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Human Biomedical Research Act (HBRA) operationalization: Key learnings for CRCs

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Research Integrity, Compliance and Ethics, SingHealth

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Learning Objectives

- HBRA and scope of Human Biomedical Research regulated
- Informed consent and appropriate consent
  - Waiver of informed consent
  - De-identification
- Human Tissue Framework and tissue banking
- Reporting of serious adverse events, contraventions

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HBRA and Regulation of Research

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Human Biomedical Regulatory Framework

1 Nov 2017 in force

HBRA

Human biomedical Research Framework

- Regulates the conduct of Biomedical Research
- Covers 2 areas:
  - Human subject research that have certain intended purposes and involve certain methodologies
  - Restricted and prohibited research

Human Tissue Framework

- Regulates dealings in human tissue
- Prohibits commercial trading in human tissue

Pending activation

Exclude :
- Service evaluation
- Clinical audit
- Surveillance
- Outbreak investigation
- Psychological responses +behaviors
- Measure human intelligence
- Public health research on infectious disease (Infectious Diseases Act)

Exclude
- National registry of diseases of health information (National Registry of Disease Act)
- Collection of health info for stats purpose (Statistics Act)
- Clinical trials of Health products (Health Products Act)
- Clinical trials of medicinal products (Medicines Act)

HBRA Implementation Timelines

Activated on 1 Jul 2016

Phase 1

Administrative provision

Activated on 1 Jan 2017

Phase 2

Prohibition against commercial tissue trading

Activated on 1 Nov 2017

Phase 3

HBRA Framework

Regulation of human biomedical research

- Functions and duties of IRB (S17)
- Functions and duties of RI (S23)
- Approval and conduct of restricted research (S31)
- Amendment to Third, Fourth and Fifth Schedules of the HBRA

Activation by Q4 2019

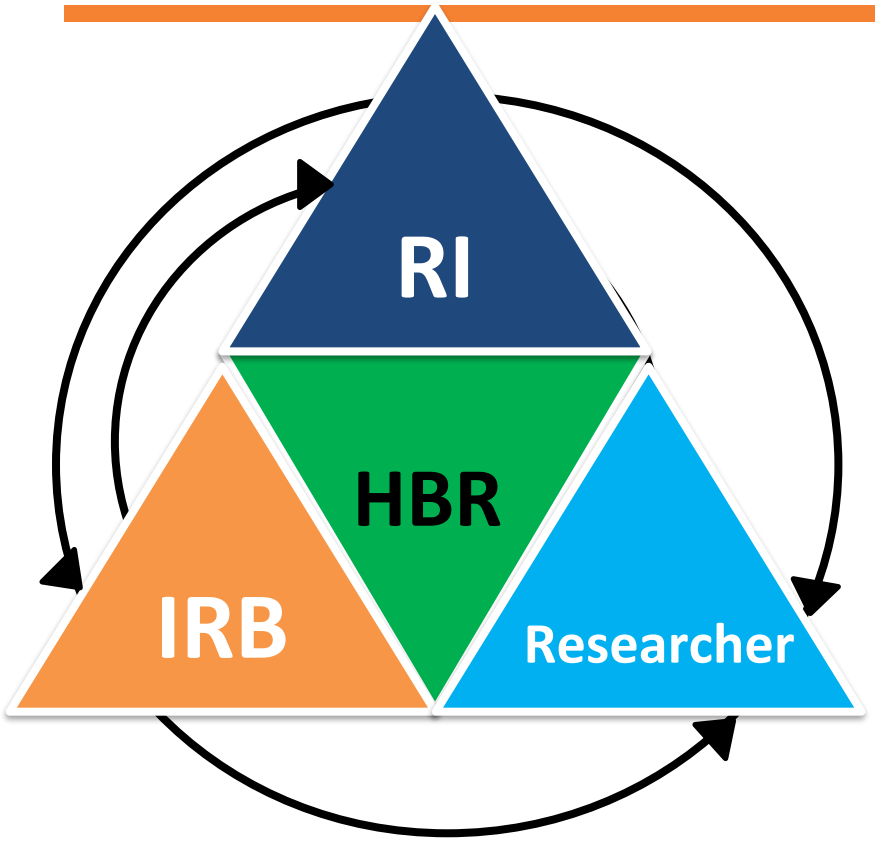
Phase 4

HTF Framework

Regulation of research tissue banking

- 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 (S64)

HBRA Key Entities



Research Institution (RI)

….. **a body of person,** whether corporate or unincorporate or other organization, or ministry or department of the Government, who or which –

a) engages (through contractual or other arrangements) one or more researchers to conduct human biomedical research; and

b) exercises supervision and control over human biomedical research conducted by the researchers he or it has engaged

✓ Appoint **Person-in-Charge,** develop internal policies, standards and systems for the proper conduct of any HBR under its supervision

Institutional Review Board (IRB)

A board **appointed by RI** to perform ethics review of HBR & other review functions

Researcher

A natural person who conducts HBR **under the supervision and control** of a "RI"

SingHealth CIRB adopts a mutual Cross Cluster Recognition with the **DSRB**.

Implications for Researchers including CRCs

- Responsible Conduct of Research
  - Practice of scientific investigation with integrity and ethics
- Proper Conduct of Research
  - Procedures and processes for compliance with regulatory and legislative requirements

Scope of "Human Biomedical Research"

(HBRA Section 3)

Research will fall within scope of the HBRA if it satisfies at least one **Purposive** element and one **Methodological** element or where it involves **Sensitive** research.

