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Personal Data Issues in Clinical Trials

Combined CRCs – CRP Forum

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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



The 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 (www.pdpc.gov.sg)
 - *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

