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| http://www.staffnet.ggc.scot.nhs.uk/SiteCollectionDocuments/Staffnet/Logos%20and%20Templates/NHSGGC20SPOT_th.jpg | **Insert Study LOGO** | | GU Logo if co-sponsored |
|  | | | |
|  | | | |
| [Full Study Title] | | | |
|  | | | |
| **Laboratory Manual – Vxx**  **NHSGGC Central Lab** | | | |
|  | |  | |
| *Short Title* | |  | |
|  | |  | |
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| *Lay Title* | |  | |
|  | |  | |
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| *EudraCT Number/ or other Reg ID* | |  | |
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| *REC Reference Number* | |  | |
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| CONFIDENTIAL | | | |

**Prepared by: CI/PM/Lab Manager Approved by: CI/Sponsor Rep**

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2. Introduction

The purpose of the Laboratory Manual is to describe the procedures to take receipt of and process category 2 and 3 samples as defined in SOP 51.028. These may be routine samples to be handled differently from standard processes, or they may be samples that are to be centrally analysed and bio-banked samples.

This lab manual is to describe processes for the laboratories processing samples for the [*insert study title*] which is sponsored by *NHS Greater Glasgow and Clyde (NHSGGC)* or *co-sponsored by NHS GG&C and University of Glasgow (GU)* [*delete as appropriate*].

Routine/Safety bloods in the trial are analysed in local NHS laboratories at a participating site and are not covered by this document. The process of handling these samples is described in the protocol and as per local procedure.

*[If the laboratory requires access to the electronic Case Report Form (eCRF) (if unblinding not an issue) include details of obtaining eCRF access and Data Centre Provider contact.*

*If there is a bespoke Laboratory Information Management System (LIMS) include responsibilities for LIMS design, administration and user access and training.*

*Describe how the samples will be linked to enable final reconciliation (SOP 51.029)*

*Describe the chain of custody of the sample and identify the final destination (for instance analysis or bio-banking).*

*Describe what happens to the samples at the end of the study.*

*Reference the NHSGGC Lab accreditation(s).*

Ensure all laboratory study documentation references the identifiers and protocol version it relates to:

|  |  |
| --- | --- |
| Full study title |  |
| IRAS ID |  |
| NHSGGC R&I number |  |
| EudraCT/Other study Reg ID |  |
| Protocol Version |  |
| [subsequent amendments] |  |

**3 Contact Information**

|  |  |
| --- | --- |
| **Role** | **Name & contact information** |
| Chief Investigator (CI) |  |
| Project Manager |  |
| Sponsor R&I representative |  |
| Laboratory technician (sample receipt) |  |
| Courier Details |  |

|  |  |
| --- | --- |
| **Participating Site** | **Contact information (person responsible for samples)** |
|  |  |
|  |  |

**4. Purpose of study sample collection**

*[Describe in this section the details of the sample being collected. For example: safety, primary endpoint, eligibility or experimental.]*

**5. Procedures**

The analysis or evaluation of clinical trial samples in accordance with this manual should be overseen by the CI who assumes responsibility for various components. Oversight of the sample analysis is likely to be delegated to the Clinical Lead for the lab. This role should be described.

|  |  |  |
| --- | --- | --- |
| **Named person** | **Role** | **Procedure** |
|  |  |  |
|  |  |  |
|  |  |  |

**5.1 Categorisation of lab tests**

State each laboratory test by category

|  |  |
| --- | --- |
| **Category** | **Description** |
| Category 1 | Standard test i.e. validated and in use in clinical practice within NHS |
| Category 2 | Standard test, with specific requirements |
| Category 3 | Nonstandard test, research tests |

|  |  |
| --- | --- |
| **Lab Test** | **Category** |
|  |  |
|  |  |

**5.2 Communication related to Safety**

Lines of communication with the CI must be detailed to ensure that any issues that may impact on study participant’s safety are reported without delay. This includes the reporting of out of the range results and significant deviations from the protocol or the study specific Laboratory Manual. If there are no potential safety issues, this should be stated in the manual.

