Clinical Research Management
Student Handbook
2023-24

The information provided in this document serves to supplement the requirements of the School of Biomedical Sciences detailed in the UNTHSC Catalog with requirements specific to the discipline of Clinical Research Management.

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Clinical Research Management

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Program Description

Clinical Research involves the testing and determination of the safety and efficacy of new unapproved products, including pharmaceuticals, devices, and biologics in human subjects. Clinical trials in humans (volunteers and patients) are required prior to marketing approval by regulatory authorities such as the U.S. Food and Drug Administration (FDA). In the U.S., the law that governs clinical research is described in Chapter 21 of the Code of Federal Regulations (CFR). In addition to requiring and legislating clinical trials, regulatory authorities define the standards by which clinical trials are to be conducted. These standards are known as Good Clinical Practices (GCPs).

In-depth knowledge of the CFR and GCP guidelines, as well as International Guidelines specifically as they relate to protecting human rights, preventing and detecting fraud, and using sound scientific principles, is a fundamental requirement for a clinical research professional. These individuals are key personnel involved in the conduct of clinical trials, which in turn are pivotal in getting new products approved and on the market.

The master's program in Clinical Research Management provides a strong foundation for career development. The rigorous curriculum provides students with a broad-based view of the biomedical sciences and in-depth knowledge of regulatory requirements (code of federal regulations, good clinical practices), ethical issues, and the medical writing and administrative skills necessary to conduct clinical research. Candidates for the degree earn 48 SCH / 36 SCH (online students), of which 18 SCH / 6 SCH (online students) are a Laboratory Internship Practicum / Capstone project (online students), the latter substituting for a thesis requirement. Students are admitted at three starting points each year: Fall, Spring, and Summer. The average time to complete the degree is eighteen months.

As part of the program, all students either complete a 26-week (40 hours/week) internship practicum or a capstone project in clinical studies and use this experience to write a detailed Internship Practicum / Capstone Project Report pursuant to receiving the Master of Science degree. The Internship Practicum / Capstone project provides a hands-on training / analytical research experience for the graduate student whose Master's degree will be in the specialized discipline of Clinical Research Management. The internship / Capstone project may occur either on campus or at an approved off-campus site in the Dallas-Fort Worth-Denton Metroplex and, in some cases, at a site in another part of the state or country. Students will be expected to provide for their transportation and housing needs during the internship/capstone project experience.

Program tracks

On-campus/hybrid Cohort Option
The cohort (on-campus/hybrid) option is designed for students who work best in a team setting alongside other students with daily faculty interaction. Cohort students will participate in didactic lectures and interact with faculty and other students in real-time. Some of their courses will be delivered in an online format. With three starting points each year, students in this program can begin classes at the most convenient time. The average time to complete the program is 18 months with full-time enrollment.

Online Track Option

The online option allows students to balance work and family responsibilities with enrollment. The MS degree is completed online except for an internship practicum. Due to the complexity of completing an internship practicum experience in a foreign or remote location other than DFW, students enrolled in the online track option will have their internship practicum replaced with a capstone project worth 6 SCH spread over two semesters (3 SCH each semester). In addition to the rigorous curriculum, students will have online access to advising. With three starting points each year, students in this program can begin classes at the most convenient time. The average time to complete the program is two years with full-time enrollment.

Campus resources are available from Financial Aid to the Library, including Career Services and the Center for Academic Performance, without traveling to our physical location.

Opportunities for Graduates in Clinical Research Management

The Clinical Research Management program graduate will be qualified to fill a beginning position as a Clinical Research Associate (CRA) / Clinical Research Coordinator (CRC) / Medical Writer / Clinical Trial Auditor / Clinical Trial Monitor / Clinical Trial Manager / Product Safety Specialist / Clinical Research Trainer. These jobs may contain any or all of the following essential tasks: regulatory, organizational, and administrative tasks related to the implementation of one or more clinical trials: patient enrollment and consenting protocol writing, data verification, trial monitoring in-house or in the field, summarization and or presentation of study results, investigational drug accountability, interactions with investigators, sponsors and Institutional Review Boards, safety reporting to regulatory authorities, trial document tracking, budgeting, etc. The online program will benefit those students who are already working in this field and would like to improve their credentials to advance in their career path.

