COMMISSION FOR HIGHER EDUCATION
Thursday, November 12, 2020

BUSINESS ITEM D-1: **Doctor of Philosophy in Regenerative Medicine and Technologies to be offered by Indiana University at Indiana University Purdue University Indianapolis**

Staff Recommendation

That the Commission for Higher Education approve the Doctor of Philosophy in Regenerative Medicine and Technologies to be offered by Indiana University at Indiana University Purdue University Indianapolis in accordance with the background discussion in this agenda item and the Program Description.

Background

Review Process. The Academic Affairs and Quality Committee discussed this program at its October 26, 2020 meeting and reacted favorably to the proposal.

Similar Programs in Indiana. In the ***independent*** or private, non-profit sector, no institution offers a research/scholarship doctoral program in regenerative medicine.

In the ***proprietary*** or private, for-profit sector, no institution offers a research/scholarship doctoral program in regenerative medicine.

Within the ***public*** sector, no institution offers a research/scholarship doctoral program in regenerative medicine.

Background. The proposed Doctor of Philosophy (Ph.D.) in Regenerative Medicine and Technologies would be offered through the Indiana Center for Regenerative Medicine and Engineering, which is housed in Department of Surgery in the Indiana University School of Medicine at Indiana University Purdue University Indianapolis. Regenerative medicine focuses on replacing or regenerating human cells, tissues, or organs that have been damaged by disease, trauma, or congenital issues to establish, restore, or enhance normal function.

Core courses in the curriculum (see Appendix 10) will cover topics such as: biomaterials and therapeutics used in regenerative medicine, including advances made in nano-materials for the delivery of therapeutics; the development and manufacturing of regenerative medicine products; multi-disciplinary collaboration and technology integration; and the

responsible conduct of research, including ethical problems. The core curriculum also includes an industry/clinical internship.

Students likely to enroll in the program include practicing M.D.s interested in strengthening their research credentials, students admitted directly into the program with bachelor's or master's degrees, and U.S. servicemembers with bachelor's degrees interested in military medicine. The program proposal has received strong industry endorsement, with letters of support received from major employers, including:

- Cook Biotech
- Eli Lilly and Company
- BioCrossroads
- Roache Diagnostics
- Techshot, Inc.
- Ossium Health, Inc.

Supporting Document

Program Description – Ph.D. Program in Regenerative Medicine and Technologies

Program Description

PhD Program in Regenerative Medicine and Technologies
Indiana Center for Regenerative Medicine and Engineering
Department of Surgery, IU School of Medicine

1. Characteristics of the Program

a. Campus(es) Offering Program: Indiana University School of Medicine, Indianapolis
b. Scope of Delivery (Specific Sites or Statewide): Indiana University School of Medicine, Indianapolis
c. Mode of Delivery (Classroom, Blended, or Online): Blended (primarily classroom, less than 30% online)
d. Other Delivery Aspects (Co-ops, Internships, Clinicals, Practica, etc.): Internship
e. Academic Unit(s) Offering Program: Department of Surgery, Indiana Center for Regenerative Medicine and Engineering

2. Rationale for the Program

a. Institutional Rationale (Alignment with Institutional Mission and Strengths)

The proposed PhD program in Regenerative Medicine and Technologies (RMAT) will be offered by the Indiana Center for Regenerative Medicine and Engineering (ICRME), Department of Surgery, IU School of Medicine, at the Indiana University Purdue University Indianapolis (IUPUI). Regenerative medicine is a field that involves replacing or regenerating human cells, tissues, or organs to establish, restore, or enhance normal function.

The RMAT graduate degree program will contribute to the mission of Indiana University by serving the citizens of Indiana, the United States, and the world through dissemination of knowledge which prepares our graduates to succeed as leaders, professionals, informed consumers, responsible citizens, and lifelong learners. One of the primary missions that the University fulfills for the State of Indiana and the nation is the graduate-level research intensive education of trainees to enter the workforce and to advance the State's economic prosperity, ecological stewardship and social well-being. The proposed RMAT graduate program is consistent with Indiana University's role as a major research university and as one of the nation's growing regional and national forces in engineering technology.

The creation of graduate degrees in RMAT will contribute to meeting the strategic goals of the University by providing affordable, accessible, and structured educational programs in translational research. The formalized degree program will provide vital and transformative STEM education that will provide world changing research opportunities to graduate students.

The program can build upon the strengths of Indiana University by leveraging resources and space from established schools like School of Medicine, School of Engineering and School of Science at Indiana University, thus potential synergy and collaborations exist with for the RMAT graduate degree program.

