Impact of Personal Data Protection Laws in Clinical Trials

RAJAH TANN

Lawyers who know Asia

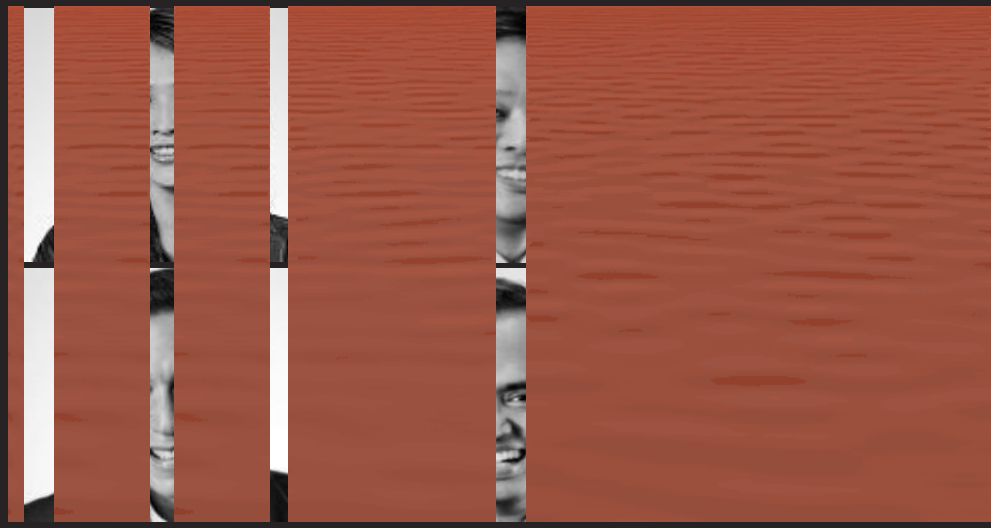
25 July 2014

Rebecca Chew

Partner, Rajah & Tann LLP

RAJAH
TANN

Lawyers who know Asia



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

Personal Data Protection Act 2012

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?

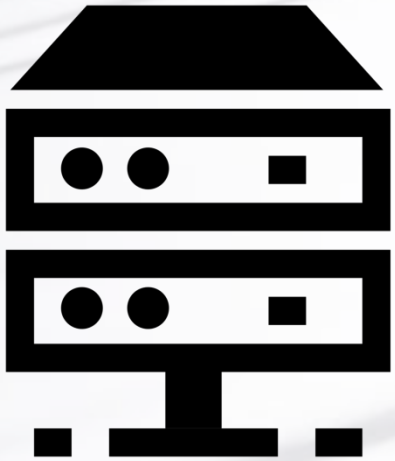
Data that can identify individuals

Name	**Phone/fax number**
Insurance information	**Address**
Email Address	**NRIC number**

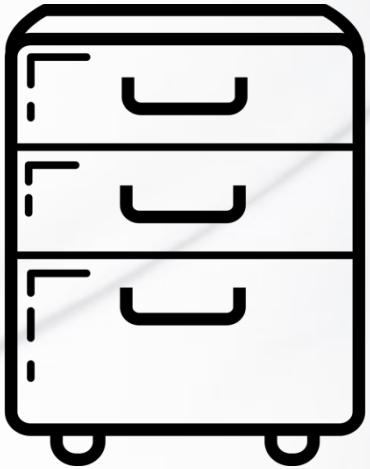
Anonymized data?

NOT covered: Unless the **organization can reverse the randomization**

What types of records are covered?



+



Electronic Data

Non-electronic Data

Source: Mister Pixel and Michela Tannoia for icon.

Collect/Use/Disclose: The Key

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

Personal Data Protection Act 2012

Exceptions include:-

- Second Schedule – Collection of Personal Data
- Third Schedule – Use of the Personal Data
- Fourth Schedule – Disclosure of the Personal Data

Personal Data Protection Act 2012

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

Personal Data Protection Act 2012

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

Impact of PDPA on Clinical Trials

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

Use/Disclosure: Clinical Trials

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

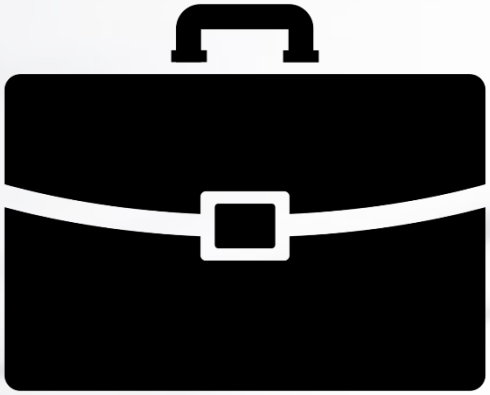
- No 'one size fits all' approach
- Design a security system considering:-
  - What kind of data am I collecting?
  - Who has access to it?
  - How is it being collected? Physical? Electronic?

Source: Edward Boatman for icon.

Storage/Retention of Personal Data

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.

Transfer of Personal Data (Within Singapore)

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

Scenario

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

For Discussion

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.

For Discussion

Do I need fresh consent to share the personal data that I collected for a clinical research with my sponsor?

Source: Cris Dobbins for icon.

For Discussion

What happens if a research participant withdraws his consent after the research has been conducted? Can we still retain his personal data?

Source: Cris Dobbins for icon.

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.

Disclaimer

The material in this presentation is prepared **for general information only and is not intended to be a full analysis** of the points discussed. This presentation is also not intended to constitute, and should not be taken as, legal, tax or financial advice by Rajah & Tann LLP. The structures, transactions and illustrations which form the subject of this presentation may not be applicable or suitable for your specific circumstances or needs and you should seek separate advice for your specific situation. Any reference to any specific local law or practice has been compiled or arrived at from sources believed to be reliable and [Rajah & Tann LLP] does not make any representation as to the accuracy, reliability or completeness of such information.

RAJAH TANN

Lawyers who know Asia

Thank You