

The University Of Toledo

Existing Graduate Course Modification Form

* denotes required fields

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Present

Proposed

Supply all information asked for in this column. (Supply core, research intensive and transfer module info if applicable)

Fill in appropriate blanks only where entry differs from first column.

College*: College Pharmacy, Pharm Sciences

College: College Pharmacy, Pharm Sciences

Dept/Academic Unit*: Medicinal and Biological Chemistry

Dept/Academic Unit: Medicinal and Biological Chemistry

Course Alpha/Numeric*: MBC 5100

Course Alpha/Numeric: MBC 5100

Course Title: Practices in Pharmaceutical Reserach

Course Title: Ethical Conduct of Research

Credit hours: Fixed: 1 or Variable: to

Credit Hours: Fixed: 1 or Variable: to

CrossListings:

CrossListings:

Insert

To add a course, type in course ID and click the Insert button.

To remove a course, select the course on left and click the Remove button.

Remove

Insert

To add a course, type in course ID and click the Insert button.

To remove a course, select the course on left and click the Remove button.

Remove

Prerequisite(s)(if longer than 50 characters, please place it in Catalog Description):

Prerequisite(s)(if longer than 50 characters, please place it in Catalog Description):

Corequisite(s)(if longer than 50 characters, please place it in Catalog Description):

Corequisite(s)(if longer than 50 characters, please place it in Catalog Description):

Catalog Description (only if changed) 75 words max: **Catalog Description** (only if changed) 75 words max:

unchanged

unchanged

Has course content changed?

Yes

No


If course content is changed, give a brief topical outline of the revised course below(less than 200 words)


The class objective is to engage students in discussing and contemplating the practical aspects of the research environment, safety regulations, legal obligations, and ethical considerations that are encountered in academic, industrial, and governmental pharmaceutical research. These topics will be addressed via in-depth discussions involving a range of guest lectures.

Proposed effective term*: (e.g. 201140 for 2011 Fall)

File Type	View File
Syllabus	View
Attachment	View

List any course or courses to be deleted.

Effective Date: 

Effective Date: 

Comments/Notes:

MBC 5100/7100 Research Practices in Pharmaceutical Research is moved from spring year 1 to summer year 1. The course will be renamed "Ethical Conduct of Research."








The proposed curriculum change, including the changes to MBC5100/7100 had been drafted at an MBC Graduate Affairs Committee meeting on November 3, 2015 and was discussed at length at MBC departmental meetings on November 12, 2015 and January 21, 2016. The changes were approved by the College Curriculum Committee on March 3, 2016.

Rationale:

The proposed change is part of an overall revision of the Medicinal Chemistry Doctoral Program that was necessary to reduce the time to graduation and the number of credits required for graduation as demanded by the State of Ohio.

Furthermore, The NIH now requires that students supported on grants be trained in ethical conduct. This course will meet that requirement.

Approval:

Department Curriculum Authority:	James T Slama, Ph.D.,		Date 2016/03/09
Department Chairperson:	Katherine A Wall		Date 2016/04/05
College Curriculum Authority or Chair:	Frederick E. Williams		Date 2016/12/09
College Dean:	Laurie Mauro		Date 2016/12/29
Graduate Council:	Constance Schall (GC 1.24.2017)		Date 2017/01/26
Dean of Graduate Studies:	Amanda Bryant-Friedrich		Date 2017/01/31
Office of the Provost :	marcia king-blandford		Date 2017/01/31

print

Administrative Use Only

Effective Date:  (YYYY/MM/DD)

CIP Code:


Subsidy Taxonomy:

Program Code:

Instructional Level:

Registrar's Office Use Only

Processed in Banner on:

Processed in Banner by:

Banner Subject Code:

Banner Course Number:

Banner Term Code:

Banner Course Title:



Ethical Conduct of Research

The University of Toledo

College of Pharmacy and Pharmaceutical Sciences, Medicinal and Biological Chemistry

MBC 5100; 001; CRN: 13412 & MBC 7100; 001; CRN:15080

Coordinator: Isaac T. Schiefer

Email: isaac.schiefer@utoledo.edu

Office Hours: T-Th 10-12 or by appointment **Office**

Location: HEB 284C (not in my office → try lab) **Office**

Phone: 4193831935

Term: Spring 2016

Class Location: Health Education Building (HEB) 276

Class Day/Time: Specified Fridays from 12:00-2 (EST)

Lab Location: HEB 275C

Lab Day/Time: n/a

Credit Hours: 1

Course Website: <http://www.utoledo.edu/dl>

COURSE/CATALOG DESCRIPTION

Advanced consideration of the scientific, ethical, and legal obligations expected in the conduct of academic and industrial pharmaceutical research.

