

## Post Award Support

### ABOUT THE INSTITUTE FOR HEALTH DISCOVERY AND INNOVATION

The Institute for Health Discovery and Innovation (IHDI) at the University of Galway is an interdisciplinary, cross college, Institute focused on supporting high quality research activity across the domains of health discovery and innovation research. The Institute's mission is to advance fundamental and applied understanding of disease and drive innovative health solutions. Its vision is to be a world-leading centre for health discovery and innovation through excellence in research, people and partnerships. The Institute prioritises developing talent and fostering internal and external collaboration.

The Institute's thematic structure includes three pillars:

1. Fundamental Discovery
2. Enabling Technologies and Innovation
3. Health-Based Challenges

### POST AWARD SUPPORT/ VALUE PROPOSITION

Post-Award support offers comprehensive assistance to help research teams **manage administrative and operational requirements** with clarity and ease. This includes guidance on **data protection** and **ethics submissions**, **coordinated project management** for kick-off meetings, planning, and progress tracking, as well as **end-to-end help with recruitment activities**. Operational workflows are strengthened through **close collaboration with central university offices**—including Legal, Insurance, Procurement, Innovation (IP), and clinical or regulatory units—to ensure processes are aligned and efficient.

### DESCRIPTION OF RESEARCH PROGRAMME

Research Ireland (Taighde Éireann—Research Ireland) is Research Ireland is the national research and innovation funding agency, formed in 2024 through the merger of Science Foundation Ireland and the Irish Research Council. The Frontiers for the Future Programme (FFP) funds high-risk, high-reward, investigator-led projects, enabling independent researchers to pursue innovative and original scientific questions.

### SELECTED KEY OUTCOMES

- 1 Establishment of a sample collection workflow and team of volunteers. Includes use of an IHDI van to collect human tissue from Merlin Park Hospital, supporting the Coleman team and 3 other research teams on campus.
- 2 DPIA completed and approved in 8 weeks  
Expanding from 1 clinical site to 3 to include international site
- 3 CRDO study registration approved in ~3 months following initial engagement in October 2024, including connections with the legal team to secure data protection agreements and material transfer agreements.
- 4 Data protection agreements secured with externally contracted service providers.

### MEET THE INVESTIGATOR

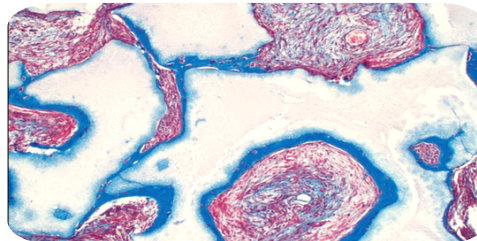
Cynthia Coleman is an Associate Professor in Cellular Manufacturing and Therapy at the University of Galway and is programme director of the award-winning MSc in Cellular Manufacturing & Therapy. Cynthia is also the lead of the IHDI Health Based Challenge: Chronic Musculoskeletal Pathologies. Before moving to Galway, Cynthia was a Senior Scientist in Cell Biology and Pre-Clinical Evaluation at Johnson and Johnson Regenerative Therapeutics (USA) and a Postdoctoral Fellow in Cartilage Biology at the National Institutes of Health (USA).



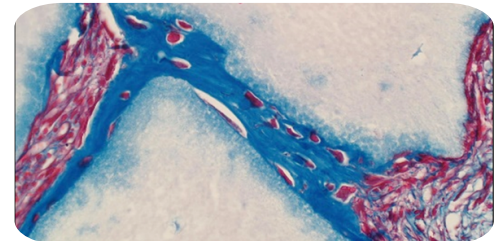
### RESEARCH ACTIVITY

This project aims to understand how type 2 diabetes mellitus (T2DM) impacts adult, human bone-marrow mesenchymal stromal cell (MSC) gene transcription resulting in decreased bone maintenance (homeostasis) and repair. T2DM is a chronic conditions where high blood sugar results from insulin resistance or insufficient insulin production. Some people with T2DM experience changes in their bones, making the bones prone to fracturing. Cynthia leads the Research Ireland-funded Midios project with co-PI Pilib Ó Broin, creating a multidisciplinary, collaborative team of biologists,

bioinformaticians, engineers, molecular biologists and clinicians with the shared goal of identifying the aetiology of diabetes-induced osteopathy and identifying RNA therapies to support bone health and repair. Midios uses primary bone marrow samples to isolate MSCs for in vitro analysis and RNA sequencing alongside paired bone samples imaged with nanoCT to characterize diabetes-induced changes in bone, adipose and vasculature. Finally, the team aims to create an in vitro model of T2DM induced osteopathy to screen molecular therapeutics.



Human Mesenchymal Stem Cells (MSCs) combined with a calcium scaffold in a process of making bone (blue illustrates the formation of bone, white illustrates the calcium scaffold)



### IHDI SUPPORT

- Ethics & Study Setup: Help with preparing ethics applications, including development of Participant Information Leaflets (PILs) and Informed Consent Forms (ICFs), and support with study registration through the Clinical Research and Development Office (CRDO) at University of Galway. The CRDO is a bi-institutional office comprising clinical research management staff from the University of Galway and the HSE West North West Health Region.
- Data Protection Impact Assessment (DPIA) Support: Assistance with developing the DPIA from initial drafting through completion, ensuring the correct institutional process is followed and all essential data elements are accurately captured.

### TESTIMONIAL

*Working with the IHDI Post-Award Support team has been transformative. With them had a genuine teammate enabling navigation of our University governance infrastructure including the CRDO, University Ethics, DPO and legal teams as well as the ethics committees of three hospitals. I have confidence that the research I undertake is in line with University policy and procedures, giving me time and energy to focus on my research. Instead of trying to discover each path forward on my own, they knew who to contact, had template documents and/or examples for inspiration at each step of the journey.*

**Dr Cynthia Coleman**

**Midios Project Lead & IHDI Health Based Challenge: Chronic Musculoskeletal Pathologies Lead**