Depending on the environment and additional relevant education or experience, starting employees can expect to remain at the initial hiring level between 6 months to 2 years before moving upward in rank, salary, and responsibility. In addition to an in-depth knowledge of the regulations and ethics governing clinical research that the students learn in the program, excellent verbal and written communication, organizational, and interpersonal skills are essential to a successful career as a clinical research professional. Furthermore, a good dose of diplomacy, flexibility, and professionalism will be a must to succeed.

Requirements

The requirements for admissions and graduation are listed in the SBS Degree Programs chapter of the UNTHSC Catalog.

Each student is responsible for completing the core requirements for the Clinical Research Management program according to the following procedures. Forms are subject to revision at any time and should be obtained from the School of Biomedical Sciences website.

By the end of the third semester, the student will be assigned a faculty mentor and an advisory committee consisting of the mentor and two other graduate faculty members. The names of these individuals will be filed with the SBS Office of Admissions and Services on the designation of the advisory committee form. A degree plan must also be filed with the SBS Office of Admissions and Services at this time.

Students must be in good academic standing prior to being allowed to start their internship at a site (cumulative GPA of 3.0). The dean or his designee can only grant exceptions to this rule.

After completing didactic coursework, the student will enroll in BMSC 5697, the Internship Practicum, or BMSC-5399, a capstone project. The student will complete a six-month unpaid internship at a site previously approved by the graduate school. The student is responsible for transportation to and from the site. During this time, the student will learn how to perform the duties expected of particular clinical research positions in clinical research centers such as a hospital or clinic, a pharmaceutical or medical device company, a clinical research organization, or a site management organization.

A formal research proposal describing how the practicum/capstone project is to be spent must be approved by the advisory committee and submitted to the graduate school 4-5 weeks after the internship/capstone project starts.

At the end of the internship practicum/capstone project, the student must submit a report and internship daily notebook to the mentor for approval. The advisory committee will meet with the student at this time and review both the notebook and written report. The student will present their work as both an oral and written report. The oral presentation will be open to the public and followed by a private meeting with the advisory committee. The written report should be given to the committee two weeks before the formal meeting. At this time, the committee will either approve or disapprove the work of the practicum/capstone project and the report. If not approved, the student may have a chance to revise the report or repeat the practicum/capstone project one time at the discretion of the committee. The mentor, together with the other members of the committee, will assign a letter grade to the final semester of the practicum/capstone project. The report must be submitted in accordance with the instructions for completing graduation requirements within the deadlines for graduation published in the academic calendar. A more detailed description of the internship practicum and report requirements may be found in the Internship Practicum Guidelines/ Capstone project guidelines available on the SBS graduation website.

It is strongly suggested that the student and major professor, as well as the major professor and the on-site mentor, communicate regularly to review the student's progress during the practicum/ capstone project.

CRM Curriculum/Degree Plan

The following curriculum is required for all students in the Clinical Research Management program. The typical time-to-degree for MS students is eighteen months.

Fall Semester		Spring Semester		Summer Semester	
BMSC 5121 Social Issues for Resp Clinical Research	2	BMSC 5504 Physiology	5	BMSC 5210 Clinical Data Management	2
BMSC 5301 Principles of Biochemistry	3	BMSC 5207 Pharmacology	2	BMSC 5300 Biostatistics for Biomedical Science	3
BMSC 5302 Molecular Cell Biology	3			BMSC 5215 Principles of Scientific Communications	2
BMSC 5206 Immunology & Microbiology	2	BMSC 5312 Intro to Clinical Research & Studies	3	BMSC 5320 Regulatory Affairs	3
BMSC 5100 Applications/Skills Workshop	1				
Total Hours	***11***	***Total Hours***	***10***	***Total Hours***	***10***

On-campus/hybrid: Internship Practicum (BMSC 5697) 18 SCH with practicum report/defense
Total Semester Credit Hours (SCH) = 49

Online: Capstone project (BMSC 5399) 6 SCH with capstone project report/defense
Total Semester Credit Hours (SCH) = 37

* The internship practicum will be replaced with a capstone project (BMSC-5399) worth 6 SCH for students enrolled in the online track option.

The Health Science Center reserves the right to make changes at any time to reflect current board policies, administrative regulations and procedures, amendments by state law, and fee changes. Information provided in this document is subject to change without notice. It does not constitute a contract between the University of North Texas Health Science Center and a student or an applicant for admission. The institution is not responsible for any misrepresentation or provisions that might arise as a result of errors in preparation.

