

SINGHEALTH TISSUE REPOSITORY

DONATION OF HUMAN BIOLOGICAL MATERIAL FOR FUTURE RESEARCH

INFORMATION SHEET

Research is an important way to advance medical knowledge and improve medical care for all patients. The donation of Human Biological Material (as defined below) enables such research to be performed. At this time, we seek your consent to donate Human Biological Material (which may be Leftover Material (as defined below) and / or Extra Material (as defined below)) to be banked in, or under the governance of, the SingHealth Tissue Repository for use in research.

Your decision on whether or not to consent to donate is entirely voluntary and will NOT affect the medical care extended to you.

This Information Sheet explains what this donation process involves. Please carefully read through and understand the information provided in this Information Sheet. Please let us know if you have any questions.

If you consent to donation, please sign the accompanying “SingHealth Tissue Repository Donation of Human Biological Material for Future Research Consent Form”.

Where we are seeking consent from you to donate Human Biological Material in your capacity as parent / legal guardian / legal representative (as the case may be) of the intended donor, the information set out below on the aspects of the donation process which refers specifically to you will apply equally to the intended donor.

1. What is Human Biological Material?

“**Human Biological Material**” refers to any biological material obtained from the human body that consists of, or includes, human cells. This includes liquid material such as blood and other bodily fluids, and solid material such as diseased tissues.

2. Why are such Human Biological Material obtained from me?

There are two main scenarios (or “**Intended Purposes**”) in which Human Biological Material may be obtained.

In the first scenario, Human Biological Material may be obtained (e.g., in an operation) as part of the diagnosis or treatment for which you are seeking care in hospital.

In the second scenario, Human Biological Material may be obtained from you as part of your participation in a specific research study, clinical trial or donation procedure for the treatment of other patients (e.g., blood donation) for which you have already given consent and which is separate and unrelated to any diagnosis or treatment for yourself.

3. What is Leftover Material, and what usually happens to it?

In both scenarios (described in section 2 above), there may be leftover Human Biological Material after the Intended Purposes have been achieved. For example, in the first scenario, if tissue was obtained for a diagnostic purpose, there may be leftover tissue after the diagnosis has been made. Alternatively, tissue may be removed without the necessity for diagnostic evaluation and which will ordinarily be discarded as unwanted tissue. In the second scenario, after the specific research study or clinical trial is completed or the tissue that you have donated is no longer necessary for the treatment of the patient in question, there may be leftover tissue. All such leftover / unwanted tissue is referred to as “**Leftover Material**”. Leftover Material will ordinarily be destroyed as biological waste.

However, we are asking for your consent to let us make use of such Leftover Material for future research.

In certain situations, e.g. when the treatment of your illness requires surgery that removes a large quantity of tissue, we may apportion tissue for banking upfront (i.e., at the time of surgery). As in all other situations, we have measures in place to ensure that your medical care, including diagnosis and further treatment, is not affected at any time.

4. What is Extra Material, and how will it be collected from me for donation?

“**Extra Material**” refers to additional Human Biological Material collected from you that is not required for the Intended Purpose, be it your diagnosis / treatment, a specific research study, a clinical trial or the treatment of other patients. Such Extra Material will only be collected for future research if it can be safely obtained from you without affecting your health or wellbeing.

5. What Human Biological Material will be collected from me?

If you consent to donate, the following Human Biological Material may be collected from you:

- a) Leftover Material
 - Any leftover Human Biological Material (tissue / lavage and serosal fluid) obtained from therapeutic, diagnostic or donation procedure.
 - Any leftover Human Biological Material obtained after completion of specific research study or clinical trial.

- b) Extra Material
 - Blood (maximum 4 tablespoons which is equivalent to 60 ml).
 - Bone marrow (maximum 2 teaspoons which is equivalent to 10 ml) will be drawn during a procedure that is performed for or in connection with your clinical care.
 - Tissue biopsy (up to 8 cores or safe limits, whichever is lower. This extra tissue biopsy will be taken only at the same procedure as the clinical biopsy. Limits of safety depend on tumour sizes and risk of complications including bleeding and infection, as determined by clinical team performing the biopsy. This is a clinical judgement and will depend on the specific donor profile and responsibility for safe biopsy is undertaken by the clinical team performing the biopsy.)
 - Cheek swab (buccal swab) which will be collected by brushing your mouth with a special swab.
 - Saliva which will be collected by spitting into a collection container.
 - Urine which will be collected by voiding into a collection container.
 - Hair which will be collected by scissors or hair clipper from between one and ten places of your head.
 - Nail clippings which will be collected from both fingers and toes.
 - Stool which will be collected in a collection container.

