**Consent Checklist for Research Studies**

This document contains consent checklists for different type of studies.

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| Part 1 | [Consent Elements for Human Biomedical Research (HBR) regulated under the Human Biomedical Research Act (HBRA)](#_Part_1:_Consent) |
| Part 2 | [Core and Situational Consent Elements for HBR regulated under the HBRA and approved by the IRB before 1 November 2018](#_Part_2:_Core) |
| Part 3 | [Consent Elements for Clinical Trials regulated under the Health Products Act (HPA) and Medicine Act (MA)](#_Part_3:_Consent) |
| Part 4 | [Consent Elements for Research Studies not regulated under the HBRA and/or HPA/MA](#_Part_4:_Consent) |

Please refer to the [CIRB Consent Template](https://www.singhealthdukenus.com.sg/research/rice/Pages/Forms%20and%20Resources.aspx) for the latest updates and recommended texts.

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| Part 1: Consent Elements for Human Biomedical Research (HBR) regulated under Human Biomedical Research Act (HBRA) |
| 1. Research study approved by IRB on or after 1 November 2018, appropriate consent must be obtained. 2. Please use **Part 1, Section A** to ensure the consent elements are present. 3. If the study involves removal, donation and use of Human Tissue, please use **Part 1, Section B** and ensure the elements are present in the Informed Consent Document. 4. Do include a negative statement of the consent elements if the study does not have a provision for it. |

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| **Section A: Consent Elements from section 12(1) of the HBRA**  *The following consent elements must be present in the consent documents.* | |
|  | 1. The investigational nature of the biomedical research. |
|  | 1. The purpose of the biomedical research. |
|  | 1. The reasonably foreseeable risks, discomforts or inconveniences to a living research participant arising from this biomedical research. |
|  | 1. The benefits which the research subject may reasonably expect from the biomedical research. |
|  | 1. Where applicable, whether there are any alternative procedures or treatments available to the research participant, and the potential benefits and risks of such alternatives. |
|  | 1. Any compensation and treatment available to the research subject in the event of injury arising from participation in the research. |
|  | 1. Any anticipated expenses the research subject is likely to incur as a consequence of participating in the biomedical research. |
|  | 1. The extent to which information identifying the research subject will be kept confidential. |
|  | 1. Whether individually-identifiable information obtained from the research subject will be used for future biomedical research. |
|  | 1. Where applicable, whether biological material taken from the research subject will be destroyed, discarded or stored for future biomedical research. |
|  | 1. Whether the research subject’s participation involves information in individually-identifiable form. |
|  | 1. The circumstances (if any) under which, the research subject or the person authorised to give consent under this Part will be contacted for further consent, including but not limited to changes in the proposed research, serious adverse events that would lead to a change in the proposed research, the development capacity by minors to make decisions and any other circumstances which could be specific to a particular research proposal. |
|  | 1. 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. |
|  | 1. The research subject’s right to withdraw his or her consent in the circumstances specified in section 14 and the limitations of such withdrawal specified in that section. |
|  | 1. The person or persons to contact to obtain further information on the biomedical research and to provide feedback in relation to the biomedical research, respectively. |
|  | 1. Such other information as the institutional review board may require. |
|  | 1. Such other information as may be prescribed |
| **Section B: Consent Elements from section 12(2) of the HBRA**  *This is mandatory for studies involving the removal, donation and use of Human Tissue.* | |
|  | 1. 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. |
|  | 1. 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. |
|  | 1. The proposed areas of research approved by the institutional review board in a case where it has waived the requirement that the removal of this tissue is primarily for a therapeutic or diagnostic purpose under section 37(3). |
|  | 1. The reasonably foreseeable risks, discomforts or inconveniences to a living donor arising from the removal of the tissue. |
|  | 1. 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. |
|  | 1. 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. |
|  | 1. Any compensation and treatment available to the donor in the event of injury arising from participation in the process of tissue donation. |
|  | 1. Any anticipated expenses the donor is likely to incur as a consequence of donating tissue. |
|  | 1. The extent to which records identifying the donor will be kept confidential. |
|  | 1. Whether individually-identifiable information obtained from the tissue donor will be used for future research. |
|  | 1. Where applicable, whether biological material taken from the tissue donor will be destroyed, discarded or stored and used for future research. |
|  | 1. Whether, and the circumstances under which, the donor or the person authorised to give consent under this part, as the case may be, will be contacted for further consent. |
|  | 1. Whether the tissue donation would result in the use of donor’s tissue in an individually-identifiable form. |
|  | 1. Whether the tissue will be used in restricted human biomedical research involving human-animal combinations. |
|  | 1. 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. |
|  | 1. 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. |
|  | 1. Whether the tissue will be exported or removed from Singapore to a place outside Singapore. |
|  | 1. Such other information as may be prescribed. |

