RESEARCH
@ SINGHEALTH DUKE-NUS ACADEMIC MEDICAL CENTRE

amri Academic Medicine Research Institute
SingHealth Duke-NUS

HOW TO BE COMPLIANT WITH THE HUMAN BIOMEDICAL RESEARCH ACT (HBRA)?

Obtain Appropriate Consent

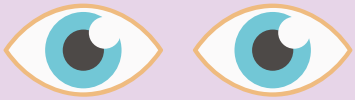
The following 4 requirements must be met in order to have obtained appropriate consent:

a) Consent must be obtained in writing

b) Consent must be obtained from the research participant or tissue donor personally or their legal proxies

c) Consent must be obtained only after the information referred to in Section 12* has been provided and explained to the research participant or tissue donor or their legal proxies

d) Consent must be obtained in the presence of a prescribed witness (when not exempted)



Appropriate Consent Checklist

Note: All HBR studies commenced on or after 1 Nov 2018 must comply with HBRA. Failure to obtain appropriate consent constitutes a contravention, the study team is required to file a Study Deviation/Non-Compliance (DNC) report to the IRB via ECOS.
*Please scan the QR code to read all the requirements in detail.

Reference: Human Biomedical Research Act Section 6

Report Serious Adverse Events & Contraventions

- Principal Investigators (PI) are required to report **Serious Adverse Events (SAEs)** and **Study Deviation/Non-Compliance (DNC)** to the IRB through ECOS.
- Events that are reportable to MOH will be identified and ORIC will work with PIs to complete the necessary submissions to MOH.

Questions?

Please contact your Institution's Research Office or RICE (**oric@singhealth.com.sg**).
For more information about HBRA and Human Tissue Framework, please refer to ORIC website for the following:

- SingHealth Docupedia - ORIC Roadshows slides and Newsletters
- MOH weblinks – Human Biomedical Research Act (including HBR and HTF Regulations)