**แบบสรุปผลการตรวจสอบการเก็บเอกสารวิจัยและคุณภาพการพิจารณาจริยธรรมการวิจัย**

**Executive Summary**

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

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