Health Research Board TMRN Trials Methodology Research Network

CRF-UCC HRB Clinical Research Facility University College Cork

ucc Coláiste na hOllscoile Corcaigh, Éire University College Cork, Ireland

DELIBERATING ETHICS IN TRIALS - SCOPE AND NECESSITY OF ETHICAL OVERSIGHT

2nd May 2024, 13:00 – 17:00 (UTC+1)

Location: Online

Cost: Free

This event is delivered by the HRB-CRF-UCC and the HRB-TMRN

In the discourse on trial ethics, navigating the scope and necessity of ethical oversight emerges as pivotal. This training day delves into the intricate layers of ethical considerations within trials and SWATs, focusing on various trial designs as well as the intersection of ethics and the law. By deliberating on ethics, it endeavours to foster a deeper understanding of how ethical frameworks shape the course of trials and trials methodology research. This will be of interest to ethics committees, trialists, methodologists, funders, health researchers, approvals agencies and anybody working in clinical trials and health related research.

List of speakers below:

Dr Frances Shiely

Prof. Charles Weijer

Prof. Mary Donnelly

Dr Amy Rogers

Dr Cory E. Goldstein

Prof. Shaun Treweek

Dr Hanne Bruhn

Dr Laura MacKey

Dr Suman Prinjha

Dr Daniël Lakens

Register at **https://www.hrb-tmrn.ie/training-education/upcoming-events/**

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SCHEDULE	
13:00 – 13:10	**Dr Frances Shiely** (University College Cork) – Welcome & Opening
Session 1	
13:10 – 13:30	**Dr Daniël Lakens** (Eindhoven University of Technology) *Methodological Review Boards*
13:30 – 13:50	**Dr Laura MacKey** (National Office for Research Ethics Committee) *When it isn't an ethical issue what is it?*
13:50 – 14:10	**Prof. Mary Donnelly** (University College Cork) *Intersection of Ethics and Law in Research Trials*
14:10 – 14:30	**Dr Suman Prinjha** (University of York) *Ethics in Action: Inclusive Trials*
14:30 – 14:50	**Dr Amy Rogers** (University of Dundee) *Ethics of decentralized clinical trials*
14:50 – 15:00	**Short Break**
Session 2	
15:00 – 15:20	**Dr Cory E. Goldstein** (Ottawa Hospital Research Institute) *A framework for the ethical design and conduct of pragmatic trials in health and social care*
15:20 – 15:40	**Prof. Charles Weijer** (University of Western Ontario) *Ethical issues in cluster randomised trials of health and social care*
15:40 – 16:00	**Prof. Shaun Treweek** and **Dr Hanne Bruhn** (University of Aberdeen) *Trial Forge Guidance 5: Ethical issues in SWATs*
16:00 – 16:15	**Short Break**
16:15 – 17:00	Panel Discussion chaired by **Dr Laura MacKey**

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SPEAKERS

Welcome address

Dr Frances Shiely

Frances is a Senior Lecturer in Patient-Focused Research, jointly appointed to the HRB Clinical Research Facility and the School of Public Health. Frances is Director of Education for the HRB CRF-UCC, a senior manager (co-investigator CRF-UCC grant) and is co-PI and UCC lead for the HRB Trials Methodology Research Network. She also leads the Trial Communication Working Group for the MRC-NIHR-TMRP, UK (Medical Research Council-National Institute for Heath and Care Research – Trials Methodology Research Partnership). She is Programme Director for the MSc Clinical Trials (online) which she founded and launched in UCC in September 2018 and supervises all the MSc projects. Frances is a member of the BSc Public Health Sciences Executive Committee which leads on curricular development and the implementation of the BSc Public Health Sciences Degree programme. She is Associate Editor for the journal Trials and is also a member of the Clinical Research Ethics Committee of the Cork Teaching Hospitals (CREC).

Ethical issues in cluster randomised trials of health and social care

Prof. Charles Weijer

University of Western Ontario

Dr. Charles Weijer is Professor of Medicine and Philosophy at Western University in London, Canada. He is a leading expert in the ethics of randomized controlled trials. From 2008 to 2013 Charles co-led a collaboration that produced the first international ethics guidelines for cluster randomized trials. He led the writing team for the World Health Organization guidance on “Ethical Considerations for Health Policy and Systems Research,” published in 2019. In 2020, Charles served on the WHO Working Group for Guidance on Human Challenge Studies in COVID-19. He held the Canada Research Chair in Bioethics from 2005 to 2019, and, in 2016, Charles was elected to the Royal Society of Canada.

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Intersection of ethics and law in research trials

Prof. Mary Donnelly
University College Cork

Mary Donnelly is Professor of Law at University College Cork, Ireland. She publishes widely in health and capacity law. She is Associate Editor of the International Journal of Law and Psychiatry and is a member of the Editorial Board of the Medical Law Review and Medical Law International. She is Chair of the National Research Ethics Committee (CT-C) and Joint-Chair of the HSE National Consent Policy Advisory Group. She was Chair of the Expert Group to develop Codes of Practice for the Assisted Decision-Making (Capacity) Act 2015 and was a member of the National Research Ethics Committee Covid-19 and the Expert Group to Review the Mental Health Act 2001.

