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| http://www.staffnet.ggc.scot.nhs.uk/SiteCollectionDocuments/Staffnet/Logos%20and%20Templates/NHSGGC20SPOT_th.jpg | **Study LOGO** | GU Logo if co-sponsored |
|  |
|  |
| [Full Study Title] |
|  |
| **Sample Handling Manual – Vxx****(Participating Site)** |
|  |  |
| *Short Title* |  |
|  |  |
|  |  |
| *Lay Title**Chief Investigator* |  |
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|  |  |
|  |  |
|  |  |
| *EudraCT Number/ or other Reg ID* |  |
|  |  |
|  |  |
| *REC Reference Number**Sponsor:* |  |
|  |  |
|  |  |
| *Sponsor Protocol Number* |  |
|  |  |
|  |  |
|  |
| CONFIDENTIAL |

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

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**2. Introduction**

The purpose of this Sample Handling Manual is to describe the procedures to collect and process the centrally analysed and biobanked *[Insert Sample type]* samples for the *[Insert study name]* study. Safety bloods in the trial are analysed in local NHS laboratories and are not covered by this document. The process for sampling of safety bloods is described in the protocol/local procedure.

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

**3. Contact Information**

|  |  |
| --- | --- |
|  | Name & contact information |
| Project Manager |  |
| Laboratory technician (e.g. sample receipt) |  |
| Courier Details |  |
| [*Insert contacts for additional supplies etc. if different from above]* |  |

**4. Purpose of study sample collection**

This manual must ***only include work that is covered by the clinical trial protocol***. The SOPs and processes in operation within the laboratory for processing and analysis of the research samples must be followed.

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

**5. Roles and responsibilities**

The processing of clinical trial samples in accordance with this manual should be overseen by a named individual(s) who assume responsibility for the conduct of this work at the trial site. The Principal Investigator or delegate at the participating site must ensure that site personnel are appropriately trained and qualified to perform the roles and responsibilities assigned to them via the delegation log and that the site has the necessary resources to process and store the samples. Participating site adherence to the Sample Handling Manual may be subject to audit by the Sponsor.

This manual should be written by the Chief Investigator (CI) or delegate, e.g. Project Manager. The manual must be jointly approved by the CI and a sponsor representative.

**6. Procedures**

**6.1** **Study specific sample logs and sample transfer forms**

For each category 2 or 3 sample processed (SOP 51.028), a study specific Sample Log should be created for the participating sites to complete. This will document the type and number of samples, type of collection vials, processing, and storage of samples (Form 51.030A). A Sample Transfer Form should also be created for the participating sites to complete at the time of transferring samples from site to the central laboratory (Form 51.030B). Completed Sample Logs and copies of Sample Transfer Forms should be stored in the Participating Investigator Site File for monitoring purposes. Any additional specific sample log/accountability instructions should be detailed in this section.

*[Inform site Sample Logs and Sample Transfer Forms will be provided to site by the project manager or designee*. *Instruct site to send a copy of the completed transfer logs with your sample shipment and retain a copy at site]*.

**6.2 Equipment**

**6.2.1 Supplies required for sample processing**

*[Detail the study specific collection & storage vials, and any other equipment required for sample processing such as pipettes, aliquots. Where needed, the site will be provided with appropriate sample collection and processing equipment and detail site supply arrangements].*

**6.2.2** **Site equipment required**

Sponsor will request the appropriate documentation to confirm participating site feasibility such as the required lab resources available, lab monitoring systems (freezer/fridge temperature logs), local reference ranges, equipment calibration or service certificates.

**6.3 Collection of Samples**

*[The processes of sample collection must be detailed below. Standard processes for inclusion are:*

* *All samples used for eligibility, primary, secondary or safety end-point analysis must be taken by trained site staff using appropriate Personal Protective Equipment (PPE) compliant with local policies and procedures.*
* *The number and type of samples, volume, and collection tubes/containers must be detailed in a summary table within this document.*
* *Appropriate sample collection tubes must be provided by the study team if they differ from routine collection sample collection tubes.*

