Responsible Conduct of Patient Oriented Clinical Research (TSCI 5070)
Responsible Conduct of Research (INTD 5082)
Fall 2016

CLASS DAYS and TIME: Mondays 3:00-5:00pm

CLASSROOM: MED 3.309L

COURSE FACULTY: Kimberly Summers, PharmD and Kay Oyajobi, PhD
Course Directors

OFFICE LOCATION and HOURS: By appointment; Summers (RAB 2.104, Greehey Campus) Oyajobi (5.518D MED, Long Campus)

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READ THIS DOCUMENT CAREFULLY - YOU ARE RESPONSIBLE FOR ITS CONTENTS.

COURSE DESCRIPTION AND OBJECTIVES

TSCI 5070: This interdisciplinary course is designed to train participants in the responsible conduct of patient-oriented clinical research. Students will have the opportunity to learn to and, by the end of the course, be required to: (1) delineate a history of hallmark abuses of humans enrolled in clinical research, (2) describe the evolution of national and international codes and regulations guiding inclusion of human subjects in clinical investigations, (3) list the elements of informed consent and describe procedures and precautions for enrolling special populations into clinical investigation, (4) write a consent form in understandable language, (5) recognize different forms of scientific misconduct, (6) describe the role and processes of a peer review board to judge violations in research ethics, (7) develop strategies for self-assessment and validation of scientific objectivity in one's own research, and (8) recognize the ethical responsibilities and consequences of whistle blowing.

INTD 5082: This foundational course introduces students to core ethical content necessary for responsible research conduct. Through interactive seminars, students will learn about (1) scientists as responsible members of society (contemporary ethical issues in biomedical research and environmental/social impacts of research), (2) policies for research with human subjects and vertebrate animals, (3) collaborative research, (4) conflicts of interest (personal, professional, financial), (5) data acquisition and laboratory tools (management, sharing, ownership), (6) responsible authorship and publication, (7) mentor/trainee responsibilities and relationships, (8) peer review, and (9) research misconduct (forms of misconduct and management policies).

Pre-requisites – none

Semester credit hours – TSCI 5070 (2 hrs) INTD 5082 (1.5 hrs)

The following lists some of the broad objectives of this course. Specific objectives for each individual lesson can be found at the end of this syllabus.

By the end of this course, each student should be able to:

- Associate the responsible conduct of research to the practice of scientific investigation with integrity.
- Be aware of and apply established professional norms and ethical principles for all activities related to scientific research (laboratory, human subjects, and live vertebrate animals).
- Recognize when laboratory practices, publication practices, and other research practices deviate from legal, ethical, or regulatory requirements.
- Describe practices that promote compliance with ethical and legal requirements for the responsible conduct of basic and clinical research.

COURSE ORGANIZATION

The main teaching modalities used in this course include:

1) Conventional didactic lectures in which information is delivered to the class by speakers, lecturers, or course directors
2) Presentations and panel discussions which are highly interactive case-based activities, encouraging two-way communication between the instructor and the class, and requiring student active participation in the learning process

Materials – See below

Computer Access – Students are required to have a laptop computer that can connect to and operate over a wireless network.

Software required:

- Microsoft Office Suite (A personal copy of the latest version can be purchased at The UTHSCSA bookstore at student pricing with a student ID)

Laptops with an Apple-based Operating System must be able to also operate using a Windows-based Operating System. It may be necessary to purchase Windows software (student pricing available at the UTHSCSA bookstore with a student ID) and a virtualization software.

All laptops will connect to the UTHSCSA network via the HSCWave broadcast wireless connection. Authentication for wireless use is based on the UTHSCSA domain username and password.

Verification of proper operation **prior** to the start of class is highly recommended.

Assistance is available through the IMS Service Desk

- Telephone:(567-7777
- E-mail (ims-servicedesk@uthscsa.edu)

Assistance is also available at the IMS Student Support Center (ALTC 106).

Reading Assignments – Required class readings and/or assignments are listed below in the class schedule descriptions for each lecture.