- **Prospective student population to be targeted**

  The program will be targeted to prospective students seeking doctoral degrees to pursue careers in Regenerative Medicine and Technology from the following sources:

  - Undergraduates in medicine/life sciences and engineering sciences
  - Practicing Medical Doctors interested in strengthening their research credentials through a PhD Program
  - Prospective PhD students admitted directly into the RMAT graduate program, either by recruitment from undergraduate/masters programs or transfers from other programs. Note that this program is separate from the IU Biomedical Gateway (IBMG) Program for PhD Study.
  - US military service personnel with a bachelor's degree interested in Military Medicine,

  The program is open for practicing Medical Doctors. It will help the physician who wish to undertake research by keeping a formal avenue open to pursue it. There are instances in past where this has happened. The courses are hosted by the Department of Surgery and the subject area has translational application (bench to bedside) and hence is more relevant and appealing to this non-traditional cohort of trainees.

b. State Rationale "Reaching Higher, Achieving More calls for institutions to develop programs that advance the specific mission and strengths of each institution."

The 21st century Cures Act provided support from US Congress for personalized medicine and laid emphasis on regenerative medicine. The act enabled Regenerative Medicine Advanced Therapy program and authority to FDA towards a new expedited option to streamline the process of approval of therapeutics involving emergent regenerative medicine approaches as these are different from conventional drug and medical device approvals. Till date, 30 firms/products have received RMAT designation from the FDA. Recent examples include Humacyl by Humacyte (acellular vessel for hemodialysis during kidney failure), KB103 by Krystal Biotech (for treating dystrophic epidermolysis bullosa), and SB-525 by Pfizer & Sangamo Therapeutics (for treating hemophilia A).

The program addresses the priories of degree completion, productivity and quality as reflected in *Reaching Higher, Achieving More*. Citizens with advanced degrees earn higher salaries and contribute more to local and regional economic prosperity. Reaching Higher, Achieving More calls for institutions to develop programs that advance the specific mission and strengths of each institution. The proposed RMAT graduate degree program will have a significant positive impact on other graduate programs at IUPUI through the expansion of graduate course electives for other programs and by the development of a minor track of course work that trainees within the IU Graduate School could pursue. The unique interdisciplinary structure in which the core disciplines of medicine and engineering will foster greater interaction and collaboration among the Schools and Departments of the IUPUI campus.