*Additional details may be required on a study or sample specific basis.]*

**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* | **🗸** | **🗸** | **🗸** |

*[Samples should be described by type e.g. Urine, Blood, Stool. The collection tube/container should be described, and any specific requirements (such as phlebotomy needle gauge; first urine of the day). Where not routine, the sponsor team should provide the appropriate equipment.*

*[Sites should be instructed to complete the relevant section for visit samples on the eCRF for each patient.]*

**6.4 Sample Labelling**

The processes of labelling samples collected must be detailed below. The clinical trial sample must be labelled in such a way as to allow their unequivocal identification at all times. This may necessitate the use of different labels depending on the processes deployed in collecting and processing samples. All samples must be anonymised. Study specific sample labels may be provided to the participating sites as appropriate. If so, a record of the serial numbers of study specific labels sent to each site must be recorded by the Project Manager for future reconciliation.

*[Detail labelling system, include LIMS instruction where required.*

*Include a Label image/description ensuring the labelling system captures the following information,*

* *Site ID*
* *Participant ID*
* *Study ID*
* *Type of Samples*
* *Time & Date collected]*

**6.5 Study specific sample processing**

*[Describe any processing of samples that is required at the participating site before samples are shipped to a laboratory for analysis. Site staff must receive documented training in the processes.*

*The required volume should be detailed and where there is processing required prior to storage or shipment this must be detailed for instance: whether the tube should be left to stand at room temperature until the sample has clotted (approximately 30 minutes). Centrifuge instructions should include speed and duration.]*

**6.6 Storage at Site**

*[Storage conditions should be described: for instance -80 freezer, or refrigeration range. All samples must be logged in and out of the freezer/fridge or storage at the participating site on the sample log (date/time) to ensure accurate tracking of samples.]*

**6.7 Withdrawal of participant consent**

*[Detail processes to be applied to samples stored at site should a participant withdraw consent. This may include destruction and may depend on what has been approved by the Research Ethics Committee*.]

When a subject withdraws consent to participate in the trial, a member of the research team (Chief Investigator, Research Fellow or Project Manager) will contact the relevant staff to inform them of the withdrawal. Where consent has also been withdrawn for use of research samples, further instruction will be given for the destruction of the samples and LIMS updated accordingly via *[insert support email address]*

Samples will be destroyed and witnessed according to local policy and should be recorded in the appropriate system e.g. eCRF/LIMS etc.

**6.8 Transport of Samples to the NHS laboratory, NHSGGC Central Laboratory or NHSGGC Biorepository**

All samples requiring external transportation involved in eligibility criteria, primary, secondary and safety outcomes **must be couriered and must not be sent in the routine mail.** A date of shipment must be agreed between the named individual responsible for sample shipment at each site and the person delegated by Sponsor to coordinate the shipments (e.g. Project Manager).

*[Detail the processes for sample transfer to laboratories for analysis or further storage. Ensure that when shipping frozen samples, the samples have been adequately frozen before placed on dry ice.*

*Describe the shipping frequency rate (dependent on the rate of local study recruitment, accumulation of aliquots at the local lab and local site needs). When shipment due from a site is required provide instructions for whom to contact and details of the courier, dry ice provision etc. 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.

It is imperative that sites follow the Packing Instruction 650 to ship their specimens, as failure to do so may result in a package being denied for transport and/or the shipper being fined.

*[Instructions should be provided to site:*

* *To contact the Project Manager if any errors with samples are noted.*
* *To ensure they have received information from the Project Manager regarding date of collection/collection reference and to keep a record of the courier consignment record sheet.*
* *To complete Sample Transfer Forms for all samples to be shipped and place these with the sample shipment and email an electronic copy to the Project Manager.*
* *Photocopies of all relevant documentation should be included with the shipment in a sealed plastic bag to protect from the dry ice. Original forms and Lab Processing & Shipment Record sheets should be retained by participating site.*
* *Ensure box is labelled with delivery address.*
* *Phone/email Project Manager to inform them that a shipment has been dispatched.*
* *Project Manager will acknowledge receipt, by email to the named site contact.*
* *On reconciliation of samples at the central lab if there are any errors then the staff will be in touch with staff at participating site]*

**6.9 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.

## 6.10 Protocol Amendments

This section must detail the processes to be followed when protocol amendments have been made, including how the amendments will be distributed and implemented.