PURPOSE

(2) Any research that is intended to study —

(a) the prevention, prognostication, diagnosis or alleviation of any disease, disorder or injury affecting the human body;

(b) the restoration, maintenance or promotion of the aesthetic appearance of human individuals through clinical procedures or techniques; or

(c) the performance or endurance of human individuals,

METHOD

where the research involves —

(i) subjecting an individual to any intervention (including any wilful act or omission) that has a physical, mental or physiological effect (whether temporary or permanent) on the body of the individual;

(ii) the use of any individually-identifiable human biological material; or

(iii) the use of any individually-identifiable health information.

SENSITIVE

(3) Any research that involves —

(a) human gametes or human embryos;

(b) cytoplasmic hybrid embryos;

(c) the introduction of any human-animal combination embryo into an animal or a human;

(d) the introduction of human stem cells (including induced pluripotent stem cells) or human neural cell into an animal at any stage of development (including a prenatal animal foetus or animal embryo); or

(e) any entity created as a result of any process referred to in paragraph (c) or (d).

Restricted Research

(HBRA Fourth Schedule, Restricted Research Regulations 2017)

☑ Requires approval from MOH and special requirements for consent taking (e.g. cooling off for oocytes and embryos)

- HBR involving human eggs or human embryos
- HBR involving
  a) Cytoplasmic hybrid embryos
  b) Human-animal combination embryos created by the incorporation of human stem cells (including induced pluripotent stem cells)
  c) Human-animal combination embryos created in-vitro by using
     - Human gametes and animal gametes, or
     - One human pronucleus and one animal pronucleus;
  d) The introduction of human stem cells (including induced pluripotent stem cells) into a pre-natal animal foetus or animal embryo;
  e) The introduction of human pluripotent stem cells (including induced pluripotent stem cells) into a living post-natal animal, but excludes the introduction of such human pluripotent stem cells into immunodeficient mice solely for the analysis of teratoma induction;
  f) The introduction of human stem cells (including induced pluripotent stem cells) or human neural cells into the brain of a living post-natal animal; or
  g) Any entity created as a result of any process in (c) - (e)

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Prohibited Research

(HBRA Third Schedule and Section 30)

- The development of human-animal combination embryos referred to in paragraph 2(a)(i) or (iii) of the **Fourth Schedule** beyond 14 days or the appearance of the primitive streak, whichever is the earlier.

- The implantation of a human-animal combination embryo mentioned in paragraph 2(a)(i) or (iii) of the Fourth Schedule into the uterus of an animal; or implantation of a human-animal combination embryo into the uterus of a human.

- The introduction of human stem cells (including induced pluripotent stem cells) or human neural cells into the brain of living great apes whether prenatal or postnatal.

- The breeding of animals which have had any kind of human pluripotent stem cells (including induced pluripotent stem cells) introduced into them.

NB: ***four types of great apes: gorillas, bonobos, orangutans and chimpanzees***

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Informed Consent and Appropriate Consent

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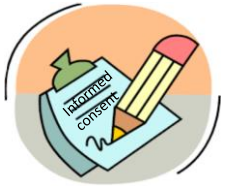
Consent Taking



For Drug Trials with a CTC/CTA/CTN (Regulated under HSA):

- Consent must be obtained by a registered medical practitioner under the Medical Registration Act or a registered dentist under the Dental Registration Act.

For Non-drug Trials or Human Biomedical Research:

- Medically qualified personnel
  - Equipped with the expert knowledge
  - E.g. Consent for interventional device trials or medical procedural trials should be done by registered medical practitioners/dentists

Other types of Human Biomedical Research:

- E.g. sample collection, questionnaires
- Appropriately qualified personnel may be delegated to obtain consent

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"Appropriate Consent" for Human Biomedical Research
(HBRA Section 6)

- In writing;
- From the research subject or tissue donor personally or otherwise obtained in accordance with below:
  - Section 7 (research for adults lacking mental capacity),
  - Section 8 (research involving minors),
  - Section 9 (removal of tissue for adults lacking mental capacity),
  - Section 10 (removal of tissue for minors lacking mental capacity),
  - Section 11 (removal of tissue for deceased)
- After the information (Section 12) has been provided and explained to the research subject or tissue donor or the person authorized to give consent on the subject's or donor's behalf
- In the presence of a **Prescribed Witness**

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Information to be provided before taking Appropriate Consent
(HBRA section 12)

Section 12 (1) Human Biomedical Research

a) Investigational nature of biomedical research
b) Purpose of the biomedical research
c) Reasonable foreseeable risk, discomforts or inconvenience to a living research
d) Benefits which the subject maybe reasonably expect from biomedical research
e) Where applicable, there are any alternative procedure or treatment
f) Any compensation and treatment available to research subject
g) Any anticipated expenses
h) Identifying research subjects' information will be kept confidential
i) Individually-identifiable information obtain will be used for future biomedical research
j) Biological material taken will be destroyed, discarded or stored for future biomedical research
k) Whether research subject involves information in individually-identifiable form
l) Research subject or person authorised to give consent to be contacted if changes in research, serious adverse events
m) Whether research subject would wish to be re-identified in the case of an incidental finding
n) Research subject's right to withdraw consent
o) Research subject to contact further information on the biomedical research
p) Other information as IRB may require
q) Such other information as may be prescribed

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Information to be provided before taking Appropriate Consent
(HBRA section 12)

Section 12 (2) Removal, Donation and Use of Human Tissue

a) Specific research purpose which tissue is intended to be used
b) Tissue will be used for any purpose
c) Proposed area of research approved IRB
d) Reasonable foreseeable risk, discomforts or inconvenience to a living donor arising from removal of the tissue
e) Donation of the tissues is voluntary and the renunciation of donor's right and any intellectual property rights
f) Donor subject's right to withdraw consent
g) Any compensation and treatment available to donor
h) Any anticipated expenses
i) Identifying donor's information will be kept confidential
j) Individually-identifiable information obtain will be used for future biomedical research
k) Donor's tissue taken will be destroyed, discarded or stored for future biomedical research
l) Donor or person authorised to give consent to be contacted for further consent
m) Whether tissue donation would result in the use of donor's tissue in individually-identifiable form
n) Whether tissue will be used in restricted human biomedical research involving human-animal combinations
o) Donor or person authorised to give consent would wish to be re-identified in the case of an incidental finding, or future research
p) Donor to contact further information on the purpose tissue will be used and provide feedback the purpose
q) Whether tissue will be exported or removed from Singapore to be place outside Singapore
r) Such information as may be prescribed

Who can be the Witness?