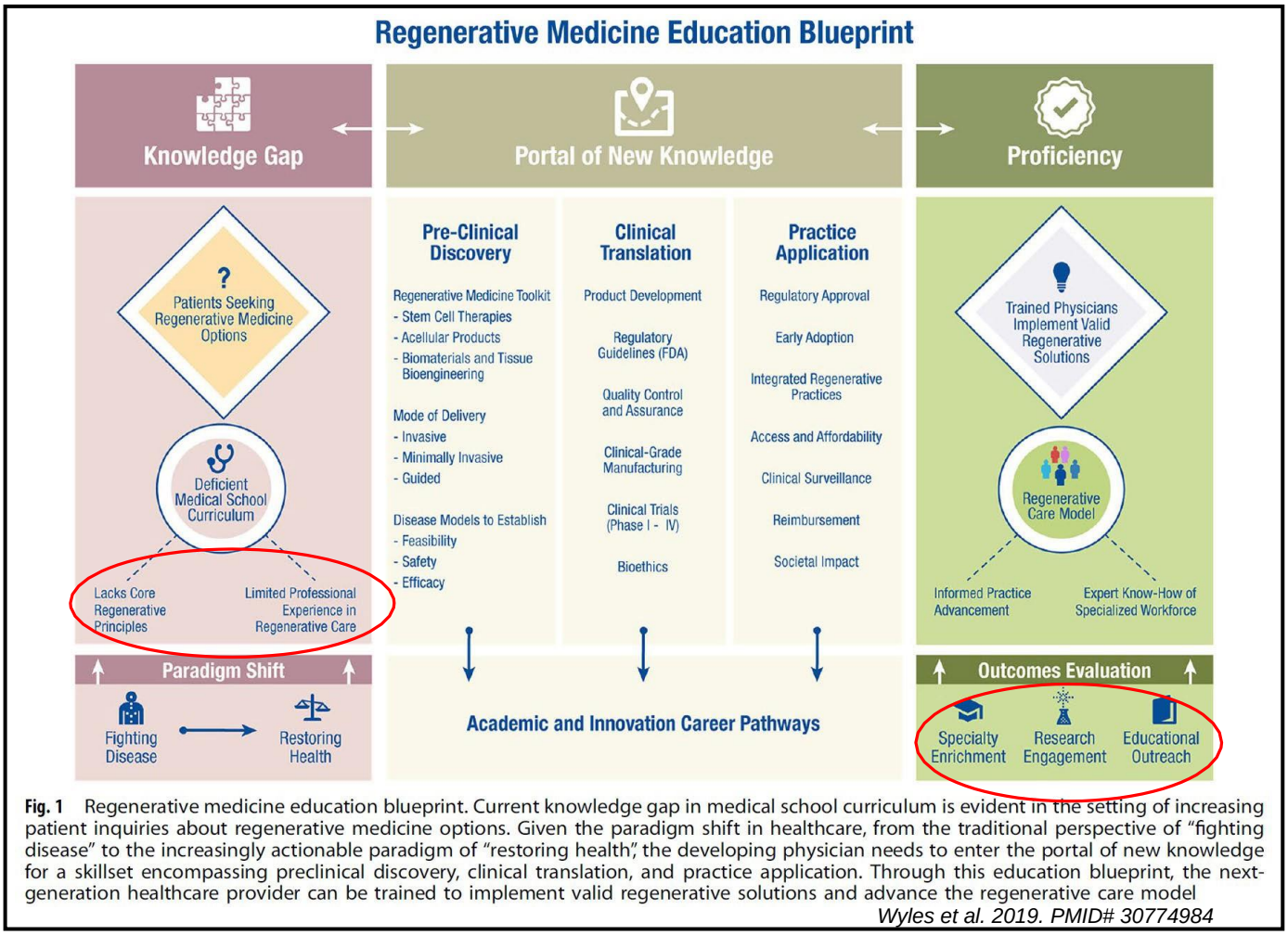


Fig. 1 Regenerative medicine education blueprint. Current knowledge gap in medical school curriculum is evident in the setting of increasing patient inquiries about regenerative medicine options. Given the paradigm shift in healthcare, from the traditional perspective of "fighting disease" to the increasingly actionable paradigm of "restoring health", the developing physician needs to enter the portal of new knowledge for a skillset encompassing preclinical discovery, clinical translation, and practice application. Through this education blueprint, the next-generation healthcare provider can be trained to implement valid regenerative solutions and advance the regenerative care model

Wyles et al. 2019. PMID# 30774984

c. Evidence of Labor Market Need

i. National, State, or Regional Need

Advance Regenerative Manufacturing Institute (ARMI), funded by the White House in 2016, is a joint initiative of federal government and industry towards advancing Regenerative Medicine. It recognizes deficit in workforce development as a major barrier in the growth of Regenerative Medicine. With this background, ICRME, is proposing the creation of this new PhD program with an aim to develop workforce in the field of regenerative medicine and technology for the state of Indiana. The emphasis on technologies in this program is meant to train scholars in regenerative medicine based innovations, regulatory science and supply chain management. The program will be unique owing to its industry and academia interface. The curriculum will emphasize areas such as applied sciences & technology, manufacturing, regulatory compliance, military medicine, industrial and clinical internship. The rigorous curriculum and innovative research undertaken by the candidates will not only meet the high standards associated with a PhD degree from Indiana University, but also position the graduates for an emerging and expanding job market. Market research in 2017 by Polaris valued the global market for regenerative medicine at $14.76 billion, and this market is expected to expand to nearly $79.23 billion by 2026. Regenerative medicine is predicted to attain favorable growth prospects on the back of the positive impact caused by swelling investments from biopharmaceutical and pharmaceutical companies for conducting research tissue replacement and personalized medicine. Government policies favoring regenerative medicine is one of the major reasons for this remarkable market growth. ARMI was created with federal support of $80M and industry support of $214M to bridge the gap between early scientific research and later-stage product development in regenerative medicine. A key focus of ARMI is workforce development to advance critical technologies and enable large-scale biological manufacturing effort. The state of Indiana is home to serveral companies with a focus on regenerative medicine, including Cook Regentec, Cook Biotech, Lilly, and Ossium Health. Cook Biotech has offered their support and are keen to hire graduates emerging from our program. Graduates are thus expected to have good job prospects in Indiana. The field of Regenerative medicine is bringing a paradigm shift to the healthcare industry. Consequently, developing dedicated graduate programs to meet this unmet need is both timely and impactful. This strategy was highlighted in a recently article by Wyles *et al.* in the journal Regenerative Medicine (Nature publishing group).

ii. Preparation for Graduate Programs or Other Benefits

The best students earning a PhD degree from the RMAT graduate degree program will be prepared and qualified to enter a Regenerative Medicine research program at IUPUI or any other top like Harvard Medical School, Department of Defense institutions, Indiana based industries (Eli Lilly, Roche, BioCrossroads, etc) or national regenerative medicine based industries (Smith & Nephew, Vomaris inc, etc).

