



USC Department of Regulatory
and Quality Sciences

MPTX 602: Science, Research, and Ethics

2 units

Summer 2022—June 25 and 26; July 6, 9, 17, 27, & 31

Location: CHP 140

Course Coordinator(s):

Terry Church: tdchurch@usc.edu

Office: CHP 140 Phone: (323) 442-0241

Office Hours:

Friday 10am-12pm - CHP-140F; or by Appointment.

Instructors:

Amanda Burkhardt: aburkhar@usc.edu

Daryl Davies: ddavies@usc.edu

Tam Phan: tamphan@usc.edu

Frances Richmond: fjr@usc.edu

IT Help:

Blackboard is the Learning Management System (LMS) used at the USC School of Pharmacy. For 24/7 help with Blackboard:

- Call (213) 740-5555 and choose Option 2.
- Send an e-mail to blackboard@usc.edu.
- Visit USC's Blackboard Online Help site for how-to videos and guides.
- Access additional Blackboard training videos on Lynda at <http://www.usc.edu/lynda>.
- **Zoom and Panopto may be used for lecture capture and delivery, Zoom and Poll Everywhere may be used as an audience response system, and Blackboard and ExamSoft may be used to administer quizzes and examinations.**
- For help with Zoom, visit <https://itservices.usc.edu/zoom/>.
- For help with Panopto, call the 24/7 Panopto support team at (855) 765-2341 or e-mail support@panopto.com
- For help with ExamSoft, call the 24/7 ExamSoft support team at (866) 429-8889, e-mail support@examsoft.com , or visit <https://learn.examsoft.com/about/examsoft-support>.
- You may also visit our Learning Environments Technical Support Specialists in PSC 102, M-F from 8:00 AM-4:00 PM, call (323) 442-0002, or e-mail pharmit@usc.edu.
- **For all other technology-related questions, call USC Information Technology Services at (213) 740-5555.**

Course Description

Pharmacists, physicians, and medical professionals constantly face ethical choices. Sometimes these choices are dramatic matters of life-and-death decisions, but more often subtle, less conspicuous choices that are nonetheless important. Ranging from situations faced in direct patient care to broader issues, this course will utilize cases studies to explore topics and the ethical framework within which practitioners make decisions about such issues as assisted suicide, conscientious refusal, pain management, and confidentiality as well as the equitable distribution of drug resources within institutions or managed care organizations and clinical studies on vulnerable populations. Ethical dilemmas in medical and pharmaceutical practice will be explored in the broader sense of healthcare and medico-legal case review.

Learning Objectives

Upon successful completion of this course, the student should be able to -

- Identify sources of moral judgements
- Describe the ethical cornerstones of beneficence, justice, and autonomy
- Critique ethical questions in terms of veracity and fidelity
- Evaluate key issues in healthcare ethics and formulate arguments in defense and interrogation of those issues
- Appraise the consequences of improper drug use and abuse and its relationship to health, economy, wellbeing, and society as presented in the literature

Course Notes

This course is designed for students who wish to have insight into difficult to remedy health care and medical issues that are almost impossible to resolve even after consideration by the judicial system. Students will be presented with reading material that consists of court cases, opinion documents, and summaries that have attempted to answer in part or in whole the dilemma that exists in consideration of each one of the healthcare / medical issues to be discussed.

Students will be presented with case studies to help explore and understand the principles guiding the conduct of healthcare professionals. In addition, issues presented will involve the welfare and consideration of others in deciding how to act ethically. The topics to be reviewed in this course include:

- Responsible conduct of research
- Roles and responsibilities within the healthcare workforce
- Rigor and Reproducibility in research
- Good Practices – Clinical, Laboratory, and Animal Research
- Conflict of Interest
- Use of data, HIPAA, confidentiality, and privacy
- Contracts, grants, and payments for research
- Managed care
- Contemporary health care legislative rulings impacting regulation and conduct of clinical trials

Required Readings and Supplementary Materials

- A list of readings will complement the lectures. At the beginning of each term in which the course is taught, a detailed agenda will be developed that identifies the dates and times of the sessions and the names of any guest speakers for that session. In addition, you will be supplied with an electronic binder that contains all the information about assignments and projects, reading materials that are unique to the lectures, biographical sketches of the instructors, and the novel or movie that bases the student project.

All this material is also posted and updated weekly on blackboard, which is our main tool for organizing materials. You will also be given information about using blackboard and our other on-line tools at that time. Each week, the instructor will identify the section of the textbook and supplementary readings in the binder that should be prepared for the session(s) that follow. Because this is an area of rapid change in policies, the readings may vary from one term to the next. Additional readings for each section that may be of added use are listed in the table below.

