GUIDELINES FOR USERS OF THE SOUTHAMPTON NIHR CLINICAL RESEARCH FACILITY (CRF)

Welcome to the CRF

Providing the environment for delivering your translational research studies

The CRF is a multi-user facility for supporting clinical research involving adults, children, healthy participants and patients. It is jointly managed by University Hospital Southampton NHS Foundation Trust (UHS) and the University Of Southampton Faculty Of Medicine. The CRF is committed to supporting research that improves the nation's health and well-being.

The CRF provides a safe and efficient working environment that respects the rights, safety and well-being of research participants and investigators, whilst ensuring that regulatory standards are met. The following guidelines have been developed to assist your use of the facility and to ensure that the optimum conditions for participants and professional colleagues are constantly maintained.

THE CRF

We have excellent participant hospitality provision, extensive outpatient, inpatient and paediatric clinical areas and full sample processing facilities with flexible laboratory support for studies.

Our specialist facilities include an environmental laboratory, a bronchoscopy suite, an air-conditioned physiology laboratory, a dedicated dual energy x-ray scanner (DXA/DEXA), Micro CT scanner, a Seca medical body composition analyser (Seca mBCA) and a range of specialist ophthalmology and respiratory equipment.

Our core opening hours are 8am to 5pm, Monday to Friday, with weekend and overnight opening for studies as required.

REGISTERING A STUDY

In order to use the CRF you will need to register your study with us. This helps us ensure that we can provide appropriate support, effectively plan and monitor the use of resources, and identify any future needs. Please note that although registration can start at any time, studies can only start in the CRF following UHS R&D confirmation.

The CRF will receive a notification from the R&D department when a study wishes to use CRF space, laboratory support or nursing support. The CRF registration process will then begin. You may be contacted if there are any queries.

Phase I studies: Phase I studies which are to be conducted in the CRF must be formally approved by the Early Phase Safety Committee (EPSC) before taking place. The PI for a Phase I study must submit a completed EPSC Risk Assessment form (and Dose Escalation Procedure form, if applicable), and this will be reviewed by the EPSC. Written approval from the EPSC must be obtained prior to registering the study.

STUDY SET UP

Following registration of a study, one of the nursing or laboratory teams will organise an initial meeting with you. This study set up meeting is essential whether or not the study requires nursing input, to confirm the resources required. Each study is allocated to a named nurse, or to the laboratory manager, whose aim is to facilitate the research and be a point of contact.

The Experimental Cancer Medicine Centre (ECMC), CRUK team and other research teams from UHS and UoS (eg: Rheumatology, Critical Care) are facilitated by their independent nursing and medical teams. Link teams are allocated from within the unit to provide

nursing support and a point of contact where needed and extra vigilance when high risk study visits are conducted.

RESEARCH GOVERNANCE

All activity in the CRF must comply with ICH GCP, UK Policy Framework for Health and Social Care (2017) and the requirements specified in the Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments [MfHU(CT)], the Medical Device regulations, Human Tissue Act and all UHS policies.

Protocols, Amendments / Changes to Protocols: Studies must strictly adhere to current written protocols. Please provide written evidence of HRA, REC, MHRA (if appropriate) approvals and UHS R&D confirmation of any substantial protocol amendments as they arise.

Research Personnel: Chief Investigators (CIs) and Principal Investigators (PIs) remain responsible for their study personnel and students while working in the CRF.

As a safety requirement any member of a clinical study team who has not worked in the CRF before will require a local induction which is arranged via the nurse allocated to your study.

Before working in the CRF laboratories all personnel must also have a laboratory induction with the CRF laboratory manager.

Medical Cover: If required (according to the registration risk assessment) medical cover must be pre-arranged. It is the PI's responsibility to ensure that the clinician who has been delegated to cover is available when necessary, and for the required period of time.