iii. Summary of Indiana DWD and/or U.S. Department of Labor Data

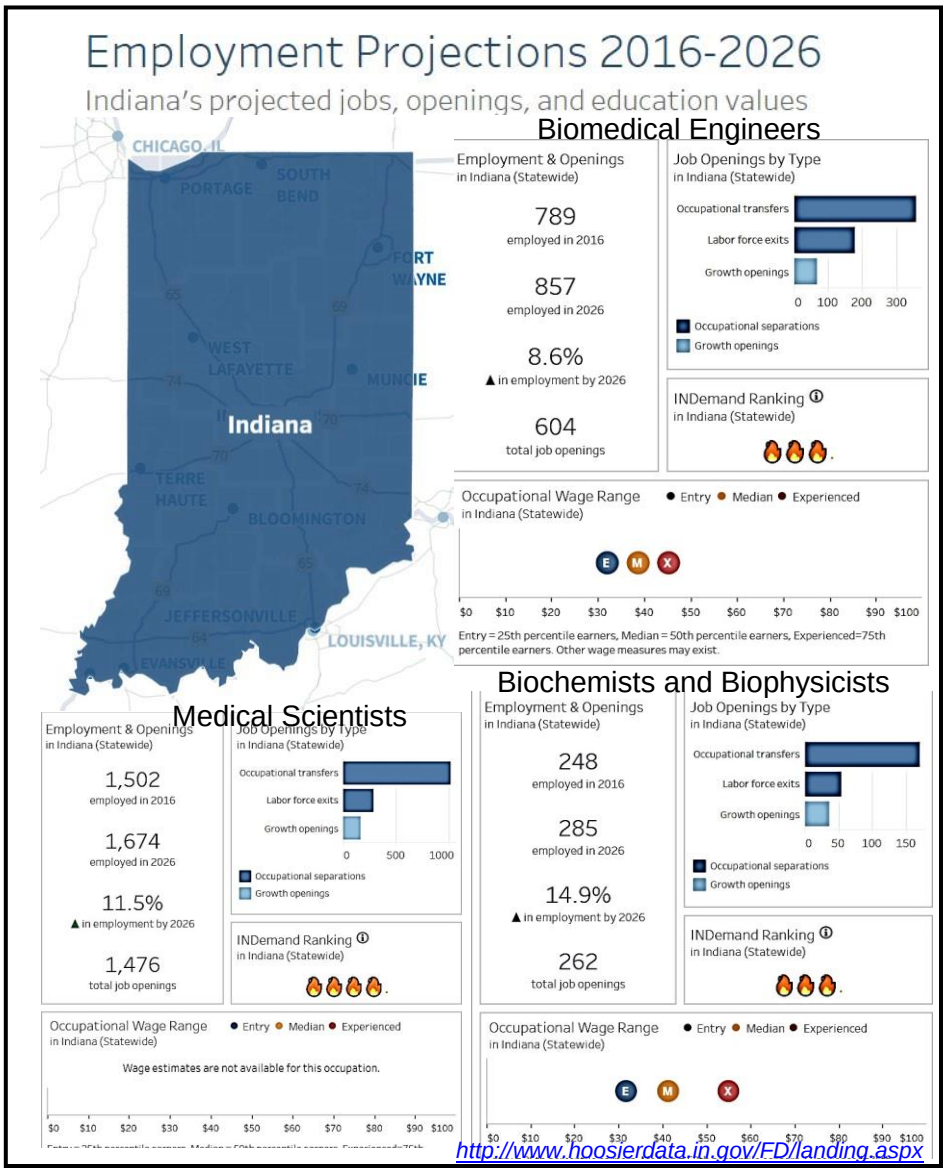
The labor market demand for new RMAT graduates is strong. The Indiana Department of Workforce Development forecasts the rate of growth for employment in fields which will employ graduates from RMAT at 8.6% for Biomedical Engineers, 11.5% for Medical Scientists and 14.9% for Biochemists and Biophysicists (Table).

• Summarize any national, state, or regional studies that address the labor market need for the program.

The national labor market has

v. Surveys of Employers or Students and Analyses of Job Postings

Job posting from Techshot Inc and Ossium Health has been attached as **Appendix 1**



Appendix 2: Letters of Support

• *Summarize, by source, the letters received in support of the program.*

- Dean, Purdue School of Engineering
- Dean, School of Medicine
- Director, Precision Health Initiative Program
- Chair, Department of Surgery
- Chair, Department of Endodontics
- Cook Biotech– Umesh Patel, President Cook Biotech
- Eli Lilly – William Heath, SVP Molecule Innovation Hub
- BioCrossroads – Patricia Martin – President& CEO
- Roche Diagnostics - Ketan Paranjape, Vice President
- Techshot, Inc. - Rich Boling, VP, Corporate Advancement
- Ossium Health Inc– Erik Woods, President

3. Cost of and Support for the Program
a. Costs

i. Faculty and Staff

Teaching faculties

- SURG-R711
  Dr. Savita Khanna, Associate Professor, ICRME (Course Director)
  Dr. Dan Spandau, Assistant Professor, IUSM
  Dr. Troy Markel, Associate Professor, IUSM
  Dr. Lava Raj Timsina, Assistant Professor, IUSM

- SURG-R712
  Dr. Sashwati Roy, Professor, ICRME (Course Director)
  Dr. Mervin C Yoder, Professor & Director Emeritus, ICRME
  Dr. Mangilal Agarwal, Professor and Director of the INDI
  Dr. Terry Loghmani, Associate Professor, IU
  Dr. Reuben Kapur, Professor, IUSM
  Dr. Yi Xuan, Assistant Professor, ICRME

- SURG-R791
  Dr. Chandan K. Sen, Professor & Director, ICRME (Course Director)
  Dr. Mithun Sinha, Assistant Professor, ICRME
  Dr. Subhadip Ghatak, Assistant Professor, ICRME

- SURG-R720
  Dr. Sashwati Roy, Professor, ICRME (Course Director)

- SURG-R780
  Dr. Chandan K. Sen, Professor & Director, ICRME (Course Director)
  Dr. Terry Loghmani, Associate Professor, IU
  Dr. Sarath Jangha, Associate Professor, IUSIC
  Dr. Todd O McKinley, Professor, IUSM

