

Confidentiality and Protection of Privacy

Standards for Ethical Review

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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

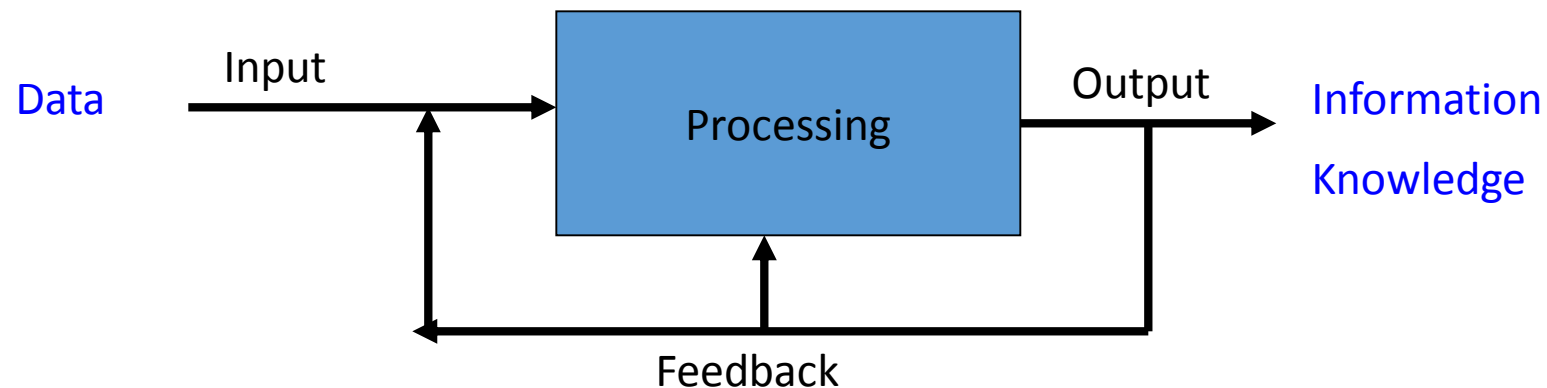
Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2, 2014; Chapter 5)

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

ETH	45
PA	30
AD	30
BR	15

Table 1

1	SI
2	SI
3	SI
4	LO

Table 2

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

Data, Information and Knowledge

ETH	45
PA	30
AD	30
BR	15

Table 1

+

1	SI
2	SI
3	SI
4	LO

Table 2

=

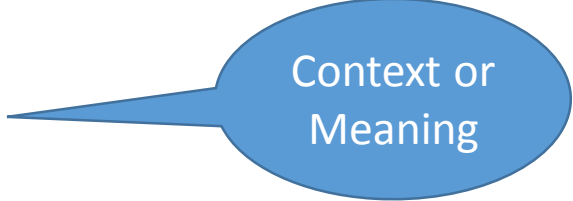
ETH	45	1	SI
PA	30	2	SI
AD	30	3	SI
BR	15	4	LO

Table 3

Data or Information?

Data, Information and Knowledge

Speaker	Duration	Session	Location
ETH	45	1	SI
PA	30	2	SI
AD	30	3	SI
BR	15	4	LO



Context or
Meaning

Data or Information?

Table 3

Data, Information and Knowledge

Speaker	Duration	Session	Location
ETH	45	1	SI
PA	30	2	SI
AD	30	3	SI
BR	15	4	LO

Table 3

Information - Data organised to have meaning

Key Concepts *continued*

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

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

Standards for Ethical Review

International Ethical Guidelines for Biomedical Research Involving Human Subject, (CIOMS 2002)

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.

