

**Clinical trials and research studies reviewed / approved by the Mater Misericordiae University
Hospital and Mater Private Hospital Research Ethics Committee (REC) 2015**

Reference "1/478" in the following report are clinical trials that fall under the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (Statutory Instruments S. I. No. 190 of 2004)

- 1.378.1694 Study title: Mitochondrial function and mitochondrial DNA mutations in Glaucoma
Principal Investigator (PI): Prof Colm O'Brien
Study site: Mater Misericordiae University Hospital (MMUH) and Mater Private Hospital (MPH)
21/01/2015: Review by REC and request for clarifications
24/02/2015: Response from PI to request for clarifications
16/03/2015: Approval granted by REC to proceed at MMUH and MPH
- 1.378.1695 Study title: Ethicus II Study
PI: Dr Colman O'Loughlin
Study site: MMUH
21/01/2015: Review and approval granted by REC to proceed at MMUH
- 1.378.1689 Study title: An evaluation of health-related-quality-of-life (HRQoL) among hepatitis C patients receiving non-interferon based treatment
PI: Dr Stephen Stewart
Study site: MMUH
21/01/2015: Review and approval granted by REC to proceed at MMUH
- 1.378.1692 Study title: Implementation of the ISBAR communication tool to improve interdisciplinary communication in an acute care setting using an action research approach
PI: Mrs Tanya King
Study site: MMUH
21/01/2015: Review by REC and request for clarifications
09/03/2015: Response from PI to request for clarifications
09/03/2015: Approval granted by REC to proceed at MMUH
- 1.378.1696 Study title: Characterization of patients with Antibody-Mediated Encephalitis
PI: Dr Shane Smyth
Study site: MMUH and MPH
21/01/2015: Review by REC and request for clarifications
08/06/2015: Response from PI to request for clarifications
24/06/2015: Approval granted by REC to proceed at MMUH and MPH
- 1.378.1677 Study title: Identification of new targets for the treatment of Osteoarthritis
PI: Prof Geraldine McCarthy
Study site: MMUH
21/01/2015: Review by REC and request for clarifications
23/02/2015: Response from PI to request for clarifications
10/04/2015: Approval granted by REC to proceed at MMUH
- 1.378.1702 Study title: The BALANCED Anaesthesia Study – A prospective, randomised clinical trial of two levels of anaesthetic depth on patient outcome after major surgery
PI: Prof Donal Buggy
Study site: MMUH
21/01/2015: Review by REC and request for clarifications
08/04/2015: Response from PI to request for clarifications
15/04/2015: Approval granted by REC to proceed at MMUH
- 1.378.1703 TMR
Study title: A study on the indication, methods, outcome, quality of reporting of DAT (123I Ioflupane) scan done in an Irish Teaching Hospital in 2013
PI: Prof Tim Lynch
Study site: MMUH
04/02/2015: Review and approval granted by REC to proceed at MMUH
- 1.378.1707 TMR
Study title: Audit of the case mix and referral patterns of general practitioner graduates from the UCD diploma in dermatology
PI: Dr Fergal Moloney
Study site: MMUH
24/02/2015: Review and approval granted by REC to proceed at MMUH

- 1.478.65 Study title: Alendronate for Prevention of AntiRetroviral Therapy-associated bone loss (APART study)
 A multi-centre, prospective, randomised trial of short course alendronate therapy or placebo combined with vitamin D and calcium to prevent loss of bone mineral density in antiretroviral-naïve, HIV-1 infected subjects initiating antiretroviral therapy
 Protocol Code: APART_2014
 EudraCT Number: 2014-004819-37
 PI: Prof Geraldine McCarthy and Dr Patrick Mallon
 Study site: MMUH and Beaumont Hospital (BH)
 26/02/2015: Review by REC and request for additional information
 24/03/2015 and 16/04/2015: Response from PI to request for additional information
 16/04/2015: Favourable ethical opinion granted by REC to proceed at MMUH and BH
- 1.378.1690 Study title: Irish Programme for Stratified Prostate Cancer Therapy (iPROSPECT)
 Protocol Number: ICORG 14-04
 PI: Dr Michaela Higgins
 Study site: MMUH and MPH
 26/02/2015: Review by REC and request for additional information
 18/03/2015: Response from PI to request for additional information
 10/04/2015: Approval granted by REC to proceed at MMUH and MPH
- 1.378.1697 Study title: An examination of the counselling experiences of a sample of patients in Ireland before undergoing total laryngectomy surgery
 PI: Ms Heather Coetzee
 Study site: MMUH
 26/02/2015: Review by REC and request for additional information
 26/03/2015: Response from PI to request for additional information
 20/04/2015: Approval granted by REC to proceed at MMUH
- 1.378.1691 Study title: Irish Prostate Cancer Outcomes Research (IPCOR study)
 PI: Mr David Galvin
 Study site: MMUH and MPH
 26/02/2015: Review by REC and request for additional information
 11/03/2015: Response from PI to request for additional information
 17/04/2015: Approval granted by REC to proceed at MMUH and MPH
- 1.378.1705 Study title: Biomarkers in Diabetic Retinopathy; Analysis of aqueous and vitreous samples for investigating proteomics and epigenetic disease modifiers (miRNAs) in diabetic retinopathy
 PI: Mr Paul Connell
 Study site: MMUH
 26/02/2015: Review by REC and request for additional information
 16/04/2015: Response from PI to request for additional information
 07/05/2015: Approval granted by REC to proceed at MMUH
- 1.378.1698 Study title: Clinical findings and polysomnographic results of large cohort of patients developing narcolepsy after H1N1 vaccine: experience of a single Sleep Centre
 PI: Dr Catherine Crowe
 Study site: MPH
 26/02/2015: Review by REC and request for additional information
- 1.378.1693 Study title: Exploring Multidisciplinary Team Members' Understanding of and Role in the Assessment and Management of Delirium
 PI: Mrs Tanya King
 Study site: MMUH
 26/02/2015: Review by REC and request for additional information
 13/03/2015: Response from PI to request for additional information
 19/03/2015: Approval granted by REC to proceed at MMUH

- 1.378.1709 TMR
 Study title: Fluid Balance and Native Lung Function in Adult Patients on Veno-Venous Extracorporeal Life Support
 PI: Dr Edmund Carton
 Study site: MMUH
 06/03/2015: Review and approval granted by REC to proceed at MMUH
- 1.378.1706
 Study title: Prevalence and predictors of oral antibiotic treatment failure in adult emergency department patients with cellulitis; a pilot study
 PI: Dr Adrian Moughty
 Study site: MMUH
 26/03/2015: Review by REC and request for additional information
- 1.378.1712
 Study title: miRNA Expression as Marker of Coronary Artery Disease States
 PI: Dr Niall Mahon
 Study site: MMUH
 26/03/2015: Review by REC and request for additional information
 05/05/2015: Response from PI to request for additional information
 18/05/2015: Approval granted by REC to proceed at MMUH
- 1.378.1704
 Study title: ROX CONTROL HTN Registry:
 To Evaluate the ROX **COUPLER** in Patients with Resistant or Uncontrolled Hypertension
 Protocol Number: RH-03
 PI: Dr Joseph Galvin
 Study site: MMUH and MPH
 26/03/2015: Review by REC and request for additional information
- 1.378.1711
 Study title: Self-Management for Head and Neck Cancer Survivors: Living Well With and Beyond HNC (Phase 2 – National Survey)
 PI: Mr Tadhg O'Dwyer
 Study site: MMUH
 26/03/2015: Review by REC and request for additional information
- 1.478.66
 Study title: A Randomized, Open Label, Phase 4 Study Evaluating the Renal Effect of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir DF or other Tenofovir DF-containing Regimens (Ritonavir-boosted Atazanavir plus Emtricitabine/Tenofovir DF or Efavirenz /Emtricitabine/Tenofovir DF) compared to Ritonavir-boosted Atazanavir plus Abacavir/Lamivudine in Antiretroviral Treatment-naïve HIV-1 Infected Adults with eGFR ≥ 70 mL/min
 Protocol GS-US-236-0140
 EudraCT Number: 2014-002095-93
 PI: Dr Gerard Sheehan
 Study site: MMUH and St James' Hospital (SJH)
 26/03/2015: Review by REC and request for additional information
 20/04/2015: Response from PI to request for additional information
 22/04/2015: Favourable ethical opinion granted by REC to proceed at MMUH and SJH
- 1.378.1710
 Study title: Attitudes to Prescribing and Prescribing Education among practicing interns in Ireland
 PI: Prof Dermot Power
 Study site: MMUH
 26/03/2015: Review by REC and request for additional information
 29/04/2015: Response from PI to request for additional information
 21/05/2015: Approval granted by REC to proceed at MMUH
- 1.378.1716
 Study title: Evaluation of diagnostic and prognostic biomarkers in gynaecological tumours
 PI: Mr Tom Walsh
 Study site: MMUH
 22/04/2015: Review by REC and request for additional information
 05/05/2015: Response from PI to request for additional information
 06/05/2015: Approval granted by REC to proceed at MMUH

