A new way to carry on another's legacy: the new waiver for the use of legacy health information under the Human Biomedical Research Act

On 2 March 2017, the Ministry of Health ("**MOH**") released a draft amendment to the Fifth Schedule to the Human Biomedical Research Act 2015 (the "**HBRA**"), which supplements the existing waiver framework under the HBRA.

The amendment will introduce a new waiver process which will enable institutional review boards ("**IRBs**") to waive the consent requirement for the use of legacy health information for research purposes, where, among other conditions, such information is collected prior to the impending commencement of the consent requirement under the HBRA and the process of obtaining such consent involves a disproportionate amount of effort and resources (the "**New Legacy Health Information Waiver**").

The intention behind the New Legacy Health Information Waiver is to be lauded as the New Legacy Health Information Waiver creates another avenue for the use of legacy health information. Its introduction seems to be a further response to ongoing concerns on the part of researchers and research institutions that their ability to utilise the vast amounts of legacy human biological material and legacy health information to conduct retrospective human biomedical research will be curtailed if they are unable to obtain consent for such use as required under the HBRA regime and are also unable to meet the requirements of the existing waiver of consent requirements under the Fifth Schedule of the HBRA (the "**Existing HBRA Framework**").

However, the limited scope of the New Legacy Health Information Waiver and the conditions attached thereto may give rise to further issues and may not be sufficient to address existing concerns.

This Update examines the New Legacy Health Information Waiver against the Existing HBRA Framework and discusses two immediate concerns that the New Legacy Health Information Waiver may raise:

- the scope of the New Legacy Health Information Waiver and the Existing HBRA Framework as well as a possible lacuna in the waiver framework; and
- how IRBs will determine whether one of the conditions under the New Legacy Health Information Waiver has been met – namely that the process of obtaining consent will involve a disproportionate amount of effort and resources relative to the research requirements.

New Legacy Health Information Waiver vs Existing HBRA Framework

Requirement for consent

Generally, the HBRA prohibits the conduct of human biomedical research unless appropriate consent has been obtained in accordance with the HBRA, including consent for:

- the use of a person's biological material (including legacy human biological material); and/or
- the use of a person's individually-identifiable health information (including legacy individually-identifiable health information).

Framework for situations where consent may not be forthcoming

The HBRA acknowledges that consent may not always be forthcoming and includes a framework for dealing with situation(s) where appropriate consent may not have been obtained or where it may not be possible to obtain consent.

In relation to legacy human biological material and legacy individually-identifiable health information, researchers and research institutions may rely on the following:

- section 64 of the HBRA to use legacy non-identifiable human biological material without obtaining consent; and
- the general framework for waivers by IRBs set out in section 13 of, and the Fifth Schedule, to the HBRA (including the New Legacy Health Information Waiver).

The table below summarises the waiver framework for the use of human biological material and health information for human biomedical research along the dichotomies (individually-identifiable vs non-identifiable; legacy vs non-legacy) suggested by the HBRA.

Waivers	Human Biological Material				Health Information		
	Individually-identifiable		Non-identifiable		Individually-identifiable		Non-identifiable
	Legacy	Non-legacy	Legacy	Non-legacy	Legacy	Non-legacy	
Section 64	✗	✗	✓	✗	✗	✗	Not restricted under the HBRA
Existing waiver in para. 3 of the Fifth Schedule ("Existing Waiver")	✓	✓	✗	✗	✓	✓	
New Legacy Health Information Waiver	✗	✗	✗	✗	✓	✗	

Table A: Summary of Waiver Framework

Non-identifiable legacy human biological material: section 64

Section 64 of the HBRA provides that certain requirements of the HBRA will not apply to "legacy human biological material".

However, the scope of the exception in section 64 is limited to legacy human biological material which have been rendered non-identifiable prior to the date of commencement of the relevant sections of the HBRA.

This creates two issues: (i) determining what would constitute "non-identifiable" within the meaning of section 27(3) without further guidance from MOH, and (ii) the possibility that human biomedical research may not practicably be conducted unless the human biological material is individually-identifiable.

The above issues together with the fact that section 64 does not apply to health information may, in effect, limit the effectiveness of section 64 when dealing with legacy human biological material and legacy health information.

Waiver framework: section 13 and the Fifth Schedule

In addition to section 64, the HBRA also establishes a framework for IRBs to waive the requirement to obtain appropriate consent for the use of human biological material or health information in specific circumstances such as those set out in the Existing Waiver.

The New Legacy Health Information Waiver is intended to supplement the Existing HBRA Framework and provide another, possibly easier, option for researchers and research institutions to continue to use legacy health information.