COURSE OVERVIEW

The class objective is to engage students in discussing and contemplating the practical aspects of the research environment, safety regulations, legal obligations, and ethical considerations that are encountered in academic, industrial, and governmental pharmaceutical research. These topics will be addressed via in-depth discussions involving a range of guest lectures.

PREREQUISITES AND COREQUISITES

NONE

REQUIRED TEXTS AND ANCILLARY MATERIALS

NONE

TECHNOLOGY REQUIREMENTS

Blackboard <http://www.utoledo.edu/dl>

UNIVERSITY POLICIES

Policy Statement on Non-Discrimination on the basis of Disability (ADA)

The University is an equal opportunity educational institution. Please read [The University's Policy Statement on Nondiscrimination on the Basis of Disability Americans with Disability Act Compliance](#).

ACADEMIC ACCOMMODATIONS

The University of Toledo is committed to providing equal access to education for all students. If you have a documented disability or you believe you have a disability and would like information regarding academic accommodations/adjustments in this course please contact the [Student Disability Services Office](#).)

ACADEMIC POLICIES

The University of Toledo Missed Class Policy



This policy provides for basic protections and reasonable accommodations for students who miss class with excused absences. Students are expected to attend every class meeting of courses in which they are registered. Only in specific, unavoidable situations does the University excuse absences from class: 1) personal emergencies, including, but not limited to, illness of the student or of a dependent of the student [as defined by the Board of Trustees' Policy on Family and Medical Leave], or death in the family; 2) religious observances that prevent the student from attending class; 3) participation in University-sponsored activities, approved by the appropriate University authority, such as intercollegiate athletic competitions, activities approved by academic units, including artistic performances, R.O.T.C. functions, academic field trips, and special events connected with coursework; 4) government-required activities, such as military assignments, jury duty, or court appearances; and 5) any other absence that the professor approves.

Students are responsible for complying with the missed class policies of their instructors. Students bear the responsibility of notifying the instructor of a planned absence by one of the methods provided by the instructor. In the event of an emergency or an unavoidably short notice of absence, the student must present the instructor with an approved written excuse upon the student's return to class. Approved written excuses will be at the instructor's discretion, including, but not limited to, doctor's notice, funeral programs, etc. It is strongly recommended that the student use two of the three aforementioned methods (email, writing, or voicemail) to insure that the instructor is properly notified of the planned absence. In the event that the instructor should not receive the student's notification, the student should be prepared to present an alternative excuse. It will be at the instructor's discretion to approve or disapprove of the alternative excuse.

Students are responsible for all material covered in classes they miss, even when their absences are excused as defined above. Students must make arrangements with instructors to complete missed assignments, labs, examinations or other course requirements. In turn, instructors are not to penalize students with excused absences

Policies on Late Work

It is up to the instructor as to the acceptance of assignments not completed by the deadline and each case will be evaluated individually.

Drop / Withdrawal

The petition for withdrawal must be received in the Office of the Registrar, Rocket Hall, Room 1100, by the deadline date either: in person, fax, or mail. When mailing, the envelope must be postmarked by the deadline date. For the fall and spring terms, it must be filed between the 15th calendar day of the term through Friday of calendar week 10.

Academic Dishonesty

Academic dishonesty will not be tolerated. Among the aims of education are the acquisition of knowledge and development of the skills necessary for success in any profession. Activities inconsistent with these aims will not be permitted. Students are responsible for knowing what constitutes academic dishonesty. If students are uncertain about what constitutes plagiarism or cheating they should seek the instructor's advice. Examples of academic dishonesty include, but are not limited to:

- *Plagiarizing or representing the words, ideas or information of another person as one's own and not offering proper documentation;*



