'this research was supported by NIHR/WT Cambridge Clinical Research Facility'

Further guidance is available from Nurse Managers.

Sharing outputs and impact of your research

We welcome updates on study progress, including outcomes, new funding, awards and information on the impact of the research findings on care/standards. Please liaise with your Study Link Coordinator to feed back any updates.

Food and Drink

A supply of beverages and snacks is available for study participants. Hot meals and sandwiches can be provided if required.

If required by the study protocol, specially prepared food can be arranged with our dietician and this should be agreed and arranged in advance via the Study Coordinator.

Researchers are welcome to use staff room facilities.

On call cover

We provide:

On-site Senior Nurse Bleep cover Mon-Fri 8-4pm
Out-of-hours Senior Nurse On-Call cover 24/7
On-call Manager support 24/7

Housekeeping

Please tidy up after yourself. Please inform a member of the CCRC staff if areas need re-stocking.

Costs

Charges for the use of facilities are applied for some types of research and use of specialist equipment. This will be made known to you at the time of application. For commercial work, the UKCRN costing template is used.

Other Issues

We welcome your feedback on any aspect of our service. Please contact any member of staff.

Key contact numbers

Head Nurse	**Tel: 01223 254818**
Senior Nurse on call	**Tel: 07885 971912**
CRF Nurse Manager	**Tel: 01223 596058**
CIW Nurse Manager	**Tel: 01223 274314**
CIW Reception	**Tel: 01223 586706**
CRF Reception	**Tel: 01223 596055**
CCRC Reception	**Tel: 01223 254800**
Director of Operations	**Tel: 01223 596057**

Study Applications
ccrc.applications@addenbrookes.nhs.uk

UNIVERSITY OF CAMBRIDGE

NHS
Cambridge University Hospitals
NHS Foundation Trust

NHS
National Institute for Health Research

Cambridge Clinical Research Centre

NIHR/WT Cambridge Clinical Research Facility
NIHR Clinical Investigation Ward
Interventional Procedures Unit
Early Phase Unit
Wellcome Trust Translational Research Facility
Clinical Research Facility

User Guidelines

Facilities

Cambridge Clinical Research Centre (CCRC) provides a comprehensive range of state-of-the-art dedicated clinical research facilities on the Cambridge Biomedical Campus for the conduct of clinical research in patients and healthy volunteers.

CCRC facilities are located within the **ACCI Building** and the **Cambridge Clinical Research Centre Building**. The ACCI building is located off the main CUH/ATC corridor and includes two CCRC units. The **NIHR/Wellcome Trust Cambridge Clinical Research Facility (CRF)** is located on level 5 and includes a **Paediatric Area** for day case/inpatient research involving children and young people; a separate **Adult Outpatient Area** and a specialist **Metabolic Research Area** with unique energy balance and body composition measurement technologies (whole-body calorimeter rooms, iDXA, gas exchange measurement, diet kitchen, universal eating monitors; exercise test room and access to metabolic magnetic resonance spectroscopy, located in the Wolfson Brain Imaging Centre). The **Clinical Investigation Ward** (CIW) is located on level 3 and provides day case and outpatient rooms suitable for late phase clinical trials with in-house expertise in chemotherapy administration.

The **CCRC building** is located between the ACCI and ATC buildings and is connected to CUH at level 3 and the ACCI at level 5. Facilities include an **Interventional Procedures Unit** on level 2 for day case procedure based research such as endoscopy and cell therapy; an **Early Phase Trials Unit** on level 3 for day case early phase trials including First In Human; a **Wellcome Trust Metabolic Translational Research Facility** on levels 4 and 6 for complex inpatient experimental medicine studies aligned to the Wellcome Trust-MRC Institute of Metabolic Science (IMS), and an **Adult Clinical Research Facility** on level 5 for complex high intensity overnight experimental medicine trials in patients and healthy volunteers.

All areas are staffed by highly trained location-specific teams.

How we work

Access to CCRC facilities is granted after approval by our Scientific Advisory Board (SAB). Investigators are required to submit an application for each study they wish to undertake. Approval is for an initial period of one year, with annual renewal thereafter. Each study is allocated a unique project identifier to reflect its location (e.g. CRF254, CIW197, CCRC-L2-012). Following SAB approval, your first contact will be with one of our Nurse Managers, irrespective of the need for nursing input. Each study is allocated to a 'named nurse' who works as Study Link Coordinator. The Study Link Coordinator will:

- Organize a set-up meeting prior to starting
- Complete local documentation to ensure the trial protocol is accurately translated into practice
- Assess, plan, implement and evaluate programmes of care for patients in line with research protocols
- Develop and maintain a local study file and ensure that the trial is conducted in line with ICH Good Clinical Practice guidelines and the UK Policy Frame work for Health and Social Care Research
- Ensure care is patient-focused and in accordance with Trust policies
- Complete appropriate training and education to ensure studies are implemented safely and effectively

Studies can start when HRA approval is in place and when our local study set-up process is complete. A mutually agreed start date will be arranged.

Research Governance

Protocols and Amendments

All activity must comply with CUH and local CCRC policies. All projects must have written protocols to which the investigator must adhere. Changes to original documents submitted at application (e.g. protocol amendments) and/or study team changes must be provided as soon as changes are made.

Adverse Event / Serious Adverse Event / Serious Adverse Reaction reporting

If an Adverse Event (AE), Serious Adverse Event (SAE) or Serious Adverse Reaction (SAR) should occur whilst the participant is attending the unit, the researcher will need to complete appropriate CUH documentation.