- GRDM-G505
  Dr. Margaret Bauer, Department of Microbiology and Immunology

- GRDM-G507
  Dr. Joseph Bidwell, Department of Anatomy, Cell Biology, and Physiology;
  Dr. Brittney-Shea Herbert, Department of Medical and Molecular Genetics

- GRDM-G661
  Dr. Kurt Kronke, Indiana CTSI

Drs. Sen, Roy and Khanna had extensive teaching and training graduate students at The Ohio State University. Drs. Timsina, Agarwal, Markel, Bauer, Bidwell, Herbert and Kronke have extensive teaching experience in IUPUI campus
Drs. Sinha, Ghatak and Xuan will act as assistants to senior faculties and will facilitate smooth completion of the courses. Drs. Sinha and Ghatak have taken classes and served as teaching assistants at Ohio State

Research mentors (Faculties who are NIH funded and can act as prospective mentors)

Dr. Chandan K Sen
Dr. Sashwati Roy
Dr. Gayle Gordillo
Dr. Mangilal Agarwal
Dr. Dan Spandau
Dr. Savita Khanna
Dr. Troy Markel
Dr. Michael Murphy
Dr. Teresa Bell
Dr. Teresa Zimmers
Dr. Mark Rodefeld

ii. Facilities

The proposed graduate program will be supported by the learning and teaching resources that exist at Indiana Center for Regenerative Medicine and Engineering, Department of Surgery at IUPUI campus. ICRME is located at the fourth floor of Medical Research Library Building with over 10,000 square feet of research and support space.

iii. Other Capital Costs (e.g. Equipment)

Equipment and other capital costs will be met through competitive funding programs for large scale equipment or with resources that are part of ICRME and Department of Surgery.

b. Support

i. Nature of Support (New, Existing, or Reallocated) The cost associated with developing the program at the proposed five PhD s for a period of five years is estimated to be ~ $1.9 million. The details are tabulated below. An initial support of $500,000 is committed by Precision Health Initiative (PHI) of the Indiana University School of Medicine. Dr. Yi Xuan from Birck Nanotechnology Center is recently recruited as new faculty at ICRME. Further, the program will draw on existing researcher faculty at the IUPUI campus. Proposed faculty list is given below.

		Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Total**
Staff	Graduate Advisor/ Coordinator (25% FTE) - Faculty	$50,000	$51,500	$53,045	$54,636	$56,275	**$265,456**
	Support Staff-Admission (50% FTE)	$27,500	$28,325	$29,175	$30,050	$30,952	**$146,002**
	Support Staff-Progression (100% FTE)	$55,000	$56,650	$58,350	$60,101	$61,904	**$292,004**
Student	5 PhD Students	$215,000	$215,000	$215,000	$215,000	$215,000	**$1,075,000**
	Annual Events/Travel Grants	$20,000	$20,000	$20,000	$20,000	$20,000	**$100,000**
	Total						**$1,878,462**

Sustainability of the program
Other than the support received from PHI, we have strategized the following mechanisms for sustaining the program beyond the given budget of five years:

1. Department of Surgery is preparing to submit T32 proposal. The effort is led by Drs. Troy Merkel and Sashwati Roy. Successful implementation of the program will provide additional support to this program.
2. From year three of the program, we will start applying for the IUPUI Block Grant application which will support 1-2 students in their first year of program.
3. In addition to the PhD program, we are proposing a Master's program in Regenerative Medicine and Technologies. The proposal will be submitted soon (pre-proposal submitted and approved). Opening the program for Master's degree too will bring additional revenue in terms of teaching credits.

• *What programs, if any, have been eliminated or downsized in order to provide resources for this program?*

None

ii. Special Fees above Baseline Tuition
None. Program will be assessed the same tuition and differential fee as other degree programs at IUPUI

4. Similar and Related Programs
a. List of Programs and Degrees Conferred

i. Similar Programs at Other Institutions
Campuses offering (on-campus or distance education) programs that are similar:

Currently, there are no graduate level programs (Ph.D.) available to students seeking a degree in Regenerative Medicine and Technologies.

ii. Related Programs at the Proposing Institution

There are no graduate level degrees in Regenerative Medicine and Technologies at Indiana University. Some Indiana graduate programs have some connection to regenerative medicine, and thus may be considered as being synergistic to the proposed graduate degree programs. However. There is active research in graduate training related to Regenerative Medicine at School of Science and School of Engineering IUPUI Purdue Schools. Also, in School of dentistry some courses related to regenerative endodontics are offered. Support letters for the RMAT graduate degree program from each of the concerned school and department has been provided in **Appendix 2**.

b. List of Similar Programs Outside Indiana

• If relevant, institutions outside Indiana (in contiguous states, MHEC states, or the nation, depending upon the nature of the proposed program) offering (on-campus or distance education) programs that are similar:

	University	**Ph.D**	**Industry internship**	**Technology component**
1	Stanford Medicine	Stem Cell Biology and Regenerative Medicine (SCBRM graduate program) http://med.stanford.edu/stemcell/phd.html	Yes	No
2	Mayo Clinic	Regenerative Sciences Training program https://www.mayo.edu/research/centers-programs/center-regenerative-medicine/education/regenerative-sciences-training-program/about	No	No

