BANGKOK HOSPITAL

แบบสรุปผลการตรวจสอบการเก็บเอกสารวิจัยและคุณภาพการพิจารณาจริยธรรมการวิจัย

Executive Summary

โครงการ	รหัสโครงการ	ชื่อโครงการ
โครงการที่ 1		
โครงการที่ 2		
โครงการที่ 3		
โครงการที่ 4		
โครงการที่ 5		

สรุปความครบถ้วนของทุกโครงการ	1	2	3	4	5
1. Incomplete assessment form					
2. Unsuitable reviewer					
3. Noncompliance with SOP					
4. Competence of PI/Conflict of interest					
5. Failure to recognize vulnerability					
6. Inappropriate study design					
7. Inappropriate Risk/benefit					
8. Incomplete/Inappropriate comments on the:					
a. Confidentiality					
b. Medical care					
c. Language and contents of ICF					
d. Voluntary participation					
e. Appropriate consent/assent forms					
f. Compensation					

สรุปความครบถ้วนของทุกโครงการ	1	2	3	4	5
g. Procedure in obtaining informed consent					

0 = No defect; 1 = Evidence of Defect

Definition of defects: 01. Incomplete assessment form: Reviewer's assessment forms have incomplete answers and/or there are no comments when it's required; 02. Unsuitable reviewer: Reviewers' qualifications (e.g. educational background, specialization, etc.) are not suitable for reviewing specific protocol and/or they don't take their responsibilities as reviewers seriously (e.g. absence during the Board Meeting, late or non-submission of accomplished reviewer's assessment forms, etc.); 03. Non-compliance with SOPs: Protocol review is in violation of standard operating procedures (e.g. required protocol documents, review timeline, etc.); 04. Failure to assess PI competence/Conflict of interest: Primary investigator(s) qualifications (including GCP training whenever necessary) and conflict of interest are not adequately reviewed by the EC/IRB; 05. Failure to recognize vulnerability: EC/IRB's failure to: a) detect the inappropriate use of vulnerable participants given that the protocol can be done in other non-vulnerable groups; b) recognize vulnerability of participants in different contexts; and c) recognize the lack of measures to protect vulnerable participants; 06. Inappropriate study design: EC/IRB's failure to detect and discuss inappropriate research design, comparator/placebo, inclusion and exclusion/withdrawal criteria, sample size, primary endpoint(s), etc.; 07. Inappropriate risk/benefit review: EC/IRB's failure to assess and comment on risks, benefits, and the balance in risk/benefit ratio; 08. Incomplete/inappropriate informed consent review: EC/IRB's failure to review incomplete and inappropriate content (e.g. important protocol details, confidentiality, voluntary participation, compensation, medical care, etc.), language (e.g. age-appropriate terms, non-inducing terms, technical terms, etc.), and process of the informed consent.