

**Physiologically Based Pharmacokinetic Modeling**  
**AP 873**  
**Spring 2018**

-- An online course for both on-campus and distance students through K-State Global campus.

**KANSAS STATE**  

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**U N I V E R S I T Y**  
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**Course Overview**

This course is designed to teach physiologically based pharmacokinetic (PBPK) modeling at a very basic level. Development of PBPK models for environmental chemicals, drugs, and nanomaterials in laboratory animals, food-producing animals, companion animals, and/or humans will be introduced. Applications of PBPK models in food safety, toxicology, risk assessment, and pharmaceutical industry will be discussed. This course will cover theory, application software, model development, optimization, validation, evaluation, and extrapolation. The expected outcome is that the student will have PBPK modeling knowledge and skills to develop a PBPK model with some mentoring from an experienced PBPK modeler.

**Course objectives**

- To provide the student with working knowledge of PBPK models and their applications in toxicology
- To provide students with the technical ability to develop PBPK models for use in their research and careers

**Course Format**

The format will include both lectures and hands-on computer lab exercises. A new Module will be posted each week, and the student is expected to:

- Read any assigned textbook chapter(s), articles, and/or supplementary materials
- Listen/watch any posted lectures/podcasts

- Participate in the Discussion Board
- Do any lab assignments, which must be submitted by Sunday of that week
- Work on a selected PBPK modeling project related to the student's graduate research or work throughout the semester

## Course prerequisites

- General knowledge of an online learning management system
- One semester of physiology, pharmacology, pharmacokinetics, toxicology, or biochemistry
- One semester of calculus or permission of the instructor (don't be afraid of calculus; we only use relatively little of that and we will review it slowly and clearly at the beginning)
- Access to a computer with reliable internet access, a microphone, and a webcam, as well as with the PBPK modeling software RStudio and Berkeley Madonna™ installed. The free version of RStudio is sufficient for this course. The Berkeley Madonna™ may cost \$49-\$299/each license depending on the student's professional status and whether or not ordering as a group. This is a perpetual license, thus the license fee is a one-time fee only and you can use this software for your modeling needs henceforth

## Recommended textbooks

- "Physiologically-Based Pharmacokinetic (PBPK) Modeling and Simulations, Principles, Methods, and Applications in the Pharmaceutical Industry" by Sheila A. Peters (2012) (Students can obtain PDF version of this book through K-State library)
- "Physiologically Based Pharmacokinetic Modeling, Science and Application" by Micaela B. Reddy, Raymond S. H. Yang, Harvey J. Clewell III, and Melvin E. Andersen (2005) (Students can obtain this book through K-State Interlibrary loan)

## Course Project

Each student's course project will be selected carefully with proper justification at the beginning of the course. The students will work with the instructor on their selected projects with inputs from fellow students and/or guest lecturers throughout the semester. The ultimate goal is that a manuscript describing the course project could be published in a peer-reviewed journal, which typically takes longer time than a semester. To achieve this goal, the instructor is happy to continue to collaborate with the students after the course.

## Discussion Board

If you have a question about the course content and materials, you are probably not alone. Please share your question with your fellow students, the instructor and guest lecturers by posting it in the Discussion Board. Students are required to participate in the Discussion Board by posting a new question/topic and/or at least one substantive response to other participants every week. Students are also encouraged to look through previous Discussions to see if anyone else has already asked a related question. The instructor will monitor the discussions and answer questions as needed.

## Netiquette

To allow for orderly learning and communication, students should follow the rules of online courtesy, including refraining from use of sexist, racist, off-color, or demeaning language or

behavior, sometimes referred to as flaming. This is a college course, and student vocabulary and word choice should be appropriate to a college classroom. Students will stay on-topic, handling non-class related matters over off-line posts. The instructor is the ultimate authority and will delete any inappropriate posts. The guidelines set forth by K-State Global Campus regarding Netiquette Rules for Electronic Communication are available by clicking [here](#).

## Course evaluation

Grades will be determined from computer lab simulation exercises/assignments (25%), participation in online discussions (25%), and two project presentations (mid-term and final exams) which demonstrate the development of a PBPK model and the application of the PBPK model in toxicology (50%).

## Grading scale

The total of all the points accumulated over the course will be converted to a percentage.