Side-by-side comparison

To facilitate the analysis of the New Legacy Health Information Waiver against the general waiver framework, a side-by-side comparison of the New Legacy Health Information Waiver and the Existing Waiver is reproduced below (*emphasis added*):

New Legacy Health Information Waiver		Existing Waiver	
3A.	Where the institutional review board is satisfied that —	3.	Where the institutional review board is satisfied that —
(*a*)	the individually-identifiable <u>health information</u> was obtained or compiled before the date of commencement of Part 3 of this Act;	-	
(*b*)	the research cannot <u>reasonably</u> be carried out without the use of the <u>health information</u> in an individually-identifiable form;	(*a*)	the individually-identifiable <u>human biological material or health information</u> research, as the case may be, may not <u>practicably</u> be carried out unless there is a waiver;

New Legacy Health Information Waiver		Existing Waiver	
(*c*)	the use of the individually-identifiable health information involves no more than minimal risk to the research subject;	(*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;
(*d*)	the waiver concerned will not otherwise adversely affect the rights and welfare of the research subject; and	(*c*)	the waiver concerned will not otherwise adversely affect the rights and welfare of the research subject or donor; 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.	-	
-		(*d*)	the human biomedical research or health information research would reasonably be considered to contribute to the greater public good.

Table B: Comparison of New Legacy Health Information Waiver vs Existing Waiver

Scope of New Legacy Health Information Waiver: "Health Information" vs "Human Biological Material"

Scope of the New Legacy Health Information Waiver

It is clear from the tables above that the New Legacy Health Information Waiver does not extend to legacy human biological material.

It appears that the New Legacy Health Information Waiver will therefore be of limited assistance to researchers and research institutions seeking to continue to use existing banks of legacy human biological material unless they de-identify the human biological material to utilise the transitional and savings provisions in section 64 or they are able to seek a waiver under the Existing Waiver provisions.

This means that, even with the New Legacy Health Information Waiver, there is no change to the *status quo* for researchers and research institutions seeking to use legacy human biological material. In other words, under the HBRA, it appears that researchers and research institutions will need to utilise one of

three possible routes if they are considering using human biological material:

- if the human biological material was obtained before the commencement of the consent requirement in the HBRA, researchers and research institutions may consider relying on section 64 provided that the human biological material is rendered non-identifiable before the date of commencement of section 64;
- if the human biological material was obtained after the commencement of section 64 or if it is not possible for the human biological material to be rendered non-identifiable, it may still be possible to utilise the Existing Waiver provided that the conditions therein are met;
- if neither section 64 nor the Existing Waiver may be relied upon, then consent will need to be obtained.

UK Human Tissue Act 2004

In considering the omission of human biological material from the scope of the New Legacy Health Information Waiver, it may be pertinent to note that the UK Human Tissue Act 2004 has an exemption for legacy human tissue which fall under the definition of "existing holding" (as defined therein). The exemption essentially allows for the use, without consent, of existing tissue which was held immediately before the coming into force of section 1 of the UK Human Tissue Act 2004.

Unlike section 64, the exemption in the UK Human Tissue Act 2004 does not differentiate between individually-identifiable and non-identifiable human tissue although there is a separate exemption for specific research where the human tissue used is non-identifiable.

A Lacuna in the Waiver Framework? The Treatment of Non-identifiable Human Biological Material

Non-identifiable Human Biological Material

From the summary provided in Table A, it would also seem that the HBRA does not provide for any scope for waiver of the consent requirement for non-identifiable human biological material other than section 64.

While the definition of "human biomedical research" in the HBRA suggests that the HBRA is not intended to regulate human biomedical research involving non-identifiable human biological material, a plain reading of section 25 suggests that consent will still be required for human biomedical research involving any

human biological material, whether individually-identifiable or non-identifiable.

Impractical to obtain consent for non-identifiable human biological material

Since section 64 of the HBRA only applies to legacy non-identifiable human biological material, the Existing Waiver only applies to individually-identifiable human biological material, and the New Legacy Health Information Waiver does not apply to human biological material, the phrasing of Section 25 of the HBRA suggests that use of non-legacy non-identifiable human biological material for human biomedical research will be *prima facie* prohibited unless consent is obtained or the IRB is satisfied that the research qualifies as emergency research.

While it may be possible to obtain consent from the relevant person for a specific research purpose contemplated at the point of removal of the human biological material and prior to rendering the material non-identifiable, it may be practically difficult, if not impossible, to obtain consent for a new research purpose once the material is rendered non-identifiable as it would then not be possible to identify the individual from whom consent is to be obtained.

Applying the Test: Disproportionate Amount of Effort and Resources

New "disproportionate" requirement

The New Legacy Health Information Waiver will introduce a new requirement for the IRB before waiver of consent can be granted. The IRB must be satisfied that the process of obtaining consent will involve a disproportionate amount of effort and resources relative to the research requirements ("**Disproportionality Condition**").

