DIVISION OF RESEARCH AND INNOVATION

Clinical Research Facility

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Title: Clinical Research Facility (CRF) Operations	
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	Name	Position
Authored by:	Beth Reeves	QA Manager
Approved by:	Christy Rowley	Operations Manager

1. Scope

This SOP is applicable to

- All CRF staff
- All Great Ormond Street Hospital for Children (GOSH) or Institute of Child Health (ICH) staff working in or using the CRF.

Further to the requirements listed in this SOP, personnel must also comply with:

- Any additional study-specific requirements mandated by the PI, Sponsor and/or local R&D.

2. Purpose

The purpose of this SOP is to outline the operation of the CRF including the services that are available and how these are managed.

3. Definitions/Abbreviations

- CTIMP – Clinical Trial of an Investigational Medicinal Product
- CRN – Clinical Research Network
- NIHR – National Institute for Health Research

4. Responsibilities

Duties may be delegated but the responsibility always remains with those listed.

4.1 Director of CRF (and deputy in the absence of the Director) has overall accountability for the unit.

4.2 Head of Nursing (and matron in the absence of the Head of Nursing) is responsible for leading the clinical staff (nursing and allied health professionals) in the CRF and for oversight of the clinical standards, clinical governance, patient experience and quality of nursing care delivered in the CRF.

4.3 Operations Manager (and CRF Service Manager in the absence of the Operations Manager) is responsible for the non-clinical team, financial management of the unit, and operational and strategic management of the unit

4.4 QA Manager is responsible for developing, implementing and maintaining systems and processes to assure the quality of clinical research undertaken in the CRF.

4.5 Clinical Team

- Band 7 team (CRF Sister/Charge Nurse and Senior Speciality Research Nurse) are responsible for leading and supporting the clinical band 3-6 team in delivering CRF research studies. They promote high standards of patient care and research practice. The CRF Sister/Charge Nurse is additionally responsible for the organisation of the clinical operations of the CRF.
- Band 3-6 team are responsible for delivering CRF research studies
- The Nurse in Charge is responsible for the day-to-day running of the unit. They ensure that the CRF Safety Checks are completed and that the unit is ready to welcome participants, their families, research teams and visitors. They are also responsible for ensuring the unit is appropriately closed down.
- Clinical Research Nurse Practice Facilitator is responsible for supporting the continuing professional development of clinical research staff in the CRF.

4.6 Play specialist is responsible for the organisation and provision of therapeutic play preparation and distraction for participants and their families within the CRF.

4.7 CRF Pharmacist is responsible for providing clinical pharmacy services to the CRF and advising clinical staff on prescribing and administration of medicinal products.

4.8 Non-Clinical Team

- Co-Ordination Team are responsible for study costings and coordination for an assigned portfolio of studies, and supporting clinical team with Study Assessment Forms (SAF), intensity tools and data management.
- Data Team are responsible for data entry, arranging monitoring visits, dealing with data queries, and accurate and timely submission of study data.

- Prep Lab Team are responsible for the processing, storage and shipping of study samples as well as contributing to capacity and capability discussions prior to lab support requests being accepted by the CRF.

- Reception Team are responsible for booking and discharging participants via CRF Manager and PiMS, front of house duties, participant expenses management, and being first point of contact for participants and families.

4.9 All staff are responsible for

- Ensuring their practice meets the requirements of this SOP, the study protocol, GCP and any applicable legislation, policies, procedures or guidelines.

5. Procedure

The NIHR CRF provides ambulatory care accommodation for paediatric clinical research studies. It is staffed by a cohort of clinical and non-clinical staff. The CRF is open Monday-Friday 08:00-18:00 (excluding bank holidays). The CRF is also available for overnight visits (usually on a Monday or Tuesday night). The facility is available to all GOSH/ICH staff undertaking clinical research that is early phase and/or complex.

