Policy

CCRC/POL003

CCRC Operational Policy

Key messages

- The Cambridge Clinical Research Centre (CCRC) provides purpose-built facilities to support the conduct of high quality experimental medicine clinical research in patients and healthy volunteers.
- The CCRC comprises:
  - A Maternal and Child Health Clinical Research Facility (CRF) with specialist metabolic investigation and adult outpatient facilities
  - A Clinical Investigation Ward (CIW) for complex later phase trials
  - An Interventional Investigation Unit with endoscopy suite
  - An Early Phase Trials Unit for Phase I - IIa drug trials
  - A Metabolic Translational Research Facility (TRF) for complex overnight metabolic studies
  - An overnight Adult Clinical Research Facility for complex, high-intensity research in adults
  - A Health and Lung Research Institute Clinical Research Facility (HLRI-CRF) for cardiorespiratory early phase trials and observational experimental medicine
- This policy outlines the functional relationships between the CCRC, Cambridge University Hospitals NHS Foundation Trust (The Trust), the University of Cambridge, GlaxoSmithKline (GSK) and the National Institute for Health Research (NIHR). It does not apply to the HLRI-CRF, the governance of which is overseen by Royal Papworth Hospital Research and Development Department
- The CCRC has appropriate security and health and safety procedures
- The application and booking processes for the use of the CCRC are detailed within this policy

1 Scope

This policy applies to all staff using the Cambridge Clinical Research Centre (CCRC), irrespective of grade and position held.

2 Purpose

To outline the services and management of the CCRC.

3 Definitions

3.1 Definitions

Term	Definition
ACCI building	The ACCI building houses the CCRC facilities: Clinical Investigation Ward; Maternal and Child Health CRF. It also houses GSK, VRU, the British Heart Foundation and Clinical Pharmacology Unit.
Cambridge Clinical Research Centre	The group of facilities comprising: Maternal & Child Health CRF; Clinical Investigation Ward; Interventional Procedures Unit; Early Phase Trial Unit; Metabolic Translational Research Facility; Adult Clinical Research Facility. This policy does not apply to the HLRI-CRF, the governance of which is overseen by Royal Papworth Hospital Research and Development Department.
Cambridge Clinical Research Centre building	The CCRC building houses: the Interventional Procedures Unit on Level 2, the Early Phase Trials Unit on Level 3; the Adult Clinical Research Facility on Level 5; The Metabolic Translational Research Facility on Levels 4 and 6.
The Trust	Cambridge University Hospitals NHS Foundation Trust.

3.2 Abbreviations

Abbreviation	Meaning
ACCI	Addenbrooke's Centre for Clinical Investigation
AED	Automated external defibrillator
CCRC	Cambridge Clinical Research Centre
CIW	NIHR Clinical Investigation Ward
CRF	Maternal and Child Health CRF
CUH	Cambridge University Hospitals NHS Foundation Trust
GSK	GlaxoSmithKline
HLRI-CRF	Heart and Lung Research Institute Clinical Research Facility
MC	Management Committee
NIHR	National Institute for Health Research
PI	Principal Investigator
PS&G	Patient Safety and Governance Committee
R&D	Research and Development
SAB	Scientific Advisory Board
SpR	Speciality Registrar
ReSPECT	Recommended Summary Plan for Emergency Care and Treatment
VRU	Vascular Research Unit
VTE	Venous Thromboembolism

4 Introduction

The areas of the Cambridge Clinical Research Centre (CCRC) covered by this policy are: a Maternal and Child Health Clinical Research Facility (CRF) with specialist metabolic investigation and adult outpatient facilities; a Clinical Investigation Ward (CIW) for late phase drug trials; an Interventional Procedures Unit with endoscopy suite (CCRC-L2) ; an Early Phase Trial Unit for Phase I - IIa drug trials (CCRC-L3); a Metabolic Translational Research Facility (TRF; CCRC-L4 and CCRC-L6) for complex overnight metabolic studies and an overnight Adult Clinical Research Facility (CCRC-L5). The CCRC receives funding from the

NIHR and the Wellcome Trust (CCRC Levels 4 and 6) to meet operational running costs to support experimental medicine (physiological studies and early phase clinical trials in drugs and medical devices).

The CCRC is led by two Directors and a Director of Operations, and is staffed by Trust employees and University research staff with Trust honorary contracts.

Patients and volunteers take part in research studies according to scientifically robust and ethically approved protocols.

The facilities are independent from the Trust inpatient bed pool. Capital funding provided to build and equip the facilities prohibits the use of the facilities for standard NHS activity.

