This questionnaire has been designed to provide sponsor oversight for laboratories that manage, process and/or analyse clinical trial samples or samples from research studies, (referred to as research samples in this document) on behalf of a Clinical Trial Unit

Use in conjunction with the UKCRC Guidance for CTU’s Assessing the Suitability of Laboratories Processing/Analysing Clinical Trial Samples.

Questions derived from guidance provided by the European Medicines Agency (EMA) and the Medicines and Healthcare products Regulatory Agency (MHRA).

The questionnaire should be filled out by a suitably qualified member of laboratory staff and reviewed according to CTU local procedures by appropriately trained staff.

**Please complete this questionnaire and return it to:**

**Contact: ………………………………………………………........................................................... Email: …………………………………………………………………….**

**Orange instructional text used throughout this document to be removed on completion*.***

All laboratories complete section A

Laboratories carrying out analysis complete both section A and B.

Processes may be documented in SOPs or policies and may be standard practice or research specific. Add as much detail as possible

|  |
| --- |
| **Laboratory service** **requested** |
| Thisis to be completed by the CTU, typically the information provided: sample processing/diagnostic or screening test/ primary/secondary/research endpoint etc. |

|  |
| --- |
| **Laboratory service** |
| This is to be completed by the laboratory. Add summary service provided: eg what services are provided. |

**Section A – This section is for all laboratories. CTU: Delete section B if the trial only requires sample processing. Delete this instruction before sending for completion**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Contact details | **Yes** | **No** | **NA** | **Details as appropriate** |
|  | Laboratory Manager or equivalent |  |  |  | Name and contact details |
|  | Do you have nominated GCP lead Proportionate GCP training is required (UKCRC guidance) |  |  |  | Name This can be a representative with understanding of general principles of GCP |
|  | Do you have a point of contact for research |  |  |  | Name, are they responsible for clinical trial samples? |
|  | Do you have a QA Manager or equivalent |  |  |  |  |
|  | How is Quality Assurance managed |  |  |  |  |
|  | How is Quality Control managed |  |  |  |  |
|  | Do you have an Archivist or equivalent |  |  |  | Person responsible for retaining laboratory records (results, SOPs, contracts etc.) |
|  | CTU comments (delete if not required) | | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Laboratory details | **Yes** | **No** | **NA** | **Details or SOP reference and title** |
|  | Which organisation hosts your laboratory |  |  |  | NHS/University/ Commercial/Other (please delete as appropriate) |
|  | Organisation name |  |  |  | Add name of organisation |
|  | Is access to the laboratory restricted |  |  |  | How often is this reviewed and by who |
|  | Is there a process for risk management |  |  |  |  |
|  | Is there a disaster recovery process |  |  |  | Describe, does it include sample storage, computer systems and equipment? |
|  | CTU comments (delete if not required) | | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Quality Assurance | **Yes** | **No** | **NA** | **Details or SOP reference and title** |
|  | Is there a Quality Management System in place |  |  |  | Documented procedures, lab management/oversight, training etc.  If No explain |
|  | Do you have a QA Manager or equivalentDo their responsibilities include: |  |  |  | If No please explain how this role is covered |
| Quality Control |  |  |  |  |
| B) Quality Assurance |  |  |  |  |
|  | Does the laboratory hold any accreditation(s) |  |  |  | e.g. ISO, UKAS, HTA or other competent authority. Detail status, dates |
|  | Has your laboratory been inspected by MHRA or other regulatory authority |  |  |  | e.g. EMA, FDA If yes, please list date. |
|  | Were any critical findings. Was the Inspection closed satisfactorily |  |  |  |  |
|  | List any external quality assurance schemes that apply |  |  |  |  |
|  | Does the laboratory work to standard operating procedures**If Yes:** How are these procedures controlled |  |  |  |  |
| Please supply a SOP list with this form |  |  |  |  |
|  | How frequently do you review your procedures |  |  |  | Details here |
|  | Do you have an internal audit plan/process |  |  |  | Details here |
|  | CTU comments (delete if not required) | | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Personnel | **Yes** | **No** | **NA** | **Details or SOP reference and title** |
|  | Do staff maintain training records**If Yes:** Does the training record include evidence of: |  |  |  | Research training extra to standard |
| Current job description |  |  |  |  |
| Recent CV |  |  |  |  |
| Laboratory equipment competency |  |  |  |  |
| Research specific training |  |  |  | Detail additional research training |
| Research specific competency |  |  |  |  |
| GCP |  |  |  |  |
|  | Is there a documented process for staff assessment |  |  |  | Short summary of process does it include competency and continual professional development |
|  | Are there procedures to re-evaluate staff competencies/training |  |  |  | Record frequency here |
|  | Is there an organisational chart or equivalent**If yes:** please supply a copy with this form |  |  |  | Showing lines of responsibility |
|  | CTU comments (delete if not required) | | | | |

