



INDIANA UNIVERSITY

SCHOOL OF MEDICINE
Graduate Division

Sherry F. Queener, Ph.D.
Director of the Graduate Office, IUPUI
Associate Dean of the Indiana University Graduate School

July 25, 2010

Dear Dr. Queener,

Please find attached proposals for:

- A new M.S. degree in Translational Science
- A new certificate in Translational Science
- A new Indiana University Graduate School Ph.D. Minor in Translational Science

As you know, the M.S. degree is part of the specific aims of the funded NIH Clinical and Translational Sciences Institute (CTSI) grant that is coordinated by the Indiana University School of Medicine and also includes other IUPUI schools, Indiana University Bloomington, Purdue University West Lafayette, and the University of Notre Dame. This degree therefore represents a collaborative educational effort that will offer resources to students at three Indiana universities.

The proposals have been authored by Dr. R. Mark Payne of Pediatrics and his colleagues at the CTSI.

Please let me know if I or Dr. Payne can answer any questions.

Thank you for your consideration,

Simon J. Rhodes, Ph.D.
Associate Dean for Graduate Studies
Indiana University School of Medicine
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Indiana University
Request for a New Credit Certificate Program

Campus: Indiana University – Purdue University of Indianapolis

Proposed Title of Certificate Program: Graduate Certificate in Translational Science

Projected Date of Implementation: Fall 2010

Faculty Member Developing / Submitting Proposal: R. Mark Payne

TYPE OF CERTIFICATE: (check one)

☐ **UNDERGRADUATE CERTIFICATES** – These programs generally require 12-29 credits of undergraduate-level academic work.

☒ **GRADUATE CERTIFICATES** – These programs generally require 12-29 credits of graduate-level academic work or undergraduate academic work carrying graduate credit.

☐ **POST-BACCALAUREATE CERTIFICATES** – These programs generally require 12-29 credits of undergraduate-level academic work, although students enrolling in these programs must have completed their baccalaureate degrees.

I. Why is this certificate needed? (Rationale)

Over the last decade, a number of disciplines, including biochemistry, immunology, cellular and molecular biology, have experienced a rapid series of bold advances. In spite of these advances, there has been a ‘lag time’ between discovery and application of these new findings, which creates a need for a new breed of scientist with a hybrid training of basic science and clinical medicine who can bridge this gap. The proposed Certificate in Translational Science provides an option for scientists and engineers who are unable to complete the entire Master of Science in Translational Science Program (Translational Science Program of Indiana – TSPI), but wish to enhance their current scientific knowledge with translational research techniques.

This 18-credit hour certificate is designed to provide students with the opportunity to develop the necessary skills for future translational research. Locally and nationally, there is a high demand for translational researchers. According to the Bureau of Labor Statistics, employers in the research and development field require new doctoral employees to participate in extensive post-doctoral fellowships in order to develop the skills needed to design and conduct independent research. This program would provide our graduates with an edge by giving them some of that needed experience and knowledge. Graduates should experience increased opportunities for advancement and employment opportunities in university, industry, or government research settings. Additionally, the Bureau of Labor Statistics (<http://www.bls.gov/oco/ocos309.htm>) indicated that of Medical Scientists:

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- 31% are employed in scientific research and design organizations
- 27% are employed in educational services
- 13% are employed in pharmaceutical and medicine manufacturing
- 10% are employed in hospitals

Furthermore, this area is expected to see continued job growth of 40%, due to its impact on improving human health.

II. List the major topics and curriculum of the certificate

A. Requirements: Minimum of 18 credit hours: 10 to 12 core credit hours, including Tools and Techniques in Translational Research (G667); Quantitative Aspects of Translational Research (New); Introduction to Research Ethics or Ethical and Policy Issues in International Research or Responsible Conduct of Research (RCR) (G504 / G505 / P555 / New); Biostatistics I or II (G651, G652, or approved equivalent). Credit may be given for up to 6 hours of student's pertinent graduate level coursework. Additional coursework (electives) is adapted to fit the needs of the student up to a total of 8 credits. Focus is on translational research training in the basic and clinical sciences for future research scientists. All required coursework is offered at the IUPUI campus.

B. Completion Requirements and Procedures for Certificate in Translational Science

1. Total number of credits required: 18 credits

2. Specific course requirements (Core Classes)

✓	Tools and Techniques in Translational Research	(G667)	3 credits
✓	Quantitative Aspects of Translational Research	(New – Grad G668)	3 credits
✓	Introduction to Research Ethics or Ethical & Policy Issues in International Research or Responsible Conduct of Research (RCR)	(G504/G505/P555/New)	1 – 3 credits
✓	Biostatistics I or II	(G651, G652, or approved equivalent.)	3 credits
	Total Core Credits		10 – 12 credits
	Electives Credits (Graduate Level Courses – approved by the Program Director)		6 – 8 credits
	Total Credits		18 credits
•	Minimum GPA requirements		
✓	Minimum overall GPA for all courses applied to Certificate		3.0 GPA

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✓ Minimum grade for any course to be applied to Certificate	B-
• Maximum number of credits that may be transferred from another institution	6 credits
• Maximum number of credits from undergraduate level courses that may be used toward the degree	0 credits
• Maximum time allowed for the completion of Certificate	5 years
• Number of credits that can be applied both to this Certificate and another degree or certificate program (i.e., overlapping credits)	12 credits
• Number of credits taken prior to admission to the Certificate program that may be counted toward completion of the Certificate program	14 credits

- There are three main types of students who will apply for this new certificate program, thus resulting in several potential pathways.

- Student A enrolls in the certificate program prior to taking any coursework.
- Student B initially enrolls as a graduate student (non degree or other appropriate course of study) and takes pertinent coursework. Later, the student realizes that by taking one or more additional courses, he or she would receive a certificate signifying knowledge and a skill-set in translational research.
- Student C will enroll in the M.S. in Translational Science Program, but may be unable to complete all of the degree requirements due to unforeseen circumstances, which may include, but are not limited to: new responsibilities, job transfer, and inability to complete Mentored Basic / Translational Research requirement. If the student meets the certificate requirements, then this student will receive the Graduate Certificate in Translational Science instead of the M.S. degree.

Thus, some of the students enrolling in the Graduate Certificate Program may have completed 14 credits prior to enrollment. Therefore, it would be desirable to apply all 14 credits into the program for students who fall in categories B and C.

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Table 1: Required Courses for Graduate Certificate

<i>Course Title</i>	<i>Course #</i>	<i>Credits</i>	Graduate Certificate
Tools & Techniques in Translational Research	GRAD G667	3	X
Quantitative Aspects of Translational Research	New	3	X
Introduction to Research Ethics or Ethical and Policy Issues in International Research or Responsible Conduct of Research (RCR)	GRAD G504/ G505 or PHIL P555 or New	1 to 3	X
Biostatistics I or II (or approved equivalent)	GRAD G651 or G652	3	X
Electives (must be graduate level and be approved by the Program Director)	GRAD XXX	6 to 8	X
Total Required Credits			18

Most or all of the courses necessary to deliver the curriculum will be offered on an annual basis.

Generally, students will average 8 credits in the fall and spring semesters and 2 to 3 credits in the summer. The table above details a likely course sequence over a one-year period.

Table 2: Sample Curriculum for Graduate Certificate

<i>Year</i>	<i>Course Title</i>	<i>Course #</i>	<i>Credits</i>
Year 1	Fall		
	Introduction to Research Ethics	GRAD G504	2
	Tools & Techniques in Translational Research	GRAD G667	3
	Elective	GRAD XXX	3
	Spring		
	Quantitative Aspects of Translational Research	New (Grad-G668)	3
	Biostatistics I	GRAD G651	3
	Elective	GRAD XXX	3
	Summer		
	Elective	GRAD XXX	1
	Total		18

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C. Existing Core Courses

1. **Tools and Techniques in Translational Research (G667): 3 credits.** This course is offered in the spring semester and provides the advanced student with an understanding of the basic technologies and techniques used in translational research today. Key to this training is understanding how and when to use these technologies, and how to interpret their results and pitfalls. The trainees develop an understanding of the components for protecting human subjects, and how to move a novel concept from the lab to a patient. Finally, the student will understand how to identify and measure target endpoints in patients, and how to assemble a multi-disciplinary team to conduct translational research. The course will use a case-based approach whereby specific technologies and problems are demonstrated in readings drawn from the textbook. This course is a new offering (initiated spring 2009) and is supported by the Indiana CTSI. **Course Director:** R. Mark Payne. Offered once in Spring 2009 and is being offered Fall 2010.
2. **Research Ethics (Responsible Conduct of Research - RCR) (G504/G505/P555): 1 - 3 credits.** All Certificate students must enroll in coursework related to RCR if they have not already done so.
 - a. **Introduction to Research Ethics (G504): 2 - 3 credits.** More intensive course than G505. Taught by the Department of Medical and Molecular Genetics and The IU Center for Bioethics. **Course Director:** Kimberly Quaid de Cordon. Offered 3 times in the past 3 years (every fall).
 - b. **Introduction to Research Ethics (G505): 1 credit.** Offered in the fall semester, G505 includes lecture and small group discussion formats and covers important issues in biomedical research, such as: 1) Scientific misconduct, 2) Conflict of interest, 3) Animal rights and welfare, 4) Ownership of data, intellectual property, and copyright management, 5) Authorship and scientific manuscripts, and 6) Informed consent and human subjects. **Course Director:** Michael J. Klemsz. Offered 3 times in the past 3 years (every fall).
 - c. **Ethical and Policy Issues in International Research (PHIL P555): 3 credits.** If students are contemplating international research, they may opt for this course. This course examines ethical and policy issues in the design and conduct of transnational research involving human participants. Topics discussed include:

