IMPORTANT: This syllabus form should be submitted to OAA (gsbs_academic_affairs@uth.tmc.edu) a week before the start of each semester.

NOTE to STUDENTS: If you need any accommodations related to attending/enrolling in this course, please contact one of the Graduate School's 504 Coordinators, Cheryl Spitzenberger or Natalie Sirisaengtaksin. We ask that you notify GSBS in advance (preferably at least 3 days before the start of the semester) so we can make appropriate arrangements.

Term and Year: **Spring 2025** Course Number and Course Title: **GS21 1014: Design and Management of Clinical Trials** **Credit Hours**: **4** Prerequisite: **Consent of Instructor** Meeting Location: **Hybrid: In-person & Online – Zoom** **Building/Room#:** To be determined **WebEx/Zoom Link:** Zoom links created and sent to registered students	**Program Required Course:** No **Approval Code:** No **(If yes,** the Course Director or the Course Designee will provide the approval code.) **Audit Permitted:** Yes **Classes Begin:** January 13, 2025 **Classes End:** May 2, 2025 **Final Exam Week:** May 5 – 9, 2025

Class Meeting Schedule

Day	Time
Online – Time and Day change based on speaker availability	

Course Director Name and Degree: **Jennifer Litton, PhD** Title: **Associate Professor** Department: **Breast Medical Oncology** Institution: **UTHH-MDACC** For questions, please contact ResearchEducation@mdanderson.org	**Instructor/s** 1. **Jonathan Aguilar, MPH** Institution: **UTHH-MDACC** Email Address : jraguilar@mdanderson.org 2. **Garret Bromley, BS** Institution: **UTHH-MDACC** Email Address : gsbromley@mdanderson.org

Course Description:

This comprehensive course offers an in-depth exploration of the design and management of clinical trials, the cornerstone of medical research. Lectures will teach the basic research concepts and principles underlying the design and day-to-day conduct of clinical trials using examples primarily from cancer trials. Topics include the nature of disease and its impact on research protocol design, medical terminology frequently encountered in clinical research, methods to monitor human subjects' response to treatment, and rules and regulations (including the Office for Human Research Protection (OHRP), the Federal Drug Administration (FDA), and ethical concerns related to clinical trials. Participants will gain a practical understanding of the scientific principles, current regulations, and ethical considerations that establish clinical research.

Learning Objectives:

- Understand the rationale for clinical trial design.
- Learn ethical strategies for participant recruitment, randomization, and data collection.
- Gain insights into interim monitoring and the principles of Good Clinical Practice.
- Develop familiarity with FDA regulations and the International Council for Harmonization's Good Clinical Practice Guidelines
- Optional opportunities to shadow various clinical research professionals in the field

Course Format:

Lectures, workshops, interactive sessions are delivered using a variety of methods including in person, live virtual sessions, as well as learner paced modules. Course content includes:
Students will work in conjunction with the Office of Clinical Research (OCR) at the University of Texas MD Anderson Cancer Center to study operational processes utilized by this office. This includes learning the protocol review process through the Scientific Review Committee and Institutional Review Board, and introduction of other teams, such as FDA Submissions, ancillary reviews, and monitoring and auditing. Students will attend lectures and meetings (virtual and in-person) with the Office of Clinical Research staff and other subject matter experts at the insitution to study the operational processes. Students will be given a primer on the ethical evolution and application of human subjects research. Students will apply these principles and regulations to experiences, helping to ensure their comprehensive understanding by following the scientific and ethical review processes of a research protocol involving human subjects. Finally, when possible, students will be paired with clinical research departments to shadow:

- Investigators as they see patients
- Clinical research staff for subject screening, eligibility and recruitment
- Clinical research staff for follow-up appointments
- Procedure appointments, including the infusion area
- Regulatory staff for protocol submission process and/or amendments
- Data staff for data entry and monitoring visits

Prerequisites:
Participants should have a basic understanding of medical terminology and human anatomy. Prior exposure to the drug development process or clinical research is beneficial but not mandatory.

Target Audience:
This course is designed for professionals within the pharmaceutical/biotechnology industry, clinical practice, and others who are involved or interested in the clinical trials process. It is also suitable for individuals aspiring to enter the clinical research field.

