

Proposal for New Track

MS in Translational Science: Track 2 for the Basic Scientist and Engineer

Campus: IUPUI

Proposed degree: Master of Science in Translational Science for the Basic Scientist and Engineer

Proposal for New M.S. Track for the Basic Scientist and Engineer in Translational Science

I. Campus: IUPUI

II. Proposed Degree: Master of Science in Translational Science – Track 2 for the Basic Scientist and Engineer

III. Projected Date of Implementation: Fall 2011 (Upon Indiana Commission for Higher Education's approval of the original MS degree proposal)

IV. Major Objectives of the Proposed Degree Track and its Chief Features: Goals/Objectives:

A. Major Objectives:

The overall objective is to offer a 2-year Master of Science program in Translational Science for basic scientists and engineers, which will integrate clinical science training in the field of human health and disease with basic science. The field of translational research is defined here as the application of basic science to problems in human health and disease.

As one of the six specific aims listed in the Indiana Clinical and Translational Sciences Institute (ICTSI) grant (5 UL1 RR025761-02), the Translational Science Program of Indiana (TSPI) will provide the training mechanism for basic scientists to develop an understanding of human disease at both a basic and clinical level. The TSPI will offer objective-based experiences in multiple basic, clinical, and translational science arenas, including courses, projects, and workshops, so that students will understand how to comprehensively conduct basic science research that impacts human health and disease. For example, students will learn how to apply basic science methodologies to human health, how to assemble a multidisciplinary team to conduct translational research, how to develop and implement a therapeutic intervention, and then develop endpoints for quantifying clinical outcome. Trainees will develop an understanding of human subject protection, intellectual property protection, and how to move a concept from the lab to a patient.

Additionally, the program will offer training to the academic population at large, but especially to students from the CTSI partnering institutions. A common academic system allows students from the partnering institutions to readily assimilate components into their programs. Furthermore, individuals who have already completed their doctoral training but are interested in adding more clinical science to their current knowledge base may be admitted into the program. 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.

- **STRATEGIES for SHORT-TERM OUTCOMES: The Translational Science Program of Indiana(TSPI) will:**
 - ✓ 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.
 - ✓ Educate translational research students who can apply sophisticated biochemical, molecular and engineering approaches to directly impact the understanding of the mechanisms of human disease.
 - ✓ Educate translational scientists who can move productively between basic and clinical settings as exemplified by collaborative papers.
 - ✓ Educate scientists and engineers who can act as teachers or mentors for basic and clinical colleagues.
 - ✓ Educate translational scientists and engineers who can develop novel molecular approaches to treat human disease utilizing their understanding of complex clinical problems.
 - ✓ Provide a program (involving graduate students, special courses and faculty) that will promote 'translational' research.

- **LONG-TERM OUTCOMES and IMPACT: The Translational Science Program of Indiana(TSPI) will accomplish:**
 - ✓ Greater awareness of basic science methodologies and how to apply them to medical problems.
 - ✓ Leadership of research teams by TSPI program graduates.
 - ✓ Ongoing partnerships and collaborations between biomedical scientists, engineers and physician scientists.
 - ✓ Greater integration of basic, translational, and clinical research.
 - ✓ Improved medical practice (i.e., applications for the treatment of disease) using/applying new biological knowledge, tools, and approaches.

B. Admissions Requirements

Admissions Requirements and Procedures

Students will be admitted through the IUPUI and University Graduate School admissions processes.

Application into the Master's Degree 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.

1. Admissions Requirements

- a. Students must possess at least a bachelor's degree from an accredited institution or institution approved by the Translational Science Assessment & Advisory Board (TSPI oversight committee).
- b. Students must have completed or be in the process of completing their doctorate degree or equivalent, such as Ph.D.
- c. Strong preference is for students with expertise in a basic science or engineering (e.g., Anatomy and Cell Biology, Biochemistry, Pharmacology, Statistics, Bioinformatics, etc.).
- d. Candidates should have as an ultimate goal a basic or translational research career: i.e., a full-time appointment to an academic faculty position with a desire to spend at least 50% of 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 combined degree 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:
 - a) 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.

- b) A grade of 6.0 or higher on the Cambridge International English Language Testing System (IELTS).
- c) Successful completion of the ELS Language Centers Level 112 Master's Intensive Program.
- d) 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.
- e) A bachelor's or higher degree from a country designated by IUPUI as predominantly native-English speaking.
- f) For residents of Japan, a "First Grade" score on the STEP Eiken.

2. Student Clientele:

The pool consists of individuals with a background in basic sciences or engineering, such as pre-doctoral students, postdoctoral fellows, and junior faculty. Most of these individuals are funded through training grants and career awards which require at least a two-year minimum of 70 - 100% of protected time for research and formal coursework. The proposed M.S. will provide the formal training needed to prepare for a translational research career. Advising prior to application will clearly indicate to the applicant that this is NOT an entry-level, professional degree to secure employment. Students from IU Bloomington, IUPUI, University of Notre Dame, and Purdue University West Lafayette, who meet these criteria, will be actively recruited by announcement via the department chairs and program director, by advertising the program over campus electronic newsletters, and by faculty recommendation of students.

