

Lone Working and Personal Security in the King's Clinical Research Facility

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Author	Sokol Shala, CRF Quality Assurance Manager
Approved by	Elka Giemza, CRF Manager
Authorised by	Professor James Galloway, CRF Deputy Director
Related documents	KCH Security of Lone Workers Policy KCH Health and Safety Policy KCH Policy for the Prevention and Management of Violence and Aggression KCH Security Policy KCH Lone Working On-Site Risk Assessment Form KCH Policy for the Management, Reporting, & Investigation of Adverse Incidents (including Serious Incidents) CRF-HS-COP-1: King's CRF Health and Safety Code of Practice CRF-QA-FRM-51 King's CRF Lone Working Risk Assessment Form
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Change History		
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06 th January 2014	1. Amended text in SOP title from "Clinical Research Facilities" to "King's Clinical Research Facility" 2. Amended name of Director to reflect new Director 3. Amended logos to update to current CRF letterhead template 4. Amended document number from CRF SOP015 to CRF-ADMG-SOP-3 to comply with QPulse document numbering 5. Amended numbers of documents referred to throughout the text to reflect revised QPulse/CRF numbers	E Giemza

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Page 1 of 9

	- Removed KCH risk assessment template and KCH Lone Working Checklist as appendices as documents available on KCH intranet - Added sections 5.7.12 and 5.7.16 to detail use and location of "ID card style" pinpoint alarm transmitters in Clinical Trials Facility	
August 2015	- Addition of a procedure for out-of-hours patient visits in the CRF (Section 5.5) - Addition of the current online Risk Assessment process via the Datix system (Section 5.6) - Section 5.8: Update to the location of the PINPOINT call buttons (EMF) and other devices (CTF) - Minor administrative amendments to text	E. Giemza
August 2017	- Minor administrative amendments to text for clarity - Sections 5.2, 5.3, 5.4: Updated procedure for risk assessments for CRF staff and CRF users - Updated relevant documents (KCH policies)	E. Giemza
October 2021	- Change to Author - Minor administrative updates	E. Giemza
April 2024	- Additional responsible roles added for CRF Lead Research Nurse and CRF Experimental Nurse Team Leader throughout the SOP - Section 5.5: Location of ID style card alarm updated; Grenade style alarm transmitter type removed as no longer in use - Datix replaced with InPhase - Removal of Wellcome Trust logo	E. Giemza
May 2026	- Sections 5.2–5.4: Updated lone working risk assessment process for CRF staff and users. - Sections 5.2–5.4: Introduced CRF-QA-FRM-51 King's CRF Lone Working Risk Assessment Form. - Sections 5.2–5.4: Clarified responsibilities for completion, submission, review and approval of lone working risk assessments. - Sections 5.2–5.4: Added requirement for Line Manager approval prior to lone working activities commencing. - Removal of old Kings Health partner logo - Addition of New Kings Health Partner Logo	E. Giemza

Review History		
Date	Review details	Approved by
06 th January 2014	Review of v1.0 conducted by Lara Edwards, CRF QA Manager, superseded by v2.0 (effective date 27 th January 2014)	E Giemza
August 2015	Review of v2.0 conducted by Georgia Bullock, CRF QA Manager. Changes made as per 'Change History' and re-issued as v3.0	E. Giemza
August 2017	Review of v3.0 conducted by Georgia Bullock, CRF QA Manager, as per the review date. Changes made as per	E. Giemza

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Page 2 of 9

Effective Date: 13 May 2026

Review Date: 13 May 2028

CRF-ADMG-SOP-3 v7.0

	'Change History' and re-issued as v4.0	
October 2021	Review of v4.0 conducted by Angelina Twumasi, CRF QA Manager, as per the review date. Changes made as per 'Change History' and re-issued as v5.0	E. Giemza
April 2024	Review of v5.0 conducted by Bidisha Chakraborty, CRF QA Manager, as per the review date. Changes made as per 'Change History' and re-issued as v6.0	E. Giemza
May 2026	Review of v6.0 conducted by Sokol Shala CRF QA Manager, as per the review date. Changes made as per 'Change History' and re-issued as v7.0	E. Giemza

1.0 Background

1.1 The King's Clinical Research Facility (CRF) is generally staffed Monday-Friday, 08.30-18.00hrs. Lone working of personnel in the CRF, both core CRF staff and users of the CRF, may sometimes be necessary in order to conduct work outside of these hours and also to accommodate personnel who work varying hours. 'Users' of the CRF include: research nurses, clinicians, radiographers, research assistants, students and psychiatrists (this list is not exhaustive).

