# Personal Data Issues in Clinical Trials

Combined CRCS – CRP Forum

Date: 26 August 2016

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RAJAH & TANN

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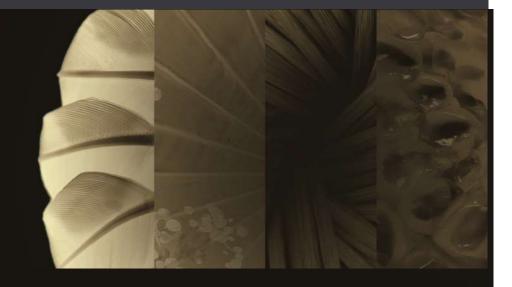


#### **Outline**

- 1) What Is Personal Data?
- 2)Overview of Personal Data Obligations
- 3) Selected Personal Data Topics
- 4) Recent Enforcement Actions
- 5) Useful Resources



# What is Personal Data?



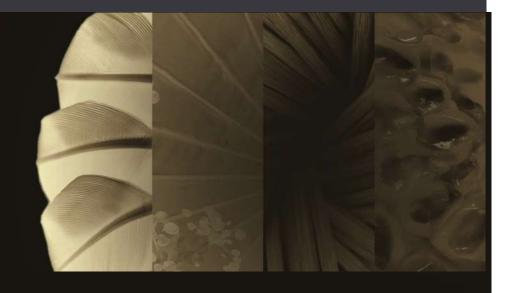
#### What is Personal Data?

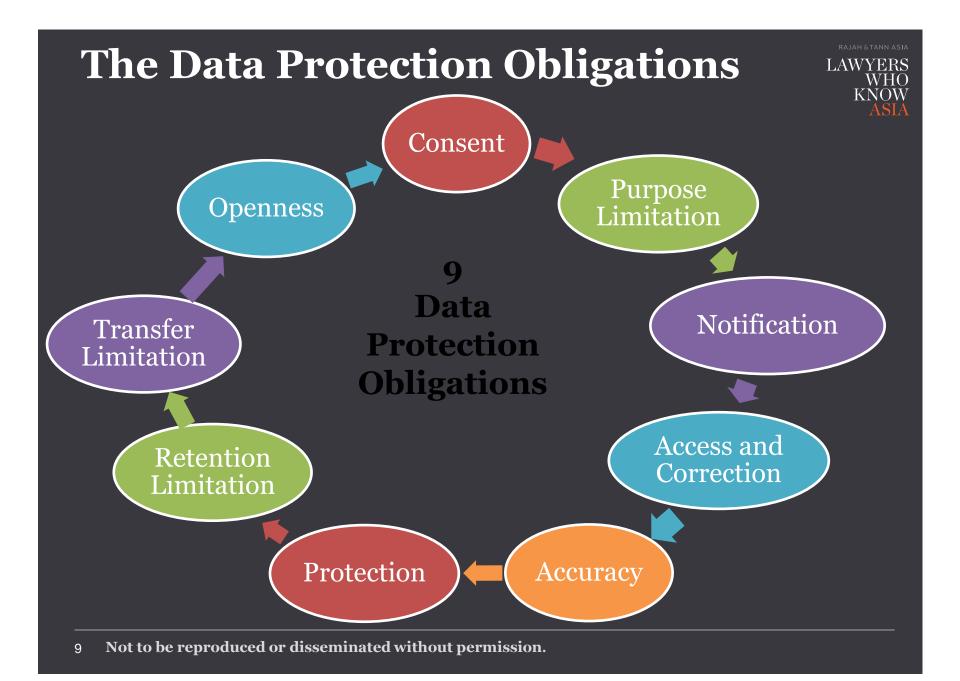


- ➤ Data about an individual, whether living or deceased, who can be identified from that data
- ➤ Anonymised data: identifying information removed and remaining data does not identify any particular individual.



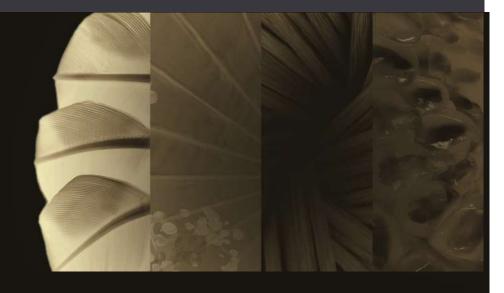
# Overview of Data Protection Obligations







# Specific Data Protection Issues In Clinical Trials



#### **Consent Obligation**



- > Individuals' consent required before organization can collect, use or disclose personal data, unless required or authorised by law
- Consent can be express or deemed
- > Consent can be obtained in various ways including consent forms, application forms, privacy policies etc.