All investigators are asked to assess the element of risk associated with their studies in terms of clinical cover. With a number of concurrent risks the highest one determines the overall allocation to one of the risk categories indicated below. At times we may require further clarification and the final classification rests with the CRF:

a) Low risk:	Medical cover / PI available via phone, clinical cover in keeping with the responsibilities of a trained, registered nurse, eg blood sampling, punch skin biopsy, measurement of body composition, cannulation
b) Medium risk:	Clinical cover above and beyond that expected of a registered nurse, but which can be provided by a doctor within the hospital, who is available by bleep, eg skin prick challenge, airway challenge, food challenge, oral glucose tolerance test, drug infusions, apheresis
c) High risk:	The level of intervention required by this study requires a physician to be present constantly in the same room, until the risk diminishes to level a) or b) above, eg bronchoscopy, liver biopsy, hyperinsulinemic euglycemic clamp, exercise ECG in 'at risk' patients

The contact number provided must be a direct number. The CRF cannot commit to providing medical cover for your study. For all CTIMP studies please ensure that there is a 24hr emergency contact available

Students: The CRF welcomes and supports nursing students, medical students working on their projects and PhD students. Prior to working in the CRF, medical and PhD students will need to attend a mandatory induction session, receive a lab induction (if lab work is required) and supply the CRF with evidence of GCP training.

For safety reasons, we do not permit students to work unsupervised in the CRF out of hours.

TOPS: To comply with MHRA recommendations on validating a participant's identity and preventing over-volunteering, the CRF uses a photographic ID check and TOPS (The Over-Volunteering Prevention System).

Participants require a photographic ID check (passport, driver's licence) and TOPS registration for the following categories of research:

- Phase I studies, using healthy volunteers or 'patient volunteers' (not Phase I studies where the subjects are patients, eg- cancer patients)
- Studies where participants receive significant incentive over and above incidental expenses.

GP Medical History Confirmation: In compliance with MHRA recommendations, the CRF requires confirmation of the health status of healthy volunteers or 'patient volunteers' participating in Phase I studies. Please contact the Senior Quality Assurance (QA) lead for further information.

Adverse Events and Serious Adverse Events: All adverse events must be reported according to UHS policy and the requirements set out in the study protocol.

Incidents in the CRF: All incidents and breaches of GCP must be reported according to the UHS incident reporting policy.

Standard Operating Procedures (SOPs): The CRF has a number of SOPs which relate to activities that are conducted in the facility. General SOP listings define which SOPs may be relevant to various staff groups, including CRF users (visiting research teams).

SOPs are accessed via Q-Pulse, a web-based document management system. Access to Q-Pulse can be arranged via the Senior QA Lead.

Please note: Due to our MHRA Phase 1 accreditation all Phase I studies conducted within the facility must adhere to the CRF's Phase I SOPs, and sponsor SOPs for Phase I studies must be reviewed to ensure that they do not conflict with these.

HOW TO USE THE CRF

Room Bookings: Rooms and facilities are booked via the 'CRF Manager' system. Room bookings will be discussed with you at the study set up meeting. Please note that room bookings cannot be accepted prior to a study being registered with us.

Medical Records for Participants: UHS is currently migrating to electronic patient medical record system known as EDMS, with an aim to have the whole UHS using this by 2019. Your nurse will discuss the requirements for your documents to be scanned to EDMS as well as access.

Our CRF admin team will be pleased to order medical notes if available, and help to register the participant to UHS system if necessary.

SAFETY IN THE CRF

The safety of our patients, visitors and staff is paramount. All users must observe UHS health and safety policies.

Physical Security: In order to safeguard security, especially as there are children on the unit, we ask all visitors, participants and parents attending the CRF to sign in and out at reception. All staff must wear their staff identification badge above the waist when in the CRF so that it is easily seen.

IT Security: For data protection reasons, computers in clinical areas are connected to the UHS network only. Access to the UHS network can be obtained from IM&T. No additional software should be loaded onto CRF computers without the agreement of the Operations Manager.

