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 Coordinator, Natalie Sirisaengtaksin, PhD. 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 2025**

Course Number and Course Title:
GS21 1014: Design and Management of Clinical Trials

Credit Hours: **4**

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.

Meeting Location: **Hybrid: In-person and Online - Zoom**

WebEx/Zoom Link:
Zoom links created and sent to registered students

Program Required Course: **No**

Approval Code: **No**

Audit Permitted: **Yes**

Classes Begin: **August 25, 2025**

Classes End: **December 12, 2025**

Final Exam Week: **December 8-12, 2025**

Class Meeting Schedule

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

Course Director
Name and Degree: Jennifer Litton, MD
Title: VP, Clinical Research
Department: Breast Medical Oncology
Institution: *UTH, UTMDACC*

Course Reviewer
Name and Degree: Dina Aziz, MSHS
Title: VP, Clinical Research Operations
Division of Clinical Research
Institution: *UTMDACC*

NOTE: Office hours are available by request. Please email ResearchEducation@mdanderson.org to arrange a time to meet.

Instructors

1. Name and Degree: **Jonathan Aguilar, MPH**
   Institution: UTMDACC
   Email Address: jraguilar@mdanderson.org

2. Name and Degree: **Garret Bromley, BS**
   Institution: UTMDACC
   Email Address: gsbromley@mdanderson.org

For questions, please contact
ResearchEducation@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 Food and 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.

Textbook/Supplemental Reading Materials (if any)

To support student learning and ensure transparency in course content, all references associated with instructional materials will be provided alongside each slide set shared with students.

Reference Materials Will Include:

- Code of Federal Regulations (CFR)
- International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines
- Journal Publications
- Additional authoritative resources relevant to clinical research practices

Learning Objectives:

- Review the clinical trial development and review process.
- Learn ethical strategies for participant recruitment, randomization, and data collection.
- Develop familiarity with FDA regulations and the International Council for Harmonisation (ICH) Good Clinica Practice (GCP) Guidelines
- Describe how clinical trials are conducted at MD Anderson Cancer Center.
- Review the elements of a protocol, the informed consent process, research documentation requirements, collecting and reporting of adverse events, and verification of compliance in clinical trials through the audit process.
- Explain concepts of Human Subject Research and Good Clinical Practice Guidelines.
- Apply knowledge gained through hands-on experience through the shadowing opportunities, as well as interactive training.

Course Format:

Lectures, interactive sessions, meetings, and clinical research shadowing opportunities. Shadowing sessions may include:

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

Target Audience:
This course is designed for students and professionals interested in the clinical trials process

Student Responsibilities and Expectations

Students enrolled in this course will be expected to aqttedn and participate in all mandatory events listed below:

1. Activities Participation – 50 points

- Attend and participate in Clinical Research Competency Training (CRCT)
- Attend Scientific Review Committee (SRC), Institutional Review Board (IRB) Meetings, and relevant pre- and post-meetings.
- Attend and participate in panel discussions.
- Participate in shadowing opportunities. Students must attend at least 2 Research Role Shadowing Experiences and 2 Group Team Meeting Experiences

2. Module Completion – 30 points

- Completion of required learner-paced online training including the Final Exam in UT Health Canvas.
- Human Subject Research (HSR) and Good Clinical Practice (GCP) training modules in CITI Program
- "Research Education: Fundamentals of Clinical Research" Course ID OPSM0067 in MD Anderson Education Center

3. Final Exam in UT Health Canvas – 10 points

- Final Exam will be available starting December 8th. You may take it more than once, and the highest score is the one that counts.
- You must obtain at least 80% grade to pass the exam.

4. Final Shadowing Experience Presentation – 10 points

- Completion of required learner-paced online training in UT Health Canvas.

Requirements for presentations:

- Presentation must be 10-15 minutes
- These are individual presentations and must include clear title, objectives, and references as applicable. Objectives should include
  - what did you expect to learn in this experience?
  - what was accomplished?
  - who did you shadow?
  - what did you gain from the experience?

- Must be created in PowerPoint and the file will be submitted as part of completion
- Present information in a clear understandable format.

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.

