|  |  |
| --- | --- |
| **OFFICIAL USE ONLY (Please do not modify)** | |
| **Doc Name: Optional Consent Form for the Donation of Leftover Biological Samples** | |
| **Doc Number: 1704-15** | |
| Doc Version: 2 | Doc Approved Date: 26 Nov 2021 |

**Optional Consent Form for the Donation of Leftover Biological Samples**

|  |
| --- |
| ***Instructions***  *Please delete these instructions once you have completed customizing this consent form.*  *This template applies only to the storage of any leftover samples from the current research to be used for future research. Storage of leftover samples for this purpose will fall under the governance of the Human Tissue Framework, and will require communication of the HBRA 12(2) ICF elements under this template to the tissue donors. Any missing mandatory 12(2) elements will preclude the PI from storing leftover samples for future research use.*   * *Please read all instructions and guidance in blue text. Delete prior to submission.* * *Text in red are to be updated by PI.* * *Highlighted text indicates optional or alternate templates for selection. Delete the options or alternate templates that do not apply. Remove all highlights prior to submission.* |
| 1. **Study details**   Protocol Title:  (Enter Full Protocol title used in the DSRB Application Form Section A1)  Principal Investigator & Contact Details:  (Enter Full Name & Contact Details) |
| 1. **What is the purpose of donating the leftover biological samples?**   *(To fulfill HBRA 12(2)(k): Where applicable, whether biological material taken from the tissue donor will be destroyed, discarded or stored and used for future research)*  Your biological samples collected under the research titled above will be utilized for the purposes of that research. However, there may be instances where there may be some samples leftover from the research. This consent form is to obtain further consent from you to allow us to continue storing these leftover samples for the following purposes:  *(To fulfill HBRA 12(2)(a): The specific research purpose for which the tissue is intended to be used, if this information is available but if not available, the purpose for which the tissue is intended to be used may be stated as for general research)*  *If the study recruits persons with mental capacity to personally consent to the study, please apply the following:*  For future general research. At present, it is not possible to describe all future medical research objectives. These can either refer to defined disease areas (e.g. cancer, cardiovascular diseases, brain disorders), or to diseases or genetic disorders that at present are still partially unknown. Thus, it is possible that your samples may also be used for future research purposes which, at this stage, are unknown.  Or  For future research studies that are related to (define scope(s)).  *(To fulfill HBRA 12(2)(b): Whether the tissue will be used for any purpose other than research and if so, the specific purpose for which the tissue will be used)*  *If the study recruits persons with mental capacity to personally consent to the study, please apply the following:*  The samples may also be used to (if samples may be used for purposes other than future research, to state those purposes here).  Or  The samples will not be used for any purpose other than for future research.  *(To fulfill HBRA 12(2)(c): The proposed areas of research approved by the institutional review board in a case where it has waived the requirement that the removal of the tissue is primarily for a therapeutic or diagnostic purpose under section 37(3))*  *If the study recruits* ***ONLY*** *persons with mental capacity to personally consent to tissue donation, please apply the following:*  This study only recruits participants who can personally give consent to the study and the donation of the leftover samples.  *If the study will recruit a mix of persons who have mental capacity to personally consent to the study, and persons who lack mental capacity or lack sufficient understanding and intelligence to personally consent to the study (thereby requiring consent from their Legally Authorized Representatives(LARs)),* ***AND*** *the tissue obtained for the research is in excess of tissue primarily removed for a therapeutic or diagnostic purpose, please apply the following:*  This study may also recruit participants who may not be able to personally consent to the donation of the leftover samples, and where consent will be obtained from their Legally Authorized Representative(s). For this population, the leftover samples will be used only for future research that are related to (define scope(s)).  *If the study will recruit a mix of persons who have mental capacity to personally consent to the study, and persons who lack mental capacity or lack sufficient understanding and intelligence to personally consent to the study (thereby requiring consent from their Legally Authorized Representatives(LARs)),* ***AND*** *the tissue obtained for the research is leftover tissue primarily removed for a therapeutic or diagnostic purpose, please apply the following:*  This study may also recruit participants who may not be able to personally consent to the donation of the leftover samples, and where consent will be obtained from their Legally Authorized Representative(s). For this population, the study will only collect leftover samples that have been primarily removed for a therapeutic or diagnostic purpose, and that is no longer required for any clinical purposes.  *(To fulfill HBRA 12(2)(n): Whether the tissue will be used in restricted human biomedical research involving human-animal combinations)*  *Please refer to the Human Biomedical Research (Restricted Research) Regulations 2017 for more information on this.