





Harbour Hotel Galway, 16<sup>th</sup> & 17<sup>th</sup> November 2017



@Irish\_RNN



**#IRNN17** 

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#### **Foreword**

On behalf of the IRNN Working Group I am delighted to welcome you to our tenth annual AGM and conference. Research Nursing in Ireland has come a long way since our first meeting in the Davenport Hotel in Dublin in 2008. There are still many challenges, but by working together we can continue to highlight the importance of the role and the necessity of a skilled research nurse resource to support the conduct of high quality research in the healthcare setting.

The IRNN conference is not just for nurses – we are delighted to welcome colleagues from other healthcare disciples, science, industry and patient organisations who join us today.

The theme of the conference is 'Yesterday's Vision, Today's Research, Tomorrow's Healthcare'. We are privileged to have expert speakers to talk about their research, and also updates on topics of concern to everyone involved in clinical research, including the General Data Protection Regulations (GDPR) and the EU Clinical Trial Regulations.

The Research Forum includes speakers presenting their own academic research projects. Abstracts submitted for this session, and for the poster presentations, are included in your conference pack. Please take time to review the posters during refreshment breaks.

The commitment of IRNN to promoting excellence in clinical research, and providing a platform for networking, education and support, was recognised in a very tangible way in the past year in the form of a grant to support the professional development of clinical research nurses. This included funding for the annual conference, and we are incredibly grateful to the Health Research Board and Clinical Research Coordination Ireland (CRCI) for their continuing support.

We hope you enjoy the day, and very much welcome your comments and feedback - #IRNN17

Deirdre Hyland

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Chairperson IRNN

With special thanks to: The Health Research Board, Clinical Research Coordination Ireland and Clinical Research Development Ireland







### **IRNN WORKING GROUP MEMBERS**



#### **Deirdre Hyland, IRNN Chairperson**

Deirdre is a registered nurse and midwife. She completed a higher Diploma in ENT Nursing in 1999, and an MSc in Nursing in 2003. Deirdre has been employed as a Clinical Research Nurse in the RCSI Clinical Research Centre since 2004, gaining experience in a range of academic research and clinical trials. Since 2009 Deirdre has been responsible for clinical research education and support, and also develops delivers GCP training courses.

#### **Hazel Smith, IRNN Communication Officer**



Hazel is the Research Coordinator for the Paediatric Intensive Care Unit at Our Lady's Children's Hospital, Crumlin and sits on the cross-hospital research committee for all three Dublin paediatric hospitals. Hazel is a published author in both medical and nursing journals, and for the Cochrane Pregnancy and Childbirth Group. Hazel has presented findings from her research internationally and is the midwifery representative for 'The review of Nursing Research Structures and Roles across the UK and Ireland to increase involvement and impact of nurses in midwives and improve patient care'. Hazel is also a guest lecturer, on maternal and child health inequities, for the Centre for Global Health, Trinity College Dublin

#### Sinead Jordan, IRNN Treasurer



Sinead started out in Beaumont hospital working on a neuro-medical ward and then moved into the community where she worked as a nurse advisor for people with Multiple Sclerosis. Sinead has been working at St Vincent's since July 2007, initially as a research nurse and subsequently as a nurse manager. The department works on a variety of clinical trials, both academic and pharmaceutical funded. These are generally phase III & IV – observational and interventional studies.

#### **Mary Clarke Moloney**



Mary is a qualified registered nurse since 1994 and an experienced clinical researcher having worked in the area of clinical research for the past 15 years. She was awarded her PhD from the University of Limerick in 2006. In her time working in clinical research Mary gained considerable experience working on a wide range of research projects from concept to publication. Mary is the Clinical Operations Manager for the Health Research Institute in the University of Limerick.



#### Valerie Trimble

Valerie trained as a general nurse in the UK in the early 80's and completed her midwifery training in St. James's Hospital in 198. She worked as a staff nurse in St. James's before moving to a research post. Valerie is a Research Nurse with the Dept. Clinical Medicine in Trinity College Dublin. Valerie completed the Postgraduate Certificate in Nursing (Clinical Research) in 2011.



#### **Carole Schilling**

Carole completed her BSc(Hons) Nursing and RGN in 1993. In 1999 Carole completed an MSc in Nursing. Carole has gained experience in both the clinical setting as a research nurse and in the pharma/CRO industry as a clinical research associate. Carole joined the RCSI CRC in March 2012 as a senior clinical research nurse. In 2013 she completed the level 9 post-graduate certificate in Nursing (Clinical Research). In 2015 Carole took on the role as RCSI Quality & Regulatory Affairs Manager.



#### Jean Foley

Jean graduated from St Vincent's Hospital, Dublin as a registered General Nurse. She holds a Certificate in Nurse Management, a Certificate in Practice Nurse and a post graduate certificate in Clinical Research from the Royal College of Surgeons, Dublin. Jean worked as a nurse in Dublin and Cork before joining Minerva where she worked as Research Nurse involved in large multinational trials. She joined Alimentary Health as Clinical Nurse specialist in research before joining the Clinical Research Facility Cork in 2012.



Maeve Kelsey Maeve

is the Clinical Trials Nurse Manager with the *Health Research Board Clinical Research Facility*, Cork (CRF-C) and has been a member of the IRNN working group since 2012. Maeve has been working in clinical research since 2005 and also has a background in working in Pharmaceutical sales. Maeve is a registered General Nurse and Midwife and she obtained a level 9 post-graduate certificate in Nursing (Clinical Research) in 2013 from RCSI. She also successfully completed her Masters in Clinical Trials with the University of Edinburgh in 2017. She is also interested in Patient and Public Involvement (PPI) in patient focussed research.



**Veronica McInerney** Veronica is a registered general nurse who holds a H.Dip in Oncology Nursing, Masters in Health Research and was awarded a PhD from the National University of Ireland Galway for research in quality of life of patients with advanced cancer. Her work in Clinical Research began in 1999 .She was instrumental in establishing and managing the Cancer Clinical Trials Unit at Galway University Hospital .In 2010, Veronica was appointed Clinical Nurse Manager in the HRB Clinical Research Facility NUI Galway, and she took up her current position of Early Phase and Cell Therapy Trial Manager at CRF NUI Galway in 2014 .