You may indicate your consent for donation of Human Biological Material in the accompanying “SingHealth Tissue Repository Donation of Human Biological Material for Future Research Consent Form”.

6. What will the donated Human Biological Material be used for?

Research is an important part of the work that we do as part of the SingHealth Duke-NUS Academic Medical Centre in order to provide the best medical care possible to our patients and to discover new cures and treatments that will potentially benefit all patients. The SingHealth Tissue Repository is a central bank in SingHealth that obtains and carefully stores or ensures the secure storage of donated

Human Biological Material in accordance with applicable regulations. The donated Human Biological Material will be used for future research purposes.

Your donated Human Biological Material will not be used for any purpose other than research.

7. Who will use my donated Human Biological Material?

Your donated Human Biological Material will be used by researchers / research institutions who / which are required to follow a strict process to apply for and gain access to donated Human Biological Material. In most situations, applications from the researchers / research institutions must be reviewed and approved by an Institutional Review Board (“**IRB**”) before they can proceed to obtain the donated Human Biological Material stored in the SingHealth Tissue Repository for research. The IRB is an independent ethics committee appointed by hospitals to conduct reviews of research involving human subjects. The IRB’s role is to make sure that the research is ethically and scientifically sound and in accordance with applicable laws and regulations, including the Human Biomedical Research Act 2015 of Singapore (“**HBRA**”).

In certain situations, for projects with no likelihood of harm to research subjects, the IRB may grant an exemption from IRB review and researchers / research institutions may obtain Human Biological Material from the SingHealth Tissue Repository under such exemption.

In addition, the Human Biological Material may be supplied in non-identifiable form to researchers / research institutions without the need for IRB review, if there is scientific merit in the proposed research.

8. Will there be any risks, discomforts or inconveniences to me resulting from donating Human Biological Material? Will I receive any compensation and treatment if I am injured?

If you consent to donate Extra Material, there may be minor risks of slight pain and mild bruising associated with venepuncture in the case of blood collection. For bone marrow collection, there may be some pain, minor bruising and minor bleeding. For collection of hair and nail clippings and the taking of a buccal swab, there may be minor discomfort. For donation of additional tissue biopsy, you may experience pain, inflammation, bleeding, swelling, and / or infection at the site of the biopsy.

In the case of Leftover Material, there is no additional risk, discomfort or inconvenience to you arising from or in connection with your donation.

SingHealth is unable to provide any compensation or treatment in relation to your donation of Human Biological Material.

9. Will I receive any benefits in return for donation of my Human Biological Material?

There will not be any direct personal benefit to you as a result of your donation. You will not receive any personal financial reward. If a new test, procedure, treatment or product is developed using donated Human Biological Material, you will not receive any share of the monetary return arising from or in connection with the developed technology, test, procedure, treatment or product, or any other commercial gain derived from the research for which your donated Human Biological Material is used.

10. Will I have any rights over the Human Biological Material I have donated?

The donated Human Biological Material is treated as an outright gift. As such, by voluntarily agreeing to donate your Human Biological Material, you will renounce all rights to such Human Biological Material and any intellectual property rights that may be generated or developed from or in connection with its use.



11. Will I incur any anticipated expenses in connection with my donation of Human Biological Material?

We do not anticipate any expense incurred by you arising from or in connection with your donation of Human Biological Material.

12. What will happen to my donated Human Biological Material?

Your donated Human Biological Material will be transferred to and stored at the SingHealth Tissue Repository or another facility within SingHealth under the governance of the SingHealth Tissue Repository until such time it is released for research purposes in accordance with strict legal and procedural requirements. For the situation in which your donated Human Biological Material is not required to be sent for diagnostic evaluation, it may be released for research promptly after collection in accordance with legal requirements.

13. What other kind of information will you require from me when using my donated Human Biological Material?

The donated Human Biological Material will be securely linked to your individually identifiable health information including name, NRIC, date of birth, gender, race, disease history, treatment, clinical investigations and laboratory results. Individually identifiable health information increases the usefulness of the Human Biological Material for research. We will securely protect the confidentiality of your health information (see section 14 below).

As part of the consent to the donation of your Human Biological Material, you agree to allow Singapore Health Services Pte Ltd and its related companies (collectively, "**SingHealth**") and their respective representatives and agents to collect, use and disclose individually identifiable health information for cataloguing purposes and data collection for future research. Auditors, the IRB and regulatory authorities may also be granted access to your individually identifiable health information for the purpose of audit and verification of the SingHealth Tissue Repository's operations, to the extent permitted by applicable laws and regulations. Your health information will otherwise be kept strictly confidential. You will be required to confirm that you have read, understood and consented to the SingHealth Data Protection Policy (as applicable to you), the full version of which is available at <http://www.singhealth.com.sg/pdpa>.

