Confidentiality and Protection of Privacy

Standards for Ethical Review

Andrea Kanneh
21st Jan 2016
Outline

• Key Concepts around Confidentiality and Privacy
• Existing Ethical Standards
• Legal Issues
• Other Issues/considerations
Examples raised before

• Reuse of Data (from Ethical and Unethical Research) - Dr Philpott-Jones
• Research Design - Data collection – Dr Roopchand-Martin
• Genetic Research - Dr Roach
• Informed Consent, Scientific Validity - Data Collection, Processing and Storage – Dr Trotman Edwards
• Research Misconduct - Fraudulent activity, Harking, Self Plagiarism, Retractionwatch.com – Dr Perkins
Key Concepts
Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2, 2014; Chapter 5)

Information

• **identifiable** - reasonable expectation to identify an individual, when used alone or combined with other available information.

• **non-identifiable** - does not identify an individual, when used alone or combined with other available information
Data, Information, Knowledge

- **Data** - Elementary/not organised representation [Non-identifiable – TCPS2]
- **Information** - Data organised to have meaning [Identifiable – TCPS2]
- **Knowledge** – data or information organised and processed to convey understanding, experience, accumulated learning and expertise [Analysed]
Data, Information and Knowledge

**Data** - Elementary/not organised representation

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Data = non-identifiable information does not identify an individual, when used alone or combined with other available information
Data, Information and Knowledge

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Data or Information?
## Data, Information and Knowledge

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## Data, Information and Knowledge

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*Information* - Data organised to have meaning
Privacy

• an individual’s right to be free from intrusion or interference by others.

• Individuals have privacy interests in relation to their bodies, personal information, expressed thoughts and opinions, personal communications with others, and spaces they occupy.

• An important aspect of privacy is the right to control information about oneself.

• The concept of consent is related to the right to privacy.
Are there any *Privacy* issues to consider in the following?

Case 30 – Donation of Stem-cell Research and
Case 45 – Genetic Research on an Island Population
Key Concepts continued

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2, 2014; Chapter 5)

Confidentiality

• the obligation of an individual or organization to safeguard entrusted information.

• …includes obligations to protect information from unauthorized access, use, disclosure, modification, loss or theft.

• …essential to the trust relationship between researcher and participant, and to the integrity of the research project.
Are there any *Confidentiality* issues to consider in the following?

Case 30 – Donation of Stem-cell Research and Case 45 – Genetic Research on an Island Population
Research involving human subjects ...may [also] either generate records or make use of existing records containing biomedical or other information about individuals who *may or may not be identifiable* from the records or information.
Among the essential features of ethically justified research ... including research with identifiable human tissue or data, are that the research offers a means of developing information not otherwise obtainable, that the design of the research is scientifically sound [integrity of data], and that the investigators and other research personnel are competent. (Recall Case 42)

... it considers provisions for monitoring of data ... 

Potential conflicts of interest of sponsors – who should access to data or analyse the data - Sponsors or Investigators/Researchers? [integrity]
Standards for Ethical Review

International Ethical Guidelines for Epidemiological Studies (CIOMS, WHO 2009)

Guideline 1 Ethical justification and scientific validity

[REC must ensure].. vigorous efforts to protect confidential data, and pooling data to larger entities are all part of good study design
What could we send to our Foreign Partner

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**Information** - Data organised to have meaning
Data Integrity

Designer → Pharmaceutical Company → Research Team → Research Participants

Business Partners → Government → Research Team → Research Participants

Designer → Manufacturing Company → Research Team → Research Participants

Video from Stanford Design School
http://dschool.stanford.edu/bernie-roth-videos/
Standards for Ethical Review
Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2, 2014; Chapter 5)

**Article 5.1 (Confidentiality)**

1. Researchers shall safeguard information entrusted to them and not misuse or wrongfully disclose it.

2. Institutions shall support their researchers in maintaining promises of confidentiality
   - applies to information obtained directly from participants, or from other researchers
   - Researchers are expected to be aware of ethical codes (such as professional codes of conduct) or laws
Standards for Ethical Review

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2, 2014; Chapter 5)

Article 5.5A – Use of Secondary Data (use in research of information originally collected for a purpose other than the current research purpose)

Researchers who have not obtained consent from participants for secondary use of identifiable information shall only use such information for these purposes

- identifiable information is essential.;
- ...it is unlikely to adversely affect the welfare of individuals...
- the researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information;
- the researchers will comply with any known preferences previously expressed by individuals about any use of their information;
- it is impossible or impracticable ...to seek consent ...,and
- the researchers have obtained any other necessary permission for secondary use of information for research purposes.
Standards for Ethical Review
International Ethical Guidelines for Epidemiological Studies (CIOMS, WHO 2009)

Review/Exempt?

Guideline 2 Ethical review committees

[REC must ensure].. some observational studies, such as those utilizing publicly available or anonymous data, may not be subject to prior review and approval by an ethical review committee under the regulations of the local jurisdiction.

When in doubt...For example, a study of sensitive topics or behavior (illicit drug use; domestic violence; etc.) may merit review because of its potential effects on a community or group even if the data were to be recorded anonymously.
Prospective subjects should be informed of limits ... of investigators to ensure strict confidentiality and of the foreseeable adverse social consequences of breaches of confidentiality.

Patients have the right to expect that their physicians .. hold all [their] information in strict confidence and disclose it only to those who need, or have a legal right to, the information.
Ethics and Law
Law Data Protection Act 2011

• Key Points to note:
  • What is data being used for?
  • What data is being used?
  • Who is using this data

• DNA is treated as identifiable data
  [Link to document](http://rgd.legalaffairs.gov.tt/laws2/alphabetical_list/lawspdfs/22.04.pdf) Pg 6

• Key enforcement: monitoring and control

DPA pg 4
Other Issues/Considerations

• Internet based Research – Authentication
• Human Error
• Process/System Error
Summary of Presentation

• Key Concepts – Privacy, Confidentiality, Integrity, Data, Information
• Existing Ethical Standards – CIOMS and TCPS2
• Legal Issues – Data Protection Act
• Other Issues – Internet Based Research, People Issues

Thank You