5.1 Unit Safety

5.1.1 Minimum Staffing

There must be a minimum of 2 registered clinical staff on the unit while participants are present. This takes into consideration the number of staff required to manage a medical emergency, should it arise. Staff attendance is documented in the rota and is also recorded on the CRF staffing board.

Study treatment must not be administered in the CRF out of hours without prior agreement from the Director of the CRF and/or Head of Nursing.

The study protocol and/or risk assessment must be followed in the event that increased or additional staff are required.

A Nurse in Charge and Clinical Band 7 will be rostered each day the CRF is open. The Nurse in Charge is responsible for the day-to-day running of the unit and the Clinical Band 7 is the main escalation point and support for the Nurse in Charge.

5.1.2 Training

All Trust medical, nursing and Allied Health Professional staff who have direct patient contact must undertake appropriate annual resuscitation training as per the Trust Resuscitation and Deteriorating Patient Policy.

All CRF and visiting clinical staff must ensure that they know the location of CRF emergency equipment (this must be included in their CRF induction).

It is also essential that all clinical staff working on the CRF know how to operate the examination chairs and beds in the event of an emergency (i.e. can lay it flat and raise it to the correct height for staff).

As per the Training SOP GOSH/ICH/SOP/R/002; all CRF clinical staff must participate in Emergency Scenario Training annually. This is in addition to scenarios conducted as part of Trust mandatory life support certification.

5.1.3 Safety checks

There are daily, weekly and monthly safety checks that must be completed and signed off in the 'Daily, Weekly & Monthly Safety Checks' folder. The daily safety checklist must be completed each morning to ensure the unit is ready and safe to receive participants. This should be completed before 9am or before the first study participant is taken to their clinical room – whichever is sooner.

5.1.4 Clinical Handover and Safety Huddles

Handover is held at 09.00 every morning the CRF is open. It is facilitated by the Nurse in Charge using the SBARD (Situation, Background, Assessment, Recommendation, and Decision) tool. The study participants due in on that day are communicated to staff along with any patient alerts, risks, visitors, meetings, and service cover (clinical and the wider CRF). Relevant information is documented in the Nurse in Charge package.

Safety Huddles are held for all clinical staff on the unit at 14:30 to review staffing, activities and the running of the unit.

When the CRF is open overnight, there is a handover between day team and night team at 19:45 and between night team and day team 08:00.

5.1.5 Clinical Monitoring

All GOSH clinically based medical and nursing staff must be trained to rapidly identify patients at risk of cardiorespiratory collapse. The Trust uses PEWS (Paediatric Early Warning System) to identify children and young people at risk of deteriorating.

As per Trust Observation and PEWS Policy, PEWS parameters (respiratory rate, work of breathing, oxygen requirements, SpO2, heart rate, blood pressure and capillary refill time (CRT)) must be recorded every time observations are required for a patient. This will help ensure that clinical deterioration is detected at an early stage and can be managed using the Trust's escalation algorithm.

5.1.6 Alarms

Alarm points are situated in the clinical rooms, shower, toilets and reception area. Alarms are tested weekly (this testing is documented in the Daily, Weekly & Monthly Safety Checks folder).

In the event the alarm system fails, the Trust Property Services team should be contacted (who may need to contact the alarm supplier). If the system is not functioning, personal emergency alarms can be obtained from Property Services and issued to each participant/family.

5.1.7 Access to bathrooms

The CRF induction for all clinical staff must include how to open the toilet/bathroom doors from the outside in an emergency.

All clinical staff must have a two pence coin attached to their ID badge that can be used to unlock the toilets from the outside in an emergency.

5.1.8 Anaphylaxis Preparation (Anaphylaxis Kits and WETFLAG)

All participants receiving IMPs (Investigational Medicinal Products) are prescribed precautionary emergency drugs in the case of anaphylaxis. Dosages are as per the Resus Council guidelines. These pre-made anaphylaxis kits must be taken into the participant room prior to the participant receiving an IMP.

For all participants, their WETFLAG information (Weight, Energy, Tube, FLuids, Adrenaline, Glucose) must be prepared and displayed on the whiteboard in the clinic room in case of an emergency resuscitation.

