
ANNUAL REPORT

RESEARCH ETHICS COMMITTEE

SOUTH-EASTERN AREA

2012



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive
South Eastern Area

Revised May 2013

OVERVIEW

'Research ethics is a type of applied (or professional) ethics that addresses the questions, dilemmas, and issues related to the ethical conduct of scientific research.'¹

Health related research continued apace within the South East in 2012 with a diverse range of projects and participant groups being selected. The Research Ethics Committee remained committed to reviewing, advising and approving research within the South Eastern area. The standards of research studies and those presenting them remained consistently high with studies having great potential to shape the way health care is delivered well into the future. The number of studies reviewed in 2012 was on a par with previous years which is encouraging given the current economic climate Ireland is experiencing. (See Appendix)

As is customary there have been a number of changes within the Research Ethics Committee membership. (See Appendix) The Committee are appreciative of the invaluable input and commitment of those members who left the Committee and conversely welcome the new members with their unique experiences and perspectives in relation to research ethics.

Significantly Dr Paula Lane stepped down as Chairperson of the Research Ethics Committee and Dr Mark Doyle, Consultant in Emergency Medicine, took up this role. All members of the Research Ethics Committee and Mr Richie Doole , Area Manager for Waterford/Wexford, were united in thanking Dr Lane for her tenure as Chairperson and were greatly appreciative of the commitment, expertise and support she afforded to the Committee over the preceding five years.

The Research Ethics Coordinator remains active in expeditiously approving research studies as well continuing to play an active role in the supervision and support of research students studying for Master of Science and PhD studies (part funded by the HSE) at the Waterford Institute of Technology. The number of students currently studying on the programme stands at five and the research topics remain as varied as they are interesting. As a member of the Wexford General Hospital Ethics Advisory Committee the Coordinator has also had the opportunity to contribute to advising upon some ethically challenging cases, which are as thought provoking as they are rewarding.

The proposed Health Information and Human Tissues Bills are expected to go before the DAIL in 2013. Both of these Bills will have implications for research and Research Ethics Committees and members await their publication with interest.

In summary, the Research Ethics Committee is heartened that the ongoing economic and health service challenges do not seem to have had a disproportionate effect on health related research. Such research ensures that health service users will be assured of evidence based, up to date treatments and care well into the future. The Research Ethics Committee is proud to be a small part of enabling and supporting this positive change.

Dr Mark Doyle,
Chairperson
Research Ethics Committee, HSE, South-Eastern Area.

Ms Caroline Lamb
Acting Research Ethics Committee Coordinator,
Research Ethics Committee, HSE, South Eastern Area

¹ *David B. Resnik. The International Encyclopedia of Ethics. Published Online: 1 FEB 2013*

TABLE OF CONTENTS

	<u>PAGE:</u>
OVERVIEW	2
Section 1: Research Studies Presented to the Research Ethics Committee, HSE, South-Eastern Area 2012	5 -7
Section 2: Studies Granted Expedited Approval 2012	9 -14
Section 3: Site Specific Assessments 2012	16-17
Section 4: Membership of Research Ethics Committee, HSE, South-Eastern Area.	19-20
Section 5: Appendices	21
Appendix 1 Breakdown of REC workload, 2011-2012	22
Appendix 2 List of incoming members of the Research Ethics Committee, HSE, South-Eastern Area.	23
Appendix 3 List of outgoing members of the Research Ethics Committee, HSE, South-Eastern Area	24

SECTION ONE

RESEARCH STUDIES PRESENTED TO THE RESEARCH ETHICS COMMITTEE 2012

RESEARCH ETHICS COMMITTEE PRESENTATIONS 2012

JANUARY 2012

Study Title:

International ADHD in Substance Use Disorders Prevalence Study (IASP).

Dr Marie Claire Van Hout/Michelle Foley

Reviewed & Approved

Study Title:

Family Experiences of Home and Self Detoxification.

Dr Marie Claire Van Hout/Michelle Foley

Reviewed & Approved

FEBRUARY 2012

Study Title:

The effects of music on neonatal behavioural states.