5 Functional relationships

- The Trust and the University of Cambridge work closely together at all levels
- Clinical, financial and administrative management lies within the R&D directorate of the Trust
- Academic accountability for the research activity undertaken within the facilities lies jointly with the University of Cambridge and the Trust
- A full range of clinical services (e.g. pharmacy; laboratory; intensive care; resuscitation team) are provided by the Trust. Non-clinical support services (hotel services; estates; communications) are provided by the Trust, University of Cambridge and GSK service providers.
- The estates management of the ACCI building lies with GlaxoSmithKline (GSK) who retain responsibility and accountability for fire safety
- The estates management of the CCRC lies with the Trust and University of Cambridge and is defined within a service level agreement for hard and soft facilities management services. It is agreed that in the event of an emergency, the Trust will attend the CCRC to complete repairs and then ongoing work will revert to the University of Cambridge.
- Responsibility and accountability for fire safety lies jointly with the University of Cambridge and CUH, with an emergency fire response provided by the Trust.

6 Governance

- The CCRC reports to the Trust Research Board
- Facilities are run in accordance with Trust policies and procedures
- Complaints and whistleblowing are run in accordance with Trust policies and procedures (see appendix 2 for our local escalation process)
- Studies must comply with the UK Policy Framework for Health and Social Care Research
- Studies defined as Clinical Trials of Investigational Medicinal Products (CTIMPs) must comply with current clinical trial regulations
- The conduct of studies must also comply with local CCRC policies and standard operating procedures
- Studies are risk assessed as appropriate in accordance with Trust and CCRC procedures (Study Risk Assessment, Early Phase Risk Assessment)
- The CCRC maintains a robust quality management system in accordance with the ICH GCP guidelines and all applicable regulatory requirements

7 Management committee

- The operational management of the CCRC lies with the Management Committee, which is comprised of Directors and senior management from the CCRC and Institute of Metabolic Science (IMS)
- Patient Safety and Governance (PS&G) and research governance issues are reported on a quarterly basis, in accordance with Trust policy

8 Study approval process

- Research activity conducted in the CCRC requires prior approval from:
    - A Research Ethics Committee | Health Research Board
    - A competent authority, as appropriate
    - Trust R&D department
    - CCRC Scientific Advisory Board (SAB)
- The SAB meets monthly to review:
    - New studies
    - Study amendments
    - Study renewals
    - Serious Adverse Events
- SAB approval is given initially for a period of one year, followed by an annual review and approval process
- Industry-sponsored research may be carried out within the CCRC
- Direct costs associated with commercial studies will be recovered in accordance with Trust and national guidelines and agreed with the Director of Operations and the R&D Department prior to the SAB review
- Other costs associated with supporting studies may also apply e.g. use of specialist equipment; supply of specialist consumables; set up and renewal charges
- Studies are allocated to the facilities according to space and staff skill requirements and prior to SAB review. Allocations may be subject to change.
- A unique project identifier number is allocated to each new study

9 Roles and responsibilities

- The Principal Investigator (PI) is responsible for patient safety, the overall conduct of the study and for members of their research team
- The PI must ensure members of their research team have appropriate contracts with the Trust (research, honorary, substantive or letter of access)
- The PI must ensure research team members have appropriate training
- The PI must provide appropriate medical cover for their participants
- It is the responsibility of the PI and study team to inform the CCRC whether or not it is appropriate for participants in a study to be subject to Trust policies and procedure regarding ReSPECT, VTE and the sending of a discharge summary to the participant's GP. This will be reviewed as part of the study application and renewal processes.
- CCRC staff will not undertake completion of the ReSPECT documentation or VTE assessment and are not responsible for the production of a discharge summary for a participant's GP. Where required, this work must be undertaken by an appropriately qualified member of the study team.
- Guidelines for users (investigators) are available on the CCRC website (https://www.cambridgecrf.nihr.ac.uk/for-researchers)
- The CCRC provides inpatient, day case, outpatient and specialist metabolic services for patients and healthy volunteers, including children.
- The CCRC is not equipped to care for patients requiring respiratory ventilation or critical care support.
- Visiting hours are open. Liaison with the nursing team is, however, encouraged due to the variability of individual study requirements.