|  | Contracts and agreements | **Yes** | **No** | **NA** | **Details or SOP reference and title** |
| --- | --- | --- | --- | --- | --- |
|  | Are agreements in place for processing research samples Contracts may not be required within the same host organisation; |  |  |  | Details for processing research samples should be agreed. e.g. Email correspondence or letter of intent/memorandum of understanding  Details here |
|  | Do the contracts/ agreements state GCP\* must be followed |  |  |  | \*CTU to state which regulation is to be followed, eg UK Regulations, ICH GCP, principles of ICH GCP etc. |
|  | Is any of this work outsourced: internal or external |  |  |  | e.g. processing or analysis  If outsourced please provide brief details |
| If **Yes:** Is there a procedure that outlines the selection of such laboratories |  |  |  | e.g. sample analysis, software companies, Vendors should be qualified and approved for use. |
|  | CTU comments (delete if not required) | | | | |

|  | Sample Shipment, Receipt and Storage | **Yes** | **No** | **NA** | **Details or SOP reference and title** |
| --- | --- | --- | --- | --- | --- |
| Are there documented procedures/SOPs for the following: | | | | | |
|  | Confirmation consent was obtained for processing /analysis of samples for research purposes |  |  |  | Details here e.g. CTU holds consent forms |
|  | Checking samples were maintained in appropriate transport conditions (if required) prior to receipt |  |  |  | Audit trail or transfer paperwork |
|  | Checking labels and the integrity of samples on receipt |  |  |  |  |
|  | Ensuring research samples are pseudonnonymised/coded If Yes: How do you |  |  |  |  |
| Manage the receipt of patient identifiable information |  |  |  | Short summary of process if there is no SOP |
| Manage the receipt of unrequested samples e.g. samples received in error |  |  |  | Short summary of process if there is no SOP |
|  | Storage of samples prior to processing/analysis |  |  |  | If documented in the protocol/lab manual state here |
|  | Monitoring of storage conditions |  |  |  | Ambient, fridges, freezers, liquid nitrogen, other |
|  | Routine sample destruction procedures |  |  |  |  |
|  | Destruction of samples and associated data if consent is withdrawn after donating samples |  |  |  |  |
|  | Chain of custody or audit trail of samples |  |  |  | Record of movement and processing of from receipt, through analysis, to final storage) |
|  | CTU comments (delete if not required) | | | | |