#### **Example**



- > John visits Hospital for the first time and fills out patient registration form.
- > Deemed to have consented to collection, use and disclosure of his personal data for medical care, associated tests, follow-up consultations and the convening of case conference with other Hospital doctors
- > Clinical research?



# **Use of Personal Data for Research Purpose Without Consent**

- Research cannot be accomplished unless personal data is in individually identifiable form
- > Impractical to seek consent for use
- ➤ Personal data will not be used to contact persons to ask them to participate in research
- ➤ Linkage of personal data to other information not harmful to individuals and benefits are clearly in public interest

## **Purpose Limitation Obligation**



- > Organizations may collect, use or disclose personal data only for purposes:
  - that a reasonable person would consider appropriate; and
  - that was disclosed to the individual
- > Cannot require individual to consent to collection, use or disclosure of his personal data beyond what is reasonable to provide the product or service

## **Example**



- > Form states that Hospital will collect, use and disclose personal data for providing him with treatment, processing payment and clinical research
- > If he does not sign he cannot get the treatment
- > Does this comply with the purpose limitation obligation?

## **Notification Obligation**



- Organisation must notify the individual of purpose(s) before collection, use or disclosure of the personal data
- ➤ "appropriate level of detail" to determine reasons for which organisation will be collecting, using or disclosing personal data
- > need not specify every activity it will undertake

#### Obtaining Personal Data from 3rd **Parties**

- > Review the participant's consent form
- > Expressly consent to collection, use and disclosure of personal data for clinical trials
- > Expressly notified and consented to personal data disclosed to organisation for clinical trials
- > Agreement with medical institutions to contain warranty that it has obtained necessary consents and also indemnities

#### **Other Relevant Obligations**



- ➤ Access obligation
- > Security obligation
- > Retention limitation obligation
- > Transfer limitation obligation

# General Compliance Measures Required For Organisations

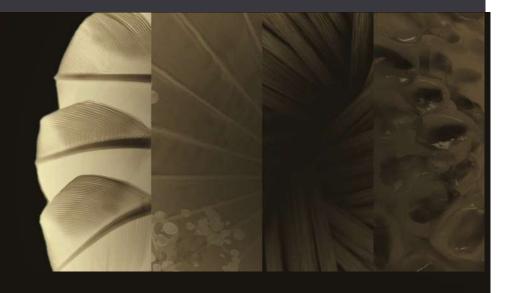


- ➤ Appoint a Data Protection Officer
- Develop policies and practices to comply with the PDPA
- Develop a process to receive and respond to PDPA related complaints
- ➤ Communicate and educate staff on their obligations and the company's PDPA procedures and policies
- ➤ Make information relating to the above processes available





# Recent Enforcement Efforts



#### Recent Instances of Data Breaches



- > 17 September 2014 : Kbox Data Leakage
- Kbox was reported to have been exposed to an attack by hackers
- ❖ Personal data of 317,000 Kbox members leaked
- ❖ Information leaked included the names, addresses, mobile phone numbers and NRIC numbers
- ❖ Kbox was fined \$50,000



#### **Recent Enforcement Actions**



- > Finantech K Box's IT contractor (fined \$10K)
- ➤ Institution of Engineers members' personal data leaked and posted online (fined \$10K)
- > Challenger Technologies emails with member's personal data wrongly sent to another member (warning issued)

#### **Recent Instances of Data Breaches**



- > 15 March 2015 : Personal Information Found Among Raffles Place Rubbish
- ❖ The Straits Times reported that documents containing personal data was found among the rubbish in the Raffles Place area.
- ❖ Some of the personal data found includes photocopies of passports, resumes of various professionals and details of commissions paid to property agents.
- Measures should have been put in place to ensure the proper disposal of personal data.



#### **Useful Resources**



#### **Useful Resources**



- > PDPC Website (<u>www.pdpc.gov.sg</u>)
  - Advisory Guidelines on Key Concepts in the Personal Data Protection Act (revised on 15 July 2016)
  - ➤ Advisory Guidelines on the Personal Data Protection Act for Selected Topics (revised on 9 Jun 2016)
  - ➤ Advisory Guidelines for the Healthcare Sector (published on 11 Sep 2014)

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# Thank You