C. Curriculum Requirements: A total of 30 semester hours is required to complete the M.S. in Translational Science, 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); Effective Techniques in Grant writing (N802 or approved equivalent); and Clinical Rotations for Scientists and Engineers (New – GRAD-G671). Credit may be given for up to 12 hours of student's pertinent doctoral level coursework. Additional coursework (electives) is adapted to fit the needs of the student up to a total of 7 credits. These electives will be selected from the enclosed list. Additionally, in order to ensure that the students receive the most from their individualized electives, students must also receive prior approval from the Program Director on which electives are taken. Focus is on translational research training in the basic and clinical sciences for future research scientists and engineers. All required coursework is offered at the IUPUI campus.

1. A training focus on understanding human disease at both a basic and clinical level to provide the

tools needed to translate discovery into patient care.

2. 22 to 24 credit core, which includes 9 credits of Clinical Rotations for Scientists and Engineers; and 6 to 8 credits of electives. The requirements are distributed as follows:

Table 1: Core Classes for Track 2 – Basic Science Background

Course Title	Course #	Credits
Tools & Techniques in Translational Research	GRAD G667	3
Quantitative Aspects of Translational Research	New (Grad G668)	3
Introduction to Research Ethics or Ethical & Policy Issues in International Research or Responsible Conduct of Research (RCR)	GRAD G504 / G505 or PHIL P555 or New	1 to 3
Biostatistics I or II (or approved equivalent)	GRAD G651 or G652	3
Techniques of Effective Grant Writing (or approved equivalent)	GRAD N802	3
Clinical Rotations for Scientists and Engineers	New (GRAD-G671)	9
Electives (graduate level coursework approved by the Program Director)	IUPUI	6 to 8
Total		30

Table 2: Completion Requirements and Procedures for Master’s Degree in Translational Science**Total number of credits required: 30 credits**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
Techniques of Effective Grant Writing	(N802 or approved equivalent)	3 credits
Clinical Rotations for Scientists and Engineers	(New – GRAD-G671)	9 credits
Total Core Credits		22 – 24 credits
Electives Credits (Graduate Level Courses – approved by the Program Director)		6 – 8 credits
Total Credits		30 credits
Minimum GPA requirements		
• Minimum overall GPA for all courses applied to M.S.		3.0 GPA
• Minimum grade for any course to be applied to M.S.		B-
Maximum number of credits that may be transferred from another institution		12 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 M.S. degree		5 years
Number of credits that can be applied both to this M.S. program and another degree or certificate program (i.e., overlapping credits)		12 credits
Number of credits taken prior to admission to the M.S. program that may be counted toward completion of the M.S. program		14 credits

TABLE 3: Sample Curriculum for M.S.

	<i>Course Title</i>	<i>Course #</i>	<i>Credits</i>
Year 1	Fall		
	Responsible Conduct of Research	New	3
	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
	Summer		
Clinical Rotations for Scientists and Engineers	New (GRAD-G671)	6	
Year 2	Fall		
	Clinical Rotations for Scientists and Engineers	New (GRAD-G671)	3
	Techniques of Effective Grant Writing	GRAD N802	3
	Spring		
	Elective	GRAD XXX	3
	Total		30

D. **Transfer Credits:** Transfer of graduate credits from other institutions will be in accordance with the regulations established by Indiana University Graduate School.

E. Financial Support:

Initially, we anticipate that part-time students will receive limited support; therefore, they will either be able to pay their own way or may even receive financial support from their employers. Full-time students may potentially access various forms of funding:

1. Fellowship appointments through faculty with grant funding from external sources;
2. Support from campus block grants to schools designed to assist faculty with their research or with the development of grant proposals;
3. Financial support from their employers;
4. Financial support through the TSPI fee support.
5. TSPI will also seek additional grant financial support for students (e.g., CTSA, T-32 grants, etc.)
6. Pay their own way

F. Program Evaluation:

1. Program Implementation and Evaluation

a. Implementation

The School of Medicine will be able to implement the program within a semester

following approval – the proposed timeline would be Fall 2011. All of the essential resources are either in place already or will be in place by that time. Upon approval, advertisement and recruitment will begin. The Executive 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.

b. Procedures for Program Evaluation and Assessment

1) Overview

The TSPI Leadership and Executive Committee (described in B, 5) 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.

2) Procedures

- a) Each student in the Master's Degree in Translational Science program will have semi-annual Program Director meetings during the summer-fall (Jul-Oct) and winter-spring (Jan-Apr) time periods. At these individual meetings, the Program Director will discuss with each student intended and completed coursework, selection of electives, and progress to date in the program. A summary of each meeting will be dictated and maintained in the student's file.
- b) 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.
- c) Students complete an annual Translational Science Program Evaluation Form each spring, in which they will be able to rate specific aspects of the Master's Degree program and provide comments and feedback for program improvement.

c. Assessment of Outcomes

Outcomes will be assessed 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.