#### **Derval Reidy**

Derval is currently working as Assistant Director of Nursing at the Wellcome HRB Clinical Research Facility at St James's hospital. Derval is responsible for the operational management of the facility, study review and study set-up. Derval has worked in Clinical research for over ten years as a research nurse and study coordinator and in the latter years managed large scale Phase II clinical trials in South Africa. Derval is a qualified general nurse, holds a degree in Industrial Microbiology from University College Dublin and a Master's degree in Public Health.



#### **Claire Magner**

Claire qualified as a Registered General Nurse in 1998, specialising in Adult Intensive Care. She went on gain qualification as a Registered Children's in 2005; specialising in Paediatric Intensive Care. Claire worked as a Clinical Audit & Research Nurse from 2009 – April 2016, and was a awarded a PhD in Clinical Nursing from RCSI in June 2014. She started her current role as Programme Director for Higher Diploma in Children's Nursing in 2016.



#### Julie Wilson

Julie registered as a general nurse in 1993 and has worked in a variety of clinical settings. She worked as a lecturer in Nursing at the University of Ulster before helping to set-up the NICRF in 2012. Julie completed a PhD evaluating smoking cessation guidelines in patients with COPD. Julie is currently the Staff Manager for the Wellcome Trust-Wolfson Northern Ireland Clinical Research Facility (NICRF) in Belfast.



#### Jo Studham

Jo has worked in clinical research for over 25 years. Her current role as Head of Operations for the INFANT Research Centre is her first in Ireland, having spent her previous career in the UK and in London in particular. She has worked as a Clinical Research Facility Manager at St George's University Hospitals NHS Foundation Trust. She was responsible for the clinical research delivery staff working in the Clinical Research Facility and across the organisation



# IRISH RESEARCH NURSES NETWORK AGM and WORKSHOPS



7	hursday 16 <sup>th</sup> November 2017, H	larbour Hotel, Galway	
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	Registration & Refreshments	Hotel Foyer	
13.30-14.00 14.00-15.00	Annual General Meeting	JB Keane Suite	
14.00-15.00	Aimual deficial Piecering	To Realie Suite	
	N.B: Open to IRNN Members Only		
	Update on IRNN Activities	Ms Deirdre Hyland, Chairperson	
	Communications Update	Ms Hazel Smyth, Communications Officer	
	Treasurers Report	Ms Sinead Jordon, Treasurer	
	Update on IMNO research nurse Section		
	Any Other Business		
Workshops	JB Keane Suite	Purtill Suite	
15.00 -	Informed Consent in Clinical Research	Writing for Publication	
17.00	and med consent in chinear research		
	Deirdre Hyland, Director of Research Nurse Education, RCSI CRC; Chairperson, IRNN Working Group  Derval Reidy, Assistant Director of Nursing, Wellcome Trust/HRB CRF, St James's Hospital; Member IRNN Working Group  Hazel A. Smith, Research coordinator, PICU, Our Lady's Children's Hospital, Crumlin; Communications officer, IRNN Working Group  An interactive workshop that includes a summary of the informed consent process, followed by scenarios and role play. Attendees will use the UKCRF Competency Assessment Tool as a guidance and discussion document.	Professor Declan Devane PhD, PGDip, MSc, BSc, Dip HE, RGN, RM, RNT Nursing & Midwifery Studies Aras Moyola NUI Galway	
19.30	Drinks Reception	Harbour Hotel Foyer	
20.00	Evening Meal	JB Keane Suite	
AGM is open to	AGM is open to active (2017) members only – membership can be renewed via the website <a href="https://">https://</a>		

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## IRISH RESEARCH NURSES NETWORK ANNUAL NATIONAL CONFERENCE



JB Keane Suite, Harbour Hotel, Galway		
	Friday 17 <sup>th</sup> Novemb	per 2017
09.00-10.00	Registration & Refreshments; Poster View	
10.00	Welcoming Remarks	
Forum 1	Chairperson: Dr Fio	nnuala Keane, COO,
	HRB Clinical Research	Coordination Ireland
10.10	Opening Address	Dr Mairead O'Driscoll, Interim Director/ Director Research Strategy and Funding, HRB
10.30	START Programme: Schools Teaching awareness of Randomised Trials	Dr Sandra Galvin HRB Trial Methodology Research Network, NUIG
11.00	Stem Cell Therapy for Arthritic Disease: A New Medicine?	Prof Frank Barry Professor of Cellular Therapy, NUIG
11.30-11.55	Refreshments/Viewing	g of stands and posters
Forum 2	Chairperson: Dr	Georgina Gethin,
	Head of School of Nurs	sing & Midwifery, NUIG
12.00	Enhancing Men's Awareness of Testicular (E-MAT) Disorders Using Virtual Reality: A Pre-Post Study	Mohamad M. Saab PhD, Lecturer, Catherine McAuley School of Nursing and Midwifery, UCC
12.20	ReseArcher and Public PERspectives of PPI in Research (RAPPER): A UCC survey	Ms. Maeve Kelsey, Clinical Trials Nurse Manager, Cork Clinical Research Facility
12.40	Nurses Experiences and Perceptions of Caring for People with Intellectual Disability who are Ageing	Ms. Niamh Walsh, Registered Nurse in Intellectual Disability, NUIG
13.00	Consent for routine neonatal procedures: A study of practices in Irish Neonatal Units and how we compare to BAPM guidelines	Ms. Mary Anne Ryan, Research Nurse/ PhD Student, INFANT Research Centre
13.20		Discussion
13.30-14.10	Lunch/Viewing of	stands and posters
Forum 3	Chairperson: Dr	Derick Mitchell,
	Chief Execut	tive, IPPOSI
14.15	The General Data Protection Regulation: Preparing for May '18	Ms Laura Flannery, Office of the Data Protection Commissioner
14.45	Implications of ICH GCP Revision and EU Clinical Trial Regulation	Ms. Sinead Curran, GCP/Pharmacovigilance Inspection Manager, HPRA
15.15	The MARIO Project	Prof. Dympna Casey, Professor of Nursing, NUIG
15.45	Chairpersons remarks; Presentation of poster prizes and close of conference	Ms Deirdre Hyland, Director of Research Nurse Education, RCSI Clinical Research Centre

### **AGM and Conference Speakers**



Ms Deirdre Hyland, MSc, H.Dip, RGN, RM.

