

Comparison of MS in Translational Research and MS in Clinical Research Curriculum

<i>Course Title</i>	<i>Course #</i>	<i>Credits</i>	MS in Clinical Research	MS in Translational Science	
				Track 1 - Clinical background	Track 2 -Basic background
Tools & Techniques in Translational Research	GRAD G667	3		X	X
Quantitative Aspects of Translational Research	GRAD G668 (New)	3		X	X
Introduction to Research Ethics or Ethical and Policy Issues in International Research	GRAD G504 or PHIL P555	2 to 3	X	X	X
Biostatistics I or II (or approved equivalent)	GRAD G651 or G652	3	X	X	X
Electives (must be approved by the Program Director)	GRAD XXX	3 to 7	X (4 to 6)	X (3 to 7)	X (4 to 6)
Techniques of Effective Grant Writing (or approved equivalent)	GRAD N802	3	X	X	X
Mentored Basic Science / Translational Research	New	7 to 9		X	
Thesis in Translational Research	New	3		X	
Clinical Rotations for Scientists / Engineers	New	9			X
Mentored Clinical Research	GRAD 664	7 to 9	X		
Clinical Research Methods	GRAD G660	3	X		X
Clinical Trials	GRAD 661	3	X		
Research Communication	GRAD 655	2	X		
Total Required Credits			30	30	30

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Course Descriptions

Requirements for all 3 MS 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).

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. Course Directors: S. Gao & P. Monahan. Offered 3 times in the past 3 years (every fall).

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).

Electives (3-7 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 both MS in Translational Science Degrees

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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.

Requirements for MS in Translational Science for people with clinical background (i.e. MD) - Proposed

Mentored Basic Science / Translational Research (New): 7 – 9 credits. This mandatory course requires the student to construct an organized translational research project under dual mentorship (M.D. and Ph.D.) by faculty. The capstone experience is the completion of a grant in the NIH format suitable for peer-review and presentation before one's peers. This course will be conducted in the fall, spring, and summer terms, graded by faculty, and should be in a format supporting submission to a funding organization. Students will enroll for 3 credits per semester for up to 3 semesters. **Course Director:** R. Mark Payne, M.D.

Thesis in Translational Research (New): 3 credits. This mandatory course requires the student to complete a research thesis based on their mentored basic science / translational research project. **Course Director:** R. Mark Payne, M.D.

Requirement for MS in Translational Science for people with Basic Science background (i.e. Ph.D.) – Proposed

Clinical Rotations for Translational Scientists and Engineers (New): 9 credits Students rotate in pairs through all rotations, and 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. Designed as practicums, these courses are particularly aimed at non-clinician scientists intending to conduct translational research.

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Requirements for MS 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.

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

Research Communication (2 credits)

This course combines a core didactic set of classes on the key elements of scientific writing along with the requirement for completion of a paper to be submitted for publication in a peer-reviewed journal. Two secondary skills are also covered. Manuscript review is addressed, including co-review of a manuscript with a mentor or other faculty scientist. The principles of presenting research at scientific meetings are also covered, including preparing an abstract, an oral presentation, and a poster.

Mentored Clinical Research (7-9 credits)

This is an organized research project in the form of an organized scientific contribution or comprehensive analysis conducted under the mentorship of a faculty scientist from the individual CITE enrollee's core discipline. The capstone experience is submission of an abstract to a scientific meeting, defense of one's research before an Advisory Committee, and completion of a first-authored paper deemed suitable for publication in a scientific journal.