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economic and political factors; study design; the role of ethics review committees; individual and group recruitment/informed consent; end of study responsibilities; national and international guidelines. **Course Director:** Eric M. Meslin. Offered 3 times in the past 3 years (every fall).

d. **Responsible Conduct of Research (New) 3 credits.**

3. **Biostatistics I (G651 or approved equivalent): 3 credits.** G651 is an introductory level biostatistics course designed for healthcare professionals. It is the first in the G651 and G652 series on biostatistics methodology. The course covers topics such as data description and presentation techniques, probability and probability distributions, sampling distributions, statistical inferences from small and large samples, analysis of categorical data, analysis of variance, correlation and simple linear regression analysis. Upon completion of the course, students will achieve a basic understanding of the concepts and techniques of data description and statistical inferences. Students will also acquire a working knowledge of SPSS, a commonly used statistical computation program. Students will be able to understand and interpret the statistical analyses in research articles published in medical journals. **Course Director:** B. Katz. Offered 6 times in the past 3 years (spring and fall semesters).

OR

4. **Biostatistics II (G652 or approved equivalent): 3 credits.** G652 is an advanced applied biostatistics course designed for students with an interest in the health sciences. Students are expected to have completed at least one semester course of basic biostatistics. Knowledge of probability and probability distributions, concepts of estimation and hypothesis testing are assumed. Topics covered in this course include multiple linear regression, multi-factor analysis of variance, analysis of covariance, analysis of repeated measures, logistic regression model, and survival analyses. Upon completion of the course, students are expected to understand the appropriate statistical models for various outcomes and be able to interpret results using statistical techniques covered in this course. Students are also expected to conduct simple analyses using SPSS on personal computers. **Course Directors:** S. Gao & P. Monahan. Offered 3 times in the past 3 years (every fall).

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5. **Electives: (6 - 8 credits)** Students must select graduate level electives. Potential electives can be found in Table 3, with the selection tailored to the student's particular research interests. Up to 12 credits may overlap with the student's current doctoral program. Electives must be approved by the Program Director.

D. New Course – Quantitative Aspects of Translational Research, (New - Grad-G668): 3

credits. Quantitative Aspects of Translational Research is an interdisciplinary weekly seminar series offered in the spring semester. Targeted toward the advanced graduate student and clinical or research based postdoctoral fellows, it will provide a forum for both Level 1 (bench to bedside) and Level 2 (clinical studies to practice) translational researchers to work together in learning both the key concepts and principles required to develop medically relevant solutions. Through a systematic exploration of diabetes mellitus, students will be exposed to the process of learning about any disease. Lecturers will represent the multiple disciplines with a stake in dealing the various aspects of disease; thus, providing students with a better global understanding. **Course Directors:** Robert Bies, Ph.D. and Jamie Dananberg, M.D.

- E. Required Courses Not Offered at IUPUI:** All required courses will be offered at the Indianapolis campus.

Table 3: Potential Elective Classes for Translational Science

List of Potential TSPI Electives (6 to 8 credits are required and must be approved by Program Director)	IUPUI	Credits
Advanced Biomedical Engineering Topics	BME 69600	1 to 6
Advanced Biomedical Polymers	BME 69500	3
Advanced Cardiovascular Physiology	G830	3
Advanced Morphologic Hematology	C802	2
Advanced Organic Chemistry	651	3
Advanced Topics in Molecular Biology	G825	2
Advances in Diagnostic Microbiology	C820	3
Angiogenesis	F713	1
Animal Models Of Human Disease	G727	1
Applied Multivariate Anal. in Pub Hlth w/Lab	PBHL E725	4
Basic Bone Biology	G 819	3
Behavioral Medicine in Rehabilitation	I614	3
Biochemical Mechanisms	636	3
Biochemistry:Structural Aspects	634	3
Bioinformatic Applications to Proteomics and Genomics	G848	2
Biological Membranes	BIOL 570	3
Biomedical Science I – Biochemical Basis of Biological Processes	GRAD G715	3

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List of Potential TSPI Electives (6 to 8 credits are required and must be approved by Program Director)	IUPUI	Credits
Biomedical Science II – Molecular Biology & Genetics	GRAD G716	3
Business of Life Sciences	X518	1.5
Cardiac & Coronary Physiology of Exercise	F708	1
Cardiovascular, Renal, & Respiratory Function in Health & Disease	G735	
Cell Physiology of Epithelial Cells	F716 / G765	1
Cellular Structure of the Nervous System	C850	3
Chromosome Instability and Disease	G746	1
Clinical Research Methods	GRAD G660	3
Clinical Trials	GRAD G661	3
Clinical Chemistry I	C700	3
Computational Systems Biology	I646	?
Concepts & Controversies in Cardiovascular Science	G831	2
Concepts in Biotechnology	G828	2
Concepts of Cancer Biology: Signaling Gone Awry	G852	2
Current Topics in Immunology	J807	2
Current Topics in Molecular Genetics of Microorganisms	J829	2
Cytogenetics of Malignancies	Q622	3
Designer Mice - Transgenes and Knockout Animals	F721 / G706	1
Development of the Vascular System	F713 / G714	1
Developmental Biology	566	3
Developmental Genetics	G726	1
Developmental Neurobiology	571	3
Diabetes & Obesity	G805	2
Diagnostic Immunopathology	C803	2
Directed Readings in Biomedical Engineering	BME 69700	1 to 3
Eukaryotic Cell Biology	G 817	3
Experimental Design & Research Biostatistics	F850 / G855	1
Functional Anatomy & Clinical Biomechanics	P513	4
Fundamentals of Human Cytogenetics	Q627	1
Fundamentals of Neuroscience I, II, and / or III	G74X	1 to 3
Fundamentals: Biochemistry & Molecular Genetics	Q626	1
Gene Transfer Approaches To Clinical And Basic Research (Gene Therapy)	G725	1
Hematopoiesis	J854	2
Human Cytogenetics	Q620	3
Human Cytogenetics Laboratory	Q621	3
In vivo Microcirculatory Physiology	F709 / G712	1
Intro to Biomolecular Imaging	F592	3
Introduction into Therapeutic Interventions	P646	4
Introduction to Research	J802	2
Introductory Biochemistry	B500	3

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List of Potential TSPI Electives (6 to 8 credits are required and must be approved by Program Director)	IUPUI	Credits
Introductory Biochemistry	533	3
Introductory Virology	530	3
Mammalian DNA Repair in Disease	G 837	3
Mechanisms of Immune Regulation	J840	2
Medical and Psychosocial Aspects of Chronic Illness	I555	3
Medical Genetics Seminar	Q660	1
Methods in Cell Biology	G823	3
Methods In Human Genetics	Q730	3
Methods in Molecular Biology and Pathology	G890	3
Methods in Proteomics	G841	3
Microbial Genetics	641	2
Microbial Pathogenicity	J821	3
Molecular & Cellular Physiology of Ion Transport	F761 / G761	1
Molecular And Biochemical Genetics	Q612	3
Molecular And Biochemical Genetics Laboratory	Q613	2
Molecular Biology	G865	3
Molecular Biology of Cancer	Biol 516	3
Molecular Cancer Genetics	G724	1
Molecular Genetics of Development	564	3
Molecular Immunology	J805	3
Neoplastic Determinants	J842	2
Physiologic Basis of Human Performance	K535	3
Physiological Proteomics	F720 / G704	1
Physiology & Pathophysiology of Lipid Rafts	F782 / G782	1
Physiology I	556	3
Physiology II	557	3
Physiology of Smooth Muscle	F726 / G707	1
Physiology of the Coronary Circulation	F715 / G703	1
Population Genetics	Q630	3
Principles of Biomedical Engineering I	BME 60100	3
Principles of Biomedical Engineering II	BME 60200	3
Principles of Molecular Biology	507	3
Principles of Pharmacology	G747	1
Principles of Toxicology II	G754	?
Principles of Toxicology III	G755	?
Principles of Toxicology: Module 1	G748	1
Psychopharmacology	I545	3
Reaction Mechanisms	657	3
Regenerative Biology and Medicine	568	3
Renal Physiology	F762	1
Select Topics in Biomedical Engineering	BME 59500	3

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List of Potential TSPI Electives (6 to 8 credits are required and must be approved by Program Director)	IUPUI	Credits
Seminar in Microbiology	J830	3
Special Topics In Human Genetics	Q640	1
Structural and Chemical Biology	G807	2
Synthetic Organic Chemistry	652	3
Techniques in Biotechnology	548	3
Theory in Statistical Genetics	Q731 (BIOS688)	3
Topics in Biotechnology	540	3
Topics in Translational & Implementation Research	G610	3
Translational Bioinformatics Applications	I656	?
Virology	J828	3

III. What are the admissions requirements?

Admissions Requirements and Procedures

Students will be admitted through the IUPUI and University Graduate School admissions processes. Application into the Certificate Program includes completion of an application to the program, interview with the Program Director, verification of the admissions requirements specified below, and formal enrollment through the IUPUI and University Graduate School admissions processes.