(Regulation 25 of HBR Regulations 2017)

The witness must be:

a) 21 years of age or older;
b) Have mental capacity; and
c) Must not be the same individual taking the appropriate consent.

- The witness must take reasonable steps to ascertain —
  a) The identity of the individual giving the appropriate consent; and
  b) That the consent was given voluntarily without any coercion or intimidation.
- A member of the study team (eg. study coordinator) may be the witness, however this member must not be the same person taking the appropriate consent.

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When can Witness be Exempted?

(Regulation 26 of HBR Regulations 2017)

- The appropriate consent of a research subject is exempted from the requirement of the witness where the research is -
  - ✗ Not Invasive;
  - ✗ Not Interventional; *and*
  - ✗ Not Restricted Human Biomedical Research.
- Research that comprises solely of a survey or collection of information from the research subjects is treated as not invasive and not interventional.
- The requirement that appropriate consent must be obtained in the presence of a witness does not apply to any consent taken before 1 Nov 2017.

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Informed Consent in Vulnerable Subjects

- ✓ Vulnerable participants are those who are relatively or absolutely incapable of protecting their own interests
- ✓ Research team must be aware of the special circumstances surrounding research involving vulnerable populations
- ✓ Requires detailed justification and additional safeguards to protect their welfare and safety
- ✓ Vulnerable subjects – minors, adults lacking capacity, research in emergency situations

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Consent for Future Research

- If there is an intent for use in future research, you need to ensure consent for use in future research (ie. element 12(1)(i/j) has been obtained for the use of individually-identifiable health information (HI) and/or human biological material (HBM).

- For donation of human tissues for use in future research, you need to ensure all section 12(2) elements are met. The broad consent form from a SingHealth Tissue Bank has included all 12(2) elements.

Note : *It is important to check thoroughly for consistency of language relating to future research in your informed consent form before you submit for IRB approval. The informed consent form must be customized accurately in accordance with the intent.*

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Guidance on Consent for ongoing studies approved before 1 Nov 2018

Based on MOH Guidance on Appropriate Consent, 17 May 2019:

MOH allows existing studies involving the use of HI or HBM to continue without the need to re-consent, if the minimal requisite set of "core (and "situational, where relevant) information elements has been provided to the research subjects and that the studies had commenced prior to 1 Nov 2018.

- All 15 elements of Section 12(1) and 17 elements of Section 12(2) have been classified either as:
  - **Core :** essential information that must be provided to the research subjects, or
  - **Situational :** information that should be communicated to the research subjects if it is relevant to the research (some situational elements must be present for interventional studies)

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Consent Taking - Implications for CRCs

- Ensure appropriate consent taking when dealing with individually identifiable information
  - Use the latest PIS and ICF approved by IRB
  - All the elements listed in Section 12(1) (for HBR studies) and Section 12(2) (for tissue collection) must be included in the consent form and communicated clearly to the subject/donor.
  - Consent taking in presence of witness
  - Consent taking according to hierarchy requirements for vulnerable population and deceased patients
- Discretion when handling individually identifiable information

Consent Taking – Implications for CRCS

- The informed consent form shall be personally signed and dated.
  - **Do not** use the date stamp.
  - Study coordinator/PI **should not** complete the **date** field on behalf of the subject.
- Study specific procedure (including a study specific questionnaire) can only be performed only after consent form is signed.
  - You ***cannot*** administer a study specific questionnaire (***even for a very simple questionnaire***) to a subject before consent is obtained.
- Documentation of informed consent process should be recorded in the hospital medical records.
- Always check entire consent form for accuracy and completeness after the subject has signed the consent form.
  - Common errors include subject dating their birthdate, writing the wrong year, yesterday's date etc.

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Other Implications of HBRA :

- Waiver of Informed Consent
- De-identification
- Incidental Findings Management

Waiver Consent for Historical information and biological material

(HBRA Fifth schedule Part 2, Section 3A and 3B)

Waiver requirements for Health Information

BEFORE 1 Nov 2017

a) the individually-identifiable health information was obtained or compiled before 1 November 2017;

b) the research cannot reasonably be carried out without the use of the health information in an individually-identifiable form;

c) the use of the individually-identifiable health information involves no more than minimal risk to the research subject;

d) the waiver concerned will not otherwise adversely affect the rights and welfare of the research subject; and

e) 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.

Waiver requirements for Human Biological Materials BEFORE 1 Nov 2017

a) the individually-identifiable human biological material was obtained or compiled before 1 November 2017;

b) the research cannot reasonably be carried out without the use of the human biological material in an individually-identifiable form;

c) the use of the individually-identifiable human biological material involves no more than minimal risk to the research subject;

d) the waiver concerned will not otherwise adversely affect the rights and welfare of the research subject; and

e) reasonable effort has been made to re-contact the person to which the individually-identifiable human biological material relates for the purpose of obtaining his or her consent.