Deirdre is Director of Research Nurse Education in the RCSI Clinical Research Centre in Beaumont Hospital. From 2009 - 2016 Deirdre co-ordinated the Postgraduate Certificate in Clinical Research Nursing which provided education and training for over 100 research nurses and other research staff. She is responsible for the education and support of clinical research staff in RCSI CRC, including delivery of Good Clinical Practice (GCP) courses, and has developed training resources that have been shared nationally. Deirdre is committed to collaboration and networking across the clinical research sector in Ireland and internationally. She serves as:

- Working group member of the Irish Research Nurses Network (IRNN)
- Member of the International Association of Clinical Research Nurses (IACRN)
- Member of the UKCRF Network Education Workstream
- Member of the Board of the Irish Platform for Patient Organisations, Science and Industry (IPPOSI)
- Clinical Representative on the Quality Working Group of Clinical Research Coordination Ireland (CRCI)
- Member of national PPI Working group



Prof Declan Devane, PhD, PGDip, MSc, BSc, RGN, RM, RNT

Declan is Professor of Midwifery at NUI Galway, Director of the Health Research Board – Trials Methodology Research Network (HRB-TMRN) and Principal Investigator with the SFI – INFANT – Irish Centre for Fetal and Neonatal Translational Research. He is an Editor with the Cochrane Pregnancy and Childbirth Group and an Honorary Senior Lecturer at Cochrane UK. Declan has a particular interest in the implementation and evaluation of models of maternity care and on methods of fetal monitoring including cardiotocography and intermittent auscultation. His methodological areas of expertise are randomised trials, systematic reviews and meta-analyses. He has published over 120 papers including numerous Cochrane systematic reviews predominantly in the field of fetal assessment. He has led a number of clinical trials recruiting from 100 to over 3000 participants and serves on a number of Trial Steering Committees including those in pregnancy (e.g., EMERGE, HOLDS, PARROT) and Data Monitoring Boards (e.g., CORD, KEEP-WELL).



Mairead O'Driscoll, Interim Chief Executive and Director of Research Strategy and Funding at the Health Research Board (HRB)

The Directorate currently manages funding programmes and commitments in health research of over €100 million. Before being appointed Director of Funding, Mairead was Head of Research Funding and Policy and subsequently Policy, Evaluation and External Relations at the HRB. She is a graduate of Trinity College, Dublin, and the University of London. She worked as a researcher in academia and the biotechnology industry before moving into policy research, firstly with the Royal Society in London and then with the Wellcome Trust. She also spent time in South Africa where she worked in the Council for Scientific and Industrial Research and the Department of Arts, Culture, Science and Technology on the development of a national research and technology foresight study



Dr Sandra Galvin, HRB Trial Methodology Research Network, NUIG

Sandra joined the School of Nursing and Midwifery in NUI Galway in 2014 as the Coordinator for the Health Research Board - Trials Methodology Research Network (HRB-TMRN) www.hrb-tmrn.ie. The goal of the HRB-TMRN is to improve the conduct and reporting clinical trials in Ireland. To accomplish this Sandra is involved in coordinating the provision of a range of activities such as educational events and liaising with experts in this area to provide a direct support service to trialists and researchers in the field. Her previous research experience (2012 - 2014) includes Ireland's largest non-pharmaceutical clinical trial The SIMPle Study where the goal was to design, implement and evaluate a complex intervention to improve antimicrobial prescribing for urinary tract infections (UTI) in general practice. This HRB funded study successfully enrolled 2,560 patients in 6 months and was carried out with the Discipline of General Practice NUI Galway. Sandra's early research (2006-2012) centred on the topic of antimicrobial resistance in bacterial pathogens, starting with her PhD from the Discipline of Bacteriology (2010), School of Medicine, NUI Galway after which she joined the Department of



Prof Frank Barry, MSc, MSc, PhD

Frank Barry is Professor of Cellular Therapy at the Regenerative Medicine Institute (REMEDI), National University of Ireland Galway. Here he directs a large group of researchers who focus on the development of new repair strategies for musculo-skeletal conditions, especially osteoarthritis. Previously he was Director of Arthritis Research at Osiris Therapeutics in Baltimore, MD and a Research Fellow at Shriners Hospital for Children, Tampa, FL. He is a founder and Director of Orbsen Therapeutics Ltd. He has served on many advisory boards including Fighting Blindness, UK Tissue Engineering Centre, Toronto Arthritis Programme and Fibrous Dysplasia Foundation. He is also Scientific Director of the Centre for Cell Manufacturing Ireland, a facility for GMP aseptic processing of cellular products. He has published widely in the areas of cell therapy, stromal cell biology and regenerative strategies in joint disease. He is the coordinator of the ADIPOA2 clincial trial that investigates the effectiveness of adipose stromal cell treatment for osteoarthritis of the knee. He was the recipient of the 2012 Marshall Urist Award for excellence in tissue regeneration research from the US Orthopaedic Research Society and was



Ms Laura Flannery

Laura Flannery is a Lead Consultation Specialist with the Office of the Data Protection Commissioner. Within the Consultation Section, Laura works in an advisory capacity with data controllers across the public and private sectors, providing data protection awareness and best practice guidance. Laura is currently a member of the eGovernment Group of the Article 29 Data Protection Working Party of the European Commission and regularly contributes to published opinions in respect of data privacy and processing of personal data. Her current areas of involvement include Codes of Conduct under GDPR. Laura holds a number of legal qualifications from NUI Galway and worked in the Department of Justice and Equality prior to taking up her current role.