- A.** Students must possess at least a bachelor's degree from an accredited institution or institution approved by the Translational Science Assessment & Advisory Board (the oversight committee for the Translational Science Program of Indiana).
- B.** Students must either be currently enrolled as an Indiana University medical student, dental student, Purdue University Veterinary Student or in a basic science doctoral program or have completed their M.D., Ph.D., D.N.S., or D.D.S. training.
- C.** Strong preference will be given to students, who have completed training or licensure in a health care profession field (e.g., physician, dentist, pharmacist, etc.) or in a scientific discipline relevant to basic or clinical research (e.g., Anatomy & Cell Biology, Biochemistry & Molecular Biology, Medical & Molecular Genetics, Biology, Microbiology & Immunology, Biomedical Engineering, Medical Neuroscience, Biomolecular Imaging & Med. Biophysics, Pathology & Laboratory Medicine, Cellular & Integrative Physiology, Pharmacology, etc.)

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- D.** Candidates should have an interest in clinical or translational research: i.e., a full-time appointment to an academic faculty position with a desire to spend some of his or her time in research, or a research career in another setting (e.g., industry or government).
- E.** Transcripts will be requested according to standard procedures and all requirements of the relevant campus graduate school (e.g., prior GPA, etc.) must be satisfied. Selection of students is based on grades (GPA must be 3.0 or higher), academic accomplishment, papers submitted / published, grants submitted/awarded, clarity of career plans, and need for this training. Admissions decisions are based on individualized review of qualifications and experience. The most important criterion is the ability to demonstrate a likelihood of having a successful and productive graduate school experience in our programs.
- F.** Candidates should complete an application as well as supply a curriculum vitae, personal statement, a letter from primary mentor, and three letters of reference with one from their department or division head or Program Director assuring that the applicant will have adequate protected time for the program.
- G.** For applicants whose native language is not English and who have not received a degree from a certified American university, the applicant must submit one of the following as satisfactory proof of English proficiency:
- 1.** TOEFL score of 600+ (paper version / PBT) or 250+ (computer-based version / CBT) or a provisional minimum of 100+ (internet-based version / KBT).
IUPUI's school code for the TOEFL is 1325.
 - 2.** A grade of 6.0 or higher on the Cambridge International English Language Testing System (IELTS).
 - 3.** Successful completion of the ELS Language Centers Level 112 Master's Intensive Program.
 - 4.** Students currently residing in Indiana may take the IUPUI English as a Second Language (ELS) Placement Test. Placement at level G011 or higher is required for students who need an I-20 from IUPUI.
 - 5.** A bachelor's or higher degree from a country designated by IUPUI as predominantly native-English speaking.

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6. For residents of Japan, a “First Grade” score on the STEP Eiken.

IV. List the major student outcomes (or set performance based standards) for the proposed certificate

A. STRATEGIES for SHORT-TERM OUTCOMES: The Translational Science Program of Indiana (TSPI) will:

1. Educate translational researchers who regularly read research literature in both basic and clinical areas, who can state the hypothesis for planned research, who can critically evaluate and choose appropriate research tools, who can explain the fundamental concepts in the discipline, and who can defend methods for analyzing data or scholarly product.
2. Educate translational research students who can apply sophisticated biochemical, molecular and engineering approaches to directly impact the understanding of the mechanisms of human disease.
3. Educate translational scientists who can move productively between basic and clinical settings as exemplified by collaborative papers.
4. Educate scientists and engineers who can act as teachers or mentors for basic and clinical colleagues.
5. Educate translational scientists and engineers who can develop novel molecular approaches to treat human disease utilizing their understanding of complex clinical problems.
6. Provide a program (involving graduate students, special courses and faculty) that will promote 'translational' research.

B. LONG-TERM OUTCOMES and IMPACT: The Translational Science Program of Indiana (TSPI) will:

1. Greater awareness of basic science methodologies and how to apply them to medical problems.
2. Leadership of research teams by Translational Science program graduates.

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3. Ongoing partnerships and collaborations between biomedical scientists, engineers and physician scientists.
 4. Greater integration of basic, translational, and clinical research.
 5. Improved medical practice (i.e., applications for the treatment of disease) using/applying new biological knowledge, tools, and approaches.
- V. Explain how student learning outcomes will be assessed (student portfolios, graduate follow-up, employer survey, standardized tests, etc.) and describe the structure / process for reviewing assessment findings for the purpose of ensuring continuous improvement of the certificate.**

A. Overview

The TSPI Leadership and Executive Committee (described in IX, A1) will monitor each student's performance, progress, and timely completion of requirements, and monitor each student's transition to further graduate education or to a professional career. Moreover, the IU Graduate School monitors all of its programs and periodically holds extensive program reviews in cooperation with the Office of Planning and Institutional Improvement.

B. Procedures

1. Students complete a course evaluation form for each course, providing an overall rating as well as specific comments on what would further improve the course. The results are tabulated, reviewed by the Program Director, and provided to the course director.
2. Every spring, TSPI Students will complete a Translational Science Program Evaluation Form, in which they will be able to rate specific aspects of the program and provide comments and feedback for program improvement.

C. Assessment of Outcomes

Outcomes will be assessed largely through exams, homework assignments, and projects (or some other series of work products) in the student's courses. Each course has a specific grading policy with defined criteria in a syllabus that has been approved by the Graduate School.

Beyond course grades, outcomes will include post-certificate research activities, specifically conducting or collaborating on research projects, research positions in academics or the private sector, publishing papers in peer-reviewed journals, and obtaining external funding to support

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translational research. Mentorship of students and fellows in translational research and teaching research courses will be other important metrics.

Regarding students who are enrolled in a degree program elsewhere, work done for the certificate can find its way into master's theses or dissertations. The program will involve frequent one-on-one advising to assess each student's progress and to ensure the quality of the student's performance. Students in the certificate program will be held to the same standard as those who are enrolled in the MS in Translational Science program

Three major overarching competencies desired of students will be assessed. Table 4 details the general outcomes, objective findings, methods for imparting and measuring the outcomes, assessment findings, and potential improvements based upon the assessment findings.

Table 4. Translational Graduate Certificate Program – Assessment Plan for Three Overarching Outcomes *

General Outcome	Objective Findings (i.e., what the student will know or be able to do)	Method for Imparting the Skill or Knowledge	Method for Measuring the Skill or Knowledge	Assessment Findings	Potential Improvements Based upon Findings
Competency in Human Subjects Protection for Clinical Research	Research and Sponsored Programs (R&SP) core knowledge for Clinical Investigators	1. In-class: Research Ethics (G504) 2. Out-of-class: R&SP on-line course	1. Exam & home-work in G504. 2. Score on R&SP on-line test	1. Score \geq 80% on final exam in G504 2. Score \geq 85% on R&SP test	<ul style="list-style-type: none"> • Revise content of G504 • Require attendance at IRB session
Practical Application of Research Skills	Lead or collaborate in writing a grant application	In-class: Tools & Techniques in Translational Research (G667), Quantitative Aspects of Translational Research (G668) and Biostatistics I or II (G651 or G652)	Submit to program director: <ul style="list-style-type: none"> • Grant application (can include project from GRAD G668) 	At least 75% of participants complete one of the three benchmarks (manuscript, abstract, or research project collaboration)	<ul style="list-style-type: none"> • Interview students who don't complete one of the 3 benchmarks to determine barriers • Inventory IUPUI clinical research opportunities

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General Outcome	Objective Findings (i.e., what the student will know or be able to do)	Method for Imparting the Skill or Knowledge	Method for Measuring the Skill or Knowledge	Assessment Findings	Potential Improvements Based upon Findings
Critical Evaluation of a Translational Research Project	Demonstrate ability to assess research hypotheses, study design, patient sampling, outcome measures, and statistical analysis	In-class: evaluate research project presentation by classmate	Oral or written evaluation of a classmate's presentation	Student correctly assesses at least 2 of following: hypotheses, study design, sampling, outcome measures, and/or analysis	Revise content of (G667 and / or G668) Quantitative Aspects of Translational Research

* Abbreviations: IRB = Institutional Review Board. SRC == Scientific Review Council. GCRC = General Clinical Research Center

VI. Describe the student population to be served

The proposed Graduate Certificate is designed for students who have completed (or are in the process of completing) their basic or clinical doctoral degree (e.g., M.D., Ph.D., DNS, DDS). The pool consists of individuals with a background in basic or clinical sciences, such as fellows and junior faculty as well as students in the final year of medical, dental or veterinary school. The proposed Graduate Certificate will provide the formal training needed to prepare for a translational research career. (Note: Advising prior to application will clearly indicate that this is **NOT** an entry-level, professional degree to secure employment.) Students, who meet these criteria, will be actively recruited by announcement via the department chairs and program directors, by advertising the program over campus electronic newsletters, and by faculty recommendation of students.

