Chair: Tracy Christofero GC#4: Major or Degree

### Request for Graduate Addition, Deletion, or Change of a Major or Degree

1. Prepare one paper copy with all signatures and supporting material and forward to the Graduate Council Chair.

2. E-mail one PDF copy without signatures to the Graduate Council Chair.

NOTE: Before you submit a request for a new Major or Degree, you must submit an INTENT TO PLAN form. Only after the INTENT TO PLAN goes through the approval process are you ready to submit this request for a new Major or Degree. For detailed information on new programs please see: <a href="http://wvhepcdoc.wvnet.edu/resources/133-11.pdf">http://wvhepcdoc.wvnet.edu/resources/133-11.pdf</a>.

3. The Graduate Council cannot process this application until it has received both the PDF copy and the signed hard copy.		
College: Medicine/Graduate	Dept/Division:Clinical and Translational Science	
Contact Person: Todd L. Green, Ph.D.	Phone: 6-3531	
Degree Program M.S. in Clinical and Translational S	And the second of the second o	
Check action requested:   Addition   Dele	ion Change	
Effective Term/Year Fall 20 16 Spring 2	0 Summer 20	
Information on the following pages must be compl	eted before signatures are obtained.	
Signatures: if disapproved at any level, do not sign. I	Return to previous signer with recommendation attached.	
Dept. Chair/Division Head	Date	
College Curriculum Chair	Date	
College Dean	Date	
Graduate Council Chair	Date	
Provost/VP Academic Affairs	Date	
Presidential Approval	Date	
Board of Governors Approval	Date	

Please provide a rationale for addition, deletion, change: (May attach separate page if needed)
ATTACHED
Please describe any changes in curriculum: List course number, title, credit hours. Note whether each course is required or optional. Enter NONE if no change. (May attach separate page if needed) ATTACHED
<b>1. ADDITIONAL RESOURCE REQUIREMENTS</b> : If your program requires additional faculty, equipment or specialized materials to ADD or CHANGE this major or degree, attach an estimate of the time and money required to secure these items.  NOTE: Approval of this form does not imply approval for additional resources. Enter NONE if not applicable.
NONE
2. NON-DUPLICATION: If a question of possible duplication occurs, attach a copy of the correspondence sent to the appropriate department(s) describing the request and any response received from them. Enter NONE if not applicable.
NONE
For catalog changes as a result of the above actions, please fill in the following pages.

#### 3. Current Catalog Description

Insert the *Current* Catalog Description and page number from the latest catalog for entries you would like to change. (May attach separate page if needed)

NOT APPLICABLE

### 4. Edits to the Current Description

Attach a PDF copy of the current catalog description prepared in MS WORD with strikethroughs to mark proposed deletions and use the highlight function to indicate proposed new text.

#### 5. New Catalog Description

Insert a 'clean' copy of your proposed description, i.e., no strikethroughs or highlighting included. This should be what you are proposing for the new description. (May attach separate page if needed)

ATTACHED

Please insert in the text box below your change summary information for the Graduate Council agenda. Please enter the information exactly in this way (including headings):

Department: Major or Degree:

Type of Change: (addition, deletion, change)

Rationale:

Department: Clinical and Translational Science

Major or Degree: MS in Clinical and Translational Science

Type of Change: Addition

Rationale:

Rapid advances in technology, genomics and translational science will change the way medical care is given such that prevention and treatment of disease is specific to each individual patient. Much of personalized medicine is dependent on clinical and translational science (CTS). Translational science is the application of the results from the basic research on cells and animals to the treatment of patients - "bench to bedside". There is a need for scientists and clinicians who can direct teams in CTS and can establish collaboration among basic and clinical scientists from different disciplines. The goal of this program is to equip physicians in training and other biomedical scientists with the information and training they need to translate basic advances into improved patient care that will enhance the quality of life for patients in the Appalachian region, particularly southern West Virginia. Additionally, an MS degree in clinical and translational science is an absolute requirement for obtaining a National Institutes of Health Clinical and Translational Science Award (CTSA) or an Institutional Development Award. The latter award is restricted to certain qualifying states including West Virginia. Both awards range between \$16-20 million over the five years of the program.

Graduates of this program will be able to lead clinical trials of new drugs and procedures in West Virginia, particularly in the rural regions of the state. The graduates of this program will also be strong applicants for positions in schools of medicine and medical centers that have Clinical and Translational Science Awards. Additionally, since 2007 there are 11 new LCME-accredited allopathic medical schools in the US, with several more in the applicant or candidate phase of accreditation. Due to the emphasis on translational and personalized medicine, these new schools will need faculty to teach and perform some research in this new discipline.

Although WVU and the University of Kentucky have an MS program in Clinical Research, they are over three hours and two hours driving distance respectively from the Marshall campus. This distance makes it unlikely that our medical students or residents would choose to apply for these degree programs. And their programs are not focused on our rural population.

#### **RATIONALE**

Rapid advances intechnology, genomics and translational science will change the way medical care is given such that prevention and treatment of disease is specific to each individual patient. Much of personalized medicine is dependent on clinical and translational science (CTS). Translational science is the application of the results from the basic research on cells and animals to the treatment of patients - "bench to bedside". There is a need for scientists and clinicians who can direct teams in CTS and can establish collaboration among basic and clinical scientists from different disciplines. The goal of this program is to equip physicians in training and other biomedical scientists with the information and training they need to translate basic advances into improved patient care that will enhance the quality of life for patients in the Appalachian region, particularly southern West Virginia. Additionally, an MS degree in clinical and translational science is an absolute requirement for obtaining a National Institutes of Health Clinical and Translational Science Award (CTSA) or an Institutional Development Award. The latter award is restricted to certain qualifying states including West Virginia. Both awards range between \$16-20 million over the five years of the program.

Graduates of the MS in CTS program will be able to lead clinical trials of new drugs and procedures in West Virginia, particularly in the rural regions of the state. The graduates of this program will also be strong applicants for positions in schools of medicine and medical centers that have Clinical and Translational Science Awards. Additionally, since 2007 there are 11 new LCME-accredited allopathic medical schools in the US, with several more in the applicant or candidate phase of accreditation. Due to the emphasis on translational and personalized medicine, these new schools will need faculty to teach and perform some research in this new discipline.

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No new faculty will have to be hired to teach in this program.

### MS IN CLINICAL AND TRANSLATIONAL SCIENCE

# PROPOSED CURRICULUM (All courses are required.)

TOTAL HOURS		43
CTS 640	Clinical Trials Journal Club*	1 CR
Spring Semester 2 BMS 680 CTS 625	Seminar Clinical Research Operations*	1 CR 5 CR
CTS 660	Molecular Phenotype of Appalachian Disorders*	3 CR
CTS 640	Clinical Trials Journal Club*	1 CR
CTS 625	Clinical Research Operations Lab*	5 CR
Fall Semester 2 BMS 680	Seminar Clinical Possarch Operations Lah*	1 CR
CTS 650	Rural Clinic Experience*	5 CR
Summer Semester		
CTS 640	Clinical Trials Journal Club*	1 CR
CTS 630	Fundamentals of Team Science*	2 CR
CTS 614	Online Survey Tools, Relational and Data Warehousing, and Data Manipulation*	3 CR
C13 010	Research*	3 CK
CTS 610	Study Design and Applied Statistics in Medical	3 CR
BMS 680	Communication Skills II Seminar	1 CR
Spring Semester 1 BMS 661	Communication Skills II	1 CR
CTS 640	Clinical Trials Journal Club*	1 CR
CTS 635	Writing and Peer Review of Scientific Publications*	1 CR
CTS 620	Basic Clinical Research Operations*	3 CR
CTS 600	Epidemiology and Biostatistics Used in Medical Research*	3 CR
BMS 680	Seminar	1 CR
BMS 660	Communication Skills I	1 CR
Fall Semester 1		

\*New Course

#### MS IN CLINICAL AND TRANSLATIONAL SCIENCE

Course Titles, Course Directors, and Catalog Descriptions

#### **NEW COURSES**

### CTS 600 - Epidemiology and Biostatistics in Medical Research (3 hours) - Todd Gress, MD

Fall

This is the practical application of epidemiology and biostatistics used in medical research. The course will primarily focus on the design and analysis of translational studies.

