SOP number	**SOP 58.005**	Version	**3.0**
Title	**CRIF Risk Assessment and Risk Mitigation**		

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SOP category	58 NHS GG&C Clinical Research Imaging Facility				
Staff category	**Staff Category**	**R**	**A**	**C**	**I**
	Clinical Research Imaging Facility (CRIF) staff		X		
	Radiologists	X			
	Principal Investigator	X			
	Clinical Research Fellow	X			
	Clinical Physicist	X			
	CRIF Authorised Users	X			

1. Scope

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

2. Purpose

The purpose of this procedure is to describe the responsibilities held by imaging staff for assessing and mitigating clinical study risk for research visits held in the Clinical Research Imaging Facility (CRIF) at Queen Elizabeth University Hospital (QEUH).

3. Procedures

All clinical studies supported by CRIF are assessed for staff, training, capacity and quality assurance (SOP 58.004).

3.1. On receipt of study/imaging protocol the Lead and Deputy Lead Research Radiographers will assess the level of risk for study visits to ensure that study related hazards are identified, analysed and controlled in line with Health Board Policy and relevant Health & Safety legislation. This ensures that the risk of harm to research participants, CRIF staff and visitors to CRIF are minimised as much as practicably possible. Each study implemented in CRIF is assessed for risk significance and also for identifying individual significant risks that may require further review and or action(s). Some clinical studies may not include safety reporting in the protocol: these will be identified during imaging study review and approval. The CRIF Risk Assessment Form (Form 58.005A) will be agreed with the Principal Investigator and Radiologist for the study and will form part of the study delivery assessment. The level of risk (exceptional, high, medium, low) will be scored for study design and management

(study risk assessment - A) and will be scored for clinical risk assessment (B). The highest level of risk for section A and B will inform the mitigating steps outlined in table 1A and table 1B.

3.2. 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 1A and 1B.

Table 1A Study Risk Mitigation Steps

Exceptional	• Study specific imaging protocol required • Review by CRIF Approval Group
High	• WIP Sequence review through CRIF Approval Group • Scan anonymization process in audit plan • Reporting tool compliance in audit plan
Medium	• Studies subject to selection for annual process audit review
Low	• Studies subject to routine process audit, monitoring and inspection

Table 1B Clinical Risk Mitigation Steps

Exceptional	• Specialty team present e.g. PICU, A&E or Paediatric Intermediate Life Support (PILS) trained nurse/midwife • Minimum x2 ILS/PBLS (Paediatric Basic Life Support) trained radiographers on duty • Investigating clinician present in CRIF • CRIF Health Care Support Worker (HCSW)
High	• Minimum x2 ILS/PBLS trained radiographers on duty • Investigating clinician present in CRIF for interventions • Trained nurse/midwife present in CRIF • CRIF Health Care Support Worker (HCSW)
Medium	• For MRI: minimum x2 authorised MR staff on duty (x1 ILS/PBLS trained) • For CT: minimum x2 CRIF staff on duty (x1 ILS/PBLS trained) • Trained nurse/midwife available on arrangement
Low	• For MRI: minimum x2 authorised MR staff on duty (x1 BLS trained) • For CT: minimum x1 CRIF staff on duty (x1 BLS trained)

3.3. 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 will trigger contingency planning to proactively detect and address issues from outset of a study.

4. Referenced documents

- Form 58.005A – CRIF Risk Assessment Form

5. Related documents

- SOP 58.001 – CRIF QEUH Adult Emergency Resuscitation Procedure
- SOP 58.002 – CRIF QEUH Paediatric Resuscitation Procedure

6. Document history

Version	Date	Description
1.0	17/10/2016	Creation of SOP
2.0	13/01/2020	Removal of BHF as a site; change of name of CRIF Group, addition of HCSW to CRIF team
3.0	23/11/2023	Update to SOP template v2.0 Addition of RACI matrix