CHICKEN SOUP FOR THE BUSY COORDINATOR

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Regulatory Guidance on Consent Requirements for Clinical Trials involving Collection and Use of Human Tissue

Dr Mark Tan, a Principal Investigator (PI), is conducting an Investigator-Initiated randomised double-blind clinical trial. The clinical trial aims to recruit healthy young adults who are aged ≤ 40 years old with borderline high cholesterol, to test the effectiveness of lifestyle intervention with addition of Drug X to lower cholesterol.

Trial participants in both treatment arms will undergo a 6-month exercise program, doctor and dietitian consultation, blood samples for endpoint assessment and interviewer-administered questionnaires at various timepoints.

Furthermore, the PI intends to collect additional blood samples from this clinical trial for future research.

The PI would like to verify if the following additional consent elements in the ICF are sufficient for this clinical trial and future research before submission to Health Sciences Authority (HSA) and Institutional Review Board (IRB) for approval. Would the additional consent elements in the ICF be appropriate?

Additional consent elements in the ICF *(In addition to the consent elements specified in Health Products (Clinical Trials) Regulation & ICH E6 Good Clinical Practice Guidelines)*	✓ That the provision of the tissue is voluntary, and the renunciation of the trial participant's rights to the tissue and any intellectual property rights that may be derived from the tissue ✓ Whether the trial participant would wish to be re-identified in the case of an incidental finding relating to the collected tissue if the clinical trial expressly provides for such re-identification ✓ Whether the tissue will be exported or removed from Singapore to a place outside Singapore.

Since this clinical trial is regulated by HSA and involves the collection of human tissue i.e., blood for the purposes of the clinical trial,

The additional consent elements in the ICF are appropriate[1].

Collection of Human Tissue for future unspecified research

- The collection, storage, supply or use of leftover tissue or additional tissue for research purposes are covered by the Human Tissue Framework under Human Biomedical Research Act (HBRA), administered by Ministry of Health (MOH)[2].
- In view that the PI intends to collect additional blood samples from trial participants for future unspecified research, the PI should refer to the MOH for further information, including the ICF requirements for collection of additional tissue samples for future unspecified research[2].

References

1. Health Products (Clinical Trials) Regulations 2016 - Singapore Statutes Online (agc.gov.sg) - Health Products (Clinical Trials) Regulations 2016 - *Regulation 19 (1)(ta)*
2. https://www.moh.gov.sg/policies-and-legislation/human-biomedical-research-act - Guide on the Requirement of Appropriate Consent for the Conduct of HBR and Handling of Human Tissue (Updated 29 October 2021)

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