- 1.378.1708 Study title: Follow-up After Cancer Treatment (FACT): Part 5 – A national discrete choice experiment survey of patient preferences for cancer follow-up
 PI: Mr David Galvin
 Study site: MMUH and MPH
 22/04/2015: Review and approval granted by REC to proceed at MMUH and MPH
- 1.378.1699 Study title: Post market clinical follow-up study of IrisFIT™ PFO (Patent Foramen Ovale) Occluder
 PI: Dr Kevin Walsh
 Study site: MMUH
 22/04/2015: Review by REC and request for additional information
- 1.378.1713 Study title: The International Access, Right and Empowerment Plus Study (IARE+ Study)
 PI: Dr Karen Ryan
 Study site: MMUH
 22/04/2015: Review and approval granted by REC to proceed at MMUH
- 1.378.1700 Study title: The impact of changing patient and healthcare related factors on the cost of HIV care in Ireland
 PI: Dr Patrick Mallon
 Study site: MMUH
 22/04/2015: Review by REC and request for additional information
 29/04/2015: Response from PI to request for additional information
 29/04/2015: Approval granted by REC to proceed at MMUH
- 1.478.67 Study title: A Multi-arm, Phase 3, Randomized, Placebo Controlled, Double Blind Clinical Trial to Investigate the Efficacy and Safety of BMS-663068 in Heavily Treatment Experienced Subjects Infected with Multi-drug Resistant HIV-1
 Protocol Number: AI438047,
 EudraCT Number: 2014-002111-41
 PI: Dr Patrick Mallon
 Study site: MMUH
 22/04/2015: Review by REC and request for additional information
 26/05/2015 and 19/06/2015: Response from PI to request for additional information
 30/06/2015: Favourable ethical opinion granted by REC to proceed at MMUH
- 1.378.1715 Study title: Irish Rare Kidney Disease and Vasculitis Registry and Bioresource
 PI: Dr Yvonne O'Meara
 Study site: MMUH
 22/04/2015: Review by REC and request for additional information
 28/07/2015: Response from PI to request for additional information
 07/09/2015: Approval granted by REC to proceed at MMUH
- 1.378.1714 TMR
 Study title: The Creation of a Novel Irish Clinical Risk Prediction Model for the Diagnosis of Prostate Cancer
 PI: Mr David Galvin
 Study site: MMUH
 23/04/2015: Review and approval granted by REC to proceed at MMUH
- 1.378.1717 Study title: Improving Nursing Handover: An action research study
 PI: Mrs Tanya King
 Study site: MMUH
 27/05/2015: Review and approval granted by REC to proceed at MMUH
- 1.378.1718 Study title: Study of molecular and immune characteristics of Lynch syndrome associated cancers
 PI: Dr David Gallagher
 Study site: MMUH and MPH
 27/05/2015: Review by REC and request for additional information