*[Detail the steps to be taken in the event of a deviation which should include:*

* *Lab staff contact designated PM.*
* *PM will contact CI and study Monitor.*
* *The study Monitor is responsible for contacting the lab staff and opening and completing a protocol deviation form as required (Form 51.008A). ]*

**5.3 Withdrawal of participant consent**

*[Describe how the study team (project manager) will notify the laboratory of what actions to implement if a participant withdraws consent. For instance, when a subject withdraws consent to participate in the trial, a member of the research team (CI, Research Fellow or Project Manager) will contact the relevant staff to inform them of the withdrawal. This will be in writing and will detail the steps to be undertaken with the affected samples. ]*

If copies of consent forms are required, please detail the process in this section

**5.4 Sample labelling, receipt, storage and chain of custody**

**5.4.1 Sample handling**

Sample handling and transport to the Laboratory is detailed in the Study Specific Sample Handling Manual *[reference manual including version]*). [*The conditions for processing, storage and transport at each shipment stage (for instance use of dry ice, ambient) should be detailed.*

*Sample collection by type and time-point should be detailed as per protocol schedule of events (this must be amended where affected by relevant protocol amendments).]*

**Example of Table with visit schedule and when samples should be collected**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Base line/Screening** | **Visit 1** | **Visit 2** |
| **Sample Type 1**  *Volume collected*  *Tube colour/number* | **🗸** | **🗸** | **🗸** |
| **Sample type 2**  *Volume collected*  *Tube colour/number* | **🗸** | **🗸** | **🗸** |
| **Sample type 3**  *Volume collected*  *Tube colour/number* | **🗸** | **🗸** | **🗸** |

*[Shipping frequency should be listed:*

*For central lab functions there should be an agreement between the central lab and participating sites on the frequency of shipments based on storage requirements and recruitment rate.]*

**5.4.2** **Sample labelling**

The clinical trial sample must be labelled in such a way as to allow their unequivocal identification at all times in the analysis or evaluation process. This may necessitate the use of different labels depending on the steps and processes deployed in analysis or evaluation.

*[Label image/description]*

*Please ensure the labelling system captures the following information:*

* *Site ID*
* *Participant ID*
* *Study ID*
* *Type of Samples*
* *Date and time of collection*

**5.4.3** **Receipt of Samples.**

**a) Sample Condition Assessment and Logging:** All samples used in eligibility criteria, primary, secondary or safety end-point analysis should be ***assessed on arrival*** to check their physical integrity. If samples have been compromised in transit this should be recorded on the sample receipt form and the project manager should be promptly notified. The date and time of receipt should be recorded.

Samples will be processed, stored and shipped by the participating site as stipulated in the Study Specific Sample Handling Manual *[reference manual including version]*.

Samples will be delivered to *[Central Lab delivery details]* by courier. The dispatching participating site should be instructed to liaise with the Project Manager for the shipment date and time. The Sample Transfer Log (Form 51.030B) will be completed by the participating site staff and accompany the samples.

Sample Arrival:

* Relevant documentation should be signed by receipting staff member to record shipment arrival
* Check the appropriate number of samples has been received against the shipment record sheets and check samples remain in appropriate condition and accompanied by appropriate documentation. Email site contact to acknowledge safe receipt.
* Receipting staff should sign off Sample Transfer Log (Form 51.030B) as confirmation of receipt. Sample Transfer Logs should be stored in the Laboratory Master Research File.

**b) Sample Reconciliation:** On receipt, laboratory staff should ensure that all samples are accounted for. If samples are poorly labelled, missing or if unexpected samples are receipted this should be recorded on the Sample Transfer Log and the Project Manager should be contacted to investigate and resolve the issue.

***Unexpected samples should not be analysed until their identity is confirmed***

* Samples should be reconciled with eCRF/Laboratory Information Management System (LIMS) and shipping logs to ensure no samples are missing.
  + Eg: Barcode scanning, plates IDs, ensuring labelling is as per manual.
* Process of reconciliation depends on sample type, vial type and equipment used.
* If samples missing then contact participating site to reconcile errors.

Any sample which can’t be identified either through electronic sample system or through paper sample log should be held in temporary storage and position documented until sample position has been reconciled between central labs and participating site. Once sample error has been reconciled the sample need to be rescanned into position for storage.

**5.4.4** **Identity of the participant.**

Samples being received at a NHSGGC Laboratory from sites out with NHGGC should not contain any patient identifiable details. The Project Manager and sponsor should be notified if patient identifiable details are included. The samples should be labelled as per section 9.2. If there is a requirement to feedback results of the lab analysis to the site, this process should be described.