All Course Descriptions can be found in the Catalog
https://catalog.unthsc.edu/preview_program.php?catoid=13&poid=1085

Description of the Student Internship Practicum

Purpose of the Internship Practicum

The Internship Practicum provides a hands-on training experience for the graduate student whose Master's degree will be in the specialized discipline of Clinical Research Management. The internship may take place either on-campus or at an approved off-campus site in the Dallas-Fort Worth-Denton Metroplex and, in some cases, at a site in other parts of the state or country. Students will be expected to provide for their own transportation and housing needs during the internship experience.

Prior to the start of the internship, students will need to complete the following:

- SBS Pre-Internship Agreement
- Complete Drug Testing Panel
- Criminal Background Check
- CITI Training
- Research Conflict of Interest Training and Disclosure

During the summer and fall semesters of the second year, the student will enroll in Internship Practicum (BMSC 5697) for 9 SCH each semester. During this time, the student will gain experience in tasks associated with the application of clinical research in a hospital or industrial clinical research setting. Internship Practicum provides a hands-on training experience for the CRM student. The internship takes approximately 2 semesters (26 weeks, 40 hrs/week) during which the student will be working under the direct supervision of an internship mentor at the internship location.

UNT Health Science Center will identify approved, off-campus internship opportunities in north Texas and will work to place students at suitable sites. For online students who are at different locations in the United States, internship opportunities may exist in the city of their location. Students are free to identify such internship opportunities on their own initiative. All such opportunities must be approved by the Graduate School at least 4 months in advance of their internship start date. It is also possible that occasional opportunities will exist on the campus. The student is responsible for transportation to and from the site, whether it is on-campus or off-campus. Due to the complexity of completing an internship practicum in a foreign location, international students enrolled in the online track option will have their internship practicum replaced with a capstone project worth 6 SCH.

UNTHSC does not offer any remuneration to the student when he/she is enrolled in BMSC 5697 Internship Practicum, and the student should not expect to be paid as an intern. The student should not expect to receive a stipend or other monetary compensation for the internship. If an internship site offers a stipend, the site will determine the amount and conditions. All interactions concerning the stipend will take place between site administration and the student. No student should consider that the internship site has any obligations to pay, hire or in any way retain a student during or after the internship or after graduation. If the site offers to remunerate the intern while he or she is

registered in BMSC 5697, the student will not attempt to collect unemployment compensation after completion of BMSC 5697 or the master's program.

A formal plan (research proposal) describing how the practicum is to be spent must be approved by the advisory committee and submitted 4-5 weeks after starting the internship. The Research Proposal Approval form may be obtained from the School of Biomedical Sciences' web site.

At the end of Internship Practicum (BMSC 5697), students will present their work as both oral and written reports. The oral presentation will be open to the public and will then be followed by a private defense with the advisory committee. The student must submit a first draft of his/her internship practicum report and internship daily journal to the major professor prior to the public seminar for review. The major professor must approve the internship practicum report prior to the student submitting it to advisory committee members. The final written report should be given to the committee no later than two (2) weeks before the formal defense. Students should coordinate the reservation of a seminar room with the Graduate School office no later than one (1) month prior to their defense. At this time the committee will either approve/or not approve the work of the internship and the report. If disapproved, the student may have a chance to revise the report or repeat the practicum one time at the discretion of the committee. The major professor together with the other members of the committee will assign a letter grade to the practicum. The report must be submitted in accordance with the instructions for completing graduation requirements within the deadlines for graduation published in the academic calendar. A more detailed description of the internship practicum and report requirements may be found in the Internship Practicum Guidelines available on the SBS graduation website.

The student is expected to keep a laboratory notebook/daily journal during this experience. The Internship Mentor will review and sign-off on the journal each week. The journal will form part of the basis for the student's final report and must be turned in to the student's Advisory Committee along with the final Internship Practicum Report.

At the end of the practicum, the student will write a report detailing the activities of the internship. The student's advisory committee must approve this report together with the laboratory notebook. The student must make a formal presentation to the advisory committee and defend the work at this time. A copy of the report and the journal must be submitted within the appropriate deadlines for graduation (see the Academic Calendar).

Function and Grading of the Student Internship Practicum

The Internship Practicum provides a hands-on training experience for the graduate student whose Master's degree will be in the specialized discipline of clinical research management. The Internship Practicum is an approved course (BMSC 5697) offered through the Department of Biomedical Sciences, School of Biomedical Sciences . The student will receive either an "Unsatisfactory (U)" or a "Satisfactory (S)" for all semesters enrolled in the Internship Practicum, until the semester the student graduates. At the end of this second semester, when the student completes all requirements for the Internship Practicum, he/she will receive a letter grade. Only this letter grade will contribute to the overall GPA. The U/S grades will not be figured into the overall GPA.

