**GCIG Template Vendor Assessment for Collaborative Groups**

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| **Purpose**  This assessment form is to evaluate an organisation carrying out sponsor activity outside the **(<<*insert country name>>*)** on behalf of **(<<insert sponsor** **name/GCIG Group name>>)** | |
| **Name and location of Institution:** | **Name and contact details of primary contact, including job title:** |
| **Summary of Services** |  |
| **Date of evaluation:** | |
| This form must be completed by a person with appropriate authority to respond on behalf of the organisation on matters relating to the service provided and quality management systems in place.  **Please complete the sections as fully as possible and return to << insert name and contact details>> by <<insert date to be returned by>>**. If information is not submitted, please indicate in the box provided the reason for non-provision, i.e. propriety information, or if not applicable. Insufficient responses will be followed up and an on- site audit may be undertaken.  I**f an SOP or working instruction (or equivalent) covers any of the criteria, please reference the SOP, or equivalent. If you would prefer to send copies of the SOPs please also reference the SOP number in the response section below.**  Any information provided within this assessment form will be treated as confidential and will not be shared with any third party organisations or departments.  On conclusion of the assessment, **(<< insert sponsor name/GCIG Group>>)** will provide feedback where appropriate. A contract will cover the specific details of the services being provided or contracted. | |

**Evaluation Criteria**

**Please answer the following questions and describe or reference the relevant SOP/Guideline or working instruction.**

**<< The questions recorded can be modified or added to as required >>**

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| **1.** | **Group History and Structure** | **Response (s)/Evidence** |
|  | 1. Please provide a brief description of history and structure of your group. |  |
| **2.** | **Process for selecting sites** | **Response (s)/Evidence** |
|  | 1. Do you have a process for selecting sites and checking whether the study protocol presents any issues? (For e.g. site feasibility questionnaire.) | **Yes** **No** |
| **If Yes – please give brief description below of process:** |
|  | 1. Do you have a SOP for selecting sites? | **Yes** **No** |
| **If Yes – please give SOP reference below:** |
| **3.** | **Indemnity arrangements** | **Response (s)/Evidence** |
|  | **Clinical Trial Insurance**   1. What kind of insurance is required by law in your country? | **Please give brief description below:** |
|  | 1. Do you hold insurance to cover the activities you are being contracted to carry out? | **Yes** **No** |
| **If Yes – please give details below:** |
|  | **Indemnity arrangements** | **Response (s)/Evidence** |
|  | 1. What is your process for checking indemnity and or insurance arrangements for the trial sites you are responsible for? | **Please give brief description below with details of SOP reference where applicable**: |
|  | **Patient Insurance**   1. Is insurance required for patients? | **Yes** **No** |
| **If Yes – please give details below:** |
|  | 1. Is there a national mechanism in your country for indemnification/ insurance? | **Yes** **No** |
| **If Yes – please give details below:** |
| **4.** | **Data Protection + Privacy + Security** | **Response(s)/Evidence** |
|  | 1. What regulations do you operate to in your country in relation to data protection and privacy? (e.g. in relation to collection of data/ personal identifiable data) | **Please detail regulation below and give brief description of rules which apply:** |
|  | 1. Do you have the capacity to share data subject to a data sharing agreement? | **Yes** **No** |
| **If Yes – please give details below:** |

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|  | **Data Protection + Privacy + Security** | **Response(s)/Evidence** |
|  | 1. Do you have validating procedures that protect the security of electronic data and correspondence (Backup storage)? | **Yes** **No** |
| **If Yes – please give brief details below:** |
| **5.** | **Ethics and Regulatory requirements** | **Response(s)/Evidence** |
|  | 1. Is your group able to carry out the ethics and regulatory submissions in your country? | **Yes** **No** |
| **If no, please advise if this would be subcontracted and give details below :** |
|  | 1. What is your timescale for submitting ethics and regulatory submissions in your country following receipt of appropriate documentation from the sponsor? | **Please give brief details below:** |
| **6.** | **Translations** | **Response(s)/Evidence** |
|  | 1. The sponsor will provide documentation in English. What is your process for translating trial specific documentation such as protocol and patient information sheet into the appropriate language? | **Please give brief description below of process with details of SOP reference where applicable:** |
|  | 1. Do you have a budget to cover costs of translations?   *(It is acknowledged the costs for translation would generally be covered by financial agreement between lead group/sponsor and participating group).* | **Yes** **No** |