- *Giving or receiving, prior to an examination, any unauthorized information concerning the content of that examination;*
- *Referring to or displaying any unauthorized materials inside or outside of the examination room during the course of an examination;*
- *Communicating during an examination in any manner with any unauthorized person concerning the examination or any part of it;*
- *Giving or receiving substantive aid during the course of an examination;*
- *Commencing an examination before the stipulated time or continuing to work on an examination after the announced conclusion of the examination period;*
- *Taking, converting, concealing, defacing, damaging or destroying any property related to the preparation or completion of assignments, research or examination;*
- *Submitting the same written work to fulfill the requirements for more than one course.*
- *While academic integrity is particularly the responsibility of the student, the faculty members also have a responsibility. Assignments and tests should be constructed and proctored so as to discourage academic dishonesty. Faculty members are expected to inform their students explicitly as to what materials and procedures are authorized for use in the preparation of assignments or in examinations (e.g., the use of calculator, computer, text materials, etc.). Should cases of academic dishonesty be found among students, the instructor may choose to counsel the student, or the following sanctions may be imposed:*
 - *The student may be assigned an F for the work in question.*
 - *The student may be assigned an F for the course. In this case the instructor should inform the Dean and the student of this action. The Dean will make certain that the student receives the F grade and is not permitted to withdraw from the course.*
 - *The student may be placed on probation or suspended for some definite period of time, dismissed or expelled by the Dean if either the seriousness of the offense or a record of repeated offenses warrants it. A notation that such a sanction has been imposed will be made part of the student's permanent record. It is expected that the Dean will consult with the instructor and the student in making such a judgment, and that the Dean will notify the student of the sanction imposed and of the appeals procedure.*
 - *A student found to be academically dishonest by a faculty member may appeal according to procedures approved by the respective colleges. The procedures for making a final appeal to the Student Grievance Committee may be found in the Student Handbook.*

Classroom Courtesy

- *The University has jurisdiction over any individual student, group of students or student organization alleged to have violated the Student Code of Conduct on the University of Toledo premises.*
- *Students must conduct themselves in a manner which is conducive to learning for themselves and others. Disruptive behaviors are not acceptable and may affect a student's final grade, or in severe cases result in a student being removed from class.*
- *Disruption of operations of the University Community. Disruption is an action or combination of actions by an individual or a group, which unreasonably interferes with, hinders, obstructs, or prevents the right*



of others to freely participate in its programs, services, or academic settings. This may include, but is not limited to a disruption by the use of pagers, cell phones and/or any other communication devices.

- The use of cell phones, pagers, iPods, MP3 players and such will not be permitted in the classroom.
- Students may audiotape lectures; otherwise, no A/V equipment or use of telephotoing is permitted.
- For issues pertaining to lecture content, contact the lecturer of the topic. For issues pertaining to grades, tests, lecture schedule, reading assignments, etc., contact the course coordinator.

COURSE EXPECTATIONS

ATTENDANCE AND PARTICIPATION ARE MANDATORY FOR THIS COURSE. This course is designed to be a lecture/discussion hybrid to encourage discussion and in-depth contemplation of the topics being covered. **EACH STUDENT MUST ASK AT LEAST ONE PERTINENT QUESTION DURING EACH CLASS PERIOD.** Attendance will be taken and each absence or lack of participation will result in an automatic reduction of your grade for that course period. Tardiness will also be noted and penalized (minus 10 % for your attendance grade for that day). Assignments will be specified on a lecture-by-lecture basis and may include pre-reading for the lecture. Assessment criteria for each lecture are briefly described in the schedule below. **THIS IS A GRADUATE LEVEL COURSE. ASSIGNMENTS WITH MISSPELLINGS AND POOR GRAMMAR WILL REDUCE THE GRADE OBTAINED. TAKE YOUR TIME AND USE SPELL CHECK.** Late submission will be penalized 20 % per/day late. Plagiarism of any kind will not be tolerated and will result in the loss of credit for that week and may result in course failure.

NOTE: One lecture period will be used to review institutional practices/procedures/regulations regarding waste management and lab safety. This will be administered in COB 2401 on the indicated date below. **NEW EMPLOYEE TRAINING AND ANNUAL RE-EDUCATION REGARDING ETHICS AND SAFETY ARE REQUIRED BY NUMEROUS GOVERNMENT ORGANIZATIONS, INCLUDING THE NATIONAL INSTITUTES OF HEALTH (NIH). YOU MUST ATTEND THESE SESSIONS EVEN IF YOU HAVE TAKEN THEM BEFORE.**

GRADING

DETERMINATION OF OVERALL GRADE:

Attendance/Participation 10 pts each (x9=90 pts) = 50 %

Assignments 10 pts each (x9=90pts) = 50 %

Note: grade scale may be modified at the discretion of the coordinator.

Timeframe – feedback and grades for each assignment will be posted within 14 days of the receipt date.

90%-100%= A

80%-89% = B

67%-79% = C

55%- 66% = D

Below 55% = F

COMMUNICATION GUIDELINES

Use the contact email listed at the top of the syllabus to contact course coordinator. Coordinator typically returns emails within 24 hr of receipt.

STUDENT SUPPORT SERVICES

As mentioned above, misspellings and poor grammar will reduce the grade obtained on student summaries. Writing help is available on the main campus, link below.

