

Alfred E. Mann School of Pharmacy and Pharmaceutical Sciences

Spring 2024: BPSI 406: Drug Safety Pharmacology and Toxicology 12.12.2023

Instructors:

Martine Culty, PhD

Associate Professor, Dept. of Pharmacology and Pharmaceutical Sciences, USC Mann School

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Office: HSC campus PSC 506; Office Hours (by appt).

Course Weight: 4 Units

Day/Time/Location: Wed 3:00 pm to 5:50 pm; Room, SOS B52.

Catalogue Description: Toxicology and Safety Pharmacology principles and procedures for the pre-clinical development of safe and efficacious small molecule drugs and biologics.

Introduction and Purpose

The clinical study of a new drug is predicated on the evaluation of drug safety. Such study involves the evaluation and study of undesirable effects of therapeutic drug products including small molecules (new chemical entities [NCEs]), biologics (proteins, cell and gene therapies), vaccines, and their excipients that may present a hazard to human health. This course focuses on the

understanding and utilization of safety pharmacology and toxicology strategies that are mandated by the global regulatory bodies (e.g., FDA, ICH, EMA) to move a new product from the discovery stage to clinical trials and market approval.

Knowledge of product safety plays a critical role in the drug development process by providing valuable insight into potential adverse effects of drug candidates prior to their use in humans. Toxicology studies are required to be conducted prior to the use of new therapeutics in humans. Data collected from safety pharmacology and toxicology studies are used to guide the FDA and other regulatory agencies in the appropriate oversight of the development process, and the clinicians in the safe conduct of clinical trials through design and execution.

A core battery of tests is required by regulatory agencies using established guidelines prior to initiation of the first-in-human trial of an investigational drug. Subsequent and longer-term testing is usually required to support later stage clinical trials and marketing. While this process may seem straightforward, many factors must be considered for the practical implementation of these studies. Further, products may need additional safety testing when the clinical model used to develop them is not part of the menu of prescribed studies. Supplemental tests may be conducted to assess specific organ system toxicities. The goal of these studies is to identify potential safety risks that may arise prior to widespread use of the drug.

The recent COVID-19 pandemic that led to the development of vaccines against SARS-CoV-2 virus has propelled discussions regarding safety testing into mainstream conversations. The debates regarding vaccine safety complicated by politization and social media illustrate the importance of the regulatory bodies overseeing the development of safe and effective medicines.

Objectives

This course is designed for undergraduates of both scientific and non-scientific majors with an interest in learning about principles and concepts underlying drug safety pharmacology and toxicology. Content presented in this course will enable students to acquire a strong understanding of the step-by-step process involved in safety evaluation during drug development, as one would encounter if conducting drug development in either an academic setting or in a pharmaceutical company. Chapters from the required textbooks will be supplemented with a variety of source materials including articles from scientific journals and public websites. Selected cases studies will be critically reviewed, and emerging "hot" topics discussed.

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

- Comprehend the overall process for safety evaluation and toxicology studies prior to first-in-human studies.
- Explain the basic principles and concepts of toxicology, and terminology common with pharmacology.
- Understand the importance of Formulations, Routes, Dosage Regimens, Bioavailability and ADME (S) in drug development.
- Identify general safety issues as well as organ specific toxicities and how to test for them.
- Explain the differences in drug development strategies applied to small molecule drugs and biopharmaceuticals.
- Generate a project describing the strategy and experimental design to implement for determining the risks of a drug candidate prior to first-in-human trials.

Assignments and Grading:

Class participation and attendance	15 pts	(7.5 %)
Short reflection essays (1 point/week)	15 pts	(7.5 %)
2 quizzes @ 10 pts each	20 pts	(10 %)
2 midterm exams @ 35 pts each:	70 pts	(35 %)
4 Student presentations @ 10 pts each	40 pts	(20 %)
1 final exam (Essay Assignment):	40 pts	(20 %)
Total: 200 pts (1		(100 %)

Class Participation and attendance (15 pts): Participation includes participating to class discussions, asking/answering questions and/or contributing to discussions in class.