Description of the Capstone project

The capstone project is a required component of the online Clinical Research Management Master's program that will replace the requirement of an internship practicum. The students will enroll for 3 SCH each in two semesters for a total of 6 SCH for their capstone project. The purpose of the capstone project is to equip students with the knowledge and skills required to contribute to the field of clinical research management. This individualized scholarly work may consist of a detailed case study, literature review and data analysis project or a clinical research project or a clinical quality improvement project. Students will be paired with a mentor from UNTHSC or our partner health care organizations to oversee their work. At the beginning of the capstone, the mentor and student will identify a topic or a specific problem to address or investigate. They will then construct an action plan or research proposal and the student will conduct the data analysis/literature review. At the end of the project, the student will complete a project report and do an oral presentation of the project.

Duration and Time of the Internship / Capstone project

The internship takes approximately 2 semesters (minimum 26 weeks, 40 hrs/week) during which the student will be working under the direct supervision of an Internship Mentor at the internship location. The capstone project will be conducted in a two-semester period (20 hrs/week). If the student does not complete the Internship Practicum / Capstone project in the time frame stipulated in his/her program, the student may register for additional hours of BMSC 5697/ BMSC-5399. During the Internship Practicum, students will be available 5 days a week, usually from 8:00 a.m. until 5:00 p.m., however the exact work schedule will be determined at each internship site. The capstone project is designed for those individuals who are already working in a clinical research space and so the student can complete the required number of hours (20 hrs/week) on weekends/off hours so that it does not interfere with their job responsibilities at their site of employment.

Activities during the Internship / Capstone project

During the internship / Capstone project, the Major Professor, graduate faculty Advisory Committee, and site administrator(s) will assign the student responsibilities that have been previously agreed upon and approved in the Internship Practicum / Capstone project Proposal. Details about the components and formatting of the Internship Practicum / Capstone project Proposal are outlined in a separate section in this handout. The student will work under the guidance and direction of an Internship / Capstone project Mentor at the project site.

As part of the internship, the student will be required to keep a daily journal of his/her activities. The Internship Mentor will review and sign-off on the journal each week. The journal will form part of the basis for the student's final report and must be turned in to the student's Advisory Committee along with the final Internship Practicum Report.

Proprietary Studies and Agreements

The Internship / Capstone project Mentor will also work with the student to ensure that no proprietary information is contained within any public documents submitted by the student to UNTHSC. For example, if a student is involved with a proprietary drug study, without approval by internship partner, the name of the drug will not be identified in the Internship Practicum Proposal, the daily journal, or the Internship Practicum Report, but will be designated by a code as approved

by the Internship Mentor. In addition, before beginning the internship, the student will sign confidentiality agreements as required by the internship partner.

Student Advisory Committee for Internships/Capstone projects

Each student will be assigned a minimum three-person Advisory Committee. This committee will include the major professor and two other members of the graduate faculty of UNTHSC. The Internship/Capstone Mentor will also be included on the committee, if he/she is not already one of the three required individuals. The committee guides the student in determining internship goals, and approves the research/internship proposal. The advisory committee reviews the Research Proposal and final Internship Practicum/Capstone Project Report, administers the final defense examination for the degree, approves the internship practicum report before submittal to the graduate school and determines the final grade for the internship. The major professor serves as chair of the advisory committee. Advisory committees for Master of Science degree students must include at least two additional graduate faculty members.*

Each student is required to meet with his/her advisory committee before beginning the BMSC 5697, Internship Practicum/ BMSC-5399, Capstone project and as necessary until the final defense.

A degree plan listing all courses must be completed by the student, approved by the student's advisory committee and submitted to the graduate dean immediately following the first advisory committee meeting. All subsequent requests for degree plan changes must be approved by the student's advisory committee and submitted in writing by the major professor to the graduate dean. The Internship Practicum / Capstone project Report will consist of a detailed account of the activities performed during the project as agreed upon in the research proposal. The students will be briefed before and during the internship / Capstone project as it relates to the required format. Previous examples can be consulted in Lewis Library. Please refer to Section "Guidelines for Final Internship Practicum / Capstone project Report and Defense" in this handout.

* Individuals at the internship / Capstone project site with master's degrees or higher may be designated as Professional Affiliate member of the graduate faculty in order to become members of the advisory committee.