Ethics in action: Inclusive trials

Dr Suman Prinjha
University of York

Dr Suman Prinjha is Associate Professor / Senior Research Fellow at University of York where she works within York Trials Unit and NIHR Research Support Service (RSS). She has over 20 years' postdoctoral experience in qualitative research, and is a practising BACP-registered psychotherapist. Suman leads research into health inequalities, ethnic minority health, and using patients' experiences of illness and healthcare to improve care, services and medical education. She is Co-Investigator and EDI theme lead on an NIHR-funded programme grant, leading work on the inclusion of Bangladeshi, Black African and Caribbean communities in a clinical trial on COPD. At the RSS, Suman provides research design support to researchers conducting mixed methods studies and clinical trials, and guidance on qualitative methods, EDI and PPI. She is a member of Diabetes UK Research Steering Group; NIHR RSS EDI committee; NHS England National Healthcare Inequalities Network; and a registered member of British Association for Counselling and Psychotherapy.

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Methodological Review Boards

Dr Daniël Lakens

Eindhoven University of Technology

Daniël Lakens, PhD., is an Associate Professor of Metascience and chair of the Ethical Review Board at the Human-Technology Interaction group at Eindhoven University of Technology in The Netherlands. Lakens' work focuses on improving research methods and statistical inferences in the social sciences. He has published more than 100 peer-reviewed articles, including highly cited papers on effect sizes, sequential analyses, equivalence testing, and sample size justification. He won the Ammodo Science award for fundamental research in the Social Sciences in 2023. He is internationally recognized for his contributions to improve research practices in psychological science. He co-edited the first Registered Reports in science with Brian Nosek in 2014, convinced the Dutch science funder NWO board to create dedicated grants to fund replication studies, and was actively involved in the design and analysis of the Reproducibility Project: Psychology. He received the Leamer-Rosenthal Prize for Open Social Science in the category "Leader in Education" in 2017. His popular massive open online course and accompanying textbook "Improving Your Statistical Inferences" that he has created have been used by tens of thousands of people to improve their statistical skills.

Ethics in action: Inclusive trials

Dr Amy Rogers

University of Dundee

Dr Amy Rogers is a Clinical Lecturer with MEMO Research at the University of Dundee. Having previously worked as a General Practitioner, Amy now researches pragmatic clinical trial methods, focusing on decentralised and healthcare-embedded clinical trials. Recent projects have included the ALL-HEART, TIME, and EVIDENCE trials and the IMI-funded Trials@Home Project. She is also particularly interested in the role of public engagement and involvement in clinical trials.

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A framework for the ethical design and conduct of pragmatic trials in health and social care

Dr Cory E. Goldstein
Ottawa Hospital Research Institute

Dr. Cory Goldstein is a Postdoctoral Fellow with the Clinical Epidemiology Program at the Ottawa Hospital Research Institute and the School of Epidemiology and Public Health at the University of Ottawa. Funded by a Canadian Institutes of Health Research fellowship award, Dr. Goldstein's research lies at the intersection of ethics and clinical trial design with a focus on developing guidance for ethical issues raised by pragmatic trials and cluster randomized trials. He received his MA and PhD in philosophy from Western University, London ON, Canada, and his BA in philosophy from McGill University, Montréal, QC, Canada.

Trial Forge Guidance 5: Ethical issues in SWATs

Prof. Shaun Treweek
University of Aberdeen

Shaun is a health services researcher interested in efficient trial design, particularly around inclusive recruitment and retention and the effective presentation of research evidence. He led the development of the NIHR INCLUDE Ethnicity Framework, a tool to help trialists design inclusive trials and PRECIS-2, a tool to match trial design decisions to what the users of the results need.

He leads an initiative called Trial Forge (http://www.trialforge.org) that aims to be more systematic about how we identify, generate and use research evidence in making trial design, conduct, analysis and reporting decisions. In 2019 Trial Forge won the international Cochrane-REWARD Prize for outstanding work in reducing waste in research. Finally, Shaun is an Editor-in-Chief of the journal Trials.

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Dr Hanne Bruhn

University of Aberdeen & University College Cork

Dr Hanne Bruhn (personal pronouns: she/her/hers). I'm an HRB-TMRN Research Associate and split my time between University College Cork and University of Aberdeen where I work on all things trial methodology with Dr Frances Shiely and Professor Shaun Treweek. I also contribute to Trial Forge and hope to meet many of you at the Trial Forge stand at ICTMC 2024 in Edinburgh.

When it isn't an ethical issue, what is it?

Dr Laura MacKey

National Office for Research Ethics Committee

Laura Mackey is Programme Officer for the National Office for Research Ethics Committees. Her main responsibility is managing applications submitted via the Clinical Trials Information System and liaising with national and European stakeholders involved in this process. Laura originally trained and worked as a chartered physiotherapist and completed a PhD titled 'Chronic Pain Management: What Role Does Health Literacy Have?' in 2016. Following this, she worked as a postdoctoral researcher in the area of Connected Health for supporting longer homestay for people with dementia. Laura brings a wealth of applied research experience as well as a familiarity in treating patients in various healthcare settings. Prior to joining the National Office Laura worked in research policy in a funding agency, focussing in particular on Open Science and Responsible Research Assessment. She is currently Chair of the 'Plain Talking' Working Group – a health literacy initiative supporting the President of EFIC (the European Pain Federation).

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