



MINISTRY OF HEALTH
SINGAPORE

Human Biomedical Research Act

Reflection on Transition

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Human Biomedical Research Act (HBRA)

- **Passed by Parliament in August 2015**
...being brought into operation gradually in phases
- **Implementation Plan & Schedule**
 - **Phase 1** : Administrative provisions – **Activated on 1 Jul 2016**
 - **Phase 2** : Prohibition against commercial tissue trading – **Activated on 1 Jan 2017**
 - **Phase 3** : Regulation of human biomedical research – **Activated on 1 Nov 2017**
 - ✓ Functions and duties of RI
 - ✓ Functions and duties of IRB
 - ✓ Approval and conduct of restricted research
 - ✓ Amendment to Third, Fourth and Fifth Schedules of the HBRA → *In response to stakeholder concern and feedback on consent requirements & rHBR scope*
 - **Phase 4** : Regulation of research tissue banking – **Target last quarter 2018**
 - ✓ *Duties of tissue bank (S34-36) and other controls to be prescribed*
 - ✓ *Restrictions on activities relating to human tissue (S37)*
 - ✓ *Compelling person to donate tissue (S38)*
 - ✓ *Restriction on disclosure of information on tissue donor (S39)*
 - ✓ *Savings & transitional provisions for legacy human biological material (64)*