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Waiver Of Appropriate Consent For Research Involving Information or Human Biological Material (effective 1 Nov 2017)

(HBRA Fifth schedule Part 2, Section 3)

Criteria below set at a relatively high bar:

a) the research cannot reasonably be carried out without the use of the human biological material or health information in an individually-identifiable form;

aa) the process of obtaining consent from the person, to which the individually-identifiable human biological material or health information relates, will involve a disproportionate amount of effort and resources relative to the research requirements;

b) the use of the individually-identifiable human biological material or health information, as the case may be, involves no more than minimal risk to the research subject or donor;

c) the waiver concerned will not otherwise adversely affect the rights and welfare of the research subject or donor; and

d) the human biomedical research or health information research would reasonably be considered to contribute to the **greater public good.**

Guidance for "Greater Public Good"
(MOH Guidance on Consent – 17 May 2019)

What is the definition of "greater public good"?

Generally, research can be considered to contribute to the greater public good if it falls under one of the following categories:

a. Epidemiology research or population wide studies at national or regional level with potential direct benefit to the public at large; or
b. Research with apparent or tangible benefits with measurable outcomes to the public at large and may include those less privileged community or a sub-community; or
c. Research that contributes or could contribute to impact at a national, regional or international level with potential to lead to improvement in policy and prevailing standards on innovation, management and practice in healthcare and other human biomedical related fields.

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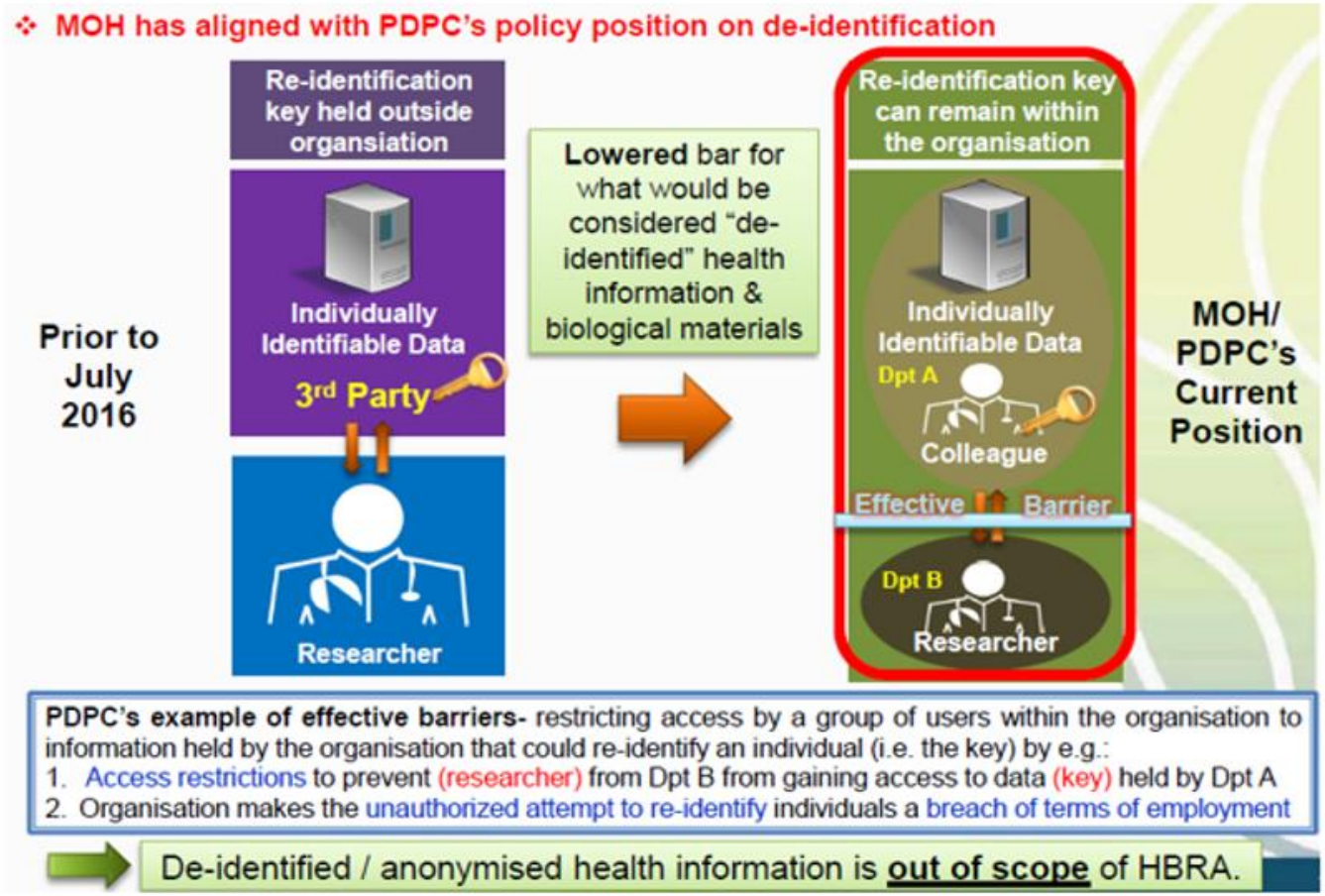
Rendering data Non-identifiable



MOH Stakeholder meeting 27 Feb 2018, SREC 2 March 2018

Incidental Findings (IF)

Definition:

Incidental Findings (IF) refers to a finding about a research subject that has potential health or reproductive importance to the research subject and is discovered in the course of conducting research but is **unrelated to the purposes, objectives or variables of the study.**

The following research areas can give rise to **IF**:

i. Genetic and Genomic Research (may include biobanks)
ii. Testing of human biological materials
iii. Research protocols which includes imaging procedures
iv. Any other studies with a potential health or reproductive importance to the research subject

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Requirement for HBRA Informed Consent
(Section 12)

- HBRA Section 12 (1) (m): whether the research subject would wish to be re-identified in the case of an incidental finding if the proposed biomedical research expressly provides for such re-identification;

- HBRA Section 12 (2) (o): whether the donor or the person authorised to give consent under this Part, as the case may be, would wish to be re-identified in the case of an incidental finding if the future research expressly provides for such re-identification;

The information on whether Incidental Findings will be returned should be provided to the research subject during the taking of appropriate consent.