Mary Grehan

Reviewed & Approved

Study Title:

LUMINOUS™: Study to observe the effectiveness and safety of ranibizumab through individualized patient treatment and associated outcomes.

Professor Stephen Beatty

Reviewed & Approved

MARCH 2012

Study Title:

The SuN Study: Supportive care Needs of head and neck cancer survivors post treatment.

Dr Linda Sharp

Reviewed & Approved

Study Title:

A quantitative study of nurses' use of physical restraints in residential care settings for the older people.

Ms. Deepa George

Reviewed & Approved

Study Title:

Health related Quality of Life and Body Image in IBD (Inflammatory Bowel Disease).

Professor Gary Courtney.

Reviewed & Conditionally Approved

APRIL 2012

Study Title:

The National History of Cystic Fibrosis Liver Disease.

Dr Marion Rowland

Reviewed & Approved

Study Title:

Correlation of Single Nucleotide Polymorphism (SNP) profile of domain 111 of EGFR to skin and/or eye toxicity and disease response to treatment with Cetuximab or Panitumumab – SNP and Cetuximab or Panitumumab response.

Dr Verena Murphy/ Dr Anne Horgan

Reviewed & Approved

Study Title

Breast Cancer Survivors – do we meet their needs?

Dr Paula Calvert

Reviewed & Approved

Study Title

Chemoradiotherapy and Rectal Cancer: Impact on Syndromes, Quality of Life and Radiosensitivity of Lymphocytes as a Prognostic Indicator.

Dr Wojciech Sasiadek

Reviewed & Approved

MAY 2012

Study Title:

Preconditioning Shields against Vascular Events during Surgery (Preconditioning SAVES): a multi-centre trial of preconditioning against adverse events during major vascular surgery.

Prof. Stewart Walsh

Reviewed & Approved

Study Title:

Economic Evaluation of Palliative Care in Ireland.

Prof. Charles Normand

Reviewed & Approved

Study Title:

Characterising the sedentary behaviour and physical activity patterns of patients with Peripheral Arterial Disease (PAD).

Mr. K. Simon Cross

Reviewed & Approved

Study Title:

Understanding Disruptions to Attachment Relationships for Children in care: Mental Health and Perceptions of Foster Care Placement Breakdowns.

Dermot O'Callaghan

Reviewed & Approved

JUNE 2012

Study Title:

A Randomised Controlled Trial of Computerised CBT for Depression and/or Anxiety.

Conal Twomey

Reviewed & Approved

JULY 2012

Study Title:

Macular pigment levels in patients with Alzheimer's disease: literature review and exploratory study.

Dr John Nolan

Reviewed & Approved

Study Title:

Men's experiences of, and satisfaction with, prostate cancer care in Ireland: The PiCTure 2 Study.

Dr Linda Sharp/Marita Hennessy

Reviewed & Approved

SEPTEMBER 2012

Study Title:

A lived experience of intellectual disability and its impact upon a person's identity.

Ms Aisling Ni Cheallaig

Reviewed & Approved

Study Title

Outcome Measures in Therapy for Stuttering: Examining Narratives of People who Stutter (PWS).

Ms Fiona Ryan

Reviewed & Approved

OCTOBER 2012

Study Title:

Public Knowledge of Peripheral Arterial disease in the South East Region.

Dr Damian McCartan

Reviewed & Approved

Study Title:

EORTC 10085/BIG 2-07: Clinical and biological characterization of Male Breast Cancer: an international retrospective EROT, BIG and NABCG intergroup study.

Dr Miriam O'Connor

Reviewed & Approved

NOVEMBER 2012

Study Title:

Intraoperative Psoas Block in Pain Management of Hip Arthroplasty Patients.

Dr Rajiv Merchant

Reviewed & Conditionally Approved

Study Title:

An Exploration of Lives of Adolescents (aged 12-18yrs) who Self-Harm in Ireland.

Ms Ellis Hayes

Reviewed & Approved

Study Title:

Cartenoids Age-Related Dementia Study (CARDS): supplementation trial.

