**Imaging Facility Vendor Assessment Form**

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| **Purpose**  This assessment form is to evaluate a vendor supplying a research service to NHS Greater Glasgow and Clyde prior to adding to an approved vendor list | |
| **Name and location of Facility:**  Click here to enter text. | **Employer of Facility:**  Click here to enter text. |
| **Contact details** | |
| **Please indicate who is responsible for the following activities**   |  |  |  |  | | --- | --- | --- | --- | | **Area of Responsibility** | **Name** | **E-Mail** | **Telephone** | | **Management of Facility** | Click here to enter text. | Click here to enter text. | Click here to enter text. | | **Quality Assurance** | Click here to enter text. | Click here to enter text. | Click here to enter text. | | **Archiving** | Click here to enter text. | Click here to enter text. | Click here to enter text. | | |
| **Date of evaluation:** Click here to enter a date. | |
| **Trial Name:** Click here to enter text. **R&I Ref No:** Click here to enter text. | |
| 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 sender by** Click here to enter a date.. 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.  If an SOP or working instruction (or equivalent) covers any of the criteria, please reference the SOP, or equivalent.  On conclusion of the assessment, NHS GG&C will provide feedback where appropriate and indicate if the organisation is accepted as vendor for provision of the service(s). | |

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| **Facility overview** | |
| 1. Does the Facility perform storage and analysis of data?   If Yes, please give the ID number of any SOPs or Processes which cover this activity. | |  |  |  | | --- | --- | --- | |  | **Analysis** | **Storage** | | **Perform** | Choose an item. | Choose an item. | | **SOP/Process** | Click here to enter text. | Click here to enter text. | |
| 1. Please describe/attach list of the services provided by the facility for the purpose of this trial, indicating if they have an impact on any of the following:   (expand as required) | |  |  |  |  | | --- | --- | --- | --- | | **Test** | **Primary / Secondary Endpoint** | **Safety** | **Clinical Care** | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |
| 1. Please provide a list of services offered by your facility other than those being utilised by this trial.   (expand as required) | |  |  | | --- | --- | | **Service Title** | **Service Description** | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |

**Evaluation criteria**

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| **1.** | **Quality Overview** | |
| a) | Please use the table beside to detail any accreditation held by the facility e.g. CAP, ISO-9001, UKAS etc.  If not applicable, please leave blank. | |  |  |  | | --- | --- | --- | | **Accreditation** | **Approval Date** | **Renewal Date** | | Click here to enter text. | Click here to enter a date. | Click here to enter a date. | | Click here to enter text. | Click here to enter a date. | Click here to enter a date. | | Click here to enter text. | Click here to enter a date. | Click here to enter a date. | | Click here to enter text. | Click here to enter a date. | Click here to enter a date. | | Click here to enter text. | Click here to enter a date. | Click here to enter a date. | | Click here to enter text. | Click here to enter a date. | Click here to enter a date. | | Click here to enter text. | Click here to enter a date. | Click here to enter a date. | | Click here to enter text. | Click here to enter a date. | Click here to enter a date. | | Click here to enter text. | Click here to enter a date. | Click here to enter a date. | |
| b) | Please identify the SOPs/Processes by their unique ID number which cover the following key elements of your Quality Management System.  (If more than one, add all relevant) | |  |  |  | | --- | --- | --- | | **Area** | **ID** | **Title** | | Document Management/Control | Click here to enter text. | Click here to enter text. | | Non-Compliance Management | Click here to enter text. | Click here to enter text. | | Training and Competencies | Click here to enter text. | Click here to enter text. | | Risk Management | Click here to enter text. | Click here to enter text. | | Audit | Click here to enter text. | Click here to enter text. | |
| c) | If required, will the sponsor be given access to audit the facility? | Click here to enter text. |

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| d) | Please provide a brief summary of what QC checks are performed, documented and retained.  In this summary provide details of who conducts this activity, frequency and details of actions taken in the event of non acceptable levels. | Click here to enter text. |
| e) | Please provide an organisational chart |  |

