

Wellcome - HRB Clinical Research Facility at St James's Hospital

User Guideline

The Wellcome - HRB Clinical Research Facility at St James's Hospital (CRF) is a multi-user facility for clinical research involving patients and healthy volunteers.

The facility is governed by Trinity College Dublin and St James's Hospital and funded by the Health Research Board (HRB) and Wellcome. The role of the CRF and its staff is to support clinical research conduct and to ensure that studies are undertaken to a high standard and that participant safety and wellbeing is protected.

We facilitate research studies in a safe and efficient working environment, ensuring that all studies comply with International Conference on Harmonisation - Good Clinical Practice (ICH GCP), hospital policies and applicable regulations.

The success of a research project in the CRF relies on collaborative planning and effective communication. This will enable the delivery of reliable research data to support high quality publications. This Guideline outlines our operational practice, and will help to facilitate the set-up of your research in the CRF.

Opening hours

Core opening hours are **Monday to Friday between 8am and 4pm**. Access to the CRF and its services outside of these hours needs to be discussed at time of application and will be considered on a case-by-case basis.

How the CRF Works

The CRF is located within St James's Hospital (SJH) on the 2nd floor of the H&H Building. It is a dedicated, state-of-the art research facility with direct access to hospital emergency services. The facility comprises 3 multi-purpose consultation rooms, a 6-bedded day ward, an exercise physiology suite, a neuropsychology room for EEG studies, isolation rooms, a pre-analytical sample processing lab and a Research Pharmacy.

The scope of services to be provided will be agreed as part of your application procedure (see below). Available services include: use of rooms and equipment, full or partial research nursing support, pharmacy support, use of laboratory, sample processing support, study management and regulatory support.

All studies in the CRF require a St. James's Hospital consultant to take responsibility for the study's conduct as Principal Investigator (PI).

Throughout the application procedure, your point of contact will be the Nurse Manager.

The role of the Nurse Manager is to:

- Ensure that all study paperwork is fully completed prior to study start.
- Facilitate appropriate training and education to ensure that studies are implemented safely and effectively.
- Provide orientation to the facility and its services as agreed for your study.
- Assist with the development and maintenance of a local study file.
- Facilitate conduct of study in adherence with Good Clinical Practice.

No study can commence in the CRF until all approvals are in place, required study documentation and induction training is complete and a formal Agreement Letter has been signed by the Principal Investigator.

Application Procedure

CRF Application Form Part I must be completed (download from <http://www.sjhcrf.ie>).

The PI submits CRF Application Form Part I to the Nurse Manager (reidyde@tcd.ie) along with:

- a) Protocol (*template available on request*)
- b) Ethics approval (or copy of application with submission date)

- c) Up to date, signed and dated research curriculum vitae (CV)
- d) Confirmation of GCP training (must be completed prior to study start)
- e) R&I application to St James's Hospital R&I
- f) HPRA approval or submission date (If applicable)
- g) Participant or any additional relevant information if available (e.g. Patient Information Leaflets, Informed Consent Forms, Investigator Brochure etc.).

- The Nurse Manager validates the submission and will request missing documentation.
- A pre-application meeting will be arranged by the Nurse Manager to address queries and scope of services.
- CRF Application Form Part II is completed jointly by the PI and Nurse Manager detailing scope of services required and a formal CRF application number is assigned.
(A separate application form will be required for use of pharmacy and laboratory services - contact Nurse Manager to arrange this).
- CRF Risk Assessment is completed by relevant CRF staff in collaboration with the PI to identify study risks relevant to the CRF.
- Application documents are presented to and reviewed by the CRF Operational Management Team.
- Application approval OR request for additional information OR approval pending receipt of final documentation is issued.
- Scope of services and costings are agreed
- Final approvals (HPRA, ethics, hospital), supporting documents, GCP certificates, CVs are assembled, as applicable.
- CRF Agreement Letter issued and the study is ready to proceed.

Study Start

Once the study is up and running you will be assigned a study research nurse as a study liaison. CRF induction training will be scheduled for the PI and delegated team.

Research Governance in the CRF

All projects must have a detailed written protocol with which the investigator and their team must adhere. We require written evidence of research ethics, local hospital and (if applicable) HPRA

approval, including approvals for any substantial amendments.

Research ethics committee for St James's Hospital: Tallaght Hospital/ St James's Hospital Joint Research Ethic Committee. Application form, guidance and fees are available at: <http://www.tallaghthospital.ie/About-us/Research-Ethics-Committee.html> or on request from Claire Hartin at: claire.hartin@amnch.ie.

Local hospital approval: Contact the Research and Innovation Office in St James's Hospital. Information available on the St James's Hospital intranet or on request from Declan O'Hanlon at: dohanlon@stjames.ie.

All research conducted in the CRF is required to adhere to ICH GCP. The PI agrees to adhere to ICH GCP, local hospital policies and applicable regulatory requirements as part of their formal Agreement Letter with the CRF.

In accordance with ICH GCP, the PI assumes all responsibility for their study personnel, including co-investigators and students.

Medical Cover

The CRF does not provide study medical cover. This cover is the responsibility of the study team. Any clinician delegated to provide medical cover must be aware of the details of the study, any procedures to be performed and the nature of any anticipated clinical problems. The PI, or named designate, must ensure clinical cover on the study day for the required period of time. The name of the covering clinician and their bleep/pager/extension number must be provided to the CRF prior to signing the Agreement Letter.

Where the CRF risk assessment has determined that there is a requirement for medical presence on-site during a study visit, this will need to be in place prior to the applicable visit activities. If agreed medical cover is not in place, the study visit will be postponed until satisfactory cover is present.