You are free to withdraw consent to the collection and use of your individually identifiable health information for future research at any time. Your withdrawal of consent will not affect your current or future medical care in any way.

14. When will my Human Biological Material or health information be used in individually-identifiable form?

To protect your confidentiality, we will de-identify all donated Human Biological Material by assigning unique code numbers. Your donated Human Biological Material and health information will be used in de-identified form for future research unless the necessary IRB approval is granted and consent is obtained from you for your individually-identifiable information to be used for a specific research study. Your identity will be kept confidential and remain protected at all times.

15. Can I change my mind after signing the consent form?

You can withdraw your consent at any time if your donated Human Biological Material is individually-identifiable and (i) has not been used for research; OR (ii) has been used for research but it is practicable to discontinue further use of the donated Human Biological Material for the research. Any remaining donated Human Biological Material will be destroyed following the withdrawal of your consent. However, any research information or data obtained before your withdrawal of consent will

be retained and may continue to be used. This is to allow a complete and comprehensive evaluation of the research study.

Withdrawal of consent to the use of your donated Human Biological Material will not affect your treatment or medical care in any way.

16. Will I be contacted in the future to provide further consent?

You may be contacted in the future to provide any required additional consent on matters related to the use of your donated Human Biological Material or health information or where otherwise required under applicable law. Where it is necessary to contact you to obtain further consent, we will obtain your contact information through your clinical care team or the responsible research study or clinical trial team.

In situations where the donor is a minor (below the age of 21 years), and has given his / her consent to the donation of Human Biological Material (in addition to consent from his / her parent or legal guardian), we will not approach such donor for re-consent when he / she turns 21 years of age.

In situations where the donor is a minor (below the age of 21 years), and has not personally given consent to the donation of Human Biological Material (in addition to consent from his / her parent or legal guardian), we will approach the donor for re-consent when the donor turns 21 years of age. In situations when the donor does not provide consent at 21 years of age or cannot be contacted, the donated Human Biological Material will be destroyed.

17. Will I be re-identified in the case of incidental findings arising from the use of my donated Human Biological Material in future research?

Incidental findings are findings that are of potential health or reproductive importance to a research subject and that are discovered in the course of conducting research but are unrelated to the purposes, objectives or variables of the research study. You will not ordinarily be re-identified and informed in the case of incidental findings in relation to donated Human Biological Material. However, if the incidental finding is significant and of a potentially life-saving nature, your clinical care team or the responsible research study team may want to contact you to ask whether you wish to receive the incidental finding after consulting with and obtaining approval from the relevant institutional Medical Board.

18. Will my donated Human Biological Material be exported or removed from Singapore?

Your donated Human Biological Material may be exported or removed from Singapore, but only in de-identified form. This is to allow for international collaborations which are integral to the research on certain diseases e.g., rare diseases with low incidence in Singapore. Any Human Biological Material exported overseas will only be released in accordance with the requirements of the HBRA and any other applicable laws.

19. Will my donated Human Biological Material be used in prohibited or restricted human biomedical research involving human-animal combinations?

Your donated Human Biological Material will not be used for research that is prohibited or restricted under the HBRA, such as research that involves human procreation or that creates human sentience in animals.

20. Who should I contact if I have further questions or wish to provide feedback on the purposes for which my donated Human Biological Material will be used?

Questions and feedback may be directed to:

SingHealth Tissue Repository (STR)
The Academia, The Ngee Ann Kongsi Discovery Tower Level 10,
20 College Road, Singapore 169856
Tel: 65767115 / 65767117 / 65767118 / 65767119
Email: tissue.repository@singhealth.com.sg

STR-SGH Satellite Bank
The Academia, The Ngee Ann Kongsi Discovery Tower Level 9,
20 College Road, Singapore 169856
Tel: 63265331
Email: str.sgh.sb@sgh.com.sg

STR-NCCS Satellite Bank
National Cancer Centre Singapore, Cryopreservation Lab, Level 3
11 Hospital Crescent, Singapore 169610
Tel: 6436 8574
Email: nccs.biobank@nccs.com.sg

Where Human Biological Material is collected from you as part of your participation in a specific research study or clinical trial, the primary point of contact for any questions or feedback will be the principal investigator or other study team member designated as the contact person in the separate specific informed consent form you have signed or will be signing for participation in the research study or clinical trial.

