**Core and Situational Consent Elements Checklist for HBR Study**

1. This checklist is to be used only for:
2. research study approved by IRB before 1 Nov 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 released on 17 May 2019.
4. Research study approved by IRB on or after 1 Nov 2018, appropriate consent must be obtained. Please use the Appropriate Consent Checklist.

Core and Situational Consent Elements

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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 participation of the research subject 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 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. 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.
 |
| [ ]  | [ ]  | 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.
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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 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 purpose for which the tissue will be used and to provide feedback in relation to such purposes, respectively.
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| [ ]  | [ ]  | 1. Whether the tissue will be exported or removed from Singapore to a place outside Singapore.
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