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| **7.** | **Biological samples** | **Response(s)/Evidence** |
|  | 1. What regulations do you operate to in your country in relation to handling, storage and transportation of human biological samples? | **Please detail regulation below and give brief description of rules which apply:** |
|  | 1. Do you have a process for checking the regulations in your country in relation to the handling, storage and transportation of human biological samples are adhered to? | **Yes** **No** |
| **Please give brief description below of process with details of SOP reference where applicable:** |
|  | 1. Is there are limit to length of time biological samples are allowed to be stored? | **Yes** **No** |
| **If Yes – please give details below:** |
| **8.** | **Monitoring and data** | **Response(s)/Evidence** |
|  | 1. Is your group able to undertake the monitoring of the sites which your group is responsible for the trial as specified in the trial protocol/monitoring plan? | **Yes** **No** |
|  | 1. If you undertake monitoring, do you have processes in place to meet the regulations in your country? | **Yes** **No** |
| **Please give brief description below of process with details of SOP reference where applicable:** |
|  | 1. Do you have a process to check consent, delegation logs and data queries for sites which you are responsible for? | **Yes** **No** |
| **Please give brief description below of process with details of SOP reference where applicable:** |
|  | **Monitoring and data** | **Response(s)/Evidence** |
|  | 1. For trials involving investigational medicinal products (IMP) what is your process for ensuring fridge and freezer temperatures at sites meet the requirements of the sponsor pharmacy manual? | **Please give brief description below of process with details of SOP reference where applicable:** |
|  | 1. What is your process to ensure sites maintain accountability records and for checking IMP destruction? | **Please give brief description below of process with details of SOP reference where applicable:** |
|  | 1. Will the IMP storage areas, accountability and destruction logs be monitored routinely at your sites during monitoring visits? | **Please give brief description below of process with details of SOP reference where applicable:** |
| **9.** | **Pharmacovigilance** | **Response(s)/Evidence** |
|  | 1. Do you have process to ensure the country specific regulatory reporting requirements for pharmacovigilance (for e.g. SUSAR reporting) are followed in your country? | **Yes** **No** |
| **Please give brief description below of process with details of SOP reference where applicable:** |
|  | 1. Is there any specific timelines (e.g. for SUSAR reporting) which need to be considered? | **Yes** **No** |
| **If yes, please give brief details below:** |
| **10.** | **Serious breaches and Non-Compliances** | **Response(s)/Evidence** |
|  | 1. Do you have a process for reporting non compliances, protocol deviations and potential serious breaches to the sponsor? | **Yes** **No** |
| **Please give brief description below of process with details of SOP reference where applicable:** |

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| **11.** | **Investigational Medicinal Product** | **Response(s)/Evidence** |
|  | 1. Do you have process in place for IMP management? | **Yes** **No** |
| **Please give brief description below of process with details of SOP reference where applicable:** |
| **12.** | **Trial set-up /activation** | **Response(s)/Evidence** |
|  | 1. Do you have a procedures for approving a study in your country (e.g. regulatory green light) country specific and site specific? | **Yes**  **No** |
| **Please give brief description below of procedures with details of SOP reference where applicable:** |
|  | 1. Contract – budget negotiation. How long does it typically take to execute a contract and budget by your group? | **Please tick to indicate timeframe:**  **< 30 days**  **31-60 days**  **61-90 days**  **>90 days** |
| **13.** | **Trial documentation and data** | **Response(s)/Evidence** |
|  | 1. Do you have processes to ensure amendments are approved and forwarded to relevant parties in your country? | **Yes** **No** |
| **Please give brief description below of process with details of SOP reference where applicable:** |
|  | 1. Do you have process in place for trial closure in your country? | **Yes** **No** |
| **Please give brief description below of process with details of SOP reference where applicable:** |

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| **14.** | **Quality Assurance** | **Response(s)/Evidence** |
|  | 1. Do you have processes to check compliance with the regulatory requirements in your country and contractual obligations for trials which your group co-ordinate are met? (Please note this relates to both the coordinating centre for your group responsible for coordination of the trial and participating sites from your country participating in the trial.) | **Yes** **No** |
| **Please give brief description below of process with details of SOP reference where applicable:** |
| **15.** | **Sub- contracting** | **Response(s)/Evidence** |
|  | 1. Does your group sub-contract any trial related duties or functions to a third party/ external vendor (e.g. monitoring)? | **Yes** **No** |
| **If Yes – please give details below of service and details of how the suitability of external vendor is assessed :** |

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| **Please provide any additional information that may be useful**  **e.g. Competent Authority inspections of your organisation, outcomes of external audits of your organisation, other organisations you provide services for.** | | |

**Evaluation completed by: Sponsor review completed by:**

**Position: Position:**

**Date: Date:**

**Additional information required by sponsor**

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| **Please could you provide the following additional information/clarification:**  **<< insert details of additional information required >>** |

**Please return to: << insert name and contact details>> by: << insert date to be returned by>>**

**Outcome of vendor assessment/ feedback**

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| **<< details of outcome of vendor assessment inserted along with any relevant feedback>>** |

**Sponsor sign off completed by:**

**Position:**

**Date:**