The assigned study research nurse **must** be notified of any changes to the contact details for medical cover. This is in the interest of participant safety.

Emergency Services and Resuscitation Equipment

All CRF research nurses receive BLS and ALERT training and there will be a minimum of one research nurse on-site in the CRF during patient visits.

In the event of a medical emergency, the St James's Cardiac Arrest Team are on-call (extension 2222).

A Resuscitation Trolley is located in the CRF and checked daily.

Bookings

For bookings, contact CRF reception at: burdzana@tcd.ie or 01 410 3900.

Bookings are accepted on the basis of room availability. Provisional bookings can be made at any time, but will only be treated as confirmed once visit details have been provided (patient study id, hospital number and visit number).

All study participants are registered as St James's Hospital patients at the CRF reception.

The CRF reception must be notified of any cancellations as soon as possible.

Security Access

Access to the CRF is by swipe access. Swipe cards are issued to approved members of the study team once all approvals are in a place and local training is complete. Swipe cards must never be shared by team members. Swipe card/Identification card must be worn at all times when in the CRF.

Training and Induction

We provide a brief induction to the CRF, which all users of the CRF must undertake prior to working in the facility. Laboratory induction training is mandatory for all members of the study team who plan to use the CRF laboratory.

All members of the study team should ensure they have appropriate training for their tasks. Examples of training that may be required include: phlebotomy, basic life support, participant consent and use of equipment. Training should be arranged through your assigned research

nurse. If you are unsure of what training you need, please discuss this with your assigned research nurse.

GCP training (within the previous two years) is also mandatory for everyone working in the CRF. Your assigned research nurse can advise you on available training courses if needed.

It is the responsibility of the PI to ensure that training records are maintained and that all study team members have been included on a delegation log prior to undertaking any study tasks (*template forms are available on request from the CRF*).

Health, Safety and Infection Control

All activity in CRF must adhere to St James's Hospital policies and CRF Health and Safety policies. Researchers must use the protective equipment provided (e.g. plastic aprons, gloves and goggles) where appropriate. All incidents should be reported to the assigned research nurse and managed in accordance with the CRF Incident Reporting SOP.

If an adverse event/Serious Adverse Event or Serious Adverse reaction should occur while the participant is attending the CRF, this must be reported immediately to CRF nursing staff.

Equipment

The CRF provides and maintains a wide range of specialist equipment.

Researchers who need to bring their own medical/electrical equipment into the CRF for use in studies should request permission from the CRF Nurse Manager. Equipment that does not comply with safety standards cannot be accepted on-site.

There is limited storage capacity in the facility, so it is not always possible to provide storage. All equipment stored in the CRF must be:

- Allocated a secure storage location for defined period.
- Clearly labelled as non-CRF equipment, with study identifier and contact details for study team.
- Maintained, serviced and safety tested in accordance with its use (responsibility of the PI).

Equipment Failures

All CRF equipment failures or maintenance problems should be reported immediately to CRF nursing staff.

IT Security

Computers in clinical areas are connected to the St James's hospital network. No additional software should be uploaded onto any of the PCs without prior agreement of the CRF and applicable IT Department.

Researchers should ensure that they are familiar with local data protection policies and comply with these at all times. All data storage containing patient information must be encrypted.

Tidiness

The CRF is a multi-user facility, so please keep the areas you are using clean and tidy. Please inform a member of the CRF team if areas need re-stocking.

Site Files

The CRF does not provide storage space for researchers. Storage of site files and documentation are the responsibility of the study team.

Laboratory

Any blood samples taken as part of a research study that require processing in St James's pathology laboratory may incur a charge and require pre-approval by the SJH laboratory manager. The PI is responsible for securing this approval.

The CRF employs a Laboratory Coordinator to oversee research sample handling activities in the CRF laboratory.

Conditions for use of the CRF laboratory:

- No member of the study team is permitted to use the laboratory without induction training and prior permission from the CRF.
- Researchers must adhere to CRF policies and procedures when working in the laboratory.
- Researchers working in the laboratories should wear appropriate personal protective equipment as instructed.

- The laboratory has limited freezer capacity for short-term sample storage (-20°C and -80°C). Sample storage space should be agreed at time of application and a sample log maintained.
- Freezers are continuously temperature monitored. Deviations outside of the acceptable temperature range will be notified to users who complete the sample log.

Publications

The CRF should be appropriately acknowledged in publications/abstracts/posters arising out of work undertaken in the CRF. The following wording is suggested:

"We would like to acknowledge the assistance and support of the Wellcome – HRB Clinical Research Facility at St James' Hospital in providing a dedicated environment for the conduct of high quality clinical research activities"

This will contribute to the performance metrics, which form part of our reports to the HRB and other funders. We encourage researchers to provide the CRF staff with updates of their study progress.

Other Issues

The CRF reserves the right to suspend work on any project conducted in the facility should staff become concerned about participant or staff safety. Studies may be delayed if there are concerns about study conduct and/or other unprofessional or unsafe practices.

Feedback

We welcome your feedback on the CRF service. Please pass on your comments or suggestions to any of the facility staff.

Key contacts

Assistant Director of Nursing	(01) 410 3919
Clinical Nurse Manager II	(01) 410 3902
Reception	(01) 410 3900
General Enquiries:	crfsjh@tcd.ie
Application Submission:	reidyde@tcd.ie
CRF Bookings:	burdzana@tcd.ie
Website:	http://www.sjhcrf.ie/