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.*

CLASS SCHEDULE

Date	Duration (Hour(s) taught by lecturer)	Lecture Topic	Lecturer /s
Aug 27th @ 2PM	1	Overview of Practicum & Requirements (ZOOM)	UTH Faculty Designee and Practicum Coordinator
TBD, Sep 18th or 19th	1	Initial Shadowing Orientation Meeting	ICT - Anjali Raina, Rabia Khan
TBD, Sept/Oct	3	Clinical Research Competency Training In-Person: Intro to Clinical Research	MD Anderson Clinical Research Training Specialist
TBD, Sept/Oct	4 - 10	Clinical Research Competency Training – ZOOM class. Must attend mandatory sessions and at least 4 optional Zoom classes of your choice.[1]	MD Anderson Clinical Research Training Specialist
TBD, Sep/Oct	1	SRC meeting expectations (Zoom)	Jenny Gay – Manager, Protocol Review and Monitoring Systems
TBD, Sep/Oct	3	SRC Meeting (ZOOM) [1]	SRC members
TBD, Sep/Oct	1	SRC Debriefing/Follow-up Meeting (ZOOM)	Jenny Gay – Manager, Protocol Review and Monitoring Systems
TBD, Sep/Oct/Nov	4 - 10	Shadowing Sessions with ICT. Must attend at least 4 sessions: 2 Research Roles Sessions and 2 Group Team-based meeting sessions	Various Research Professionals within ICT.

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 • *FDA Submissions* Ashwinder Kaur, Director • *Auditing & Monitoring* Mary Beth Storms, MS, RN, Manager, Clinical Research Quality Ashley Morphey, Manager, Clinical Research Quality
TBD, Oct/Nov	0.5	IRB Meeting Expectations (ZOOM) before meeting **(Prereq - Watch IRB Video in CANVAS)**	Michelle Williams, M.D. – Professor, Pathology & IRB 5 Chair
TBD, Oct/Nov	3	IRB 5 Meeting (ZOOM) [1]	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
TBD, Nov	2	ICT Shadowing Experience Presentation	Students will be expected to give a 10-15 min PPT presentation about what they learned during their shadowing experience
Nov 24 – 28		Thanksgiving Break	
Self-Paced Due by Dec 5th		Good Clinical Practice Training (CITI Program)	
Self-Paced Due by Dec 5th		Human Subjects Research (CITI, or USHHS)	

Self-Paced Due by Dec 5th		Research Education: Fundamentals of Clinical Research Course ID OSPM 0067 (MD Anderson Education Center)	
Self-Paced Due by Dec 5th		CANVAS modules (read/watch Online modules- UTH CANVAS system)	
Due Dec 5th		Course Feedback Survey (Qualtrics email)	
Dec 8-12th		Final Exam Due CANVAS – UTH System	
Dec 16th		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.

SHADOWING EXPERIENCE SCHEDULE

Content	Duration	Time	Date(s)	Person to meet with	Location and contact information
Initial Information Meeting - MANDATORY	1 hour	11.00 am - noon	xx-September	Anjali Raina, Rabia Khan	FC12. 2012/ Faculty Center - MD Anderson
Research Role Options					
Regulatory presentation	1 hour	AM	xx-Sept, xx-Oct, xx-Nov	Regulatory Specialist	ZOOM
Study Coordinator/Research Nurse	1 hour	10.00 AM - 1.00 PM	xx-Sept, xx-Oct, xx-Nov	CSC / Research Nurse	Faculty Center - MD Anderson
Follow Physician	1 hour	10.00 am - 2.00 pm	xx-Sept, xx-Oct, xx-Nov	Dr. Hong, Dr. Meric	R11.xxxx - Main Building - MD Anderson
Follow Advanced Practice Provider	1 hour	AM	xx-Sept, xx-Oct, xx-Nov	Nurse Practitioner	TBD
Group Team Options					
Journal club (Mon) - Weekly	1 hour	4.00 PM - 5.00 PM	xx-Sept, xx-Oct, xx-Nov	N/A	ZOOM
Clinical Trials Meeting (Wed) - Weekly	1 hour 15 MINUTES	8.00 AM - 9.15 AM	xx-Sept, xx-Oct, xx-Nov	N/A	ZOOM
Monday Grand Rounds - Weekly	1 hour	8.00 AM - 9.00 AM	xx-Sept, xx-Oct, xx-Nov	N/A	ZOOM
Physician team meeting - Weekly	1 hour	Varies	xx-Sept, xx-Oct, xx-Nov	Dr. Meric or Dr. Hong	Faculty Center - MD Anderson or ZOOM
Thursday Research Training Meeting - Weekly	1 hour	8.00 AM - 9.00 AM	xx-Sept, xx-Oct, xx-Nov	N/A	ZOOM

Friday New employee meeting	1 hour	12.00 AM - 1.00 PM	xx-Sept, xx-Oct, xx-Nov	N/A	ZOOM
Final Shadowing Presentation - MANDATORY	2 hours	TBD	xx -November	Anjali Raina, Rabia Khan, Jonathan Aguilar	In-person Faculty Center - MD Anderson

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