21. Other matters

Please read this Information Sheet carefully and ensure that you fully understand the contents. If you have any questions, please ask your doctor. Your signature on the accompanying consent form is required if you agree to donate Human Biological Material to the SingHealth Tissue Repository. A signed consent form will be retained by the SingHealth Tissue Repository and other relevant departments while you will receive a duplicate copy.

SINGHEALTH TISSUE REPOSITORY
DONATION OF HUMAN BIOLOGICAL MATERIAL FOR FUTURE RESEARCH
CONSENT FORM

I voluntarily consent to donate my Human Biological Materials which will be collected on the day of the scheduled procedure / protocol for future research in the manner stated in the Information Sheet. (Please tick (✓) as appropriate)

Leftover Material:

from therapeutic / diagnostic / donation procedure: _____

from IRB project / clinical trial: _____

IRB reference number: _____

Contact person for the IRB project / clinical trial: _____

Extra Material:

Blood (10 ml) Blood (other amount, specify: _____ ml) Bone marrow (10 ml)

Buccal swab Hair Nail clipping Saliva Stool

Tissue biopsy (up to 8 cores), _____ (please specify site) Urine

Declaration by patient / participant / parent or legal guardian of patient / legal representative of patient

The nature of this donation has been explained to me in English or other language / dialect (please specify: _____) by consent taker / interpreter _____ (name).

I confirm the following:

- (i) I have received, read and understood the Information Sheet and fully discussed the purpose and procedures involving my donation.
- (ii) I have had the opportunity to clarify any and all queries that I may have had regarding my donation.
- (iii) I understand that my donation of the Leftover Material and / or Extra Material is in accordance with this consent form and the Information Sheet.
- (iv) I understand that my individually identifiable health information will be collected, used and stored as stated in sections 13 and 14 of the Information Sheet.
- (v) I understand that I may be contacted in the future if further consent is required from me.
- (vi) I understand that in the case of an incidental finding, I will not be re-identified and cannot therefore be informed of such incidental finding, except in the case of a significant and potentially life-saving incidental finding and only with my express consent to be informed.
- (vii) I understand that my Leftover Material and / or Extra Material may be exported overseas in de-identified form if any future research involves overseas collaboration.
- (viii) I understand that my donated Leftover Material and / or Extra Material will not be used in prohibited or restricted research under the Human Biomedical Research Act as specified in the Information Sheet.
- (ix) I understand that I will receive a copy of this consent form.

	Name (as stated in NRIC / passport)	Signature or left / right thumbprint	Date signed
Patient / Participant*			Date must be written by patient / participant
Parent / Legal Guardian / Legal Representative **	Required where the patient / participant is below 21 years of age and / or lacks mental capacity		Date must be written by parent / legal guardian / legal representative

* Where the patient / participant is a minor (i.e. a person who is below 21 years of age and has never been married) and is assessed by the consent-taker to have sufficient understanding and intelligence to understand what is proposed in the donation procedure, his / her consent to the donation of any Leftover or Extra Material **must** be obtained **in addition to** the consent from his / her parent / legal guardian / legal representative.

** No Extra Material may be collected from any patient / participant (a) lacking mental capacity or (b) who is below 21 years old and lacking sufficient understanding and intelligence to understand what is proposed in the donation procedure, using this consent form.

Declaration by witness (Witness must be 21 years old & above.)

I, the undersigned, certify that:

- (i) I witnessed this consent form and the Information Sheet being provided, and their contents being explained, to the patient / participant and / or the parent / legal guardian / legal representative (where applicable) and was present for the entire time.
- (ii) I have taken reasonable steps to ascertain the identity of the patient / participant and, where applicable, the parent / legal guardian / legal representative of the patient giving the appropriate consent.
- (iii) I have taken reasonable steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

	Name (as stated in NRIC / passport)	Signature	Date signed
Witness			

Declaration by person obtaining consent

I, the undersigned, certify to the best of my knowledge that the patient / participant or the parent / legal guardian / legal representative signing this consent form clearly understands the nature of the donation and the use of the Leftover Material and / or Extra Material and health information.

Where the patient / participant is a minor, I certify to the best of my knowledge that the patient / participant who has signed above **has** sufficient understanding and intelligence to understand what is proposed in the donation procedure.

Where the patient / participant is a minor, and **does not** have sufficient understanding and intelligence to understand what is proposed in the donation procedure, I will conduct an assent discussion in accordance with the Assent Form.

	Name (as stated in NRIC / passport)	Signature	Date signed
Person obtaining consent			