SOP number	**17.048**	Version	**3.0**
Title	**Glasgow Clinical Research Facility Risk Assessment and Mitigation**		

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SOP category	17 NHS GG&C Clinical Research Facility – Clinical

Staff category

Staff Category	R	A	C	I
Nursing	X			
Administration	X			
Principal Investigator	X			
Clinical Research Fellow	X			
GCRF Manager		X		
Site Clinical Trials Pharmacy				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

The purpose of this procedure is to describe the responsibilities held by Glasgow Clinical Research Facility (GCRF) staff and clinical study teams for assessing and mitigating clinical risk for participant visits held in NHS Greater Glasgow & Clyde (NHS GG&C) research facilities.

3. Procedures

All study visits performed in GCRF are reviewed for clinical risk. Studies hosted by GCRF are reviewed for support which includes assessment of staff resource, clinical equipment, identification of training needs. Pharmacy clinical trials staff have assessed supply, storage, stability, dispensing instructions. Resource and study responsibilities are documented in the Local Information Pack.

3.1. Risk Assessment of clinical studies

The clinical research team will assess the level of study risk, this ensures the risk of harm to research participants and staff is minimised as much as practicably possible. Each study performed in GCRF is given a risk score generating an overall estimate of risk significance. This identifies individual significant risks that may require further review and or action(s).

The risk significance score is derived from calculating the potential consequence and likelihood of an adverse event occurring outlined in **Table 1** below:

Table 1

Hazard	Something (e.g. an object, a property of a substance, a phenomenon or an activity) that can cause adverse effects
Likelihood	The likelihood of a hazard resulting in an incident *(1= rare; 2= unlikely, 3=possible, 4=likely; 5=highly likely)*
Consequence	The severity of the incident if it were to occur *(1=insignificant; 2=minor, 3=moderate; 4=severe, 5=catastrophic)*
Risk Significance	The likelihood of a hazard resulting in an incident set against the severity of that incident if it does occur. The risk score is calculated by multiplying: Consequence (C) x Likelihood (L) = Risk Significance (R)

The Study Risk Assessment Form (Form 17.048A) will form part of the GCRF support assessment and approval process. This will be completed at planning stage by the research team.

Once the initial risk significance score has been generated, individual risks are managed in line with Health Board procedure. The initial risk assessment may be reviewed in response to any substantial amendments, particularly those which may significantly alter the hazard profile, or following the occurrence of incidents or near misses related to the study.

3.2. Risk Mitigation for Clinical Visits

In addition to the quality system SOPs, mandatory training and study specific training, additional steps will be in place depending on the level of risk. Study protocols and Sponsor contract will dictate specific specialist expertise required which may demand additional steps to those outlined in **Table 2**.

For some clinical studies, proximity to other services, such as ICU/PICU/neonatal care, or the intervention itself, such as surgery/interventional radiology, will preclude the study visit from being delivered within GCRF. These studies will still be scored as per risk assessment (Form 17.048A). For those considered to have exceptional risk the risk mitigation is to conduct the intervention within the agreed clinical specialty.

Table 2

Exceptional	• Follow the high risk mitigation in agreed clinical specialty
High	• Protocol trained study medic present during intervention • During intervention, minimum x3 ILS trained senior research nurses on duty (min x2 PILS + 1 ILS for paediatric studies) • Intervention risk profile documented with ICU and on call pharmacist pre-visit • Complete NEWS/CEWS during admission • Within core hours IMP delivery/procedure
Medium	• Study medic on site • Minimum x2 ILS/PILS trained research nurses on duty • Within core hours IMP delivery/procedure

Low	• Study team contact details available • Minimum x2 trained research nurses with BLS on duty, at least 1 Band 6 level

3.3. Contingency Planning

Risks may be identified which impact participant safety and study outcome. Mitigation and contingency planning can be prepared to avoid an impact on the study. The risk assessment scores will trigger contingency planning to proactively detect and address issues from outset of a study.

4. Referenced documents

- Form 17.048A – GCRF Study Risk Assessment Form

5. Related documents

None

6. Document history

Version	Date	Description
1.0	08/08/17	First release
2.0	26/08/2019	Minor administrative changes Change SSIF to Local Information Pack Add BLS requirement to table 2 low risk Remove FORM 17.048A signoff step
3.0	04/09/2023	Update to SOP template v2.0 Addition of RACI matrix Minor changes to wording to include all studies performed in GCRF