Role of a Clinical Research Associate (CRA)

Singapore Healthcare Management 2018

LEONG Mei Hui
Jason LIM Yung
CHAN Yee Fong
Emily LIM Sook Ai
Grace WONG Chui Pinn
TAN Kok Tin
SingHealth HQ, Office of Research Integrity and Compliance

SingHealth

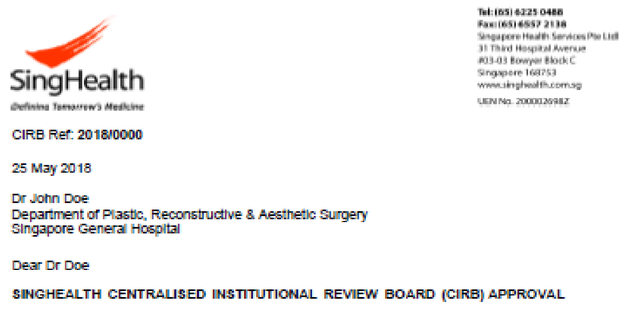
INTRODUCTION

- Under the Office of Research Integrity and Compliance (ORIC), Clinical Research Associates (CRAs) are responsible for providing quality assurance to the research conducted in SingHealth.
- Using different monitoring approaches, CRAs monitor the progress of clinical research and ensures that the research is conducted in accordance with protocol, SOPs, ICH GCP E6(R2) and HBRA.

METHODOLOGY

- Due to the high volume of research studies, not all studies are selected for monitoring.

CRA assigned contacts the Principal Investigator (PI) to arrange monitoring visit



SingHealth
Defining Tomorrow's Medicine

Tel: (65) 6225 0488
Fax: (65) 6557 2138
Singapore Health Services Pte Ltd
31 Third Hospital Avenue
#03-03 Bowyer Block C
Singapore 168753
www.singhealth.com.sg
UEN No. 200002998Z

CIRB Ref: **2018/0000**

25 May 2018

Dr John Doe
Department of Plastic, Reconstructive & Aesthetic Surgery
Singapore General Hospital

Dear Dr Doe

SINGHEALTH CENTRALISED INSTITUTIONAL REVIEW BOARD (CIRB) APPROVAL

Protocol Title: Analgesic ABC used in Patients with Breast Augmentation

We are pleased to inform you that the SingHealth CIRB X has approved the above research project to be conducted in Singapore General Hospital.

This approval is mutually recognised by NHG Domain Specific Review Board (DSRB).

The documents reviewed are:
a) Protocol version 1.0, dated 1st April 2018
b) Participant Information Sheet version 1.0, dated 1st April 2018

The SingHealth CIRB operates in accordance with the ICH/ Singapore Guideline for Good Clinical Practices, and with the applicable regulatory requirement(s).

The approval period is from **25 May 2018** to **24 April 2019**

Yours sincerely,

Dr Jane Roe
Chairman
SingHealth Centralised Institutional Review Board X

cc: Institution Representative, SGH
Head, Department of Plastic, Reconstructive & Aesthetic Surgery, SGH

This submission is reviewed online. No signature is required.

PATIENTS. AT THE HEART OF ALL WE DO.

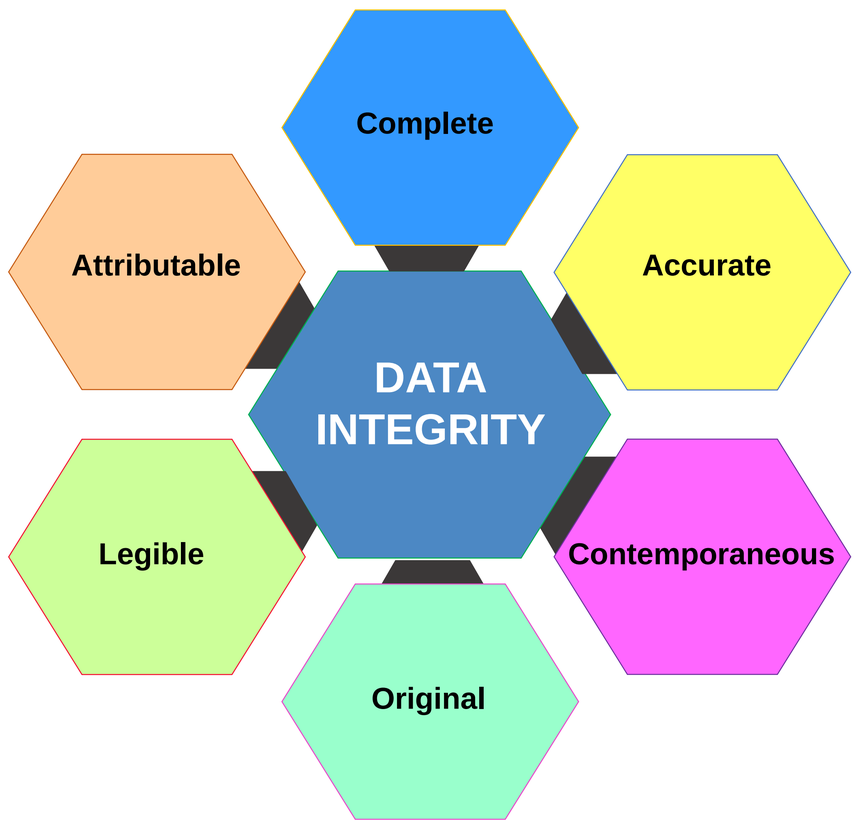
SingHealth Academic Healthcare Cluster
Singapore General Hospital • KK Women's and Children's Hospital
National Cancer Centre Singapore • National Dental Centre Singapore • National Heart Centre Singapore • National Neuroscience Institute
Singapore National Eye Centre • SingHealth Polyclinics • Bright Vision Hospital • Sengkang Health

Provide guidance to ensure proper setup, continuous compliance and quality according to protocol, GCP and HBRA

INVESTIGATOR SITE FILE CONTENT
Investigator's Brochure
Study Protocol and Amendments
Informed Consent Form
Institutional Review Board (IRB)
Health Sciences Authority (HSA)
Study Personnel
Investigational Product (IP)

Studies are risk stratified and selected

Ensure overall data and study integrity are met, and publication goals met



- Monitoring activities and issues identified are documented in monitoring visit report.
- Major findings that impacts subject's safety of credibility of data will be escalated to IRB and ORIC management.
- In serious cases, study may be suspended or terminated by IRB, HSA or MOH.

RESULT

- Observations and recommendations are discussed with research team for possible improvements and resolution.
- Source data verification are performed to ensure data accuracy.
- Overall quality and performance metrics are generated and analysed.

	Issue Type	Description	Action Required/Taken By Site
1	Informed Consent Form (ICF)	Superseded version of the ICF was used.	- To obtain consent from subject with the latest approved ICF at the earliest time possible. - To promptly report the non-compliance to IRB. - To notify HSA of non-compliance if PI has assessed it as a serious breach.
2	Protocol Deviation/Non-Compliance	Study procedures were performed prior to signing of ICF.	- To promptly report the non-compliance to IRB. - To notify HSA of non-compliance if PI has assessed it as a serious breach.

CONCLUSION

Monitoring is an integral part of clinical research quality assurance process to provide compliance oversight and ensure that research is conducted with integrity.