3	Keck School of Med at University of Southern California	Development, Stem Cell and Regenerative Medicine (DSR graduate program) https://keck.usc.edu/pibbs/phd-programs/development-stem-cell-and-regenerative-medicine	No	No
4	Thomas Jefferson University	Cell Biology and Regenerative Medicine (CBRM graduate program) https://www.jefferson.edu/university/life-sciences/degrees-programs/phd-programs/cell-biology.html	No	No
5	Wake Forest school of Medicine	Regenerative Medicine concentration https://school.wakehealth.edu/Education-and-Training/Graduate-Programs/Biomedical-Areas-of-Concentration/Regenerative-Medicine	No	No
6	University of Chicago	Development, Regeneration and Stem Cell Biology (DRSB graduate program) https://biosciences.uchicago.edu/programs/development-regeneration-and-stem-cell-biology	No	No

c. Articulation of Associate/Baccalaureate Programs

Not applicable

d. Collaboration with Similar or Related Programs on Other Campuses

• Indicate any collaborative arrangements in place to support the program.
Not applicable

5. Quality and Other Aspects of the Program

a. Credit Hours Required/Time To Completion

• *Credit hours required for the program and how long a full-time student will need to complete the program*

The degree will require 30 hours of coursework credit, the majority of which will be in the form of didactic classroom lectures and research seminars. The remaining credits (a minimum of 45 credit hours but up to 60 hours) will be laboratory research credits and will be supervised by their Graduate Faculty mentor and an advisory/research committee selected by the student and his/her mentor. **A candidate is required to complete 90 credits for PhD degree**.

Our curriculum, combined with research and rotation opportunities, provide a flexible educational opportunity for doctoral students to specialize in the broad subject of translational medicine while emphasizing doctoral research leading to fundamental discoveries in Regenerative Medicine and Technologies. The RMAT doctoral program provides an avenue for graduate education to merge cutting edge basic research with clinical application.

The curriculum will appeal to students who wish to focus primarily at the basic science level as well as those who wish to focus specifically on innovation such as a new device to solve a clinical problem. All students, regardless of their career goals, will enroll in the unique RMAT core courses SURG-R711, R712, R791, R720, GRDM- G505 and G507. These courses will provide the unique material required for a firm foundation in RMAT. **SURG-R711** is a unique offering that combines didactic lectures to understand principles of developmental and stem cell biology, fundamental biological processes, and medical engineering tools essential for tissue regeneration. **SURG-R712** will provide knowledge of current Regenerative Medicine technologies and their applications in health care and will also appraise the different standards of products and therapies in regenerative medicine. **SURG-R720** is research rotation course. It is aimed to evaluate the compatibility of one's research skills and interests with the in-detail research topics under investigation in the laboratory. It will help to develop critical thinking skills, the ability to meaningfully design biomedical studies, a work ethic consistent with those of a professional scientist, and time management skills. **SURG-R791** is an industry/clinical internship course. The student will perform key internship tasks outlined in the internship plan with critical thinking and professional skills (time management, communication, etc.) that are required by a professional in an institution similar to the

internship site. This will also help the scholar to develop interpersonal and team skills required to complete the assigned tasks. GRDM-G505 is an existing course in the campus meant to cater research ethics and responsible conduct of research. GRDM-G507 is also an existing course meant to teach scholars the importance of reagent validation in research. A candidate must earn 3.0 GPA. For each course, a minimum of Grade B is required. We expect students to complete coursework to PhD core courses. On average, it will take five years to complete the degree course. However, it may take fewer years (3-4) if the candidate has previous graduate degree with equivalent course work.

The curriculum is tailored to each student's career goals and sets the stage for the student to translate research successfully beyond the academic sphere. The courses are progressive and synergistic. All aspects of the curriculum and research are conducted in a supportive and rigorous scientific environment with the intention that students are expected to maximize their scientific potential and contribute to future healthcare applications.

Details on the curriculum can be found in **Appendix 3**.

Appendix 3: Contains Course details

b. Exceeding the Standard Expectation of Credit Hours

Not required

c. Program Competencies or Learning Outcomes

• List the significant competencies or learning outcomes that students completing this program are expected to master.

1. Ability to bench-to-bedside translation
2. Understand principles of developmental and stem cell biology, fundamental biological processes, and medical engineering tools essential for tissue regeneration
3. Appraise the use of different biomaterials used in regenerative medicine
4. Develop critical thinking ability to address the immediate requirements for products in regenerative medicine using appropriate biomaterials.
5. Demonstrate knowledge of current Regenerative Medicine technologies and their applications in health care.
6. Generate clinical grade products of translational relevance. Investigate the interplay of applied multi-disciplinary sciences and integrated technologies to create products of translational relevance.
7. Perform key internship tasks outlined in the internship plan with critical thinking and professional skills (time management, communication, etc.) that are required by a professional in an institution similar to the internship site
8. Demonstrate interpersonal and team skills required to complete the assigned tasks.
9. Learn Government policy on RMAT
10. Commitment to practice RMAT in a professional and ethically responsible
11. Ability to effectively communicate with the non-technical public as well as the technical community.

d. Assessment

Program level:
This program is designed to have discipline specific accreditation requirement that is covered by IUPUI Higher Learning Commission (HLC) accreditation. We will evaluate the success of program and assess student learning through a variety of means. The most important will be the participation in IUPUI and IUSM program review process. This program will work with IUPUI office of Planning & Institutional Improvement and with IUSM Graduate Division to conduct a program review every 5 years. This program review will examine operation, effectiveness and achievement of program-level and course level student learning outcomes and academic program quality.