Attendance in person at all classes is required. Following a class on zoom is restricted to specific cases, such as a *justified health issue which has been communicated to the instructor before class*. Students are expected to read the assigned papers prior to the lecture and be prepared to discuss background, current understanding, and gaps in knowledge for the topic in each lecture.

On a scale of 15, 0-indicates no participation and/or unjustified absence(s); 15-indicates good participation and attendance to in person classes. You can increase the chance of a higher mark by being proactive in terms of asking (relevant) questions.

Short reflection essays (15 pts) should summarize in \sim 1 page what the student learned in a class, what he/she/they liked, and how they think the class could be improved. You can increase the chance of a higher mark by writing reflection essays for all classes.

2 Quizzes (10 pts each) There will be 2 quizzes over the course of the semester that will primarily be based on questions pulled from the textbooks and lectures.

Midterm exams (35 points each) will include multiple choice questions, T/F questions, fill-in the blank questions, and short answers. Midterm 1 will include questions from weeks 1 to 6. Midterm 2 will include questions from weeks 7 to 11.

Student presentation (10 points each): Students will give 4 oral presentations, which can be done individually or in team, focusing on 4 subjects related to safety pharmacology and toxicology, illustrating failures and successes of drug development:

- (1) An example of failure of a safety pharmacology/toxicology process to predict/prevent adverse effects.
- (2) An example of post-market identification of adverse effect leading to black box warning / restricted use or drug ban.
- (3) A success story of safety pharmacology such as: (a) describing the steps used in the development of a successful drug; (b) explaining how safety pharmacology revealed potential adverse effects of a drug leading to structure modification to prevent the undesired effects; (c) the re-purposing or re-targeting of a drug to take advantage of the therapeutic effects while avoiding adverse effects in some patients.
- (4) An example of drug toxicity on an organ/biological system not discussed in detail during class, explaining the mechanism of toxicity of the drug and what precautions/interventions can be used to prevent the adverse effects while using the drug.

Essay assignment instead of a final exam, a 5-page double-spaced essay (deliverable) will be due by email to <u>culty@usc.edu</u> by11:59 pm on Friday, May 3, 2024

Guidelines: Include a brief description of the drug principle and design strategy (e.g. mRNA vs protein vaccine; small molecule, biologic, biomimetic); its history, what type of safety pharmacology/toxicology tests were used (if not available, try to predict from what you learned in class); give some information on the clinical trials (say few words on FDA emergency approval if applicable) and the fate of the drug at the time when you are generating your report.

A grading rubric will be available on the web. Additional details will be presented during the first week of class and included in Week 1 PPT slides.

Notes, books, calculators, electronic dictionaries, regular dictionaries, cell phones or any other aids are not allowed during exams.

Students will be asked to complete an anonymous critical evaluation of the course at its completion.

Course Readings

Required Readings

Casarett and Doull'S Essentials of Toxicology. 3rd Edition.

CD Klaassen and JB Watkins III editors. Lange

Print ISBN-13: 978-1259255359; ISBN-10: 1259255352

Online version of 3rd and 4th Editions available at USC libraries

https://accesspharmacy-mhmedical-com.libproxy2.usc.edu/book.aspx?bookid=3000

Safety Pharmacology in Pharmaceutical Development Shayne C. Gad (A)

- Approval and Post Marketing Surveillance. 2nd Edition.

CRC Press, Taylor & Francis Group, LLC

First issued in paperback 2019: ISBN-13:978-0-367-38145-5

Drug Safety Evaluation, 3rd Edition Author(s): Shavne Cox Gad (B)

First published: 31 October 2016

Print ISBN:9781119097396 |Online ISBN:9781119097440 |DOI:10.1002/9781119097440

PDF format available at USC libraries.

Additional text that students may find helpful:

NIH ToxTutor website: https://toxtutor.nlm.nih.gov

Drug Discovery and Development: Technology in Transition, 2nd Edition Raymond G. Hill & Humphrey P. Rang; ISBN-13: 978-0702042997 PDF format available at USC libraries.

Although neither text is mandatory, it is strongly suggested that the students purchase (download) at least one of the textbooks for this course as it will greatly improve the students grasp on the Drug Discovery/Development process. The students will be able to use identified chapters in the text to support their learning process throughout the semester.