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| Part 2: Core and Situational Consent Elements for HBR regulated under the HBRA and approved by the IRB before 1 November 2018 |
| 1. **Part 2** is to be used only for: 2. research study approved by IRB before 1 November 2018, and 3. the allowable scenarios described in the “Guidance on the Requirement of Appropriate Consent for the Conduct of Human Biomedical Research and Handling of Human Tissue” (“MOH Guidance”) that was last updated on 29 October 2021. 4. Research study approved by IRB on or after 1 November 2018, appropriate consent must be obtained. Please use **Part 1** of this document. |

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| **Consent Elements from Section 12(1) of HBRA** | | |
| Section A1: **Core** Consent Elements | | |
|  | 1. The investigational nature of the biomedical research. | |
|  | 1. The purpose of the biomedical research. | |
|  | 1. The reasonably foreseeable risks, discomforts or inconveniences to a living research participant arising from this biomedical research. | |
|  | 1. The benefits which the research subject may reasonably expect from the biomedical research. | |
|  | 1. The extent to which information identifying the research subject will be kept confidential. | |
|  | 1. Whether the research subject’s participation involves information in individually-identifiable form. | |
|  | 1. The research subject’s right to withdraw his or her consent in the circumstances specified in section 14 and the limitations of such withdrawal specified in that section. | |
| Section A2: **Situational** Consent Elements from Section 12(1) of HBRA  *Check “Yes” if it is applicable and “No” if it is not applicable to the research.* | | |
| Yes | No |  |
|  |  | 1. Where applicable, whether there are any alternative procedures or treatments available to the research subject, and the potential benefits and risks of such alternatives. |
|  |  | 1. Any compensation and treatment available to the research subject in the event of injury arising from participation in the research. |
|  |  | 1. Any anticipated expenses the research subject is likely to incur as a consequence of participating in the biomedical research. |
|  |  | 1. Whether individually-identifiable information obtained from the research subject will be used for future biomedical research. |
|  |  | 1. Where applicable, whether biological material taken from the research subject will be destroyed, discarded or stored for future biomedical research. |
|  |  | 1. The circumstances (if any) under which, the research subject or the person authorised to give consent under this Part will be contacted for further consent, including but not limited to changes in the proposed research, serious adverse events that would lead to a change in the proposed research, the development capacity by minors to make decisions and any other circumstances which could be specific to a particular research proposal. |
|  |  | 1. 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. |
|  |  | 1. The person or persons to contact to obtain further information on the biomedical research and to provide feedback in relation to the biomedical research, respectively. |
|  |  | 1. Such other information as the institutional review board may require. |
|  |  | 1. Such other information as may be prescribed. |

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| **Consent Elements from Section 12(2) of HBRA**  *This is mandatory for studies involving the removal, donation and use of Human Tissue. The consent obtained must have ALL the following Core Consent Elements.* | | | |
| Section B1: **Core** Consent Elements from Section 12(2) of HBRA | | | |
|  | | 1. 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. | |
|  | | 1. 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. | |
|  | | 1. The extent to which records identifying the donor will be kept confidential. | |
| Section B2: **Situational** Consent Elements from Section 12(2) of HBRA  *Check “Yes” if it is applicable and “No” if it is not applicable to the research.* | | | |
| Yes | No | |  |
|  |  | | 1. 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. |
|  |  | | 1. The proposed areas of research approved by the institutional review board in a case where it has waived the requirement that the removal of this tissue is primarily for a therapeutic or diagnostic purpose under section 37(3). |
|  |  | | 1. The reasonably foreseeable risks, discomforts or inconveniences to a living donor arising from the removal of the tissue. |
|  |  | | 1. 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. |
|  |  | | 1. Any compensation and treatment available to the donor in the event of injury arising from participation in the process of tissue donation. |
|  |  | | 1. Any anticipated expenses the donor is likely to incur as a consequence of donating tissue. |
|  |  | | 1. Whether individually-identifiable information obtained from the tissue donor will be used for future research. |
|  |  | | 1. Where applicable, whether biological material taken from the tissue donor will be destroyed, discarded or stored and used for future research. |
|  |  | | 1. Whether, and the circumstances under which, the donor or the person authorised to give consent under this Part (as the case may be) will be contacted for further consent. |
|  |  | | 1. Whether the tissue donation would result in the use of donor’s tissue in an individually-identifiable form. |
|  |  | | 1. Whether the tissue will be used in restricted human biomedical research involving human-animal combinations. |
|  |  | | 1. 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. |
|  |  | | 1. 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. |
|  |  | | 1. Whether the tissue will be exported or removed from Singapore to a place outside Singapore. |
|  |  | | 1. Such other information as may be prescribed. |

