The Wellcome Trust/HRB Clinical Research Facility at St. James’ Hospital

Professor Michael Gill, Director
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Part of a Programme jointly funded by the Wellcome Trust and HRB

Components:

– Dublin Centre for Clinical Research (DCCCR) Network involving TCD, RCSI, UCD and Molecular Medicine Ireland (2009 - 2015) – funded by HRB

– Development of the Clinical Research Facility at St. James’s Hospital (2013). Building and equipment costs funded by the Wellcome Trust.

“It is our mission to improve health outcomes and quality of life by leading and enabling high quality, innovative translational clinical research”
The Design

CAMI 3T MRI
Neurophysiology Suite (EEG)
Exercise Physiology Lab
Six Bed Unit
Four Isolation Rooms
Clean Room Research Pharmacy

Wellcome Trust - HRB Clinical Research Facility at St. James’s Hospital
## Trinity Translational Medicine Pathway

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<th>TRANSLATION</th>
<th>CLINICAL RESEARCH</th>
<th>TRANSLATION &amp; ADOPTION</th>
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<td>Discovery and Translation to Humans</td>
<td>Discovery to Patients</td>
<td>Translation to Practice</td>
<td>Translation to Population Health</td>
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- **T1**: Discovery and Translation to Humans
  - TCIN, CRANN, TBSI
  - Trinity Translational Medicine Institute
- **T2**: Discovery to Patients
  - Wellcome Trust/HRB CRF at SJH
- **T3**: Translation to Practice
  - Institute of Population Health
- **T4**: Translation to Population Health
  - Center for Global Health

**Courtesy**: Professor Padraic Fallon
Governance

CRF Governance
• Joint Governance between Hospital and University
• CRF staff are appointed by TCD but all have SJH staff appointments and/or staff numbers

Clinical Governance
• CRF is on the SJH Hospital Corridor – all subjects attending are patients of SJH and have a SJH Medical Registration Number (MRN).
• All Principle Investigators are SJH consultants or joint SJH/TCD academic clinicians (professor/consultant)
• The CRF is a designated entity under the Clinical Indemnity Scheme (January 2015)
The Spectrum of Studies supported

- Investigator led Clinical Research/Experimental Medicine/Advanced therapeutics studies.
- Investigator initiated Clinical Research/Clinical Trials (IMP or medical device)
- Pilot studies/clinical research/experimental medicine to obtain data to support future grant application
- Clinical Research/Clinical Trials – Industry Sponsored
- Health Services research – testing of treatment protocols
- Nursing Research Studies
- Studies by Allied Health Professionals including Bioengineering, Nutrition, Psychology, Pharmacy and Physiotherapy
- Studies involving healthy volunteers.
First Patient to Attend the CRF
– October 2013

• Prof. Richard Reilly, Bioengineering
• Prof. Richard Costello, Respiratory Physician
• DCCR Network Study
• WT/HRB CRF

Sally Couper, CRF
CRF Activity during the first year of operation

- 56 applications
  - 4 applications rejected
  - 16 applications approved awaiting start
  - 10 studies active in CRF
  - 10 studies active outside CRF
  - 13 studies completed or closed

- 549 new subjects recruited
- 857 subject visits

- 26 Clinical Research, investigator led
- 8 Clinical Trials
  - 1 - medical device (investigator led)
  - 1 - Phase 1 (investigator led)
  - 2 - Phase 3 (commercial)
  - 4 - Phase 4 (commercial)
Operational

• Service Level agreement between SJH and TCD
• Multidisciplinary Quality Framework
• Clear application and assessment procedure for new studies
• Emergency cover as part of the hospital – emergency trolley maintained by hospital
• All CRF studies have a named SJH consultant as PI and a named house doctor available for non urgent events
• All CRF vital systems and equipment procured and maintained by the hospital
• All CRF staff and study personnel are GCP trained
Quality & Regulatory Affairs

• Quality Management System implemented
  – Policies, SOPs, Work Instructions, Study Procedures
• Training Matrix developed:
  – Outlines training requirements per job role for CRF staff
• Staff training records implemented
• Regulatory Tracker set up:
  – Tracks regulatory and ethics submissions to ensure compliance with regulatory requirements
• Training courses developed for internal & external staff
CRF operations - Application process.

- Brief application form and study protocol submitted
- CRF staff meet with PI to complete detailed information on the study and requested CRF resources
- Completed application reviewed by Operational Management team and application approved or additional information required.
- Study feasibility and risk assessment completed
- Study start-up only when all documentation and regulatory requirements are in place and all study staff trained.
The Role of the CRF

• To provide experienced research staff
  • Assistance with protocol development
  • Assistance with Regulatory and Ethical Submissions
  • Conduct day-to-day research activities

• To provide Quality Assurance
  • Conduct internal audits
  • Ensure study/facility is inspection ready
  • Provide training
  • Implementation of standard procedures

• To promote high quality research which is in compliance with applicable regulations
Development Plan, 2015

• Research and Development Hub – joint TCD/SJH initiative

• Access and support for other non medical clinical disciplines – nursing, physio, pharmacy

• Access and support for non clinical disciplines

• Participation in new HRB funded Irish Clinical Trials Research Network

• Clinical Trial Sponsorship by Trinity College
St. James’ Hospital - an Academic Medical Centre