Student level:
In order to assess whether students master learning outcomes appropriate for their degree, course content will be mapped to the program learning outcomes. An advisory committee composed of the Graduate Faculty will review the Plan of Study of each student to ensure that program learning outcomes are achieved at the

appropriate level. Each student must obtain approval for a Plan of Study from their Graduate Advisory Committee. The Graduate School regards the Plan of Study as an individualized curriculum designed by the advisory committee to assist a student in achieving career objectives and programmatic educational outcomes.

e. Licensure and Certification

• *State License:*
Graduates of the Ph.D. program in RMAT will not earn a license through the State of Indiana's Professional Licensing Agency.

• *National Professional Certifications (including the bodies issuing the certification):*
Not applicable
• *Third-Party Industry Certifications (including the bodies issuing the certification):* The RMAT graduate program is not intended to prepare students for any specific third party certifications.

f. Placement of Graduates

Regenerative Medicine and Technologies graduates are employed in Biotech companies, Academic labs, Medical device manufacturing and logistics companies. PhD graduates are usually in supervisory or project leadership positions. Regenerative medicine is a multidisciplinary field. Graduates are responsible for large and complex projects and supervise or coordinate with faculties from other disciplines. A broad technical background provided by advanced education and experience is essential for this responsibility. The letter of support provided as **Appendix 2** substantiates the willingness of the Indiana based companies to hire graduate coming out of this program. Besides, the graduate office of IBMG and RMAT will advise and guide the candidates in their professional development.

g. Accreditation

• *Accrediting body from which accreditation will be sought and the timetable for achieving accreditation.*
Not required

6. Projected Headcount and FTE Enrollments and Degrees Conferred

• *Report headcount and FTE enrollment and degrees conferred data in a manner consistent with the Commission's Student Information System*

To support the program we will need 1.75 FTE. One full time Staff for progression management, one staff at 50% FTE for admissions and one at 25% FTE to act as Graduate Advisor and coordinator.

NEW ACADEMIC DEGREE PROGRAM PROPOSAL SUMMARY

Institution/Location:	Indiana University Purdue University Indianapolis
Program:	PhD in Regenerative Medicine and Technologies
Proposed CIP Code:	26.0401

	Year 1 2020-21	Year 2 2021-22	Year 3 2022-23	Year 4 2023-24	Year 5 2024-25
Enrollment Projections (Headcount)					
Full-time Students	5	10	15	20	20
Part-time Students	-	-	-	-	-
	5	10	15	20	20
Enrollment Projections (FTE)*					
Full-time Students	5	10	15	20	20
Part-time Students	-	-	-	-	-
	5	10	15	20	20
Degree Completion Projection	-	-	-	5	5

CHE Code:	26.0401
Campus Code:	IUPUI - 001813
County Code:	Marion - 49
Degree Level:	Doctoral - Research
CIP Code:	26.0401

Appendix 10

Description of the proposed curriculum (listing of existing and proposed courses)

The degree will require 30 hours of coursework credit, the majority of which will be in the form of didactic classroom lectures and research seminars. The remaining credits (up to 60 credit hours) will be laboratory research credits and will be supervised by their Graduate Faculty mentor and an advisory/research committee selected by the student and his/her mentor. **A candidate is required to complete 90 credits for PhD degree**.

***Core Courses* (16 credits)**

SURG-R711 Regenerative Medicine, Biomaterials and Therapeutics (2 cr.)
This sixteen-week course will cover eleven lectures by prominent experts Students will have an overview of biomaterials and therapeutics used in Regenerative Medicine. Emphasis will be given on fundamentals and advancements made in nano-biomaterials for delivery of therapeutics in Regenerative Medicine. The curriculum will also include a paper presentation at the end.

SURG-R712 Regenerative Medicine Technology Development and Manufacturing (2 cr.)
Students will have an overview of development and manufacturing of Regenerative Medicine products. From the science behind groundbreaking discoveries to regulatory and manufacturing challenges, the curriculum will detail multi-disciplinary collaboration and technology integration with a student seminar at the end.

SURG-R791 Industry/Clinical Internship (4 cr.)
An internship course allowing incoming doctoral graduate students enrolled in programs (minors, etc.) that require internships. Required as part of the Regenerative Medicine and Technologies doctoral major.