All entering students will be provided with a brochure through the graduate school describing the program at the time of their matriculation. All students expressing interest will be encouraged to speak with the program director (Payne) or one of the Executive Committee members (Rhodes, Kroenke, Moe, Fife, Hetrick, or Heath) for further details. We will also provide the brochure for undergraduates visiting the school as part of our general recruiting programs, for distribution to minority-based colleges and universities during recruiting visits (to help develop a pipeline of trainees), and through our web sites.

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Table 5: # of Incoming Fellows (over the past 5 years)

Year	Average Incoming Class Size	Average % URM*	Average % Women
2008-2009	161	26	71
2007-2008	158	26	42
2006-2007	159	26	39
2005-2006	158	27	38
2004-2005	95	22	35

* Underrepresented Minorities (URM) are Black, Hispanic, Alaska Native, American Indian,

VII. How does this certificate complement the campus or departmental mission?

The current program is compatible with IUPUI's mission of promoting educational development through innovative collaborations and external partnerships. The Translational Science Program of Indiana is a result of the collaborative initiative of Indiana ICTSI, which is a partnership of Indiana University School of Medicine (IUSM), Purdue University (PU), University of Notre Dame (ND), and Indiana University (IU). Students from these institutions, who also meet the admissions criteria, will be actively recruited to participate in the TSPI program. The current program would incorporate IU Hospital, Riley Hospital for Children, Wishard Memorial Hospital, Roudebush VA Medical Center, and LaRue Carter Psychiatric Hospital into the training program. Additionally, the students could potentially collaborate with the ~40 research institutes on campus through mentorship or research-related projects. Also, due to the importance of translating research findings into practice, collaborative efforts will be made with the established pharmaceutical, new biotechnology, and medical device companies including Eli Lilly, Dow, Cook, Endocyte, and Guidant. In addition, collaborative efforts will be made through BioCrossroads, which is an academic-government-industry collaboration that facilitates interactions among investigators and industry.

Moreover, the four units have established working relationships. This program would extend the already established collaboration between IUSM and its IUPUI neighbors in Science and Dentistry by allowing graduate students to participate in interdisciplinary programs and faculty to have joint appointments. Similarly, The Translational Science Program of Indiana would build upon the collaborative program between IUSM and PU BME, which has been in place for >25 years and has led to pioneering contributions in medicine, including the development of cardiac defibrillators, a significant commercial success; discovery of a biomaterial scaffold for the regeneration of blood vessels; invention of guidance systems for clinical catheters; design of controlled release devices for

Indiana University
Request for a New Credit Certificate Program

drug delivery, and development of the first integrated modeling technique to design improve artificial knee joints. This joint effort extends the current academic and fiscal relationship in training MD-PhD students: IUSM supports the MD training and BME supports the physician-engineers during the PhD through a common system so that support is seamless for the students.

VIII. Describe any relationship to existing programs on the campus or within the university

A. Master of Science in Translational Science

The parent graduate program for this new certificate will be the Master of Science in Translational Science Degree Program. This multi-disciplinary program proposal is currently undergoing the approval process. The Translational Science Program of Indiana (TSPI) will award one of the following: a Graduate Certificate in Translational Science, a Ph.D. Minor in Translational Science, or an M.S. in Translational Science for students already possessing a doctoral degree, depending upon the student's need.

Students can pursue four options of obtaining translational science training. Option 1 entails taking selected coursework through the Graduate Non-Degree program to provide specific training to supplement one's current knowledge. Option 2 consists of enrolling in and completing the Master's degree program in Translational Science. Option 3 provides students with the opportunity to obtain a Graduate Certificate in Translational Science to bolster their graduate training. Option 4 allows current doctoral students to add a Ph.D. Minor in Translational Science.

The underlying philosophy of the program is that an understanding of human disease at both the basic and clinical science level is fundamental to all translational researchers. The Graduate Certificate Program would be available for pre- and post-doctoral scientists, who are interested in the training. The program would allow current students on the IUPUI campus to incorporate translational training into their doctoral-level study through a Graduate Certificate, a Ph.D. Minor or an M.S. in Translational Science. Individuals, who already possess their terminal doctoral degree, would not be able to transfer in any of their coursework from their previously granted graduate-level degree. The long term goal is to establish a training program that addresses the critical need for generating talented research scientists, who can pursue a career that lies at the interface between basic and clinical investigative medicine.

B. Master of Science in Clinical Research

Indiana University
Request for a New Credit Certificate Program

In the past several years, our Clinical Investigator and Translational Education (CITE) program has been particularly successful in training clinician-scientists in epidemiology, clinical trials, health outcomes and Level 2 translational research. This includes:

1. 53 junior investigators successfully receiving K-23 and other career development awards
2. 108 trainees have completed or are currently enrolled in our M.S. in Clinical Research degree program; and
3. 262 students have completed or are currently enrolled in CITE courses.

We believe that creating a parallel program in Level 1 translational research will reap similar benefits. We initially thought a single program in clinical research training might cover the spectrum of biomedical research education. However, we have discovered what many other programs have learned, namely that level 1 translational research training requires its own coursework, program leadership skill set, and advisory committee structure. While many training programs have been successfully created in epidemiology, clinical trials, and outcomes research, far fewer have been developed with robust curricula in Level 1 translational research. Critical to facilitating this training is a curriculum relevant to translational research, program leadership, intercampus educational collaborations, and multidisciplinary mentorship for predoctoral and postdoctoral trainees. The long term goal is to establish a T1 training program that addresses the critical need for generating talented research scientists who can pursue a career that lies at the interface between basic and clinical investigative medicine.

Additionally, the Translational Science Program joins with the CITE Program as part of the training portion of the ICTSI. A clear goal of ICTSI is to develop and implement training programs for both T1 research (bench to bedside) and T2 research (bedside to community). Training programs in T2 research are already well established at IUSM, such as the M.S. program in Clinical Research (CITE program) directed by Dr. Kurt Kroenke. We have leveraged the ICTSI to provide administrative and infrastructure support for the Translational Science Program and plan for ICTSI to incorporate support for this program with renewals. Secondly, there is commitment from the Deans of IUSM and IUPUI, as well as the department chairs from IUSM and IUPUI to provide financial and administrative support for this program to continue. As documented in the letters of support, all view this program as integral to the development of a robust translational research enterprise in Indiana. Finally, applications will be

Indiana University
Request for a New Credit Certificate Program

made to foundations for grants, such as the Eli Lilly Foundation which has generously endowed IU and IUSM over the recent years.

C. Indiana Clinical and Translational Science Institute (ICTSI)

The new Certificate in Translational Science will be administered, taught, and evaluated by the same director, education committee, and faculty as the parent Master degree program in Translational Science. This program in Translational Science at IUSM is a natural outgrowth of the planning and implementation of ICTSI that was awarded in 2008 by the NIH. It was jointly designed by several basic and physician scientists, who have worked together on models of human disease and on training in translational research in the Departments of Internal Medicine, Pediatrics, Biochemistry and Molecular Biology, and Physiology/Pharmacology. The Translational Science Program joins with the Clinical Investigator and Translational Education (CITE) Program as part of the training portion of the Indiana CTSI. A clear goal of the Indiana CTSI is to develop and implement multi-disciplinary training programs for both T1 research (bench to bedside) and T2 research (bedside to community). Training programs in T2 research are already well established at IUSM, such as the M.S. program in Clinical Sciences (CITE program) directed by Dr. Kurt Kroenke.

IX. List and indicate the resources required to implement the proposed program. Indicate sources (e.g., reallocations or any new resources such as personnel, library holdings, equipment, etc.)

A. Existing Learning Resources: This certificate program will be administered by the same faculty, staff, and resources established for the Master's Degree Program in Translational Science (currently submitted for approval).

