**Consent Checklist for Clinical Trials regulated under HPA/MA**

1. This is applicable to clinical trials regulated under Health Products Act (HPA) and Medicine Act (MA).
2. Please use 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 Section B.
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).

Consent element 12(2)(k) of the HBRA is not mandatory. It depends on the study design. For the rest of consent elements, they must be included even if the study does not have a provision for it.

For example, if the study does not have incidental findings and/or no re-identification will be provided, the section on “Incidental Findings” has to be included in the consent documents.

Please complete Section C and ensure the elements are present in the consent document as well.

| **Section A: Consent Elements from section 19(1) of the Health Products (Clinical Trials) Regulations and the Medicines (Clinical Trials) Regulations** | |
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|  | 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 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. |
|  | 1. Any other information which the Authority may require to be given. |

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| **Section B: Consent Elements from section 19(1)(ta) of the Health Products (Clinical Trials) Regulations and the Medicines (Clinical Trials) Regulations**  *If the trial involves the collection of tissue from the subject for use in the trial, the additional consent elements should be included.* | |
|  | 1. 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. |
|  | 1. Whether the tissue will be exported or removed from Singapore to a place outside Singapore; and |
|  | 1. 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. |

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| **Section C: Consent Elements from section 12(2) of HBRA**  *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). The consent elements are mandatory except (k).* | |
|  | 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 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 purpose 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. |