OFFICE OF HUMAN RESEARCH PROTECTION PROGRAMME (OHRPP)

12. STUDY CLOSURE

BIOMEDICAL DOMAINS A-E



POPULATION HEALTH - DOMAIN F

Reference:

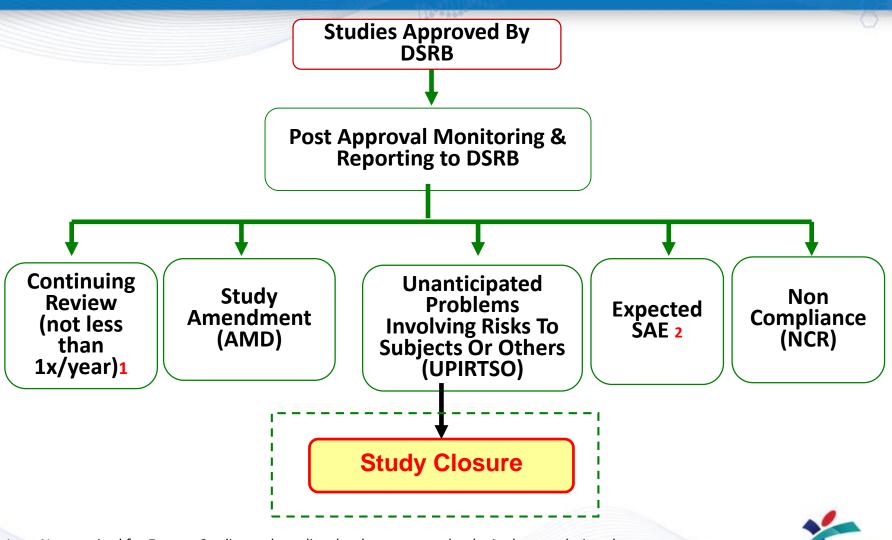
NHG Investigator Manual

NHG Group Research

Version November 2022



Study Closure



- 1. Not required for Exempt Studies and studies that have reported to be in data analysis only stage
- 2. Only applicable to Human Biomedical Research (HBR) studies



Study Closure

A research study is said to be completed when all of the following cr	iteria are
fulfilled:	

fulfilled:		
1	The is permanently closed to enrollment of new participants	\checkmark
2	All participants have completed all research-related interventions	\checkmark
3	Collection and analysis of individually identified data have been completed	

What should you do?	PI should submit a study completion report 4-6 weeks after completion of the study using DSRB Study Status Report Form.	
What will DSRB do?	 DSRB will review the Study Status Report Form and obtain any outstanding information or documentation from PI. If there are any inconsistencies or if clarification is needed, additional information will be requested. 	

For more information, refer to:

- NHG IM Chapter 4.9.3 Study Completion
- NHG Proper Conduct of Research_501-B09 Study Completion Activities



Suspension & Termination

A study may be closed before completion due to:

- Termination by the PI or other parties including sponsors, DSRB, Institution Representatives of withdrawal of funding.

- Activation of Study Suspension / Termination by DSRB when:
 - Inappropriate involvement of human subjects in research
 - Inhibition of the rights or welfare of participants.
 - Serious or continuing non-compliance with regulations or DSRB policies.
 - New information regarding increased risk to human participants.
 - Expiry of approval.
- Activation of Study Suspension / Termination by Institution, PI or Sponsor:
 - PI should submit a report within 7 days to DSRB



Questions?

Refer to www.research.nhg.com.sg
Or contact the NHG Research
Education Unit @
researchcoord@nhg.com.sg