Dr John Nolan

Reviewed & Approved

NO MEETING DECEMBER 2012.

SECTION TWO

**RESEARCH STUDIES GRANTED
EXPEDITED APPROVAL 2012.**

STUDIES GRANTED EXPEDITED APPROVAL 2012

JANUARY 2012

Study Title:

Over the Counter Cold Medication Use in the Paediatric General Practice Population.

Ms Anna Donovan

Number of feedback sessions required: 1 2 3 4 5 6 7 8 9 10 11
√

Study Title:

An Investigation into Referral Agent Perceptions of the Waterford HSE Community Services Psychology Drop-In Service.

Dr Barry Coughlan

Number of feedback sessions required: 1 2 3 4 5 6 7 8 9 10 11
√ .

Study Title:

Investigation of Patient Satisfaction with Community Intervention Team (CIT).

Mr David Healy

Number of feedback sessions required: 1 2 3 4 5 6 7 8 9 10 11
√

Study Title:

Prevalence and Determinants of Non-Adherence to Immunosuppressant Therapy in Adult Renal Transplant Recipients.

Mr. Dermot O'Farrell

Number of feedback sessions required: 1 2 3 4 5 6 7 8 9 10 11
√

Study Title:

A study of women's practices, perceptions and knowledge levels of exercise during pregnancy.

Ms Mary O'Donnell

Number of feedback sessions required: 1 2 3 4 5 6 7 8 9 10 11
√

Study Title:

Medication Management in Nursing Homes: the Nurses' perspective.

Dr Pauline Meskell

Number of feedback sessions required: 1 2 3 4 5 6 7 8 9 10 11
√

Study Title:

Satisfaction with information about Phosphate Binding Medications (PBMs) and factors contributing to non adherence to PBMs among adult haemodialysis (HD) patients.

Ms Susan Rajai

Number of feedback sessions required: 1 2 3 4 5 6 7 8 9 10 11
√

Study Title:

An exploration of the role of the Liaison Mental Health Nurse in developing evidence based clinical pathways for management of Substance Use Disorders in emergency departments.

Ms Teresa Hunston

Number of feedback sessions required: 1 2 3 4 5 6 7 8 9 10 11
√

Study Title:

AURA Study: A retrospective non-interventional study to assess the effectiveness of existing Anti-vascular endothelial growth factor (anti-VEGF) treatment Regimens in patients with wet Age-related macular degeneration.

Professor Stephen Beatty

Number of feedback sessions required: 1 2 3 4 5 6 7 8 9 10 11
√

MARCH 2012

Study Title:

Reviewing and evaluating the impact the introduction of a Crisis Assessment and Treatment Nursing Team (CATT) had on the numbers and illness profile of adult admissions to an acute psychiatric unit. A quantitative two phase study.

Not Approved.

Mr. Joseph Slattery

Number of feedback sessions required: 1 2 3 4 5 6 7 8 9 10 11
√

Study Title:

Evaluation of the EntericBio system for the detection of verotoxin producing *E. coli* (VTEC) in faeces.

Ms Coleen Cunningham

Number of feedback sessions required: 1 2 3 4 5 6 7 8 9 10 11
√

MAY 2012

Study Title:

Amendment:

An exploration of the perceptions of low risk pregnant women and their care providers regarding the provision of antenatal care services for low risk women.

Ms Annette Murphy

Number of feedback sessions required: 1 2 3 4 5 6 7 8 9 10 11
√

Study Title:

Uptake and impact of adjuvant chemotherapy in older patients with locoregional Colon Cancer.

Dr Anne Horgan

Number of feedback sessions required: 1 2 3 4 5 6 7 8 9 10 11
√

Study Title:

Outcomes of Out-Of-Hours GP visits to Palliative care patients.

Dr Louise Rainey

Number of feedback sessions required: 1 2 3 4 5 6 7 8 9 10 11
√

Study Title:

A randomised Phase 111 Trial of Two Fractionation Schemes in the treatment of Malignant Spinal Cord Compression.

