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Welcome

Welcome to the second edition of the **DIU News Digest**.

We had great feedback from our inaugural edition last month and are excited to build upon that to continue to deliver timely, relevant and helpful news. You've told us you want more of it, so we're planning a communications strategy and activities to support you in your research work.

Above and beyond our usual ethics and governance responsibilities this month, we have been busy preparing a thought-provoking, challenging and collaborative program for ResearchFest over this week and next week. The format is slightly different to previous years and hope that we have your support and engagement as we present a number of sessions from the Melbourne Brain Centre.

The program promises our usual celebration of research activity across our different craft groups, but also a few standout events that will explore our conference theme: Data to decisions – Research in the age of AI.

Highlights include:

- Keynote address by A/Prof Fiona Brownfoot and Dr Deb Karmakar: Humans, machines and the future of care: Research in the age of AI
- 'AI in Action at Austin' Panel facilitated by Prof Paul Johnson featuring Alan Pritchard, A/Prof Natasha Holmes, Prof David Berlowitz and Mozhdeh Dehghani
- In the Spirit of Rinaldo: Honouring Prof Rinaldo Bellomo's profound contribution to global research: A tribute to Prof Rinaldo Bellomo featuring reflections from friends and colleagues

For details of these events, plus the schedule for the broader program, please visit the ResearchFest pages on the Austin website. I look forward to seeing you around campus!

Warm regards,

Heidi

Heidi Gaulke
Director, Operations
Discovery & Innovation Unit
Austin Health

Clinical trials governance: A clear path forward to 2029

The Australian Commission on Safety and Quality in Health Care has extended the use of the Maturity Rating Scale for National Clinical Trials Governance Framework (NCTGF) assessments until 31 December 2029.

This move is to support HSOs and Accrediting Agencies in building capacity to meet all NCTGF requirements. The extension will enable a streamlined transition to the third edition of the National Safety and Quality Health Service (NSQHS) Standards in January 2030.

This extension provides clarity and continuity for clinical trial services nationwide, allowing organisations to focus on progressive improvement and capability building. At Austin Health, this means we have a clear runway to continue embedding research into routine care – strengthening our systems, refining our governance, and growing our impact, especially in the context of our Research Strategy.

The maturity scale – categorising services as initial, growing, or established – offers a structured way to assess and improve how we deliver safe, high-quality clinical trials. It's not just about compliance; it's about transformation.

What does this mean for us?

It's an opportunity to:

- Build on our strengths in clinical trial delivery
- Identify and close gaps in governance and integration
- Support our researchers and clinicians with systems that enable innovation and excellence
- Prepare for the future, including the transition to the third edition of the NSQHS Standards in 2030

As we look ahead, our focus will be on growing and governing research well; not just meeting standards, but setting them.

Let's use this momentum to continue shaping a research culture that's robust, responsive and ready for what's next.

[Find out more here](#)

HREC meeting rescheduled

As many members of our research community will be involved in the activities of ResearchFest next week, we've made the considered decision to reschedule the November HREC meeting.

Please note:

- There will be no meeting on Thursday 6 November

- The next meeting will take place on Thursday 13 November

We understand that many of you are invested in the outcomes of the next HREC meeting and have been planning around existing timelines. While this change may be frustrating, it ensures we can give each event the attention it deserves.

To allow time for outcomes from the 13 November meeting to be processed and shared meaningfully, we kindly ask that you refrain from seeking updates until five business days after the meeting.

Looking ahead:

- Only **two meetings remain for 2025**
- The **first meeting of 2026 will be in February** – we'll share next year's schedule with you as soon as possible

Thank you for your understanding and continued engagement. We look forward to seeing many of you at ResearchFest and again at the November meeting.

[View HREC dates](#)

New URL for Research Architect

Following on from our change of email address back to research@austin.org.au, we've also updated the Research Architect URL to better reflect the management and ownership of our research platform.

The new URL for Research Architect is www.researcharchitect.austin.org.au so please update your bookmarks to reflect the new address.

