HBRA-CSIG-2022-001-AUD
August 2022

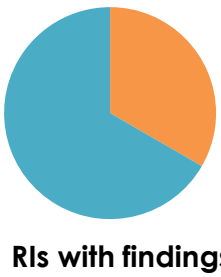
MINISTRY OF HEALTH
SINGAPORE

Human Biomedical Research Act

HBR Regulatory Audit – Highlights

ENSURING COMPLIANCE WITH HBRA REQUIREMENTS FOR RESEARCH INSTITUTIONS

MOH has audited **36 research institutions** in the first cycle of audits. A total of **46 findings** were detected.



Findings were found in 67% of RIs audited.

Most findings were related to:

1. Consent
2. Protocol Deviation

Studies involving minors or individuals lacking mental capacity were found to have more findings.

PRACTICES OBSERVED THAT HELP ENSURE COMPLIANCE

1 Ensure compliance with IRB-approved protocols

RIs should proactively put in place internal monitoring processes to detect and report suspected offences or contraventions (SOCs) promptly.

Even if the RI delegates its duties under the HBRA to another entity or service provider, the RI should still be familiar with the requirements under the HBRA as it is still legally liable.

PRACTICES OBSERVED THAT HELP ENSURE COMPLIANCE

2 Ensure that appropriate consent has been obtained

Where minors or vulnerable participants are recruited, researchers should check that consent is obtained from the parent or person authorised to consent on their behalf.

Researchers should check the consent forms to ensure that they are of the latest version and form is complete.

RIs and researchers could explore e-consent or digital tools to obtain parental signature after explaining the research to the parents through phone/video calls in the presence of a witness. (e.g., follow-up through email, obtain signature through the Sign with Singpass service)

3 Ensure familiarity with requirements under HBRA

RIs should establish policies and systems to guide study teams and researchers to comply with the HBRA, particularly on appropriate consent, data management, management of SOCs/SAEs, etc.

Researchers should ensure that the study teams are adequately briefed and trained to conduct the research procedures. (e.g. consent-taking, performing interventions)

Questions?

Contact us at hbr_enquiries@moh.gov.sg

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