The University of Southampton network is accessible from a selection of CRF computers. Portable devices can use "UHSFTguest" network to access the internet.

Fire Safety: UHS policy should be followed with regards to fire safety. CRF induction will include a local fire tour with one of our UHS Fire Wardens.

Resuscitation: We have three resuscitation trolleys that are maintained according to UHS policy. No items should be removed from the trolleys except in the case of an emergency.

Emergency and patient call bells are situated throughout the CRF. Please familiarise yourself with these before commencing work in the facility.

The CRF is covered by the UHS Resuscitation Team. In an emergency, DIAL 2222, give your location (NIHR Clinical Research Facility, C Level, West Wing, room number), and state whether a paediatric or adult emergency.

If you have concerns regarding deterioration in the physical condition of a participant, please alert a senior member of the CRF nursing team or nurse-in-charge. A photograph of both the adult and children's nurse are displayed near to the reception desk.

First Aid: First Aid boxes are located in the reception and laboratory areas. All research staff who receives first aid treatment or experience near misses should complete a UHS Incident Form.

Overnight Studies: It is a requirement that at least two people are on duty whenever a patient or study participant is present in the CRF. This applies to any overnight studies taking place in the CRF or studies undertaken at the weekend and where the participants arrive or leave outside normal opening times.

Study Drugs: UHS policy requires that drug keys remain locked in a key safe and that the code is changed monthly. Controlled drug keys remain with the nurse in charge or a delegated nurse during CRF opening hours.

To maintain security and accountability, all drugs are stored in a minimum number of clearly defined locations. Stored items must be clearly labelled and must be logged in and out of storage areas according to our procedures.

All our drug storage areas are temperature monitored using an automated alert system.

EQUIPMENT

We maintain a wide range of specialist equipment. Any researcher bringing their own equipment into the CRF must liaise with the Operations Manager to arrange this. We ask that investigators remove their equipment from the CRF in a timely fashion on the completion of the study.

Equipment Failures: All CRF equipment failures or maintenance problems must be reported immediately to both the CRF team attached to the study and the Operations Manager. If appropriate, a UHS Incident Form must be completed.

CONSUMABLES

Standard ward consumables in reasonable amounts are provided for use in research studies at no additional charge. Specialist items may be provided by or charged to investigators. Investigators are responsible for ensuring that study specific consumables are stored appropriately, are clearly labelled with study number and contact details, and that items are not present in the CRF beyond their expiry date. Further information is available from the CRF team allocated to your study or the CRF/Operations Manager.

INFECTION PREVENTION AND CONTROL

The CRF, in line with other clinical areas within UHS, follows the Trust Infection Prevention and Control policies.

All waste material and dirty linen should be disposed of as per UHS policy.

LABORATORY AREAS

The CRF employs a dedicated Laboratory Manager and laboratory team to oversee work in the laboratories and to ensure compliance with specific Health and Safety policies that cover these.

- Researchers working in the laboratories should adhere to our procedures relating to good practice and wear necessary personal protective equipment.
- Arrangements for the order, delivery and funding of specialist laboratory consumables should be made by the study team unless prior agreement has been reached with the CRF Laboratory Manager. Basic items such as transfer pipettes and Eppendorf tubes are provided free of charge.
- Study specific requirements for processing, storing and shipping samples must be provided for the laboratory study file. Any amendments to protocols must be provided as soon as possible.
- Shipping of samples to other sites must be coordinated by the study team.
- Samples must be appropriately labelled and transferred to the lab following CRF procedures.

Fridges and freezers: Fridges and freezers within the CRF are temperature monitored, supported by an out-of-hours emergency procedure.

PAEDIATRICS

Environment: Research involving children must be conducted in the paediatric area or in an environment that is appropriate to their needs and separate from adults.

Security: All researchers in contact with children must have a DBS check.