Ms. Sinead Curran, GCP/Pharmacovigilance Inspection Manager, HPRA

Sinead Curran holds a Bachelor of Science and Masters in Pharmaceutical Medicine. She started in clinical development in 2003, and worked in the areas of regulatory affairs and project management. In 2007, she joined the Health Products Regulatory Authority (HPRA, formerly Irish Medicines Board) as a Good Clinical Practice and Pharmacovigilance Inspector and remained with the authority for 8 years, also working as PV surveillance assessor for one year. In 2015, she left HPRA, and worked in both the commercial and non-commercial settings in GxP quality assurance. She then returned to the HPRA in March of this year, to assume the role of GCP/PV Inspection Manager. She is the Irish delegate to both the GCP and PV Inspectors Working Groups of EMA.



Prof. Dympna Casey, RGN, BA, MA, PhD

Professor Dympna Casey (RGN, BA, MA, PhD) has a clinical background in care of older people. For the past 20 years she has worked in nursing education in the National University of Ireland Galway. She teaches across a range of programmes and supervises students at Masters and PhD level. She has a keen interest in promoting healthier lifestyles for older people and in examining ways of supporting and maintaining the health and functional capacity of older people. She has specific expertise in case studies, mixed methods and qualitative research methodologies. Her research skills also include designing and developing interventions for RCT's and ensuring that such interventions are informed by users and other key stakeholders. She has extensive experience in leading collaborative interdisciplinary and inter institutional research projects at local and national level. She is currently leading an EU Funded Horizon 2020 project entitled MARIO (Managing Active & Health Aging with the use of caring service robotics) within the thematic section 'Societal Challenge on Health, Demographic Change and Wellbeing'.

Research Forum Abstract 1	Mohamad M. Saab, PhD, MSc, BSc, RN, PGCTLHE, Catherine McAuley School of Nursing and Midwifery, UCC
Abstract Title:	Enhancing Men's Awareness of Testicular (E-MAT) Disorders Using Virtual Reality: A Pre-Post Study
Author/s	Mohamad M. Saab, Margaret Landers, Eoghan Cooke, David Murphy, Martin Davoren, Josephine Hegarty

**Background:** Men's awareness of testicular disorders is lacking and their intention to seek help for scrotal symptoms is low. Few studies promoted awareness of testicular disorders with none using innovative technologies. The aim of this study was to enhance men's testicular awareness via an intervention delivered using virtual reality and underpinned by a novel theoretical framework.

**Methods:** A one-group pre- and post-test design was used. Men (n=53) aged between 18 and 50 years were recruited using non-probability sampling and were asked to play a 3-level educational game using a virtual reality headset and controller. Knowledge, awareness, perceived risk, implementation intentions, help-seeking intentions, and behaviour were measured at three time points: baseline, immediately post-test, and one month post-test. Data were analysed using descriptive and inferential statistics.

**Results:** Men's knowledge and awareness of the normal testes and testicular symptoms and diseases; intentions to examine their testes; intentions to seek help for testicular symptoms; and behaviours pertaining to feeling their testes increased over time. This increase was found to be statistically significant. Men who intended to feel their testes at baseline reported having done that one month post-test. In contrast, men's perceived risk for developing a testicular disorder was low at baseline and did not increase over time.

**Conclusion:** The intervention proved successful in enhancing men' testicular awareness, implementation intentions, help-seeking intentions, and behaviours. The plan is to conduct a randomised controlled trial and to test the intervention using a larger sample size.

Research Forum Abstract 2	Maeve Kelsey, RGN RM and MSc Clinical Trials Candidate, Clinical Trials Nurse Manager, Clinical Research Facility Cork
Abstract Title:	ReseArcher and Public PERspectives of PPI in Research (RAPPER): A UCC survey
Author/s:	Maeve Kelsey

**Background** Patient and Public Involvement (PPI) in health research is becoming more prevalent worldwide. A formalised and widespread approach to PPI is a relatively new concept in Ireland. Ireland's largest state funding agency is now encouraging researchers to involve patients and the public in research. This is likely to result in increased awareness and participation in PPI.

**Objectives:** To examine current levels of PPI within the Clinical Research Facility Cork (CRF-C) and University College Cork (UCC) and to explore researcher and public perspectives of implementing a PPI service in UCC.

**Methods:** 78 UCC Researchers and 51 Public representatives from patient support groups across Ireland completed an online survey. Quantitative and qualitative data were analysed.

**Results:** High levels of public involvement were reported by both groups, although qualitative analysis suggested that some respondents misinterpreted PPI as being participants in a research study. The main barriers identified were lack of awareness amongst researchers of PPI and how to access PPI representatives. The public were less convinced than the researchers about the level of impact PPI had on projects. There also appeared to be a contrast in priorities of where the public could contribute most effectively in future studies. Researchers want to involve the public in their research. Both groups were interested in receiving training in PPI, albeit researchers more so than the public.

**Conclusions:** The survey provided a snapshot of how PPI was being integrated in UCC led research projects and highlighted the need for training and support resources. The results will inform a strategy for implementing a PPI service in UCC.

Keywords: patient and public involvement, health research.

Research Forum Abstract 3	Niamh Walsh, RNID, PGDip, MSc, Registered Nurse in Intellectual Disability,
	National University of Ireland Galway
Abstract Title:	Nurses Experiences and Perceptions of Caring for People with Intellectual
	Disability who are Ageing
Author/s:	Niamh Walsh & Dr Catherine Houghton

The aim of this study was to explore the experiences and perceptions of nurses caring for the ageing person with intellectual disability.

The world population is continuing to grow older and live longer and this is also true of the population of individuals with intellectual disability. While there is research examining individuals, who are ageing with an intellectual disability and their family care-givers, there is little research on the experiences and perceptions of nurses caring for ageing people with intellectual disability. This study employed a qualitative description design guided by the VIPS framework (Brooker, 2015). Semi-structured interviews were conducted with ten participants providing nursing care to adults with intellectual disability. Data were analysed using framework analysis managed by QSR NVivo 11.