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| Part 3: Consent Elements for Clinical Trials regulated under the Health Products Act (HPA) and Medicine Act (MA) |
| 1. **Part 3** is applicable to clinical trials regulated under HPA and MA. 2. Please use **Part 3, Section A** to ensure the consent elements are present. 3. New clinical trials which involve storing of tissues that are submitted to H.S.A after 1 August 2021 have to include the additional consent elements from **point (ta)**. 4. If the trial involves collection, storage, supply or use of additional human tissue/ leftover human tissue for purposes outside of the regulated clinical trial, the consent elements should comply with the requirements of the HBRA Section 12(2). Please refer to **Part 1, Section B**. 5. Do include a negative statement of the consent elements if the study does not have a provision for it. |

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| **Section A: Consent Elements from section 19(1) of the Health Products (Clinical Trials) Regulations and the Medicines (Clinical Trials) Regulations** | |
|  | 1. That the trial involves research. |
|  | 1. The purpose of the trial. |
|  | 1. The treatments or procedures to be administered in the trial and the probability for random assignment of each treatment or procedure. |
|  | 1. The procedures to be followed in the trial, including all invasive procedures. |
|  | 1. The responsibilities of the subject. |
|  | 1. The aspects of the trial which are experimental. |
|  | 1. The reasonably foreseeable risks or inconveniences to the subject and, where applicable, to any embryo, foetus or nursing infant. |
|  | 1. The reasonably expected benefits, including whether there is any intended clinical benefit to the subject. |
|  | 1. Any alternative procedures or treatments available to the subject, and their potential benefits and risks. |
|  | 1. Any compensation and treatment available to the subject in the event of injury arising from participation in the trial. |
|  | 1. The circumstances which may result in the pro-ration of payment to the subject for participating in the trial. |
|  | 1. Any anticipated expenses to the subject from participating in the trial. |
|  | 1. That the subject’s participation in the trial is voluntary and that the subject’s participation in the trial may be refused, or the subject withdrawn from the trial, at any time without penalty or loss of benefits which the subject would be entitled. |
|  | 1. The persons who will be granted access to the subject’s medical records and the extent of such access, including the possibility that the Authority may inspect the records. |
|  | 1. The extent to which records identifying the subject will be kept confidential. |
|  | 1. That —   (i) any person whose consent is required under regulation 16 or 17 (including a subject who regains capacity to consent); or  (ii) the family member contacted under regulation 17(5), in circumstances where the consent of neither the subject nor the legal representative has been obtained,  will be informed in a timely manner of any information which becomes available and which may be relevant to the decision of the potential subject being, or the subject continuing to be, a subject (as the case may be). |
|  | 1. The persons to contact for further information relating to the trial and the rights of subjects in the event of injury arising from participation in the trial. |
|  | 1. Any foreseeable circumstances under or reasons for which a subject’s participation may be terminated. |
|  | 1. The expected duration of the subject’s participation in the trial. |
|  | 1. The approximate number of subjects involved in the trial. |
|  | ta. Where the trial involves the collection of tissue from the subject for use in the trial —  (i) that the provision of the tissue is voluntary, and the renunciation of the subject’s rights to the tissue and any intellectual property rights that may be derived from the tissue;  (ii) whether the tissue will be exported or removed from Singapore to a place outside Singapore; and  (iii) whether the subject would wish to be re-identified in the case of an incidental finding, if the clinical trial expressly provides for such re-identification. |
|  | 1. Any other information which the Authority may require to be given. |

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| Part 4: Consent Elements for Research Studies not regulated under the HBRA and/or HPA/MA |
| 1. **Part 4, Section A** is applicable to other research studies not regulated under the HBRA and/ or HPA/MA. 2. Please use **Part 4, Section A** to ensure the basic elements of informed consent are present in the Informed Consent Document. 3. The IRB may request to include other elements of informed consent in the Informed Consent Document as required. |

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| **Section A: Consent Elements for Research Studies not regulated under the HBRA and/or HPA/MA** | |
|  | 1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant's participation, a description of the procedures to be followed, and identification of any procedures which are experimental. |
|  | 1. A description of any reasonably foreseeable risks or discomforts to the participant. |
|  | 1. A description of any benefits to the participant or to others which may reasonably be expected from the research. |
|  | 1. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant. |
|  | 1. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained. |
|  | 1. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. |
|  | 1. An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant. |
|  | 1. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled. |
|  | 1. One of the following statements about any research that involves the collection of identifiable private information or identifiable human biological materials:   (1) A statement that identifiers might be removed from the identifiable private information or identifiable human biological materials and that, after such removal, the information or human biological materials could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the participant or the legally authorized representative, if this might be a possibility; or  (2) A statement that the participant's information or human biological materials collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies. |