*  There may be a possibility that we may use the leftover samples in future research that involves human and animal combinations. Human-animal combinations are created through certain research techniques in which genes, cells or tissues from humans may be incorporated into animals (and vice versa) to facilitate the study of specific diseases. This type of research is strictly regulated and may only be conducted in accordance to the Human Biomedical Research Act. Please indicate on this form whether you consent to the use of your leftover samples for future research involving this area.  (Participant’s initials) Yes, I consent to the use of my leftover samples in future research that may involve human and animal combinations.  (Participant’s initials) No, I do not consent to the use of my leftover samples in future research that may involve human and animal combinations.  Or  Your leftover samples will not be used in future research that involves human and animal combinations. To explain briefly, human-animal combinations are created through certain research techniques in which genes, cells or tissues from humans may be incorporated into animals (and vice versa) to facilitate the study of specific diseases. We will ensure that such research will not be conducted with your samples. |
| 1. **How will your leftover samples and associated information be stored and used?**   *The storage period stated here should correspond with the period stated in the DSRB Application Form Section S1(vii)(a).*  We will store your leftover samples for the purposes mentioned above for a period up to (specify years) Or until they are all used up.  *(To fulfill HBRA 12(2)(i): The extent to which records identifying the donor will be kept confidential & HBRA 12(2)(m): Whether the tissue donation would result in the use of the donor’s tissue in an individually-identifiable form))*  We will separate your personal identifiers, i.e. name and any other information that may possibly identify you, from your samples stored. These will be replaced with a code, We will create a master list linking the code to your identifiers. This master list will be kept secure and accessible only to select study team members.  This means that any person(s) using your samples for the purposes stated above will not be able to directly identify who the samples belong to.  *(To fulfil HBRA 12(2)(m): Whether the tissue donation would result in the use of the donor’s tissue in an individually-identifiable form & HBRA 12(2)(j): Whether individually-identifiable information obtained from the tissue donor will be used for future research)*  There may be instances where the samples may be used with your personal identifiers or your information that was collected for the study. This may be for correlation purposes in the future research. In such instances, we will take careful steps to keep your personal identifiers and information secure.  Or  Any information that was collected for the study will also be coded and may be used with your coded leftover samples in future research. We will not attempt to link these back to your personal identifiers.  We will keep your samples and information in access-controlled storage. This means that only persons authorized may have access to the stored samples and information.  However, the Ministry of Health and the (National Healthcare Group (NHG) Tissue Compliance Committee/ if other RI, please state) will be granted direct access to your (original medical records/ study records) to check tissue banking-related procedures and data, without making any of your information public.  *(To fulfill HBRA 12(2)(l): Whether, and the circumstances under which, the donor or the person authorized to give consent under this Part, as the case may be, will be contacted for further consent)*  Please note that we will not contact you for further consent each time your leftover samples and Information are used in future research. |
| 1. **Information on “Incidental Findings” from future research conducted with leftover samples**   *(To fulfill HBRA 12(2)(o): Whether the donor or the person authorized 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)*  “Incidental Findings” are findings that have potential health or reproductive importance to research participants like you, and are discovered in the course of conducting research, but are unrelated to the purposes, objectives or variables of the research. These findings may affect your current or future life and/ or health insurance coverage.  We do not plan to contact you or your regular doctor with any incidental findings from future research conducted with your leftover samples. This is because research tests are often done using experimental procedures, so the results may not help in making decisions on managing your health.  In the rare case that any incidental findings reveal a condition likely to be life-threatening or grave, and can be avoided or ameliorated, the Principal Investigator/ a qualified healthcare professional will try contact you to ask if you would like to receive the finding. At the point of contact, you can choose to receive or refuse the finding.  If an incidental finding has public health implications (for example, infectious diseases) that are mandated by law to be notified to the relevant authorities, the Principal Investigator/ a qualified healthcare professional will contact you to inform you of the finding, and the implications of the finding.    *If the study intends to return other incidental findings from future research, please apply the following:*  In the case that a finding gives information that could affect the health of you or your family, the Principal Investigator/ a qualified healthcare professional will try to contact you. Information is considered important if it could have an impact on your health or well-being, or cause you to make different decisions related to your healthcare.  Please indicate under this section if you wish to be identified and contacted in the future to receive such information. At the point of contact, you can still choose to receive or refuse the result or finding.  (Participant’s initials) Yes, I want to be contacted when there is important information about my health.  In the event that I cannot be reached, please contact my next of kin  Name of next of kin:  Contact number:  (Participant’s initials) No, I do not want to be contacted when there is important information about my health.  If you have been communicated on any incidental findings, please seek further medical attention and confirmation of the result(s) in an accredited clinical laboratory. The costs for any care related to this would not be paid for by this research. These costs would be your responsibility. |
| 1. **Are there any risks from donating my leftover samples for future research?**   *(To fulfill HBRA 12(2)(d): The reasonably foreseeable risks, discomforts or inconveniences to a living donor arising from the removal of the tissue)*  Other than the initial physical risk from the removal of your biological material as described in the main research consent form, there are no additional physical risks expected from the collection of your leftover samples.  *If the future research may involve genetic testing, please apply the following:*  We may use your leftover samples for future research that involves genetic testing. Your body’s genetic makeup is unique to you. So, there is a risk in genetic research that even with all the security measures in place, someone using your samples or genetic information may still find out which data is yours. However, this risk today is small, but it may increase with time since science and technology are developing rapidly.    *If the option to receive incidental findings was offered under Section 4 of the ICF, please apply the following:*  If you had indicated under this Consent Form that you want to be contacted in the future if we find something that is important for your health, the findings may affect your current or future life and/ or health insurance coverage. |
| 1. **Will you benefit from donating your leftover samples for future research?**   You should not expect to get direct health benefits from donating your leftover biological samples for future research. The main reason you may want to donate your samples is to help researchers find new ways to prevent, detect, and treat health problems in the future. |
| 1. **What if I choose not to donate my leftover samples, or change my mind after I have consented?**   *(To fulfill HBRA 12(2)(e): The donation of the tissue is voluntary and the renunciation of the donor’s rights to the tissue and any intellectual property rights that may be derived from the use of the tissue & HBRA 12(2)(f): The donor’s right to withdraw his or her consent in the circumstances specified in section 14 and the limitations of such withdrawal as specified in that section)*  Choosing whether or not to donate your leftover samples for future research is voluntary. It is your choice whether or not to give consent for the storage and use of your samples and information, as described in this Consent Form. Choosing not to donate will not affect your medical care or cause you to lose benefits to which you are entitled.  Even if you decide now that your leftover samples can be stored for future research, you may still change your mind at any time. If this happens, you must tell the Principal Investigator that you have changed your mind.  In such a case, any results that arose from research conducted with the samples before your consent was withdrawn may be retained and used for the research. The reason is to enable a complete and comprehensive evaluation of the research. However, you retain your right to ask the Principal Investigator to discard or destroy any remaining samples that have not been used if the samples can still be linked to your personal identifiers, and it is practicable to discontinue its further use.  The leftover samples donated for future research will be deemed to be gifted to (Institution) and will not be returned to you. You will not have any right or claim to the samples at all or any intellectual property rights that may be derived from the use of the samples. |
| 1. **Are there any costs or payments if I consent to the donation of my leftover samples for future research?**   *(To fulfill HBRA 12(2)(h): Any anticipated expenses the donor is likely to incur as a consequence of donating tissue)*  There will not be any additional reimbursement for the donation of your leftover tissue for future research. You are also not expected to incur any costs from this donation.  *(To fulfill HBRA 12(2)(g): Any compensation and treatment available to the donor in the event of injury arising from participation in the process of tissue donation)*  As this consent pertains only to the donation of your leftover samples, there will not be any compensation or treatment for injury as we do not anticipate any physical injuries from this donation. |