ATTENDANCE

Attendance at scheduled classes and examinations is crucial to meeting course objectives. Therefore, regular attendance in class is expected of each student.

- Attendance is defined as being present within 15 minutes after the scheduled beginning of the class and until 15 minutes before the scheduled ending of the class. A student has to arrive no later than 15 minutes after the start of the class to receive credit for attendance for that class. Any student that leaves more than 15 minutes before the end of the class WILL NOT receive credit for attendance for that class.
- Excused absences may be granted by the Course Director in cases such as formal presentations at scientific meetings, illness, or personal emergency.
- Excused absences are considered on an individual basis and require electronic communication with the Course Director to request an excused absence. The e-mail request to the Course Director for consideration of an excused absence must provide details regarding the circumstances and specific dates.
- It is expected that students will provide *advanced notice* of absence for scheduled events.
- If a student has excessive unexcused absences in a given course, they will automatically receive a grade of *unsatisfactory* unless *makeup* has been approved by the Course Director.
- Makeup of absences (both excused and unexcused) is allowed at the discretion of the Course Director.
- Allowable unexcused absences will be determined by the credit hours of the course as follows:

Course Semester Credit Hours	Allowable Unexcused Absences
2.0 (TSCI 5070)	2
1.0 (INTD 5082)	1

TEXTBOOKS

Required: None

Recommended: None

GRADING POLICIES AND EXAMINATION PROCEDURES

1 Class attendance is essential for anyone who wishes to obtain credit for the course. You must attend >85% in order to obtain credit for the course. You can make up any sessions missed due to unexpected schedule conflicts, professional travel, or other extenuating circumstances, provided you contact your course director as soon as you know you will need to miss a class. Any student who fails to meet this requirement will receive an UNSATISFACTORY grade for the course.

2 One assignment must be completed during the semester. This assignment will be posted and scored on a 100-point scale. ***You must complete and present the assignment on time and receive a minimum score of 70/100 points in order to receive credit for the course.***

3 A student who receives an INCOMPLETE must meet with the Course Director and develop a plan of action to complete the outstanding work. All outstanding work must be completed within 6 months after the end of the course; otherwise the grade will be changed to UNSATISFACTORY.

4 A student who receives an UNSATISFACTORY grade must enroll and retake the course and meet all requirements to receive a grade of satisfactory.

Grading System

The grading will be conducted on a pass fail basis and both assignments need a Satisfactory in order to pass the course.

S = Satisfactory U = Unsatisfactory

REQUESTS FOR ACCOMODATIONS FOR DISABILITIES

In accordance with policy 4.2.3, **Request for Accommodation Under the ADA and the ADA Amendments Act of 2008 (ADAAA)**, any student requesting accommodation must submit the appropriate request for accommodation under the American with Disabilities Act (ADA, form 100). to his/her appropriate Associate Dean of their School and a copy to the ADA Coordinator. Additional information may be obtained at http://uthscsa.edu/eeo/request.asp.

ACADEMIC INTEGRITY AND PROFESSIONALISM

Any student who commits an act of academic dishonesty is subject to discipline as prescribed by the UT System Rules and Regulations of the Board of Regents. Academic dishonesty includes, but is not limited to, cheating, plagiarism, collusion, the submission for credit of any work or materials that are attributable in whole or in part to another person, taking an exam for another person, signing attendance sheets for another student, and any act designed to give unfair advantage to a student or the attempt to commit such an act. Additional information may be obtained at http://catalog.uthscsa.edu/generalinformation/generalacademicpolicies/academicdishonestypolicy/

TITLE IX AT UTHSCSA

Title IX Defined:
Title of the Education Amendments of 1972 is a federal law that prohibits sex discrimination in education. It reads "no person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance."

University of Texas Health Science Center San Antonio's Commitment:
University of Texas Health Science Center San Antonio (UTHSCSA) is committed to maintaining a learning environment that is free from discriminatory conduct based on gender. As required by Title IX, UTHSCSA does not discriminate on the basis of sex in its education programs and activities, and it encourages any student, faculty, or staff member who thinks that he or she has been subjected to sex discrimination, sexual harassment (including sexual violence) or sexual misconduct to immediately report the incident to the Title IX Director.