Even when there is no intention to return Incidental Findings, the negative fact should still be conveyed to the research subject.

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Human Tissue Framework and Tissue Banking

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Draft Human Tissue Framework (HTF)

Overview of Tissue Banking Regulation

TISSUE BANKING REGULATION

1 Commencement & Cessation
- ✓ Notification of Operation
- ✓ PPIC
- ✓ Notification of Cessation

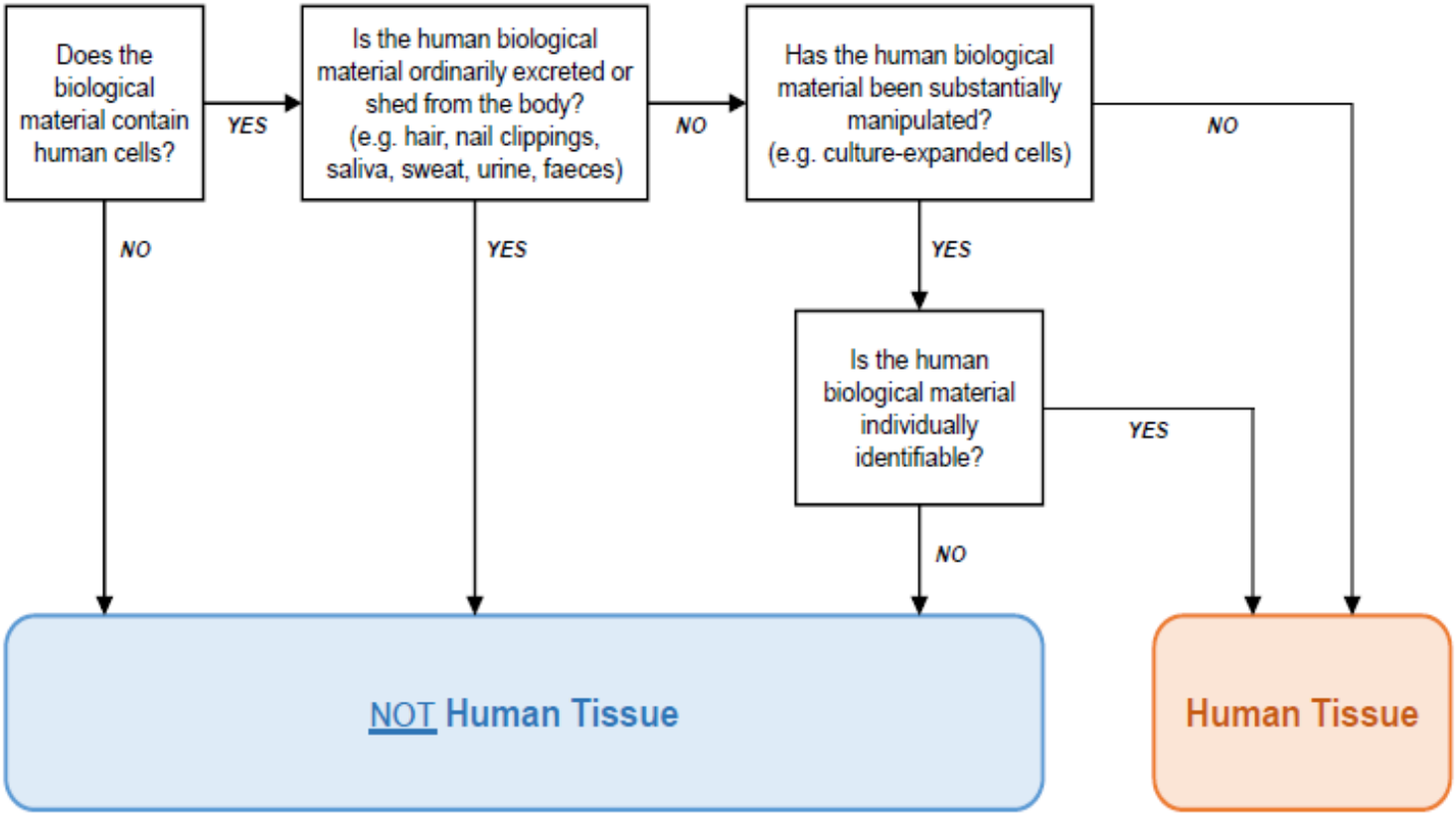
2 Operational requirements
- ✓ Declaration of Compliance
- ✓ Requirements before human tissue is released, supplied or exported
- ✓ Documentation
- ✓ Protection of confidentiality of donor's information
- ✓ Safety and welfare of donors

5 SAE & Contravention
- ✓ Notification by recipient of HT to TB
- ✓ Notification to Director by TB

4 Consent Requirement
- ✓ Tracking of consent and integrity of records
- ✓ Exemption from requirement for witness
- ✓ Exemption from need for appropriate consent if tissue collected before "Operational date"

3 Tissue for Human Tissue Transplantation Research
- ✓ Additional requirements before tissue is released, supplied or exported
- ✓ Management of Tissue Contamination Quality and Safety Management System