Also, 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 Science Degree 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	<ol style="list-style-type: none"> In-class: Research Ethics (G504) Out-of-class: R&SP on-line course 	<ol style="list-style-type: none"> Exam & home-work in G504. Score on R&SP on-line test 	<ol style="list-style-type: none"> Score \geq 80% on final exam in G504 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 manuscript, preparing abstract, collaborating on research project, and completing a research thesis.	<ol style="list-style-type: none"> In-class: Tools & Techniques in Translational Research (G667), Advanced Tools & Techniques in Translational Research (G668), Clinical Rotations for Scientists and Engineers(New – G671), and Biostatistics I or II (G651, G652, or approved equivalent) Out-of-class: working with mentor or research collaborator 	Submit to program director either: <ul style="list-style-type: none"> Manuscript Abstract submitted to scientific meeting Letter from collaborator verifying work on project Thesis 	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
Critical Evaluation of a Translational Research Project	Demonstrate ability to assess research hypotheses, study design, patient sampling, outcome measures, and statistical analysis	<ol style="list-style-type: none"> In-class: evaluate research project presentation by classmate Out-of-class: evaluate protocol on IRB, SRC, or PDT 	<ol style="list-style-type: none"> Oral or written evaluation of a classmate's presentation Oral or written evaluation of IRB, SRC or PDT protocol 	Student correctly assesses at least 2 of following: hypotheses, study design, sampling, outcome measures, and/or analysis	<ul style="list-style-type: none"> Revise content of (G667 and / or New) Advanced Tools & Techniques in Translational Research Provide practicum experience in PDT to address deficiencies

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

V. Justification for the New Degree Track

Translational research has the unique requirement that new discoveries must cross disciplines to be effective, i.e., a new basic discovery in a laboratory-based arena must cross into the discipline of medicine in order to reach the patient. This requires a new training paradigm in which scientists, engineers, and physicians are trained together so that each field understands the language and methodology of the others. This creates the collaborative leadership needed to move new discovery from bench to bedside.

Currently, the MS program provides training for only one part of the translational science team – clinical scientists such as physicians. Track 2 would provide the necessary training for another important part of the team – basic scientists and engineers. Furthermore, this additional track furnishes the interdisciplinary component necessary for both training tracks.

VI. Target Trainee:

The proposed program was initially designed for students who have completed a terminal doctoral degree or the equivalent in a clinical science area (e.g., M.D., D.N.S, D.D.S.). The need for translational scientists reaches to all of areas of science; as such, the proposed Translational Science degree program needs to expand its student pool to include basic scientists as well as engineers. This proposed Track in Translational Science is designed for students who have completed (or are in the process of completing) a doctoral degree (e.g., Ph.D.) in a basic science field. Students will consist of post-docs and junior faculty, as well as students in the final year (s) of graduate school. They would enter the M.S. program with protected time for research and class work, and would be assigned dual mentorship (e.g., M.D. and Ph.D. mentorship) to oversee their training, typically through a thesis committee.. Upon graduation, these scientists would be uniquely positioned to seek academic and industry careers as translational scientists, and participate in multi-disciplinary teams engaged with translational research projects.

VII. Relationship to Campus and Departmental Missions:

The current program is compatible with IUPUI's mission of promoting educational development through innovative collaborations and external partnerships. The TSPI Program is a collaboration among Indiana University School of Medicine (IUSM), Purdue University (PU), University of Notre Dame (ND), and Indiana University (IU). The current program would incorporate IU Hospital, Riley Hospital for Children, Wishard Memorial Hospital, Roudebush VA Medical Center, Methodist Hospital, and LaRue Carter Psychiatric Hospital into the training program. Additionally, the students will potentially collaborate with the ~40 research institutes on campus through mentorship or research-related projects. Finally, due to the importance of translating research findings into practice, collaborative training opportunities will be encouraged and pursued with the well-established pharmaceutical, new biotechnology, and medical device companies in Indiana including Eli Lilly,

Dow, Cook, Endocyte, and Guidant. Moreover, collaborative efforts will be made through BioCrossroads, which is an academic-government-industry collaboration that facilitates interactions among investigators and industry.

VIII. Relationship to Existing Degree Programs within the IU System

The MS in Translational Science complements the current degree tracks by adding an interdisciplinary component that they lack. Additionally, it complements the current translational and clinical research coursework by providing training to basic scientists and engineers, which is not currently offered. It would supplement other basic science programs by providing students with the ability to add clinical knowledge to their repertoire.

IX. Resources Required for the Implementation of the Proposed Degree Track

The program utilizes already existing resources within the MS in Translational Science program. It requires the mentioned faculty below, 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.