10 Facilities

10.1 Maternal and Child Health Clinical Research Facility (ACCI Level 5)

- Separate waiting areas for adults and young people

- Parent waiting room
- 8 inpatient beds comprising 5 single and 2 twin-bed rooms
- 5 consulting rooms
- 2 investigation rooms
- Paediatric phlebotomy suite
- Sample processing room
- Tissue Culture room with ducted Class 2 biosafety cabinet
- Electronmagnetically sealed room for electrophysiology measurement
- Specialist Paediatric Nurse outreach to support trial delivery in other CCRC units
- Operates 7 days per week, 24 hours per day

10.2 Clinical Investigation Ward (ACCI Level 3)

- 7 day-case beds
- 2 specialist investigation rooms:
    - Neurophysiology Testing Laboratory including equipment for pain stimulation and assessment
    - Clinical Vision Laboratory, equipped to facilitate clinical research in ocular and neurological disorders
- 2 consulting rooms
- Patient waiting room
- Sample processing room
- Cytotoxic drug preparation room
- Operates Monday to Friday, 8am to 6pm

10.3 Interventional Investigation Unit (CCRC-L2)

- Evelyn Trust Research Endoscopy suite including:
    - Equipment for therapeutic procedures including endoscopic mucosal resection, argon plasma coagulation, heat coagulation and radiofrequency ablation
    - bespoke multispectral endoscope and light source system
    - confocal microscope for real-time histological assessment
    - audiovisual link for videoconferencing of live procedures
    - theatre airflow compliance at 30 cycles per minute
- Theatre-standard procedure unit
- Automated endoscope reprocessor and drying room
- 2 single-sex recovery rooms, each containing 2 beds observable from the nurse base
- 2 patient changing rooms
- 2 consulting rooms
- Mobile air filtration units for aerosol-generating procedures
- Sample processing room
- Dedicated patient waiting room
- Operates Monday to Friday, 8am to 5pm

10.4 Early Phase Trials Unit (CCRC-L3)

- 6 high-dependency-unit specification beds in rooms with en-suite bathrooms
    - 3-bedded ward directly observable from nurse station
    - 2-bedded ward directly observable from nurse station
    - 1-bedded side room
- Cardiac telemetry
- 2 consulting rooms
- Resident medical officer on-call room
- Drug preparation room including biosafety cabinet

- Complex sample processing room
- Operates 7 days a week, 24 hours a day

10.5 Adult Clinical Research Facility (CCRC-L5)

- 6 inpatient single rooms
- 'Near-patient testing' facilities, with hatches to patient rooms
- Nurse-led lumbar puncture expertise for cerebral spinal fluid collection
- Remote cardiac telemetry
- Exercise testing room
- Sample processing room
- Clinical Trial Administration team
- CRF Outreach Team delivering experimental medicine research in the host NHS Trust inpatient population
- Operates 7 days per week, 24 hours per day

10.6 Metabolic Research Facilities (CCRC-L4 and L6; ACCI Level 5)

- 8 inpatient, bariatric beds with en-suite bathrooms
- 2 consulting rooms
- 1 procedure room
- Eating behaviour observation suite, including separate adult and child lounges and dining rooms
- Play room
- Diet kitchen for preparation and storage of ready meals of defined composition
- Sample processing room
- Operates 7 days a week, 24 hours per day
- A separate Metabolic Research Area containing facilities for measurements of body composition, with a specialist team led by a Research Physiologist
    - For energy expenditure assessments:
        - 2 calorimeter rooms for 24-hour gas exchange measurement
        - 4 portable indirect calorimeters
        - Exercising gas exchange system
        - Diet kitchen
    - Body composition assessments:
        - GE Lunar iDXA scanner
        - BodPod®
        - PeaPod®
    - Exercise testing suite:
        - Cycle ergometry
        - Treadmill
        - Sub and maximal testing
        - Physical activity monitoring

11 Allocation of studies

Studies are allocated to a specific unit. However, when necessary (and with the agreement of the study team), studies may be undertaken in any CCRC accommodation deemed appropriate, with the exception of paediatric studies which will generally be undertaken on the CRF or CCRC Levels 4 and L6.

11.1 Booking and cancellation of participants

- Booking for beds and rooms is via a central booking service
- Bookings should be confirmed (with patient name) at least two weeks prior to the date requested
- Unconfirmed bookings will be re-allocated to other study teams within 2 weeks of the date requested
- The email address for all bookings is cuh.ccrcroombook@nhs.net
- Where necessary, telephone bookings can be made via the following numbers:
- Clinical Admissions Nurse: 07821808900 or 01223 274779 (ext 274779)
- Clinical Admissions Administrator on 01223 274779 (ext 274779)

12 Personnel

- **See CCRC/INF003 CCRC Organisational Chart**
- Expert nurses provide total nursing care for patients & volunteers
- Nursing staff are able to undertake a wide range of invasive and non-invasive monitoring and therapeutic interventions following study specific, local and hospital procedures
- Bank nurses are accountable to the Team Leaders and Matrons