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| **2.** | **SOPs/working instruction(s)** | |
| a) | Please provide a list of all SOPs/working instructions/Policy documents used within the facility in respect of the tests being requested. Please ensure any overarching SOPs relating to equipment are included.  (expand table to accommodate) | |  |  |  |  | | --- | --- | --- | --- | | **ID Number** | **Title** | **Version** | **Release Date** | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |
| b) | Describe the process for reporting deviations from the Facilities SOPs or policies to the Sponsor of a clinical trial. Include reference to any timelines for reporting.  n.b. if this process is described within an SOP you may provide the SOP in place of summary. | Click here to enter text. |

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| **3.** | **Training** | |
| a) | How are staff involved in the analysis and/or evaluation of samples for clinical trials appropriately educated, experienced and trained? | Click here to enter text. |
| b) | Please describe what training staff have received in relation to GCP. | Click here to enter text. |
| c) | Please describe the process for training of staff including how this is evidenced and any review periods of training.  n.b. if this is detailed with an SOP you may provide the SOP in place of this summary. | Click here to enter text. |
| d) | Do the training records include up to date signed and dated CV’s and job descriptions? | Click here to enter text. |

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| **4.** | **Facilities and equipment** | |
| a) | Does all of the equipment used for analysis and/or evaluation have an individual maintenance period?  Describe how maintenance of equipment is controlled.  n.b. if this is detailed within an SOP then this may be provided in place of a summary. | Click here to enter text. |
| b) | Please describe the process for equipment failure and how any potential loss of data is managed.  n.b. if this is described within an SOP then you may submit this SOP in place of a summary. | Click here to enter text. |
| c) | Is your facility self contained? | Click here to enter text. |
| d) | Are methods used for analysis validated? | Click here to enter text. |
| e) | Are computerised systems used? | Click here to enter text. |
| f) | If computerised systems are used, is the system validated? | Click here to enter text. |

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| **5.** | **Records and Data Management** | |
| a) | Are all records of maintenance, servicing and calibration of equipment available and up to date?  Please make note any SOPs or processes which govern this activity as well as a summary of how this is managed. | Click here to enter text. |
| b) | Describe the process for archiving and retrieval of data as well as the anonymization process if necessary.  n.b. if this is described within an SOP then you may submit this SOP in place of a summary. | Click here to enter text. |
| c**)** | Describe the process for the upload of data externally. | Click here to enter text. |
| d) | Describe the security system for access to the system used. | Click here to enter text. |
| e) | How is participant data stored and viewed/accessed? | Click here to enter text. |
| f) | Describe the process used to ensure participant/non-departmental staff safety. | Click here to enter text. |
| g) | Are contrast media/medications lot numbers and batches documented? | Click here to enter text. |

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| **6.** | **Reporting** | |
| a) | Please provide a brief summary of the process for handling potential serious breaches of GCP in relation to the protocol.  n.b. if this is contained within an SOP a copy of this may be provided in place of the summary. | Click here to enter text. |
| b) | Please provide a brief summary of the process on how unexpected results are reported  n.b. if this is contained within an SOP a copy of this may be provided in place of the summary. | Click here to enter text. |
| c) | Describe how the facility is informed if consent is withdrawn | Click here to enter text. |
| d) | Please describe the process for dealing with scan data that have had consent withdrawn. | Click here to enter text. |
| e) | Are tests carried out relating to patient safety? If yes, what is the process for reporting results that are out with normal ranges? | Click here to enter text. |
| f) | Describe the process on how incidental findings are reported. | Click here to enter text. |

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| **7.** | **Study management** | |
| a) | Do you have a process of reviewing any amendments to the protocol as supplied by the Sponsor to assess impact to the services you are contracted for?  Please describe any filing system currently in place and any mechanism for Version control of documents, i.e. if a protocol is updated. | Click here to enter text. |
| b) | Does each trial/study have a specific file containing the protocol and amendments or relevant sections? | Click here to enter text. |
| c) | If the trial/study protocol is not provided, is a work instruction prepared for each trial/study, detailing the methods and procedures used to conduct the analysis or evaluation?  If not applicable, mark as not applicable. | Click here to enter text. |
| **Please provide any additional information that may be useful as part of the vendor assessment programme** | | |

**Evaluation completed by:**

**Position:**

**Date:**