Decision Tree for Human Tissue



Adapted from : Ministry of Health. A Guide to the Prohibition Against Commercial Trading of Human Tissue. Human Biomedical Research Act. February 2017

Legacy Tissue

"**Legacy Human Biological Material**" means

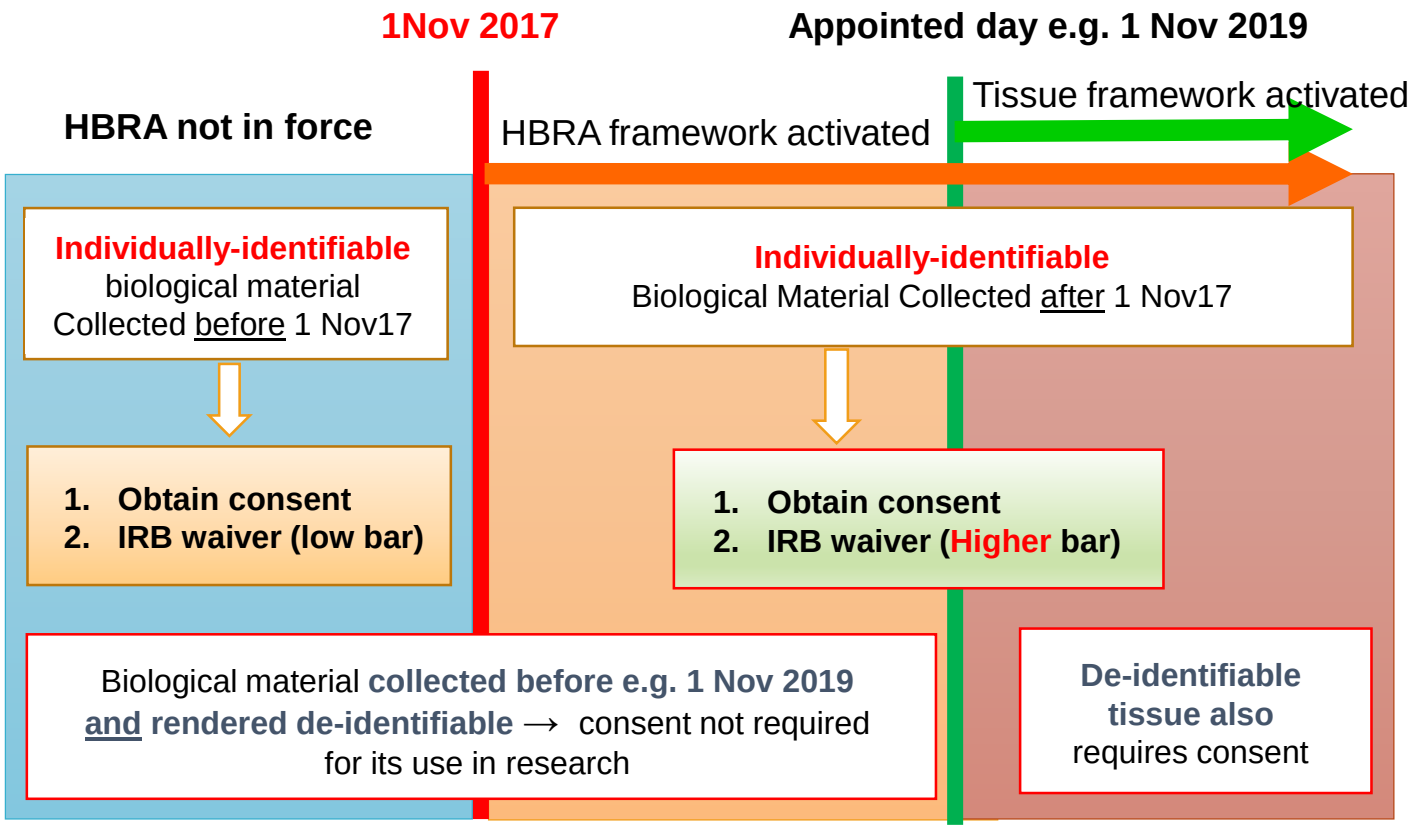
a) Any human biological material which has been removed from a human body, whether living or dead, at any time before the appointed day;

b) Any biological material from the body of a dead person which has been stored for the purposes of human biomedical research at any time before the appointed day.

And which has been rendered **non-identifiable** within the meaning of section 27(3) at anytime before the appointed day

The Act does not apply to any legacy biological material or any information derived from such material.
However this will not apply if tissue is used for Prohibited Human Research, Restricted research, commercial trading, advertisement.

Appropriate Consent Requirement for use of Human Tissue



Before 1 Nov 2019

(A) Storage, supply and use of human tissue obtained before 1 November 2019:

Donor's consent should be obtained after **the following "core elements" of information from section 12(2) have been provided to the tissue donor:**

- 12(2)(a) specific research purpose for which the tissue is intended to be used, if this information is available, otherwise, the purpose may be stated as for general research;
- 12(2)(f) the donor's right to withdraw his or her consent and the limitations of such withdrawal; and
- 12(2)(i) the extent to which donor records will be kept confidential.

