

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***

Restricted, Sensitive - Normal ©  
National Healthcare Group Pte Ltd



Adding years of healthy life

# Study Closure

Studies Approved By  
DSRB

Post Approval Monitoring &  
Reporting to DSRB

Continuing  
Review  
(not less  
than  
1x/year)<sup>1</sup>

Study  
Amendment  
(AMD)

Unanticipated  
Problems  
Involving Risks To  
Subjects Or Others  
(UPIRTSO)

Expected  
SAE <sup>2</sup>

Non  
Compliance  
(NCR)

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

[2]

# Study Closure

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

1	The is permanently closed to enrollment of new participants	<input checked="" type="checkbox"/>
2	All participants have completed all research-related interventions	<input checked="" type="checkbox"/>
3	Collection and analysis of individually identified data have been completed	<input checked="" type="checkbox"/>

<b>What should you do?</b>	PI should submit a study completion report <b>4-6 weeks</b> after completion of the study using DSRB <b>Study Status Report Form</b> .
<b>What will DSRB do?</b>	<ul style="list-style-type: none"> <li>• DSRB will review the Study Status Report Form and obtain any outstanding information or documentation from PI.</li> <li>• If there are any inconsistencies or if clarification is needed, additional information will be requested.</li> </ul>

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](http://www.research.nhg.com.sg)

Or contact the NHG Research  
Education Unit @  
researchcoord@nhg.com.sg