

**IMPORTANT:** This syllabus form should be submitted to OAA ([gsbs\\_academic\\_affairs@uth.tmc.edu](mailto:gsbs_academic_affairs@uth.tmc.edu)) a week before the start of each semester.

**NOTE to STUDENTS:** If you need any accommodations related to attending/enrolling in this course, please contact the Graduate School's 504 Coordinator Natalie Sirisaengtaksin, PhD. We ask that you notify GSBS in advance (preferably at least 3 days before the start of the semester) so we can make appropriate arrangements.

<p>Term and Year: <b>Summer 2026</b></p> <p>Course Number and Course Title: <b>GS12 1411: Translational Pathology in Drug Development</b></p> <p><b>Credit Hours: 1</b></p> <p><b>Prerequisites:</b> None</p> <p><b>Meeting Location:</b> Basic Science Research Bldg.</p> <p><b>Building/Room#:</b> BSRB S3.8355 (<b>GSBS Conference Room</b>)</p>	<p><b>Program Required Course:</b> No</p> <p><b>Approval Code:</b> No</p> <p><b>Audit Permitted:</b> Yes</p> <p><b>Classes Begin:</b> May 21, 2026</p> <p><b>Classes End:</b> July 30, 2026</p> <p><b>Final Exam Week:</b> August 6, 2026</p>
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**Class Meeting Schedule**

Day	Time
Wednesdays	10 am-12 pm CST

<p><b>Course Director</b></p> <p>Name and Degree: <b>Manu Sebastian, DVM, PhD</b></p> <p>Title: <b>Professor</b></p> <p>Department: <b>Veterinary Medicine &amp; Surgery</b></p> <p>Institution: MDACC</p> <p>Email Address: <a href="mailto:mmsebastian@mdanderson.org">mmsebastian@mdanderson.org</a></p> <p><b>NOTE:</b> Office hours are available by request. Please email me to arrange a time to meet.</p>	<p><b>Instructors</b></p> <ol style="list-style-type: none"> <li><b>Susanne Je-Han Lin, DVM, PhD</b> Institution: MDACC, DVMS Email Address: <a href="mailto:SLin7@mdanderson.org">SLin7@mdanderson.org</a></li> <li><b>Natalie Fowlkes, DVM, PhD</b> Institution: MDACC, Stem Cell Transplantation Email Address: <a href="mailto:nwfowlkes@mdanderson.org">nwfowlkes@mdanderson.org</a></li> <li><b>Rajneesh Pathania, DVM, PhD</b> Institution: MDACC, DVMS Email Address: <a href="mailto:rpathania@mdanderson.org">rpathania@mdanderson.org</a></li> <li><b>Brian Simons DVM, PhD</b> Institution: Baylor College of Medicine Email Address: <a href="mailto:Brian.Simons@bcm.edu">Brian.Simons@bcm.edu</a></li> </ol>
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**Course Description:**

In vivo studies are critical components of translational medicine and drug development. In vivo studies are performed for testing the efficacy of a drug, its safety, knowledge about target engagement etc. Different methods are used for testing these parameters and one of the most important methods is evaluating tissue responses using

different histopathology techniques. Current course will discuss in detail the response of rodent and other animal models of human diseases and evaluation of the tissues using staining methods, quantification of the responses using image analysis, tissue biomarkers for precision medicine, etc. The course provides insights into the regulatory process for approval of drugs.

This course will also provide basic knowledge on the histology of all mammalian organs, how tumors are visualized in tissues, how to identify specific protein expressions of the tumors, spatial biology of tumors etc. Some classes include a visit to the pathology laboratory, peer discussions, and literature review. Students taking this course will receive a foundation knowledge of in vivo tissue evaluation of drug development and translational medicine which will prepare them for a career in biopharma or academia.

### **Textbook/Supplemental Reading Materials ( optional for further reference)**

- Comparative Anatomy and Histology: A Mouse, Rat, and Human Atlas 2nd Edition Piper M. Treuting.
- Haschek and Rousseaux's Handbook of Toxicologic Pathology, Volume 4: Toxicologic Pathology of Organ Systems, 4th Edition by Wanda M. Haschek
- Casarett & Doull's Toxicology: The Basic Science of Poisons, 6th Edition, by Curtis Klaassen
- Journals: The American Journal of Pathology; Toxicologic Pathology, Journal of Translational Medicine; American Journal of Cancer Research

### **Course Objective/s:**

Upon successful completion of this course,

A challenge for the graduate student is to apply the best experimental in vivo approach to investigate and solve research problems for translational medicine. The purpose of this course is to convey fundamental knowledge needed to perform valid and interpretable tissue-based response using different animal models with emphasis on mouse models. The course will feature a diverse group of instructors covering a wide variety of subjects necessary to understand the importance of the appropriate use of mouse models, advanced tissue-based evaluation technology for target engagement of the drug.