Child Protection: All researchers in contact with children must be able to demonstrate completion of appropriate levels of child protection training as per UHS policy. Child protection concerns should be raised with one of the Children's Senior Research Sisters, the study PI and/or the CRF Director. UHS child protection policies are available on Staffnet.

Qualifications: All children's research nurses working with children in the CRF are required to have appropriately qualifications and experience. After prior agreement has been obtained, under certain circumstances adult trained nurses may work with children with support from our Children's Senior Research Sisters.

Supervision: Any child other than the participant is the responsibility of the parent/guardian concerned.

CRF FACILITIES

Food and Drink: Meals, drinks and snacks may be ordered for participants through our Ward Hostess who is usually available from 08.00am to 2.30pm, but arrangements can be made outside these hours. Please note that a charge for meals may be applicable.

You are most welcome to use our staff room to store food and drinks for personal consumption.

Storage: We have a small amount of storage space for additional equipment and items such as Investigator Site Files. If you want to bring large items of equipment or bulky consumables into the CRF please check first whether there will be suitable storage space.

On-Call Facilities: The CRF can provide a single-person on-call room for overnight studies. This facility should be booked in advance. You will be expected to make the bed up yourself and remove the bed linen the next morning.

Tidiness: The CRF is a multi-user facility so please keep the areas you are using clean and tidy. Please ensure all items are appropriately removed, returned or disposed of when you have finished. Please inform a member of the CRF staff if areas need re-stocking.

CRF OPERATIONAL MANAGEMENT

CRF Directors:

The CRF Directors ensure 24 hour, 365 day / year clinical and research governance management to the CRF for adult and paediatric research. The Directors report to the UHS Medical Director and UoS Faculty of Medicine Dean.

CRF Manager:

The CRF Manager is responsible for the day-to-day running of the facility including operations, facilities and information management. Responsibilities include departmental budget, physical resources, and line-management of non-clinical staff.

CRF Matrons:

The Matrons are professionally accountable to the Head of Nursing/AHP – Research and Development Manager and is responsible for ensuring compliance with policies, procedures and standards to ensure that the CRF is clinically fit for purpose for the conduct of research, providing a safe environment for research participants/patients and staff.

CRF Laboratory Manager:

The Laboratory Manager (LM) is professionally accountable to the Laboratory Operations Manager and is responsible for the CRF laboratories. The LM ensures that all laboratory support of clinical projects is carried out in compliance with the policies, procedures and standards of UHS and national regulatory bodies.

RESEARCH OUTPUTS

Authors submitting items for publication must acknowledge the organisations and funders involved in the research. This acknowledgement is critical to the success of the Southampton partnership by raising the profile of the institutions, improving their visibility through search engines and ensuring we remain an attractive investment for funding bodies and industry partners. Guidance on appropriate text and formats for affiliations and acknowledgements is available in the Joint Policy on Affiliations and Acknowledgements which is available on request.

Information regarding facility use, participant numbers and other study data is also essential for resource management and strategic development.

We welcome interaction with the media within the CRF. Filming, press interviews or other recording should be reported in advance to a member of the Senior Management Team. Consent forms for non-clinical photography or filming of participants, volunteers and staff are available from the UHS communications team.

ADDITIONAL INFORMATION

Additional information can be found on the NIHR CRF website, http://www.uhs.nhs.uk/Research/Research.aspx or by contacting a member of staff (023 8120 4989).

The mail point number for the CRF is MP218. This is used for post to all staff, deliveries, collections and clinical results, delivered to and collected from the CRF reception.

We hope you enjoy working with us. Please ask a member of staff if unsure of any processes or procedures. We are here to help.

The CRF reserves the right to suspend work immediately on any project conducted in the facility or by its staff elsewhere, should the staff become concerned about participant or staff safety. Studies may also be suspended if there are concerns about a protocol violation (or deviation) or other unprofessional or unsafe practices.