- 1.378.1719 Study title: Diffusion Weighted Imaging (DWI) versus Two-dimensional (2D) Magnetic Resonance Imaging (MRI) of the Lumbar Spine at 3 Tesla (3T)
 PI: Dr Peter MacMahon
 Study site: MMUH
 27/05/2015: Review by REC and request for additional information
 08/06/2015: Response from PI to request for additional information
 22/06/2015: Approval granted by REC to proceed at MMUH
- 1.378.1722 Study title: HepCare
 PI: Dr Jack Lambert
 Study site: MMUH and General Practitioner Practices (GPP)
 27/05/2015: Review by REC and request for additional information
- 1.378.1724 Study title: Tomosynthesis of the scaphoid bone; a cadaveric study
 PI: Mr James Cashman
 Study site: MMUH
 27/05/2015: Review and approval granted by REC to proceed at MMUH
- 1.378.1720 Study title: PATHway (Physical Activity Towards Health): An exploration of stakeholder requirements for the design of an exercise programme
 PI: Ms Anne Gallagher
 Study site: MMUH
 27/05/2015: Review by REC and request for additional information
- 1.378.1721 Study title: PATHway (Physical Activity Towards Health): An exploration of patient requirements for the design of an exercise programme
 PI: Ms Anne Gallagher
 Study site: MMUH
 27/05/2015: Review by REC and request for additional information
- 1.378.1723 TMR
 Study title: A low KiloVoltage (KV) contrast bolus monitoring technique significantly reduces breast radiation dose exposure for CT Pulmonary Angiography
 PI: Dr Peter MacMahon
 Study site: MMUH
 08/06/2015: Review and approval granted by REC to proceed at MMUH
- 1.378.1726 TMR
 Study title: A Retrospective Cohort Study Protocol: To determine whether on-site analysis of serum voriconazole in MMUH patients optimises maintenance of target levels compared to off-site analysis
 PI: Prof Ciaran Meegan
 Study site: MMUH
 11/06/2015: Review and approval granted by REC to proceed at MMUH
- 1.378.1734 TMR
 Study title: An Audit of Dolutegravir in infectious diseases clinic of Mater Hospital
 PI: Dr Jack Lambert
 Study site: MMUH
 23/06/2015: Review and approval granted by REC to proceed at MMUH
- 1.478.68 Study title: A Phase 3b, Randomized, Double-Blind, Switch Study to Evaluate F/TAF in HIV-1 Infected Subjects who are Virologically Suppressed on Regimens containing ABC/3TC
 Short Title: 1717 – Phase 3b switch study with F/TAF in HIV-1 infected subjects
 Protocol Number: GS-US-311-1717
 EudraCT Number: 2015-000871-28
 PI: Dr Patrick Mallon
 Study site: MMUH and SJH
 25/06/2015: Review by REC and request for additional information