(Core Leadership Team)

Program Director	R. Mark Payne, M.D. (Professor in Indiana University School of Medicine)
Program Coordinator	Carrie Hansel
Executive Committee	Simon J. Rhodes, Ph.D. (Professor and Associate Dean in Indiana University School of Medicine)

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Request for a New Credit Certificate Program

Kurt Kroenke, M.D., (Chancellor's Professor of Medicine, Director of Clinical Investigation and Translational Education (CITE) Program, Senior Scientist in Regenstrief Institute, Director of Indiana Clinical and Translational Sciences Institute (CTSI) Education Programs, and Associate Director of Education in the General Clinical Research Center)

Hunter Heath, III, M.D. (Adjunct Professor of Medicine, Division of Endocrinology and Metabolism, Indiana University School of Medicine)

Sharon M. Moe, M.D. (Professor of Medicine and Vice-Chair for Research in Indiana University School of Medicine)

Rose Fife, M.D., M.P.H. (Associate Dean for Research, Associate Director of the Indiana CTSI, Co-Director of the IU Family Violence Institute, Barbara F. Kampen Professor of Women's Health, Professor of Medicine and Biochemistry and Molecular Biology, Indiana University School of Medicine)

William P. Hetrick, PhD (Professor of Psychological and Brain Sciences and of Neuroscience at Indiana University, Bloomington, Adjunct Professor of Clinical Psychology in the Department of Psychiatry, IU School of Medicine)

*Additional Faculty
Involved in the
Program*

Jon A. Story, Ph.D. (Associate Dean of Purdue University Graduate School)

Stephen R. Dlouhy, Ph.D. (Associate Scientist in Medical & Molecular Genetics; Associate Director of the Medical & Molecular Genetics DNA Services Laboratory; Director of the Cell Repository)

Edward Srour, Ph.D. (Robert J. and Annie S. Rohn Professor of Leukemia Research; Professor of Medicine; Professor of Pediatrics; Professor of Microbiology & Immunology; Director of Flow Cytometry Resource Facility)

Tatiana Foroud, Ph.D. (Michael Conneally Professor of Medical and Molecular Genetics; Director of Hereditary Genomics Division)

David A. Flockhart, M.D. / Ph.D. (Harry and Edith Gladstein Chair in Cancer Genomics; Professor of Medicine, Medical Genetics and Pharmacology; Indiana University School of Medicine & Division of Clinical Pharmacology)

Yunlong Liu, Ph.D. (Adjunct Assistant Professor of Informatics; Assistant Professor of Medical & Molecular Genetics; Adjunct Assistant Professor of Medicine - Biostatistics)

Narayanan Perumal, Ph.D. (Assistant Professor, Bioinformatics)

Ken Cornetta, M.D. (Joe C. Christian Professor & Chairman of Medical & Molecular Genetics; Professor of Medicine & Microbiology/Immunology)

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Carl Garner, Ph.D. (Senior Director, Pharmaceutical Projects Management Eli Lilly and Company)

Brad Ackermann, Ph.D. (Research Fellow - Laboratory for Experimental Medicine; Translational Medicine Eli Lilly and Company)

Deborah W. Knapp, D.V.M., M.S. (Dolores L. McCall Professor of Comparative Oncology; Director of Purdue Comparative Oncology Program)

Marie Kerbesian, Ph.D. (Vice President for Technology Commercialization)

Jeremy Schieler, Ph.D. (Senior Technology Manager)

Jamie Dananberg, M.D. (Executive Director, Exploratory and Program Medical - Eli Lilly and Company)

Robert Bies, Pharm.D., Ph.D. (Associate Professor of Clinical Pharmacology; Director, Disease Modeling Program, CTSI Member; Center for Computational Biology and Bioinformatics)

1. **Administration of the Program:** Upon approval, the Program Director will be appointed as the chair of the Executive Committee. The Executive Committee will be composed of the Program Director (R. Mark Payne, M.D.), Drs. Simon Rhodes, Kurt Kroenke, Sharon Moe, Rose Fife, William Hetrick, and Hunter Heath, III. The members of this multi-disciplinary committee reflect strong training achievements, collaborative skills, and broad experience. This committee will be responsible for selection of trainees to enter the program, provide oversight of the trainees, provide input and advice to the Program Director on program direction and standards, and evaluation of the outcomes of the trainees as determined from the yearly surveys. These latter evaluations will be used to provide feedback to refine the program curriculum and set future program goals. The Executive Committee will also review faculty performance on a yearly basis and provide recommendations to the Program Director for recruiting new faculty, or removing faculty who are not active in the program.
2. **Communications:** Communication of Program philosophies, goals, news, and outcomes will be important given that the students and faculty will come from many departments and different campuses. Accordingly, a quarterly 1 page newsletter containing program news and updates will be developed by the Program Coordinator (Carrie Hansel) and delivered electronically to the heads and graduate program directors of all departments involved with TSPI for distribution to their faculty. Contact information for the Program

Indiana University

Request for a New Credit Certificate Program

will be included with each newsletter. This will also be the mechanism announcing the Programs' availability of positions (slots) every year to the ICTSI campuses.

3. **External Review and Program Oversight:** The administrative structure and performance of the Training Program will include yearly review and oversight. A yearly report of Program activities and progress will be generated by the Executive Committee and sent for formal assessment by the Assessment and Advisory Board chaired by Dr. Trudy Banta (see evaluation plan). The Assessment and Advisory Board consists of Dr. Banta, Dr. S. Queener, Dr. Kurt Kroenke (Program Director for the Clinical Scientist Development program of the Indiana CTIS), and 2 faculty from the graduate programs. This external committee will evaluate the Program's progress and outcomes, and determine if the Program is meeting its stated goals and objectives. Their critique will be returned to the Executive Committee as a memo followed by a meeting between the program directors and the External Committee.

B. Resource Materials

Indiana University has an extensive array of learning resources and facilities that will be available to the proposed Graduate Certificate in Translational Science Program in support of its educational and research mission. These include system, campus and participating school resources. State-of-the-art data, video and voice technologies are present to create a sophisticated learning environment.

Students in the Graduate Certificate Program of Translational Science will need access to the libraries, journals and databases on the IUPUI and IU Bloomington campuses. Additionally, students will need access to various opportunities on campus, including but not limited to: seminars, study groups, lectures, and research experiences.

C. New Learning Resources Needed

The program requires the above-mentioned faculty, an administrative support position, additional funds for supplies and expenses, office space, secure location for filing confidential student information and funds for additional financial assistance. (This certificate program will use the same resources and be administered by the same faculty and staff established for the Master's Degree Program in Translational Science - currently submitted for approval.)

Indiana University
Request for a New Credit Certificate Program

X. Describe any innovative features of the program (e.g., involvement with local or regional agencies or offices, cooperative efforts with other institutions, etc.)

A. Distinctive Features & Strengths of the Program: Currently, training in human disease at both a basic and clinical level is not well-addressed by current training programs, which leaves a nationally unmet need for translational scientists. The proposed program will fill this unmet need by offering clinical science students a Graduate Certificate in Translational Science that is specifically designed for them. The final product will be a graduate with a Graduate Certificate in Translational Science who understands human disease at both the basic and clinical level.

In addition to the direct opportunities and objectives of the Translational Science Program of Indiana, several indirect benefits are expected. This program will enhance the interaction between M.D.s in clinical departments with scientists in basic departments who are engaged in fundamental bench research focused on human disease. This program will also facilitate the interaction of scientists interested in common problems and increase the cross-pollination of ideas between scientists in basic and clinical departments. This program will also facilitate the interaction of scientists interested in common problems and increase the cross-pollination of ideas between scientists in basic and clinical departments. A program which achieves both the specific goals and the indirect benefits outlined above will prepare these translational scientists with a better understanding of basic and clinical science and the implications on their research in the area of human disease and facilitate desperately-needed translational research in all areas of medicine and science. We believe that these innovations are critically important at a time when advances in basic science can rapidly impact the diagnosis and treatment of human disease.

In many major academic medical centers in this country, these advances have started to erase the historical divisions between basic and clinical scientists. For modern-day clinicians to understand and take advantage of these new developments, they often must spend a great deal of time at both the bedside and the bench. On the other hand, the potential to understand mechanisms of disease and have an impact on the treatment of human diseases has lured some basic scientists to move closer to their clinical counterparts. This movement into the clinical arena facilitates the challenge of viewing a complex clinical disorder through the eyes of the basic scientist. Moreover, ideas generated in a clinical setting by the basic scientist can often quickly transcend into an understanding of the role of a particular biological process in a human disease and ultimately the development of a treatment for that disease. These developments have given rise to the need for training programs that can produce a hybrid biomedical scientist who can understand human disease at both a basic and clinical level.

Indiana University Request for a New Credit Certificate Program

Fundamental changes in academic and pharmaceutical biomedical operations have dictated the need for the training of more ‘translational’ researchers. For example, managed care has put more pressure on those with clinical training to participate in patient care. As a result, those scientists with the most clinical insight are spending much less time carrying out basic research as it relates to clinical problems. At the same time, there has been a major emphasis by national, private and industrial granting organizations to fund basic research that has the potential to immediately impact human disease. The NIH, for example, has recognized this need and responded with several RFAs. Additionally, in the pharmaceutical and biotechnology industries, most traditional departments have now been restructured with major foci on disease areas. Thus, it is becoming increasingly important for scientists who move into these industries to be well versed in basic science methodologies as well as to have an intimate understanding of human disease. The Translational Science Program of Indiana (TSPI) has been designed to train researchers, who will fill the critical niches described above in major medical centers and industry.

