NHG RESEARCH QUALITY MANAGEMENT – PRINCIPAL INVESTIGATOR SELF-ASSESSMENT FORM (PISAF)

Principal Investigator :	
ECOS Reference Number:	**Date of Completion of PISAF:**

1. Objectives:

- To familiarise investigators with IRB & Regulatory requirements of proper research conduct.
- To identify areas for improvement in their conduct of research.

2. Guide on completion of PISAF:

- Please tick '**Yes'** if the question is applicable to your study and you have fulfilled requirements.
- Please tick '**No'** if the question is applicable to your study but you have not been conducting the activities according to requirements.
- Please tick '**NA'** if the question is not applicable.
- Please provide comments if further elaboration is required.

3. All reference (NHG Proper Conduct of Research (PCR) SOPs, templates and logs) can be found via:
https://ethics.gri.nhg.com.sg/pcr-sop-templates/

1.	**IRB REQUIREMENTS**	Yes	No	NA
1.1	Have you filed all the IRB related records in the investigator file? *E.g. approval letters, approved study documents, IRB submissions, safety reports, deviation and non-compliance report (DNC).* **You may refer to NHG PCR 507-002 Investigator File Content Template for guidance on what to file.* *Comments:*	☐	☐	☐
1.2	Have you ensured that <u>all</u> revisions to the study were submitted via a study amendment and approved by the IRB prior to implementation? **If 'No', please submit a deviation and non-compliance report (DNC) to the IRB.* *Comments:*	☐	☐	☐
2.	**REGULATORY REQUIREMENTS**	Yes	No	NA
2.1	Where applicable, have you kept all HSA/MOH related documents in the investigator file? *E.g. HSA/MOH approvals*,*	☐	☐	☐

	appropriate licences, CRM notification, status reports, significant correspondence. **Under the HBRA, MOH approval is required if you are conducting Restricted Research.* **If 'No', please ensure a copy of the documents are filed in the Investigator File.* *Comments:*			
3.	**STUDY TEAM (PCR SOP 501-A02, 501-A03 and 501-B03)**	Yes	No	NA
3.1	Have you recorded relevant trainings for all study team members, including the PI, and filed the records in the investigator file? *E.g. training record form/log to record the training on the study, CITI/GCP/HBR training certs, CVs.* **You may refer to NHG PCR Form 505-001 for the training record form.* *Comments:*	☐	☐	☐
3.2	Did you document all study specific roles and responsibilities: a. for study team members in the study responsibility/delegation log (e.g. consent taking, data entry, investigator file maintenance) and b. for external parties (e.g. service providers) with agreements in place if applicable? **You may refer to NHG PCR Log 509-002 for the study responsibility/delegation log.* *Comments:*	☐	☐	☐
3.3	For changes to PI, Site-PI or Co-I, have you informed the IRB? **If 'No', please update the IRB via a study amendment and submit a deviation and non-compliance report (DNC) if the PI/ Site-PI/ Co-I had conducted study activities prior to IRB approval.* *Comments:*	☐	☐	☐
4.	**INFORMED CONSENT FORM (ICF) AND CONSENT PROCESS (PCR SOP 501-C01)**	Yes	No	NA
4.1	If the study involves consent taking (*i.e. written or verbal*) from subjects, did you use the appropriate approved form/script? **If 'No', please submit a deviation and non-compliance report (DNC) to the IRB.* *Comments:*	☐	☐	☐

4.2	Did you consent non-English speaking subjects or Legal Representative (LR) using the appropriate consent forms (e.g. fully translated consent form or translated short consent form)? **If 'No', please submit a deviation and non-compliance report (DNC) to the IRB.* *Comments:*	☐	☐	☐
4.3	Was the ICF personally signed and dated by all relevant parties where appropriate? *I.e. subject, person taking consent, LR or partial/impartial witness*. **a. If 'No' and relevant parties are capable of personally signing and dating the ICF, please submit a deviation and non-compliance report (DNC) to the IRB.* **b. If the date was entered by an impartial witness for physically/visually impaired subjects, this should be explained in the medical records/source records.* *Comments:*	☐	☐	☐
4.4	Was the consent process (written or verbal consent) documented in the medical records or other source records (if medical records are not available)? **Documentation of the consent process should be done after signing the informed consent form, in the medical records or other source records.* **If consent process was not documented in the source records, please generate a note to file/addendum, signed and dated by the individual who had obtained consent to explain the consent process.* **Please note that the consent process documentation should minimally include the following information:* *1. Protocol reference (e.g study title or reference no.)* *2. Date of informed consent* *3. Informed consent process (e.g. use of substiuite consent, partial/impartial witness, translator, and the reason for engaging these individuals)* *4. Whether a complete signed copy of the ICF was provided to subject/LR* *Comments:*	☐	☐	☐

