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

Facilities

Consulting and examination rooms

Research Pharmacy

Clean Room/Compounding Facility

Exercise Physiology Suite

Six bedded Day Ward

Sample Processing Laboratory

Four isolation rooms

Bioengineering Workshop

Neuropsychology Suite

Services

Regulatory affairs advice and support

IMP Management

Statistical advice and support

Aseptic preparation of novel therapeutics

Protocol development

Data management

ICH GCP training

Support with ethics applications

www.sjhcrf.ie

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

Facilities and Services to support Clinical Research

A Hospital and TCD Partnership

St. James's Hospital and Trinity College Dublin (TCD), with support from the Wellcome Trust and Health Research Board (HRB) operate a state-of-the-art Clinical Research Facility (CRF) within St. James's Hospital. The 1,300m^2 purpose built facility is located adjacent to the Centre for Advanced Medical Imaging (CAMI), the Institute of Cardiovascular Sciences and once complete, the Mercer's Institute for Successful Aging (MISA). The CRF is jointly governed by St. James's Hospital and TCD and will function like other clinical units within the hospital. Because the CRF is jointly governed by TCD and the hospital, research nurses and other health professionals working in the CRF will work within clinical governance structures agreed by both institutions. In due course the CRF will become an important feature of Trinity Health Ireland and governance arrangements for the CRF will evolve to reflect this.

The CRF is staffed to conduct high quality clinical research. The CRF team includes a Nurse Manager, a Research Pharmacist and a Quality and Regulatory Affairs Manager who will provide resources and assistance to investigators undertaking research.

A large flexible space devoted to clinical research

Key features of the facility include:

- Multipurpose rooms that can be adapted to a range of clinical studies involving patients and healthy volunteers
- Consultation and examination rooms for assessing and interviewing participants
- Four inpatient isolation rooms – 2 negative pressure and 2 positive pressure
- A six bedded day-ward/infusion room
- A neuropsychology suite that will facilitate high quality EEG and cognition studies
- A dedicated Pharmacy Dispensary and Clean Room Compounding Facility for the management of Investigational Medicinal Products (IMPs) and aseptic preparation of novel therapeutics
- An on-site sample processing laboratory for rapid sample receipt, preparation and short term storage

A range of clinical research studies will be facilitated

The facility is available to a wide range of researchers to conduct the following types of research studies:

- Experimental Medicine studies
- Early to late phase clinical trials of medicinal products and medical devices
- Investigator-led clinical research studies
- Nursing research studies
- Studies by Allied Health Professionals including bioengineering, clinical nutrition, psychology, pharmacy and physiotherapy
- Studies involving healthy volunteers

Highly trained research nurses

Research nurses are at the core of the clinical research facility. A lead research nurse is attached to each study and works closely with investigators and CRF specialists to develop:

- A study protocol that comprehensively describes the study
- A study budget that identifies the time, effort and types of resources required to deliver a study
- An application to the Hospital Research Ethics Committee (REC) where needed
- Study specific procedures that help to ensure the quality and consistency of clinical research activity.

The lead research nurse can assist with all aspects of a project from participant recruitment, to conducting protocol required assessments, managing participant samples and completing study documentation. All research nurses are compliant with ICH GCP and hold other relevant courses and qualifications. In addition many have achieved the Certificate Course in Research Nursing.

A research pharmacy service to facilitate clinical trials

Pharmacy services are essential to the safe conduct of clinical trials involving IMP. The CRF at St. James's Hospital hosts a state-of-the-art clean room facility for compounding novel therapeutics. This supports IMP trials conducted both within the CRF in addition to clinical trials taking place elsewhere in the hospital. Key services provided by the research pharmacy include:

- Aseptic preparation of IMP in the dedicated clean room facility
- Preparation of prescription templates, training aids and other documents
- Protocol development assistance
- Temperature controlled storage of IMP and associated trial products
- IMP receipt, accountability and stock management
- Dedicated Pharmacists and Dispensary for dispensing IMPs to clinical trial participants attending the CRF
- Management of IMP returns, including monitoring for compliance
- Destruction of IMP, as required.