The Graduate Certificate Program in Translational Science at IUSM is a natural outgrowth of the planning and implementation of the Indiana Clinical Translational Science Institute (CTSI) that was awarded in 2008 by the NIH. It was jointly designed by several basic and physician scientists, who have worked together on models of human disease and on training in translational research in the Departments of Internal Medicine, Pediatrics, Biochemistry and Molecular Biology, and Physiology/Pharmacology. This group realized that historically in the best major medical centers in this country, there has been a very valued group of scientists, who has worked at the interface of basic science and human health. This program has been designed to enhance the clinical training of medical students and fellows with basic science approaches to focus on the application of these approaches to human disease. This graduate program differs from other graduate programs by offering a new pathway for clinical scientists to gain a comprehensive knowledge of clinical and basic science methodologies, as well as, learn how to collaborate with other scientists in a translational research environment, regardless of their specialty. An overall goal of TSPI is to produce exceptional ‘translational’ researchers in a fashion that saves both time and expense when compared to more conventional ‘translational’ training routes.

B. Collaborative Arrangements

The program will offer training to the partnering institutions: Indiana University-Purdue University Indianapolis, Purdue University West Lafayette, University of Notre Dame, as well as the IUSM biomedical programs in Indianapolis and Bloomington. As the program grows,

Indiana University
Request for a New Credit Certificate Program

collaborative agreements will be established between partnering universities to allow students to readily assimilate components into their programs. The long term goal is to establish a training program that addresses the critical need for generating talented research scientists, who can pursue a career that lies at the interface between basic and clinical investigative medicine.

Table 7: Comparable Programs

University	Certificate Name	Credits Required	Length of Program	Required Course Info
Mayo Clinic	Clinical & Translational Science	12	1 year	<ul style="list-style-type: none"> • CTSC 5600: Statistics in Clinical Research • CTSC 5300: Intro to Clinical Epidemiology • CTSC 5000: Intro to Clinical Research • CTSC 5310: Clinical Epidemiology II • CORE 6000: Responsible conduct of Research • CTSC 5010: Clinical Research Protocol Development Elective Courses - 4 credits required Required Workshops: Writing for Biomedical Publication
Robert Wood Johnson Medical School	Clinical & Translational Science	18	1 year	Required Courses <ul style="list-style-type: none"> • Statistics in Clinical and Translational Research • Clinical Trial Design • Ethics and Regulations in Clinical Research • Commercializing Innovation* • Basic Concepts in Drug Development* • Leveraging Public and Private Funds for Translational Research*
University of Kentucky	Clinical & Translational Science	13	??	<ul style="list-style-type: none"> • Methods and Technologies of Clinical and Translational Science • Interdisciplinary Protocol Development • Ethical Issues in Clinical Research • Biostatistics I • Seminar in Clinical and Translational Science • Research Practicum
University of Pennsylvania	Translational Research	??	??	<ul style="list-style-type: none"> • Introductory Biostatistics • Mechanisms of POR: Designing A Protocol • Scientific and Ethical Conduct • Disease Measurement Complete Research Project
University of Vermont	Clinical & Translational Science	19	1 year	<ul style="list-style-type: none"> * Designing Clinical & Translational Research * Analyzing Clinical & Translational Research * Multivariate Methods for Clinical & Translational Research

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Request for a New Credit Certificate Program

University	Certificate Name	Credits Required	Length of Program	Required Course Info
				<ul style="list-style-type: none"> * Conducting Clinical & Translational Research * Presenting Clinical & Translational Research * From Cell to Society * Seminar in Clinical & Translational Research
University of Cincinnati	Clinical & Translational Research	14	1 year (most can be completed in 8-week summer session)	<ul style="list-style-type: none"> • Introduction to Epidemiology • Introduction to Biostatistics • Ethics in Research <p>One or two of the following electives:</p> <ul style="list-style-type: none"> • Study Design & Analysis (3 credits) • Principles of Clinical Trials (3 credits) • Molecular Epidemiology (3 credits) • Introduction to SAS Programming (2 credits) • Regression Analysis (4 credits) • Biostatistics in Research (3 credits) • Mentored Research (3 credits)
IUPUI	Translational Science	18	1 year	<ul style="list-style-type: none"> • Tools & Techniques in Translational Research • Quantitative Aspects of Translational Research • Ethic Courses • Biostatistics I (or approved equivalent) <p>Electives (6 to 8 credits) – graduate level coursework approved by Program Director</p>



SCHOOL OF MEDICINE

INDIANA UNIVERSITY

Office of the Dean

July 19, 2010

TO: Indiana Commission for Higher Education
Indiana University Trustees
Indiana University – Purdue University of Indianapolis Graduate Committee
Indiana University Bloomington Academic Leadership Committee

RE: R. Mark Payne, M.D.
Professor of Pediatrics (Cardiology)

On behalf of the Indiana University School of Medicine (IUSM), R. Mark Payne, M.D., Professor of Pediatrics in IUSM's Department of Pediatrics, has prepared a proposal for the Translational Science Program of Indiana (TSPI). The Translational Science Program of Indiana (TSPI) is designed to allow physicians and medical students in training to integrate translational research into their training utilizing the wealth of resources available through IUSM and the Indiana Clinical and Translational Sciences Institute (ICTSI).

As Dean of the IUSM and on behalf of its basic and clinical sciences faculty and departmental chairs, I enthusiastically support this proposal. Specifics of the program are detailed in the proposal itself, but the long-term goal is to establish a training program to address the critical need for generating translational research scientists who are able to operate at the interface between basic and clinical investigative medicine. Operationally, the program will be open to all interested 4th year medical students, fellows, junior faculty, and ultimately all life sciences graduate students, including those of the IUSM in Indianapolis and Bloomington, at Indiana University - Purdue Indianapolis (IUPUI), and at Purdue University in West Lafayette. TSPI students will be able to choose from options ranging from coursework, a minor, a graduate certificate in molecular medicine, or a Master of Science in Translational Science.

This program builds upon existing collaborative relationships with Purdue (i.e., the M.D. / Ph.D. program) and IUPUI (interdisciplinary cross-campus Ph.D. programs in medical neuroscience, biophysics, and biomolecular imaging). The TSPI fits well with the developing strengths of the CTSI, and represents a University commitment to develop translational training programs as detailed in the CTSI application. The IUSM is committed to the long-term success of the TSPI and will commit necessary faculty and staff time to develop and maintain the program. Because an understanding of translational medicine is fundamental to all life sciences researchers, including both physicians and basic scientists, it is clear that the TSPI program will provide a common academic system which will allow students and trainees to move forward with careers in translational science. Therefore, I urge you to give this proposal your utmost consideration.

Sincerely,

D. Craig Brater, M.D.
Dean and Walter J. Daly Professor

June 1, 2010

TO: Indiana Commission for Higher Education
Indiana University Trustees
Indiana University – Purdue University of Indianapolis Graduate Committee
Indiana University Bloomington Academic Leadership Committee

RE: R. Mark Payne, M.D.
Professor of Pediatrics (Cardiology)

Review Committee,

The Weldon School of Biomedical Engineering at Purdue University is pleased to be a contributing partner to the Translational Science Program of Indiana (TSPI) described in this proposal being submitted by Dr. Payne. We were immediately supportive of this new proposal given the successes of our previous and ongoing collaborations with the Indiana University School of Medicine (IUSM), especially around our Medical Scientist Training Program (MSTP) and the new Indiana Clinical and Translational Sciences Institute (CTSI). The proximity of our campuses, the many strong research collaborations, and the fact that many of our faculty and students already utilize the Indianapolis campus as a critical base, make this an extremely feasible curricular complement. The curricular program will be greatly facilitated also by the extant mechanisms for efficient communication and educational delivery between the two campuses which currently serve our two joint doctoral programs.

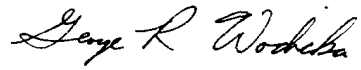
The translational and cross-disciplinary nature of the research and educational programs of the Weldon School require that our graduate students have direct and repeated exposure to clinical mentors, collaborators, and medical educational training. At the inception of our doctoral program we established a requirement for such clinical exposure. We are very excited that the TSPI program will offer biomedical engineers the opportunity to train side-by-side with biomedical scientists and physician scientists in very objective-based experiences, including projects and workshops. The multiple clinical and translational arenas proposed will match well with the diversity of interests of our biomedical engineering students. We are convinced that in order for our students to become the next generation of leaders in translating medical devices and technologies, they absolutely need to understand how to comprehensively conduct research in clinical settings. This must include learning how to participate in multi-disciplinary teams, how to develop and implement effective therapeutic interventions, and how to collaboratively establish quantitative endpoints for clinical outcomes, which are all components of this program.

We have a long-term commitment to this proposed program's success and will provide resources in support of our students participating in this program if needed. We believe strongly that our students will benefit enormously from the training offered in the TSPI program. This integrated and additional training will not only make our exceptional engineers uniquely able to contribute to

critical clinical programs in their career, but will greatly impact their research focus even during their graduate studies.

As Head of the Weldon School, I assure you that the curricular program described in this proposal has our full and enthusiastic support. We are confident that the implementation will be successful and that the educational outcomes of the all of the schools involved will be very positively impacted.