Other course materials including but not limited to the syllabus, supplemental reading assignments and additional handouts will be posted on http://blackboard.usc.edu/. The students will also be encouraged to use the online discussions among students via Blackboard.

Recommended Supplemental Readings

Hamdam J et al. Safety pharmacology - Current and emerging concepts. Toxicology and Applied Pharmacology 273 (2013) 229-241

Pugsley MK, Authier S, Curtis MJ. Review: Frontiers in Pharmacology. Principles of Safety Pharmacology. British Journal of Pharmacology (2008) 154, 1382-1399.

ICH Safety guidelines: https://www.ich.org/page/safety-guidelines

FDA guidances: https://www.fda.gov/regulatory-information/search-fda-guidance-documents

Toxicology Education Foundation videos and info: https://toxedfoundation.org

The Thalidomide Tragedy: Lessons for Drug Safety and Regulation: https://helix.northwestern.edu/article/thalidomide-tragedy-lessons-drug-safety-and-regulation

Vargesson N. Review: Thalidomide-Induced Teratogenesis: History and Mechanisms. Birth Defects Research (Part C) 105:140–156, 2015.

Shah U and Mailankody S. Emerging immunotherapies in multiple myeloma. *BMJ* 2020;370:m3176. http://dx.doi.org/10.1136/bmj.m3176.

Sulfanilamide Disaster—FDA Consumer magazine: https://www.fda.gov/files/about%20fda/published/The-Sulfanilamide-Disaster.pdf

The FDA Issues Two Toothpaste Recalls: https://www.wtoc.com/story/6664587/the-fda-issues-two-toothpaste-recalls/

MedWatch: The FDA Safety Information and Adverse Event Reporting Program: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program

Vioxx adverse effects and removal from market by Merck: https://www.drugwatch.com/vioxx/

Conviction by a federal jury of owner and employees of the Compounding Center NECC for causing the 2012 nationwide fungal meningitis outbreak: http://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/december-13-2018-owner-and-four-former-employees-new-england-compounding-center-convicted-following

Victims of contaminated steroids still hurting: 'My Life's Upside-Down': https://www.npr.org/sections/health-shots/2017/01/24/511442863/victims-of-contaminated-steroids-still-hurting-my-lifes-upside-down

- França, K., Kumar, A., Fioranelli, M., Lotti, T., Tirant, M., & Roccia, M. G. (2017). The history of Botulinum toxin: from poison to beauty. *Wiener Medizinische Wochenschrift*, 167(1), 46-48.
- Molina, C., & Earn, D. J. (2015). Game theory of pre-emptive vaccination before bioterrorism or accidental release of smallpox. *Journal of The Royal Society Interface*, 12(107), 20141387.
- Rubinstein, M. L., Delucchi, K., Benowitz, N. L., & Ramo, D. E. (2018). Adolescent exposure to toxic volatile organic chemicals from e-cigarettes. *Pediatrics*, 141(4), 1-11.
- Sohail, H. A., Gutiérrez, J. M., Mebs, D., Rowan, E. G., Sohail, M., & Warrell, D. A. (2020). Venoms, poisons and toxins: evolution and impact of amazing molecules. *Journal of Venom Research*, 10, 1-6.
- Stewart, S. (2019). "Gleaming and Deadly White": Toxic Cosmetics in the Roman World. In P. Wexler (Ed.), *Toxicology in Antiquity (Second Edition)* (2nd ed., pp. 301-311): Academic Press.

Online learning Etiquette

- o If it is not possible to have you webcam on during the entire class, do you best to have it on when speaking
- o Turn off your microphone when not speaking
- o If you need to step away from your computer during class (e.g. get a drink of water, use the bathroom, attend to a family member/pet) please do so quietly and without disturbing your classmates. Return to the class when you can.
- o Be aware the contents of conversations typed into the chat box, even private conversations, are visible by the instructors

Course Outline

This course will be in the format of a directed seminar/lecture under the guidance of the instructor for the specific session. During each weekly session the instructor(s) will engage the students with questions and draw comments or interpretations primarily based on the assigned reading. Students are expected to ask questions and participate in an interactive fashion.

