-use of research data, protection of participants and safeguarding of personal data
 - data anonymisation
 - regulate data access
- Data sharing is NOT violation of DPA or research ethics

How archives enable confidential research data to be shared

- Obtain informed consent (early planning)
also for data sharing and future storage
- Protecting identities
e.g. anonymisation
- Restricting/regulating access
e.g. by group, use, time
- Securely storing personal or sensitive data

Always in dialogue with participants

Regulating access to data

At UK Data Archive:

- archived data NOT in public domain
- use of data for specific purposes only after user registration
- data users sign legally binding End User Licence – e.g. not identify any potentially identifiable individuals
- stricter access regulations for confidential data (case by case basis):
 - access to approved researchers only
 - requiring data access authorisation from data owner prior to data release
 - confidential data under embargo for given time period
 - secure access to data

Researchers:

- consider access to data and safe storage

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

The future ...

- Increased drive by Research Councils, funders and publishers towards data sharing (national and international)
- More formal data sharing policies
- Data Management Planning requirements
- Better guidelines, technologies and support for researchers to enable data sharing, especially where confidential data are involved

Resources

- British Sociological Association
[\[http://www.britsoc.co.uk/equality/Statement+Ethical+Practice.htm\]](http://www.britsoc.co.uk/equality/Statement+Ethical+Practice.htm)
- British Sociological Association - Visual Sociology Group – Ethical guidelines
[\[http://www.visualsociology.org.uk/about/ethical_statement.php\]](http://www.visualsociology.org.uk/about/ethical_statement.php)
- Clark, A. 2006. Anonymising research data. NCRM Working Paper Series 7/06. ESRC National Centre for Research Methods. [\[http://www.ncrm.ac.uk/research/outputs/publications/WorkingPapers/2006/0706_anonymising_research_data.pdf\]](http://www.ncrm.ac.uk/research/outputs/publications/WorkingPapers/2006/0706_anonymising_research_data.pdf)
- Data Protection Act 1998 [http://www.uklegislation.hmso.gov.uk/acts/acts1998/ukpga_19980029_en_1]
- ESRC Framework for Research Ethics
[\[http://www.esrcsocietytoday.ac.uk/ESRCINFOCENTRE/OPPORTUNITIES/research_ethics_framework/\]](http://www.esrcsocietytoday.ac.uk/ESRCINFOCENTRE/OPPORTUNITIES/research_ethics_framework/)
- Freedom of Information Act 2000 [http://www.opsi.gov.uk/acts/acts2000/ukpga_20000036_en_1]
- Human Rights Act 1998 [http://www.opsi.gov.uk/acts/acts1998/ukpga_19980042_en_1]
- Methodological Issues in Qualitative Data Sharing and Archiving
[\[http://www.cardiff.ac.uk/socsi/hyper/QUADS/index.html\]](http://www.cardiff.ac.uk/socsi/hyper/QUADS/index.html)
- National Centre for Research Methods - informed consent project [<http://www.southampton.ac.uk/socsci/sociology/research/projects/informedcontent.html>]
- Oral History Society guidelines [<http://www.ohs.org.uk/ethics/>]
- Social Research Association [<http://www.the-sra.org.uk/ethical.htm>]
- UKDA Manage and Share Data [<http://www.data-archive.ac.uk/sharing/>]