University of Maryland School of Medicine

COIRI
Center for Orthopaedics, Injury, and Research Innovation

Issue 1 '24

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A Message from the COIRI Team

More than 5 million Americans sustain an extremity fracture each year, one million of whom require surgical treatment. Despite the impact of these injuries, orthopaedic trauma research is vastly underrepresented in major medical journals, and there are no NIH-sponsored clinical research centers dedicated to improving outcomes after orthopaedic injury.

In response, we have established the Center for Orthopaedics, Injury, and Research Innovation (COIRI). We are dedicated to supporting the expertise of the orthopaedic trauma research community by offering a breadth of clinical research consulting and design services, as well as immersive mentorship opportunities.

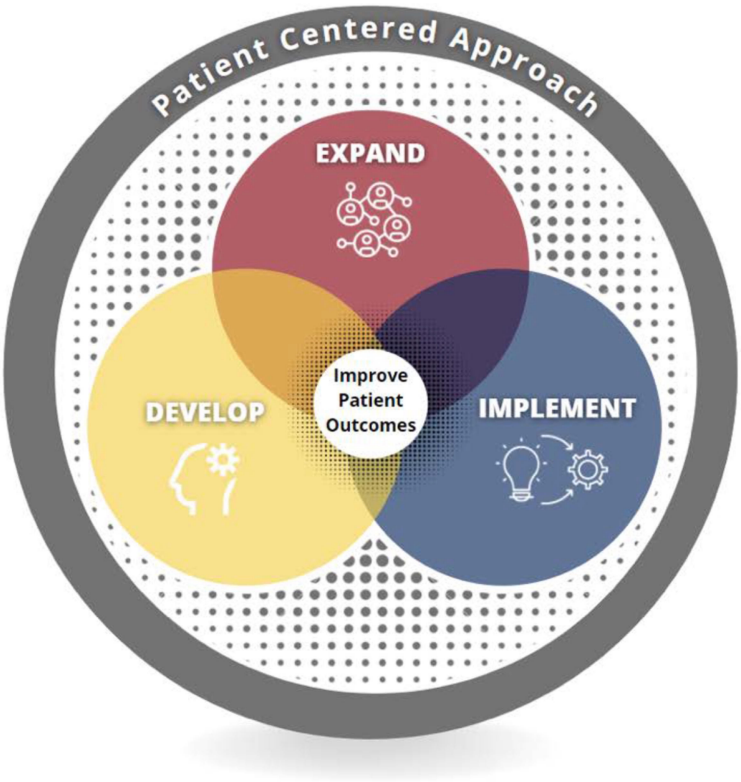
Together, we can make a lasting impact for emerging surgeon-scientists, our patients, and our community.

Sincerely,
Gerard Slobogean, MD MPH
Surgeon Scientist

Nathan O'Hara, PhD MHA
Quantitative Methodologist

Our Mission

Clinicians, research methodologists, and trainees from diverse backgrounds coalesce through the Center. Together, with our patient partners and stakeholders, we strive to:



Aim 1

Expand Research Expertise

Aim 2

Develop New Ideas

Aim 3

Implement Rigorous Methods

1. **Expand** the clinical research methods expertise of the orthopaedic fracture community. To accomplish this, COIRI provides various teaching and mentorship opportunities. One of these avenues for teaching and mentorship is through our early career grant writing workshop at the annual OneAO meeting, or a Research Fellowship at the University of Maryland School of Medicine R Adams Cowley Shock Trauma Center.

2. **Develop** new research ideas capable of improving clinical outcomes. Leveraging access to our large clinical trial data sets and our network of collaborating recruitment hospitals, COIRI users are able to generate research questions that can be scaled from exploratory studies to large multi center clinical trials.

3. **Implement** rigorous research methods for orthopaedic fracture surgery studies. We strive to match COIRI users with the resources they need to execute high-quality research and provide the technical expertise and support required to advance the rigor of projects.

Innovation

- COIRI is developing the first adaptive platform trial designed to compare common treatments for musculoskeletal injury.
- This novel work is funded by a NIAMS R34 planning grant (1R34AR084718).
- The trial will use our most innovative techniques, such as:
    - Win Ratio composite outcome
    - Bayesian stopping rules
    - Adaptive design for interventions to be added and dropped
    - Variable randomization schemes
- This platform is perfect for investigators with a great idea looking to benefit from an established master protocol already funded by the NIH.

Where Evidence and Investigators Grow

Leah Gitajn MD, MS (Orthopaedic Surgeon, Dartmouth-Hitchcock Medical Center)

"Dr. Slobogean's mentorship has helped me to develop into a clinician scientist with funding from both the NIH and the DoD with a research portfolio, including clinical trials and high-impact translational research. Over the past 8 years, Dr. Slobogean has provided direct education and mentorship around grant writing/grantsmanship as well as around building a robust research team through several means including: (1) Biweekly discussions; (2) By including me in his research program as co-investigator and/or on protocol committees; and (3) By inviting me to serve as faculty for research-related courses including AO PEER as well as grant writing and young investigator courses. It is impossible to fully capture in writing how much Dr. Slobogean's mentorship and guidance over the years has impacted my career."

