# Purpose

Evaluation of safety reporting and site compliance to the protocol and GCP at NHS GG&C sites

# Principles:

Risk-based approach

Risk assess non-commercial trials only (assume commercial have oversight via monitoring by sponsor)

Risk assess trials following R&I approval due to timelines for approvals

## Step 1 – assess trials (see appendix A)

Criteria for selection of trials

|  |  |  |
| --- | --- | --- |
| Criteria | Rationale | Scoring |
| 1. PV process    * comprehensive and described in detail in protocol    * protocol describes PV method but not   in detail   * + No sponsor process described(possibly) only definitions | If Sponsor has well  defined system and PV office, unblinding procedure/emergency proecedures there should be more emphasis on patient safety | 1.1) comprehensive PV  process  Score = 0 1.2) Partially process  Score = 1  1.3) No defined process  Score = 3 |
| 1. Oversight    * Full on-site monitoring(intitiation   , visits, closedown)   * + Partial on-site monitoring   + Central monitoring only   + No monitoring | Trials that are monitored already have check of SAE reporting and SDV checks | * 1. ) Full on-site monitoring   Score = 0   * 1. ) Partial on-site monitoring   Score = 1   * 1. Central monitoring   Score = 2 2.4) No monitoring  Score = 3 |
| 1. Resource at GG&C site    * Sponsor has Project manager overseeing/provided site file to support site and has dedicated co- ordinator at site as part of registered CTU    * CRF /network nurse | Sponsor support of  site and number and type of staff (including experience and history of compliance) supporting trial at site influences completion of GCP activities | * 1. ) Dedicated PM and   site file/documentation assigned to trial  Score = 0   * 1. ) CRF/ network nurse/s assigned to trial   Score = 1   * 1. PI and one other only |

|  |  |  |
| --- | --- | --- |
| support , or CTU  (registered) support at site   * trial team composed of PI , PI and nurse or support from CTU (not registered) * PI only |  | Score = 2  3.4) PI only involvement Score = 3 |
| 1. Trial design    * Phase 4    * Phase 3    * Phase 2    * Phase 1 | Safety profile of IMP  less well established in earlier phase trials. Consider whether IMP has well known safety profile or is first in man | * 1. ) Phase 4 or well   known safety profile Score = 0   * 1. ) Phase 3   Score = 1   * 1. ) Phase 2 or little safety data available   Score = 2 4.4) Phase 1 or first in man  Score = 3 |

Scores can range from 0 to 12, 0 being lowest risk and 12 being highest risk.

A score of 9 or above will be considered high risk and the corresponding trial will be included in step 2 of the assessment.

A score of 6-8 will be considered medium risk. A score of 0-5 will be considered low risk.

## Step 2 – select trials (see appendix B)

Trials will be scored in step 1. Trials scored as high risk will form basis for audit (although one medium and/or low risk trial may also be included).

Trial: Investigator:

**APPENDIX A: RISK SCORING TABLE**

Name & role of person completing table:

|  |  |  |
| --- | --- | --- |
| **Criteria** | **Score** | **Comments** |
| * 1. Comprehensive PV   Score = 0   * 1. Partially described PV   Score = 1 1.3) definitions/no PV  /unclear  Score = 3 |  |  |
| * 1. Full on-site monitoring   Score = 0   * 1. Partial on-site monitoring Score = 1   2. Central monitoring   Score = 2 2.4) No monitoring  Score = 3 |  |  |
| 3.1) Dedicated PM/ TMF  Score = 0 3.2) CRF/network nurse support or dedicated  experienced trial team of greater than 2 people  Score = 1   * 1. PI and one other managing trial at site   Score = 2   * 1. PI only involvement   Score = 3 |  |  |
| 4.1) Phase 4  Score = 0 4.2) Phase 3  Score = 1 4.3) Phase 2  Score = 2 4.4) Phase 1  Score = 3 |  |  |
| TOTAL SCORE |  |  |
| RISK RATING (to be  completed by reviewer) |  |  |

Name of reviewer:

Signature: Date:

**APPENDIX B: TRIAL SELECTION DECISION**

Trial: Investigator:

|  |  |
| --- | --- |
| **Indicator** | **Result/Answer/comment** |
| Risk Score |  |

Is this trial selected for the audit (Y or N)?

Specify rationale

Name of reviewer: Position:

Signature: Date:

Research Governance Manager

Signature: Date: