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: **Fall 2024** Course Number and Course Title: **GS21 1014: Design and Management of Clinical Trials** Credit Hours: **4** Meeting Location: **Online via Zoom** **WebEx/Zoom Link:** Zoom links created and sent to registered students	Program Required Course: **No** Approval Code: **No** Audit Permitted: **No** Classes Begin: **August 26, 2024** Classes End: **December 6, 2024** Final Exam Week: **December 9-13, 2024**

Class Meeting Schedule

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

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

Course Description:

The lectures will teach the basic research concepts and principles that underlie the design and actual 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, appropriate statistics to use, medical terminology frequently encountered in clinical research, methods to monitor human subjects' response to treatment,

monitoring of clinical research laboratories; rules and regulations (including the Office of Human Research Protections, the Federal Drug Administration, and the state), and ethical concerns related to clinical trials

Three practicums, 24 hours each, will be available to students. Each student must complete two. The practicums include:

(1) Topics in Regulatory and Ethical Concepts in Human Subjects Research within the Office of Human Subjects Protection/Institutional Review Board (IRB) Office.

Students will work in conjunction with the Office of Human Subjects Protection /IRB Office staff at M.D Anderson to study the operational processes utilized by this office to allow for application of informed consent process and compliance with regulatory guidelines. Students will be given a primer in 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 from conception to termination by following a protocol from scientific review to IRB review process.

(2) Topics in Compliance and Auditing of Responsible Conduct of Research within the Office of Clinical Research.

Students will receive advanced instruction in the principle areas of monitoring and auditing clinical trials to ensure compliance with Responsible Conduct of Research as defined by the US Public Health Service that specifically apply to clinical trials and human research. Students will conduct a project within this office where they will follow an investigational new drug (IND) application.

(3) Topics in Data Management in Cancer Clinical Trials within the Phase I Program.

Students will be taught methods of collecting and interpreting data in clinical trials, and the requirements and methods to insure data security and patient confidentiality. Students will learn how to supervise/coordinate the actual data collection and monitoring aspects of clinical trials. Students will participate as a member of a clinical trials project team under the direction of the course director and directors/coordinators of ongoing studies at MD Anderson.

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 – Education Center, USHHH, or CITI	All prerequisite modules need to be completed with an 80% score to receive credit. * 4 hrs
Good Clinical Practice Training (GCP) – Online	Online – Education Center, STUDY	There is 1 module that needs to be finished with an 80% score to receive credit. * 1 hrs
Clinical Research Competency Training	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
Aug 29	1	Overview of Practicum & Requirements (ZOOM)	UTH Faculty Designee and Practicum Coordinator
TBD, Sep/Oct	1	SRC Meeting Expectations (ZOOM) before meeting	Jenny Gay – Manager, Protocol Review and Monitoring Systems
TBD, Sep/Oct	3	SRC Meeting (ZOOM)	SRC members
TBD, Sep/Oct	1	SRC Debriefing/Follow-up Meeting (ZOOM)	Jenny Gay – Manager, Protocol Review and Monitoring Systems
TBD, Sep/Oct	4 – 10	Clinical Research Competency Training – (ZOOM class)	MD Anderson Clinical Research Training Specialist
TBD, Oct/Nov	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, Oct/Nov	0.5	IRB Meeting Expectations (ZOOM) before meeting	Michelle Williams, M.D. – Professor, Pathology & IRB 5 Chair
TBD, Oct/Nov	3	IRB 5 Meeting (ZOOM)	IRB5 committee members
TBD, Oct/Nov	0.5	Debriefing/Follow-up Meeting with Dr. Williams (ZOOM) -after IRB meeting	Michelle Williams, M.D. – Professor, Pathology & IRB 5 Chair
Nov 18 by 5:00 PM		(OPTIONAL) SRC & IRB Paper Rough Draft due - If feedback desired **	
Nov 25 – 29		Thanksgiving Break	
Dec 6 by 12:00 Noon		SRC & IRB Paper Final Draft due	
Self-Paced Due by Dec 6		Good Clinical Practice Training (MD Anderson – Education Center)	
Self-Paced Due by Dec 6		Human Subject Protection Training (MD Anderson – Education Center, CITI, or USHHS)	
Self-Paced Due by Dec 6		CANVAS modules (8 assigned online modules- UTH CANVAS system)	
Dec 9 – 11		Final Exam Due CANVAS – UTH System	
Dec 17		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 Monday,

November 18th, 2024. 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 November 22nd, 2024.