<u>The Oral Defense</u>

The student must file an "Intent to Defend" form in the graduate school no later than one month before the date of the oral defense. Each student must present his/her practicum work/ capstone project to the public in a formal lecture and then defend it in front of the Advisory Committee in private immediately after the public presentation. After submitting the practicum/capstone project report to the Advisory Committee (at least 2 weeks prior to the defense), it is the student's responsibility to set up his/her oral defense. All members of the Committee must be in attendance. In addition, the student should reserve a room for the oral presentation and defense at least 1 month prior to the defense. The capstone project defense can be conducted in a virtual setting (Zoom or MS Teams)

Role of Advisory Committee Members

Major Professor

Each student will be assigned a major professor. The major professor serves as chair of the advisory committee and thus, is responsible for overseeing the professional development of the student and assisting the student to optimize his/her entire educational experience. It is also the major professor's responsibility to read the student's research/practicum proposal and practicum/ capstone project report before these go to the entire advisory committee and give feedback on each to the student in a timely manner. The student will then use this feedback to revise the document in question before handing it to the other members of the committee.

The major professor gives the interim satisfactory/unsatisfactory practicum/ capstone project grades after consulting with the internship/capstone project mentor and, along with the rest of the advisory committee, determines the final letter grade for the internship practicum/ capstone project.

Internship/ Capstone project Mentor

The student will work under the guidance and direction of an Internship/ Capstone project Mentor at the internship/ project site and thus, the Internship/ Capstone project Mentor plays a critical role in the success of the internship/ project experience. The Internship/ Capstone project Mentor will be the immediate supervisor of the student at the internship site. This individual will be an employee of the internship site. In some cases, the internship mentor and the major advisor may be the same individual.

As part of the internship/ Capstone project, the student will be required to keep a daily diary/log of his/her activities. The Internship/ Capstone project Mentor will review and sign-off on the log each week. The diary will form part of the basis for the student's practicum / Capstone project report and must be turned in to the student's advisory committee along with the practicum / Capstone project report.

The Internship / Capstone project Mentor will be a member of the Advisory Committee and will attend all committee meetings and have input into all decisions regarding the Internship Practicum / Capstone project. The Internship / Capstone project Mentor provides oversight and guidance while the student is being trained. At no time during the internship will the delegation of tasks constitute a delegation of responsibility. The Internship / Capstone project Mentor remains responsible.

Expectations and Focus of the Internship Practicum

The Internship Practicum (BMSC 5697) for the Clinical Research Management Program should take place in an environment where drugs and or devices are tested according to F.D.A. regulations. This may be either a clinical site, e.g. a physician's office or medical clinic, or a sponsor site, e.g. a pharmaceutical company or a clinical research services firm. The student works under the daily guidance of an onsite Internship Mentor and is exposed to activities typical for the profession of clinical research management. These include, but are not limited to, the activities listed below. Students will function and practice under the supervision of the internship mentor, and may assist or observe other site personnel. They observe clinical trial protocol implementations and learn all the processes and administrative duties involved.

- Institutional Review Board (IRB) Interactions/Communications
- Writing or editing Informed Consents
- Observe and practice patient consenting process
- Data Collection and Verification of Source Documents
- Maintaining Study Files
- Assisting with Writing and/or Reviewing Protocols
- Interacting with Study Personnel and/or Study Laboratories
- Onsite and/or Field Monitoring
- Drug/Devise Accountability
- Assisting with Patient and/or Site Recruitment
- Exposure to Budgeting
- Adverse Event Reporting

Students will not be allowed to draw the patient's blood. Handling and shipping of specimen will require prior tutorial provided by the site.

Tasks may be delegated to the student by the internship mentor; however, responsibilities are not delegated to the student at any time during the internship. As part of the Practicum the student will have an independent project involving one or more of the activities listed above that will allow he/she to explore more fully a particular aspect or research study in the clinical research management field. This project will form the basis of the student's Internship Practicum Report, which is described in more detail elsewhere in this handbook.

At the end of the program, it is expected that the student will possess the tools and confidence to pursue a career in clinical research management either at a clinical or sponsor site. The graduate can either anticipate to be hired at a starting level position as either a Clinical Research Coordinator (CRC) at a clinical site or a Clinical Research Associate (CRA-assistant or CRA-level 1) at a sponsor site. With additional past experience in the field or related fields (e.g. an RN or previous work in clinical research), the graduate may be able to apply for higher level positions.