Precision medicine in oncology identifies patients for targeted immunotherapy by analyzing tumor tissue for biomarkers, like PDL1 expression. The course will discuss in detail the tissue-based biomarker analysis which can be applied for designing targeted therapy. The course also discusses in detail the different phases of drugs development process including preclinical and clinical phases, safety evaluation and regulatory process which are the pillars of drug development. Different advanced digital and spatial biology technology platforms used in translational medicine and drug development will be discussed in detail.

### ***Specific Learning Objectives:***

1. Students will have learned the basic concepts of mouse biology, histology and clinical pathology needed to design and interpret in vivo studies.
2. Students will have learned about the advantages and disadvantages of the use of the laboratory mouse as an animal model and interpretation of tissue response to experimental drug treatment.
3. Students will have learned how to responsibly design, conduct, and interpret results using mouse models and will be familiar with the influence of genetic background, strain-related lesions, and environment.

4. Students will be exposed to tissue biomarkers, digital pathology for image analysis, spatial biology, interpretation of pathology data of mouse models, and integrate pathology into experimental design and translational medicine.
  
5. Students will be exposed to different stages of drug development, from target discovery, preclinical testing, toxicology assessment, and the regulatory pathway leading to clinical trials. Emphasis will be placed on how mouse models are used to generate data to support the process, and how preclinical animal studies translate basic scientific discoveries to clinical advancement.

**Student responsibilities and expectations:**

Students enrolled in this course will be expected to perform the following activities each week.

1. Read, process, and review (study) material from 1 or 2 seminal reviews relating to the week's topic.
2. Read 2 research articles (e.g., primary research)
3. Participate in and contribute to course discussions during lectures.
4. Prepare for and take a midterm and final examination based on the lecture and some reading materials.

Students are expected to complete all assigned reading material (reviews and research literature) prior to class. While you may work and discuss all course materials and assignments in groups, all writing assignments must be your own. Plagiarism and failure to properly cite scientific literature and other sources will not be tolerated and are grounds for dismissal from the course and further GSBS disciplinary action. Cheating or engaging in unethical behavior during examinations (quizzes and final) will be grounds for dismissal from the course without credit and further GSBS disciplinary action.

**Grading System:** Letter Grade (A-F)

**Student Assessment and Grading Criteria:**

Percentage	Description
Midterm Exams (30 %)	<b>In person open book exam (Multiple Choice, T/F, Essay) supervised by faculty. Midterm exam will cover materials from the first 4 lectures</b>
Final Exam (30 %)	<b>In person open book exam (Multiple Choice, T/F, Essay) supervised by faculty. Final exam will cover materials from the last 4 lectures</b>
Participation and/or Attendance (40 %)	<b>10%-Attendance, 10% -Participation in the discussion/ 20%- Reading/Oral Assignment</b>

**CLASS SCHEDULE - Summer 2026**

Date	Duration (Hour(s) taught by lecturer)	Lecture Topics	Description	Lecturer/s
5/21	2 hours	<p><b>Introduction to Translational Pathology / Histology of Mouse/ Comparison with Human organs- Different Organs/Systems (50-min)-Discussion (5-min)</b></p> <p><b>10-minute break</b></p> <p><b>Phenotyping of mouse/ Spontaneous lesions of inbred strains of mouse.</b></p> <p><b>(50-min)-Discussion (5-min)</b></p>	<p>Introduction to the 2026 Course- Discussion on the different phases of drug development- preclinical and clinical trials</p> <p>Comparison of mouse tissue biology with human tissues and interspecies difference, underscoring translational value of mouse studies.</p> <p>Mouse Phenotyping Background lesions in different mouse strains, C57BL/6 mice, FVB/N mice/ 129 mice.</p>	<p><b>Dr. Manu Sebastian</b></p>
5/28	2 hours	<p><b>Tissue Processing &amp; Clinical Pathology (50-min)-Discussion– (5-min)</b></p> <p><b>10-minute break</b></p> <p><b>Tour of Histology &amp; Clinical Pathology Laboratory (50-min)-Discussion (5-min)</b></p>	<p>Basic concepts of histopathology process including Immunohistochemistry and clinical pathology comparing with human blood chemistry/complete blood count etc. for translational studies</p>	<p><b>Dr. Susanne Lin</b></p>
6/4	2 hours	<p><b>Mouse Models of Cancer (50-min)-Discussion– (5 min)</b></p> <p><b>10-minute break</b></p> <p><b>Mouse Models of Immunology (50-min)-Discussion (5-min)</b></p>	<p>Discussion on different models including Genetically engineered models, Xenotransplant, Orthotopic and Patient derived model's, advantages and limitations in translational medicine application</p>	<p><b>Dr. Raj Pathania</b></p>