**Remaining section 12(2) elements not listed above should not be conducted if the information has not been communicated to the donor prior to obtaining his or her consent.*

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Reporting of Serious Adverse Events/ Contraventions

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HBR Serious Adverse Event

(HBRA Section 2)

(a) **in relation to human biomedical research, means any untoward medical occurrence as a result of any human biomedical research which —**

i. results in or contributes to death;

ii. is life-threatening;

iii. requires in-patient hospitalisation or prolongation of existing hospitalisation;

iv. results in or contributes to persistent or significant disability or incapacity;

v. results in or contributes to a congenital anomaly or birth defect; or

vi. results in such other event as may be prescribed

HBR Serious Adverse Event

(HBRA Section 2)

(b) **in relation to tissue banking activity, means any untoward occurrence associated with the procurement, testing, processing, storage or distribution of human tissue (including gametes or embryos) intended for human application which —**

i. results in or contributes to death;

ii. is life-threatening

iii. requires in-patient hospitalisation or prolongation of existing hospitalisation;

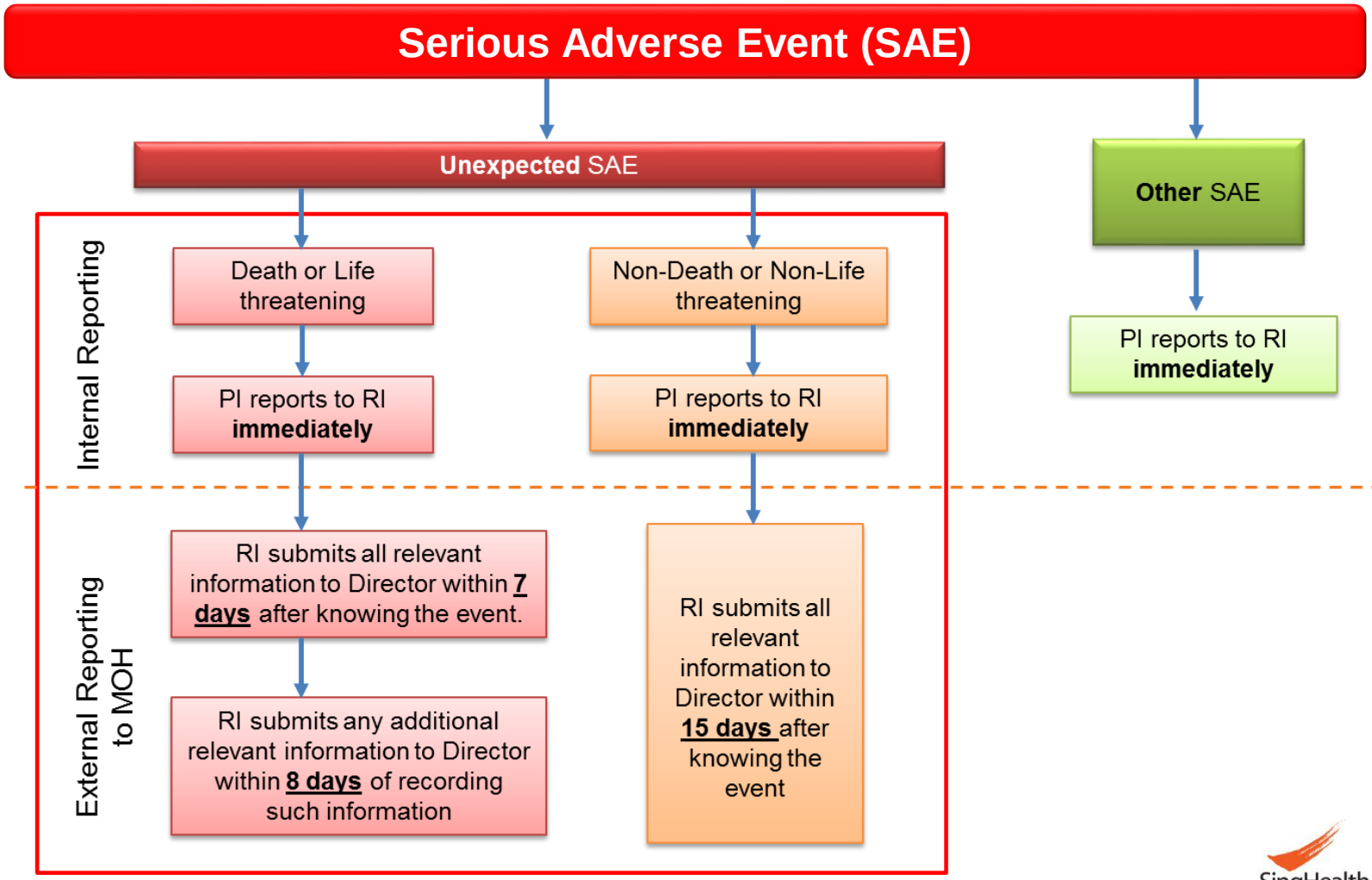
iv. results in or contributes to persistent or significant disability or incapacity;

v. results in the transmission of a communicable disease;

vi. results in any misidentification or mix-up of any type of tissue, gametes or embryo; or

vii. results in such other event as may be prescribed

MOH Requirement for SAE Reporting



CIRB Requirement for SAE Reporting

Please refer to the latest
"Reporting Requirement and Timeline for SAE-AE"
from CIRB website:

https://research.singhealth.com.sg/Pages/CentralisedInstitutionalReviewBoard.aspx

PI is required to adhere to the IRB reporting timelines. The timelines may vary according on the nature of the SAE.