<http://www.utoledo.edu/success/writingcenter/services.html>



CLASS SCHEDULE

Date Instructor	<i>(1) Weekly Topics</i>	<i>(2) Student Learning Outcome</i>	<i>(3) Assessment Method</i>
Meeting 1 Isaac Schiefer, Ph.D., MBC Assist. Prof.	Lab Problems: Safety, Fraud, and Ethics <i>Case Studies: Session 1</i>	Understand the history and consequences of unsafe/fraudulent research	Pre-lecture: reading assignments Lecture: Each student will lead discussion for 10-15 min of a case.
Meeting 2 Paul Erhardt, Ph.D., MBC Distinguished University Professor	Ethical Protection of Intellectual Property	Be able to critically evaluate original research reports and identify gaps of current knowledge. Be able to independently design, plan and execute a research program in an area of specialization relevant to modern drug development and discovery.	Preparation of Markush structure for assigned class of potential therapeutics with defensible ethical patent claims
Meeting 3 William S. Messer Jr., Ph.D., Pharmacology Prof UT Vice Pres. for Res.	Ethics in Translational Research: "The Story of CDD- 0102"	Develop skills to carry out duties in accordance with accepted legal, ethical, social, economic, and professional practices.	Post-lecture: written summary of ethical aspects of translational drug discovery
Meeting 4 Isaac Schiefer, Ph.D., MBC Assist. Prof.	Ethics and Responsible reporting of research	Develop skills to carry out duties in accordance with accepted legal, ethical, social, economic, and professional practices.	Post-lecture: written summary of ethical publishing ethics
Meeting 5 Isaac Schiefer, Ph.D., MBC Assist. Prof.	Lab Problems: Safety, Fraud, and Ethics <i>Case Studies: Session 2</i>	Understand the history and consequences of unsafe/fraudulent research	Each student will revisit a Meeting 1 topic and debate

Proposed changes to the Medicinal Chemistry PhD program

Due to recent changes in the way that the state of Ohio funds higher education, the state universities in Ohio must reduce the time to degree. For all students, this means that we must pay attention to the total credits earned before graduation. For PhD students this is 90 credits and 4 to possibly 5 years. So that our students do not have to self-fund at the end of their allowed tuition waiver amount, we must change our graduate curricula. At the same time, we are updating and coordinating our content to improve outcomes.

The proposals presented here had been drafted at an MBC Graduate Affairs Committee meeting on November 3, 2015 and were discussed at length at MBC departmental meetings on November 12, 2015 and January 21, 2016. The changes were approved by the College Curriculum Committee on March 3, 2016.

A comparison of the current curriculum and the proposed changes are summarized in the attached spreadsheet for the Medicinal Chemistry PhD program and are detailed here.

Changes to the PhD program that require approval:

1. There is no change to the total number of credits required for the PhD degree. The new program more closely meets the total of 90 credits than the previous program, which resulted in students taking many more credits than required in order to finish.
2. MBC 6300/8300 Biomedical Chemistry Lab I reduced from 4 to 1 credit hour
 - a. This course is a laboratory rotation to introduce the student to a potential lab for dissertation research.
 - b. The students have a large course load this semester and do not have time to devote so many hours to research. They do not yet have sufficient research background to be productive.
 - c. The new credit hour will be more appropriate to the time that can be devoted to this course, 3 hours of laboratory work per week.
3. MBC 6310/8310 Biomedical Chemistry Lab II will be reduced from 4 to 3 credit hours.
 - a. This course is a second laboratory rotation, usually taken in the summer.
 - b. We have added a course to the summer semester that was previously taken in the Spring, reducing the time for research. Therefore, the reduction in hours is appropriate.
4. MBC 5620/7620 Biochemical Techniques (2 credits) will be eliminated as a required course and its content combined with MBC 6200/8200 Biomedical Chemistry (4 credits unchanged).

- a. We will adjust the content of MBC 6200/8200 so that it incorporates the essential elements of Biochemical Techniques, but in a more coherent way and combined with essential elements of Biomedical Chemistry. Some techniques will be taught in a different context, such as UT training courses or in research labs.
5. MBC 5100/7100 Research Practices is moved from spring year 1 to summer year 1. The course will be renamed "Ethical Conduct of Research."
 - a. The course currently teaches ethical conduct along with introducing the regulatory requirements with regard to research with animals, humans, and biohazards.
 - b. The University provides training on many of the technicalities of working with animals, humans, and biohazards.
 - c. The NIH requires that students supported on grants be trained in ethical conduct.
 - d. Therefore, we will focus on ethical conduct of research and make use of UT provided training in other areas. The students will take the UT training when they begin research, and will not have to wait for this course.
 - e. The catalog description of the course is unchanged. "Consideration of the scientific, ethical and legal obligations of the graduate student researcher."