PASS

A: 90% - 100%

B: 75% - 89%

C: 60% - 74%

Fail

D: 45% - 59%

F: 0 – 44%

## Accommodations for students with disabilities

Any student with a disability that needs a classroom accommodation, access to technology or other assistance in this course should contact Disability Support Services and/or their instructor.

## Academic honesty

Kansas State University has an Honor & Integrity System based on personal integrity, which is presumed to be sufficient assurance in academic matters to ensure one's work is performed honestly and without unauthorized assistance. Undergraduate and graduate students, by registration, acknowledge the jurisdiction of the Honor & Integrity System. The policies and procedures of the Honor System apply to all full and part-time students enrolled in undergraduate and graduate courses on-campus, off-campus, and via distance learning. A component vital to the Honor & Integrity System is the inclusion of the Honor Pledge which applies to all assignments, examinations, or other course work undertaken by students. The Honor Pledge is implied, whether or not it is stated: "On my honor, as a student, I have neither given nor received unauthorized aid on this academic work." The default in this class is that ALL work will be accomplished individually, UNLESS the instructor's permission is given in advance of an assignment/quiz/exam/take-home exam/final. If you are in doubt, please ask. A grade of XF can result from a breach of academic honesty. The F indicates failure in the course; the X indicates the reason is an Honor Pledge violation. For more information, visit the Honor & Integrity System home web page at: <http://www.ksu.edu/honor>.

## Copyright notification

All the class materials, in PDF format, will be given to the students during the course. Students are prohibited from selling (or being paid for taking) notes during this course to or by any person or commercial firm without the express permission of the instructor.

## Course Instructor

Dr. Zhoumeng Lin is an Assistant Professor of Pharmacology and Toxicology in the Institute of Computational Comparative Medicine (ICCM), Department of Anatomy and Physiology, College of Veterinary Medicine, Kansas State University. Dr. Lin has 8 years of experience in PBPK modeling for environmental chemicals, drugs, and nanoparticles in laboratory rodents, food-producing animals, companion animals and humans. He received graduate training in Toxicology and PBPK modeling from Dr. Nikolay M. Filipov and Dr. Jeffrey W. Fisher at The University of Georgia. He received postdoc training in Pharmacology, Toxicology, and PBPK modeling from Dr. Jim E. Riviere, Dr. Nancy A. Monteiro-Riviere and Dr. Ronette Gehring at Kansas State University. He learned how to teach PBPK modeling from the PBPK Modeling Workshop for Beginners offered by Dr. Raymond S. H. Yang at Colorado State University. He taught this PBPK modeling course in Spring 2017 when all modeling exercises were done in Berkeley Madonna™. He will teach this course every Spring semester and from Spring 2018 on, all modeling exercises will be done in both Berkeley Madonna™ and R language. For more information about Dr. Lin's research and teaching, please visit his laboratory website.



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Laboratory Website: <http://www.vet.k-state.edu/education/anatomy-physiology/faculty-staff/faculty/lin/lab/index.html>