- Severity (eg. Death, life threatening, not life threatening)
- Nature (eg. Expected, Unexpected)
- Causality (eg. Relatedness)
- Reporting Requirements (eg. 24hrs depending on event)
- Oncology Research (long term follow up)

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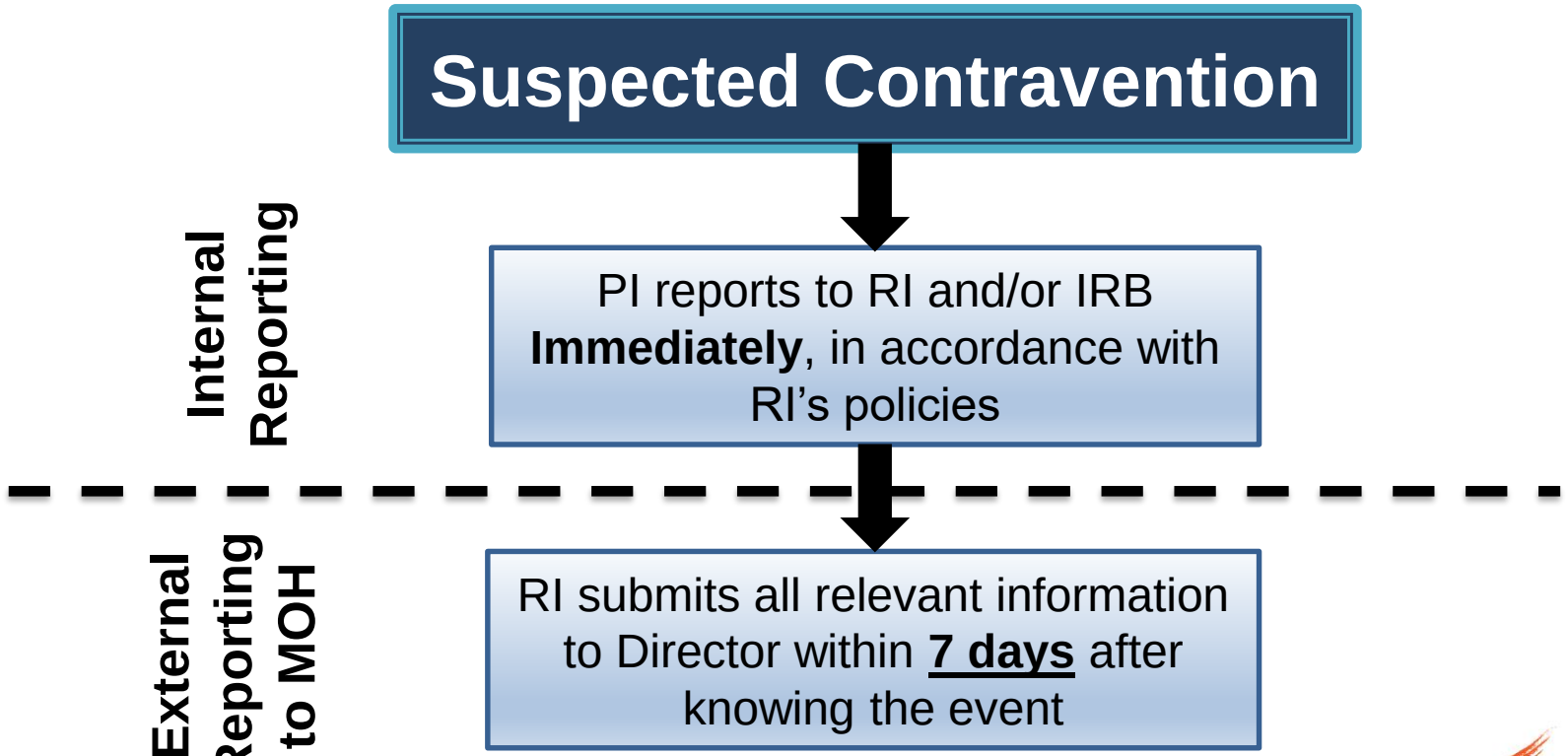
Contraventions Reporting to MOH

- Research institutions (RIs) are required to report all suspected offence or contravention under HBRA



HBR Contraventions Definition

SingHealth has adopted the following definitions for Reportable Contraventions:

Health Science Authority (HSA)

"Serious Breach"

A breach which is likely to affect to a significant degree:

a) The safety, of physical or mental integrity, of any subject, or
b) The scientific value of the study

ADDITIONAL CONSIDERATIONS:

I. Caused by site/study team
II. Potential harm to subject
III. Direct contravention (e.g. HBRA appropriate consent issues)

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Non-Compliance Reporting to IRB

- A Protocol Deviation/ Non-Compliance Report Form should be submitted to the IRB (eg. through iSHaRe or ROAM).
- Report should be submitted immediately when Principal Investigator is aware of the protocol deviation/ non-compliance but no more than 14 calendar days.
- Within SingHealth, for serious breaches (e.g. data breaches), PI to report via the Institution's Incident Reporting procedure and at the same time inform Institutional Representative (IR), IRB and ORIC.

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Summary

- Research will fall within scope of HBRA if it meets at least one **Purposive** element and one **Methodological** element or where it involves **Sensitive** research.
- Researchers should ensure **Appropriate consent** must be taken for HBR studies approved by the IRB after 1 Nov 2018.
- Researchers are required to report **Serious Adverse Events (SAE)** and **Non-Compliance to IRB** as per current research workflow.
- Determine if the human biological material collected are regulated under HTF and if tissues are required to be rendered non-identifiable (**legacy tissues**).

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HBRA Essentials eLearning Course

SingHealth Office of Research Integrity and Compliance (ORIC) has released a **Human Biomedical Research Act (HBRA) Essentials course** on the SingHealth eLearning portal.

The course is mandatory for **SingHealth** Researchers (including PIs, co-I) and research administrators (including CRCs, Research Assistants, Administrators, Tissue Banks) involved in HBR and HBR related processes.

The course consists of **6 Sections and 1 Final Quiz** (30 Questions) at the end of the course. A certificate will be awarded upon passing of the course (85% passing mark).

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Q & A

Email: **oric@singhealth.com.sg**

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