In an emergency, victims of sexual abuse should call 911. For non-emergencies, they may contact UPD at 210-567-2800. Additional information may be obtained at http://students.uthscsa.edu/titleix/

EMAIL POLICY

Every student is issued a University e-mail address and account at the time of enrollment. As a matter of University Policy, communications between students and faculty that occur using the student's University e-mail address is considered official business. Therefore, students are expected to check their university email inboxes on a regular basis so that any announcements, instructions, or information regarding this course will be received in a timely way. Missed communications due to inadequate monitoring of incoming emails on the University's email server will not suffice as a valid excuse for unsatisfactory academic progress.

USE OF RECORDING DEVICES

Recording of lectures and other learning activities in this course by any means (e.g., video, audio, etc.) is only permitted if approved by the instructor or required for compliance with Americans with Disabilities Act (ADA).

ELECTRONIC DEVICES

Cell phones must be turned off during all class meetings and exams. Computers and electronic tablets are allowed but only for participating in classroom activities (e.g., viewing slides presented in lecture or conference materials).

Texting, tweeting, emailing, web-surfing, gaming, or any use of electronic devices that is not directly connected with classroom activities is NOT permitted.

TENTATIVE CLASS SCHEDULE

Responsible Conduct of Patient Oriented Clinical Research (TSCI 5070)
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Fall 2016

Wk	Date	Module		Topic - Instructor
1	08.22.2016	**5070**	**5082**	History – Eugenics to the Nuremberg Code - **Lichtenstein**
2	08.29.2016	**5070**	**5082**	History - Tuskegee to the Common Rule - **Lichtenstein**
3	09.05.2016			**LABOR DAY – UT Health Science Center Holiday**
4	09.12.2016	**5070**	**5082**	Organizational Structure of Research Oversight – **Summers/Oyajobi**
5	09.19.2016	**5070**	**5082**	Conflicts of Interest **–** **Sertich**
6	09.26.2016	**5070**	**5082**	Data Acquisition, Management, Sharing and Ownership – **Gelfond/Fritz**
7	10.03.2016	**5070**	**5082**	Research Misconduct – **Oyajobi, Sun, Lechleiter, Morilak**
8	10.10.2016	**5070**	**5082**	Peer Review –**Ahuja**
9	10.17.2016	**5070**	**5082**	Ethics and Responsibility in Authorship and Publication –**LoVerde**
10	10.24.2016	**5070**	**5082**	Ethical Use of Animals in Biomedical Research - **Kiel**
11	10.31.2016	**5070**	**5082**	Mentoring (Mentor/Mentee Responsibilities and Expectations) - **McManus**
12	11.07.2016	**5070**	**5082**	Safe Laboratory Practices –**Berton**
13	11.14.2016	**5070**	**5082**	Good Clinical Practice (GPC) – **Roache**
14	11.21.2016	**5070**		Elements of Consent and Protecting Confidentiality – **Taranova/James**
15	11.28.2016	**5070**		Drafting and Editing Consent Forms – **McGeary**
16	12.05.2016	**5070**		Recruiting Fairly: Inclusion of Special Populations in Research – **Hazuda**
17	12.12.2016	**5070**		Community Based Research and Consent –**Summers**

Responsible Conduct of Patient Oriented Clinical Research (TSCI 5070)
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Week 1

Date and Time: 08/22/2016 3-5pm

Location: MED 3.309L

Topic: HISTORY: Eugenics to the Nuremberg Code

Lecturer: Michael Lichtenstein, MD

Class Objectives:

1. Describe the history of the eugenics movement in the United States during the 19th and 20th Century
2. Provide examples of how eugenics affected U.S. public policy in the first half of the 20th Century
3. Contrast 21st century issues related to gene therapy with 20th century eugenics practices
4. Describe the differences between medical treatment compared to biomedical research
5. Describe how Nazi medical care arose out of the eugenics and race medicine theories of the time.
6. Describe one example, in detail, of Nazi medical experiments conducted in concentration camps.
7. Discuss the responsibility of individual investigators conducting research with human subjects
8. Delineate the influence the Nuremberg Code was to have on subsequent human subject regulations.

Class Readings and/or Assignment:

1. Caplan, AI, McGee, G, Magnus, D. What is immoral about eugenics? BMJ 1999; 319: 1284-1285.
2. Miclos, D, Carlson, E. Engineering American society: the lesson of eugenics. Nature Reviews: Genetics 2000; 1:153-158.
3. Grodin, MA. Historical Origins of the Nuremberg Code. Chapter 7 pages 121-144, in The Nazi Doctors and the Nuremberg Code: Human Rights and Human Experimentation. Annas, GJ, Grodin, MA, Editors, Oxford University Press, New York, 1992
4. Mozes-Kor, E. The Mengele Twins and Human Experimentation: A Personal Account. Chapter 4 pages 53-59, in The Nazi Doctors and the Nuremberg Code: Human Rights and Human Experimentation. Annas, GJ, Grodin, MA, Editors, Oxford University Press, New York, 1992

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Week: 2

Date and Time: 08/29/2016 3-5pm

Location: MED 3.309L

Topic: HISTORY: From Tuskegee to the Common Rule

Instructor: Michael Lichtenstein, MD

Learning Objectives – Participants will be able to:

1. Present the rationale for the initiation of the study in the context of the 1930s
2. Present the arguments for and against the treatment of participants with penicillin in the 1950s
3. Describe potential effects of social and economic factors in the recruitment and retention of subjects
4. Determine whether the methodology of the study is sufficiently rigorous to provide valid information
5. Describe the development and purposes of the Declaration of Helsinki
6. Compare and Contrast the Nuremberg Code with the Declaration of Helsinki
7. Discuss the underlying principles in the Belmont report: Respect for Persons, Beneficence, Justice
8. Relate the principles outlined in the Belmont report to the context of the Nuremberg Code, the Tuskegee Experience, and the Declaration of Helsinki.
9. Describe the history of adoption of a common federal code for the conduct of research with human subjects in the United States
10. Identify the elements of informed consent as laid out in the Common Rule
11. Outline the structure of Institutional Review Boards as specified in Federal Law

Class Readings and/or Assignment:

1. Internet Resources: Centers for Disease Control (CDC) National Center for HIV, STD, and TB Prevention (http://www.cdc.gov/tuskegee)
    a. Timeline – The Tuskegee Syphilis Study: A Hard Lesson Learned
    b. Aftershocks: How Tuskegee Changed Research Practice
    c. Mission Statement; Tuskegee Health Benefit Program
    d. President Clinton's Statement: Remarks by the President in Apology for Study Done in Tuskegee
2. Jones JH, "A Moral Astigmatism," Chapter 1, pp 1-15, in *Bad Blood: The Tuskegee Syphilis Experiment*. 1st Edition, The Free Press, New York, 1981
3. Benedek T. The "Tuskegee Study" of Syphilis: Analysis of Moral versus Methodologic Aspects. Journal of Chronic Diseases 1978; 31: 35-50.
4. The Declaration of Helsinki – 52nd World Medical Association General Assembly – Edinburgh, Scotland, October 2000.
5. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. OPRR Reports April 18, 1979.
6. The Common Rule. Federal Policy for the Protection of Human Subjects; Notices and Rules – Part II, Federal Register, June 18, 1991 – Reprinted April 2, 1996.

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Week 3
Date and Time: 09/05/2016
Topic: NO CLASS – Labor Day Holiday