About your instructor(s)

Dr. Martine Culty: PhD, Associate Professor, in the Department of Pharmacology and Pharmaceutical Sciences, USC Mann School. PhD in <u>Expertise</u>: Male reproduction, reproductive endocrinology and toxicology. Research focus on identifying the mechanisms regulating male germ cell development and how perinatal exposures to endocrine disrupting chemicals (EDCs) and drugs such as NSAIDs and acetaminophen disrupt testis development, in relation to infertility and testicular cancer.

Dr. Daryl L. Davies: PhD, Assoc. Dean of Undergraduate Education, Professor of Clinical Pharmacy at USC Mann school. Expertise and research focus: alcohol use disorders and the effects of ethanol on the brain and liver. Role of the microbiome, interaction on CNS (gut/brain axis) and

impact on human health. Neurodegenerative diseases. Development of pharmaceuticals and herbal therapies (e.g., Chinese Traditional Medicines) to advance human health.

Dr. Hovhannes (Hovik) Gukasyan: Associate Professor of Pharmacology and Pharmaceutical Sciences; USC Mann. Expertise: Supported > 80 pipeline projects in pharmaceutical industry for 18 years, leading to several marketed drugs (@Pfizer, Allergan-AbbVie Aesthetics, etc. Currently independent medicinal product development lead consultant for several pharma-biotech companies. Expert in pharmaceutical R&D towards development, characterization, and application of novel drug delivery technologies, modeling and simulations methods in early clinical studies

Dr. Mary Ellen Cosenza: PhD. Adjunct Faculty, Department of Regulatory and Quality Sciences, USC Mann. Expertise: toxicology, Worked in the Pharmaceutical Industry for over 35 years. A large portion of her efforts at Amgen in Thousand Oaks, CA. Past-President of the American College of Toxicology, currently serving as Treasure of IUTOX.

Dr. Husam Younis: has over 20 years experience in the pharmaceutical/biotechnology industry leading research and development teams to advance drug candidates to first-in-human and proof-of-concept clinical studies across multiple drug modalities and therapeutic areas. Currently leading toxicology, pharmacokinetic/DMPK, and biomarker functions at Avidity Biosciences (San Diego, CA). Previous positions at NGM Biopharmaceuticals (South San Francisco, CA), Ionis Pharmaceuticals (Carlsbad, CA) and Pfizer Inc (San Diego, CA) in nonclinical development and translational medicine.

Dr. Yasi Mojab, MSPS, PharmD, PhD (c) is the program coordinator for USC summer and winter programs and lecturer at USC Mann School of Pharmacy. <u>Expertise</u>: Nuclear Medicine and Radiopharmacy. She is currently pursuing her Ph.D. in pharmaceutical and translational sciences from University of Southern California. <u>Research focus</u>: Structural based drug design, computational chemistry, and educational research.