Dr Dayle Hacking and Dr. Wojciech Sasiadek

Number of feedback sessions required: 1 2 3 4 5 6 7 8 9 10 11
√

Study Title:

Electronic Nurse Rostering Systems: An evaluation of the effectiveness of Automated Nurse Rostering Systems to satisfy nurse rostering constraints in practice.

Ms Linda Ennis

Number of feedback sessions required: 1 2 3 4 5 6 7 8 9 10 11
√

JUNE 2012

Study Title:

A Randomised Controlled Trial of Computerised CBT for Depression and/or Anxiety.

Mr Conal Twomey

Number of feedback sessions required: 1 2 3 4 5 6 7 8 9 10 11
√

AUGUST 2012

Study Title:

Investigation of Leucocyte Esterase in the Diagnosis of Paediatric Septic Arthritis.

Dr Enda Kelly

Number of feedback sessions required: 1 2 3 4 5 6 7 8 9 10 11
√

SEPTEMBER 2012

Study Title:

Electronic National Early Warning Scorecard (eNEWS).

Dr John O'Donoghue

Number of feedback sessions required: 1 2 3 4 5 6 7 8 9 10 11
√

OCTOBER 2012

Study Title:

Cardiac Rehabilitation Treatment at a South East Hospital.

Dr Suzanne McCarthy

Number of feedback sessions required: 1 2 3 4 5 6 7 8 9 10 11
√

Study Title:

Amendment:

ANZGOG 0701-Symptom Benefit Study.

Ms Linda Sullivan

Number of feedback sessions required: 1 2 3 4 5 6 7 8 9 10 11
√



Study Title:

Advanced Nurse Practitioners' (Emergency); perceptions of their role, professional positionality and professional identity.

Ms Lisa Kerr

Number of feedback sessions required: 1 2 3 4 5 6 7 8 9 10 11
√

Study Title:

Amendment:

A Clinical Trial Using 3-Dimensional Conformal Radiation Therapy to Reduce the Toxicity of Palliative Radiation for Lung Cancer.

Dr Dayle Hacking and Dr. Wojciech Sasiadek

Number of feedback sessions required: 1 2 3 4 5 6 7 8 9 10 11
√

NOVEMBER 2012

Study Title:

Economic Evaluation of Palliative Care in Ireland: Amendment

Professor Charles Normand

Number of feedback sessions required: 1 2 3 4 5 6 7 8 9 10 11
√

Study Title:

Feasibility Analysis of Key Performance Indicators (KPIs) for Emergency Departments in Ireland.

Dr Abel Wakai

Number of feedback sessions required: 1 2 3 4 5 6 7 8 9 10 11
√

Study Title:

An exploration of the influences of enquiry and practice based learning in postgraduate nurse education on sustaining practitioner and practice development.

Ms Frances Finn

Number of feedback sessions required: 1 2 3 4 5 6 7 8 9 10 11
√

Study Title:

Tools for Tots: An investigation into the assessment practices of Irish Speech and Language Therapists when working with preschool children.

Ms Niamh O'Connor

Number of feedback sessions required: 1 2 3 4 5 6 7 8 9 10 11
√



DECEMBER 2012

Study Title:

Exploratory study of effects of Methadone Maintenance Therapy on individuals receiving this treatment in Waterford City.

Ms Katriona Barry

Number of feedback sessions required: 1 2 3 4 5 6 7 8 9 10 11
√

SECTION THREE

SITE SPECIFIC ASSESSMENTS FOR THE HSE SOUTH- EAST 2012

SITE SPECIFIC ASSESSMENTS 2012

15th February 2012

Trial Title:

NSABP PROTOCOL B-47 A Randomized Phase 111 Trial of Adjuvant Therapy Comparing Chemotherapy Alone (Six Cycles of Docetaxel Plus Cyclophosphamide or Four Cycles of Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel) to Chemotherapy Plus Trastuzumab in Women with Node-Positive or High-Risk Node-Negative HER2-Low Invasive Breast Cancer.