Responsible Conduct of Patient Oriented Clinical Research (TSCI 5070) Responsible Conduct of Research (INTD 5082)
Week: 4
Date and Time: 09/12/2016 3-5pm
Location: MED 3.309L
Topic: Organizational Structure of Research Oversight
Instructors: Kimberly Summers, PharmD and Kay Oyajobi, PhD
Learning Objectives – Participants will be able to: 1. Describe the organization and structure of the Institutional Review Board (IRB) 2. Describe the purpose and organization of research oversight entities, e.g., OHRP 3. Describe the interrelationships between investigators, universities, and research oversight entities
Class Readings and/or Assignment: 1. Students will work in teams and, using the Internet, look up and research the functions of one of the following entities: OHRP -- Office of Human Research Protections FDA -- Food and Drug Administration DHHS--Dept of Health and Human Services ORI --Office of Research Integrity AAHRPP -- Association for the Accreditation of Human Research Protection Programs PCBE – President's Council on Bioethics ICH – International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals 2. Prepare a 1-2 page handout to share with your classmates (20 copies) describing: A. The purpose of the agency or entity B. It's regulatory responsibility, if any C. It's relationship to (a) the other entities (how do they work together, if at all), and to (b) investigators (individuals, universities, companies) 3. Each team gives a 10 minute class presentation on the background and information discovered.

Responsible Conduct of Patient Oriented Clinical Research (TSCI 5070)
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Week: 5

Date and Time: 09/19/2016 3-5pm

Location: 3.309L

Topic: Conflicts of Interest

Instructor: Gary Sertich, JD

Learning Objectives – Participants will be able to:

1. Describe how conflicts of interest interfere with scientific integrity
2. Delineate methods for identifying different forms of conflicts of interest
3. Know the local UT Health Science Center policies and procedures for identifying and disclosing conflicts of interest
4. Delineate and recognize forms of conflict of commitment

Class Readings and/or Assignment:

1. Conflicts of Interest – Part I. N Engl J Med 372;19: 1860-1864
2. Conflicts of Interest – Part II. N Engl J Med 372;20: 1959- 1963
3. Conflict of Interest – Part III. N Engl J Med 372;21: 2064- 2068
4. Justifying conflicts of interest in medical journals: a very bad idea. http://www.bmj.com/content/350/bmj.h2942

Responsible Conduct of Patient Oriented Clinical Research (TSCI 5070) Responsible Conduct of Research (INTD 5082)
Week: 6
Date and Time: 09/26/2016 3-5pm
Location: MED 3.309L
Topic: Data Acquisition, Management, Sharing, and Ownership
Instructors: Jonathan Gelfond, MD, DrPH, and John Fritz, MBA
Learning Objectives – Participants will be able to: 1. Delineate requirements, standards, and procedures for accurately obtaining and recording data 2. Annotate, document, lock and store databases for replicable analyses 3. Present procedures and steps for sharing information and preserving intellectual property
Class Readings and/or Assignment: To be determined

Responsible Conduct of Patient Oriented Clinical Research (TSCI 5070) Responsible Conduct of Research (INTD 5082)
Week: 7
Date and Time: 10/03/2016 3-5pm
Location: MED 3.309L
Topic: Research Misconduct
Instructors: Kay Oyajobi, PhD, LuZhe Sun, PhD, James Lechleiter, PhD, David Morilak, PhD
Learning Objectives – Participants will be able to: 1. Identify conflicting roles and responsibilities in research conduct 2. Find resources and help when misconduct is identified
Class Readings and/or Assignment: 1. Review the following on-line resources from the Department of Health and Human Services' Office of Research Integrity (ORI): a. The Research Clinic: http://ori.hhs.gov/TheResearchClinic b. The Lab: https://ori.hhs.gov/thelab 2. In reviewing the videos, select roles and be prepared to articulate different team members' responsibilities and approaches to identifying and managing misconduct 3. Articulate the impact of research misconduct on the individual, the institution, and society

Responsible Conduct of Patient Oriented Clinical Research (TSCI 5070)
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Week: 8

Date and Time: 10/10/2016 3-5pm

Location: MED 3.309L

Topic: Peer Review

Instructors: Sunil Ahuja, MD

Learning Objectives – Participants will be able to:

1. Define the editorial and grant peer review process
2. Discuss the goals of the parties invovled in the peer review process
3. Articulate issues to consider when deciding whether to review a manuscript or grant
4. Consider ethical issues when reading and reviewing the manuscript or grant

Class Readings and/or Assignment:

Reading Assignment:

"Ethics of Peer Review: A Guide for Manuscript Reviewers" by Sara Rockwell, PhD; available at http://ori.hhs.gov/sites/default/files/prethics.pdf

Bibliography:

"Ethics of Peer Review: A Guide for Manuscript Reviewers" by Sara Rockwell, PhD and references contained within; available at http://ori.hhs.gov/sites/default/files/prethics.pdf

"Resources for Peer Reviewers"- List of articles and guides for peer review from various journals complied by American Academy of Family Physicians; available at http://www.aafp.org/dam/AAFP/documents/journals/afp/reviewer-resources.pdf

"The Peer Review Process"- A Report to the JISC Scholarly Communication Group by F. Rowland; available at http://www.jisc.ac.uk/uploaded_documents/rowland.pdf

Responsible Conduct of Patient Oriented Clinical Research (TSCI 5070)
Responsible Conduct of Research (INTD 5082)

Week: 9

Date and Time: 10/17/2016 3-5pm

Location: MED 3.309L

Topic: Ethics and Responsibility in Authorship and Publication

Instructor: Phillip LoVerde, PhD

Learning Objectives – Participants will be able to:

1. Describe the contributions to research that merit inclusion as an author on a paper.
2. Delineate reasons for disclosing potential conflicts of interest in publication.
3. Identify processes for determining who should be an author among investigators.
4. Determine whether the order of authorship really means anything.

Class Readings and/or Assignment:

1. The Editors of the *Lancet*. *Retraction* – Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. This retraction published online, February 2, 2010.

2. Wakefield AJ, SH Murch, A Anthony, J Linnell, DM Casson, M Malik, M Berelowitz, AP Dhillon, MA Thomson, P Harvey, A Valentine, SE Davies, JA Walker-Smith. Ileal-lymphoid nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. *The Lancet*. 351: 637-641, 1998

3. Chen RT, F DeStefano. Vaccine adverse events: causal or coincidental? *The Lancet*, 351:611-612, 1998.

4. Wakefield AJ, Author's reply. *The Lancet*, 351, 908, 1998.

5. Poland GA, R Spier. Fear, misinformation, and innumerates: how the Wakefield paper, the press, and advocacy groups damaged the public health. Vaccine, 28: 2361-2362, 2010.

6. Deer B. The *Lancet's* two days to bury bad news. *British Med J* 342: 200-342, 2014.

Responsible Conduct of Patient Oriented Clinical Research (TSCI 5070)
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Week: 10

Date and Time: 10/24/2016 3-5pm

Location: MED 3.309L

Topic: Ethical Use of Animals in Biomedical Research

Instructors: Jeffery Kiel, PhD

Learning Objectives – Participants will be able to:

1. Delineate the rationale for using animals and animal models in biomedical research
2. Cite examples of hallmark cases where animals have not been used appropriately
3. Describe the social and political climate regarding the use of animals in research
4. State the major provisions of the Animal Welfare Act regulations
5. Understand how the IACUC review process works and the main items of concern for reviewers
6. Identify and access local resources for appropriate use and protection of animals in research

Class Readings and/or Assignment:

Handouts at the time of the class.

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Week: 11

Date and Time: 10/31/2016 3-5pm

Location: MED 3.309L

Topic: Mentoring (Mentor/Mentee Responsibilities and Expectations)

Instructors: Linda McManus, PhD

Learning Objectives – Participants will be able to:

1. Delineate a plan for determining your mentoring needs.
2. Develop a strategy for identifying potential mentors.
3. List expectations that:
   a. A trainee might expect from a mentor
   b. A mentor might expect from a trainee
4. Describe characteristics of a successful trainee-mentor relationship.
5. Initiate a negotiating plan for working with a potential mentor

Class Readings and/or Assignment:

Handouts of Slides

Responsible Conduct of Patient Oriented Clinical Research (TSCI 5070) **Responsible Conduct of Research (INTD 5082)**
Week: 12
Date and Time: 11/07/2016 3-5pm
Location: 3.309L
Topic: Safe Laboratory Practices
Instructor: Michael Berton, PhD
Learning Objectives – Participants will be able to: 1. Describe key principles of biological risk assessment and basic biosafety practices in the laboratory setting 2. Describe and know when to use universal precautions 3. Describe best practices to minimize laboratory acquired infections 4. Understand biological containment requirements at the BSL1, 2 ,3 and 4 levels 5. Describe basic decontamination and disinfection methods
Class Readings and/or Assignment: To be identified

Responsible Conduct of Patient Oriented Clinical Research (TSCI 5070) Responsible Conduct of Research (INTD 5082)
Week: 13
Date and Time: 11/14/2016 3-5pm
Location: 3.309L
Topic: Good Clinical Practice (GCP)
Instructor: John Roche, PhD
Learning Objectives – Participants will be able to: 6. Understand the historical perspective on the importance of GCP 7. Define GCP 8. Discuss how FDA Regulations apply to clinical research 9. Describe lessons-learned tools to facilitate GCP
Class Readings and/or Assignment: To be identified

Responsible Conduct of Patient Oriented Clinical Research (TSCI 5070)
Week 14
Date and Time: 11/21/2016 3-5pm
Location: 3.309L
Topic: Elements of Consent and Protecting Confidentiality
Instructors: Anna Taranova, MD, CCRP and Kathleen James
Learning Objectives – Participants will be able to: 1. List the elements of consent that must be included in a consent form. 2. Discuss the current Federal and State guidelines for acceptance of surrogate consent. 3. Explain the development and intent of the Health Insurance Protability and Accountability Act of 1996 (HIPAA) 4. Analyze the significance of the "Privacy Rule" as it affects research 5. Differentiate between the "Privacy Rule" , the Common Rule, and FDA human subjects regulations as related to confidentiality and privacy
Class Readings and/or Assignment: 1. Read the Common Rule and IRB Handbook on writing a consent form 2. Review the HIPAA information that must be included with a consent form 3. Consent forms from course participants' work. 4. UTHSCSA IRB Policies and Procedures available at: http://research.uthscsa.edu/irb/handbook.shtml.

Responsible Conduct of Patient Oriented Clinical Research (TSCI 5070)
Week: 15
Date and Time: 11/28/2016 3-5pm
Location: 3.309L
Topic: Drafting and Editing Consent Forms
Instructor: Donald McGeary, PhD
Learning Objectives – Participants will be able to: 1. Effectively edit a consent form for their research project 2. Provide and receive feedback in the preparation of a consent form.
Class Readings and/or Assignment: 1. Participants will bring draft copies of consent forms to the class. Working in pairs, they will read and edit each other's consent forms. 2. The consent forms will then be presented to the class for discussion and input.

Responsible Conduct of Patient Oriented Clinical Research (TSCI 5070)
Week: 16
Date and Time: 12/05/2016 3-5pm
Location: 3.309L
Topic: Recruiting Fairly: Inclusion of Special Populations in Research
Instructor: Helen Hazuda, PhD
Learning Objectives – Participants will be able to apply the principle of justice to: 1. Debate the merits of inclusion or exclusion of special populations (children, women of reproductive potential, prisoners, persons with diminished mental capacity) in research studies. 2. Describe methods for appropriately advertising for subjects 3. Recognize when incentives may become coercive 4. Identify potential conflicts when indigent persons may be enrolled in research studies 5. Identify safeguards for enrolling students or subordinates in University based studies 6. Recognize the potential conflict of interest when physician investigators recruit subjects from their patient populations.
Class Readings and/or Assignment: To be identified

Responsible Conduct of Patient Oriented Clinical Research (TSCI 5070)
Week: 17
Date and Time: 12/12/2016 3-5pm
Location: 3.309L
Topic: Community Based Research and Consent
Instructors: Kimberly Summers, PharmD
Learning Objectives – participants will be able to: 1. Identify barriers to research conduct in settings where consent may not be obtainable – e.g., trauma, sudden death 2. Discuss the strengths and weaknesses of processes for ethically conducting research with human subjects in these circumstances. 3. Describe the processes of community consent.
Class Readings and/or Assignment: Handouts of Slides