1.2 To mitigate any risk to personnel working alone in the CRF, all CRF staff and users of the CRF must be aware of their individual responsibilities, the potential risks and hazards they may be exposed to and how to ensure their own safety when working alone. The King's College Hospital NHS Foundation Trust's (KCH) lone working and security policies and Health and Safety policy must be adhered to at all times, as well as all relevant CRF Standard Operating Procedures (SOPs) and policies.

2.0 Purpose

2.1 The purpose of this Standard Operating Procedure (SOP) is to describe the procedures and systems which are in place for lone working and personal security within the CRF.

3.0 Scope

3.1 This SOP applies to all core CRF staff and all users of the CRF.

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Page 3 of 9

3.2 The CRF consists of the Experimental Medicine Facility (EMF), Clinical Trials Facility (CTF) and Cellular Therapy Unit (CTU). This SOP is applicable to staff working in the EMF and CTF only, as the CTU maintains and controls its own SOPs to ensure compliance with Good Manufacturing Practice (GMP). For CTU staff, lone working procedures and specific responsibilities with regards to security are detailed in separate CTU documents.

4.0 Responsibilities

4.1 All lone working staff within the CRF are required to take reasonable care, be aware of any potential risks involved and to be aware of their own health and safety. **NO CRF staff member or CRF user may commence lone working without prior approval from the CRF Manager.**

4.2 The CRF Manager and CRF Quality Assurance (QA) Manager/CRF Lead Research Nurse/CRF Experimental Nurse Team Leader have the responsibility to ensure that a risk assessment is conducted prior to any personnel (core CRF staff and CRF users) working alone in the CRF, all personnel have been provided with this SOP and all personnel are aware of the CRF's security procedures, including the emergency security system (PINPOINT).

4.3 KCH has a legal duty to ensure that the appropriate training, policies and (where appropriate) equipment is provided to ensure that staff are able to work safely as lone workers.

5.0 Procedure

5.1 All CRF staff and users of the CRF must ensure that they are familiar with the CRF procedures for lone working and also on the use of the PINPOINT system. Training will be provided as part of the local CRF induction for both core staff and CRF users.

5.2 A risk assessment must be completed for all episodes of lone working in the CRF. Personnel intending to undertake lone working must complete CRF-QA-FRM-51 King's CRF Lone Working Risk Assessment Form and submit it to the CRF QA Manager, CRF Lead Research Nurse, or CRF Experimental Nurse Team Leader prior to commencing lone working activities. The assessment will consider the nature of the proposed

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Page 4 of 9

activities, the working environment, access to communication and emergency assistance, relevant training, and any identified risks associated with lone working.

5.3 The CRF Manager, CRF QA Manager, CRF Lead Research Nurse, or CRF Experimental Nurse Team Leader will review the completed assessment and ensure any significant risks are appropriately addressed prior to approval of lone working activities.

Core CRF Staff:

- All episodes of lone working must be agreed with the individual's Line Manager prior to commencing lone working activities.
- The staff member requesting lone working is responsible for completing **CRF-QA-FRM-51 King's CRF Lone Working Risk Assessment Form** and obtaining Line Manager approval.
- CRF-QA-FRM-51 King's CRF Lone working risk assessment form to be submitted to the CRF QA Manager, CRF Lead Research Nurse, or CRF Experimental Nurse Team Leader prior to lone working.
- Risk assessments for 'one-off' lone working sessions will be performed on an as-required basis and approved by the CRF Quality Assurance Manager.
- Risk assessments for regular, planned out-of-hours lone working will be performed once, approved by the CRF Manager and reviewed every two years.

5.4 Users of the CRF:

- Users of the CRF may occasionally need to conduct study visits outside of the CRF's normal working hours (e.g. evenings and weekends) to accommodate participant availability.
- All users of the CRF must contact the CRF Manager, CRF QA Manager, CRF Lead Research Nurse, or CRF Experimental Nurse Team Leader in advance to request out-of-hours working.
- Where possible, researchers should arrange for another member of their study team to be present during the visit to avoid working alone with a study participant.

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Page 5 of 9

- Where lone working is required, the CRF user must complete CRF-QA-FRM-51 King's CRF Lone Working Risk Assessment Form and obtain approval from their Line Manager prior to the planned activity.
- The CRF Manager, CRF QA Manager, CRF Lead Research Nurse, or CRF Experimental Nurse Team Leader may review the assessment and discuss any identified concerns with the CRF user where necessary.