A. Program Faculty and Administrators

1. Existing Graduate Faculty (Core Leadership Team)

- a. **R. Mark Payne, M.D. (Professor in Indiana University School of Medicine).** Dr. Payne will serve as the Program Director for this training program. His research focus is on the role of mitochondrial biology in mediating heart disease in children, and on developing gene therapies for mitochondrial defects. In addition, he is an experienced physician–scientist who has created and directed a translational research graduate training program before at a previous institution. Many of the plans in the current application reflect his experience with the previous program. He will be responsible for administration of the program and represent the program to the multiple institutions involved. He will also participate in teaching, mentoring the students (both clinical and scientifically), oversee recruiting and selection of students (a key activity), and oversee placement and training of the students on the clinical rotations. Ten percent of his time is committed to the clinical treatment of children with heart disease and the remainder is committed to research. Dr. Payne has an extensive history of training graduate students and postdoctoral fellows in basic and translational research. He helped to establish and direct the Molecular Medicine Graduate Training Program at Wake Forest School of Medicine (Winston-Salem, NC), and was successful in funding it with a T32 grant from NIH (T32 GM063485-01A1. Training Program in Molecular Medicine, 2004 - 2009). This translational research training program accepted 6 - 8 students per year leading to the Ph.D. degree in Molecular Medicine, and was only the second program in the nation

to become a funded Molecular Medicine program. Dr. Payne moved to IUSM in 2005. He is the director of the young investigator (postdoctoral) Translational Research training program for the Indiana Clinical Translational Science Institute, and is also the director of the Pediatric Cardiology clinical fellowship.

- b. **Simon J. Rhodes, Ph.D. (Professor and Associate Dean in Indiana University School of Medicine).** Dr. Rhodes will serve as a member of the Executive Committee for this training program. He is a Professor of Cellular & Integrative Physiology and the Associate Dean for Graduate Studies for the Indiana University School of Medicine (IUSM). His research group investigates the molecular basis of human pituitary development and he has translated this work to the clinic to facilitate the diagnosis and treatment of severe pediatric compound hormone deficiency diseases. Fifty percent of his time is committed as the IUSM Associate Dean for Graduate Studies to administering the M.S. and Ph.D. graduate programs, the M.D.-Ph.D./MSTP program, and the postdoctoral affairs office. He has excellent working relationships with all of the programs served by this proposed program: the IUSM graduate programs, the IUPUI Science, IUPUI Dental Science, and IUPUI biomedical engineering programs in Indianapolis, and the Purdue University biomedical engineering program at West Lafayette (an established partner in the M.D. / Ph.D. training program). He will participate in teaching of the students, administration of the program, and recruitment and selection of the students and minority students, and evaluation of the program. He will serve as Program Director should Dr. Payne be unable to continue.
- c. **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).** Dr. Kroenke will serve as a member of the Executive Committee. Dr. Kroenke has directed clinical research training programs since 1988, first at the Uniformed Services University of the Health Sciences (USUHS) and, since 1997, at IU School of Medicine. Dr. Kroenke's research interests have been in the areas of common symptoms and mental disorders in primary care with a secondary interest in medical education. He has over 260 publications in peer-reviewed journals. He is a past President of the Society of General Internal Medicine (SGIM), which represents nearly 3000 academic general internists and is a key organization for physicians engaged in health services and outcomes research. He is a Board Member of the Association for Clinical Research Training (2005-2009) which promotes training directors and other leaders of clinical research training programs nationally.

- d. **Hunter Heath, III, M.D. (Adjunct Professor of Medicine, Division of Endocrinology and Metabolism, Indiana University School of Medicine).** Dr. Heath will serve as a member of the Executive Committee for this training program. He is an endocrinologist and investigator in calcium and bone metabolism, with a track record of 21 continuous years of NIH funding. Dr. Heath has published more than 100 original research reports in peer-reviewed journals. He was Head of the Endocrine Research Unit at the Mayo Clinic, and Chief, Division of Endocrinology & Metabolism, University of Utah School of Medicine before joining Eli Lilly and Company in 1996. He was Executive Director of the U.S. Medical Division, Lilly Research Laboratories, until his retirement in 2007. Currently, he operates Hunter Heath Consultancy, LLC, a biopharmaceutical research, development, and commercialization consultancy.
- e. **Sharon M. Moe, M.D. (Professor of Medicine and Vice-Chair for Research in Indiana University School of Medicine).** Sharon M. Moe, M.D., is Professor of Medicine and Vice-Chair for Research in the Department of Medicine at IUSM. Dr. Moe will serve as a program Core Leader for the clinical rotations on Internal Medicine for the students, and 2% effort is requested for her release time for teaching. She will be responsible for integrating the students into the Medicine clinical rotations, and supervising their clinical immersion experience in Medicine. Her experience in translational research and training is extensive. She served as Director of the Clinical Trials Program from 1998 to 2003, and was the Associate Dean for Research Support from 2001-2005, where she oversaw research compliance for the School of Medicine. As Vice-Chair for Research she oversees the administration of extramural funding for Medicine, is responsible for mentoring junior faculty, and enabling multi-disciplinary research. She is active within the Indiana CTSI, has won awards for teaching and continues to lecture, and is active in multiple programs and committees related to clinical and translational research. She is especially active in mentoring young investigators, many who are now NIH K-awardees. Dr. Moe is the principal investigator for several ongoing clinical and basic research studies in the field of vascular calcification and bone and mineral metabolism in kidney disease. Her research is funded by the Veterans Affairs Department, NIH, and Pharmaceutical Companies. She has authored over 100 scientific manuscripts about renal osteodystrophy and vascular calcification, and serves on national committees related to kidney and bone disease.
- f. **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).** Dr. Fife will serve as a