|  | Trial conduct | **Yes** | **No** | **NA** | **Details or SOP reference and title** |
| --- | --- | --- | --- | --- | --- |
| Do you follow the procedures in the: | | | | | |
|  | 1. Protocol and amendments |  |  |  |  |
| 1. Relevant sections of the protocol and amendments |  |  |  |  |
| 1. Lab manual or equivalent and amendments |  |  |  |  |
| 1. Sample Analysis Plan (or equivalent) |  |  |  |  |
|  | If Yes: Who has responsibility for these documents and where are they kept |  |  |  | Name/role, where are the files kept |
|  | Are processing details recorded and signed for |  |  |  | Worksheets /trial notebook /other specify |
|  | When sample processing/analysis is requested for a new trial/amendment, is there a process to ensure there is capability and capacity to meet the new requirement |  |  |  | Is processing in accordance with GCP. Brief details here or SOP ref |
|  | Is there a procedure for reporting the following: |  |  |  |  |
| Serious Breaches to GCP including data breaches |  |  |  |  |
| Protocol non- compliance |  |  |  |  |
| Non-compliance from standard procedures |  |  |  |  |
|  | For any trial specific requirements please document here: | | | | |
|  | CTU comments (delete if not required) | | | | |

|  | Equipment | **Yes** | **No** | **NA** | **Details or SOP reference and title** |
| --- | --- | --- | --- | --- | --- |
|  | Are there service contracts in place for analytical equipment to be used for this trial |  |  |  | e.g. Analysers, centrifuges, pipettes |
| Do you keep equipment registers/logs |  |  |  |  |
| Maintenance records |  |  |  |  |
| Calibration certificates |  |  |  |  |
|  | Are there documented procedures for:Qualification and or validation |  |  |  | Process to ensure equipment is fit for the intended use |
| Temperature Monitoring |  |  |  | Fridges/Freezers/Liquid Nitrogen Ambient |
|  | Trial specific equipment should be listed here |  |  |  | List new equipment to be purchased/validated/effect on lead times |
|  | Is specialist equipment required |  |  |  |  |
|  | CTU comments (delete if not required) | | | | |

|  | Data handling procedures and computer system validation (CSV) | **Yes** | **No** | **NA** | **Details or SOP reference and title** |
| --- | --- | --- | --- | --- | --- |
|  | Do you have procedures to protect the security of data **If Yes:** |  |  |  |  |
| Is access to computers and laboratory systems controlled by an individual username and password system |  |  |  | Record here if shared log-ins or generic user profiles are used |
| Are databases backed up routinely to prevent loss |  |  |  | Record the frequency of back up, is this on or off site |
|  | Is there a process for CSV including maintenance of the validated state |  |  |  | Validation to prove the system works as intended |
|  | Is there a process for revalidation after upgrades or maintenance |  |  |  |  |
|  | Is there a process for data capture, storage and review |  |  |  |  |
|  | Is there a process for data transfer |  |  |  |  |
|  | CTU comments (delete if not required) | | | | |

|  | Records retention/archiving | **Yes** | **No** | **NA** | **Details or SOP reference and title** |
| --- | --- | --- | --- | --- | --- |
|  | Is there a process detailing which records are provided to the sponsor and which are retained by the laboratory |  |  |  |  |
|  | Is there a documented procedure for archiving If Yes:does it detail: |  |  |  |  |
| Which records are kept |  |  |  | Equipment validation & maintenance, training records, etc. |
| Where records are kept |  |  |  | Is there a dedicated facility/area for archived records |
| How long records are retained |  |  |  |  |
| Who has access to archived records |  |  |  |  |
| Removal of material from the archive |  |  |  | Who can remove material from the archive |
| Return of material to the archive |  |  |  |  |
| Electronic archiving including instrument records, audit trails etc |  |  |  | Include applicable correspondence if data is kept live document here |
|  | CTU comments (delete if not required) | | | | |

***Delete these instructions before finalising the form***

***For laboratories processing samples only delete following sections keeping the signature box***

***For laboratories analysing samples include section B***

**Section B This is an additional section for laboratories performing analysis/imaging. CTUs: Delete this section for trials that require sample processing only. Delete this instruction before sending for completion**