Your research governance and ethics queries are managed by the Discovery & Innovation Unit at **Austin Health**, so it makes sense that the tools we use live within our IT environment.

We have a redirect in place that will forward any hits on www.researcharchitect.victri.org.au to the Austin domain for the next six months, so you have time to update your address book and get into new habits.

Hopefully things will be a lot clearer now that we're back on a centralised domain.

[Login to Research Architect](#)

Survey results

Thank you to everyone who completed the Research Architect survey last month to tell us what they wanted to see on their dashboard. We're collating the results and working with our developers to incorporate your feedback and create an intuitive and useful dashboard. Stay tuned!

ICH-GCP @ Austin

The TGA recently invited feedback on the proposed annotations to ICH E6(R3) *Guidelines for Good Clinical Practice: Principles and Annex 1* and a 12-months transition period to support implementation.

These annotations aim to align the international guidelines with Australia's legislative framework for clinical trials of medicines and biologicals regulated under the Clinical Trials Notification (CTN) and Clinical Trials Approval (CTA) scheme.

Austin Health aligns with the TGA guidance, that until the adoption of ICH E6 (R3), the ICH E6 (R2) with TGA annotations remains the current version applicable to clinical trials of medicines and biological regulated under the CTN and CTA scheme. GCP training in R3 is not an expectation of any Austin Health researchers and research support staff, until the TGA have adopted ICH E6 (R3), and Austin Health will support a transition period to align with the TGA guidance. Please note this relates to all clinical research including clinical trials.

[Find out more on the TGA website](#)

ResearchFest 2025 Keynote: Humans, Machines and the Future of Care

We're thrilled to kick off ResearchFest 2025 with a keynote address that promises to challenge, inspire and energise.

Join A/Prof Fiona Brownfoot and Dr Debjyoti Karmakar as they explore **Humans, Machines and the Future of Care: Research in the Age of AI** - a compelling look at how emerging technologies are reshaping medicine and research.

This dynamic session will cover:

- The future of care through novel technologies
- Pathways to device development and commercialisation
- The many faces of AI and their applications
- A real-world case study in fetal monitoring (CTG)

A/Prof Brownfoot and Dr Karmakar bring a powerful blend of clinical expertise, scientific rigour and technological innovation. Their work is transforming how we diagnose, monitor and treat women's health conditions - and this keynote sets the tone for the entire ResearchFest program.

Don't miss it - this is the one that sets the stage.

Meet our speakers

	
A/Prof Fiona Brownfoot (MBBS, FRANZCOG, PhD) is a clinician scientist, an obstetrician at the Mercy Hospital for Women and the Epworth Freemasons and a laboratory trained scientist at The University of Melbourne. She leads the Obstetric Diagnostics and Therapeutics Group, a multidisciplinary team of clinicians, scientists and engineers focused on improving outcomes for mothers' and babies'. Fiona's focus is on developing novel devices and using artificial intelligence to improve fetal monitoring and identifying treatments for placental disease. She is translating concepts from laboratory experiment to commercial medical grade device. Fiona has authored over 85 publications in journals including Nature's npj Digital Medicine, BMJ, American journal of Obstetrics and Gynaecology among others and has been the CI on research grants over \$10 million and commercial grants over \$2.6 million. She has received national and international awards for her work and given over 15 invited presentations. Find out more about A/Prof Brownfoot	Dr Debjyoti Karmakar is a Clinician Researcher and Consultant Obstetrician and Gynaecologist at the Mercy Hospital for Women and the University of Melbourne. He has completed subspecialty fellowships in urogynaecology and advanced laparoscopy. He is a member of the Obstetric Diagnostics and Therapeutics Group, a multidisciplinary collaboration between clinicians, scientists, and engineers focused on improving outcomes for women and babies. Deb is proficient in advanced statistical modelling, computer programming (Python), and epidemiological analysis, applying these skills to translational research in women's health. His research leverages data science and artificial intelligence to enhance diagnosis and prediction in fetal monitoring and gynaecological disorders. Find out more about Dr Karmakar