Analysis revealed key themes within the VIPS framework that described how nurses care for this particular client group. Some of the issues nurses described included how they coped with staffing levels, changes in the ageing person with intellectual disability, how they provided person centred care, the supports they required to provide this care and their education and training needs.

This study highlights that nurses require many supports to care for the ageing person with intellectual disability. Future planning for end-of-life care for this client group needs to be considered. Further research is required to explore person centred models of care for people with intellectual disability who are ageing.

Research Forum Abstract 4	Mary Anne Ryan, RGN/RSCN/RM, BSc Nursing, MComm., MSc., Research Nurse/ PhD student, INFANT Research Centre
Abstract Title:	Consent for routine neonatal procedures: A study of practices in Irish Neonatal Units and how we compare to BAPM guidelines
Author/s:	Mary Anne Ryan; Prof CA Ryan; Prof E Dempsey; Dr Rhona O'Connell.

The legal requirement of consent and its underlying ethical principal of autonomy extends to all forms of investigations and treatment carried out on or behalf of the HSE. There is a requirement that these principles are adapted to all neonatal units where the degree of dialogue with parents will vary depending on the procedure. Whilst it would be impractical to seek consent for all neonatal procedures, parental autonomy implies that parental input/understanding of all actions and how they are in the infant's best interest is required.

The objective of this study was to explore the current practices for obtaining consent for a group of 25 randomly chosen routine neonatal procedures. Participants (CNM's of neonatal units) were asked to indicate if consent for each procedure was assumed, or explicitly consent sought (with or without the support of a signature). A comparison of findings was made with the BAPM guidelines, which for the purpose of this study were identified as 'gold standard'.

Findings include inconsistencies in practices, questionable 'ad hoc' documentation of process of informed consent between neonatal units and little support for 'gold standard' guidelines at times. Significant findings related to consent for the screening of an infant for suspected substance abuse, EEG with video, lumbar puncture, administration of Vitamin K in the neonatal unit, GI imaging and the use of contrast medium, transfer to another unit and fortification of breast milk.

There is a need for the development of Irish guidelines consistent with Irish culture in this current time. Caution must be expressed in ensuring that the requirement for explicit consent is not eroded by an assumption of consent for vulnerable infants in neonatal units.

	Deirdre Hyland, RGN; RM, MSc. Director of Research Nurse Education, RCSI Clinical Re-
Poster Abstract 1	search Centre
Abstract Title:	Good Clinical Practice (GCP) Training: A Positive Force or a Necessary Evil?
Author/s:	Deirdre Hyland, Carole Schilling, Mandy Jackson

**Introduction:** GCP training is mandatory for all researchers involved in drug and device clinical trials, and is increasingly offered to individuals engaged in other types of human subject research. This survey explores attitudes to completion of GCP training and preferences for mode of delivery of repeat (refresher) GCP training.

**Aims & Objectives:** Explore attitudes to attendance before and after GCP course completion; Elicit opinions about course content and delivery; Discover if attendance led to changes in practice; Determine preferences for delivery mechanism of GCP refresher courses

**Methods:** Survey of attendees at GCP training courses in one institution over the preceding 2 years, sent via email where contact details were available (n=245).

**Data Collection:** 10 item questionnaire sent via Survey Monkey. Consent was implied by return of completed questionnaire.

**Findings:** Positive attitudes to completing GCP training; High degree of satisfaction with content and format of currant courses; Preferences for mode of delivery of refresher courses differed between disciplines

**Conclusions:** GCP Training is a Positive Force – not a Necessary Evil! Medical staff experience difficulty finding time to attend training, and express a preference for on-line courses for refresher courses.

**Recommendations:** Continue to deliver on-line and refresher GCP training in classroom setting; Refresher courses to focus on shared revision and updates; Develop on-line refresher course option

**Limitations:** Transitory nature of research posts and medical appointments impacted on contact details and response rate. However, respondents strongly representative of clinical research staff.

Poster Abstract 2	Maeve Kelsey, RGN RM and MSc Clinical Trials Candidate, Clinical Trials Nurse Manager, Clinical Research Facility Cork	
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**Background** Patient and Public Involvement (PPI) in health research is becoming more prevalent worldwide. A formalised and widespread approach to PPI is a relatively new concept in Ireland. Ireland's largest state funding agency is now encouraging researchers to involve patients and the public in research. This is likely to result in increased awareness and participation in PPI.

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**Conclusions:** The survey provided a snapshot of how PPI was being integrated in UCC led research projects and highlighted the need for training and support resources. The results will inform a strategy for implementing a PPI service in UCC.

Keywords: patient and public involvement, health research.

Poster Abstract 3	Anne Marie Cusack, RGN/MPH, Clinical Research Nurse/PhD Candidate, UCC
Abstract Title	The impact of breastfeeding on stress, cognition and the gut microbiota in adults
Author/s	AM Cusack, PJ Kennedy,D Mullins Stanton, JF Cryan , P O'Toole ,TG Dinan.

Humans live in a symbiotic relationship with the gut microbes providing them with a constant source of nutrition, while in return they help us in a variety of ways including enabling optimal brain development and subsequent functioning.

At birth the human brain is highly underdeveloped and the gut is largely sterile. Initial colonization of the gut microbiota during the postnatal stages of central nervous system and brain development plays a key role in later hypothalamic pituitary adrenal axis and immune response to stress, behaviour and cognition. A major source of bacterial colonization of the infant gut is through the bacteria from breast milk, which has been reported to contain more than 700 species.

In this study 30 breast fed males and 30 formula fed males aged 18-24 years were recruited. Neuroendocrine responses to stress were determined by collecting multiple saliva samples for cortisol analysis during the Tier Social Stress Test (TSST) and to measure the cortisol awakening response (CAR). Stool samples were collected to establish the composition of the gut microbiota. The participants completed self –reporting questionnaires to assess stress, depression and anxiety. The Cambridge Neuropsychological Test Automated Battery (CANTAB) was used to assess cognition.

Studies on the gut microbiota may play an important role in advancing the understanding of their role in cognition and stress.

