

RESEARCH

@ SINGHEALTH DUKE-NUS
ACADEMIC MEDICAL CENTRE

Reporting Workflow for Protocol Deviation and Non-compliance in Clinical Research

1 Protocol Deviation & Non-Compliance Identified

Examples



Incorrect dose or route of Investigational Product administered



Unapproved or superseded Informed Consent Form used



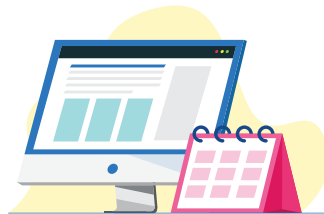
Lapse in IRB validity approval period during conduct of research

2 PI Reports Immediately to IRB (via ECOS)

SERIOUS BREACH IN CLINICAL TRIALS



Sponsor reports to HSA within 7 calendar days.
(For IIT, the institution is the sponsor)



SUSPECTED CONTRAVENTION IN HUMAN BIOMEDICAL RESEARCH



SingHealth RICE reports to MOH within 7 calendar days or consolidates for annual reporting.



PI to provide additional information to RICE for the MOH reporting. This should be done via ECOS.



For more information on reporting of Suspected Offence or Contraventions (SOC) on ECOS
Scan the QR code to refer to RICE website



HAVE A QUESTION?

Please contact your Institution's Research Office or ORIC (oric@singhealth.com.sg)



REFERENCES

MOH - Human Biomedical Research Act
HSA - Clinical Trial Guidance - Notification of Serious Breach