- 1.478.69 Study title: Ketamine for relapse prevention IN recurrent DepRessive Disorder: a randomised, controlled pilot trial with blood biomarker evaluation: The KINDRED Trial
Protocol Number: SPMHS Ref: 12/15
EudraCT Number: 2015-002020-37
PI: Prof Declan McLoughlin
Study site: St Patrick's University Hospital (SPUH)
25/06/2015: Review by REC and request for additional information
- 1.378.1725 Study title: Prospective Randomised Phase II Trial Evaluating Adjuvant Pelvic Radiotherapy using either Intensity Modulated Radiotherapy (IMRT) or 3-Dimensional Planning for Endometrial Cancer
Research Study: ICORG 09-06
PI: Dr Charles Gillham
Study site: MPH Limerick
25/06/2015: Review by REC and request for additional information
- 1.378.1726 Study title: The Dublin Neurological Institute Biobank – the search for molecular and genetic markers in neurological diseases
PI: Prof Tim Lynch
Study site: MMUH
25/06/2015: Review by REC and request for additional information
- 1.378.1731 Study title: A Systemic Understanding of Engaging Adolescents in Family Therapy
PI: Ms Deirdre Dooley
Study site: MMUH
25/06/2015: Review by REC and request for additional information
- 1.378.1732 Study title: An exploration of trainee Reflecting Team members' experience of working in an all-female reflecting team in family therapy training
PI: Ms Deirdre Dooley
Study site: MMUH
25/06/2015: Review by REC and request for additional information
- 1.378.1730 Study title: Development of salivary cortisol as a diagnostic assay using LC-MS/MS and generation of an adult reference range
PI: Dr Maria Fitzgibbon
Study site: MMUH
25/06/2015: Review and approval granted by REC to proceed at MMUH
- 1.378.1735 TMR
Study title: Differential Diagnostic of Whole Body PET/CT Bone Marrow
PI: Dr Martin O'Connell
Study site: MPH
08/07/2015: Review and approval granted by REC to proceed at MPH
- 1.378.1736 TMR
Study title: MOTH Project – Mater Oxxygen Therapy Project An audit of current oxygen therapy prescription & delivery at the Mater Misericordiae University Hospital
PI: Ms Dervilla Danaher
Study site: MMUH
16/07/2015: Review and approval granted by REC to proceed at MMUH
- 1.378.1727 Study title: The Spectrum of Critical Care Acute Valvulopathies
Principal Investigator (PI): Dr Frances Colreavy
Study site: Mater Misericordiae University Hospital (MMUH)
23/07/2015: Review and approval granted by REC to proceed at MMUH
- 1.378.1728 Study title: Randomised Control Study assessing the Role of Negative Pressure Wound Therapy (NPWT) in connection with antimicrobial dressing in the prophylaxis of wounds complication in high risk surgical patients undergoing surgery
PI: Mr Conor Shields
Study site: MMUH
23/07/2015: Review by REC and request for clarifications

- 1.478.70 Study title: Botulinum toxin A treatment of Raynaud's phenomenon
Research Proposal, KC/TAC:04-2015
EudraCT Number: 2015-001947-36
PI: Mr Kevin Cronin
Study site: MMUH
23/07/2015: Review by REC and request for clarifications
- 1.378.1738 Study title: A Prospective, Open, Comparative, Multi-Centre Photopatch Test Study of Patients Suspected of Photoallergy to Organic Sunscreens and Topical Non-steroidal Anti-inflammatory Drugs Used Within Europe
PI: Dr Nicola Ralph
Study site: MMUH
23/07/2015: Review by REC and request for clarifications
12/08/2015: Response from PI to request for clarifications
03/09/2015: Approval granted by REC to proceed at MMUH
- 1.378.1729 Study title: Functional Investigation of Genetic Cardiac conditions using Induced Stem cells
FIGCIS Ireland
PI: Dr Catherine McGorrian
Study site: MMUH
23/07/2015: Review by REC and request for clarifications
- 1.378.1737 Study title: Involuntary Psychiatric Admission: The Role of Gender
PI: Prof Brendan Kelly
Study site: MMUH
23/07/2015: Review by REC and request for clarifications
03/09/2015: Response from PI to request for clarifications
18/09/2015: Approval granted by REC to proceed at MMUH
- 1.378.1739 Study title: The relationship between performance on cognitive screening tests and functional abilities in individuals with Mild Cognitive Impairment
PI: Dr Joseph Duggan
Study site: MMUH
23/07/2015: Review by REC and request for clarifications
03/09/2015: Response from PI to request for clarifications
16/09/2015: Approval granted by REC to proceed at MMUH
- 1.378.1743 TMR
Study title: The implementation of a standardised nutrition assessment structure and a standardised nutrition diagnosis, using standardised terminology, in Irish dietetic documentation
PI: Ms Mary McKiernan
Study site: MMUH
03/09/2015: Review and approval granted by REC to proceed at MMUH
- 1.378.1744 TMR
Study title: A 10-year retrospective Audit of antibiotic susceptibility patterns in urinary isolates in the Mater Misericordiae University Hospital
PI: Dr Maureen Lynch
Study site: MMUH
03/09/2015: Review and approval granted by REC to proceed at MMUH
- 1.378.1745 TMR
Study title: Audit of Topical Photodynamic Therapy in the Treatment of Actinic Keratosis, Bowens Disease and Basal Cell Carcinoma in the Dermatology Department, Mater Misericordiae University Hospital
PI: Dr Fergal Moloney
Study site: MMUH
03/09/2015: Review and approval granted by REC to proceed at MMUH