Chief Investigator: Dr Miriam O'Connor, Consultant Oncologist, Waterford Regional Hospital

RECRUITMENT ONGOING

27th February 2012

Trial Title:

Phase 11 study of single agent sorafenib in the treatment of relapsed oesophageal/gastric adenocarcinoma in platinum pre-treated patients.

Chief Investigator: Dr Paula Calvert, Consultant Oncologist, Waterford Regional Hospital

RECRUITMENT ENDED

16th July 2012

Trial Title:

A Phase 111 Randomised Study to assess the Efficacy and safety of Perifosine added to the combination of Bortezomib and Dexamethasone in Multiple Myeloma Patients previously treated with Bortezomib.

Chief Investigator: Dr Brian Hennessy, Consultant Oncologist, Waterford Regional Hospital

RECRUITMENT ONGOING

16th August 2012

Trial Title:

The Myocet/Lapatinib study: A phase 1/11 study of lapatinib plus non-pegylated liposomal doxorubicin in patients with HER2+ve metastatic breast cancer following disease progression during, or after, treatment with trastuzumab and taxanes.

Chief Investigator: Dr Miriam O'Connor, Consultant Medical Oncologist, Waterford Regional Hospital

RECRUITMENT ONGOING

23rd July 2012

Trial Title:

A Multi –Center, Randomised, Placebo-Controlled Phase 11 Study of Regorafenib in combination with FOLFIRI (Irinotecan, 5-Fluorouracil, and leucovorin) versus Placebo with FOLFIRI as Second Line Therapy in Patients with K-RAS or BRAF Mutant Metastatic Colorectal Cancer.

Chief Investigator: Dr Anne Horgan, Consultant Medical Oncologist, Waterford Regional Hospital

RECRUITMENT ONGOING

17th October 2012.

Trial Title:

A Phase 111 Prospective, Two-Cohort, Non-Randomized, Multi-Centre, Multinational, Open Label Study to Assess the Safety of Assisted and Self-Administered Subcutaneous Trastuzumab as Adjuvant Therapy in Patients with Operable HER2-positive Early Breast Cancer [SafeHer Study].

Chief Investigator Dr .Miriam O'Connor , Consultant Medical Oncologist, Waterford Regional Hospital

RECRUITMENT ONGOING



SECTION FOUR.

MEMBERSHIP OF THE RESEARCH ETHICS COMMITTEE, HSE SOUTH- EAST 2012

**MEMBERSHIP OF RESEARCH ETHICS
COMMITTEE
HSE, SOUTH EASTERN AREA 2012**

NAME	ADDRESS	QUALIFICATION	ETHICS EXP	TITLE	
Dr Paula Lane Chairperson	Waterford Institute of Technology	PhD, LLM, BNS (Hons) PFRCSI, Dip.N , RGN,RM	Research Ethics Committee South East	Project Leader for Graduate Nursing	1/1/2005
Dr Mark Doyle Alternate Vice Chair	Waterford regional Hospital	Awaiting C.V.		Consultant Emergency Medicine	27/09/2010
Oonagh Keating	South Tipperary General Hospital	Awaiting C.V.		Asst. Director of Nursing	16/4/2012
Fr. Edward O'Callaghan OFM	Franciscan Friary Lady Lane Waterford	M.A. Lic-en-Phil, STL, PhD	Nursing Ethics, MidWestern Health	R.C. Priest	5/12/2011
John Halley	Cashel Hospital, Tipperary	Leaving Cert Nat. Cert. in Farming	Research Ethics Committee HSE South East	General Porter	16.07.2007
Meta Cummins	Wexford General Hospital	BSc Pharm	Research Ethics Committee HSE South East	Chief Pharmacist Wexford General Hospital	20/03/2006
Angela Quinlivan	Tipperary	Leaving Cert	Research Ethics Committee HSE South East	Chairperson Patient Rep Ass. STGH	20/03/2006
Eithne Malone	Wexford	Qualified Primary Teacher 1970	Research Ethics Committee HSE South East	Retired Teacher	16/02/2009
Marie Kennedy	H.S.E. Community Care Head Quarters Kilkenny	B.S.S. in Social Studies MSc Health Services	Research Ethics Committee HSE South East	Child Care Manager	16/03/2008
Valerie O'Donnell	St. Luke's Hoospital Kilkenny	BSc(Hons) Speech & Language	Research Ethics Committee HSE South East	Senior Speech & Language Therapist	15/12/2008
Dr John Phelan	Waterford Institute of Technology	BSc,MSc, PhD Biochemistry	Research Ethics Committee HSE South East	Biomedical Research Scientist	17/05/2010
Dr John Carson	Wexford General Hospital	Hospital Consultant		Consultant Paediatrician	27/09/2010
Dr Brian Creedon	Waterford Regional Hospital	Hospital Consultant	Awaiting C.V.	Consultant in Palliative Medicine	27/09/2010
Dr Stephen Browne	Waterford Regional Hospital	Hospital Consultant	Awaiting C.V.	Consultant Psychiatrist	14/02/2011