Description and Assessment of Assignments

10% Journal Post: "What Are Ethics"? This is a reflective essay.

30% Group Ethical Debate (10% identified article and powerpoint; 20% oral debate)

10% Summary essay of recent Clinical Trial issue

20% Midterm Exam

30% Final Exam

Methods

Teaching Methods

Before Event

- Assigned reading/writing (texts)
- Assigned reading (journal or papers)

During Event

- Classroom lecture
- Small group discussion
- Role play
- Simulation
- Student presentation
- Polling questions

After Event

- Reflection

Not Associated with an Event

- Group project

Assessment Methods

Examination

- Short answer

In Class

- Oral presentation
- Team based learning
- Small group evaluation

Longer term

- Reflective writing
- Group assignment

Grading Breakdown

Assignment	Percent
Journal Post "What Are Ethics"?	10
Group debate: Identified article and ppt	10
Group debate: Oral debate	20
Summary essay of Clinical Trial issue	10
Midterm exam	20
Final exam	30

Grading Scale

A	95-100
A-	90-94
B+	87-89
B	83-86
B-	80-82
C+	77-79
C	73-76
C-	70-72
D+	67-69
D	63-66
D-	60-62
F	59 and below

Additional Policies

Policy Regarding Class Recordings

All class recordings (Zoom, Panopto, etc.) are accessible only to students currently enrolled in the class, instructors, and TAs. These recordings may not be shared or used for purposes outside of this course. Students are also not permitted to record or distribute any course materials or activities on their own without the instructor's permission. Please refer to the University guidance towards the appropriate use and handling of these recordings under existing SCampus policies in Part C on class notes (policy.usc.edu/scampus/).

Policy Regarding Assignments and Examinations

The following actions are all violations of academic integrity and subject to disciplinary action.

- a. Any use or attempted use of external assistance in the completion of an academic assignment and/or during an examination, or any behavior that defeats the intent of an examination or other classwork or assignment, unless expressly permitted by the instructor.
- b. The following are examples of unacceptable behaviors: communicating with fellow students during an exam, copying or attempting to copy material from another student's exam; allowing another student to copy from an exam or assignment; possession or use of unauthorized notes, calculator, or other materials during exams and/or unauthorized removal of exam materials.
- c. Additional examples of academic misconduct can be found in SCampus in Part B, Section 11, "Behavior Violating University Standards" policy.usc.edu/scampus/.

Policy Regarding Missed Examinations

The policy for this course will follow the policy contained within the Academic Policies and Procedures section of the Student Handbook located on the [USC School of Pharmacy Intranet](#). Students who miss an examination are referred to this policy.

Technological Requirements and Software Updates

Students may be required to bring an internet-enabled device with browser capabilities, such as a cell phone, tablet, or laptop to class. During class time, it is expected that students will use their devices only to participate in activities guided by the instructor. Use of devices for other purposes is not permitted during class time.

The USC School of Pharmacy recommends that students purchase a computer that meets, at minimum, the "medium" level hardware requirements that are also recommended for faculty and staff:

<https://itservices.usc.edu/recommendations/>.

Students who use Zoom should be running the latest version of Zoom available at <https://zoom.us/download>.

Students who use ExamSoft will also be required to have the latest version of Examplify installed on their laptops at all times compatible with their operating system. Occasional updates to the software may be asked of you throughout the year. It is your responsibility to read your USC e-mails regarding Examplify and follow the instructions as listed.

Policy on Learning & Assessment Feedback (LAF)

Feedback on examinations/assessments will be provided using the following methods.

- In-office review (with specific conditions to be defined for each assessment)
- In-class review (with specific conditions to be defined for each exam)

University Policy on Absences

University policy grants students excused absences from class for observance of religious holy days. Faculty are asked to be responsive to requests when students contact them IN ADVANCE to request such an excused absence. The student should be given an opportunity to make up missed work because of religious observance. Students are advised to scan their syllabi at the beginning of each course to detect potential conflicts with their religious observances. Please note that this applies only to the sort of holy day that necessitates absence from class and/or whose religious requirements clearly conflict with aspects of academic performance. For additional program-specific absence policies, please refer to the Student Handbook on the [USC School of Pharmacy Intranet](#).

School of Pharmacy Policy for Written Assignments Regarding Citation Style

All written assignments in the course should use the uniform style of the School of Pharmacy for formatting in-text citations and reference lists. This style corresponds to the AMA (American Medical Association) format and can be found through this following guide <https://libguides.usc.edu/ama11> and handout https://libguides.usc.edu/ld.php?content_id=54130825. The complete AMA Manual of Style is also available as an e-book at tinyurl.com/y9oqj4ht.

Statement on Academic Conduct and Support Systems

Academic Conduct

Plagiarism – presenting someone else’s ideas as your own, either verbatim or recast in your own words – is a serious academic offense with serious consequences. Please familiarize yourself with the discussion of plagiarism in SCampus in Part B, Section 11, “Behavior Violating University Standards” policy.usc.edu/scampus-part-b/. Other forms of academic dishonesty are equally unacceptable. See additional information in SCampus and university policies on [Research and Scholarship Misconduct](#).

Students and Disability Accommodations

USC welcomes students with disabilities into all of the University’s educational programs. The Office of Student Accessibility Services (OSAS) is responsible for the determination of appropriate accommodations for students who encounter disability-related barriers. Once a student has completed the OSAS process (registration, initial appointment, and submitted documentation) and accommodations are determined to be reasonable and appropriate, a Letter of Accommodation (LOA) will be available to generate for each course. The LOA must be given to each course instructor by the student and followed up with a discussion. This should be done as early in the semester as possible as accommodations are not retroactive. More information can be found at osas.usc.edu. You may contact OSAS at (213) 740-0776 or via email at osasfrontdesk@usc.edu.

Support Systems

Counseling and Mental Health - (213) 740-9355 – 24/7 on call
studenthealth.usc.edu/counseling

Free and confidential mental health treatment for students, including short-term psychotherapy, group counseling, stress fitness workshops, and crisis intervention.

National Suicide Prevention Lifeline - 1 (800) 273-8255 – 24/7 on call

suicidepreventionlifeline.org

Free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week.

Relationship and Sexual Violence Prevention and Services (RSVP) - (213) 740-9355(WELL), press "0" after hours – 24/7 on call

studenthealth.usc.edu/sexual-assault

Free and confidential therapy services, workshops, and training for situations related to gender-based harm.

Office for Equity, Equal Opportunity, and Title IX (EEO-TIX) - (213) 740-5086

eeotix.usc.edu

Information about how to get help or help someone affected by harassment or discrimination, rights of protected classes, reporting options, and additional resources for students, faculty, staff, visitors, and applicants.

Reporting Incidents of Bias or Harassment - (213) 740-5086 or (213) 821-8298

usc-advocate.symplicity.com/care_report

Avenue to report incidents of bias, hate crimes, and microaggressions to the Office for Equity, Equal Opportunity, and Title for appropriate investigation, supportive measures, and response.

The Office of Student Accessibility Services (OSAS) - (213) 740-0776

osas.usc.edu

OSAS ensures equal access for students with disabilities through providing academic accommodations and auxiliary aids in accordance with federal laws and university policy.

USC Campus Support and Intervention - (213) 821-4710

campussupport.usc.edu

Assists students and families in resolving complex personal, financial, and academic issues adversely affecting their success as a student.

Diversity, Equity and Inclusion - (213) 740-2101

diversity.usc.edu

Information on events, programs and training, the Provost's Diversity and Inclusion Council, Diversity Liaisons for each academic school, chronology, participation, and various resources for students.

USC Emergency - UPC: (213) 740-4321, HSC: (323) 442-1000 – 24/7 on call

dps.usc.edu, emergency.usc.edu

Emergency assistance and avenue to report a crime. Latest updates regarding safety, including ways in which instruction will be continued if an officially declared emergency makes travel to campus infeasible.

USC Department of Public Safety - UPC: (213) 740-6000, HSC: (323) 442-120 – 24/7 on call

dps.usc.edu

Non-emergency assistance or information.

Office of the Ombuds - (213) 821-9556 (UPC) / (323-442-0382 (HSC)

ombuds.usc.edu

A safe and confidential place to share your USC-related issues with a University Ombuds who will work with you to explore options or paths to manage your concern.

Occupational Therapy Faculty Practice - (323) 442-3340 or otfp@med.usc.edu
chan.usc.edu/otfp

Confidential Lifestyle Redesign services for USC students to support health promoting habits and routines that enhance quality of life and academic performance.