Poster Abstract 4	Joanne Walsh, BSc, H.Dip ICU, RGN, Research Nurse, RCSI Clinical Research Centre
Abstract Title:	Using the Inhaler Compliance Assessment (INCA™) device to provide individualised inhaler education is more effective than standard inhaler education: a case study.
Author/s:	J. Walsh, L. Lombard, MC. Mokoka, E. Mac Hale, C. Carpenter, L.Tompkins, B. Cushen, S. Bergin, N. Thompson, RW. Costello. Clinical Research Centre, RCSI, Dublin

Despite the use of regular inhaled corticosteroids and beta2 agonists, many asthma patients remain uncontrolled, which may be due to poor adherence. We hypothesise that the provision of personalised patient education using data from  $INCA^{T}$  (an audio recording device) will improve adherence.

We report the outcome of a patient randomised to receive INCA<sup>™</sup> directed inhaler education in a multi-centre, prospective, randomised controlled study of uncontrolled asthma (INCA SUN). In this study, patients receive standard inhaler education and then, are randomized to receive either INCA<sup>™</sup> directed inhaler education or standard inhaler education.

Graph 1 shows the patient's inhaler use in the first month following standard education. Incorrect technique (yellow diamonds) was detected in 89% of recordings. The patient was re-educated based on their most common error ('blister present, no inhalation detected') derived from their INCA<sup>™</sup> device. In the following month, the number of technique errors dropped considerably, to only 8% (Graph 2). Additionally the patient achieved improved asthma control and quality of life scores and maintenance therapy was successfully reduced.

In this case study using the INCA<sup>™</sup> device to provide individualised inhaler education was shown to be more effective than standard inhaler education. Please see Figure 1 below

Graph 2

#### Figure 1

Usage Technique

Usage Technique

Usade Correctly
Technique Error

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Poster Abstract 5	David O Riordan, MPharm, MPH, Pharmacovigilance Officer, University College Cork
Abstract Title:	Prevalence of potentially inappropriate prescribing among older European adults: a cross-sectional study.
Author/s:	David O Riordan, Carole Elodie Aubert, Kieran A. Walsh, Anette Van Dorland, Nicolas Rodondi, Robert S. Du Puy, Rosalinde K. E. Poortvliet, Jacobijn Gussekloo, Carol Sinnott, Stephen Byrne, Rose Galvin, J. Wouter Jukema, Simon P. Mooijaart, Christine Baumgartner, Vera McCarthy, Elaine K. Walsh, Tinh-Hai Collet, Olaf M. Dekkers, Manuel R. Blum, Patricia M. Kearney.

**Objectives:** To estimate and compare the prevalence and type of potentially inappropriate prescribing (PIP) and potential prescribing omissions (PPOs) amongst community-dwelling older adults (≥65 years) in three European countries.

**Design:** A secondary analysis of the Thyroid Hormone Replacement for Subclinical Hypothyroidism Trial (TRUST) dataset.

**Participants:** A subset of 51/80 PIP and 22/34 PPOs indicators from the STOPP/START V2 criteria were applied to prescribed medication data for 532/737 trial participants in Ireland, Switzerland and the Netherlands.

**Results>** The overall prevalence of PIP was similar in the Irish (8.7%), Swiss (16.7%) and Dutch (12.5%) participants (p=0.15). The overall prevalence of PPOs was approximately one-quarter in the Swiss (25.3%) and Dutch (24%) participants and lower in the Irish (14%) participants (p=0.04). The hypnotic Z-drugs were the most frequent PIP in Irish participants, (3.5%, n=4), while it was NSAID and oral anticoagulant combination, sulphonylureas with a long duration of action, and benzodiazepines (all 4.3%, n=7) in Swiss, and benzodiazepines (7.1%, n=18) in Dutch participants. The most frequent PPOs in Irish participants were vitamin D and calcium in osteoporosis (3.5%, n=4). In the Swiss and Dutch participants, they were bone anti-resorptive/anabolic therapy in osteoporosis (9.9%, n=16; 8.6%, n=22) respectively. The odds of any PIP after adjusting for age, sex, comorbidities and polypharmacy were ([aOR]) 3.34 (95% CI 1.43-7.78, p<0.01) for Swiss participants and aOR 1.91 (95% CI 0.85-4.28, p=0.12) for Dutch participants compared to Irish participants. The odds of any PPOs were aOR 3.44 (95% CI 1.65-7.17, p<0.01) for Swiss participants and aOR 2.81 (95% CI 1.42-5.60, p<0.01) for Dutch participants compared to Irish participants.

**Conclusions:** The prevalence and type of PIP and PPOs varies considerably among this cohort of community-dwelling older adults. Further research is needed into the impact of system level factors as this has important implications for patient safety, healthcare provision and economic costs.

Poster Abstract 6	Moira Maxwell, MSc, GDip, RNP, BSc(Hons)., Research Nurse, Sligo University Hospital
Abstract Title:	Modifiable Factors Associated With Adherence To Adjuvant Endocrine Therapy Among Breast Cancer Survivors.
Author/s:	Moira Maxwell

**Background:** Adjuvant Endocrine Therapy (AET) reduces risk of breast cancer recurrence and improves overall survival in women diagnosed with early stage hormone receptor positive breast cancer. Adherence levels of < 80% are associated with poorer health outcomes and reduced survival rates. The study aim was to investigate correlations between modifiable factors and AET adherence in a population of women attending a hospital in the North-West of Ireland.

**Methods:** A cross-sectional approach was used to invite all women who met the eligibility criteria. Multiple questionnaires (MMS-8, BMQ-specific and modifiable-factors questionnaire) were posted to the sample population (n = 146). Frequencies, bivariate correlations and ANOVA tests were employed to analyse the data.

**Results:** Among 108 women, 75% (n = 81) were adherent to AET. The factors that promoted adherence were *establishing a medication-taking routine* (r = .299, p = .002), *frequent clinic visits* (r = .227, p = .013) and *support from nurses* (r = .193, p = .050). Factors that mitigated against adherence were *concern* beliefs about AET (r = .272, p = .015), *difficulty in communicating with healthcare providers about their treatment apprehensions.* (r = .261, p = .012), *depression* (r = .261, p = .006), *anxiety* (r = .261, p = .015) and *uncontrolled side effects* (r = .255, p = .015).

