

Undergraduate Interdisciplinary Certificate in Clinical Research Management – Expanding the research workforce while enhancing education



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Background

- In mid-2018, Eli Lilly expanded their local clinical research staff, adding 100 positions. Within 4 months, the IU Simon Cancer Center lost ~20% of their research professional workforce, impacting the ability to conduct critical clinical trials.
- Other IU research divisions experienced similar losses.

Objectives

- Expanding the available research workforce.
- Reduce the cost of staff turnover by providing foundational training to future job candidates.
- Introduce students to a new potential career path.

Methods

- Collaborate with IUPUI School of Health of Human Science to develop undergraduate certificate program
- Research existing programs
- Compile job data
- Recruit industry partners
- Gain support from institutional leadership

Results

- Learning objectives defined and mapped to existing courses

Learning Objective	Course	Credits
Critically evaluate study design and data collection strategies	HIM-M 425 Quantitative Analysis of Health Information	3
Identify and manage potential conflicts of interest in research	HSC-W 314 Ethics and Health Professionals	3
Develop a working knowledge of bioethical principles that guide clinical research		
Explain the IRB review and approval process		
Define and differentiate studies requiring exempt, expedited, and full-board review		
List major principles needed to ensure data safety and security.	INFO-I 330 Legal and Social Informatics of Security	3
Describe the security procedures needed to ensure compliance with HIPPA and FERPA	INFO-B 483 Security and Privacy Policies and Regulations for Healthcare	3
Participate in subject consent, screening, and eligibility verification	KINE-P499 Undergraduate Research in Physical Education	3

- Reviewed programs at eight other institutions (none in Indiana)
- Certificate supports ACRP or SOCRA certification
- Job growth projected at ~10% annually
- **Pre-proposal approved by IUPUI and supported by Eli Lilly**

Discussion

- We realized the win-win, with the certificate program introducing students to a new potential career path while hopefully reducing the cost of staff turnover for IU SOM research units

Next Steps

- Full proposal undergoing final revisions with goal to launch program spring 2021
- Developing companion internship in the IUSCCC Clinical Trials Office
- Participate in IUPUI Career Fairs
- Track progress and future careers of candidates

Collaborators

- IUPUI Health and Human Sciences
- Dr. Rafael Bahamonde - Dean
 - Dr. Mark Urtel – Chair Kinesiology
 - Laura Masterson – Director of Student Success IUSCCC
 - Mario Contreras – CTO Administrator
 - Sandra Milescu
ELAM
 - Deborah DeWaay