Standards for Ethical Review

International Ethical Guidelines for Biomedical Research Involving Human Subjects Studies (CIOMS, 2002)

Guideline 1 Ethical justification and scientific validity

*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

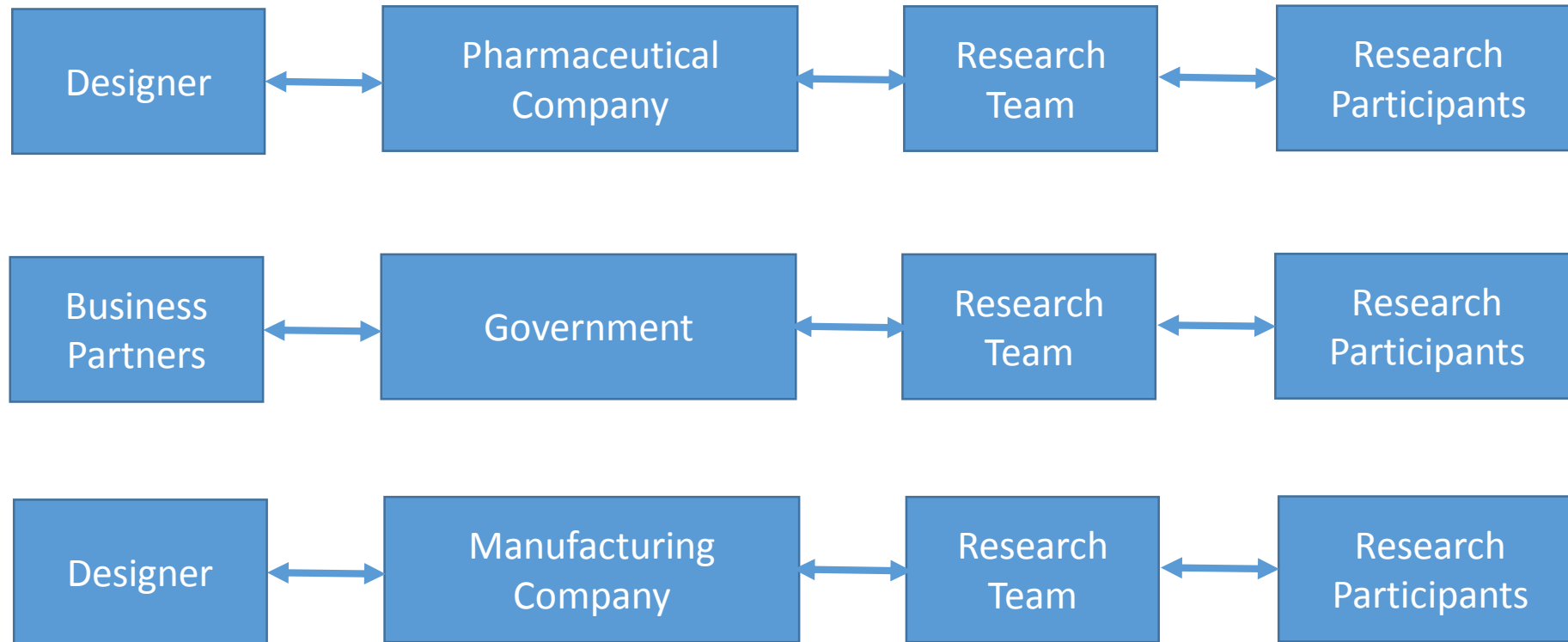
What could we send to our Foreign Partner

Key	Speaker	Duration	Session	Location	Time	Usefulness	Difficulty
E010	THE	45	1	SI	1	1	2
E011	AP	30	2	SI	1	1	2
E012	DA	30	3	SI	1	1	2

Table 3

Information - Data organised to have meaning

Data Integrity



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**

Standards for Ethical Review

International Ethical Guidelines for Biomedical Research Involving Human Subjects Studies (CIOMS, 2002)

Guideline 18: Safeguarding confidentiality

*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
http://rgd.legalaffairs.gov.tt/laws2/alphabetical_list/lawspdfs/22.04.pdf Pg 6
- Key enforcement: monitoring and control

PART III	
PROTECTION OF PERSONAL DATA BY PUBLIC BODIES	
29.	Personal information.
30.	Collection of personal information.
31.	Personal information to be collected directly.
32.	Individual to be informed of purpose.
33.	Retention of personal information used for an administrative purpose.
34.	Accuracy of personal information.
35.	Protection of personal information.
36.	Storage and access of personal information in Trinidad and Tobago.
37.	Disposal of personal information.
38.	Use of personal information.
39.	Consistent purpose.
40.	Limitation on processing of sensitive personal information in possession of public body.

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