12.1 Medical responsibility for patients and volunteers

- Responsibility for medical cover lies with the Principal Investigator (PI) or named deputy for each study
- Agreed cover and contact numbers must be provided for all patients and volunteers. In the absence of the PI or deputy or in an emergency the specialty on-call registrar will be called. If there is no speciality registrar available, the on-call general medical SpR will be called (see appendix 1)
- All patients/volunteers admitted onto the CCRC overnight will be assessed by a designated member of the research study team. This will be clearly documented in their electronic patient record
- Clinical advice is available to CCRC staff from the CCRC Directors

12.2 Clinical Bleep holder and On–Call responsibilities

- 24/7 support is available to staff via the following routes:

    - The **Clinical Bleep Holder** rota
        - Provides first-line support and takes responsibility for active studies, staffing, equipment and facilities
        - Mon-Fri 08:00 – 16:00
        - Contactable via Bleep 156-2097

    - The **Senior Nurse On Call** rota
        - Acts as the route of escalation for the Clinical Bleep Holder during core hours- Contactable via Bleep 156- 2362
        - Provides out-of-hours cover for the Bleep Holder role, Mon-Thurs 16:00-08:00 and Fri 16:00 – Mon 08:00
        - Contactable via:
            - Mobile: 07885 971912
            - email: cuh.ccrconcall@nhs.net

    - A **CCRC On-Call Manager**

- available 24/7 to provide support to, and the route of escalation for, the Senior Nurse On Call
- Contactable via the Senior Nurse On Call (07885 971912)

13 Patient and volunteers

- Study participants (patients and healthy volunteers) will be regarded as patients under the clinical care of CUH, and will undergo appropriate clinical assessment by the PI or suitable research team member prior to study participation
- All participants must give their informed consent prior to taking part in the studies
- Participants of all ages take part in studies conducted on the CCRC

13.1 Paediatric arrangements

- All clinical research involving children and young people is reviewed at the CCRC Scientific Advisory Board (SAB). At the SAB, study placement is considered including appropriate oversight of medical, nursing and trial conduct
- The primary location for research involving children and young people is the Maternal and Child Health Clinical Research Facility (CRF)
- Children and young people taking part in metabolic research studies may be located on the Wellcome Metabolic Translational Research Facility when it is appropriate to do so
- Paediatric studies are overseen by a qualified CCRC paediatric nurse or an adult nurse with paediatric experience contactable via the Maternal and Child Health Clinical Research Facility (CRF) between the hours of 8-4pm, Monday- Friday. Paediatric trained staff provide advice/support for clinical, research governance and safeguarding issues
- Additional support/advice is available via established links with the 007 bleep holder for CUH paediatric services
- Oversight of paediatric studies outside the hours of 8am – 4pm, Monday-Friday is the responsibility of the study team
- All staff are DBS (Disclosure and Barring Service) checked prior to employment and receive child protection updates and paediatric basic life support training
- High-risk areas have restricted access via key pad locks
- Children must be accompanied by a parent or guardian at admission and discharge, and supervised by a parent or guardian during their stay
- In the event that both children and adult participants are present on the Maternal and Child Health Clinical Research Facility (CRF) simultaneously (excluding parent/guardian), CRF staff will segregate both groups to comply with child safety recommendations
    - Adult participants will be seen in the outpatient area and will use the main reception waiting area
    - Children and young people will be taken straight to their allocated room

14 Data management

- Research source data collected within the CCRC will be the responsibility of the PI
- Source data collected by CCRC staff will be handed over to the research team at the end of the participant's visit
- We provide data management for studies on an individual request and with approval of Directors

14.1 Local information systems

- Within the CCRC there is access to both NHS and University IT systems
- Both systems are incrementally backed up daily and full back ups are performed weekly with off-site back up

- WiFi is available

14.2 Stand-alone databases

- **iDXA –** scan source data is given to the research team and the data are backed up daily to the University group drive
- **BodPod –** source data is given to the research team and transcribed into the log book. Data is also backed up to floppy disc
- **CRFManager™ –** used for booking participant visits and backed up in line with the University IT policy

15 Emergency services

15.1 CCRC CUH emergency cover:

- Cardiac Arrest teams (Adult | Paediatric & Obstetric)
- Fire Response team
- Security team
- Rapid Response Team

15.2 Emergency access

- Emergency access for the Trust cardiac arrest team, including support staff, is via a dedicated emergency access corridor linking Trust L3 ATC corridor with CCRC Level 3 and lifts to other floors.