member of the Executive Committee. Dr. Fife is leading the new CTSI K award program supporting basic scientists in translational research projects, using a two-mentor system (one basic science mentor and one clinical mentor). She will participate in the development of the new curricula, especially as they apply to the needs of basic scientists beginning in the field of translation research. Dr. Fife has a long history of involvement in translation research, from her years as a bench researcher studying the role of metalloproteinases in cartilage and cancer, including angiogenesis and metastasis. She directed the IU Outpatient Research Facility from its inception in 1993 until 2008 and has conducted many clinical trials in rheumatoid arthritis and osteoarthritis. She also has served as President of the Central Society for Clinical Research and as Chair of the AAMC Group on Research and Development (GRAND) and is a member of its Steering Committee. She served on the AAMC Task Force II on Clinical Research, which published “Promoting Translational and Clinical Research: The Critical Role of Medical Schools and Teaching Hospitals. Washington, DC: AAMC, 2006.” Dr. Fife is Associate Editor of Translational Medicine and serves on the Editorial Board of the Journal of Women’s Health. She is Program Director for the Regulatory Program of the CTSI. She also is Co-Director of the IU Family Violence Institute and studies the epidemiology of family violence. She has had a T35 short-term training grant from NIA for medical and other professional students interested in studies on aging and women’s health (currently being submitted for renewal). The next iteration of this T35, when funded, will include translational research exposure as one of its goals.

- g. **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).** Dr. Hetrick will serve as a member of the Executive Committee. Dr. Hetrick is director of the Bloomington office of the Indiana Clinical Translational Science Institute (CTSI). He is heavily involved in graduate and post-graduate training, serving as a preceptor of two NIH T32 training grants. He has served regularly on NIMH predoctoral and postdoctoral fellowship review committees and is a frequent chair of the NSF Psychology Graduate Research Fellowship review panel. Dr. Hetrick’s research interests focus on the biological and behavioral bases of severe mental illnesses, such as schizophrenia and bipolar disorder. He uses translational animal models and experimental paradigms in his work, which includes studies of experimental cognitive and pharmacological interventions. He has over 60 publications in peer-reviewed journals. His teaching is focused on abnormal psychology, evidence-based practice, intervention and evaluation, and foundations of clinical psychology at both the baccalaureate and doctoral levels. He

is involved in the research training of psychology, neuroscience, psychiatry, and neurology doctoral students. He won an IU Trustee's Teaching Award in 2007. With clinical cognitive neuroscience laboratories in both Bloomington and Indianapolis, appointments across departments and programs, and with heavy involvement in the administration of the Indiana CTSI, he is well positioned to aide in the implementation of this translational science education program.

2. Program Leadership

- a. **The Program Director** (Mark Payne, M.D.) will be responsible for the overall program direction and priorities, and will chair the quarterly meetings of the Executive Committee. In consultation with the Executive Committee (below), he will establish the program standards and goals, as well as the curriculum and training programs for the students. The Program Director will oversee and provide timely feedback to the students within the program and ensure effective communication of progress reports to the home departments of the trainees. He will communicate with the thesis committee chairs of the graduate students regarding their progress, and with the fellow's research committees on their progress. The Program Director will also be responsible for the fiscal management of the training program, and will prepare annual reports as required. He will be assisted in these responsibilities by the by the Executive Committee and Program Coordinator. Dr. Payne will devote 5% effort to program administration.
- b. **The Program Coordinator** (Carrie Hansel) will be responsible for day to day activities and administrative support of this program. She will handle all correspondence, and communicate with the multiple faculty and clinical services required for this program. She will also handle advertising of the program, prepare applications for review, prepare data for Assessment at the end of each year, and track students after their graduation. Funds are requested to support 100% effort, and the institution is supporting 100% effort. Currently, her effort is supported by the Indiana CTSI in synergistic activities. In the future, additional administrative support will be necessary so the program committee would desire to transfer the CTSI funds to this additional support.

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 will be included with each newsletter. This will also be the mechanism announcing the

Programs' availability of positions (slots) every year to the 4 campuses.

- c. 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. The Executive Committee will meet on a quarterly basis.
- d. 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 CTSI), 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.

3. Administration of the Program

List of faculty and staff involved in the program

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

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

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. P. (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)

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)

B. Administration:

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.

- c. **Library:** Indiana University has an extensive array of learning resources and facilities that will be available to the proposed Master of Science in Translational Science 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 Master's Degree 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.