Lucas Marchand, MD (Orthopaedic Surgeon, University of Utah)

"The mentorship provided by COIRI has been a true highlight in my early career and pivotal in my evolution as an academic surgeon. The team at COIRI has been instrumental in my development as a surgeon trialist and researcher, helping me successfully obtain my first national level grant. The partnership with COIRI has proven to be extremely valuable and in many ways positively changed the trajectory of my career. I have learned much about grant writing, clinical trial design, statistical analysis, and trial execution from this team. The value of the many things I have learned from COIRI are priceless, and cannot be learned in a classroom. I look forward to future work with COIRI and the many studies we may run to positively affect Orthopaedic trauma care."

Joseph Patterson, MD (Orthopaedic Surgeon, University of Southern California)

"COIRI's clinician-researcher mentorship program has been instrumental in my progress toward independent investigation. The experiential learning with COIRI has been phenomenal along my path from secondary analysis of COIRI's large trials, assuming larger responsibilities in nascent investigations, and developing my own clinical trial from grant writing through the pilot phase. Committed, consistent mentorship from each of the cores has guided my team as we built an orthopaedic trauma clinical research division from the ground up around these activities."

Roman Natoli, MD, PhD (Orthopaedic Surgeon, Indiana University)

"The team at COIRI not only cares about elevating the science in Orthopedics, but they also care about developing you as an investigator. Their feedback is on point, with appropriate rigor and real-life lessons on logistics and operational aspects of conducting impactful, large-scale, prospective, and meaningful research. It's rare to have a clinician and statistical expert present to weigh in on the discussion at the same time. While simultaneously incorporating cutting edge trial designs, a truly unique feature of their services is being able to take the clinical questions and frame them into hypotheses and specific aims that are precise and testable. This last part is perhaps the most important lesson I have learned from my interaction with COIRI."

Lily Mundy, MD (Plastic Surgeon, Johns Hopkins University)

"I have worked with Drs. Slobogean and O'Hara closely over the past 18 months in developing a multi-center, international RCT as well as a K23 Career Development Award. The mentorship and support that I have received from COIRI has been instrumental in my path to becoming an independently funded researcher. With their guidance, I have grown tremendously in my research knowledge base and grant writing skills, gained confidence in decision making, and expanded how I think about the trajectory of a research project to optimize grant strategy and funding."

Natasha McKibben, MD (Orthopaedic Surgery Resident & Past Research Fellow, Oregon Health & Science University)

"COIRI has been instrumental in my orthopaedic training, offering the research experience, training, and mentorship essential for my development as a future surgeon-scientist. Through COIRI, I have acquired advanced data analysis skills resulting in multiple national presentations and publications as well as success with my own resident research, including a funded OTA resident research grant. Their dedicated mentorship has been invaluable to my profession growth, from providing opportunities to work with large, funded trials to facilitating international research collaborations."

Zachary Working, MD (Orthopaedic Surgeon, Oregon Health & Science University)

"Through our partnership with COIRI, OHSU was able to jump forward and prepare a professional and competitive DOD application on our first offering. In our initial work stages COIRI was instrumental in study design, leading to budgetary logistics, followed by vetting grant targets. The team was side-by-side with us through the proposal and full application stages, leveraging their extensive granting and trial experience into strategic advice. We could not have delivered on the promise of our pilot trial without their partnership."

The Power of Collaboration

COIRI Accomplishments

- An active funding portfolio supported by the US Department of Defense (DoD), Patient Centered Outcomes Research Institute (PCORI), National Institutes of Health (NIH), and Agency for Healthcare Research and Quality (AHRQ).
- Contributed to the design and analysis of multi-center clinical trials led by METRC and McMaster University:
    - PREP-IT (n=10,123), $14 million jointly funded by PCORI & DoD
        - Lancet. 2022 Oct 15;400(10360):1334–44
        - NEJM. 2024 Feb 1; 390(5):409-20
    - PREVENT CLOT (n=12,211), $11 million funded by PCORI
        - NEJM. 2023 Jan 19;388(3):203-13.
- Rapidly expanding cohort of early career investigators awarded or submitting federal grants > $2 million per trial.

COIRI Research Summit

- What is a COIRI Research Summit?
    - An invitation from an early career investigator or Department to host a 1-2 day in-person development meeting.
    - We bring our team to your institution with a focus on conversation & idea sharing.
    - Grounded in our 3 aims, the time spent together focuses on:
        - Expanding the research expertise of your team.
        - Developing your research ideas into fundable & feasible projects.
        - Implementing rigorous and novel research methods to increase the impact and likelihood of successful projects.

Case example: Oregon Health & Science University

- 1.5-day session with OHSU faculty investigators, residents, research coordinators, and COIRI team
- COIRI presentations:
    - Grant tips
    - Bayesian Analyses
    - Novel Apple health metrics
- OHSU Presentations:
    - Resident research projects
    - New trial ideas
- Highlighted results:
    - Cancer group resubmitted foundation grant within 3 months (Awarded $1M)
    - Multiple PI model created for mid-career and graduating resident researchers to co-manage large RCT
    - Design and full-service support of $5M DoD CDMRP grant proposal submitted within 4 months
    - Facilitated introductions for emerging investigators to work with European research experts in causal inference

Contact Us

If you would like to collaborate, have a project idea, or would like to employ our services, please complete the COIRI Intake Form by scanning the QR code. Our **Linkedin & Twitter channels** can also be accessed via this code.