1.378.1751 TMR

Study title: Retrospective analysis of patients with Type 1 Diabetes
PI: Dr Siobhan McQuaid
Study site: MMUH
03/09/2015: Review and approval granted by REC to proceed at MMUH

1.378.1742 TMR

Study title: An investigation of radiation dose associated with EVAR (endovascular aneurysm repair) procedures
PI: Mr Martin O'Donohoe
Study site: MMUH and MPH
04/09/2015: Review and approval granted by REC to proceed at MMUH and MPH

1.378.1748

Study title: A European Prospective Observational Study Assessing the Effectiveness and Outcomes Associated with Enzalutamide Treatment in Patients with Metastatic Castration Resistant ProState CancEr (mCRPC) – PREMISE
European Observational Study of Enzalutamide in Metastatic Castration Resistant Prostate Cancer
PI: Prof John McCaffrey
Study site: MMUH and Mater Private Hospital (MPH)
24/09/2015: Review by REC and request for additional information

1.378.1746

Study title: Breast density discrimination and the association with interval cancers
PI: Dr Fidelma Flanagan
Study site: MMUH
24/09/2015: Review by REC and request for additional information

1.378.1747

Study title: ECHO: Epidemiology of HPV Infection in Oral Cancer in Ireland
PI: Prof Conor O'Keane
Study site: MMUH
24/09/2015: Review by REC and request for additional information

1.378.1740

Study title: Does delay to admission through Emergency Department result in loss of physical function in over 65s?
PI: Prof Dermot Power
Study site: MMUH
24/09/2015: Review by REC and request for additional information

1.378.1752

Study title: Breast Surgery Recovery: The Clinical and Psychosocial Impact of the THEYA Recovery Range
PI: Mr Maurice Stokes
Study site: MMUH and MPH
24/09/2015: Review by REC and request for additional information

1.378.1750

Study title: Imbuing Medical Professionalism in relation to Safety (IMP –Safety)
PI: Prof Eilish McAuliffe
Study site: MMUH
24/09/2015: Review by REC and request for point of clarification

1.378.1741

Study title: How do Therapist and Family Members Create Therapeutic Relationships in Family Therapy?
PI: Ms Deirdre Dooley
Study site: MMUH
24/09/2015: Review by REC and request for additional information

1.378.1756 TMR

Study title: The Surgical and Interventional Workload of Adult Congenital Heart Disease in the National Cardiothoracic Unit, Ireland: a retrospective observational study 2009 - 2013
PI: Mr Lars Nolke
Study site: MMUH
09/10/2015: Review and approval granted by REC to proceed at MMUH