An analysis of the new "disproportionate" requirement against the backdrop of a recent practical guidance issued by the Personal Data Protection Commission (the "**PDPC**") on 25 August 2016 (the "**PDPC Practical Guidance**") in relation to a research exemption waiver for personal data suggests that this new requirement may be an easier test in comparison to the "impracticability of research" test in the Existing Waiver.

PDPC Practical Guidance on what is "impracticable"

The PDPC Practical Guidance was issued in response to requests for clarification in relation to, *inter alia*, the factors that the PDPC considers relevant in assessing what is "impracticable" in the context of the research purpose exemption under the Personal Data Protection Act (the "**PDPA**").

Similar to the HBRA, the PDPA generally prohibits the use of personal data of an individual unless consent is obtained or a statutory exception from the consent requirement applies.

One of the statutory exceptions from the consent requirement available under the PDPA is an exception specific to collection, use or disclosure of personal data for research purposes (the "**Research Exception**").

The Research Exception provides that an organisation may use personal data about an individual for a research purpose without the consent of the individual provided that certain conditions are met, including a condition that "it is impracticable for the organisation to seek the consent of the individual for the use". In issuing the PDPC Practical Guidance, the PDPC referred to disproportionality as one of the factors which would go towards determining "impracticability".

In the PDPC Practical Guidance, the PDPC stated that whether it would be "impracticable" for an organisation to seek the consent of the individual would depend on the specific facts of the case, and indicated that the following factors may be considered relevant:

- the organisation does not have current contact information nor sufficient information to seek up-to-date contact information. The organisation should be able to demonstrate that the potential research subject cannot be reached using the contact information, such as by attempting to contact the potential research subject;

- given the target population required for meaningful conclusions to be drawn from the research, the quantum of the research grant and the period allotted for the research as a condition of the research grant, the financial and organisational costs of attempting to seek consent from each potential research subject would impose such disproportionate research demands and burden on the organisation or take up so much time (assuming the organisation has made every reasonable effort to provide for the required time and resources) that carrying out the research is no longer viable; and

- exceptional circumstances where seeking the research subject's consent would affect the validity or defeat the purposes of the research.

In particular, when considering what would be "disproportionate", the PDPC mentioned that the assessment may include the required number of research subjects, whether or not there is an existing relationship with the individuals, and other factors affecting the difficulty of contacting the required research subjects.

The PDPC also mentioned that factors like mere inconvenience (to the organisation or the potential research subject), additional costs or time delays resulting from having to contact individuals for consent, are on their own, insufficient to demonstrate "impracticability", but may be relevant considerations if the added financial or organisational costs of having to seek consent is so onerous that the research is no longer viable.

It is important to bear in mind that the above factors elucidated by the PDPC were in the context of the PDPA and the PDPC explicitly stated that the scope of the queries were in relation to medical related research falling outside the ambit of the HBRA and that the PDPA's position does not affect any authority, right or obligation arising under any other law.

Notwithstanding this, the PDPC Practical Guidance may still be useful in understanding and applying the Disproportionality Condition.

Is "disproportionate" narrower than "impracticability of research"?

The PDPC's analysis in the PDPC Practical Guidance subsumes the "disproportionate" concept into the factors which determine whether it would be "impracticable" to obtain consent.

Although the analysis under the PDPC Practical Guidance was in the context of the Research Exception, it is arguable that the same analysis can be extended to the HBRA.

It would seem that the new "disproportionate" requirement in the New Legacy Health Information Waiver is narrower than the test of impracticability for research to be carried out in the Existing Waiver.

A narrower test may be restrictive

If the "disproportionate" requirement in the New Legacy Health Information Waiver is indeed narrower, this could be a double-edged sword.

As can be seen from the PDPC Practical Guidance, the determination of impracticability is a holistic test which takes into account a multitude of factors and the particular factual matrix of the waiver sought.

By narrowing the "impracticability" test in the Existing Waiver down to a "disproportionate" test in the New Legacy Health

Information Waiver, researchers and research institutions could find it easier to satisfy the test by showing disproportionality in research demands and burden in seeking consent, but it is then questionable whether the test is a holistic one which may take into account other factors such as those elucidated in the PDPC Practical Guidance (e.g. exceptional circumstances where seeking the research subject's consent would affect the validity or defeat the purposes of the research).

Other jurisdictions

There has been jurisprudence in the United Kingdom and the European Union as to what constitutes "disproportionate effort". However, the considerations there were in a different context – that of an individual's right to be informed of the use of the individual's personal data and an individual's right of access to such data. It remains to be seen whether the considerations raised in those situations may also be relevant in the present context.

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