

# CONDUCTING MEDICAL DEVICE CLINICAL TRIALS

The conduct of Medical Device Clinical Trials is regulated under the Human Biomedical Research Act (HBRA). The manufacture, import and supply of the Medical Device used as a clinical research material (CRM) in Singapore must comply with the regulatory controls for CRM.

SingHealth Research Integrity, Compliance and Ethics (RICE) and SingHealth Medical Technology Office (MTO) will jointly host a webinar to share on pre-study planning and the regulatory requirements of conducting Medical Device Clinical Trials.

## Webinar Highlights:

- Planning a Medical Device project with Clinical Trial intentions
- Risk Assessment Process before IRB submission
- Requirements for Clinical Research Material Notification (CRM-N)
- Regulatory Requirements on the conduct of Medical Device Clinical Trials

## **Registration is required.**

After registering, you will receive a confirmation email containing information about joining the webinar.

**14 SEPTEMBER 2021 (TUE)**  
**12:00 PM - 1:45 PM**

SCAN HERE



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For enquiries, please email [oric@singhealth.com.sg](mailto:oric@singhealth.com.sg) (HBRA matters) or [mto@singhealth.com.sg](mailto:mto@singhealth.com.sg) (Medical Technology matters).