4.5	Was a complete copy of the signed ICF given to each subject/LR ? **If subject/LR did not receive a copy of the signed ICF, please submit a deviation and non-compliance report (DNC)to the IRB.* *Comments:*	☐	☐	☐
5.	**SUBJECT RECRUITMENT(PCR SOP 501-C02)**	Yes	No	NA
5.1	If the study involves subject enrollment, have you ensured that eligibility is assessed only by qualified and trained study team members who are delegated on the study responsibility/delegation log? **You may refer to NHG PCR SOP 501-A02, 501-A03 and 501-C02 for details on the responsibilities of the study team and subject recruitment.* *Comments:*	☐	☐	☐
5.2	Have you recorded the eligibility assessment on the source document? *E.g. medical records, study specific eligibility checklist.* The eligibility assessment should be documented in the source records. The documentation should include who conducted eligibility assessment, when & what assessment(s) was performed, and whether subject met all eligibility criteria. * The study team may develop an eligibility checklist based upon the study inclusion and exclusion criteria to verify the eligibility of each subject who have consented to participate in the study. The eligibility checklist should be signed off by the study team member who had performed the eligibility assessment. **You may refer to NHG PCR Document 504-008 for the Eligibility Checklist.* *Comments:*	☐	☐	☐
5.3	Have you recruited subjects according to the method(s) approved by the IRB? **If 'No', please submit a deviation and non-compliance report (DNC)to the IRB.* *Comments:*	☐	☐	☐

5.4	Have you maintained subject logs in the investigator file? *E.g. subject screening/enrollment log, subject identification (ID) log*. **If 'No', please create subject screening/enrollment/ ID logs for the study. You may refer to NHG PCR Log 509-007 and 509-014.* **For medical record review studies, please ensure that a list of subjects included in the study are maintained to keep track of the number of subjects reviewed.* *Comments:*	☐	☐	☐
5.5	If randomization is performed, please ensure that randomization records (e*E.g. master randomization codes, unblinding procedures, used and unused randomization envelopes, record of persons performing the randomisation)* are kept in the investigator file. Unless you have additional comments, no response is required for this question. *Comments:*			
6.	**INVESTIGATIONAL PRODUCT (IP) (PCR SOP 501-B06)** *This section is applicable to Investigational Products (e.g. device, therapeutic products) and Comparators, regardless of whether the comparators are placebos or locally registered medicinal/ therapeutic products. If your study does not involve the use of IP, please select 'NA'*	Yes	No	NA
6.1	If the study involves the use of IP, have you maintained proper documentation on IP management? *E.g. delegation of staff, temperature logs, shipment record, written IP management procedures, IP accountability log.* *Comments:*	☐	☐	☐
7.	**BIOLOGICAL SPECIMENS (PCR SOP 501-C04)** *If your study does not involve collection of biological specimens, please select 'NA'*	Yes	No	NA
7.1	Are specimens collected and handled in accordance to the approved study method? **If they are not handled in accordance with the approved study method, please submit a deviation and non-compliance report (DNC) to the IRB.* *Comments:*	☐	☐	☐

7.2	If biological specimens are stored, do you secure the storage area with access control and appropriate temperature monitoring? **If they are not stored in appropriate storage conditions, please submit a deviation and non-compliance report (DNC) to the IRB.* *Comments:*	☐	☐	☐
7.3	Do you have proper documentation on biological specimen(s) management? *E.g. shipment record, written specimen management procedures/workflow, biological specimen log, lab certificate, normal reference range, calibration records.* **You may refer to NHG PCR Log 509-009 Biological Specimen Log for more information.* *Comments:*	☐	☐	☐
8.	**DATABASE (PCR SOP 501-B08)**	Yes	No	NA
8.1	Is your database secure and appropriately maintained? E.g. access limited to study team, password protected, subjects' identifiers are stored separately from the research database, stored only in corporate approved secure data storage facilities/devices. **You may refer to your Institutional Research Data Policy and NHG PCR SOP 501-B08 for details on data collection/management.* Comments:	☐	☐	☐
9.	**MAINTENANCE OF STUDY RECORDS** *All research studies (including medical records review research) are required to maintain essential records in an investigator file. Source record(s), the methods of data capture and their location should be documented and updated when needed.*	Yes	No	NA
9.1	Do you maintain the investigator file(s) and source records, and ensure it is stored in a secure place with access limited to the study team members? **You may refer to PCR document 507-002 Investigator File Content Template and 507-003 Investigator File Dividers for a guide on what to maintain.* *Comments:*	☐	☐	☐
10.	**(Optional) FEEDBACK ON USING PISAF** We would appreciate if you could spare a few minutes to provide feedback on the PISAF. Your feedback will help us in assessing the effectiveness of this tool. If you do not wish to participate in the survey, you may skip this section.	Yes		No

	Thank you for completing the PISAF.		
10.1	Through completing the PISAF, do you have greater awareness of current IRB and regulatory requirements? *Comments:*	☐	☐
10.2	Through completing the PISAF, were you able to identify areas where the conduct of your research study can be improved? *Comments:*	☐	☐
10.3	Was the PISAF an effective self-assessment tool for this study? *Comments:*	☐	☐
10.4	Please let us know if you have any other comments or suggestions on PISAF. *Comments:*	☐	☐