**Conclusion:** To optimise the efficiency of AET, adherence to the treatment should be discussed with patients and concerns about the treatment explored. Side effects of AET should be assessed frequently and prompt treatment of them implemented.

Poster Abstract 7	Michelle Barrett, RGN, MSc. Research Nurse, Our Lady's Hospice & Care Services
Abstract Title:	Subjective and Objective Taste & Smell Abnormalities in Treatment-Naïve Cancer Patients
Author/s:	M.Barrett, P.Uí Dhuibhir, N.O'Donoghue, C.Gillham, N.El Beltagi, D.Walsh

**Background:** Taste and smell abnormalities (TSA) in cancer are associated with chemotherapy and radiotherapy or may occur as a result of cancer itself. These abnormalities can increase risk of weight loss and malnutrition as a result of food aversions and reduced dietary intake.

**Aims:** To subjectively and objectively assess taste and smell in newly diagnosed non-head and neck cancer patients; To examine nutritional status in those with taste and smell changes.

**Methods:** Consecutive pre-treatment cancer patients were recruited from radiation oncology clinics in this prospective observational study. A 12-item Taste & Smell Survey evaluated the presence, severity and characteristics of taste and smell dysfunction and the Abridged Patient-Generated Subjective Global Assessment (abPG-SGA) measured nutritional status and symptoms. Burghart Taste Strips and 'Sniffen' Sticks Olfactory Test objectively assessed taste and smell.

**Results**: Thirty newly diagnosed (< 4 months) patients were recruited. Diagnoses included breast cancer (11) gynaecological cancer (14) and colorectal cancer (5). Over half (n=18, 60%) reported subjective taste and/or smell changes or had abnormal objective tests. Of these, eight reported taste and smell changes, four taste only and one smell only. Sixteen (54%) were identified as being at risk of malnutrition (abPG-SGA score  $\geq$  6), of whom 10 also had chemosensory changes. Those with taste and smell changes were at statistically significant risk of malnutrition (p=0.03).

**Conclusions:** Subjective and objective taste & smell testing were well tolerated. The majority of patients had abnormalities before treatment, consistent with a previous study. Subjective assessment identified more abnormalities than objective.

Poster Abstract 8	Mary Anne Ryan, RGN/RSCN/RM, BSc., MComm., MSc . Research Nurse/ PhD student, IN-FANT Research Centre
Abstract Title:	Consent for routine neonatal procedures: A study of practices in Irish Neonatal Units and
	how we compare to BAPM guidelines
Author/s:	Mary Anne Ryan; Prof CA Ryan; Prof E Dempsey; Dr Rhona O'Connell.

The legal requirement of consent and its underlying ethical principal of autonomy extends to all forms of investigations and treatment carried out on or behalf of the HSE. There is a requirement that these principles are adapted to all neonatal units where the degree of dialogue with parents will vary depending on the procedure. Whilst it would be impractical to seek consent for all neonatal procedures, parental autonomy implies that parental input/understanding of all actions and how they are in the infant's best interest is required.

The objective of this study was to explore the current practices for obtaining consent for a group of 25 randomly chosen routine neonatal procedures. Participants (CNM's of neonatal units) were asked to indicate if consent for each procedure was assumed, or explicitly consent sought (with or without the support of a signature). A comparison of findings was made with the BAPM guidelines, which for the purpose of this study were identified as 'gold standard'.

Findings include inconsistencies in practices, questionable 'ad hoc' documentation of process of informed consent between neonatal units and little support for 'gold standard' guidelines at times. Significant findings related to consent for the screening of an infant for suspected substance abuse, EEG with video, lumbar puncture, administration of Vitamin K in the neonatal unit, GI imaging and the use of contrast medium, transfer to another unit and fortification of breast milk.

There is a need for the development of Irish guidelines consistent with Irish culture in this current time. Caution must be expressed in ensuring that the requirement for explicit consent is not eroded by an assumption of consent for vulnerable infants in neonatal units.

Poster Abstract 9	Caroline Cullen, RPN BSc (Hons) MSc., Clinical Research Nurse, Wellcome Trust HRB, Clini-
	cal Research Facility, St. James's Hospital, Dublin 8
Abstract Title:	Immune Response and Social Cognition in Schizophrenia (iRELATE)
Author/s:	Caroline Cullen, Clinical Research Nurse in Mental Health; Niamh Daly Ryan, Psychology Re-
	search Assistant

**Introduction and Background:** European Research Council funded project examining the impact of genes, early life experiences and the immune system on the brain. There is growing evidence that each of these factors are associated with schizophrenia and other mental health problems. In this study we are interested in looking at how a person's environment and genes influence their brain.

Aims/Objectives: The aim of the study is to gain a better understanding of how the environment and genes influence brain structure and function for people living with schizophrenia. A particular focus of the research is on examining whether these effects are related to changes in the immune system. The two questions we want to address in this research are: (1) Does the effect of genes increase illness risk because of changes in our immune system? (2) Does our early social environment (e.g. our childhood relationships) modify this relationship?

**Description of the initiative:** A sample of 150 patients with a diagnosis of schizophrenia/schizoaffective disorder and 250 healthy controls are being recruited to the study from two sites; St. James's Hospital and Galway University Hospital. Currently 24 patients and 76 healthy controls have taken part in the study. Social cognition is measured with neuropsychological and neuroimaging measures. Immune response, DNA and RNA will be analysed using blood samples.

**Outcomes/Results:** Across the two sites, data has been collected on 100 participants, consisting of 24 patients and 76 healthy controls. Based on this data we intend to investigate how genetic and environmental factors combine to influence social cognition.

**Plan for sustainability/future plans:** Throughout the study, at the Dublin site, patients expressed the importance of being involved in research and that it gave them a voice and a sense of empowerment. To explore this further, a qualitative analysis of patients' experiences of the study is being conducted.

