SOP number	**57.016**	Version	**2.0**
Title	**EDGE Clinical Research Management System**		

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SOP category	57 NHS GG&C Clinical Research Facility – Administration

Staff category

Staff Category	R	A	C	I
Nursing	X			
Administration	X			
R&I Finance	X			
Site Clinical Trials Pharmacy	X			
Clinical Research Imaging Facility (CRIF)	X			
GCRF Manager		X		
GCRF Associate Director				X
Senior R&I Manager				X

1. Scope

This procedure applies to all staff working within Glasgow Clinical Research Facility (GCRF).

2. Purpose

This standard operating procedure applies to all users (nursing, medical, administrative, pharmacy, finance and imaging) of the EDGE™ Clinical Research Management System.

3. Procedures

Glasgow Clinical Research Facility and associated teams use an external web based database, EDGE. The EDGE Clinical Research Management System is available to support all research activities hosted by GCRF and allows monitor/tracking of the research pathway. The system is an essential tool in the day-to-day running of the facility.

3.1. Administrators

Local EDGE Administrators have full edit rights to all areas of the system including creating records (study and user) and writing reports.

Local Administrators for GCRF EDGE are:
GCRF Manager

GCRF Quality Assurance Lead
GCRF Information Manager
GCRF Administration Manager

There will be instances additional administrative permissions are granted to specific EDGE users to support job role and GCRF associated departments using the system e.g. Clinical Research Imaging Facility (CRIF) and Clinical Trials Pharmacy teams.

EDGE is used by the Site Clinical Trials Pharmacy team and Clinical Research Imaging Facility (CRIF) team to capture research activity and associated costs with their activities. This includes GCRF supported studies and also those not supported by GCRF that these teams carry out research activity on. The pharmacy and CRIF team have dedicated team members with EDGE administrative permission to run ad hoc reports on costings and studies. R&I Pharmacy team support the Site Clinical Trials Pharmacy teams with administration on EDGE.

The R&I pharmacy and CRIF teams require to record their activity for all of the trials that they support and some of these are not supported by GCRF staff. These will be added the system, the following prefix:

- Pharmacy – PHARMGXXXXXXXX
- CRIF – CRIFXXXXXXXX ,

New study requests should be submitted following section 3.5. Once the study record is available, the R&I pharmacy and CRIF teams will be add as much as the minimum dataset following GUI 57.016G as practically possible. The GCRF Information Manager is aware during data audits to remove CRIF and pharmacy only studies as the minimum dataset may not be available to record.

The R&I Finance department require EDGE administrator permissions to run reports on all of the activity for all teams who record information on hosted study costs and patient appointments.

3.2. EDGE Champions

A group of high-level EDGE users, with a variety of roles within GCRF, formed an EDGE Champions Group. The group, supports training of new and existing users and any works through new system developments with the Information Manager, Chair of the Champions Group.

3.3. Creating a new user

New user requests must be submitted to GCRF Information Team, on Form 57.016A. Guidance document, GUI 57.016A must be followed by GCRF Information Team when creating a new user. New users to EDGE must receive training appropriate to their role either from GCRF Information Manager or an EDGE Champion. Users not employed by NHS Greater Glasgow & Clyde must have an Honorary Contract or Letter of Access issued by the R&I department.

3.4. Training

Regular EDGE training sessions will be conducted for all new GCRF staff by the GCRF Information Manager or the EDGE Champion Group. A standard EDGE training package will be used to ensure consistency across the facility. Ad hoc training requests for specific users and/or system

functionality can be made to the GCRF Information Manager. All EDGE users must follow the EDGE Minimum Dataset GUI 57.016G to ensure minimum amount of data recorded for each study record.

3.5. Creating new study

New applications for GCRF study support must be made by completing Form 57.010A and submitting to the Information Management Team at ggc.gcrfstudysupport@ggc.scot.nhs.uk. GCRF Planning Meetings are frequently held to discuss new requests and discuss capacity. New EDGE study records must be created following GUI 57.010B.

For teams who work on studies that are not supported by GCRF staff, a request for these studies to be added to EDGE can be made by completing Form 57.010A, noting not all fields will be required in this circumstance.

3.6. Costing template

The budget negotiations for commercial studies are completed by R&I and sponsor using the NIHR (National Institute for Health Research) interactive Costing Tool (iCT). The final agreed costing template can be imported to the EDGE study record. To ensure the correct costs are recorded for each research activity to be performed, GUI 57.016C must be followed to import the costing template to the EDGE study record.

Non-commercial study costs are negotiated and confirmed in the site contract, GUI 57.016D must be followed when importing non-commercial costs.

3.7. EDGE workflows

Workflows are developed to capture activities on EDGE, mapping out each stage of a process.

GCRF have several workflows that should be used during research study lifecycle. GUI 57.016F should be followed by administrators when adding an EDGE workflow.

3.8. Reporting

All clinical research data for studies hosted by GCRF and other associated teams are recorded on EDGE. It is important to have a robust output function of these data to assure data quality, performance metrics and information sharing. The system has several generic reports that can be run be by users with specific permissions to access Shared Reports, the GCRF Information Manager must grant user access to the shared reports. Ad-hoc reports can be created by system administrators only, the reports can however be saved and shared with specific users.

4. Referenced documents

- GUI 57.016A – New user access
- GUI 57.016B – Creating new study record
- GUI 57.016C – Importing commercial costing templates
- GUI 57.016D – Recording non-commercial study costs

- GUI 57.016E – New User Information
- GUI 57.016F – EDGE Workflows
- GUI 57.016G – EDGE Minimum Dataset
- Form 57.016A – New User Request
- Form 57.010A – GCRF Study Support

5. Related documents

None

6. Document history

Version	Date	Description
1.0	02/08/2023	First release
2.0	19/10/2023	Minor changes Addition of Pharmacy and CRIF only studies