Textbook/Supplemental Reading Materials (if any)

- Supplemental Reading Materials provided online through CANVAS

Course Objective/s:
Upon successful completion of this course, students will:

Clinical Trial Management (CTM)

- Students will gain knowledge on how clinical trials are conducted at MD Anderson Cancer Center.
- Students will learn about how the FDA and other entities protect human subjects who participate in clinical trials.
- Students will study the elements of a protocol, site initiation visits, the informed consent process, research documentation requirements, collecting and reporting of adverse events, and verification of compliance in clinical trials through the audit process.
- Students will also acquire Human Subject Protection Training, Good Clinical Practice Training and Clinical Research Training certifications, which are required for all MD Anderson Workforce employees participating in the conduct of human subjects research.
- Students will receive hands-on experience, as well as interactive training.

Institutional Review Board (IRB)

- To provide knowledge about the Human Research Protection Program (HRPP) at the University of Texas MD Anderson Cancer Center (MD Anderson), the Office of Human Subjects Protection department (OHSP) and its mission, vision, and philosophy, as well as the policies and procedures that govern the Human Subjects Research process at MD Anderson.
- To give instruction concerning the roles of research regulation team members and processes related to Human Subjects Research at Anderson.

Student Responsibilities and Expectations:

Students enrolled in this course will be expected to:

1) **Attend the mandatory events listed below. Participate in and contribute to course discussions during lecture, review sessions**

2) **Submit a paper on Scientific Review Committee (SRC) and Institutional Review Board (IRB) meetings (optional rough draft and required final draft) – 30 points**

The requirements for the paper are as follows:

Graded Paper - Debriefing of SRC and IRB Meetings

- Paper must be double-spaced (Times New Roman font, no larger than 12-point font size). The paper will also be graded based on grammar, formatting, and composition.
- Paper must be 2-3 pages
- Paper grade is based on the following components:

- This is a debriefing of your SRC and IRB meeting experiences.
- There should be a detailed discussion of research ethics and regulations that govern human subjects research.
- Address how you can apply knowledge from your IRB Practicum experience to your current and future career(s) in research

Papers will be graded by a committee that is comprised of OCR management who are certified in clinical research regulations. The committee will review the paper and provide a pass or fail grade.

3) Virtual Activities Participation and Module Completion - 60 points

Clinical Research Competency Training (CRCT) attendance, Human Subject Protection Training (HSPT) and Good Clinical Practice (GCP) training modules, and Online lecture modules in Canvas. Attendance at panel discussions, SRC, and IRB meetings.

4) Final Exam - 10 points

20 question multiple choice exam in CANVAS over the online modules and virtual activities.

Completion of all assignments will also be included in the cumulative points. A total score of 80 points or more is considered a passing grade for the practicum, which will result in Pass/Fail grade for this practicum.

Course Policies:

- Attendance in Zoom sessions is required. Please talk with the course instructor individually about excused absences.
- If extenuating circumstances arise, talk to the course instructor, at least one week before the due date, regarding the possibility of an extension or other options.

Academic Integrity:

- Any work submitted by a student in this course for academic credit will be the student's own work.
- You are encouraged to study together and to discuss information and concepts covered in the in-house sessions with other students. However, each student should complete the assignments independently
- Should copying or unethical practices of any kind occur, the student(s) involved in the infraction will automatically fail the practicum.

*Employees will complete the modules in the Education center. Non-MD Anderson employees will complete HHS.gov/OHRP's version of HSPT and the GCP course in MD Anderson STUDY platform meet these requirements.

Grading System: Pass/Fail

Student Assessment and Grading Criteria : *Completion of all assignments will also be included in the cumulative points. A total score of 80 points or more is considered a passing grade for the practicum, which will result in Pass/Fail grade for this practicum.*

Percentage	Description
Mandatory Attendance and Module Completion (60%)	Clinical Research Competency Training attendance, HSPT and GCP training modules, and Online lecture modules in Canvas. Attendance at panel discussions, SRC, and IRB meetings.
Final Graded Paper (30%)	Graded Paper - Debriefing of SRC and IRB Meetings
Final Exam (10%)	20 question multiple choice exam in CANVAS over the online modules and virtual activities.