Poster Abstract 10	Eilis O'Toole, BSc. Nursing; H Dip Midwifery, MSc. Candidate; Research Nurse, Wellcome
	Trust/HRB Clinical Research Facility, St James's Hospital
Abstract Title:	Developing a Patient & Public Involvement (PPI) Role within a Clinical Research Facility
Author/s:	Eilis O'Toole

Public & Patient Involvement remains a relatively new concept within an Irish health care setting. This Abstract focuses on the development of a PPI role within an Irish CRF.

<u>Purpose:</u> Create a PPI initiative to help inform and engage with both Investigators and patients; Educate Investigators at all career levels regarding PPI; Forge links with Patient support services (IPPOSI/CRCI); Create a partnership with Trinity to support the Implementation of the PPI Ignite strategy; Establish a working relationship at a national and International level with other Clinical Research Facilities

<u>Methods:</u> Create a database of patient support groups; Engagement with existing hospital patient groups; Engage with external patient organisations; Create a PPI training programme for all CRF staff; Assist Investigators organise patient information events; Use Social Media to engage with public via St James's Hospital Twitter/ Facebook; Develop a PPI initiative 'Helping Education & Research Together' (HEART) – This initiative incorporates the above points as key deliverables

<u>The CRF contribution:</u> Dedicated PPI nurse employed (0.5 FTE) to develop & implement effective engagement; A patient feedback form was placed in the CRF building; A display board reported patient feedback and highlighted the CRF listened and changed services based on feedback.

<u>Results:</u> 17 Patient Organisations on database; 50 Investigators & staff trained on PPI; PPI nurse a member of – HRB/CRCI - PPI - WG; A patient & visitor survey was developed to give visitors of the CRF the opportunity to express their thoughts and experiences.

<u>Conclusion:</u> Continuous developments are in progress to further promote and Implement an effective PPI strategy within the CRF. It is clear more education is required to narrow the gap between researcher and patient. The Trinity PPI ignite call will provide a platform at a University level to incorporate a PPI strategy. The role of the PPI lead with the CRF will continue to contribute to a wider national/international network supportive of PPI.



# HRB-CRCI/IRNN Research Nurse/Midwife Support & Development Grant (2017)

The purpose of this HRB-CRCI/IRNN Research Nurse/Midwife Support & Development Grant is to provide current nursing/midwifery members of the IRNN with the opportunity for professional development and engagement through participation at conferences and courses (this can include workshops). By funding or subsidising the cost of attending either the conference or course, the grant allows Research Nurses/Midwives to participate in network building and professional development opportunities, unique learning experiences and educational programmes, to the benefit of individual Research Nurse/Midwife and the wider research nurse/midwife community.

### HRB-CRCI/IRNN Research Nurse/Midwife Support & Development Grant Awardees

The Grant provided support for six research nurses to travel to the UKCRF Conference in Glasgow in July, and three to travel to other international research conferences. It also contributed to course fees for 2 postgraduate programmes for research nurses, as well as funding the IRNN Annual conference and redevelopment of the IRNN Website. Carole Schilling (Quality & Regulatory Affairs Manager, Royal College of Surgeons Ireland) and Maeve Kelsey (Clinical Research Nurse Manager, Clinical Research Facility-Cork) were both awarded funding to attend, and present at, the International Association of Clinical Research Nurses (IACRN) 9<sup>th</sup> Annual Conference in Rhode Island, USA. They describe, below, the opportunities afforded to them through attendance at this conference:

**Carole:** I, along with my colleagues Deirdre Hyland and Mandy Jackson, had submitted a poster to the IACRN on 'Good Clinical Practice (GCP) Training: A Positive Force or a Necessary Evil?'. The grant allowed me to attend the IACRN conference and present our poster, which I am delighted to say won 2<sup>nd</sup> prize!

**Maeve:** I submitted a poster which reports on the results of a questionnaire survey I carried out earlier this year. The main objective was to examine current levels of Patient and Public Involvement (PPI) in research within the Clinical Research Facility Cork (CRF-C) and University College Cork (UCC) and to explore researcher and public perspectives of implementing a PPI service in UCC.

At the IACRN Conference both Carole and Maeve were invited by Dr. Susan Hamer's (Director of Learning and Organisational Development, NIHR, UK) to participate in a plenary session "Using CRN Scope and Standards to Guide Practice: An International Perspective". They, along with research nurses from Japan and China, joined Dr Hamer on the platform, and talked about their roles and how research nursing has evolved over the years. This provided both Carole and Maeve the opportunity to showcase the role of Irish research nurses/midwives, clinical research facilities in Ireland and the IRNN!



# Irish Research Nurses Network Survey on Research Nurses/Midwives in Ireland

Dear Research Nurse/Midwife,

The role of the <u>Irish Research Nurses Network</u> (IRNN) is to provide support and act as a resource for research nurses and midwives in Ireland.

This morning (Friday 17<sup>th</sup> November) we have sent an email inviting all nurses/midwives in Ireland (both Northern Ireland and the Republic of Ireland) who are employed as research staff to complete an anonymised questionnaire on SurveyMonkey. The aim of this questionnaire is to collect some baseline information on the qualifications of research nurses/midwives, what roles they are performing and the types of employment contracts offered to research nurses/midwives. The information provided to us will help the IRNN to continue, and achieve, more supports and resources for nurses and midwives, who undertake research.

Please let us know if you did not get the survey and we will forward the questionnaire to you. This survey is open to all research nurses/ midwives and the strength of the report will come from the number of responses that we get.

### WHY WE DO RESEARCH!







#WhyWeDoResearch is an international twitter campaign aimed at raising research awareness for healthcare professionals, patients and public.

To join in just pose for a photograph holding a placard (there is one in every conference pack!) explaining in simple terms why doing research is important. Tweet your picture using the hashtag #WhyWeDoResearch and the best tweet from the conference will win a #WhyWoDoResearch t-shirt!









Follow @Irish\_RNN on twitter for information on job vacancies, conferences and other events that are of interest to research nurses & midwives and all the latest updates on clinical research.