D. Learning Resources

1. **Existing Learning Resources** Indiana University has an extensive array of learning resources and facilities that will be available to the proposed Master of Science in Translational Science 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 Master's Degree 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.

Library holdings, equipment, laboratories, clinical and research facilities available: Indiana University has an extensive array of learning resources and facilities that will be available to the proposed Master of Science in Translational Science 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.

Library holdings: The libraries on the Bloomington and Indianapolis campuses will be important resources for students in graduate health programs. Ranked as 19th in the Association of Research Libraries, IU Bloomington Libraries offer access to more than 500 databases, over 4.6 million volumes and almost 70,000 journals. The IUPUI campus, meanwhile, has a new, state-of-the-art library completed in 1993. There are more than 1.3 million volumes, including access to over 36,000 periodicals and journals. As one of the most technologically-sophisticated libraries in the country, the library has two networked classrooms as well as both faculty and student networked study rooms and hundreds of individual study carrels. Students have access to several databases

for bibliographic searches. Moreover, it houses the Robert Payton Philanthropic Studies Library, which has an extensive collection of references and volumes about the nonprofit or third sector. The Ruth Lilly Medical Library, located in the Medical Research Building, serves the Schools of Medicine, Nursing, and Allied Health Sciences. With state-of-the-art study facilities available 24-hours every day of the year, this library houses over 194,000 volumes. Through MEDI ARS, BRS and Dialog, students have access to over 400 databases such as Medline, CINAHL, HEALTH, CANCERLIT, and the Cochrane Library. There is a History of Medicine special collection. Individual school libraries with specialized collections in business, dentistry, law, optometry and public affairs are also available to graduate students. The IUPUI University Library has a media library room, and both the University and Medical Libraries have audiovisual materials and other special collections. The IU system's library holdings are available to all students through interlibrary loan and on-line searches. In addition, students have access to library collections in Indiana, at Big Ten Universities, and at institutions around the country.

Special Equipment & Collections: The Bloomington and Indianapolis campuses have state-of-the-art electronic technologies for instructional design and distance learning. There are facilities for special classroom set-ups and video production. The University is part of the Indiana Higher Education Telecommunication System (IHETS), a consortium of universities in the state that provides distance learning programs at over 300 locations around Indiana. Computer laboratories on the campuses give students access to databases for bibliographic searches and to statistical packages for research. There are eighteen such learning centers on the IUPUI campus, including centers in the Ruth Lilly Medical Library, the University Library, and the business, dental, and nursing schools. Within the School of Medicine, Medical Educational Resources Program (MERP) and Medical Illustrations are additional sources of visual and electronic equipment and resources. The campuses and schools are linked by local area networks that facilitate communication and sharing of materials with people in different departments and schools.

Clinical Facilities: The State of Indiana has a population of over 6,000,000. Indiana University Medical Center acts as a primary care center for metropolitan Indianapolis with a population of about 800,000, the nation's 14th largest city. In 1997 University Medical Center comprising University Hospital with 332 beds, Riley Hospital for Children with 243 beds, and Methodist Hospital with 760 beds merged to form Clarian Health. In 2008 Clarian Health had 50,686 admissions with 319,862 total patient days and 751,133 total outpatient visits. This merger more than doubled the number of beds, tripled the number of admissions and doubled the number of outpatient visits of the original Indiana University Medical Center. In addition, Wishard Hospital has 473 beds and 17,574 inpatient admissions annually, with 21 clinics handling 165,000 outpatient visits. Veterans Hospital has 176 beds, 60 nursing home beds, 5,967 inpatient

admissions and 284,271 outpatient visits annually. LaRue Carter Psychiatric Hospital has 145 beds, 203 inpatient admissions and 6,250 outpatient visits per year. Clarian Health acts as the major secondary and tertiary referral center for the State of Indiana. It has the patient population and the resources to withstand changes induced by managed care to support clinical research at the highest level.

Laboratories: Indiana University – Purdue University of Indianapolis offers around 1 million square feet in research facilities and research support space. In 1992, a new wing of University Hospital, (150,000 square feet dedicated to Ambulatory Care) was opened, and the contiguous Lilly Pharmaceuticals Clinical Research Center of 82,334 sq. ft. was opened in April 1998. In 1996 the Clinical Cancer Pavilion of 120,000 gross square feet contiguous with Indiana University Hospital was opened and in 1997 the Cancer Research Institute of 63,950 net square feet was completed. The Institute houses the 5 key groups that make up the laboratory research arm of the IU Cancer Center: the National Gene Vector Laboratory, the Experimental Therapeutics Program, the Adult Hematology/Oncology Research Program, and the Herman B Wells Center for Pediatric Research and the Walther Oncology Center. Also in 1997, the Children's Cancer Center of 18,622 net square feet within the James Whitcomb Riley Hospital for Children was opened. In 2002, the campus added an additional 184,496 square footage through the Research II building as well as Biotechnology Research and Training Center. Moreover, in 2006, the campus opened the Health Information and Translational Science (HITS) building, which provided an additional 149, 062 square feet. In 2009, the campus opened an additional 261, 960 square feet of research facilities through Walther Research Hall in 2009.