5.5 PINPOINT:

- The PINPOINT security system is installed throughout the EMF and CTF (and CTU).
- **Experimental Medicine Facility (EMF):** In the EMF there are wall-mounted transmitters with orange call buttons (see **Figure A**) that can be used in the event of an immediate security risk that requires the attendance of the KCH security team. There are call buttons present in the following areas:

Ground Floor: 4-bed ward, ITU and MRI suite

First Floor: Reception, Nurses' Station, Interview Rooms 1, 2, 3, 4 and 5, Trial Procedures Room and Clinical Rooms 1 and 2

Second Floor: Tea-point, QC laboratory and Write-Up Room

- These are activated in an emergency by pushing the orange call button which instantly relays a signal towards the Receiver Unit located with KCH Security which pinpoints the source of the alarm within the EMF.



Figure A: Orange PINPOINT call button units. The example in the centre of Fig. A is the model installed in the EMF which includes an orange call button, reassurance LED and a disarm/reset key switch.

- Orange LED over-door lights are also positioned strategically over doors within the EMF to allow the Security team to easily locate the source of the alarm, see **Figure B:**

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Page 6 of 9



Figure B: Orange LED over door lights.

- **Clinical Trials Facility (CTF):** In the CTF, there are 'ID-style card' alarm transmitters which can be worn round the neck with a lanyard like a standard ID card. These are kept in the CTF Security office in the reception area and if required, can be obtained through the CTF Housekeeper or CTF Security officer.
- To activate the ID-style' alarm transmitter, press the round button at the back of the ID card. This will send a coded infrared signal to the Infrared Receiver Units instantly and relay the alarm signal to the KCH Security Desk.
- The PINPOINT system is tested regularly to ensure that it is working correctly and that the KCH security team receive the alarms and respond in a timely manner.
- All appropriate devices can be moved throughout the CTF as necessary and carried with a staff member if required but they **MUST** be returned to their original locations after use.

5.6 Any staff member who has any concerns whilst working alone in the CRF should contact KCH Security (**extn. 4567**). If an immediate response is required, KCH Security can be contacted on the emergency number (**extn. 2444**) or the PINPOINT alarm system should be triggered. Any worker who is verbally or physically abused, assaulted or threatened should immediately report the incident to KCH Security and should attend the Emergency Department if a physical injury has been sustained.

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Page 7 of 9

5.7 Any incident that meets the definition of an Adverse Incident (AI), as defined in the KCH Policy for the Management, Reporting, & Investigation of Adverse Incidents (including Serious Adverse Incidents), occurring in **any area within the CRF**, must be **reported** using the **InPhase**, as per KCH policy

[Create new LFPSE Incident \(inphase.com\)](http://inphase.com)

5.8 Non-KCH personnel who cannot access the KCH intranet to report an adverse incident via InPhase must report the incident to a member of CRF staff as soon as possible, who will then report it via InPhase.

6.0 Related documents & References

6.1 <http://kingsdocs/Pages/Home.aspx>

6.1.1 KCH Security of Lone Workers Policy

6.1.2 KCH Health and Safety Policy

6.1.3 KCH Policy for the Prevention and Management of Violence and Aggression

6.1.4 KCH Security Policy

6.1.5 KCH Lone Working On-Site Risk Assessment Form

6.1.6 KCH Policy for the Management, Reporting, & Investigation of Adverse Incidents (including Serious Incidents)

6.2 Risk Assessments and Adverse Incidents: [Create new LFPSE Incident \(inphase.com\)](http://inphase.com)

6.3 CRF-HS-COP-1: King's CRF Health and Safety Code of Practice

6.4 CRF-QA-FRM-51 King's CRF Lone Working Risk Assessment Form

7.0 List of Appendices

N/A

8.0 Approval and sign off

Author:

Name: Bidisha Chakraborty

Position: CRF Quality Assurance Manager

Signature:

Date:

Approved by:

Name: Elka Giemza

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Page 8 of 9

Effective Date: 13 May 2026

Review Date: 13 May 2028

CRF-ADMG-SOP-3 v7.0

Signature:

Date:

Authorised by:

Name: Professor James Galloway

Position: CRF Deputy Director

Signature:

Date:

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Page 9 of 9

Effective Date: 13 May 2026

Review Date: 13 May 2028

CRF-ADMG-SOP-3 v7.0