About Your Instructor(s)

Dr. Church is currently an Assistant Professor in Regulatory and Quality Sciences at the University of Southern California, School of Pharmacy. He is Associate Director of Pharmacy Undergraduate Programs, and teaches in the Pharmacy Undergraduate Program. Prof. Church's academic focus is on application of pharmaceutical regulations, patterns of addiction, disaster management, and education and training. His areas of interest and expertise include biorepository regulation and ethics; drug addiction and regulation of controlled substances; regulatory practices for continuity and disaster planning; and policies and ethics of academic research. Dr. Church is a faculty fellow of the USC Center for Excellence in Teaching and associate director of the educational committee of the Institute for Addiction Sciences. He serves as co-director of the STAR science educational program with BRAVO Medical Magnet High School of Los Angeles and USC.

Summary of Course Schedule

Date	Lecturer	Event
Sat 06/25/22 09:00a - 05:00p	Terry Church	Terrain of Ethics
Sun 06/26/22 09:00a - 05:00p	Terry Church Amanda Burkhardt	Human Subjects Research
Wed 07/06/22 05:30p - 06:30p	Terry Church	Virtual Touchpoints with Students
Sun 07/17/22 09:00a - 05:00p	Terry Church Frances Richmond	Fraud and International Standards
Wed 07/27/22 05:30p - 06:30p	Terry Church	Virtual Touchpoint with Students
Sun 07/31/22 09:00a - 05:00p	Terry Church Daryl Davies Tam Phan	Conflicts, Mentorship, and Current Issues
Wed 08/03/22 05:30p - 06:30p	Terry Church	Virtual Touchpoint with Students

Expanded Course Schedule

Date	Lecturer	Event
Sat 06/25/22 09:00a - 05:00p	Terry Church	Terrain of Ethics Time Session Title Speaker(s) 1 9:00 AM Terrain of Modern Bioethics Terry Church 10:15 AM Break 2 10:30 AM Moral Standing and Development of Regulations Terry Church 11:45 AM Discussion of Deliverables Terry Church 12:00 PM Lunch 3 1:00 PM Laws, Ethics, and Biomedical Standards Terry Church 2:00 PM Break 4 2:15 PM Human Subjects Violations and Protections Terry Church 3:30 PM Break 5 3:15 PM Human Subjects: Workshop* Terry Church
Sun 06/26/22 09:00a - 05:00p	Terry Church Amanda Burkhardt	Human Subjects Research Time Session Title Speaker(s) 1 9:00 AM Informing Consent and Breaking Promises Terry Church 10:15 AM Break 2 10:30 AM Requirements of Healthcare Relationships Terry Church 3 11:15 AM Allocation of Healthcare Resources Amanda Burkhardt 12:00 PM Lunch 4 1:00 PM Organ Transplant Amanda Burkhardt 2:15 PM Break 5 2:30 PM Genetics and Modifying Human Nature Amanda Burkhardt 6 3:30 PM Ethics of Human Tissue Procurement and Retention Terry Church
Wed 07/06/22 05:30p - 06:30p	Terry Church	Virtual Touchpoints with Students Discuss format of student debates and project background

Date	Lecturer	Event
Sun 07/17/22 09:00a - 05:00p	Terry Church Frances Richmond	Fraud and International Standards Time Session Title Speaker(s) 1 9:00 AM Fraud and Corruption Frances Richmond 10:00 AM Break 2 10:15 AM The Foreign Corruption Practices Act Frances Richmond 3 11:15 AM Student Project Group 1 4 11:45 AM Student Project Group 2 5 12:15 PM Student Project Group 3 12:30 PM Lunch 6 1:30 PM The Ethical, Legal, and Social Implications of Gene Therapy Ashley Hall 3:00 PM Break 7 3:15 PM International Standards and Practices Terry Church
Wed 07/27/22 05:30p - 06:30p	Terry Church	Virtual Touchpoint with Students Issues in Multicenter Trials and International Studies
Sun 07/31/22 09:00a - 05:00p	Terry Church Daryl Davies Tam Phan	Conflicts, Mentorship, and Current Issues Time Session Title Speaker(s) 1 9:00 AM Avoiding Killing; Death and Dying Terry Church 10:00 AM Break 2 10:15 AM Ethics of Multicenter / Multisite International Clinical Trials Terry Church 3 11:00 AM Conflicts of Interest Terry Church 12:00 PM Lunch 4 1:00 PM Mentorship and Role Models Daryl Davies 2:15 PM Break 5 2:30 PM Current Issues in Clinical Management Tam Phan
Wed 08/03/22 05:30p - 06:30p	Terry Church	Virtual Touchpoint with Students Final exam review