<Date>

<Principal Investigator Name>

<PI Address>

Dear <Principal Investigator>

|  |  |
| --- | --- |
| **Study Title** |  |
| **R&I Number** |  |
| **Date of R&I Permission** |  |
| **GCRF Site** |  |
| **GCRF Portfolio Team** |  |
| **GCRF Research Nurse Manager** |  |
| **GCRF Lead Study Nurse** |  |
| **GCRF Study Risk Assessment Score** |  |

Glasgow Clinical Research Facility are pleased to confirm your study is now open to recruitment.

GCRF are committed to ensure research hosted by the facility is conducted to the highest quality, ensuring that all studies are audit and inspection ready at all times.

The following Standard Operating Procedures must be followed and can be found on Q-Pulse and at [www.glasgowctu.org/Home/SOPs](http://www.glasgowctu.org/HOme/SOPs) Please ensure that you read and acknowledge these on QPulse at your earliest convenience if not already done so.

SOP 17.001 – Adult Emergency Resuscitation Procedures in GCRF – *Adult PIs only*

SOP 17.012 – Obtaining Informed Consent (Adults) – *Adult PIs only*

SOP 17.013 – Study site coordination and delivery of an ATIMP

SOP 17.041 – Management of Samples

Sop 17.042 – Paediatric Emergency resuscitation procedures in GCRF – *Paediatric PIs only*

SOP 17.045 – Case Report Form Completion

SOP 17.048 – GCRF Risk Assessment and Mitigation

SOP 17.055 – Obtaining Informed Consent (Children) – *Paediatric PIs only*

SOP 50.013 – Set-up and maintenance of training files: NHS

SOP 53.001 – Handling urgent safety measures for CTIMPs

SOP 53.002 – The handling of poor quality and fraud in clinical research

SOP 57.001 – Managing a Monitor Visit

SOP 57.005 – GCRF Hosted Study Documentation and Data Management

SOP 57.006 – GCRF Principal Investigator Responsibilities

SOP 57.008 – External Audit and Inspection

SOP 57.010 – GCRF Study Planning, Set-up and Start-up

SOP 57.011 – GCRF Study Management

SOP 57.014 – GCRF Support of Early Phase Clinical Trials

If you are also working on a study using the imaging facility, the below SOPs should also be read and acknowledged.

SOP 58.001 – CRIF QEUH Adult Emergency Resuscitation procedures

SOP 58.002 – CRIF QEUH Paediatric Emergency resuscitation procedures

SOP 58.005 – CRIF Risk Assessment and Risk Mitigation

SOP 58.008 – CRIF QEUH controlled access

SOP 58.009 – CRIF Study data and document management

The following SOPs should be read and followed as required however do not need to be acknowledged:

SOP 17.047 – Transfer of the unwell research participant to acute care

SOP 51.008 – Handling non-compliance with GCP and/or trial protocol in clinical research sponsored, co-sponsored or hosted by NHS GG&C

SOP 51.009 – Notification of serious breaches of GCP or the trial protocol for CTIMPs

SOP 53.003 – Temporary halt or early termination of CTIMPs

SOP 57.004 – GCRF Booking, admission and discharge of research participants

SOP 57.012 – GCRF Security and Access

As Principal Investigator you must ensure all members of the study team are suitably trained in the protocol, have a current Good Clinical Practice training, and are delegated appropriately to complete research activities before recruiting. Any category A amendments to the study should only be implemented once R&I permission received and study team are fully trained.

As part of the agreement for use of the GCRF please ensure the study team:

* Work in accordance with Good Clinical Practice (GCP) or UK Policy Framework for Health and Social Care Research;
* Complete the visitor induction – this will include access arrangements, fire safety and room booking procedure;
* Read, acknowledge and comply with the GCRF Standard Operating Procedures through Q-Pulse;
* Aware the study will be included in the GCRF audit programme to assess compliance with our Quality Management System, and be required to share monitoring reports, external audits with the GCRF Quality team. The study team will also be expected to notify the Quality team of any pending regulatory inspections, audit, urgent safety measures or issues that required the sponsor to suspend research activity;
* Aware they will be required to comply with NHS GGC policies and procedures such as DATIX, hand hygiene, uniform policy, sharps disposal, email usage etc;
* Are aware of the competency requirements when using GCRF laboratory equipment for spinning and storing samples (maximum storage 12 weeks);
* Enter the following datasets to EDGE (Clinical Research Management system):
  + Patient details and study status (e.g. consent, randomised, in follow-up etc)
  + Patient appointments

*These data are used to inform NHS GG&C Research and Innovation Department of recruitment milestones and included in specialty specific portfolio reports.*

* + Notify GCRF team when study status changes (e.g. from open to recruitment to in follow-up) and when the study has had the last patient last visit and can be closed out.

Please be aware GCRF is fully staffed in office hours and arrangements to be in the facility outside of core hours must be made with the GCRF management team prior to use.

Each year GCRF hold a training day for all GCRF staff and close the unit for the day (usually in January). There are also two cleaning days a year where all staff are required to assist with archiving, equipment management etc. You will be informed in advance of these days.

Study progress is discussed at speciality operational group meetings which are held four times a years, attendance at these is strongly encouraged.

During your study if you require support from the wider GCRF team please see below for relevant contacts:

|  |  |
| --- | --- |
| **GCRF Director** | **Jesse Dawson (Jesse.Dawson@nhs.scot)** |
| **GCRF Associate Director** | **Dr John Haughney (John.Haughney@nhs.scot)** |
| **Senior R&I Manager** | **Chloe Cowan (**[**chloe.cowan7@nhs.scot**](mailto:chloe.cowan7@nhs.scot)) |
| **CRF Manager** | **Lynn Prentice (**[**lynn.prentice3@nhs.scot**](mailto:lynn.prentice3@nhs.scot)**)** |
| **Lead Nurse** | **Karen Duffy (**[**Karen.Duffy3@nhs.scot**](mailto:Karen.Duffy3@nhs.scot)**)** |
| **Education & Quality Lead** | **Naomi Hickey (**[**naomi.Hickey@nhs.scot**](mailto:naomi.Hickey@nhs.scot)**)** |
| **Quality Lead** | **Helen Hart (**[**helen.hart@nhs.scot**](mailto:helen.hart@nhs.scot)**)** |
| **Clinical Research Education Team** | [**ggc.glasgowcrfeducation@nhs.scot**](mailto:ggc.glasgowcrfeducation@nhs.scot) |

Yours sincerely

**Lynn Prentice**

**GCRF Manager**

|  |
| --- |
| 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. |