Current Assets for Research:

The Indiana University School of Medicine (IUSM) was established in 1903. It is currently one of the nation's largest medical schools. It is located on the 93-acre Indiana University Medical Center (IUMC) campus in Indianapolis and consists of four hospitals (University, Wishard Memorial, Roudebush Veteran's Administration, and the James Whitcomb Riley Hospital for Children). The world-renowned Regenstrief Institute for Health Care shares this campus. In 1997, the Indiana University Hospital merged with a nearby private, not-for-profit hospital (Methodist Hospital), one of the largest private hospitals in the country, to form Clarian Health Partners, Inc. The Methodist Hospital campus is approximately one mile from IUMC and is connected by a monorail system.

The medical center campus, which includes the only Schools of Medicine and Dentistry in Indiana and the largest School of Nursing in the state, is part of the larger Indiana University Purdue University at Indianapolis (IUPUI) campus. IUPUI currently has over 29,000

undergraduate and graduate students in Schools of Science, Engineering and Technology, Liberal Arts, Social Work, Law, Business, to name a few. Approximately 5,000 of the students on campus are enrolled in one of the health sciences schools. Half of the first- and second-year medical school students take their classes on the IUSM campus; the other half are located at one of other eight IUSM medical campuses around Indiana, which are located on or near satellite campuses of IU and home campuses of other universities in the state (including Purdue, Notre Dame, Ball State University, Indiana State University, and the University of Southern Indiana). All of the students spend their third and fourth years in Indianapolis. Current IUSM enrollment for all four years includes 1,251 M.D. students. In addition, 189 Ph.D., 96 M.S., 153 M.P.H., and 43 M.D./Ph.D., and 35 certificate students are enrolled in IUSM graduate programs. There are also 18 M.D./M.B.A., one M.D./M.A, and 3 M.D./M.P.H. students at IUSM.

For the year 2007-2008, Indiana IUSM received approximately \$244 million in research funding (\$104.3 million from NIH, \$42.2 million from other federal sources), which included funding for the only federally sponsored gene vector production and research facility, for one of three molecular hematology research centers in the country, and for a National Cancer Institute-designated Cancer Research Center (see Figure below.) There are 505 primary investigators on the IUSM campus. As indicated below, IUSM hosts 16 research centers or program projects supported by PHS/NIH or other federal funds, as well as 33 supported by non-federal funds. Currently, there are 13 T32, two T35, one T15, two R25, two HRSA, 8 F-series, and 31 K-series federally-funded training programs and grants at IUSM.

In 2000, IUSM was awarded a \$105 million grant from Lilly Endowment Inc. to establish the Indiana Genomics Initiative (INGEN). This was the largest single grant ever received by the University and the largest single gift ever awarded by the Lilly Endowment. The Indiana Genomics Initiative helped develop a world-class biomedical enterprise, building on existing resources at IUSM to advance the work of the Human Genome Project. Another award of \$50 million was subsequently made by the Lilly Endowment. In 2008, IUSM, in collaboration with IUPUI, IU Bloomington, University of Notre Dame, and Purdue University, received a \$25M Clinical and Translational Sciences Award from NIH to establish the Indiana Clinical and Translational Sciences Institute (ICTSI).

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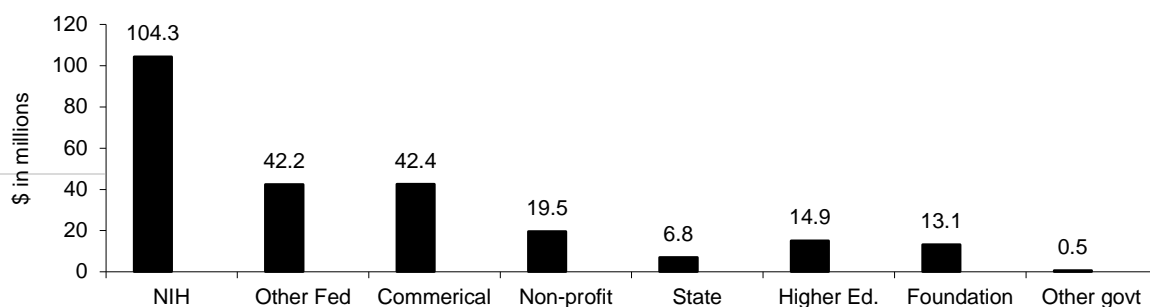