5.1.9 Clinical Emergency Trolley (Crash Trolley)

The Trust Resuscitation and Deteriorating Patient Policy must be followed.

The CRF clinical emergency trolley must be safely maintained in a state of readiness always. The trolley must be kept clean and free of any items not listed on the standard contents list.

The trolley contents must be checked by an appropriately qualified member of staff at least once every 24hours the CRF is open and immediately following the conclusion of any resuscitation event. A signed, written record of each check must be kept in the designated folder kept on top of the trolley.

5.1.10 Trust Clinical Emergency Team

The Trust Escalation Algorithm and Trust Resuscitation and Deteriorating Patient Policy must be followed.

To summon the Clinical Emergency Team (24hr) call 2222.

State “Clinical Emergency” and CRF location, i.e.:

“*Clinical Emergency, Clinical Research Facility, Level 1, Frontage Building*”

All members of the Trust Clinical Emergency Teams (CET) are experienced in advanced paediatric resuscitation skills with a current

nationally recognised EPALS (European Paediatric Advanced Life Support) or APLS (Advanced Paediatric Life Support) qualification.

In the event the call system fails, the Trust will issue alternate contacts.

5.2 Staff

5.2.1 CRF New Starters

New staff must undergo a Local Induction as per Trust Policy. When staff start; their manager must inform the QA Manager and CRF Service Manager so the staff member can be added to CRF lists and systems (e.g. mailing list, organogram, Q-Pulse). Training requirements for CRF staff are in SOP 'Training Requirements for Staff Participating in Clinical Research'.

5.2.2 Study Allocation

Clinical and non-Clinical staff are allocated to a study based on therapeutic area, relevant training and experience, and capacity. Staff allocation decisions are made by respective team-leads and are stored on Q-Pulse.

5.2.3 CRF Leavers

When staff leave; their manager must inform the QA Manager and CRF Service Manager so the staff member can be removed/inactivated from CRF lists and systems (e.g. mailing list, swipe access list, organogram, Q-Pulse, shared drives).

5.2.4 Visiting Researchers

Visiting researchers who will be working in the CRF must undergo a Local Induction (as per Training SOP GOSH/ICH/SOP/R/002).

5.3 Requesting CRF Support

CRF Support (Clinical, Data, Prep Lab, coordination and/or clinical room) must be requested via crf.registration@gosh.nhs.uk. The support decision will be made at the Clinical Research Support Meeting (CRSM) after the capability and capacity of the CRF to deliver the study have been assessed. This meeting is held every 2 weeks. More information can be found in the CRSM Terms of Reference.

5.4 Study Participants

5.4.1 Bookings

The procedures for booking study appointments that are in and/or supported by the CRF (including telephone appointments), for admitting and discharging participants to/from the CRF and for transferring participants from the CRF to other GOSH wards/departments are described in SOP 'Booking Appointments, Admission, Discharge and Transfer of Study Participants in the CRF'.

5.4.2 Clinical Care

Clinical care of study participants should be as per Trust Clinical Guidelines and/or the study protocol.

5.4.3 Out of Hours Care

The CRF does not provide medical assistance out of hours. Each study should have a procedure for out of hours contact (e.g. an emergency contact card).

In the event that a study participant calls the GOSH switchboard out of hours the call would be directed to the Clinical Site Practitioners (CSPs). To cover this eventuality, the CRF clinical team will forward a list of all active CRF CTIMP study participants plus emergency study contact details to the CSPs on a weekly basis on the last day of the working week.

5.5 Medical Notes

If paper medical notes are required these should be ordered through the CRF Reception Team from the Trust's Medical Records Department the week before they are required to reduce the risk of delays occurring on the day. All paper medical notes that are being used in the CRF must be tracked in to the CRF on PiMS by the CRF Reception Team. All paper notes tracked in to the CRF are stored in the Records Store (Room M1008) when not in use/outside of the CRFs opening hours. There is a swipe access unit on the Records Store doors ensuring only authorised staff can enter the room.

