MINISTRY OF HEALTH
SINGAPORE

APPROPRIATE CONSENT REQUIREMENTS UNDER THE HBRA

3 DECEMBER 2019

Appropriate consent for HBR

Does my consent fulfill the requirements of "appropriate consent" as required under the HBRA?

You would be considered to have "appropriate consent" if it was obtained

(a) in writing;

(b) from the research subject personally or their legal proxies;

(c) after the information referred to in section 12(1) has been provided and explained to the research subject or the persons authorised to give consent on the subject's behalf under this Part, as the case may be; and

(d) in the presence of a witness (N.B. : (1) not invasive, not interventional and not restricted research or (2) intervention involves no more than minimal risk, research subject is able to read and sign on the consent form and study is not restricted HBR).

Withdrawal of consent:
Consent may be withdrawn at any time by the subject or his proxy.

N.B. Withdrawal does not affect any research info or data obtained before the consent is withdrawn.

Appropriate consent for HBR

Exemption of appropriate consent for use of individually-identifiable HI/HBM obtained prior to 1 November 2018

To exempt compliance with the consent obligations under sections 12, 22(2)(c) and 25 for the use of individually-identifiable HI/HBM any time before 1 November 2018, where relevant consent has been obtained in writing, after the minimal set of "core" information has been provided and explained.

The "core" information refers to the following:

- 12(1)(a) investigational nature of the research;
- 12(1)(b) purpose of the research;
- 12(1)(c) reasonably foreseeable risks, discomforts or inconveniences to the research subject arising from the research;
- 12(1)(d) benefits which the research subject may reasonably expect from the research;
- 12(1)(h) the extent to which information identifying the research subject will be kept confidential;
- 12(1)(k) whether the participation of the research subject involves information in individually-identifiable form; and
- 12(1)(n) the research subject's right to withdraw his or her consent and the limitations of such withdrawal from the research.

The relevant consent must not have be withdrawn any time before 1 November 2018.

Witness Requirement

The witness requirement under the HBRA is intended to ensure research subjects are not coerced into participating in a study unwillingly, especially if there is a risk of physical harm to the subject.

Witness requirement as part of appropriate consent is <u>exempted</u> if :

1. The consent was taken <u>before</u> 1 November 2017; or
2. HBR is not invasive, not interventional **<u>and</u>** not a restricted HBR; or
3. Intervention involves no more than minimal risk, research subject is able to read and sign on the consent form **<u>and</u>** study is not a restricted HBR

Do I need a witness during consent-taking for HBR which uses leftover biopsy tissue?

No, a witness is not required during consent-taking as the HBR is **not invasive and not interventional**.

What is considered "invasive" and "interventional"?

Research is considered invasive if it involves any procedure that is incisional, i.e. cutting into the tissues of the body.

- Examples of invasive procedures: venepuncture, fingerprick / skin-prick test, muscle biopsy.

Research is considered to involve "intervention" if the research procedure(s) has a physical, mental or physiological effect (whether temporary or permanent) on the body of the individual.

- Examples of procedures which would be considered "intervention": venepuncture*, functional MRI, chest X-ray.

**Where blood is drawn for the sole purpose of research or where excess blood is drawn beyond the amount required for clinical use, for research purposes.*

Waiver of appropriate consent

What if I am not able to obtain appropriate consent from the research subjects?

- You can consider applying for a waiver of appropriate consent from the IRB.
- To make it easier for researchers to qualify for waiver of appropriate consent, the waiver criteria for HBM/HI collected before 1 Nov 2017 has been lowered* - **such studies do not need to demonstrate "greater public good",** which generally relates to population wide / epidemiological studies in which there will be tangible benefits/outcome applicable to the general population at large.

MOH's Position

- As far as possible, appropriate consent should be obtained to ensure that prospective subjects are adequately informed and given the opportunity to decide whether to participate in a HBR. **Mere inconvenience should not be the sole factor for waiver of consent.**

Waiver of appropriate consent – criteria for waiver

For Historical ID HBM/HI (*before 1 Nov 2017*)

IRB must be satisfied that – Lower bar!

1. The individually-identifiable human biological material was obtained or compiled before 1 November 2017;
2. the research cannot reasonably be carried out without the use of the human biological material in an individually-identifiable form;
3. the use of the individually-identifiable human biological material involves no more than minimal risk to the research subject;
4. the waiver concerned will not otherwise adversely affect the rights & welfare of the research subject; **AND**
5. For HBM: 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

   For HI: 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.

For ID HBM/HI *(after 1 Nov 2017)*

IRB must be satisfied that –

1. the research cannot reasonably be carried out without the use of the health information in an individually-identifiable form;
2. 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.
3. the research involves no more than minimal risk to subject;
4. the waiver will not adversely affect the rights & welfare of the research subject or donor;
5. the research would reasonably be considered to contribute to the **greater public good (e.g. epidemiology research & population wide study- BAC report 2002)- High Bar**

E.g. of "reasonable effort": Notification to be served by mail/electronically, subjects given 30 + 30 days to respond*)

Waiver of appropriate consent to be obtained in writing

Waiver for obtaining written consent	Conditions for Waiver
	**IRB must be satisfied that –** 1. The research or use of the human tissue involves no more than minimal risk to the research subject or donor and involves no procedures for which written consent is ordinarily required outside of a research context; **OR** 2. The only record linking the subject/donor and the research/tissue is the consent form and the principal risk to the subject/donor is the potential harm resulting from unauthorised disclosure of confidential information.

Appropriate consent for use of Human Tissue in Research

Does my consent fulfill the requirements of "appropriate consent" as required under the HBRA?

