Impact of Personal Data Protection Laws in Clinical Trials

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Overview

Points to be covered:-

• Personal Data Protection Act 2012 ("PDPA")
• PDPA in clinical trials setting
• Collection/Use/Disclosure of Personal Data
• Practical examples for discussion
Personal Data Protection Act 2012

Two regimes in PDPA:

- Do Not Call (DNC) – came into force on 2 January 2014
- Data protection – came into force on 2 July 2014
- Proposed advisory guidelines for healthcare sector was released on 16 May 2014
  - Public consultation closed on 6 June 2014
  - Final guidelines likely to be released before October 2014
Coverage of PDPA:-

• All data from which an individual, living or deceased, can be identified

• Apply to personal data collected/ used/ disclosed in Singapore

• Apply to all organizations except the Government or any statutory body
Why PDPA?

To address concerns in relation to the collection, use, storage & disclosure of personal data

Individual’s right to protect personal data

Needs of the Organization
General Compliance with PDPA

Every organization must have a system to ensure compliance with these obligations under the PDPA:

- Consent
- Purpose
- Accuracy
- Access & Correction
- Protection
- Retention
- Transfer
- Openness
What is personal data?

<table>
<thead>
<tr>
<th>Data that can identify individuals</th>
<th>Anonymized data?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>NOT covered: Unless the <strong>organization can reverse the randomization</strong></td>
</tr>
<tr>
<td>Phone/fax number</td>
<td></td>
</tr>
<tr>
<td>Insurance information</td>
<td></td>
</tr>
<tr>
<td>Address</td>
<td></td>
</tr>
<tr>
<td>Email Address</td>
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<tr>
<td>NRIC number</td>
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What types of records are covered?

Electronic Data + Non-electronic Data

Source: Mister Pixel and Michela Tannoia for icon.
Consent Given

Fully notified & informed of the purpose

Deemed Consent

Data voluntarily provided and it is reasonable that the data is voluntarily provided

Consent Given

Verbal consent is good enough, but obtaining consent in writing is good practice

Unless exceptions apply
Exceptions include:

• Second Schedule – Collection of Personal Data
• Third Schedule – Use of the Personal Data
• Fourth Schedule – Disclosure of the Personal Data
Do Not Call (DNC) Regime

• Duty to comply with certain obligations before sending specified messages to individuals through a Singapore telephone number

• There are certain exclusions from the scope of the DNC Regime
Exclusions include:-

• Message sent by public agency etc which is not for a commercial purpose

• Message sent by an individual acting in a personal or domestic capacity

• Message for the sole purpose of conducting market survey or market research
Section 4(6) of PDPA:-

“Unless otherwise expressly provided in this Act-

(a) Nothing in Parts III to VI shall affect any authority, right, privilege or immunity… including legal privilege…; and

(b) The provisions of other written law shall prevail to the extent that any provision of Parts III to VI is inconsistent with the provisions of that other written law.”
Impact of PDPA on Clinical Trials

PDPA will not override these obligations:-

• Medicines (Clinical Trials) Regulations  
  – Regulation 11 provides that no individual shall be included in a clinical trial unless written consent has been obtained

• Singapore Good Clinical Practice Guidelines

• Collection/Use/Storage/Disclosure of Personal Data is covered in the Patient Informed Consent
Collect/Use/Disclose: Clinical Trials

- Deemed consent NOT applicable
- General rule: Written Consent required
- Exceptions include:
  - Regulations 11(2) and (3) of the Medicines (Clinical Trials) Regulations
  - Regulation 12 of the Medicines (Clinical Trials) Regulations
  - Internal quality assurance
  - Internal review/service improvement
Are there exceptions under the PDPA touching on use/disclosure of personal data for research?

- Research can only be done if data is provided in an individually identifiable form
- Impracticable to seek consent
- Data will **not be used to contact persons** to ask them to participate in the research
- Linkage of data to other info is **not harmful** to the individuals **AND** the benefits derived from the linkage are clearly in the **public interest**
Other exceptions?

To collect/use/disclose personal data without consent for:-

• Responding to an emergency
• Data publicly available
• Necessary to obtain legal services
• Necessary for any purpose that is clearly in the interest of the individual, but consent cannot be obtained in time and the individual would not reasonably be expected to withhold consent
Protection of Data

• No ‘one size fits all’ approach
• Design a security system considering:
  – What kind of data am I collecting?
  – Who has access to it?
  – How is it being collected? Physical? Electronic?

Source: Edward Boatman for icon.
No retention of data unless necessary for the purposes which that data was collected for, or:-

Business purposes

Legal purposes

Source: S Madsen and Yamin Alanis for icon.
No need fresh consent if:-

- Organization validly acts on behalf of individual
- Consent for disclosure given
- Collecting organization’s purposes are in accordance with the purposes which the individual consented to
Transfer of Personal Data (Overseas)

NO transfer of data outside of Singapore, unless:-

• Consent is given
• Necessary for performance
• Exemption is granted by the Commission
What if I want to collect data from a patient seeking medical care for purposes beyond those that are reasonable to provide such medical care (e.g. marketing)?

**Consent**

for that specific purpose

but cannot make it a condition to give consent
Am I permitted to use the patients’ phone numbers (e.g. provided during check-up) to call the patients to ask whether they wish to participate in a research study? Do the DNC provisions apply?

Source: Cris Dobbins for icon.
Do I need fresh consent to share the personal data that I collected for a clinical research with my sponsor?
What happens if a research participant withdraws his consent after the research has been conducted? Can we still retain his personal data?
For Discussion

What if a research participant has donated his tissue samples for research but subsequently withdraws his consent? Am I allowed to retain the tissue sample?

Source: Cris Dobbins for icon.
For Discussion

What should you do when a research subject demands to know how the research organization has been using his data?

Source: Cris Dobbins for icon.

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