If paper medical notes are to be transferred to off-site CRF offices they must be transported using a medical records approved note carrier and returned to the CRF Records Store when not in use/outside of the CRF's opening hours. Notes must be tracked to the off-site CRF office on PiMS and tracked back to the CRF when returned at the end of the day.

5.6 Study Finance

5.6.1 Study Costings

Every study supported by the CRF has to be costed to ensure the CRF is appropriately recompensed for the service(s) provided. Study specific costs are discussed by a team within the CRF and costs are sought from other Trust teams as required. The costs must be approved by the Operations Manager (or Service Manager) and study PI. Once approved, the costs are agreed with the Sponsor (with the assistance of the CRN for Portfolio studies).

5.6.2 Participant Expenses Returns

Each study will have an arrangement for participant expenses that will be detailed in the study agreement and participant information sheet (e.g. to refund costs for travel and/or subsistence). The Lead Nurse for the study

must check the allowed expenses and reimbursement arrangements prior to recruitment.

5.7 Access to the CRF

The CRF is located in level 1 Frontage Building and is accessible by lift or stairs from Main Reception. The CRF is only accessible via swipe access. People without a suitable ID badge (e.g. participants or monitors) must ring the buzzer to request access. The staff on the CRF reception desk can remotely open the door (having first checked the security camera). All visitors to the CRF without a suitable ID badge must sign- in. Sign-in sheets are kept for 2 years.

All GOSH staff will have access to CRF Reception using their ID badge.

The CRF meeting room and clinical rooms do not have swipe access but are lockable. Other rooms within the CRF are only accessible via swipe access to restrict access to these rooms to staff that require entry to perform their role.

Requests for swipe access from non-CRF staff must be made to the QA Manager in writing and will be reviewed on case by case basis (following discussion with Operations Manager and/or Head of Nursing).

Faults with the swipe access must be reported to Trust Security. If the swipe access is not working the room should be suitably secured using lock and key (particularly out of hours).

5.8 Medicines Administration, Ordering & Storage

The process for the storage and administration of medicinal products, including IMPs and controlled drugs, in the CRF is outlined in SOP 'Ordering, Storage and Administration of Medicines in the CRF'.

5.9 Equipment and Consumables

5.9.1 Medical Equipment

The Trust Medical Equipment Policy must be followed.

The Trust Biomedical Engineering Department (BME) are responsible for the management of Trust medical equipment. This includes managing the Trust asset register, equipment maintenance and repair, and advice on service contracts.

If a Sponsor has provided equipment for a study, the Sponsor is responsible for the management of the equipment and providing training. The Lead Research Nurse for the study must ensure that BME are aware of any equipment that is brought into the Trust.

All staff are responsible for ensuring that the medical equipment that they use is fit for purpose and that they have been trained and are competent to use the equipment appropriate to their role. Staff must not use medical equipment if they have not been trained/assessed as competent to use it.

Medical equipment that requires routine scheduled maintenance is labelled with the date of the next required maintenance. All equipment users should check this date and are responsible for ensuring that the equipment is appropriate serviced/calibrated and is not used past this service date. All equipment should be visually inspected for any damage prior to each use and, if required, basic functional checks completed.

The CRF Sister/Charge Nurse is responsible for ensuring all equipment is checked on a monthly basis and reporting to BME any equipment which is due servicing/calibration (recorded on Monthly Safety Checks).

Faulty equipment should be reported to the Biomedical Engineering Department (or Sponsor if provided by the Sponsor).

5.9.2 Computer Systems

CRF computer systems must be appropriately validated before use.

5.9.3 Consumables

The CRF uses stock, non-stock and study specific consumables in order to facilitate the research activities that take place in the unit. These are located in the treatment room, equipment stores and in lockable trolleys in each of the clinic rooms.

It is the responsibility of all clinical and lab staff to check the expiry date of consumables before use.