Week & Date		Lecture	Readings	
Instructors				
Week 1	MC	<u>Introduction</u> : course objectives, format, instructors		
Jan 10	HG	Overview of drug Development Process: Safety pharmacology.	C&D, Ch 1-4	
		Drug discovery & development - History and goals of preclinical		
	MC	Safety. FDA, ICH		
	MC	General principals of toxicology, Hazard, exposure and risk	Gad A & B, Chapters 1, 2	
Week 2	HG	Pharmaco & toxico dose responses, TI, therapeutic window etc. ADME (S), bioavailability, Formulations, Routes, and Dosage	C&D Ch 3	
	110	Regimens (DMPK).	Gad B, Ch 5; Hill/Rang Ch16	
Jan 17		Regimens (DWI K).	Gad B, Cli 3, Illii/Rang Cli 10	
	MC	Cardiac toxicology and safety pharmacology	C&D 18; Gad A Ch 4	
Week 3	HG	Ocular and visual toxicology	C&D Ch 17	
Jan 24				
Q1 (wks 1-2)		Case studies illustrating why we have the FDA		
Week 4	MC	Liver toxicology and safety pharmacology	C&D, Ch 13	
Jan 31			Gad B discussed in Ch 6-7	
	YM	Kidney toxicology and safety pharmacology	C&D, Ch 14; Gad A Ch 7	
Week 5	HY	CNS toxicology and safety pharmacology and regulations,	C&D Ch 16	
Feb 7		FDA/ICH guidance	Gad A Ch 5; Gad B Ch 7 &	
		Case study	18	
Week 6	MC	History of Food Toxicology and Food Safety Regulation	Bloom & Sinclair books	
Feb 14	TD 6		Gad B discussed in Ch 2	
	YM	Food Safety Goals & Regulations: FDA Food Safety &	FDA websites; selected	
		Modernization Act – Comparison with European system	articles (Kinsey 2005)	
		Project: choose a product & report the safety vs toxicity of its ingredients	https://www.choicesmagazine.org/2005-4/supplychain/2005-4-	
		ingredients	11.htm	
		Midterm 1 (wks 3 to 5) (online Feb 14)		
Week 7	MC	Developmental (teratogenicity) and Reproductive toxicology	C&D, Ch 10, 20	
Feb 21			Gad B Ch 13	
	MEC	Pediatric Product Safety Assessment	Gad B Ch 23	
Week 8	MEC	Evaluation of drugs for genotoxicity and carcinogenicity	C&D, Ch 8, 9	
Feb 28			Gad B Ch 9, 14	
		Evaluation of Blood and Immunotoxicology	C&D Ch 11, 12	
*** 1 0	MEG	Immunotoxicity in Drug Development	GAD A Ch 9; Gad B Ch 11	
Week 9	MEC	IND-enabling tox - Pre-clinical Drug Safety/Toxicology	Gad B Ch 7, 8	
Mar 6		Assessment: Supporting drug clinical development	GAD A Ch 1.5 (Study design)	
Q2 (wks 6-8)		Drug Safety Evaluation from a Contract Research Organization	Gad B Ch 8, 18	
		(CRO) perspective	Gad D Ch 6, 16	
Spring Recess Sunday, March 10, 2024 to Sunday, March 17, 2024				
Week 10	MEC	Small Molecules vs Biopharmaceuticals. Special Concerns for	Hill/Rang Chapters 13	
Mar 20		Preclinical Evaluation of Biotechnology-derived products	Gad, Chapter 19	
		_		
	HY	Case study: Development of RNA therapeutics	Nucleic Acids Research, 2023,	
XX7 1 1 1	MEC	https://doi.org/10.1093/nar/gkad415	Vol. 51, No. 12 5901–5910.	
Week 11	MEC &	Post-Marketing Safety Evaluation	Gad, Chapter 29 https://lawshelf.com/videocours	
Mar 27	MC	T 1 1 Date 1	esmoduleview/legal-and-	
		Legal and Ethical concerns in drug development	ethical-considerations-in-drug-	
			development-module-1-of-5/	

Week 12 Apr 3	HG, MC YM	Student presentation 1 - Learning from our errors: Story of a failed drug safety pharmacology and/or toxicology assessment		
Midterm 2 (wks 9 to 11) (online Apr 3)				
Week 13 Apr 10	HG MC YM	Student presentation 2 - Learning from our errors: Story of post-market safety issue leading to box warning, restricted use or ban		
Week 14 Apr 17	HG MC YM	Student presentation 3: - Success story of a drug: proper steps used, elimination of adverse effects, repurposing, retargeting		
Week 15 Apr 24	MC MEC HG YM	Student presentation 4: success story of a drug		
Final Exam: Essay due by 11:59 pm on Friday, May 3, 2024				

Course Content Distribution and Synchronous Session Recordings Policies

USC has policies that prohibit recording and distribution of any synchronous and asynchronous course content outside of the learning environment.

Recording a university class without the express permission of the instructor and announcement to the class, or unless conducted pursuant to an Office of Student Accessibility Services (OSAS) accommodation. Recording can inhibit free discussion in the future, and thus infringe on the academic freedom of other students as well as the instructor. (<u>Living our Unifying Values: The USC Student Handbook</u>, page 13).

Distribution or use of notes, recordings, exams, or other intellectual property, based on university classes or lectures without the express permission of the instructor for purposes other than individual or group study. This includes but is not limited to providing materials for distribution by services publishing course materials. This restriction on unauthorized use also applies to all information, which had been distributed to students or in any way had been displayed for use in relationship to the class, whether obtained in class, via email, on the internet, or via any other media. (Living our Unifying Values: The USC Student Handbook, page 13).