EXPERT ADVISORS (No Vote)

Ms. Joan Heneghan	Waterford Regional Hospital	MB BCh BAO MRCPI FFR RCSI		Consultant Radiologist
Mr Peter Roche	Waterford Regional Hospital			Information Technology Department Head
Mr. Neil Van Dokkum	Waterford Institute of Technology.	BS ocSs, LLM, P.G. Cert. Con Law		Lawyer
Ms. Yvonne Dowling	St Lukes' Hospital, Kilkenny			Medical Scientist
Ms. Una O'Brien	Old School of Nursing, W.R.H.	MSc Nursing BSc Nursing		Nurse Practice Development Co-ordinator
Ms Anne Coyne-Nevin	St. Patrick's Hospital, Waterford			Assistant Director of Nursing

RESEARCH ETHICS COMMITTEE CO-ORDINATOR & SECRETARY (No Vote)

Ms. Caroline Lamb	Waterford Regional Hospital	RGN,ICU,CCU, MA Health Care Ethics. PG Dip. Medical Law	Research Ethics Committee Co- ordinator	A/CNM 2	09/05/2005
Ms Anne Cottrell	Waterford Regional Hospital	Leaving Cert Certificate in Counselling.	Secretary Ethics Committee	Clerical Officer	13/09/2004



APPENDICES.

APPENDIX 1.

BREAKDOWN OF APPLICATIONS FOR ETHICAL APPROVAL.
HSE, SOUTH EAST. 2005- 2012

Year	REC Presented Studies	Expedited Approved Studies.	Site Specific Applications	Total
2005	38	0	0	38
2006	27	15	5	47
2007	34	37	13	84
2008	21	42	9	72
2009	20	34	11	65
2010	18	33	5	56
2011	21	37	4	62
2012	26	31	6	63

APPENDIX 2.

**Incoming members of the Research Ethics Committee HSE, South
Eastern Area 2012.**

1. Ms Oonagh Keating – Assistant Director of Nursing, South Tipperary General Hospital, Clonmel
2. Ms Marie Baldwin, Layperson. Kilkenny
3. Dr Edgar Lonergan, Clinical Psychologist, HSE South, Cork Road Waterford
4. Dr Denise Hayes, Registrar, Palliative Care, Waterford Regional Hospital.
5. Mr Liam Quinn, Senior Manager S.O.S. Kilkenny
6. Ms. Anne Slattery, General Manager, St. Luke's Hospital, Kilkenny.

APPENDIX 3.

**Outgoing members of the Research Ethics Committee HSE, South
Eastern Area 2012.**

1. Dr. Eamon Tierney, Consultant Anesthetist, Wexford General Hospital.
2. Ms Tereasa Boland, Midwife, St Luke's Hospital, Kilkenny.
3. Ms Carole Broadbank, Acting General Manager, South Tipperary General Hospital, Clonmel.
4. Mr Ezzat Tadross, Consultant Breast Surgeon, Waterford Regional Hospital.
5. Dr Niall Colwell, Consultant Cardiologist, South Tipperary General Hospital, Clonmel
6. Ms Catherine Brennan, Layperson
7. Mr. Richard Kennedy, Layperson