SURG-R720 Research Rotation (3 X 2 cr.) = 6 cr.
A laboratory research rotation course allowing incoming Regenerative Medicine and Technologies doctoral graduate students in the School of Medicine (IUSM) to take research rotations in laboratories affiliated with any of the nine IUSM PhD programs. Permission of instructor required.

GRDM-G505 - Responsible Conduct of Research (1 cr.)
The purpose of this course is to provide its students with a formal setting to learn about the basic rules and acceptable standards required for anyone conducting scientific research. It will help its students obtain knowledge and develop skills for dealing with potential ethical problems in the research laboratory on their own.

GRDM-G507 Reagent Validation as a Means for Enhanced Research Reproducibility (1 cr.)
This course is designed to provide training for pre-doctoral students in the area of appropriate reagent utilization by focusing on biological variables, with particular attention to murine models, and on biological and chemical resources, with particular attention to cell line authentication, plasmid verification, and antibody utilization.

***Elective Courses* (3 credits)**

BME 52700 Implantable Systems (3 cr.)
Engineering constraints surrounding the selection of a power source for an implantable system and in particular how the control of the target organ system impacts power plant design. The organ specific design of cochlear neuroprosthetics, functional neuromuscular stimulation systems and cardiac pacemakers are presented in detail as but three examples of technically mature implantable systems that have had broad clinical impact. For each, there is a brief introduction to the related anatomy, physiology and neurophysiology of the target organ system so that students may gain perspective on the functional limits of the artificial control of these organ systems. Several implantable systems

presently in the early stages of bioengineering design or in the early stages of clinical trials are presented as state-of-the-art examples. Particular attention is given to practical bioengineering issues related to the ever expanding use of implantable biomedical sensors in order to provide real-time control of the implant and improved response to challenges to the homeostasis of organ system function. Issues related to ethical and regulatory considerations related to implantable system design including animal testing, human clinical trials and FDA premarket approval are also introduced.

BME 58200 Advanced Biomedical Polymers (3 cr.)
This is an advanced polymer course that provides the most recent development of biomedical polymers and their applications and covers a variety of biomedical areas such as in cardiovascular, dental, orthopedic, ophthalmologic and wound healing research. Drug, cellular and gene delivery are also covered. This course is designed for all the senior undergraduate and graduate students (M.S. and Ph.D. level) in biomedical areas. Except for learning, students are also required to discuss the related topics and write term papers related to the assigned special topics in the class.

BME 59500 Biomolecular Engineering (3 cr.)
This course covers the experimental and computational tools useful to analyze biological molecules and molecular systems, potential applications of DNA/protein molecules for designing nano-scale motors, switches, and computers. The topics include electrophoresis, genome-wide molecular analysis, network analysis, DNA manipulations, protein interactions, and microfluidics.

BME 59500 Cellular Mechanotransduction (3 cr.)
This course will cover the biochemical signaling in response to various mechanical stresses in the context of physiology and pathophysiology. Topics include the behavior of live cells during cell motility, force generation, and interaction with the extracellular matrix; the advanced biomechanical testing tools used for in vitro characterization of living cells; mechanotransduction that converts mechanical forces into biochemical signaling.

BME 59500 Tissue Engineering (3 cr.)
This course will cover biological principles and physiological phenomena underlying cellular regulation during development, homeostasis, and wound healing. Topics also include tissue engineering fundamentals, such as cell sources, transplantation immunology, processing of scaffolding materials, integration at cell-material interfaces, mechanisms of incorporation and release of biologics, engineered culture environments, and host-transplant integration. Students will have opportunity to evaluate clinically relevant tissue engineering products and cutting-edge tissue engineering research.

SURG-R780 Advanced Topics in Regenerative Medicine and Technologies (3 cr.)
This sixteen-week course will cover eleven lectures by prominent experts to provide an overview of groundbreaking discoveries, regulatory and manufacturing challenges, Emphasis will be given on advanced regenerative medicine technologies, manufacturing regulations, and standards for healthcare applications. The curriculum will detail multi-disciplinary collaboration and technology integration.

GRDM-G661 Clinical Trials (3 cr.)
This course includes topics in conducting clinical trials, including design, recruitment, informed consent, randomization, blinding, data collection and analysis, safety monitoring, study closeout, and alternative designs such as crossover and nonrandomized trials. Some important research areas besides clinical trials are also covered.

GRAD-G715 Biomedical Science I (3 cr.)
One of three biomedical science courses intended for incoming doctoral graduate students in the School of Medicine or other graduate students. The material presented addresses molecular and metabolic aspects of cellular function. The course will explore topics in the biochemical basis of biological systems, including biological macromolecules, protein ligand interactions, cell signaling, and metabolic processes

Minor in Ph.D (12 credits)

All PhD students at IU must select a minor. Note that courses taken for the minor must be different from those required by the program and cannot be counted for both the program and the minor.

***Research Courses* (up to 60 credits)**

SURG-R800: Research in Regenerative Medicine (variable cr.) – *Not yet submitted for approval*
Research Course for students conducting research in a lab with a mentor

Kindly note: The new courses SURG-R711, R712, R791, R720 & R780 has been uploaded to the remonstrance list