Sincerely,



George R. Wodicka
Professor and Head



**DEPARTMENT OF
PSYCHOLOGICAL AND
BRAIN SCIENCES**

INDIANA UNIVERSITY

Bloomington

June 1, 2010

TO: Indiana Commission for Higher Education
Indiana University Trustees
Indiana University – Purdue University of Indianapolis Graduate Committee
Indiana University Bloomington Academic Leadership Committee

RE: R. Mark Payne, M.D., Professor of Pediatrics (Cardiology)
Translational Science Program of Indiana

This letter is to confirm the interest of the Indiana University Bloomington in your proposed the Translational Science Program of Indiana (TSPI) which is to provide graduate training for basic and clinical investigators. IU Bloomington has a strong interest in clinical translational science, especially pre- and postdoctoral training opportunities in this area because translational research is an increasingly important avenue for scientific discovery and transfer of basic knowledge to human care. Your program will permit us to provide cutting-edge training to our current students as well as attract new translational scientists.

Investigators at Indiana University Bloomington are consistently funded by NIH/NCI, NIH/NIDR, and foundation/industry support. Translational investigator training has been a significant challenge. To date, it has been provided primarily by individual instruction and mentoring by experienced translational investigators, and by scientists serving as secondary investigators in controlled trials to develop both experience and credibility. These junior investigators also attended existing graduate courses in biostatistics and clinical research methodologies. However, more extensive training in translational tools and techniques, research ethics, grantsmanship, manuscript writing, and scientific presentations was not possible and was acquired only through experience—often incidental experiences.

Thus, the existence of the proposed Translational Science Training Program will not only provide a much more intensive and complete background for junior translational investigators, but it will also provide a much higher quality of training in a much more efficient manner. As a result we anticipate that some of our research-oriented graduate students in the basic sciences and applied science will take advantage of this program to prepare for a career in translational research. Postdoctoral students and research scientists might also appreciate the opportunity to specialize in this exciting area. Therefore, we strongly support the proposed program and hope that it will be given favorable consideration.

Sincerely,

William P. Hetrick, Ph.D.

Professor of Psychological and Brain Sciences, Neuroscience, and of Psychiatry
Director, Bloomington Office of the Indiana Clinical Translational Science Institute



INDIANA UNIVERSITY

June 23, 2010

TO: Indiana Commission for Higher Education
Indiana University Trustees
Indiana University – Purdue University of Indianapolis Graduate Committee
Indiana University Bloomington Academic Leadership Committee

RE: R. Mark Payne, M.D.
Professor of Pediatrics (Cardiology)

As the leaders of the Ph.D. programs at IU School of Medicine, the Basic Science Council has reviewed and discussed the new graduate proposal entitled, “*The Translational Science Program of Indiana (TSPI)*.” We are in strong support of this new graduate program. If approved, this program would broadly benefit the life science graduate students in our programs at Indiana and Purdue University campuses. The design of the program will allow Ph.D. students in the life sciences to participate. The TSPI program will permit these students to choose from mentored training experiences ranging from coursework to improve their knowledge of clinical and translational science in to completing interactive clinical experiences in order to earn a Ph.D. degree minor or a graduate certificate in Translational Science.

We believe this program fills a critical need in our training programs by increasing the clinical understanding and improving training of our doctoral students in a multi-disciplinary setting. We anticipate the students will bring this knowledge to their research projects. The program will thereby improve the quality and clinical relevance of research performed in our various units, promote basic/clinical student and faculty interactions, promote collaborative research between the Departments, the Schools, and the Universities, and most importantly will produce students that will be leaders in future translational research teams. We look forward to working with Dr. Payne on this new and exciting training program.

Sincerely,

Michael R. Vasko, Ph.D.
Chair, Basic Science Council
Paul Stark Professor of Pharmacology



INDIANA UNIVERSITY

July 20, 2010

TO: Indiana Commission for Higher Education
Indiana University Trustees
Indiana University – Purdue University of Indianapolis Graduate Committee
Indiana University Bloomington Academic Leadership Committee

RE: R. Mark Payne, M.D.
Professor of Pediatrics (Cardiology)

Dear Review Committee,

As the Chair of the Department of Internal Medicine, I am writing to express my strong support of the training program entitled, the Translational Science Program of Indiana (TSPI), submitted by Dr. Payne. This translational research program will blend in beautifully with the Indiana CTSI, extending earlier educational offerings in translational research, and represents a training commitment within the original Indiana CTSI. If approved, this program will broadly benefit the many medical and life sciences students in our programs at the Indiana and Purdue University campuses, including physicians in training.

I am supportive of this program, which will provide an avenue for interdisciplinary collaboration between clinical and basic scientists. The program will bolster the basic science background of physicians who want to work in translational research, while providing a clinical immersion experience for Ph.D. graduate students in our departments. We fully support this concept and will work with Dr. Payne to help structure appropriate, supervised rotations for the students. We will also help to identify appropriate faculty to provide clinical mentorship for the students.

This is an important and exciting program that will increase collaborations between our multiple departments, campuses, and faculty in ways that advance translational research both here, and nationally. By awarding a Minor, a Graduate Certificate, or a Master of Science degree in Translational Science to these students, the value of their dual degrees and training will be markedly increased. This will continue to maintain high quality students in our programs and provide leaders in future translational research programs. We look forward to beginning work on this program.

Sincerely,

David W. Crabb, MD
John B. Hickam Professor
of Medicine
Chair, Dept. of Medicine

Indiana University – Purdue University, Indianapolis



INDIANA UNIVERSITY

July 20, 2010

TO: Indiana Commission for Higher Education
Indiana University Trustees
Indiana University – Purdue University of Indianapolis Graduate Committee
Indiana University Bloomington Academic Leadership Committee

RE: R. Mark Payne, M.D.
Professor of Pediatrics (Cardiology)

Dear Review Committee,

As the Chairs of the Departments of Pediatrics and Radiology, we are writing to express our strong support of the training program entitled, the Translational Science Program of Indiana (TSPI), submitted by Dr. Payne. This translational research program will blend in beautifully with the Indiana CTSI and represents a training commitment within the original Indiana CTSI. If approved, this program will broadly benefit the many medical and life sciences students in our programs at the Indiana and Purdue University campuses, including physicians in training.

We are excited that the program will provide an avenue for interdisciplinary collaboration between clinical and basic scientists. The program will bolster the basic science background of physicians who want to work in translational research, while providing a clinical immersion experience for Ph.D. graduate students in our departments. We fully support this concept and will work with Dr. Payne to help structure appropriate, supervised rotations for the students. We will also help to identify appropriate faculty to provide clinical mentorship for the students.

This is an important and exciting program that will increase collaborations between our multiple departments, campuses, and faculty in ways that advance translational research both here, and nationally. By awarding a Minor, a Graduate Certificate, or a Master of Science degree in Translational Science to these students, the value of their dual degrees and training will be markedly increased. This will continue to maintain high quality students in our programs and provide leaders in future translational research programs. We look forward to beginning work on this program.

Sincerely,

Valerie P. Jackson, MD
Eugene C. Klatte Professor
of Radiology
Chair, Dept. of Radiology

D. Wade Clapp, MD
Richard L. Schreiner Professor
of Pediatrics
Chair, Dept. of Pediatrics



INDIANA UNIVERSITY
INDIANA CLINICAL AND TRANSLATIONAL
SCIENCES INSTITUTE
School of Medicine

July 8, 2010

TO: Indiana Commission for Higher Education
Indiana University Trustees
Indiana University – Purdue University of Indianapolis Graduate Committee
Indiana University Bloomington Academic Leadership Committee

RE: R. Mark Payne, M.D.
Professor of Pediatrics (Cardiology)
Translational Science Program of Indiana

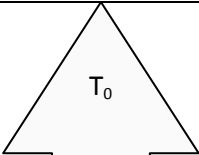
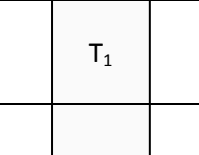
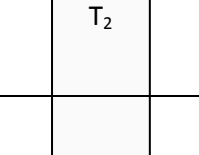
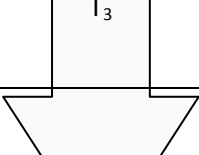
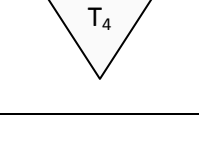
On behalf of the Indiana Clinical and Translational Sciences Institute (ICTSI), R. Mark Payne, M.D., Professor of Pediatrics in IUSM's Department of Pediatrics, has prepared a proposal for Master's Degree in Translational Science Program. The Translational Science Program of Indiana (TSPI) is designed to allow for cross-pollination of ideas between scientists in basic and clinical research by utilizing the wealth of resources available through IUSM and the Indiana Clinical and Translational Sciences Institute (ICTSI); thus, providing the foundation for translational research. As one of the specific aims listed on our CTSA grant, the TSPI provides the means of training future translational researchers for our state. Furthermore, by opening the program to all interested 4th year medical students, fellows, junior faculty as well as all life sciences graduate students, collaborative research opportunities will open among the partnering institutions (Indiana University – Purdue University of Indianapolis, Indiana School of Medicine, Indiana University Bloomington, and Purdue University) in addition to other entities within the region as they join the ICTSI.