| 1. **Will your leftover samples be shared overseas?**   *(To fulfill HBRA 12(2)(q): Whether the tissue will be exported or removed from Singapore to a place outside Singapore)*  Your leftover samples collected from this study will not be transferred out of Singapore.  Or  Your leftover samples collected from this study may be transferred out of Singapore. This is because researchers may want to use samples in large collaborative research with international institutions or commercial companies. We would like to seek your consent for your samples to be exported out of Singapore for research.  *If only coded samples will be transferred out of Singapore, please apply the following:*  Only coded samples will be transferred out of Singapore for future research. We will not release any personal information that could directly identify you without your permission.  \_\_\_\_\_ (Participant’s Initials) Yes, I give consent for my coded samples to be transferred out of Singapore for research.  \_\_\_\_\_ (Participant’s Initials) No, I do not give consent for any of my samples to be transferred out of Singapore for research.  *If individually-identifiable samples will be transferred out of Singapore, please apply the following:*  The samples containing your personal identifiers or information that may directly identify you will be transferred out of Singapore for future research. (Name of institution transferring the samples and information) will take appropriate steps to ensure it complies with the data protection requirements in the Personal Data Protection Act while your samples with personal information to be transferred remains in its possession or under its control.  \_\_\_\_\_ (Participant’s Initials) Yes, I give consent for my samples with identifiers to be transferred out of Singapore for research  \_\_\_\_\_ (Participant’s Initials) No, I do not give consent for any of my samples to be transferred out of Singapore for research |
| 1. **Who can you contact if you have further questions on the donation of your leftover samples?**   *(To fulfill HBRA 12(2)(p): The person or persons to contact to obtain further information on the purposes for which the tissue will be used and to provide feedback in relation to such purposes, respectively)*  If you have any further questions about the donation of your leftover samples for future research, or if you have any feedback in relation to this, you may contact the following:  Principal Investigator & Contact Details:  (Enter Full Name & Contact Details)  *If there are any additional contact points, please include:*  (Name & Contact Details)  If you want an independent opinion to discuss problems and questions, obtain information and offer inputs on your rights as a donor, you may contact the (NHG Tissue Compliance Committee Secretariat at 6496-6005/ if other RI, please state). You can also find more information about the (NHG Tissue Compliance Committee and its review processes at [www.research.nhg.com.sg/](http://www.research.nhg.com.sg/) if other RI, please state).  If you have any complaints or feedback in relation to this, you may contact the Principal Investigator or the (NHG Tissue Compliance Committee Secretariat/ if other RI, please state). |
| **CONSENT FORM**  **Protocol Title:**  (Enter Full Protocol title used in the DSRB Application Form Section A1)  **Principal Investigator and Contact Details:**  (Enter Full Name & Contact Details)  **Declaration by Participant**  I voluntarily consent to donate my leftover biological samples as described in this Consent Form. I have fully discussed and understood the purpose and procedures involved in the donation. This Informed Consent Form has been explained to me in a language that I understand. I have been given enough time to ask any questions that I have about the donation, and all my questions have been answered to my satisfaction.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Name of Participant |  | Signature |  | Date |     *If the study involves the recruitment of participants who will require consent from a Legally Authorized Representative (LAR), please include the following:*   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Name of Legally Authorized  Representative |  | Signature |  | Date |   *If the participant/ LAR is unable to understand English or read any of the translated consent document or short form consent forms available, please include the following:*  **Translator Information**  The details of the informed consent document has been explained to the participant in  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ by *\_\_\_\_\_\_*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (specify language) (name of translator)    Witness Statement  I, the undersigned, certify that:   * I am 21 years of age or older. * To the best of my knowledge, the participant signing this informed consent form has the informed consent document fully explained in a language understood by him/ her and clearly understands the nature, risks and benefits of donating leftover samples for future research. * I have taken reasonable steps to ascertain the identity of the participant/ the participant’s Legally Authorized Representative giving the consent. * I have taken steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.  |  |  |  |  |  | | --- | --- | --- | --- | --- | | Name of Witness |  | Signature |  | Date |  Declaration of Person obtaining consent I, the undersigned, certify that I have explained the donation of the leftover biological samples to the participant and to the best of my knowledge the participant signing this informed consent form clearly understands the nature, risks and benefits of his / her donation.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Name of Person Administering Consent |  | Signature |  | Date | |