## Guest Lecturers

Dr. Jeffrey W. Fisher is a Research Toxicologist with the U.S. Food and Drug Administration, National Center for Toxicological Research. He was formerly a Professor in the Department of Environmental Health Science, College of Public Health at The University of Georgia (UGA). He joined The University of Georgia in 2000 and served as Department Head of the Department of Environmental Health Sciences from 2000 to 2006 and Director of the Interdisciplinary Toxicology Program at UGA from 2006-2010. He spent most of his career at the Toxicology Laboratory, Wright Patterson AFB, where he was Principal Investigator and Senior Scientist in the Toxics Hazards Division and Technical Advisor for the Operational Toxicology Branch. Dr. Fisher's research interests are in the development and application of biologically based mathematical models to ascertain health risks from environmental, food-borne and occupational chemical exposures and develop pediatric PBPK models for drugs. Dr. Fisher's modeling experience includes working with chlorinated and non-chlorinated solvents, fuels, pesticides, perchlorate and bisphenol A. He has developed PBPK models for use in cancer risk assessment, estimating lactational transfer of solvents, understanding in utero and neonatal dosimetry, quantifying metabolism of solvent mixtures and developing biologically motivated models for the hypothalamic-pituitary-thyroid axis in rodents and humans. He has developed PBPK model for methylphenidate to address age specific pharmacokinetic questions. Dr. Fisher has 30 years of experience in physiological modeling and has trained several graduate students and postdoctoral fellows on the concepts and application of physiological models. He was a Visiting Scientist at the Chemical Industry Institute of Toxicology in 1996 and at the NIOSH Taft Laboratory in 1999. During this time, he also served as Adjunct Professor in the Department of Pharmacology and Toxicology at Wright State University. Dr. Fisher has published over 150 papers on pharmacokinetics and PBPK modeling in laboratory animals and humans. He has served on several national panels and advisory boards for the DoD, ATSDR, USEPA and non-profit organizations. He was a U.S. delegate for the North Atlantic Treaty Organization. Dr. Fisher served on the International Life Sciences Institute Steering Committee, which evaluated chloroform and dichloroacetic acid using EPA-proposed Carcinogen Risk Guidelines. He is Past President of the Biological Modeling Specialty Section of the Society of Toxicology, reviewer for several toxicology journals, and was Co-Principal Investigator on a NIH-supported workshop on Mathematical Modeling at The University of Georgia in the fall of 2003. He was a member of the National Academy of Sciences subcommittee on Acute Exposure Guideline Levels (AEGs) from 2004-2010 and Science Advisory Board for the US EPA (2007-2010). He is an ad hoc member of the SAB for dioxin. He is a fellow of the Academy of Toxicological Sciences and an Associate Editor for Toxicological Sciences. Dr. Fisher has a B.S. degree in Biology from the University of Nebraska at Kearney, a M.S. degree in Biology from Wright State University, and a Ph.D. in Zoology/Toxicology from Miami University.



Dr. Raymond S. H. Yang is Professor Emeritus of Toxicology and Cancer Biology, Department of Environmental and Radiological Health Sciences, Colorado State University. Dr. Yang has more than 50 years of experience in academic, industrial and government research settings including the National Institute of Environmental Health Sciences/National Toxicology Program (NIEHS/NTP), Union Carbide Corporation, North Carolina State University, Cornell University, Albany Medical College, Colorado State University, and the USEPA National Center for Environmental Assessment (NCEA) at Cincinnati. His research interests include toxicology of chemical mixtures, toxicologic interactions, carcinogenesis, developmental toxicology, and physiologically-based pharmacokinetics/pharmacodynamics (PBPK/PD) and other biologically-based computer modeling. He has had extensive experience in training and mentoring graduate students, postdoctoral fellows, junior and senior faculty members and he created and developed an interdisciplinary research program on Quantitative and Computational Toxicology at Colorado State University. Since 1992, Dr. Yang has organized 26 national and international workshops on PBPK/PD Modeling and Risk/Safety Assessment at Colorado State University (1992, 1994, 1996, 1999, 2001, 2003, 2005, 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015), Pfizer Inc., Groton, CT (October 2002), California Environmental Protection Agency/OEHHA, Oakland, CA (September 2000), the National Health Research Institutes, Zhunan, Taiwan (August-November, 2006), and USEPA, National Center for Environmental Assessment (NCEA), Cincinnati (April-May 2008; March-August 2009), and British American Tobacco, Southampton, UK (November 2009), California Environmental Protection Agency/Department of Pesticide Regulation, Sacramento, CA (two Workshops in May and September, 2011; one to be held in June 2016), California Environmental Protection Agency/OEHHA, Sacramento, CA (August-September, 2011; November-December 2015).