Academic Integrity

The University of Southern California is foremost a learning community committed to fostering successful scholars and researchers dedicated to the pursuit of knowledge and the transmission of ideas. Academic misconduct is in contrast to the university's mission to educate students through a broad array of first-rank academic, professional, and extracurricular programs and includes any act of dishonesty in the submission of academic work (either in draft or final form).

This course will follow the expectations for academic integrity as stated in the <u>USC Student Handbook</u>. All students are expected to submit assignments that are original work and prepared specifically for the course/section in this academic term. You may not submit work written by others or "recycle" work prepared for other courses without obtaining written permission from the instructor(s). Students suspected of engaging in academic misconduct will be reported to the

Office of Academic Integrity.

Other violations of academic misconduct include, but are not limited to, cheating, plagiarism, fabrication (e.g., falsifying data), knowingly assisting others in acts of academic dishonesty, and any act that gains or is intended to gain an unfair academic advantage.

The impact of academic dishonesty is far-reaching and is considered a serious offense against the university and could result in outcomes such as failure on the assignment, failure in the course, suspension, or even expulsion from the university.

For more information about academic integrity see the <u>student handbook</u> or the <u>Office of Academic Integrity's website</u>, and university policies on <u>Research and Scholarship Misconduct</u>.

Statement on Academic Conduct and Support Systems

Academic Integrity:

The University of Southern California is a learning community committed to developing successful scholars and researchers dedicated to the pursuit of knowledge and the dissemination of ideas. Academic misconduct, which includes any act of dishonesty in the production or submission of academic work, comprises the integrity of the person who commits the act and can impugn the perceived integrity of the entire university community. It stands in opposition to the university's mission to research, educate, and contribute productively to our community and the world.

All students are expected to submit assignments that represent their own original work, and that have been prepared specifically for the course or section for which they have been submitted. You may not submit work written by others or "recycle" work prepared for other courses without obtaining written permission from the instructor(s).

Other violations of academic integrity include, but are not limited to, cheating, plagiarism, fabrication (e.g., falsifying data), collusion, knowingly assisting others in acts of academic dishonesty, and any act that gains or is intended to gain an unfair academic advantage.

The impact of academic dishonesty is far-reaching and is considered a serious offense against the university. All incidences of academic misconduct will be reported to the Office of Academic Integrity and could result in outcomes such as failure on the assignment, failure in the course, suspension, or even expulsion from the university.

For more information about academic integrity see <u>the student handbook</u> or the <u>Office of Academic Integrity</u>'s website, and university policies on <u>Research and Scholarship Misconduct</u>.

Please ask your instructor if you are unsure what constitutes unauthorized assistance on an exam or assignment, or what information requires citation and/or attribution.

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

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

988 Suicide and Crisis Lifeline - 988 for both calls and text messages – 24/7 on call The 988 Suicide and Crisis Lifeline (formerly known as the National Suicide Prevention Lifeline) provides free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week, across the United States. The Lifeline is comprised of a national network of over 200 local crisis centers, combining custom local care and resources with national standards and best practices. The new, shorter phone number makes it easier for people to remember and access mental health crisis services (though the previous 1 (800) 273-8255 number will continue to function indefinitely) and represents a continued commitment to those in crisis.

<u>Relationship and Sexual Violence Prevention Services (RSVP)</u> - (213) 740-9355(WELL) – 24/7 on call

Free and confidential therapy services, workshops, and training for situations related to genderand power-based harm (including sexual assault, intimate partner violence, and stalking).

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

<u>Reporting Incidents of Bias or Harassment</u> - (213) 740-5086 or (213) 821-8298 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.

<u>The Office of Student Accessibility Services (OSAS)</u> - (213) 740-0776 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) 740-0411

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

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.

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

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.

<u>USC Department of Public Safety</u> - UPC: (213) 740-6000, HSC: (323) 442-1200 – 24/7 on call Non-emergency assistance or information.

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

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) 442-2850 or otfp@med.usc.edu

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