

Managing and sharing research data: focus on consent, confidentiality and disclosure

Managing and Sharing Research Data workshop
London, 2 December 2009

Workshop topics

- Legal and ethical aspects of managing and sharing confidential research data
- Dealing with confidential research information and personal data
- Developing agreements for obtaining informed consent from participants (incl. consent for data sharing)
- Anonymisation techniques and access regulations to enable re-use and sharing of research data
- Planning data management and links with ethical review

Focus

- Confidential research data
- Research with people as participants / studied subjects

- Managing and sharing data:
 - Primary research data use
 - Data use in teams of researchers / institutions
 - Data re-use
 - Data publishing
 - Data archiving

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 is 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)

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

How we deal with confidential research data obtained from people as participants is informed by...

- Ethical aspects
- Legal aspects

Research ethics

Researcher has:

- 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 intelligent beings, able to make their own judgements and 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, databased, 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)

Legal aspects

- Data Protection Act (1998)
- Freedom of Information Act (2000)
- Statistics and Registration Services Act (2007)
- Human Rights Act (1998)
 - enshrines the right to respect for private and family life (Art. 8)
- Environmental Information Regulations 2004
 - public has access rights to environmental information held by a public authority (incl. universities), in response to requests; similar to Fol Act

Data Protection Act

Applies only to personal data, not to all research data, not to all confidential data

Personal data:

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

Data Protection Act – cont.

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
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- 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 is anonymised (personal identifiers removed) then the Act will not apply as this no longer constitutes 'personal data'

Data Protection Act – cont.

Exceptions for personal data collected as part of research:

- can be retained indefinitely (if needed)
- can be used for other purposes in some circumstances, but people should still be informed
- sensitive personal data can only be processed for research purposes if:
 - explicit consent (ideally in writing) has been obtained; or
 - medical research by a health professional or equivalent with duty of confidentiality; or
 - analysis of racial/ethnic origins for purpose of equal opportunities monitoring; or
 - in substantial public interest and not causing substantial damage and distress

Data Sharing Review of the DPA

- Carried out in 2008 , requested by Prime Minister
- Concludes *inter alia* 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>)

Freedom of Information Act

Little relevance for researchers, for data sharing and for dealing with confidential research data

Primary purpose: increase transparency in public sector

- People have right to request access to recorded information held, or be informed whether info is held
- Applies to public sector only (incl. universities)
- Research data can be requested; copyright stays with original researcher
- Might be superseded by terms of Depositor Agreement (UKDA)
- Does not apply to personal data

Exceptions (applicable to research):

- Info accessible by other means (e.g website, publications for sale,..)
- Info intended for future publication – balance between when publication intended to be due and what is in public interest (if in public interest to release info earlier, then may be granted)
- Commercial interest (applicable to certain research)
- Collating and providing info too costly

Statistics and Registration Services Act

No immediate relevance for research data created by academics

- Applies only to ONS data (Office of National Statistics)
- Section 39 of Act – disclosure of ‘personal information’ is a criminal offence
- Exceptions, e.g. notion of an ‘approved researcher’

Conclusion ethical / legal aspects

- Ethical guidelines – crucial
- DPA – only for personal data
- FoIA, SRSA, HRA, EIA – marginal

Implications for research with people and dealing 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)

Confidential research data can be used and shared by

- Obtaining informed consent
 - 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

Researchers applying ethical and legal aspects

Inform research participants about (where relevant):

- 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,...

and gain informed consent ...

Foundations for consent

- Historical – Nuremberg, Geneva Convention, Declaration of Human Rights
- 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

Why has IC permeated 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
- Makes compliance with DPA easier
- 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
 - Should IC be required for vaccinations?
- Real purpose of IC – to avoid deception or coercion (O’Neill)

What types of consent are sought?

- 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?

Research ethics reviews

- Most 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

Research ethics reviews – cont.

- Data sharing is NOT violation of DPA or research ethics
- Reconcile data sharing with ethical review:
 - protect personal data and preserve confidentiality where explicitly required, unless consent for disclosure
 - exclude identifiable information from data sharing (unless consent)
 - plan data sharing when designing research
 - research data with sensitive or confidential information – consider data sharing carefully, but do not dismiss as impossible

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

The future ...

- Increased drive by Research Councils, funders and publishers towards data sharing (national & 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>]
- British Sociological Association - Visual Sociology Group – Ethical guidelines [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]
- Data protection Act 1998 [http://www.uklegislation.hmso.gov.uk/acts/acts1998/ukpga_19980029_en_1]
- ESRC Research Ethics Framework [http://www.esrcsocietytoday.ac.uk/ESRCInfoCentre/Images/ESRC_Re_Ethics_Frame_tcm6-11291.pdf]
- 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/socsci/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/>]
- Research ethics in art, design, media [<http://www.biad.uce.ac.uk/research/rti/ethics/>]
- Social Research Association [<http://www.the-sra.org.uk/ethical.htm>]