**HBR
Framework**

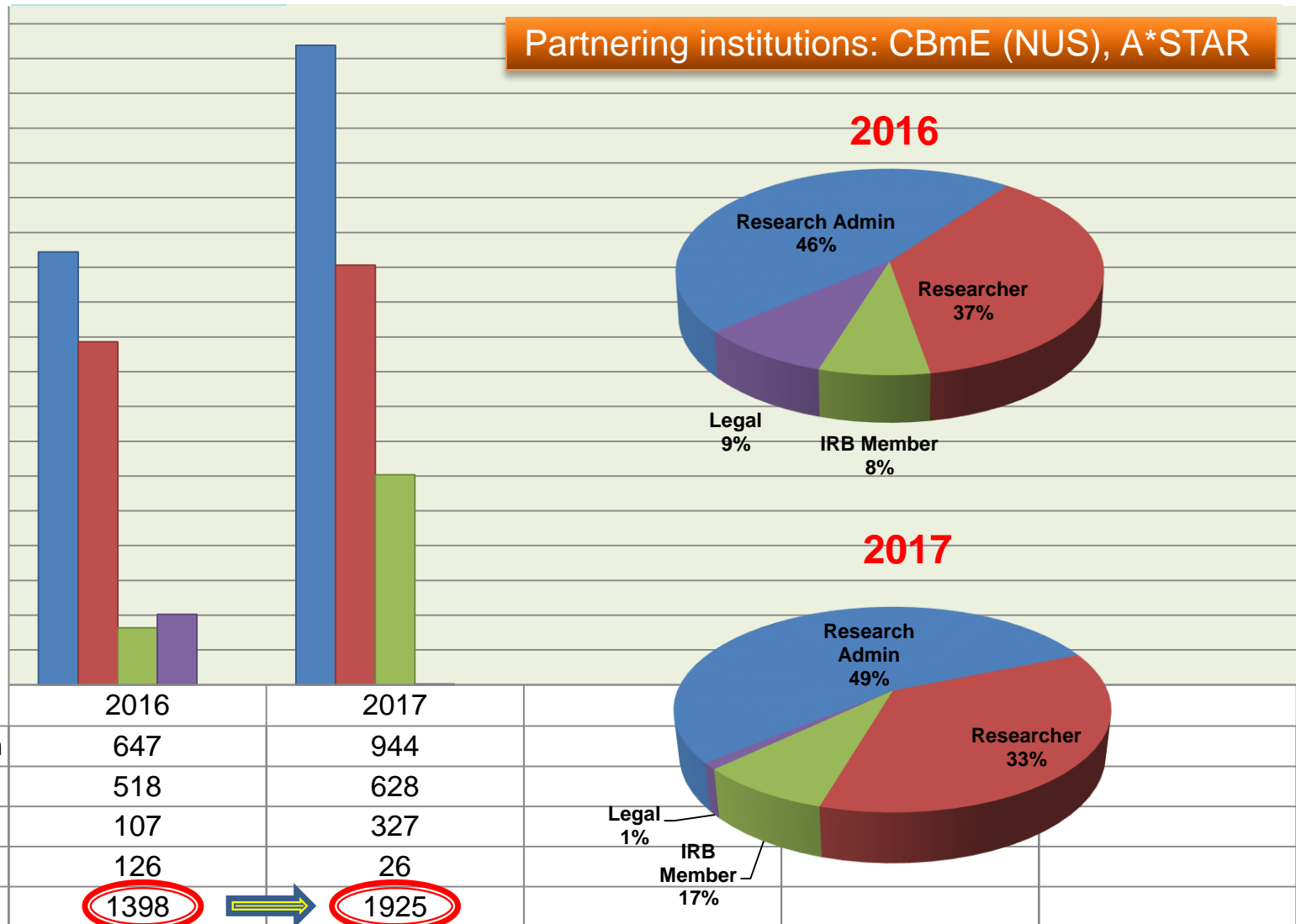
**HTR
Framework**

Extensive stakeholder communication and engagement effort from MOH

Partnering institutions: CBmE (NUS), A*STAR

Number of Attendees

975
925
875
825
775
725
675
625
575
525
475
425
375
325
275
225
175
125
75
25

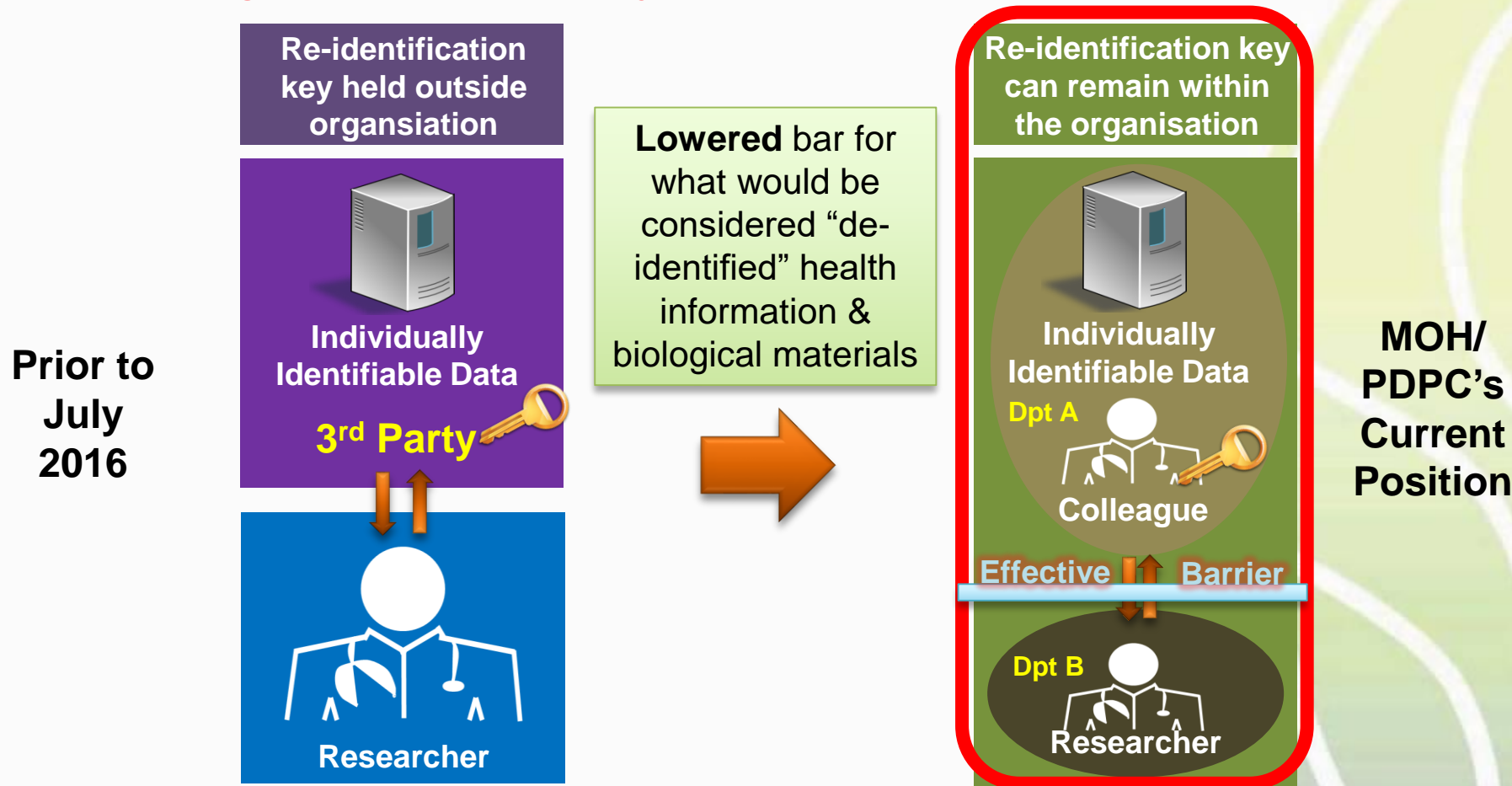


* Stakeholders consulted before HBRA was passed in Parliament in Aug 2015: 647

Various feedback received and considered which led to policy & legislative changes

1. Concern on difficulty in fulfilling the requirement for “de-identification”

❖ MOH has aligned with PDPC’s policy position on de-identification



PDPC’s example of effective barriers- restricting access by a group of users within the organisation to information held by the organisation that could re-identify an individual (i.e. the key) by e.g.:

1. Access restrictions to prevent (researcher) from Dpt B from gaining access to data (key) held by Dpt A
2. Organisation makes the unauthorized attempt to re-identify individuals a breach of terms of employment

De-identified / anonymised health information is **out of scope** of HBRA.