## Course Schedule:

<p><b>Module 1</b> (January 16-21, 2018)</p>	<p><b>Learning Objectives:</b></p> <ol style="list-style-type: none"> <li>1. Define PBPK modeling</li> <li>2. Describe the differences between PBPK modeling and traditional pharmacokinetic modeling</li> <li>3. Identify advantages of PBPK modeling compared to traditional pharmacokinetic modeling</li> <li>4. Describe the history of PBPK modeling</li> <li>5. Know your fellow students' knowledge background and research interests</li> </ol> <p><b>Scheduled Lectures:</b></p> <ol style="list-style-type: none"> <li>1. Course description and expectation</li> <li>2. Introduction of PBPK modeling</li> <li>3. History of PBPK modeling</li> <li>4. PBPK modeling software</li> <li>5. Introduction of Berkeley Madonna</li> </ol>
<p><b>Module 2</b> (January 22-28, 2018)</p>	<p><b>Learning Objectives:</b></p> <ol style="list-style-type: none"> <li>1. To describe typical PBPK model structure</li> <li>2. To list common physiological parameters</li> <li>3. To name chemical-specific parameters</li> <li>4. To describe factors affecting physiological and chemical-specific parameters</li> <li>5. To discuss the rationale of designing a PBPK model</li> <li>6. To develop a simple 2-compartment PK model</li> </ol> <p><b>Scheduled Lectures:</b></p> <ol style="list-style-type: none"> <li>1. PBPK model structure</li> <li>2. Physiological parameters in a PBPK model</li> <li>3. Chemical-specific parameters in a PBPK model</li> <li>4. Development of a simple 2-compartment model</li> </ol>
<p><b>Module 3</b> (January 29-February 4, 2018)</p>	<p><b>Learning Objectives:</b></p> <ol style="list-style-type: none"> <li>1. To describe the rationale of selecting a PBPK modeling project</li> <li>2. To understand the physiological significance of PBPK model code</li> <li>3. To describe absorption and distribution of chemicals or nanomaterials using mathematical equations</li> <li>4. To develop a simple 4-compartment PBPK model</li> <li>5. To decide your PBPK modeling projects</li> </ol> <p><b>Scheduled Lectures:</b></p> <ol style="list-style-type: none"> <li>1. Select your interested PBPK modeling project</li> <li>2. Model development - mathematical description of absorption</li> <li>3. Model development - mathematical description of distribution</li> <li>4. Development of a simple PBPK model using Berkeley Madonna</li> </ol>
<p><b>Module 4</b> (February 5-11, 2018) Feb 5 is the last day for 100% refund for a regular</p>	<p><b>Learning Objectives:</b></p> <ol style="list-style-type: none"> <li>1. To describe the objective, significance, novelty, feasibility, and justifiability of your project</li> <li>2. To debug PBPK models</li> <li>3. To develop a 7-compartment PBPK model</li> </ol> <p><b>Scheduled Lectures:</b></p> <ol style="list-style-type: none"> <li>1. Objective, significance, novelty, feasibility, and justifiability</li> <li>2. Pharmacokinetic data search</li> <li>3. PBPK model debugging</li> </ol>

session course	4. Development of a 7-compartment PBPK model
<b>Module 5</b> (February 12-18, 2018) Feb 12 is the last day for 50% refund for a regular session course	<p><b>Learning Objectives:</b></p> <ol style="list-style-type: none"> <li>1. To review the basic concepts about PBPK modeling</li> <li>2. To extract pharmacokinetic data from published literature</li> <li>3. To describe slowly and richly perfused tissues</li> <li>4. To develop a membrane-limited PBPK model</li> </ol> <p><b>Scheduled Lectures:</b></p> <ol style="list-style-type: none"> <li>1. Learning the Lingo</li> <li>2. Pharmacokinetic data extraction</li> <li>3. Slowly and richly perfused tissues</li> <li>4. Development of a membrane-limited PBPK model</li> </ol>
<b>Module 6</b> (February 19-25, 2018)	<p><b>Learning Objectives:</b></p> <ol style="list-style-type: none"> <li>1. To derive the Michaelis-Menten equation</li> <li>2. To describe different ways of mathematically simulate the metabolism of chemicals</li> <li>3. To develop a membrane-limited PBPK model with intramuscular injection</li> </ol> <p><b>Scheduled Lectures:</b></p> <ol style="list-style-type: none"> <li>1. Derivation of Michaelis-Menten equation</li> <li>2. Model development – mathematical description of metabolism</li> <li>3. Development of an intramuscular injection PBPK model</li> </ol>
<b>Module 7</b> (February 26-March 4, 2018)	<p><b>Learning Objectives:</b></p> <ol style="list-style-type: none"> <li>1. To describe different excretion pathways of chemicals</li> <li>2. To understand the mechanisms of renal excretion and hepatobiliary excretion</li> <li>3. To describe different ways of mathematically simulate renal excretion of chemicals</li> <li>4. Describe different ways of mathematically simulate biliary excretion of chemicals</li> <li>5. To develop a multiroute PBPK model with intravenous injection, intramuscular injection, and oral exposure</li> </ol> <p><b>Scheduled Lectures:</b></p> <ol style="list-style-type: none"> <li>1. Excretion pathways</li> <li>2. Model development - Mathematical description of renal excretion</li> <li>3. Model development - Mathematical description of biliary excretion</li> <li>4. Development of a multiroute PBPK model</li> </ol>
<b>Module 8</b> (March 5-11, 2018)	<p><b>Learning Objectives:</b></p> <ol style="list-style-type: none"> <li>1. To understand the basic concepts of allometric scaling</li> <li>2. To describe the application of allometric scaling in traditional PK modeling</li> <li>3. To describe the application of allometric scaling in PBPK modeling</li> <li>4. To incorporate allometric equations into a PBPK model</li> </ol> <p><b>Scheduled Lectures:</b></p> <ol style="list-style-type: none"> <li>1. What is with the scaling</li> <li>2. Allometric scaling - traditional PK parameters</li> <li>3. Allometric scaling - PBPK parameters</li> <li>4. Allometric scaling - coding examples</li> </ol>
<b>Module 9</b>	<p><b>Learning Objectives:</b> We have reached the halfway mark of the semester! This week we will review what we have learned so far. All lecture PDF files of</p>