## CTS 610 - Research Design and Biostatistics (3 hours) - Todd Gress, MD Spring

Students will participate in an internship with faculty in providing consultation services in study design and statistics for medical research projects.

## CTS 614 - Online Survey Tools, Relational and Data Warehousing, and Data Manipulation (3 hours) - Alfred Cecchetti, PhD

Spring

This course will introduce Redcap, explore relational DB terms, I2B2, a research data warehouse counting tool, and data manipulation using MS SQL queries, functions, procedures along with C# using LINQ.

### CTS 620 - Basic Clinical Research Operations (3 hours) - Todd Davies, PhD Fall

This course will focus on the operation of clinical research trials, providing an overview of the critical aspects involved in all stages of clinical trials.

## CTS 625 - Clinical Research Operations Lab (5 hours) - Todd Davies, PhD Fall, Spring

This course is a hands-on experience in Clinical Research trial operation. The course provides an opportunity for students to work with clinical research professionals on FDA-directed clinical trials.

## CTS 630 - Fundamentals of Team Science (2 hours) - Darshana Shah, PhD Spring

This course offers practical guidance about how best to engage in team science to pursue complex science questions and work effectively with team members.

### CTS 635 - Writing and Peer Review of Scientific Publication (1 hour) - Darshana Shah, PhD

Fall

This course teaches students to become more effective writers of scientific publications.

### CTS 640 - Clinical Trials Journal Club (1 hour) - Todd Green, PhD

Fall, Spring

This course will be presentations and discussions of the recent literature in the area of clinical trials. Fundamental principles and new discoveries will be emphasized.

### CTS 650 - Rural Clinic Experience (5 hours) - Todd Gress, MD and Uma Sundaram, MD

Summer I

This course will acquaint students with the issues of rural community health and wellness, which will allow them to participate in clinical studies in a rural environment.

### CTS 660 - Molecular Phenotype of the Appalachian Disorders (3 hours) - Richard Egleton, PhD

Fall

The course will describe the clinical presentations, epidemiology and molecular phenotype of disorders common in the Appalachian region.

#### **EXISTING COURSES**

### BMS 660 - Communication Skills for the Biomedical Sciences I (1 hour) - Beverly Delidow, PhD

This course trains students to plan, prepare and deliver effective scientific presentations. Students are evaluated by attendance and participation.

### BMS 661 - Communication Skills for the Biomedical Sciences II (1 hour) - Beverly Delidow, PhD

This course trains students to plan, prepare and deliver effective scientific presentations. Students are evaluated by attendance and participation.

#### BMS 680 - Seminar (1 hour) - Todd Green, PhD

This course teaches students how to prepare and deliver different types of scientific presentations. Students are evaluated by attendance.

### **NEW CATALOG DESCRIPTION**

### CLINICAL AND TRANSLATIONAL SCIENCE, M.S.

#### PROGRAM DESCRIPTION

The Clinical and Translational Science (CTS) Department in the Marshall University Joan C. Edwards School of Medicine offers a Master of Science (M.S.) degree in Clinical and Translational Science. The goal of this program is to equip physicians in-training and other biomedical scientists with the information and training they need to translate basic clinical advances into improved patient care that will enhance the quality of lifefor patients in the Appalachian region, particularly southern West Virginia.

Students will receive education in clinical trial design, epidemiology, statistics, informatics, and translational research. Graduates of this program will be able to lead clinical trials of new drugs and procedures in West Virginia, particularly in its rural regions. CTS graduates also will be strong applicants for positions in schools of medicine and medical centers that have Clinical and Translational Science Centers.