2. Concern on inability to re-contact patients to seek consent for research

❖ Requirement of Consent to Re-contact Patients to Seek Consent for Research

PDPC clarified that **consent is not required for re-contacting patients** for the purpose of seeking their consent for research. This position is **not based on the 'deemed consent' provision** under the PDPA, but **on the principle that the act of re-contacting the patients facilitates consent taking**.

➔ MOH RHS Guidance (post PDPA) on 'who' should re-contact:

- For research using individually-identifiable health information, only **members of the care team/related to the care team** (e.g. employees of that organisation who are working with the treating physician) should contact patients to obtain consent to participate in Human Biomedical Research
- The institutions have the **flexibility** to determine by themselves who among their personnel would be considered as being part of a "care team"



Scenario : Obtaining consent for Human Biomedical Research

Peter visits hospital *ABC* for his medical review of his colon cancer condition. His treating physician informs Peter of a human biomedical research conducted by a researcher in research institute *DEF* looking at colon cancer prevention study. The treating physician asks if Peter is willing to consider to participate in the research. Peter agreed to the referral and was subsequently contacted by the researcher for his consent to be obtained to participate in the human biomedical research.

3. Concern on difficulty in fulfilling the criteria of “impracticable”

Lowered the standard of “impracticable” (almost impossible) to “disproportionate”

❖ HBM – Human Biological Material ❖ HI – Health Information

Waiver of Requirement for Appropriate Consent for HBM and HI

IRB must be satisfied that –

- The research may not be practicably carried out unless there is a waiver;
- The research involves no more than minimal risk to subject;
- The waiver will not adversely affect the rights & welfare of the research subject or donor; **AND**
- The research would reasonably be considered to contribute to the **greater public good** – High Bar

- Standard of ‘impracticable’ is aligned with PDPC’s interpretation.
- The standard of ‘greater public good’ is a **high bar** (e.g. epidemiology research & population wide study- BAC report 2015)

Revised

Waiver of Requirement for Appropriate Consent for HBM and HI (1 Nov 2017)

IRB must be satisfied that –

- the research cannot reasonably be carried out without the use of the health information in an individually-identifiable form;
- the process of obtaining consent from the person, to which the individually-identifiable health information relates, will involve a disproportionate amount of effort and resources relative to the research requirements.
- the research involves no more than minimal risk to subject;
- the waiver will not adversely affect the rights & welfare of the research subject or donor;
- the research would reasonably be considered to contribute to the **greater public good** – High Bar

Note : 1 Nov 2017 – The activation date of the Human Research Framework under the HBRA

4. Concern on difficulty in obtaining consent for historically collected HBM/BI

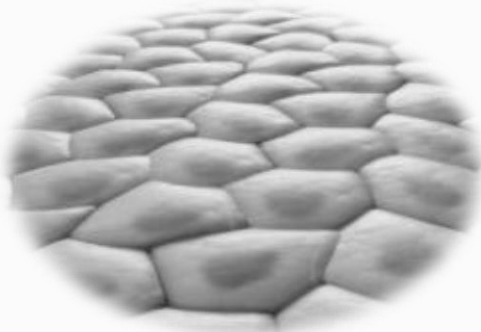
Human Tissue Framework – regulates research tissue bank and tissue banking activities
~ *Targeting Q4 2018*

General Rules for removal, storage, supplying and use of human tissue for research :

1. **There must be appropriate consent.**
2. The activity must be conducted in accordance with any conditions specified as part of the consent.

Section 64

LEGACY TISSUE

Legacy tissues	Exception to facilitate the use of legacy tissues
	<p>“Legacy human biological material” – which had been removed from the donor’s body AND rendered non-identifiable, prior to the Act coming into force.</p> <p>Exceptions will be made to allow such non-identifiable legacy tissues to be used in research without appropriate consent.</p>

Note : Appropriate consent should always be taken for the storage, supply and use of individually identifiable or de-identifiable tissue for research prospectively, after the appointed day of Human Tissue Framework.

