**แบบตรวจสอบคุณภาพการพิจารณาจริยธรรมการวิจัย**

วัน/เดือน/ปี ที่ประเมิน …………………….………………………….. ผู้ประเมิน ......................................................................

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| --- | --- | --- | --- | --- | --- | --- |
| ความครบถ้วนของรายการ | โครงการ 1 | โครงการ 2 | โครงการ 3 | โครงการ 4 | โครงการ 5 | รวม |
| 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 nconsent
 |  |  |  |  |  |  |

0 = No defect; 1 = Evidence of Defect

|  |  |  |
| --- | --- | --- |
|  |  โครงการ Code/Number | ชื่อ โครงการ |
| โครงการ 1 |  |  |
| โครงการ 2 |  |  |
| โครงการ 3 |  |  |
| โครงการ 4 |  |  |
| โครงการ 5 |  |  |

Definition

1. Incomplete assessment form: Assessment form with incomplete filling the evaluation forms and/ or no comment where required
2. Unsuitable reviewer: reviewer is not suitable for reviewing that specific protocol and/or not taking responsibility of reviewer
3. Non-compliance with SOP/ guidelines: protocol review with violation of SOPs or guideline
4. Competence of PI/Conflict of interest: Fail to assess the competency and/ or COI of PI
5. Fail to recognize vulnerability: Fail to detect protocol that uses vulnerable subjects when it can be done in other non-vulnerable group or without recognition of vulnerability of subject in different context and without measure to protect vulnerable subjects
6. Inappropriate study design: Fail to detect or mention about inappropriate design (including insufficient background to support the design of the study), comparator/placebo, fail to review subject inclusion (detect or mention about inappropriate subject selection i.e. not selecting subjects that would provide desired result), fail to review subject exclusion/ withdrawal i.e. fail to detect or mention about study that does not exclude subjects that can be at a higher risk or withdraw subject at an appropriate time and condition or fail to review sample size: fail to comment on sample size or discuss about inappropriate of the primary endpoint
7. Inappropriate Risk/Benefit: Fail to detect or mention about the specific risk of the study that could result in inappropriate R/B ratio, including the lack of background that could justify the use of product in human
8. Incomplete/ Inappropriate comments on the:
9. Confidentiality: Fail to detect or discuss on how to protect confidentiality
10. Medical care: Fail to detect or discuss on the treatment or post trial treatment (if applicable)
11. Language of ICF: Fail to detect inadequacy of content and language for subjects e.g. incomplete or too much information (that may confuse subjects) or language not simple enough for the study population
12. Voluntary participation: Fail to detect or discuss about the process of taking informed consent or statement in the ICF that could enhance the voluntariness of vulnerable participants or those who are vulnerable to coercion and exploitation (e.g. Level of literacy, Health status, organization of the community etc.)
13. Appropriate consent/ assent forms: Fail to detect the need of different type of CF
14. Compensation: Fail to comment on compensation
15. Procedure in obtaining informed consent : Fail to detect or comment on the procedure in obtaining informed consent

**แบบตรวจสอบคุณภาพ**

วัน/เดือน/ปี ที่ประเมิน …………………………………………….. ผู้ประเมิน ...................................................................

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Defect Types | Panel 1 | Panel 2 | Panel 3 | Total |
| 1. Assessment Forms
 |  |  |  |  |
| 1. Reviewer
 |  |  |  |  |
| 1. SOP compliance
 |  |  |  |  |
| 1. Competence PI
 |  |  |  |  |
| 1. Vulnerable Subjects
 |  |  |  |  |
| 1. Study design
 |  |  |  |  |
| 1. Risk/benefit
 |  |  |  |  |
| 1. Insufficient ICF
 |  |  |  |  |
| Total |  |  |  |  |

**Overall assessment**

Good practices

1. ………………………………………………………………………………………………………………………….……
2. ………………………………………………………………………………….……………………………………………
3. …………………………………………………………………………………….…………………………………………

Recommendations

1. ……………………………………………………………………………….………………………………………………
2. ………………………………………………………………………………………….……………………………………
3. ……………………………………………………………………………………………….………………………………