(March 12-18, 2018) (Society of Toxicology Meeting Week)	<p>Modules 1-8 will be posted. Please go through these files one more time to refresh your memory, continue working on your course projects, and then you can proceed with the mid-term exam.</p> <p><b>Scheduled Lectures:</b></p> <ol style="list-style-type: none"> <li>1. No lecture is scheduled</li> </ol>
<b>Spring Break</b> (March 19-25, 2018)	<p><b>Learning Objectives:</b></p> <ol style="list-style-type: none"> <li>1. Complete the Mid-term Exam</li> </ol> <p><b>Scheduled Lectures:</b></p> <ol style="list-style-type: none"> <li>1. No lecture is scheduled</li> </ol>
<b>Module 10</b> (March 26-April 1, 2018)	<p><b>Learning Objectives:</b></p> <ol style="list-style-type: none"> <li>1. To calibrate a PBPK model by estimating parameters of which measured values are not available</li> <li>2. To evaluate a PBPK model by simulating independent datasets based on WHO PBPK modeling guidelines</li> <li>3. To assess PBPK model simulation results using quantitative statistical approaches</li> <li>4. To develop a PBPK model for enrofloxacin and its main metabolite ciprofloxacin in cattle</li> </ol> <p><b>Scheduled Lectures:</b></p> <ol style="list-style-type: none"> <li>1. PBPK model calibration and parameterization</li> <li>2. PBPK model evaluation</li> <li>3. PBPK model performance assessment</li> <li>4. Development of a PBPK model for enrofloxacin and its metabolite ciprofloxacin</li> </ol>
<b>Module 11</b> (April 2-8, 2018)	<p><b>Learning Objectives:</b></p> <ol style="list-style-type: none"> <li>1. To conduct local sensitivity analysis</li> <li>2. To conduct uncertainty and variability analysis</li> <li>3. To develop a population PBPK model for penicillin G in swine</li> <li>4. To run Monte Carlo simulation using the population PBPK model</li> </ol> <p><b>Scheduled Lectures:</b></p> <ol style="list-style-type: none"> <li>1. Sensitivity analysis</li> <li>2. Uncertainty and variability analysis</li> <li>3. Development of a population PBPK model for penicillin G - Part 1</li> <li>4. Development of a population PBPK model for penicillin G - Part 2</li> </ol>
<b>Module 12</b> (April 9-15, 2018)	<p><b>Learning Objectives:</b></p> <ol style="list-style-type: none"> <li>1. To learn some background information about risk assessment using PBPK models</li> <li>2. To apply the TCA PBPK model for non-cancer risk assessment</li> <li>3. To learn some specifics of PBPK modeling of dichloromethane (methylene chloride) in mice and humans</li> </ol> <p><b>Scheduled Lectures:</b></p> <ol style="list-style-type: none"> <li>1. Non-cancer risk assessment using TCA PBPK model</li> <li>2. Cancer risk assessment using DCM PBPK model</li> </ol>
<b>Module 13</b> (April 16-22, 2018)	<p><b>Learning Objectives:</b></p> <ol style="list-style-type: none"> <li>1. To learn to use PBPK and BMDS [(Benchmark Dose Software, USEPA, National Center for Environmental Assessment (NCEA)) modeling to do dose-response and risk assessment</li> <li>2. To learn different forms of presenting cancer risk: slope factor, unit risk, and risk based on 1/10000, 1/100000, or 1/1000000</li> </ol>