6/11	2 hours	<p><b>Discovery/Efficacy studies for drug Development with tissue endpoints (50 min)/ (Discussion-5 min)</b></p> <p><b>10-minute break</b></p> <p><b>Tissue scoring for identifying response of treatments/drugs to different mouse models in different organs</b></p> <p><b>(50-min)/(Discussion-5-min)</b></p>	<p>Discussion of different scoring systems used in different organs for identifying the efficacy of treatment in mouse tissues/organs with specific examples for different cancers and other diseases eg: How lung cancer is evaluated for therapeutic efficacy using tissue-based evaluation</p>	<b>Dr. Brian Simons</b>
6/18		<b>MID TERM</b>		
6/25	2 hours	<p><b>Introduction to Digital Pathology (50-min)/ (Discussion-5 min)</b></p> <p><b>10-minute break</b></p> <p><b>Digital Pathology &amp; Image Analysis (50 min)-Discussion (5-min)</b></p>	<p>Introduction to Digital pathology and use of different software's Digital pathology and image analysis for tissue-based endpoint evaluation with specific examples</p>	<b>Dr. Susanne Lin</b>
7/2	2 hours	<p><b>Other species of laboratory animals used in Translational studies</b></p> <p><b>In-vivo Safety testing of Drugs (50-min)/ (Discussion-5 min)</b></p> <p><b>10-minute break</b></p> <p><b>Tissue Biomarkers used for safety evaluation including toxicity targets</b></p> <p><b>(50-min)-Discussion (5 min)</b></p>	<p>Discussion on other species used in translation drug development studies.</p> <p>Discussion of different invitro and in vivo preclinical studies for regulatory approval</p> <p>Tissue biomarkers for safety evaluation and patient stratification in clinical trials for precision medicine</p>	<b>Dr. Manu Sebastian</b>
		<b>Tissue Biomarkers and Translational Pathology</b>	<p>Discuss in detail the application of IHC and multiplex</p>	

<b>7/9</b>	<b>2 hours</b>	<b>Immunohistochemistry/ Multiplex IF, image analysis</b> <b>(50-min)/ (Discussion-5-min)</b>  <b>10-minute break</b>  <b>Spatial biology and tissue biomarkers for diagnostics and precision medicine</b> <b>(50-min)-Discussion (5-min)</b>	Immunofluorescence in translational medicine  Spatial biology platforms for diagnostics and precision medicine biomarkers	<b>Dr. Natalie Fowlkes</b>
<b>7/16</b>	<b>2 hours</b>	<b>Regulatory Process for Drug approval</b> <b>Preclinical Regulatory studies including GLP safety studies</b> <b>(50 min)/ (Discussion-5 min)</b>  <b>10-minute break</b>  <b>Different Clinical Phase studies for regulatory approval</b>  <b>(50 min)-Discussion (5 min)</b>	Discuss the regulatory preclinical safety studies used for filing first in Human (FIH) drug studies  Discuss in detail the different phases of Clinical trials and use of tissue biomarkers for safety and efficacy evaluation in precision medicine	<b>Dr. Manu Sebastian</b>
<b>7/23</b>	<b>2 hours</b>	<b>Pathology Focused Manuscript discussion</b>	Discussion of pathology focused manuscripts in translational medicine. Students will be assigned manuscripts in advance and will discuss in detail the pathology evaluation techniques. This is the reading assignment.	<b>Dr. Manu Sebastian</b>
<b>7/ 30</b>	<b>1-1:5 hours</b> <b>TBD</b>	<b>Guest Lecture and discussion with Senior Pathologist from Biotech Industry (based on availability/ by Zoom)</b>	Invited lecture by Drug development executive from biotech industry to discuss real life experience of drug development	<b>Dr. Manu Sebastian</b>
<b>8/6</b>		<b>FINAL EXAM</b>		