- 1.378.1749 Study title: Nutritional Status of Cancer Patients at Dietitian Referral
Principal Investigator (PI): Dr Lorraine Walsh
Study site: Mater Private Mid-Western Radiation Oncology Centre, University Hospital Limerick (MPMWROC)
21/10/2015: Review by REC and request for clarifications
12/11/2015: Response from PI to request for clarifications
30/11/2015: Approval granted by REC to proceed at MPMWROC
- 1.378.1760 Study title: Evasion of immune editing by circulating tumour cells is an exercise-modifiable mechanism underlying aggressive behaviour in obese men with prostate cancer – The ExPeCT Study
PI: Prof John McCaffrey
Study site: Mater Misericordiae University Hospital (MMUH) and Mater Private Hospital (MPH)
21/10/2015: Review by REC and request for clarifications
- 1.378.1753 Study title: Establishing Irish normative data for the Psychometric Hepatic Encephalopathy Score (PHES) test
PI: Dr Stephen Stewart
Study site: MMUH
21/10/2015: Review by REC and request for clarifications
- 1.378.1759 Study title: Blood Pressure Variability in the Presence of Continuous Flow Left Ventricular Assist Devices
PI: Prof Jim O'Neill
Study site: MMUH
21/10/2015: Review by REC and request for clarifications
- 1.378.1762 Study title: 3D Printing of Human Anatomy: Production of Anatomically Accurate Models for the Purpose of Surgical Planning and Education and Training
PI: Dr Tomas Breslin
Study site: MMUH
21/10/2015: Review by REC and request for clarifications
- 1.378.1757 Study title: PATHway (Physical Activity Towards Health): Focus group exploration of patient requirements for the design of an exercise programme
PI: Dr Anne Gallagher
Study site: MMUH
21/10/2015: Review by REC and request for clarifications
- 1.378.1758 Study title: The Efficacy of a 6 Week Exercise and Education Intervention for Fibromyalgia
PI: Dr Derville Danaher
Study site: MMUH
21/10/2015: Review by REC and request for clarifications
03/11/2015: Response from PI to request for clarifications
10/11/2015: Approval granted by REC to proceed at MMUH
- 1.378.1767 TMR
Study title: Retrospective analysis of Short Synacthen® Test Results
PI: Dr Siobhan McQuaid
Study site: MMUH
19/11/2015: Review and approval granted by REC to proceed at MMUH
- 1.378.1777 Study title: Randomised Phase II Study of Pre-operative 3-D Conformal Radiotherapy (3-DCRT) versus Intensity Modulated Radiotherapy (IMRT) for Locally Advanced Rectal Cancer TRI-LARC Study ICORG 12-38
PI: Prof John McCaffrey
Study site: Saint Luke's Radiation Oncology Network / St James's / Beaumont / St Luke's Hospital
26/11/2015: Reviewed by REC; this research study does not require our REC approval

- 1.378.1778 Study title: A Randomized Phase III Clinical Trial Evaluating Post-Mastectomy Chestwall and Regional Nodal XRT and Post-Lumpectomy Regional Nodal XRT in Patients with Positive Axillary Nodes Before Neoadjuvant Chemotherapy Who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy NSABP B-51 / RTOG 1304, ICORG 15-03
PI: Prof John McCaffrey
Study site: Saint Luke's Radiation Oncology Network / Galway University Hospital / Cork University Hospital 26/11/2015:
26/11/2015: Reviewed by REC; this research study does not require our REC approval
- 1.378.1755 Study title: Frailty in Heart Failure and Cardiovascular Disease
PI: Dr Niall Mahon
Study site: MMUH
26/11/2015: Review by REC and request for clarifications
- 1.378.1770 Study title: Non-interventional Study on Edoxaban Treatment in Routine Clinical Practice in Patients with Venous Thromboembolism in Europe
ETNA-VTE-Europe Protocol Number: DSE-EDO-05-14-EU
PI: Dr Brian McCullagh
Study site: MMUH
26/11/2015: Review by REC and request for clarifications
- 1.378.1768 Study title: Changes in the lung and gut microbiome of cystic fibrosis patients following lung transplant
PI: Dr Margaret Hannan
Study site: MMUH
26/11/2015: Review by REC and request for clarifications
- 1.378.1766 Study title: A prospective observational pilot study assessing the diagnostic accuracy of Intestinal Fatty Acid Binding Protein in critical care patients with suspected intestinal ischaemia iFABP Study
PI: Dr Brian Marsh
Study site: MMUH
26/11/2015: Review by REC and request for clarifications
- 1.478.71 Study title: The Bronchoscopic Electro Spray Delivery of Methylene Blue for the Enhanced Diagnosis of Lung Cancer
HPRA CT Number: CT 2048/1/1 – Methylthioninium Chloride
EudraCT Number: 2015-002823-25
PI: Prof Jim Egan
Clinical trial sites: MMUH and MPH
26/11/2015: Withdrawn by PI following meeting - no opinion issued by REC
- 1.378.1764 Study title: Does the use and purpose of circular questions in this research study live up to the purpose of circular questions as documented in the literature?
PI: Ms Deirdre Dooley
Study site: MMUH
26/11/2015: Review by REC and request for clarifications
- 1.378.1780 TMR
Study title: Retrospective audit of portable abdominal radiography
PI: Dr Peter MacMahon
Study site: MMUH
01/12/2015: Review and approval granted by REC to proceed at MMUH
- 1.378.1781 TMR
Study title: An Assessment of the Impact of Electronic Prescribing on the Quality and Safety of Parenteral Chemotherapy Prescriptions for Oncology/Haematology in the Mater Misericordiae University Hospital
PI: Prof Ciaran Meegan
Study site: MMUH
04/12/2015: Review and approval granted by REC to proceed at MMUH