15.3 Resuscitation equipment

- **CRF**– one paediatric resuscitation trolley by nurses' station and one adult resuscitation box and adult/paediatric AED in the adult outpatient area
- **CIW** – one adult resuscitation trolley with Philips Health Care Heartstart XL+ by nurses' station
- **CCRC Level 2** - one adult resuscitation trolley with Philips Health Care Heartstart XL+ by nurses' station
- **CCRC Level 3** - one adult resuscitation trolley with Philips Health Care Heartstart XL+ by nurses' station
- **CCRC Level 4** - one adult resuscitation trolley with Philips Health Care Heartstart XL+ and one paediatric resuscitation trolley by nurses' station
- **CCRC Level 5** - one adult resuscitation trolley with Philips Health Care Heartstart XL+ and one paediatric resuscitation box by nurses' station
- **CCRC Level 6** - one combined adult and paediatric resuscitation box and AED by workstation in south corridor – in alcove in front of Room 06-022
- Portable suction is available in all clinical areas
- Each bed space is equipped with piped O_2 and suction

15.4 Emergency Telephone numbers

- CUH Fire Response/Security — Ext 3333
- CUH Cardiac Arrest/Resuscitation team — Ext 2222
- CUH Estates and Facilities helpdesk — Ext 216696
- University Maintenance Unit help desk — 01223 337784
    - (Mon-Fri 08:00-17:00) or, out of hours: University Security Control Centre — 01223 331818
- CUH IT helpdesk — Ext 216757
- CUH Switchboard — Ext 100

• Emergency Ambulance	9999
• CCRC On-Call Bleep Holder	Bleep 156-2097
• CCRC Senior Nurse On Call	07885 971912
• CCRC On-Call Manager	see Senior Nurse on call rota

16 Security

16.1 Maternal and Child Health Clinical Research Facility (CRF) and Clinical Investigation Ward (CIW) (ACCI building)

- CCTV cameras operate at the entrances to the Maternal and Child Health Clinical Research Facility (CRF) and Clinical Investigation Ward (CIW)
- An immediate response service is provided by the porters/security staff
- For any security emergencies, contact extension 3333
- Panic systems are located at the reception and at nurses' stations within the Maternal and Child Health Clinical Research Facility (CRF) and Clinical Investigation Ward (CIW) to alert other staff of any potential danger
- Emergency door release buttons are located at the nurses' station in CRF and CIW

16.2 CCRC Levels 1-6 (CCRC building)

- CCTV cameras operate at all entrances to CCRC facilities on levels 1 and 2
- An immediate response service is provided by Trust porters/security staff
- For any security emergencies contact extension 3333
- Panic systems are located at the reception, within clinical and administrative areas
- Emergency door release buttons are located at each nurses station
- Video entry systems are located in the lift lobbies, and at the front door for out of hours access

16.3 Access

- Access to all CCRC facilities is governed by the Trust lone working policy
- Access is arranged through the CCRC Administration Team and Trust Access Centre
- Access to the CCRC is controlled by staff ID swipe card
- CCRC staff have authorised access to all facilities
- Investigators and their research teams have access granted for limited times, depending on their study requirements
- Patient and visitor access is via call bell, at the main entrance of all units
- Trust Porters, Trust contracted cleaners, Shift Technicians, Cardiac Arrest teams and Fire Response teams have appropriate access
- GSK maintenance and security staff have 24/7 access to the Maternal and Child Health Clinical Research Facility (CRF) and Clinical Investigation Ward (CIW) service risers in ACCI building
- VRU staff, patients and visitors access VRU through the Clinical Investigation Ward (CIW)

16.4 Keys and digital locks

- Keys are managed according to Trust security policy (MERLIN Document ID 7907; Record ID 21165) and local standard operating procedures
- Trust security staff, GSK security staff and carpenters hold a master key for emergency access to ACCI (Maternal and Child Health Clinical Research Facility (CRF) and Clinical Investigation Ward (CIW))

- Trust security staff hold master keys for emergency access to CCRC (all levels), except the Level 3 glass doors (keys to which are held locally, with additional ward keys accessible via the Senior Nurse on call).
- Digital keypad locks are used throughout the units
- Lock codes are changed in accordance with CCRC standard operating procedures

16.5 Closure of CCRC units

- If the units are closed:
    - All rooms must be checked and doors must be locked
    - Drug cupboard keys and the master key must be locked in the coded key cabinet located at each nursing station
    - The code to the key cabinets is known to the nurse in charge and is available via the Senior Nurse on call outside of opening hours.