|  | Analysis Method validation /Quality Control | **Yes** | **No** | **NA** | **Details or SOP reference and title** |
| --- | --- | --- | --- | --- | --- |
|  | Do you use recognised externally certified standards to ensure the quality of results |  |  |  |  |
|  | Are procedures used for research samples validated**If Yes:** |  |  |  | Details here if the assay is trial specific |
| Is acceptance criteria defined and in accordance with accepted standard/validated ranges |  |  |  |  |
| Are external quality processes used to validate results (e.g. commercial standards, external QA) |  |  |  |  |
| **If No:**What controls do you use to assure the quality of the assay |  |  |  |  |
|  | Are new or modified procedures used for research samples**If Yes:** |  |  |  | If any changes are made to the manufacturer’s instructions have these been validated |
| How is acceptance criteria determined |  |  |  | e.g. defined by kit, commercial standards used to produce standard curve |
|  | Is there an audit trail of assay conduct**If Yes:** |  |  |  | Including instrument access (should be user specific), instrument settings, reagent logs etc. |
| Is the audit trail checked |  |  |  |  |
|  | Is equipment software validation in accordance with manufacturers recommendations If Yes: |  |  |  |  |
| Is there a process for revalidationfollowing upgrades or equipment failures |  |  |  |  |
|  | CTU comments (delete if not required) | | | | |

|  | Recording and reporting of results | **Yes** | **No** | **NA** | **Details or SOP reference and title** |
| --- | --- | --- | --- | --- | --- |
|  | Are research results reported in the same way as non-research results**If No:** are there documented procedures for: |  |  |  |  |
| Reporting of trial/research results |  |  |  |  |
| Expedited reporting of atypical results that may necessitate urgent safety measures |  |  |  | Urgent/ atypical results may affect trial conduct or patient safety |
|  | Is there a process for reporting laboratory deviations which may impact the validity of results obtained |  |  |  | Where is this documented, SOP, contract, other please specify |
|  | CTU comments (delete if not required) | | | | |

|  | Repeat analysis | **Yes** | **No** | **NA** | **Details or SOP reference and title** |
| --- | --- | --- | --- | --- | --- |
|  | Is there a documented procedure for repeatanalysis to confirm outliers in the event ofprocedure failure/atypical results**If Yes:** |  |  |  |  |
| Do you have procedures for reporting the original and repeat results |  |  |  |  |
|  | CTU comments (delete if not required) | | | | |

|  | Blinded trials | **Yes** | **No** | **NA** | **Details or SOP reference and title** |
| --- | --- | --- | --- | --- | --- |
|  | Is there a procedure detailing how to manage blinded trials**If Yes:** does this include |  |  |  |  |
| Maintenance of blinded state when reporting results |  |  |  |  |
| Storage and access of unblinding codes |  |  |  |  |
| Procedure for unblinding samples, if required |  |  |  |  |
|  | CTU comments (delete if not required) | | | | |

***Delete this section if not required***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Trial specific | **Yes** | **No** | **NA** | **Details or SOP reference and title** |
|  | Examples; assay for diagnosis, stratification, safety |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  | CTU comments (delete if not required) | | | | |

***Delete this section if not required***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | For laboratories that prepare and distributeClinical trial kits and sample containers | **Yes** | **No** | **NA** | **Details or SOP reference and title** |
| 11.2 | Are there dedicated areas for the preparation and/or receipt and storage of clinical trial kits If Yes: |  |  |  |  |
| Are these areas temperature controlled/monitored |  |  |  |  |
| Are records kept of component batch numbers |  |  |  |  |
| Are QC checks performed before they are shipped |  |  |  | e.g. expiry dates, volume of additives, label generation completeness of kit stability |
| Is there a documented recall procedure |  |  |  | Does this include communication with users & sponsor |
|  | CTU comments (delete if not required) | | | | |

|  |  |
| --- | --- |
| **Questionnaire completed by:** | |
| **Name:** | **Position:** |
| **Signature:** *electronic or wet signature according to local policy* | **Date:** |

|  |  |
| --- | --- |
| **Reviewed on behalf of CTU by:** | |
| **Name:** | **Position:** |
| **Signature:** *electronic or wet signature according to local policy* | **Date:** |