	<p>3. To learn to address the issue of uncertainty and variability using Monte Carlo simulation</p> <p><b>Scheduled Lectures:</b></p> <ol style="list-style-type: none"> <li>1. Dichloromethane cancer risk assessment II A</li> <li>2. Dichloromethane cancer risk assessment II B</li> <li>3. Dichloromethane cancer risk assessment III</li> </ol>
<p><b>Module 14</b> (April 23-29, 2018)</p>	<p><b>Learning Objectives:</b></p> <ol style="list-style-type: none"> <li>1. To learn the basic modeling environment of GastroPlus</li> <li>2. To understand the physiology, mathematics, and pharmacokinetic mechanism of PBPK models in PBPKPlus module</li> <li>3. To do some basic PK and PBPK exercises using GastroPlus</li> <li>4. To understand the applications of GastroPlus in Toxicology and in the pharmaceutical industry</li> </ol> <p><b>Scheduled Lectures:</b></p> <ol style="list-style-type: none"> <li>1. GastroPlus Quick Start Guide</li> <li>2. SOT BMSS webinar by John DiBella - Saying I do to the QSAR/PBPK marriage in GastroPlus to predict chemical exposure for safety evaluation</li> <li>3. SOT BMSS webinar by Fagen Zhang and Leah Lina - Validation of the GastroPlus Software Tool and Applications</li> <li>4. Chapter 5.4.5 PBPKPlus - Physiologically Based Pharmacokinetics Module in GastroPlus Manual</li> </ol>
<p><b>Module 15</b> (April 30-May 6, 2018)</p>	<p><b>Learning Objectives:</b></p> <ol style="list-style-type: none"> <li>1. To learn the basic concepts about In Vitro to In Vivo Extrapolation (IVIVE)</li> <li>2. To predict partition coefficients using mechanistic equations</li> <li>3. To understand biologically based dose-response (BBDR) modeling</li> <li>4. To understand probabilistic risk assessment using PBPK models</li> </ol> <p><b>Scheduled Lectures:</b></p> <ol style="list-style-type: none"> <li>1. In Vitro to In Vivo Extrapolation (IVIVE)</li> <li>2. Prediction of Partition Coefficients I</li> <li>3. Prediction of Partition Coefficients II</li> <li>4. Biologically based dose response (BBDR) modeling – Using Biologically motivated models for thyroid hormone production and hypothyroxinemia</li> <li>5. PBPK modeling and probabilistic risk assessment</li> </ol>
<p><b>Final Exam Week</b> (May 7-11, 2018)</p>	<p><b>Learning Objectives:</b></p> <ol style="list-style-type: none"> <li>1. Complete the Final Exam</li> </ol> <p><b>Scheduled Lectures:</b></p> <ol style="list-style-type: none"> <li>1. No lecture is scheduled</li> </ol>

**Note:** This is a tentative schedule based on the Spring 2017 schedule. New content will be added, so the actual schedule for Spring 2018 will be slightly different.

## Registration

On-campus K-State students can enroll in this course through KSIS and should select session “AP 873-A”. Distance students and non-K-State students can enroll in this course through [K-State Global Campus](#) and should select session “AP 873-ZA”. Individuals not enrolled at KSU can enroll in this course as “Nondegree-seeking Graduate Students”. Click [here](#) for detailed instructions. The maximum enrollment is 20 students.

## **Fees**

In the Spring 2017 semester, the registration fee for degree-seeking and nondegree-seeking graduate students was \$2,486.40 and for DVM students was \$3,126.00. The registration fees for the Spring 2018 semester will be similar.

## **Cancellation and Refund Policy**

This course will be cancelled if a minimum of 2 students is not reached. Cancellation by Dr. Lin: 100% refund. According to K-State Academic Calendar, February 5th is the last day for 100% refund for a regular session course and February 12th is the last day for 50% refund for a regular session course.

Please contact Dr. Lin at [zhoumeng@ksu.edu](mailto:zhoumeng@ksu.edu) for further information.