17 Health and Safety Governance and Risk Management

- The CCRC complies with Trust Health and Safety policies and procedures
- The CCRC has a designated Risk Lead and Risk Officers
- Governance and risk issues, including complaints, incidents and research-related events are reported and managed via the CCRC Patient Safety and Governance (PS&G) meetings, held quarterly
- Workplace health and safety inspections are undertaken and studies and work processes will be appropriately risk assessed, with any outcomes shared via the CCRC Patient Safety and Governance (PS&G) meetings, held quarterly
- Incidents are reported via the Trust Quality and Safety Information System (QSiS) and via the processes described in **CCRC/SOP105 Reporting and Management of Research-Related Events**
- The CCRC Risk Lead participates in the ACCI Health and Safety Committee meetings via GSK

17.1 All staff

- CCRC staff and visiting staff are required to comply with Trust policies and procedures
- Staff responsibilities for health and safety are:
    - To report incidents and near misses using the Trust Quality and Safety Information System (QSiS) and **CCRC/SOP105 Reporting and Management of Research-Related Events**
    - To undertake immediate action to manage any incidents and identifying actions needed to minimise the chances of recurrence
    - To take action to deal with simple health and safety hazards which are within their scope of responsibility e.g. mopping up spillages to prevent slips, trips and falls
    - To take reasonable care of their own safety and the safety of others
    - Not to interfere with or misuse any items or equipment provided in the interests of health and safety
    - To comply with Trust policies and procedures
    - To be familiar with the Trust's risk management policies and departmental risk issues
    - To be aware of emergency procedures relevant to their area of work
    - To escalate any unresolved health and safety issues to their risk officer

17.2 First aid

- The appointed person for first aid is the Shift Coordinator.

- Any member of staff suffering an injury that requires specialist attention must go to the Emergency Department
- The first aid box is located in:
    - Maternal and Child Health Clinical Research Facility (CRF): clean utility room and diet kitchen
    - Clinical Investigation Ward (CIW): treatment room (drug cupboard)
    - CCRC building: Sample handling rooms & kitchens
- Eye wash kits are located in:
    - Maternal and Child Health Clinical Research Facility (CRF), Clinical Investigation Ward (CIW) and CCRC L2, 3, 4, 5, sample handling rooms
    - Tissue Culture Laboratory areas
    - CCRC-L3 drug preparation room
- For further information, refer to the Trust First Aid at Work procedure (MERLIN Document ID 2673; Record ID 18468)

17.3 Hazardous substances

- Hazards will vary and are dependent on studies undertaken within the unit
- Studies are risk assessed prior to opening on the unit in accordance with the Trust Risk Management Strategy and Policy (Document ID R18427D2700) and local risk assessment.
- Management of any hazard will be documented in the Study Flowsheet for the study and staff informed.
- Under normal conditions of use, most substances are non-hazardous.
- Others require control measures. These include but are not limited to:
    - Blood
    - Cytotoxic drugs
    - Endoscopy washing chemicals
    - Gene therapy drugs
    - Nitrogen gas
    - Dry ice
    - Ionising radiation
    - Liquid nitrogen
- The Control of Substances Hazardous to Health (COSHH) assessments for the CCRC are available in the Q-Pulse Quality Management System.
- Appropriate safety precautions are taken prior to handling any hazardous substance.

17.4 Drug storage

- All drugs must be ordered, stored and processed in line with Trust policy
- Spare keys for drug storage areas are retained by the CCRC Matrons and Director of Operations

18 Fire Safety

- All staff must be familiar with and comply with the Trust's Fire Safety Policy (MERLIN Document ID 344; Record ID 20842)

18.1 Break glass fire points

- **Maternal and Child Health Clinical Research Facility (CRF)**: ACCI level 5 break glass fire points are located at:
    - ACCI lift lobby entrances to ward
    - Reception/ main entrance
    - Staff room/ GSK entrance

- Patient kitchen corridor

- **Clinical Invesgation Ward (CIW)**: ACCI level 3 break glass fire points are located at:
  - ACCI lobby entrance to ward
  - Corridor to right of reception desk
  - Corridor to right of specimen handling room

- **CCRC building** break glass fire points are located at**:**
  - Main entrances to building; every lift lobby and Level 7 at top of West staircase
  - CCRC L1: Lift lobby, at each side of the double grey fire doors
  - CCRC L2: Main entrances to building; lift lobby; entrances to floors; at each side of grey fire doors
  - CCRC L3: Lift lobby; entrances to floors; at each side of grey fire doors
  - CCRC L4: Lift lobby; entrances to floors; at each side of grey fire doors
  - CCRC L5: Lift lobby; entrances to floors; at each side of grey fire doors
  - CCRC L6: Lift lobby; entrances to floors; at each side of grey fire doors