- 1.378.1779 TMR
 Study title: Outcomes in Patients with Ankylosing Spondylitis following traumatic spinal injury
 PI: Mr Seamus Morris
 Study site: MMUH
 08/12/2015: Review and approval granted by REC to proceed at MMUH
- 1.378.1765
 Study title: An Observational Cohort Study of the Safety of Brentuximab Vedotin in the Treatment of Relapsed or Refractory CD30+ Hodgkin Lymphoma and Relapsed or Refractory Systemic Anaplastic Large Cell Lymphoma Post-Authorisation Safety Study (PASS) ARROVEN Study_MA25101 Millennium
 PI: Dr Anne Fortune
 Study site: MMUH
 16/12/2015: Review by REC and request for clarifications
- 1.478.72
 Study title: A Phase 3 Randomized, Placebo-Controlled, Blinded Study to Investigate the Safety and Efficacy of a Topical Gentamicin-Collagen Sponge in Combination with Systemic Antibiotic Therapy in Diabetic Patients with an Infected Foot Ulcer
 Protocol Number: INN-TOP-005
 EudraCt Number: 2015-000934-31
 HPRA CT Number: CT
 PI: Dr Mensud Hatunic
 Clinical trial sites: Keogh Practice, Waterford City, Mallow Primary Healthcare, County Cork and MMUH
 16/12/2015: Review by REC and request for clarifications
- 1.378.1761
 Study title: AMPLATZER™ Amulet™ Observational Post-Market Study
 PI: Dr Kevin Walsh
 Study site: MMUH and MPH
 16/12/2015: Review by REC and request for clarifications
- 1.378.1773
 Study title: Real World Evidence of the Effectiveness of ABT-450/r – Ombitasvir, ± Dasabuvir, ± Ribavirin in Patients with Chronic Hepatitis C - An Observational Study in Ireland
 PI: Dr Stephen Stewart
 Study site: MMUH
 16/12/2015: Review by REC and request for clarifications
- 1.378.1754
 Study title: Survey of older adults' room preference in an acute hospital setting: single versus shared accommodation
 PI: Dr Lorraine Kyne
 Study site: MMUH
 16/12/2015: Review by REC and request for clarifications
- 1.378.1774
 Study title: Non-interventional study on Edoxaban treatment in routine clinical practice for patients with non valvular atrial fibrillation ETNA-AF-Europe
 Protocol Number: DSE-EDO-04-14-EU
 PI: Prof Peter Kelly (Consultant Neurologist)
 Study site: MMUH
 16/12/2015: Review by REC and request for clarifications
- 1.378.1782
 Study title: The effects of introducing a 'Water Protocol' in dysphagia management for an acute geriatric population
 PI: Dr Joseph Duggan
 Study site: MMUH
 16/12/2015: Review by REC and request for clarifications
- 1.378.1783
 Study title: Mater Hospital Hip Fracture Rehabilitation with Serial Quantitative Timed Up and Go (QTUG) Assessments Study
 PI: Prof Dermot Power
 Study site: MMUH
 16/12/2015: Review by REC and request for clarifications