4. Concern on difficulty in obtaining consent for historically collected HBM/HI

→ Lowered the bar for the use of individually identifiable HI or HBM collected before 1 Nov 2017

Fifth Schedule (NEW!!) ❖ HBM – Human Biological Material ❖ HI – Health Information

Waiver of Requirement for Appropriate Consent for HI or HBM (Before 1 Nov 2017)

- a) the individually-identifiable HI or HBM was obtained or compiled before 1 Nov 2017;
 - b) the research cannot reasonably be carried out without the use of the HI or HBM in an individually-identifiable form;
 - c) the research involves no more than minimal risk to the research subject;
 - d) the waiver will not otherwise adversely affect the rights and welfare of the research subject;
- AND**
- e) For health information (HI) - the process of obtaining consent from the person, to which the individually-identifiable HI relates, will involve a **disproportionate amount of effort and resources relative to the research requirements**.
 - e) For human biological material (HBM) - reasonable effort* has been made to **re-contact the person** to which the individually identifiable HBM relates for the purpose of obtaining his or her consent.

e.g.** notification can be served by mail/electronically twice, subjects given **30 + 30 days to respond]

Summary of consent requirements for **use** of health info & biological material

1 Nov 2017

Appointed day E.g. 1 Nov 2018

HBRA not in force

HBR framework activated

Tissue framework activated

Individually-identifiable
health information
collected before 1 Nov 17

Individually-identifiable
health information collected after 1 Nov 17

1. Obtain consent
2. IRB waiver (low bar)

1. Obtain consent
2. IRB waiver (**higher** bar)

De-identified health information → consent not required for its use in research

Individually-identifiable
biological material
collected before 1 Nov 17

Individually-identifiable
biological material collected after 1 Nov 17

1. Obtain consent
2. IRB waiver (low bar)

1. Obtain consent
2. IRB waiver (**higher** bar)

Biological material **collected before** e.g. 1 Nov 2018 and **rendered de-identified** → consent not required for its use in research

Use of all tissue requires consent

5. Concern on difficulty in having a witness during consent taking

Section 26 of the Regulation



General rule-

“Appropriate consent” must be obtained:

1. In **writing**;
2. From the subject **personally**;
3. After subject is **given full explanation** on research & expected involvement
4. **Prior** to subject involvement (intervention OR use of ID material OR ID health info)
5. In the presence of a **witness**

Exemption from the requirement for witness if the research is :

- a) Not invasive;

Definition of ‘invasive’: Procedures that are incisional (i.e. penetrates the skin) would be considered invasive. Examples of invasive procedures are finger prick tests, venipuncture and skin punch biopsies.

- b) Not interventional; **AND**

Definition of ‘interventional’: Procedures that have any physical, mental or physiological effect (whether temporary or permanent) on the body of the research subject

- c) Not restricted human biomedical research

Research that comprises solely of a survey or collection of information from the research subjects is considered not invasive and not interventional hence does not require witness to be present

6. Clarification on Scope of Human Biomedical Research (HBR)

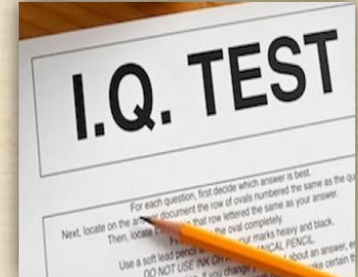
Types of research and studies **out of the scope HBR**:

Activities conducted in accordance with:

1. Section 59A of the Infectious Disease Act (Cap. 137)
2. National Registry of Diseases Act (Cap. 201B)
3. Statistics Act (Cap. 317)
4. Health Products Act (Cap. 122D)
5. Medicines Act (Cap. 176)



Normal psychological responses and behaviours



Measurement of human intelligence

The HBRA is not intended to regulate 'research studies' presented in the form :



Service evaluation



Clinical audit



Surveillance



Outbreak investigation

Factors for consideration: **Intent**, focus of study, design, **existing evidence**, **benefits to subject**, responsibility of activity engager, sharing of generalizable knowledge, approach and minimal risk. Etc.

- ❖ **Large-scale engagement sessions (open to everyone including the public)**
To be in MOH premises, to communicate the requirements of the Act.
- ❖ **‘Roadshow’ sessions upon request for any institution/organisation**
We encourage institutions to invite us for these presentations to help disseminate the requirements of the Act.
- ❖ **Regulatory Assistance Forum**
For MOH and all regulatees to share guiding principles, best practices and feedback to facilitate solution finding for challenges in complying with certain requirements of the HBR Act.
- ❖ **Deep-dive competency workshops (in collaboration with CBmE-NUS)**
Full-day sessions jointly facilitated by MOH and the NUS Centre for Biomedical Ethics (CBmE) and includes round-table case study discussion for stakeholders to apply the principles of the HBR Act.
- ❖ **Enhancing national ethics competency (partnership with CBmE-NUS)**
As part of Singapore’s ongoing efforts to promote ethical research, MOH will continue to partner with CBmE by providing funding to enable an increased competency in Bioethics (clinical + research) work and familiarity with regulatory requirements through interactive learning and sharing.



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Thank you