TABLE 8: Research Cores IU Cancer Center	
Angiogenesis and Endothelial Progenitor Cell	Center for Computational Biology and Bioinformatics Service Core
Chemical Synthesis & Organic Drug Lead Development	Center for Structural Biology
Clinical Pharmacology Analytical Core	Center for Medical Genomics (Genotyping and Gene Expression Core)
Clinical Research Office	Center for Neuroimaging
Flow Cytometry Resource Facility	Chemical Genomics Core Facility
Immunohistochemistry Core	Computational Molecular Science Facility
In Vivo Therapeutics	DNA Bank and Cell Repository
Transgenic and Knock-Out Mouse	Electron Microscopy Center
Tissue Procurement & Distribution Facility	Immunohistochemistry Research Laboratory
Translational Genomics	Indiana Center for Biological Microscopy
Advanced Information Technology Core	Indiana CTSI Specimen Storage Facility
Biochemistry Biotechnology Facility (DNA Sequencing Core)	Indiana Institute for Biomedical Imaging Sciences
Biostatistics	Mead Johnson Mass Spectrometry Core
Cancer Clinical Research	Micro Services
Cardiovascular Ischemia and Vasculogenesis Core	Molecular Signatures Core
Cardiovascular Physiology Core	Murine Cytogenetic Core
Cell and Protein Expression Core	Oxidative Stress and Environmental Analysis
Preclinical Histology Core	Quantitative Amino Acid Analysis
Peptide Synthesis Core	Rodent Neuropsychopharmacological Testing and Phenotyping Core
Proteomics Core	Vector Production Facility

Regenstrief Institute for Health Care (RIHC): The RIHC was established in 1969 and is maintained by the philanthropic Regenstrief Foundation. The RIHC houses 43 investigators and an additional 46 investigators hold affiliated scientist positions. RIHC provides substantial in-kind support for a fellowship program that includes 12 trainees in health services research, medical informatics, and geriatrics. The Regenstrief Institute also houses two major research centers. The Diabetes Research and Training Center is one of six such federally-funded centers in the country, and the Center for Aging Research is a campus-wide multidisciplinary consortium. The Regenstrief Medical Record System (RMRS) is one of the largest general medical data systems in the world. Established in 1974, The RMRS has registered more than 6 million patients, has over 20 million dictated records, and is accessed nearly 5 million times each year. Currently, the RMRS is used at more than 40 inpatient and outpatient facilities in Indianapolis and surrounding counties and is the largest coded, continuously operated medical records system in the United States.

2. 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.

X. Innovative Features of the Proposed Degree Track:

Presently, training in human disease at both a basic and clinical level is not well-addressed by traditional training programs, which leaves a nationally unmet need for translational scientists. The proposed program will fill this unmet need by offering basic science and engineering students a new Master's Program in Translational Science specifically designed for them. The final product will be a graduate with an M.S. in Translational Science who understands human disease at both the basic and clinical level.

This program will enhance the interaction between physicians in clinical departments with scientists and engineers in basic departments who are engaged in fundamental bench research focused on human disease. Additionally, this program will also facilitate the interaction of scientists and engineers 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 provide graduates with a better understanding of basic science and its implications on their clinical research in the area of human disease while also facilitating 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.

The M.S. 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 physicians 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 sciences approaches to focus on the application of these approaches to human disease. This graduate program differs from other graduate programs on campus by offering a new pathway for engineers and basic scientists to gain a comprehensive knowledge of basic and clinical science methodologies, as well as learn how to collaborate with clinical scientists and engineers in a translational research environment regardless of their specialty. An overall goal of this training program is to produce exceptional 'translational' researchers in a fashion that saves both time and expense when compared to more conventional 'translational' training routes.

XI. Appendix: List of existing courses and proposed new courses

A. 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 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) **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).
 - 3) **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).

4) Responsible Conduct of Research (New) 3 credits. Look in New Coursework section b 4).

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

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).

4. Techniques of Effective Grant Writing (N802 or approved equivalent): 3 credits. This is an intensive course / workshop designed to teach fellows and graduate students how to write and review an NIH application. Trainees will write an NRSA, R03, or K-award application. This will serve as the M.S. student thesis and must be submitted for review by their committee. **Course Directors:** Paul Lysaker & Alan Breier. Offered 3 times in the past 3 years (every fall).

5. Electives (3 – 7 credits) Master's degree students must select graduate-level electives and receive prior approval from the Program Director. The selections will be tailored to the student's

particular research interests. Up to 12 credits may overlap with the student's current doctoral program. Electives are subject to approval by the Program Director.

B. New Courses

1. Clinical Rotations for Scientists and Engineers (New – GRAD-G671): 9 credits. This mandatory course is a clinical immersion course. The current course consists of three practicums offered across the summer, fall, and spring semesters. Across these semesters, students will be paired in individualized rotations through various medical fields, such as Medicine, Pediatrics, and Radiology (3 credits each), . An effort is made to only have 2 students on each rotation at a time to maintain a high quality experience. These courses serve to both introduce the students to clinical medicine, and acclimatize them to the language and environment of hospital-based and out-patient medical care. **Course Director:** R. Mark Payne, M.D.

2. Responsible Conduct of Research (New) 3 credits. A new course currently being developed by John Baumann, Ph.D. (Executive Director, Research Ethics, Education and Policy, Office of Vice President for Research, Indiana University) **Course Director:** John Baumann

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