Grading Guidelines

Introduction	Online – ZOOM meeting	Discussion of Syllabus & Course requirements – 0.5 hr
Human Subject Protection Training (HSPT) Curriculum - Online	Online – CITI	All prerequisite modules need to be completed with an 80% score to receive credit. * 4 hrs
Good Clinical Practice Training (GCP) – Online	Online – CITI	There is 1 module that needs to be finished with an 80% score to receive credit. * 1 hrs
Clinical Research Competency Training	In-Person & ZOOM classes	Must be present for at least 4 zoom classes – instructor will check for attendance - 4 - 10 hrs
CANVAS Modules	Online – UTH CANVAS system	8 modules to view in their entirety – 4 hrs
Overview, HRPP, Ethics, and HIPAA presentations – Panel Discussion*	ZOOM	Course coordinator will check for attendance – 1 hr
Regulatory Review & Clinical Processes – Panel Discussion*	ZOOM	Course coordinator will check for attendance – 1 hr
SRC Meeting	ZOOM	Course coordinator will check for attendance – 3 hr

CLASS SCHEDULE

Date	Duration (Hour(s) taught by lecturer)	Lecture Topic	Lecturer/s
TBD, Jan 13th week	1	Overview of Practicum & Requirements (ZOOM)	UTH Faculty Designee and Practicum Coordinator

TBD, Jan 22	1	In-Person: Intro to Clinical Research	UTH Faculty Designee and Practicum Coordinator
TBD, Jan/Feb	1	Intro to SRC (Zoom)	Jenny Gay – Manager, Protocol Review and Monitoring Systems
TBD, Feb/Mar	3	SRC Meeting (ZOOM)	SRC members
TBD, Feb/Mar	1	SRC Debriefing/Follow-up Meeting (ZOOM)	Jenny Gay – Manager, Protocol Review and Monitoring Systems
TBD, Feb/Mar	4 – 10	Clinical Research Competency Training – (In-Person & ZOOM class)	MD Anderson Clinical Research Training Specialist
TBD, Feb/Mar	1 – 2	<u>Panel Discussions</u> Regulatory Review & Processes OHSP, OCR, IND Regulatory, & Compliance	Potential Speakers Include: • *Institutional Review Board (IRB) & Human Subjects Protection Program* Hallie Kassan, MS, Director • *Review of Research Ethics and Compliance* Mark Chambers, DMD, MS – Professor, Oral Oncology & Executive Institutional Review Board (IRB3) Chair • *HIPAA/Protected Health Information (PHI)* Matt Bourgeois, JD – Legal Officer, Institutional Compliance • *Scientific Review Committee (SRC) Process* Jenny Gay – Manager, Protocol Review and Monitoring Systems • *FDA Submissions* Sean O'Connor, PhD, Director • *Auditing & Monitoring* Mary Beth Storms, MS, RN, Manager, Clinical Research Quality
TBD, Mar/Apr	0.5	IRB Meeting Expectations (ZOOM) before meeting	Michelle Williams, M.D. – Professor, Pathology & IRB 5 Chair
TBD, Mar/Apr	3	IRB 5 Meeting (ZOOM)	IRB5 committee members
TBD, Mar/Apr	0.5	Debriefing/Follow-up Meeting with Dr. Williams (ZOOM) -after IRB meeting	Michelle Williams, M.D. – Professor, Pathology & IRB 5 Chair
April 16 by 5:00 PM		(OPTIONAL) SRC & IRB Paper Rough Draft due - If feedback desired **	
April 23 by 12:00 Noon		SRC & IRB Paper Final Draft due	

Self-Paced Due by April 18		Good Clinical Practice Training (CITI Program)	
Self-Paced Due by April 18		Human Subject Protection Training (CITI, or USHHS)	
Self-Paced Due by April 18		CANVAS modules (8 assigned online modules- UTH CANVAS system)	
May 5-9		Final Exam Due CANVAS – UTH System	
May 14		Final Grades Due to UTH	

Additional Footnotes

*Students who do not attend presentations will be expected to submit an additional project or paper as part of their final grade.

** Students who have had their rough drafts reviewed by their instructors have historically obtained better grades. We are more than happy to do this for you; however, you must have your paper to us by 5:00 PM on or before Wednesday, April 16, 2025. This will give us ample time to review, suggest changes and return to you in a timely manner, allowing you the opportunity to make the necessary changes and meet the scheduled due date. We will return it to you no later than 5:00 PM on or before April 18, 2025.