Sample processing to the highest quality standards

The CRF includes a sample processing laboratory for the initial processing and storage of samples taken from participants involved in research studies. Basic sample processing will be provided within the CRF, but more complex laboratory analysis will take place at other facilities including:

- Histopathology, Blood Biochemistry and Microbiology at the Sir Patrick Dunne Laboratory
- Genomics and Genotyping at the Institute of Molecular Medicine (IMM)
- Immunoassays and virology at the IMM and the Trinity Biosciences Institute
- Proteomics and Metabolomics analysis at the IMM.

The CRF will work closely with associated laboratories to ensure the safe and timely transfer of samples from the CRF Laboratory.

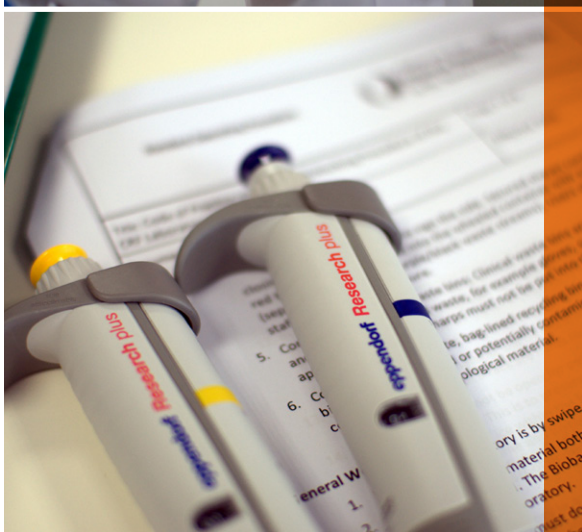
Quality and Regulatory Affairs

The Quality and Regulatory Affairs Manager ensures that research undertaken within the CRF is conducted to the highest standards. Compliance with national and international legislation and guidelines will be achieved through the implementation of quality management systems within the CRF.

The Quality and Regulatory Affairs Manager is available to assist investigators with their clinical research studies by:

- Assisting with protocol, essential document and study specific procedure development
- Coordinating Research Ethics and Regulatory (Irish Medicines Board) submissions
- Providing ICH GCP and other regulatory training for study staff
- Conducting audits of ongoing studies to ensure compliance.

The Quality and Regulatory Affairs Manager is available to provide advice about the set-up, conduct and reporting of clinical research studies. Through the Quality and Regulatory Affairs Manager the CRF will contribute to the ongoing development of a quality improvement and patient safety framework for clinical research on the St. James's Hospital campus.



Come and talk to us about your study

The CRF is open to facilitating a wide range of clinical research conducted by healthcare professionals.
A straightforward process for investigators is in place.

Step 1—Contact the CRF Nurse Manager at +353 1 410 3919 or reidyde@tcd.ie for an initial discussion of needs

Step 2—Complete the CRF's Standard Application Form

CRF Staff will help you complete a short form that allows investigators to briefly describe their proposed study. A copy of the form is available for download from the website at www.sjhcrf.ie or by calling the CRF reception at 01 410 3900 or by email to reidyde@tcd.ie.

Step 3—Applications are reviewed

Applications are reviewed by the CRF's Operational management Team, within a 10 day period in most cases. This results in approval, rejection, or requests for further information from the applicant.

Step 4—Conduct of Study

Following its approval the study is initiated and conducted. It is continually reviewed by the Operational Management Team to ensure it is achieving the study objectives.

CRF Contact Information

Those wishing to learn more about the CRF, or with questions on how to bring a study into the CRF are invited to contact one of the following:

Ms. Derval Reidy, Nurse Manager
01 410 3919 & reidyde@tcd.ie

Professor Michael Gill, Director
01 896 2241 & mgill@tcd.ie

Professor Colm Bergin, Associate Director
01 416 2507 & cbergin@stjames.ie

Supported by wellcome trust

HRB Health Research Board

ST. JAMES'S HOSPITAL

Find the Clinical Research Facility in 6 easy steps

Step 1
Enter hospital through revolving doors or by lift from underground car park.

Step 2
Follow the Yellow Route –Route 3.

Step 3
Pass The Daffodil Cancer Centre.

Step 4
Turn left through red doors towards CAMI.

Step 5
Go to end of corridor through two sets of yellow doors.

Step 6
Take the lift to Level 2.