You would be considered to have "appropriate consent" if it was obtained

(a) in writing;

(b) from the tissue donor personally or their legal proxies

(c) after the information referred to in section 12(2) has been provided and explained to the tissue donor or the persons authorised to give consent on the donor's behalf under this Part, as the case may be; and

(d) in the presence of a witness (N.B. : Witness is not required where only leftover diagnostic tissue is used, or where the tissue removal is of no more than minimal risk and the donor is able to read and sign the consent form; research must not be restricted HBR).

Withdrawal of consent:

Consent may be withdrawn at any time by the subject or his proxy if :

1. the tissue is individually-identifiable and has not been used for the research; or
2. the tissue is individually-identifiable and has been used for the research but it is practicable to discontinue further use of the tissue in research.

N.B. Withdrawal does not affect any research info or data obtained before the consent is withdrawn

Section 37

HTF Consent Requirements

General Rules : ***-For removal, storage, supplying and use of tissues-***

1. There must be appropriate consent.
2. Research must be conducted in accordance with conditions specified by donor.

Setting	Specific Controlling Provisions for Removal of Tissue
Diagnosis & Therapy 	1. Where tissue is removed for a therapeutic or diagnostic purpose but *will also be used for research purposes*, appropriate consent must be obtained for the research purposes *in addition to* the consent obtained for the therapeutic or diagnostic procedure. 2. Cannot store, supply or use the tissue for research or any other purpose unless the medical practitioner or the healthcare institution has completed all the necessary therapeutic or diagnostic procedures.
Research 	Where the tissue is to be removed for a research purpose, appropriate consent must be obtained for the tissue to be removed from the donor. • Where the donor is an adult, consent is obtained from the donor. • Where the donor is a minor with sufficient understanding and intelligence, consent is obtained from both the minor and at least one adult parent or guardian.

Appropriate Consent Requirements – use of Human Tissue in Research

Exemption from need for appropriate consent if tissue collected before 1 November 2019

To exempt compliance with the consent obligations under sections 12 and 37 to — the storage, supply and use of human tissue removed any time before 1 November 2019, where consent has been obtained in writing, after the minimal set of "core" information has been provided and explained.

The "core" information refers to the following:

- 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.

The relevant consent must not have be withdrawn any time before 1 November 2019.

Consent with "Core" Elements

What does it mean if my existing consent form contains the "core" elements?

If the consent for the tissue donated before 1 November 2019 contains the "core" elements, you can continue to use these tissue in your existing or future research without the need to re-consent.

**If the core elements are missing, you would need to re-take consent from tissue donors or seek waiver of consent (in the context of HBR) in order to use these tissue in the individually identifiable form in research.*

Consent Requirements for Imported Tissue and Legacy HBM

Imported tissue and legacy human biological material (includes human tissue)

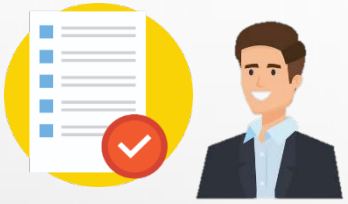
Imported tissue

There must be documentary evidence that consent has been obtained in accordance with the legal or ethical requirements of the place where the tissue is imported from.

Legacy Human Biological Material

For "legacy human biological material" which had been removed from the donor's body and rendered non-identifiable prior to 1 November 2019, the requirements of the HBRA will not apply except for: (1) prohibition against commercial trading of human tissue, (2) advertisement relating to the prohibition against commercial trading of human tissue, (3) restricted human biomedical research and (4) prohibited human biomedical research.

Appropriate Consent Requirements – use of Human Tissue in Research



Exemption of witness requirement when obtaining appropriate consent from tissue donor

The requirement for a witness to be present during appropriate consent may be exempted in the following two scenarios:

Scenario 1

The tissue:
(a) is removed primarily for a therapeutic or diagnostic purpose; and
(b) is not to be used for restricted HBR.

Scenario 2

(a) tissue removal involves no more than minimal risk to tissue donor;
(b) tissue donor is able to read and sign the appropriate consent form; and
(c) appropriate consent is not for the purpose of restricted HBR.

APPROPRIATE CONSENT FROM SPECIAL CLASSES OF RESEARCH SUBJECTS/ TISSUE DONORS

Section 8, 10

Consent for Research Involving Minors

Minor class	Condition	Additional Requirement
	Those **with** sufficient understanding and intelligence to understand the proposed research	**Both** the minor and at least one adult parent/guardian to give consent*
	Those **w/o** sufficient understanding and intelligence to understand the proposed research	1. At least **one** adult parent/ guardian to give consent* 2. Research of comparable effectiveness cannot be carried out without the participation of this class of persons 3. **Tissue removal: primary purpose must be for treatment** Cannot participate in restricted research
	Those who **lack** mental capacity (e.g. Down syndrome)	

**Parental consent may be waived, subject to very stringent conditions.*

Sections 7, 9, 11

Proxy Consent for Deceased & Mentally Incapacitated Adults

Group	Condition	Additional Requirement
	Those who are deceased Cannot participate in restricted research	**Consent hierarchy**: Spouse → adult son/daughter → either parent/ guardian → bro/sis → administrator/executor → person authorised to dispose of the body of the deceased person *MTERA: Medical (Therapy, Education & Research) Act*
	Those who lack capacity (Mental Capacity Act) to give consent. Cannot participate in restricted research	1. Donee/deputy, → **MTERA** → *named person*. 2. Research of comparable effectiveness cannot be carried out without the participation of this class of persons. 3. **Tissue removal: primary purpose must be for treatment (therapy/diagnosis)**

MTERA

Thank you for your attention!

QUESTIONS?