Standard Operating Procedures (SOPs)

A compendium of local SOPs is available to researchers for use where appropriate. The nursing team will be pleased to help with the formulation of any new SOPs should this be required for your study.

Protocol deviations and violations

We reserve the right to suspend work on any project should staff become concerned about participant or staff safety or research governance e.g. violation or deviation from study protocols.

Visit Bookings

Bookings are made on a 'first come, first served' basis. Provisional bookings can be made at any time, but will only be treated as confirmed once the name of the participant has been provided. Confirmation should be provided at least two weeks prior to the date of admission. Confirmed bookings (i.e. with a named participant) will take precedence over provisional bookings, other than in exceptional circumstances.

To book a room:

For CRF and CCRC Levels 4 and 5 email:
crfl4l5@addenbrookes.nhs.uk

For CIW and CCRC Levels 2 and 3 email:
ciwl2l3@addenbrookes.nhs.uk

Or phone the bookings coordinators on:
01223 596251 (internal ext: 596251) or
01223 596078 (internal ext: 596078)

Electronic Patient Record - EPIC

Assessment/completion of EPIC documentation regarding Venous Thromboembolism (VTE), Universal Form of Treatment Options (UFTO) and Discharge Summaries is the responsibility of the Investigator to complete for their participant.

Medical Cover

We do not provide medical cover for research participants. It is the responsibility of the study team to provide medical cover appropriate to the type of study being undertaken. This may be specified by the SAB as a condition of approval. The clinician must be aware of the details of the study, including procedures to be performed and likely anticipated clinical problems. The PI or named designate must confirm clinical cover for each booking. The name of the covering clinician and their bleep/pager/extension number must be provided to nursing staff.

Where a physical medical presence in the unit has been specified, this must be in place prior to the commencement of study interventions. If agreed medical cover is not in place, research interventions will be suspended until satisfactory cover is present.

Contracts, induction and training

We provide a brief mandatory local induction for all researchers, nurses and students prior to starting. Before working in sample handling rooms they must also undertake a separate induction. It is the responsibility of the PI to ensure that all study team staff have either substantive or Honorary Research Contracts or Letter of Access with the Trust prior to undertaking clinical research activity.

All members of the study team should also ensure they are compliant with CUH mandatory training, any relevant clinical equipment training, and be up to date with GCP training. If you are unsure of what training you need, please discuss this with the study coordinator.

Health and safety

All researchers are required to comply with CUH and local policies and procedures. If you are unsure what training you need, please discuss this with the study coordinator.

Physical Security

All researchers must wear a Trust identification badge. Researchers may not access or use any facilities unless CCRC staff are present.

IT Security

Hot Desk spaces are provided with access to University and NHS networks. PCs in clinical areas are only connected to the Trust network. University and NHS WiFi is also available.

Data protection

Data storage and sharing of personal identifiable information must comply with Trust policy. For emails, this means that:

- Email sent within the Trust must be sent to and from an addenbrookes.nhs.uk email address
- Email sent to other NHS organisations should be sent to and from an nhs.net email address
- Email sent to non-NHS external organisations must be either anonymised or sent as an encrypted attachment

We have two safe haven fax numbers. Researchers should ensure they are familiar with the Trust Data Protection policy and comply with this at all times.

Resuscitation

Adult and Paediatric Resuscitation Trolleys are located in the clinical areas. Resuscitation equipment is checked according to Trust policy. A CUH Resuscitation Team will attend in the event of a cardiac arrest. The cardiac arrest team can be called on Ext 2222. Our clinical staff undertake annual emergency simulation training and Trust Resuscitation training.

Equipment and storage

We have a wide range of specialist equipment available to researchers. Researchers wishing to bring in specialist study-specific equipment must discuss their requirements with the study link coordinator or Nurse Manager to ensure compliance with Trust safety standards prior to the start of the study. We have very limited storage capacity. It may not be possible for you to keep your equipment or paperwork on the unit. If we are able to store your equipment, it must be clearly labelled (department of origin, study number and contact name and number). Researchers are responsible for running costs, electrical testing, maintenance and servicing of their own equipment. Evidence will be requested for regulatory compliance purposes. Medical electrical equipment used in close proximity to participants must have passed the relevant tests currently undertaken by CUH Clinical Engineering Department, and evidence of this must be provided.

Equipment Failures

All CCRC equipment failures or maintenance problems should be reported immediately to CCRC staff. The equipment affected should be removed from use.

Infection Control

Researchers must adhere to CUH Infection Control policies and use personal protective equipment (PPE) provided where appropriate.

Sample Handling Rooms

Compliance with relevant procedures in sample handling rooms is mandatory. Induction and equipment training is mandatory prior to use. Please ensure that you are aware of and adhere to these policies when using the sample handling rooms. Use of PPE is mandatory in sample handling rooms (white laboratory coats, gloves and goggles). Food or drink Is prohibited at all times.

Researchers are responsible for ensuring that they clean up any equipment/spillages after using the facility. We have limited freezer capacity (-20ºC, -40ºC and -80ºC). Please discuss your short-term storage requirements at the study set–up meeting. Samples should be removed by research teams as soon as possible (preferably within a week). An online 24 hour freezer alarm call-out system is in place.

NIHR acknowledgment in Publications

The operating costs of our facilities are funded by the National Institute for Health Research (NIHR). The NIHR requires you to acknowledge the NIHR in all publications / abstracts / posters / press releases / media coverage arising from work undertaken in our facilities, as follows:

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