**5.4.5 Sample storage conditions.**

The storage conditions throughout the chain of custody must be detailed in the manual. At participating sites there should be an assessment of local sample storage conditions and monitoring processes to ensure fit for purpose prior to site initiation. Central Laboratory staff should monitor storage conditions to ensure that samples have been stored in a manner to ensure that they are fit for purpose. Evidence of monitoring and action taken in the event of any excursions from the specified ranges should be documented and retained. [*List freezer/temp monitoring system and keep a record of certificates of calibration/maintenance with study specific documentation.]*

**5.5 Blinding**

*[The sponsor must ensure that appropriate measures are implemented to ensure blinded individuals are not exposed to information which can compromise the blinding. In situations in which where samples from blinded trials are supplied to a laboratory and the data generated by the laboratory may un-blind the trial, it is important that data is only sent to an established point of contact. This must be fully detailed within the manual.]*

**5.6 Equipment**

Any new equipment must be maintained in accordance with the laboratories standard practice and added to the respective laboratory equipment inventory. Calibration and maintenance documentation should be stored in the Laboratory Master Research File.

**5.7 Method Validation**

Analysis should be performed using appropriately validated methods with defined acceptance criteria. For category 3 tests the process for validating the methods should be detailed. The analytical methodology should include details of expected range, suitability tests and quality control samples, inter-and intra-assay variation and accuracy. Study specific SOPs for novel assays may be required and should be reviewed and approved by the Laboratory Quality Manager.

**5.8 Data recording**

All data should be recorded directly, promptly, accurately and legibly, for instance using validated LIMS, eCRF, template sample logs. The data and identify of the person conducting the work should be recorded. Laboratory data quality assurance should form part of the audit plan for the study and where possible the audit plan for the Laboratory.

**5.9 Reporting**

*[The manner in which the laboratory data will be reported and the number of reports should be documented prior to study commencement. The results of a clinical analysis may be supplied as electronic source data, printouts from the analytical equipment used to perform the tests, or a report which contains data and interpretation of results.]*

**5.10 Data Transfer**

*[This section should detail the processes for data transfer from the laboratory to the data management centre. The analysis results output format must be agreed with Data Centre Provider and include a method to protect data integrity. A copy of results should be held by sponsor at the end of the study.]*

**5.11 Computerised systems**

All computerised systems used for the capture, processing, reporting and storage of data should be developed, validated and maintained in order to ensure the validity, integrity and security of the data. [*If an eCRF is in use then it may be appropriate for the Laboratory team to have access to this assuming that this will not affect blinding. This section should reference the training provision.]*

**5.12 Retention of trial data.**

Trial specific documents should be retained in accordance with the requirements of GCP and national legislation and archived in accordance with the Sponsor archive standard operating procedures [SOP 51.024]: refer to study protocol.

Non trial specific documents should be retained in accordance with the laboratory policies.

All copies of shipping logs/bio-banking logs/relevant documentation should be retained in study specific files prior to archive.

**5.13 Retention and destruction of trial samples.**

*[Detail how samples will be stored, retained or destroyed in accordance with the protocol and as defined in the ethical application. The duration that samples are to be kept and the site that they are to be stored* ***must be detailed*** *below. Category 2 samples will be destroyed in accordance with the Laboratory standard operating procedures, unless otherwise stated.*

*Where consent has also been withdrawn for use of research samples, further instruction will be given for the destruction of the samples and LIMS/eCRF updated accordingly.]*

**5.14 Non compliances and potential serious breaches in GCP**

*This section must detail the processes to be followed when incidents occur that are considered to be a noncompliance with GCP and/or potential serious breaches in GCP. Definitions of such incidents may require to be included.*

**5.15 Protocol Amendments**

*This section must detail the processes to be followed when protocol amendments have been made. This must include how the Sponsor will risk assess the impact to the Study Specific Laboratory Manual an ensure updates to it are distributed and implemented accordingly*.

**6. Inter-Lab Transfer**

*[Detail plans for sample selection/generating a pick list of required samples and identify appropriate staff member who is responsible for overseeing LIMS/eCRF, and describe the process for rescanning/ further shipment.]*

**7. Transporting dangerous goods.**

For transportation of dangerous goods: ensure the person(s) preparing the “dangerous goods” for shipping is/are appropriately trained and responsible for ensuring that the package, when shipped, meets the requirements of all applicable laws.

The technical information presented in this manual is not intended to be, and should not be considered as, regulatory training in the handling of “dangerous goods”. Any questions you may have about requirements for shipping dangerous goods should be directed to appropriate consultants, counsel, or your appropriate regulatory authorities.

* For the dry ice shipment; the packaging must be marked “UN3373 Biological substance, Category B packed in UN1845, Dry Ice Class 9”

***IATA Note:*** *Diagnostic specimens shipped in carbon dioxide, solid (dry ice), or liquid nitrogen must comply with the provisions of the DGR applicable to those substances in addition to the requirements of Packing Instruction 650.*