#### CLINICAL AND TRANSLATIONAL SCIENCE, M.S. ADMISSION POLICY

Applicants must meet both the requirements of Graduate Admissions and the Marshall University Joan C. Edwards School of Medicine Clinical and Translational Science Department Admissions Committee. Interested persons may contact the Office of Research and Graduate Education via e-mail at <a href="mailto:mubiomed@marshall.edu">mubiomed@marshall.edu</a> or learn more at <a href="mailto:www.marshall.edu">www.marshall.edu</a>/bms/future-students/application-information.

Entrance into the Clinical and Translational Science, M.S. program is restricted to fall semester only. Applicant materials should be received by March 1 in the Graduate Admissions Office to have the best chance for admission.

The complete application process includes:

- 1. Submission of the Marshall University Graduate College Application available online at <a href="https://www.marshall.edu/graduate">www.marshall.edu/graduate</a>. Select "Degree Seeking."
- 2. Receipt of the application fee (submitted online at the time of application).
- 3. Receipt of official transcript(s) from every institution attended documenting that the applicant has:
  - a. Completed a bachelor's degree from an accredited institution of higher learning. The degree must be completed prior to matriculation.
  - b. Achieved an overall Grade Point Average of 3.0 or better.
  - c. Successfully completed one academic year of biology and its associated labs.

- d. Successfully completed one academic year of general chemistry and its associated labs.
- e. Successfully completed one academic year of organic chemistry and its associated labs.
- f. Successfully completed one academic year of physics and its associated labs.
- g. It should be noted that successful completion of undergraduate courses in biochemistry and cell biology are highly recommended, but not required.

#### 4. Official letters

- a. Three letters of recommendation signed and on formal letterhead from individuals familiar with the applicant's relevant academic/professional performance (May be e-mailed as attachments)
- b. Written statement describing the applicant's educational and career goals, and why he or she should be admitted to the CTS, M.S. program. (May be e-mailed as an attachment)

Completed applications received in the Graduate Admissions Office by March 1 will be considered for admission. The CTS Admissions Committee will review completed applications then interview the top applicants.

#### WHO SHOULD APPLY

- · Undergraduates.
- Medical students at an LCME-accredited U.S. medical school with a current GPA of at least a 3.0.
- Postgraduate medical residents or fellows who have an M.D. or D.O. with a graduating GPA of 3.0 or better (equivalent GPA for foreign medical graduates).
- Ph.D.'s in biomedical sciences or Pharm.D.'s with graduating GPAs of 3.0 or better.

Medical students will apply to the program during their third year of training. After completing the requirements for the MS degree, students will finish the fourth year of medical school.

Medical residents and fellows who are admitted into this program will need to integrate coursework into a reduced clinical workload, thus extending their postgraduate medical education by two years.

#### **Duration of the Program**

Students will attend full-time and complete the requirements for the Master of Science degree in two years. This includes attending during the summer between years one and two.

### **Degree Requirements**

CTS 640

All students are required to meet the general requirements of the Graduate College for receipt of a master's degree. A minimum of 36 credit hours is required for a non-thesis degree. In addition, all students must pass a written and/or oral comprehensive exam.

All students will take the following courses.

Fall Semester 1	
BMS 660	Communication Skills I
BMS 680	Biomedical Sciences Seminar
CTS 600	Epidemiology and Biostatistics Used in
	Medical Research
CTS 620	Basic Clinical Research Operations
CTS 635	Writing and Peer Review of Scientific
	Publications
CTS 640	Clinical Trials Journal Club
Spring Semester 1	
BMS 661	Communication Skills II
BMS 680	Biomedical Sciences Seminar
CTS 610	Study Design and Applied Statistics in Medical
	Research
CTS 614	Online Survey Tools, Relational and Data
	Warehousing, and Data Manipulation
CTS 630	Fundamentals of Team Science
CTS 640	Clinical Trials Journal Club
Summer Semester	
CTS 650	Rural Clinic Experience
Fall Semester 2	
BMS 680	Biomedical Sciences Seminar
CTS 625	Clinical Research Operations Lab
CTS 640	Clinical Trials Journal Club
CTS 660	Molecular Phenotype of Appalachian Disorders
Spring Semester 2	
BMS 680	Biomedical Sciences Seminar
CTS 625	Clinical Research Operations

Clinical Trials Journal Club