RESEARCH
@ SINGHEALTH DUKE-NUS ACADEMIC MEDICAL CENTRE

amri Academic Medicine Research Institute SingHealth Duke-NUS

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

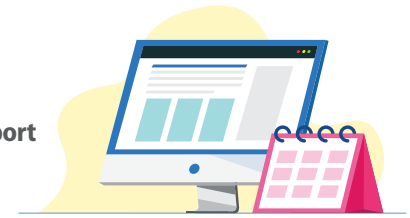
Unapproved or superseded Informed Consent Form used

Lapse in IRB validity approval period during conduct of research

2 PI Reports Immediately to IRB (via iSHaRe or ROAM)

SERIOUS BREACH IN CLINICAL TRIALS

PI or Sponsor report to HSA within 7 calendar days.



SUSPECTED CONTRAVENTION IN HUMAN BIOMEDICAL RESEARCH

SingHealth RICE report to MOH within 7 calendar days or consolidate for annual reporting.

PI to provide additional information to RICE for submission to MOH.

For more information on Suspected Contravention and Serious Breach
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