18.2 Fire equipment

- The **Maternal and Child Health Clinical Research Facility (CRF)**: ACCI level 5 has the following fire equipment available:
  - CO_2 + foam extinguishers; opposite meeting room; opposite sluice; opposite nurse's station; specimen handling room corridor and at both ACCI level 5 lift lobbies
  - Fire blankets are situated in patient kitchen and diet kitchen.
  - Straps are held in the CRF level 5 lift lobby areas for use under mattresses
  - Access to fire hydrant risers in both ACCI level 5 lift lobbies
- The **Clinical Investigation Ward (CIW)**: ACCI level 3 as the following fire equipment available
  - CO_2 extinguisher main entrance reception
  - CO_2 + foam extinguishers entrance to Vascular Research Unit
  - CO_2 + foam extinguishers and access to fire hydrant riser in the level 3 ACCI lobby
  - Straps are held in the level 3 ACCI lobby for use under mattresses
- **CCRC L1** has the following fire equipment available**:**
  - CO_2 + foam extinguishers in recessed cupboards in lift lobby
  - CO_2 + foam extinguishers located in plant room
  - CO_2 + foam extinguishers at bottom of West staircase
- **CCRC L2** has the following fire equipment available**:** CO_2 + foam extinguishers located in recessed cupboards in lift lobby; at nurse station; in corridors
- **CCRC L3** has the following fire equipment available**:** CO_2 + foam extinguishers located in recessed cupboards in lift lobby; at nurse station; in corridors
- **CCRC L4** has the following fire equipment available**:** CO_2 + foam extinguishers located in recessed cupboards in lift lobby; at nurse station; in corridors
- **CCRC L5** has the following fire equipment available**:** CO_2 + foam extinguishers located in recessed cupboards in lift lobby; at nurse station; in corridors
- **CCRC L6** has the following fire equipment available**:** CO_2 + foam extinguishers located in recessed cupboards in lift lobby; at nurse station; in corridors
- **CCRC L7** has the following fire equipment available**:** CO_2 + foam extinguishers located in rooftop plant rooms

18.3 Fire alarms

- The alarm system in the ACCI and CCRC buildings are a two stage system:

- **Intermittent alarm:**
  Alerts people to a potential fire in their immediate area. This alarm sounds either when a fire detector operates or when a manual call point is operated.
- **Continuous sounding alarm:**
  Fire alarm staff should prepare to evacuate to the next fire resistant box with the assistance of the Trust Fire Response Team (FRT) In the unlikely event of a continuous alarm sounding with no previous intermittent fire alarm, where the Fire response team are not present, the nurse in charge should search the area for signs of fire and if none are found they should phone 3333 to request attendance of the Trust FRT

18.4 Evacuation

- Evacuation, if required, is to the adjacent fire resistant box. This includes lateral transfer between ACCI and CCRC at level 5 if indicated.
- The nurse in charge of the unit must take the following documents kept at the nurse's station to cross check staff and patients:
  - Daily patient list and off duty rota
- Further evacuation, if required, should be discussed with the Trust FRT if there is no immediate threat from fire.

18.5 Fire escapes

- Fire escapes must be kept clear at all times and are located as follows:
  - **Child and Maternal Health Clinical Research Facility (CRF):** via main ward entrance to ACCI and service lift lobbies in Level 5
  - **Clinical Investigation Ward (CIW):** via main ward entrance to ACCI level 3 lobby
  - **CCRC building:** via the East or West staircase to Level 2 for all floors except Level 1, which uses the West staircase to Level 2 or the Level 1 exit to the Trust corridor
- The nearest assembly points are located as follows:
  - **Child and Maternal Health Clinical Research Facility (CRF):** Via stairs to level 3, then as for CIW or ia ACCI level 5 GSK stairs to level 2 Rosie Hospital / ATC corridor
  - **Clinical Investigation Ward (CIW):** Level 3 Main Theatres Corridor
  - **CCRC:** Via exits to outside on Level 2, proceeding to the large covered reception area within the ATC

19 Monitoring compliance with and the effectiveness of this policy

a. Process for Monitoring Compliance and Effectiveness

Review of incident forms as recorded on the Risk Management Information System for non-compliance. The results are presented to the CCRC Risk Group and Management Governance Committee.
The effectiveness of the process is monitored as part of regular audit.

b. Standards/ Key Performance Indicators

This process forms part of a quality management system.
Documents are reviewed every three years.