In an effort to make the training more accessible to individuals at various stages of their careers, TSPI students will be able to choose from options ranging from coursework, a minor, a graduate certificate in Translational Science, or a Master of Science in Translational Science. Building upon existing collaborative relationships among Purdue University, Indiana University, IUPUI, and several public and private organizations, the Translational Science program will produce scientists and physicians who are able to operate at the interface between basic and clinical investigative medicine. As the Associate Dean for Translational Research, I enthusiastically write in support of this proposal.

ICTSI is committed to the long-term success of the TSPI and will commit necessary resources, faculty and staff time to develop and maintain the program. Because an understanding of basic science and clinical medicine is essential to translational research, we believe the TSPI will provide a common academic system that will allow both physician and basic scientists to advance their careers in translational science. Therefore, I urge you to give this proposal your utmost consideration.

Sincerely,

Anantha Shekhar, MD, PhD
Director, Indiana CTSI
Associate Dean for Translational Research
Raymond E. Houk Professor of Psychiatry
Professor of Pharmacology and Neurobiology
Indiana University School of Medicine

Which Research Program would cover this?	Research Phase	Definition	Type of Research	Examples
Translational Science		Identification of opportunities & approaches to health problem.	Basic research question	Are there specific gene mutations associated with breast cancer?
Translational Science		Discovery of candidate health application	Phase I & II clinical trials; observational studies	Is there an association between BRCA mutations and breast cancer?
Clinical Research		Health application to evidence-based practice guidelines	Phase III clinical trials; observational studies; evidence synthesis & guidelines development	What is the positive predictive value of BRCA mutations in at-risk women?
Clinical Research		Practice guidelines to health practices	Dissemination research; implementation research; diffusion research Phase IV trials	What proportion of women who meet the family history criteria are tested for BRCA and what are the barriers to testing?
Clinical Research		Practice to population health impact	Outcomes research (includes many disciplines); population monitoring of morbidity, mortality, benefits, and risks studies	Does BRCA testing in asymptomatic women reduce breast cancer incidence or improve outcomes?

Adapted from Khruory et al. (2007). The continuum of translation research in genomic medicine: How can we accelerate the appropriate integration of human genomic discoveries into health care and disease prevention? *Genet Med*, 9 (10), 665-674.

(<http://www.iths.org/about/translational>)

Comparison of Cert. in Translational Research and Cert. in Clinical Research Curriculum

<i>Course Title</i>	<i>Course #</i>	<i>Credits</i>	Certificate in Clinical Research	Certificate in Translational Science
Tools & Techniques in Translational Research	GRAD G667	3		X
Quantitative Aspects of Translational Research	GRAD G668 (New)	3		X
Introduction to Research Ethics or Ethical and Policy Issues in International Research	GRAD G504 or PHIL P555	2 to 3	X	X
Electives (must be approved by the Program Director)	GRAD XXX	5 to 8	X (5 - 6)	X (6 - 8)
Biostatistics I or II (or approved equivalent)	GRAD G651 or G652	3	X (Students may take this OR Clinical Trials)	X
Clinical Trials	GRAD 661	3		
Clinical Research Methods	GRAD G660	3	X	
Total Required Credits			14 - 15	18

Comparison of Cert. in Translational Research and Cert. in Clinical Research

Course Descriptions

Requirements for both certificates degrees

Research Ethics (Responsible Conduct of Research - RCR) (G504/ P555): 2 - 3 credits. All M.S. students must enroll in coursework related to RCR if they have not already done so.

1. Introduction to Research Ethics (G504): 2 - 3 credits. More intensive course than G505. Taught by the Department of Medical and Molecular Genetics and The IU Center for Bioethics. Course Director: Kimberly Quaid de Cordon. Offered 3 times in the past 3 years (every fall).
2. Ethical and Policy Issues in International Research (PHIL P555): 3 credits. If students are contemplating international research, they may opt for this course. This course examines ethical and policy issues in the design and conduct of transnational research involving human participants. Topics discussed include: economic and political factors; study design; the role of ethics review committees; individual and group recruitment/informed consent; end of study responsibilities; national and international guidelines. Course Director: Eric M. Meslin. Offered 3 times in the past 3 years (every fall).

Electives

(5 - 8 credits)

Example electives include graduate level courses in more advanced biostatistics, epidemiology, clinical pharmacology, genetics, molecular biology, and computer sciences. However, enrollees may select electives from the entire offering of graduate courses at both Indiana University and Purdue University at Indianapolis as well as IU at Bloomington. Must be approved by Program Director.

Requirements for Certificate in Translational Science

Tools and Techniques in Translational Research (G667): 3 credits. This course is offered in the spring semester and provides the advanced student with an understanding of the basic technologies and techniques used in translational research today. Key to this training is understanding how and when to use these technologies, and how to interpret their results and pitfalls. The trainees develop an understanding of the components for protecting human subjects, and how to move a novel concept from the lab to a patient. Finally, the student will understand how to identify and measure target endpoints in patients, and how to assemble a multi-disciplinary team to conduct translational research. The course will use a case-based approach whereby specific technologies and problems are demonstrated in readings drawn from the textbook. This course is a new offering (initiated spring 2009) and is supported by the Indiana CTSI. **Course Director:** R. Mark Payne. Offered once in Spring 2009 and is being offered Fall 2010.

Quantitative Aspects of Translational Research, (New - Grad-G668): 3 credits. Quantitative Aspects of Translational Research is an interdisciplinary weekly seminar series offered in the spring semester. Targeted toward the advanced graduate student and clinical or research based postdoctoral fellows, it will provide a forum for both Level 1 (bench to bedside) and Level 2 (clinical studies to practice) translational researchers to work together in learning both the key concepts and principles required to develop medically relevant solutions. Through a systematic exploration of diabetes mellitus, students will be exposed to the process of learning about any disease. Lecturers will represent the multiple disciplines with a stake in dealing the various aspects of disease; thus, providing students with a better global understanding. **Course Director:** Robert Bies, Ph.D. and Jamie Dananberg, M.D.

Biostatistics I (G651 or approved equivalent): 3 credits. G651 is an introductory level biostatistics course designed for healthcare professionals. It is the first in the G651 and G652 series on biostatistics methodology. The course covers topics such as data description and presentation techniques, probability and probability distributions, sampling distributions, statistical inferences

Comparison of Cert. in Translational Research and Cert. in Clinical Research

from small and large samples, analysis of categorical data, analysis of variance, correlation and simple linear regression analysis. Upon completion of the course, students will achieve a basic understanding of the concepts and techniques of data description and statistical inferences. Students will also acquire a working knowledge of SPSS, a commonly used statistical computation program. Students will be able to understand and interpret the statistical analyses in research articles published in medical journals. Course Director: B. Katz. Offered 6 times in the past 3 years (spring and fall semesters).

OR

Biostatistics II (G652 or approved equivalent): 3 credits. G652 is an advanced applied biostatistics course designed for students with an interest in the health sciences. Students are expected to have completed at least one semester course of basic biostatistics. Knowledge of probability and probability distributions, concepts of estimation and hypothesis testing are assumed. Topics covered in this course include multiple linear regression, multi-factor analysis of variance, analysis of covariance, analysis of repeated measures, logistic regression model, and survival analyses. Upon completion of the course, students are expected to understand the appropriate statistical models for various outcomes and be able to interpret results using statistical techniques covered in this course. Course Directors: S. Gao & P. Monahan. Offered 3 times in the past 3 years (every fall).

Requirements for Certificate in Clinical Research

Clinical Research Methods (3 credits)

This course covers the major types of study design (other than clinical trials) used in clinical research, including cohort, case-control, cross-sectional, survey, and secondary database studies. Fundamental themes in clinical research – and how to appropriately investigate them – are also addressed, such as diagnostic tests, therapy, etiology, and prognosis. Other topics include questionnaire design, meta-analysis, economic analysis, health status measurement, qualitative research, computerized searching, and health services and outcomes research.

Biostatistics I (G651 or approved equivalent): 3 credits. G651 is an introductory level biostatistics course designed for healthcare professionals. It is the first in the G651 and G652 series on biostatistics methodology. The course covers topics such as data description and presentation techniques, probability and probability distributions, sampling distributions, statistical inferences from small and large samples, analysis of categorical data, analysis of variance, correlation and simple linear regression analysis. Upon completion of the course, students will achieve a basic understanding of the concepts and techniques of data description and statistical inferences. Students will also acquire a working knowledge of SPSS, a commonly used statistical computation program. Students will be able to understand and interpret the statistical analyses in research articles published in medical journals. Course Director: B. Katz. Offered 6 times in the past 3 years (spring and fall semesters).

OR

Clinical Trials (3 credits)

This course covers core 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 cross-over and nonrandomized trials. Also, regulatory and special topics are covered including drug trials phase I through IV, patenting and other legal issues, institutional review boards, cancer trials, cells and human tissue, and trials involving special populations.