School of Medicine

Clinical Research

OFFICE OF CLINICAL RESEARCH

February 2025

OCR Welcomes Dr. McGill

James (Jim) McGill, MD recently joined IU Health as the Executive Director of Clinical Research. He will work closely with both IU Health and IU School of Medicine clinical research teams to develop strategy and enable clinical research growth across our organizations. Dr. McGill left a lengthy career at Eli Lilly and Company to lead our research team.

IU Health Transitions to ENFit

IU Health has been transitioning to ENFit, a standardized connector system designed for enteral feeding devices. It was developed to reduce the risk of misconnections between different types of medical tubing, which can lead to serious patient harm. IU Health implemented a rolling go-live for implementing ENFit. University Hospital was scheduled to go live on February 18th. Methodist Hospital's go live date was earlier in the week on February 25th.

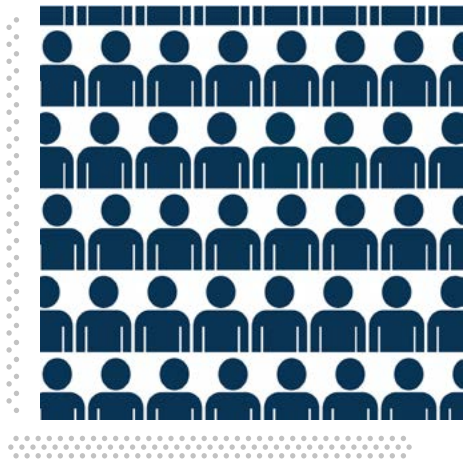
Here are some key points about ENFit:

- Universal Standard: ENFit connectors are part of a universal standard (ISO 80369-3) that ensures only enteral devices can connect to each other.
- Safety: The design includes a reverse luer-lock mechanism, which helps prevent accidental disconnections and ensures a secure fit.
- Transition: There are transition connectors available to bridge the gap between non-ENFit and ENFit devices, making it easier for healthcare providers to switch to the new system.
- Global Adoption: ENFit is supported by organizations like the Global Enteral Device Supplier Association (GEDSA), which promotes its adoption to enhance patient safety

To learn more, please sign up for the Oracle Learn module titled, "ENFit® Conversion (30 min)." The ID Course number is "SWNPCS20220401C."

For more information about EnFit, please see *stayconnected.org*. There are multiple resources available on this website.

If you have a study patient currently receiving oral medications via an enteral feeding device (Gastric tube, etc.) reach out to *IDS@iuhealth.org* to discuss the transition and how it affects your study patients. IDS will continue to use up all currently available oral syringes for oral doses, but once those run out, they will transition to the ENFit syringes. There must be communication between IDS and the study team for any patients with an enteral device to ensure that we know what type of tubing the patient has. IDS can supply the proper adaptors for the patients in the event they have a legacy tube (without the ENFit connection).



OnCore Summary Accrual

Enhanced Reporting Requirements

Summary Accrual is a feature within OnCore that requires periodic updates on the total number of participants enrolled in a clinical study. This option is available for certain studies that do not require individual registration of participants.

All researchers who plan to conduct preclinical or clinical research that utilizes resources from Indiana University (i.e., facilities, employees, funding) or IU Health patients, patient records, facilities, or sanctioning, must document accrual.

Requests to access the Summary Accrual function must be submitted to the Office of Clinical Research for approval.

Recent enhancements have been implemented regarding the data required for summary accrual entry, and these updates have now been communicated to all pertinent stakeholders. In addition to the mandatory monthly reporting of study enrollments, it is necessary to include participants' gender, age group, ethnicity, and race when updating accruals in OnCore. These enhancements will facilitate more comprehensive reporting of the demographic characteristics of clinical research participants. Certain exceptions may be permitted.

For details on which studies qualify for Summary Accrual in OnCore as well as the data required for Summary Accrual entry, please visit the *Office of Clinical Research* website and the OnCore quick reference guide *How to Enter: Summary Accrual*. (Note: The reference guide requires an IU log in.)

OCR and CTSI Clinical Research Pillar

2025 Objectives and Priorities

IU Health & IU School of Medicine Enterprise Goals

We will engage with and support our IU School of Medicine (IUSM) and IU Health partners and stakeholders to optimize and expand clinical research capacity and capability to accelerate progress in achieving the enterprise goal of 6% of IU Health patients consenting to participate in a clinical study.

OCR Systems, Contracts, Coverage Analysis

In partnership with the Office for Research Administration (ORA) and the Enterprise Clinical Research Operations (ECRO), we will conduct a comprehensive six-sigma project to review current workflows while evaluating customer and stakeholder communications, interactions, and associated processes to reduce repetition, comprehensively streamline, and optimize to meet customer needs.

Clinical Study Status Tracking

We aim to automate the process for clinical study status tracking and make the information readily available to relevant functions as well as key stakeholders and customers.

Clinical Study Portfolio Prioritization and Metrics

We will work with the IU School of Medicine-IU Health Institutes and IUSM department leaders to define clinical study portfolio prioritization criteria, along with assessing key performance indicators to monitor clinical study execution.

Research Coordinator Training and Education Programs and Personnel Development

We plan to evaluate existing training and education programs and provide more resources to ensure the programs are robust as well as effectively developed and deployed.

OCR Personnel Development

We will consistently focus on career and personal development goals for personnel leveraging IU/IUSM performance management objectives-setting and development goals process, while utilizing training and development resources as well as identifying cross-training opportunities.

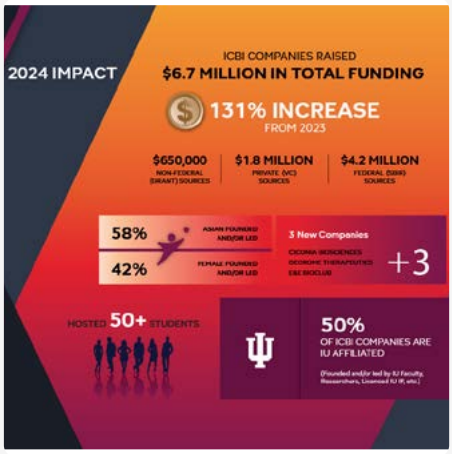
Communication Priorities

We will prioritize effective communication with key customers, stakeholders and clinical research personnel. Important areas of focus include the status of planning for clinical research in the new hospital i.e., clinical research space pillar progress and plans; OCR website content and utilization; progress toward achieving the IU Health and IUSM enterprise goal 6 % of IU Health patients consenting to participate in a clinical study and effectively enable the IU School of Medicine-IU Health Institutes and IUSM department clinical research teams to achieve study goals and priorities.

News from the ICBI

ICBI releases 2024 Annual Report

View the Annual Report ❯



Have you been wondering what the Indiana Center for Biomedical Innovation does? View the latest Annual Report to see a recap of the ICBI's last year, its impact on the community, and its member companies.

Lab camp to prepare for 57th Chemistry Olympial to be held at ICBI

Learn more ❯

The International Chemistry Olympiad (IChO) is an annual competition for the world's most talented chemistry students at the secondary school level. The lab camp at ICBI, which takes place the 3rd week of April, will provide students with hands-on laboratory techniques training and mock exams to excel in the IChO's practical exams and give them a competitive edge on the international stage. Each country around the world sends a team of four students.

IU School of Medicine
340 W 10th St
Indianapolis, IN 46202