20 Equality and diversity statement

This document is designed to comply with the Trust's **Equality, diversity and inclusion in employment** policy (Record ID 18288; Document ID 2645).

21 Disclaimer

It is **your** responsibility to check against Q-Pulse that this printed out copy is the most recent issue of this document.

22 Document management

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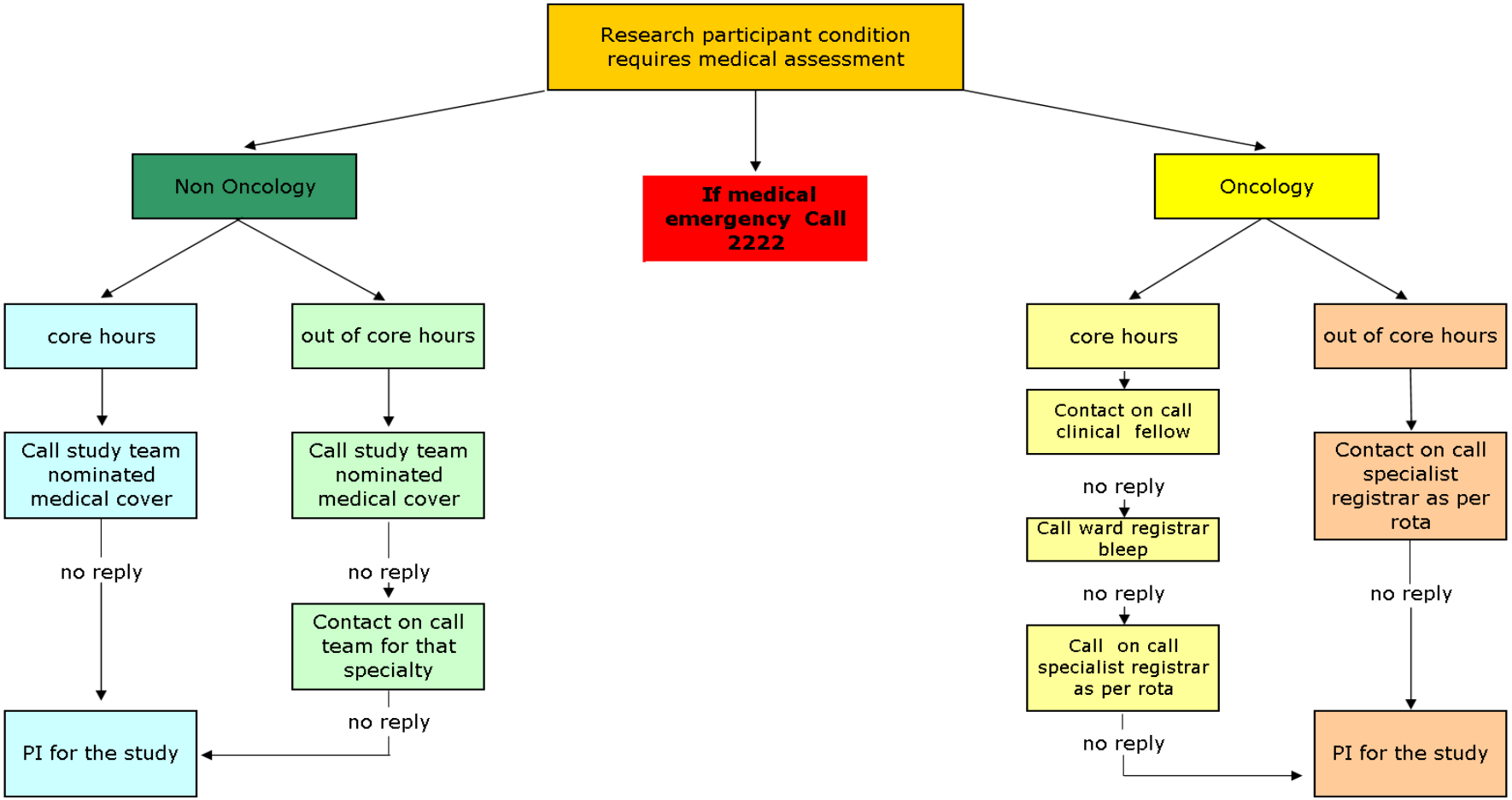
File name:	CCRC_POL003 Operational Policy
Supersedes:	Version 13
Version number:	14
Local reference:	CCRC/POL003 version 14

Appendix 1 – CCRC process for ascertaining medical cover and obtaining medical support



Appendix 2 – Complaints escalation process