It is the responsibility of the CRF Sister/Charge Nurse to ensure the stock levels and expiry date of stock and non-stock consumables are checked on a monthly basis and disposed of and/or re-ordered as necessary as per usual Trust procedure (recorded on Monthly Safety Checks).

5.9.4 Study Equipment and Consumables

The CRF should not accept any equipment or study specific supplies until the study contract has been signed by the Sponsor and GOSH and the research team have confirmed acceptance to ship.

If equipment or supplies are sent prior to a contract being fully executed, the research team should inform the Sponsor it cannot be accepted and will be returned or disposed of. GOSH assumes no liabilities for any disposals prior to a contract being in place between Sponsor and GOSH.

It is the responsibility of the study Lead Research Nurse to check the stock level and expiry date of study specific consumables regularly to ensure they are prepared for study visits. Study specific stock should be ordered as per agreement with the study Sponsor; appropriate records should be kept in the site file.

Study equipment or consumables that are no longer needed (e.g. expired, broken, or at the end of study) should be disposed of as per relevant Trust procedures (e.g. Medical Equipment Policy and/or Waste Management Policy) or returned to the Sponsor; whichever has been agreed with the Sponsor. Appropriate records should be kept in the site file.

5.10 CRF Clocks and Time Keeping

The clinical rooms, nurse's office, lab, staff room and dirty utility room are equipped with synchronised clocks. These clocks are connected to the Trust IT network and receive their power and time signal through this connection.

These synchronised clocks should be used for actioning and recording study procedures, unless otherwise required by the study protocol.

Any problems with the synchronised clocks should be raise with the CRF Service Manager or QA Manager. Faulty clocks should be removed (or clearly labelled as out of order) to ensure they are not used; and should be repaired or replaced as soon as possible. If a clock is out of order, another reliable clock should be used (e.g. computer, mobile phone, or synchronised fob).

5.11 Temperature Monitoring

The CRF uses the Tutela Wireless Monitoring System for monitoring the temperature of storage areas in the Treatment Room and Prep Lab. The system will alarm and automatically contact key personnel if the storage temperature goes outside of the allowed range or a problem is detected. Actions to be taken in the event of an alarm are in SOP 'Ordering, Storage and Administration of Medicines in the CRF' and SOP 'Storage of Research Samples in the CRF Prep Lab'.

5.12 Filming, Photography and Recording In The CRF

Photography, videography and audio-recording can only occur with the permission of the CRF and must align with the Trust Policy.

5.13 Staff Room and Food Refrigerators

The CRF does not provide meals for study participants (though light snacks are available). The Trust Ward Kitchen Management Policy must be followed. All staff are responsible for keeping the staff room and food refrigerators clean and tidy, a cleaning rota is used to facilitate this.

5.14 Compliance

Compliance will usually be reviewed during routine monitoring or audit. Deviations should be reported as per the usual Trust and study processes.

Systematic or persistent failure to comply with CRF, Research and Innovation, Trust and/or study procedures will be seen as non-compliance to GCP and should be bought to the attention of the Head Nurse, Operations Manager and QA Manager who will decide upon the appropriate action.

6. Related Documents

- CRF Safety Checklist
- SOP/R/002 - Training Requirements for Staff Participating in Clinical Research
- Trust Observation and PEWS Policy
- Trust Escalation Algorithm
- Trust Resuscitation and Deteriorating Patient Policy
- CRSM Terms of Reference (TOR)
- SOP/CRF/002 - Booking Appointments, Admission, Discharge and Transfer of Study Participants in the CRF
- SOP/CRF/001 - Ordering, Storage and Administration of Medicines In the CRF
- Trust Medical Equipment Policy
- Trust Waste Management Policy
- SOP/CRF/005 Storage of Research Samples in the CRF Prep Lab
- Trust Ward Kitchen Management Policy

7. References

NA.

8. Appendices

8.1 CRF Floor Plan

(Internal Area 502m²)