**Laboratory Vendor Assessment Form**

|  |  |
| --- | --- |
| **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 Laboratory:**  Click here to enter text. | **Employer of Laboratory:**  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 Lab** | 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. | | **Scientific Analysis** | 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). | |

|  |  |
| --- | --- |
| **Laboratory overview** | |
| 1. Does the laboratory perform storage, receipt and analysis of clinical samples?   If Yes, please give the ID number of any SOPs or Processes which cover this activity. | |  |  |  |  | | --- | --- | --- | --- | |  | **Analysis** | **Storage** | **Receipt** | | **Perform** | Choose an item. | Choose an item. | Choose an item. | | **SOP/Process** | Click here to enter text. | Click here to enter text. | Click here to enter text. | |
| 1. Please describe/attach list of what tests are requested to be undertaken within the laboratory, indicating if they have an impact on any of the following:   (expand as required) | |  |  |  |  | | --- | --- | --- | --- | | **Test** | **Primary / Secondary/Exploratory Endpoint** | **Safety** | **Clinical Care** | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |
| 1. Please provide a list of services offered by your facility other than tests listed above.   (expand as required) | |  |  | | --- | --- | | **Service Title** | **Service Description** | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |

**Evaluation criteria**

|  |  |  |
| --- | --- | --- |
| **1.** | **Quality Overview** | |
| a) | Please use the table beside to detail any accreditation held by the facility e.g. CAP, CLIA, ISO-9001, ISO-17025, ISO-15189, 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. |

|  |  |  |
| --- | --- | --- |
| 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) | Do you have a documented process for the management of vendors/suppliers? If so, provide process number/id.  (It will be your responsibility to manage your own vendors. This will not be assessed by NHS GG&C R&I.) | Click here to enter text. |
| f) | Please provide an organisational chart |  |

|  |  |  |
| --- | --- | --- |
| **2.** | **SOPs/working instruction(s)** | |
| a) | Please provide a list of all SOPs/working instructions/Policy documents used within the laboratory in respect of the tests being requested. Please ensure any overarching SOPs relating to equipment are included.  (expand table to accommodate, this may also be provided as a separate file) | |  |  |  |  | | --- | --- | --- | --- | | **ID Number** | **Title** | **Version** | **Release Date** | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |
| b) | Describe the process for reporting deviations from the Laboratory 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. |

|  |  |  |
| --- | --- | --- |
| **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.  Also describe the frequency of training in GCP that is required for staff. | 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. |

|  |  |  |
| --- | --- | --- |
| **4.** | **Transportation, receipt and storage** | |
| ***For all of the following questions, please make note of any SOPs or processes which define the activities involved. These documents may be submitted in place of a summary.*** | | |
| a) | Are fridge and freezer temperature monitored? | Click here to enter text. |
| b) | Describe the process to confirm consignment of samples received | Click here to enter text. |
| c) | Describe the process if samples received are non-compliant  e.g. not labelled, wrong packaging, damaged etc. | Click here to enter text. |
| d) | Describe the process for receipt of unexpected samples | Click here to enter text. |
| e) | Describe the process for dealing with receipt of clinical trial samples that have identifiable information on them. | Click here to enter text. |
| e) | Describe the process of sample storage prior to analysis | Click here to enter text. |
| f) | What alarm systems are in place to detect equipment failures? | Click here to enter text. |
| g) | What alarm systems are in place to alert for temperature excursions of storage area? | Click here to enter text. |

|  |  |  |
| --- | --- | --- |
| **5.** | **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) | Describe how reference ranges are monitored | Click here to enter text. |
| c) | Describe the controls that are in place for assays and test protocols. | Click here to enter text. |
| d) | Please describe the process to resolve when temperature excursions occur  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. |
| e) | Please describe the process for fridge/freezer failure?  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. |
| f) | Is your laboratory self contained? | Click here to enter text. |
| g) | Are methods used for analysis validated? | Click here to enter text. |
| h) | Are computerised systems used? | Click here to enter text. |
| i) | If computerised systems are used, is the system validated? | Click here to enter text. |

|  |  |  |
| --- | --- | --- |
| **6.** | **Records** | |
| 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) | Are records kept demonstrating the preparation of buffers and reagents? | Click here to enter text. |
| c**)** | Please detail which process is followed to ensure traceability of reagents.  Provide a summary of this process or a copy of the relevant SOP. | Click here to enter text. |
| d) | How are lot numbers and batches documented? | Click here to enter text. |
| e) | Please detail which procedure is in place to document sample disposal/destruction and provide a summary or a copy of the relevant SOP. | Click here to enter text. |

|  |  |  |
| --- | --- | --- |
| **7.** | **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 laboratory is informed if consent is withdrawn | Click here to enter text. |
| d) | Please describe the process for dealing with samples that have had consent withdrawn. | Click here to enter text. |
| e) | Are tests carried out on samples relating to patient safety? If yes, what is the process for reporting results that are out with normal ranges? | Click here to enter text. |

|  |  |  |
| --- | --- | --- |
| **8.** | **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) | 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:**

|  |
| --- |
| This Form is a controlled document. The current version can be viewed on the GCTU website.  Any copy reproduced from the website may not, at time of reading, be the current version. |