Development of a Self-assessment Tool to Determine Research Compliance in a Research Institution

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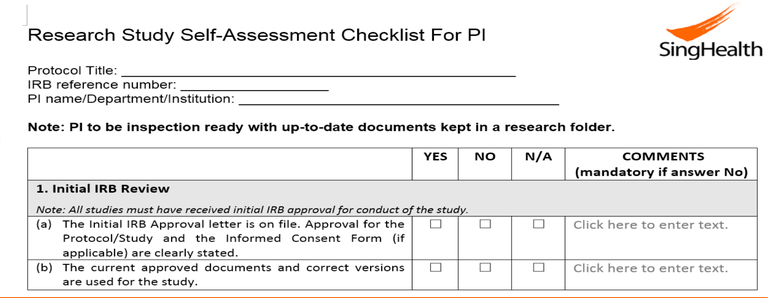
SingHealth

INTRODUCTION

- The regulation of Human Biomedical Research (HBR) in Singapore under the Human Biomedical Research Act (HBRA) had been activated since 1 Nov 2017. SingHealth, as an Research Institution, is required to submit a declaration of compliance to the regulatory authority for HBR conducted between 1 Nov 2017 and 31 Dec 2018.
- In order to assess compliance of HBR, a self-assessment checklist was developed for the Principal Investigator (PI)s to self-assess the conduct of their HBR and also for SingHealth to monitor compliance rates.



Research Study Self-Assessment Checklist For PI

SingHealth

Protocol Title: _____
IRB reference number: _____
PI name/Department/Institution: _____

Note: PI to be inspection ready with up-to-date documents kept in a research folder.

	YES	NO	N/A	COMMENTS (mandatory if answer No)
1. Initial IRB Review *Note: All studies must have received initial IRB approval for conduct of the study.*				
(a) The Initial IRB Approval letter is on file. Approval for the Protocol/Study and the Informed Consent Form (if applicable) are clearly stated.	☐	☐	☐	Click here to enter text.
(b) The current approved documents and correct versions are used for the study.	☐	☐	☐	Click here to enter text.

METHODOLOGY

Questions in the Checklist include:

- ❖ Institutional Review Board (IRB) Review including continuing IRB Review
- ❖ Training of the PI and Study Team Members
- ❖ Informed Consent Process and Documentation
- ❖ Restricted Human Biomedical Research
- ❖ HSA Regulated Study (Clinical drug trial)/ Medical Device Study
- ❖ Human Biological Materials (HBM)
- ❖ Accountability of Investigational Product (IP)/Medical Device/ Other Investigators Procedures
- ❖ Database Security Systems and Processes
- ❖ Serious Adverse Events and Protocol Non Compliance Reporting

- This checklist was developed for the PIs to self-evaluate and answer. PIs had to answer the checked boxes accordingly (Yes/No/NA) and could also provide comments in the form.
- The PI self-assessment form was distributed to all SingHealth institutions on 2 Nov 2018 for completion by 2 Jan 2019. The completed forms were followed up until March 2019 for data entry.
- All PIs conducting Investigator Initiated Studies are required to complete the PI self-assessment form. Industry sponsored studies and studies which are exempted from the IRB review are excluded.

RESULTS

- A total of 1718 PIs have participated across the SingHealth cluster.
- The compliance rates are illustrated in a table, example for 3 institutions.
- Areas of deficiencies are identified for further action.

Institutions	A	B	C
Number of Studies	59	43	159
	Compliance Rates (%)		
Q. PI and all study team members have completed the CITI training and a current valid certificate is on file.	54	98	98
Q. The current IRB approved documents and correct versions are used for the study.	98	98	96
Q. There is documentation in subject's medical records regarding the process of informed consent.	23	57	92
Q. The Investigational Product/ Device dispensing and accountability log are maintained. Records reconcile with current IP inventory.	100	100	56

CONCLUSION

- Overall, this self-assessment tool raises awareness of compliance among PIs and encourage discussion on potential non-compliance matters with study team to minimize recurrent events.
- Some limitations are associated with the self-assessment tool as the data are not verified and ambiguous responses might be provided by the PIs. The form can be further improved for clarity.
- This tool provides insight into the areas for quality improvement in research conduct across the cluster.
- The deficiency areas will be followed by monitoring or internal audit team during on-site visits. Training curriculum can be developed to customize training in accordance to the identified gaps for each institution.