Obtaining UNTHSC IRB Approval

https://www.unthsc.edu/research/protection-of-human-subjects/

Procedures Involving Human Subject Research during Internship / Capstone project
All internship practicum / Capstone projects involving human subjects conducted by students of the UNTHSC must occur within an existing IRB-approved protocol.

Given the limited time frame associated with internships / Capstone project, as part of their CRM internship Capstone project experiences, students are not allowed to initiate and conduct their own "stand-alone" research project involving human subjects. Thus, students interested in being engaged as researchers/investigators/key personnel in human subject research (clinical trials, survey studies, experiments, etc.) must conduct such activities within a mentor's or principal investigator's already ongoing IRB-approved project. This is accomplished by simply being added as key personnel (engaged in research) to the existing protocol allowing the student to experience the operation of that research project at close hand.

Sites at UNTHSC: If the internship activity is conducted at UNTHSC and involves interaction with human subjects or their identifiable data, the activity must be specifically stated in the existing UNTHSC-IRB Approved protocol. In all cases the student must be added to the existing protocol as new key personnel and comply with all university and federal regulations as directed by the UNTHSC Office of Research Compliance (ORC).
The student is responsible for submitting the following items to the UNTHSC Office of Research Compliance:

- A signed memo from the student's Clinical Research Management (CRM) faculty advisor (Program Director) that includes: the student's name, the title and IRB protocol number of the UNTHSC research project, and a statement acknowledging the student's involvement as being engaged in research within the specified UNTHSC research project.

- Evidence that the student has been approved as key personnel on the UNTHSC research project.

Note that students are not allowed to create their own research project or otherwise investigate new elements "inside" an existing IRB-Approved protocol.

Other Sites: If the internship/Capstone project activity is conducted off-site (not at UNTHSC) and involves interaction with human subjects or their identifiable data, the project must fall within the framework of an existing protocol that has been reviewed and *approved by that site's IRB*. In such cases the student must be added to the existing protocol as new key personnel and comply with all of those site's policies as well as federal regulations.

In order for the university to verify that the student's off-site internship activity is also compliant with UNTHSC's adherence to federal regulations, it is the student's responsibility and obligation to provide to the UNTHSC Office of Research Compliance written documentation of the other site's IRB-approved protocol in which they are participating.

Specifically, the student is responsible for submitting the following items to the UNTHSC Office of Research Compliance:

- A signed memo from the Clinical Research Management (CRM) Program Director that includes: the student's name, the title and IRB protocol number of the "off-site" research project, and a statement acknowledging the student's involvement in the specified "off-site" research project.

- A hard/soft copy of the "off-site's" IRB approval letter

- A hard/soft copy of the "off-site's" IRB-approved research documents (e.g., protocol synopsis, consent form, etc.)

- Evidence that the student has been approved as key personnel on the "off-site" research project

The Office of Research Compliance will contact representatives from that site to verify the student's involvement in that IRB-Approved protocol. This step is to assure that the student is also following

UNTHSC policy that all university personnel engaged in human subject research be compliant with federal regulations.

To facilitate student off-site human subject research involvement, the university will develop, wherever possible, inter-institutional agreements with the respective sites to allow for acceptance of these off-site IRB reviews in compliance with UNTHSC policy and procedures.

The Director of the CRM Program shall provide to the Office of Research Compliance a list of upcoming student internship site placements in a timely manner to facilitate a development of this external IRB acceptance process and documentation.

Important Reminder:

Note that under no circumstances shall a student become engaged in research involving human subjects for their practicum project / Capstone project until the UNTHSC Office of Research Compliance and/or the UNTHSC IRB has reviewed and acknowledged/approved that activity.

Any activity involving research with a human subject related to the student's practicum project / Capstone project prior to UNTHSC ORC or IRB approval shall be considered research non-compliance and will be reported to the Dean, Graduate Studies in Biological Science, the Vice President for Research and the Division of Student Affairs for appropriate action.

Timetable for the Internship Practicum / Capstone Project

The internship will take 26 consecutive weeks (40 hrs/week; 1040 hours). The Capstone project will be conducted in two consecutive semesters.

Any change in the internship practicum / capstone project dates requires previous approval from Program Director and Graduate Advisor.

Summer/Fall/Spring Start:

Date	Task
April/June/November	Assignment of internship / capstone project site and advisory committee
Mid-May/Late July/Early Dec	Pre-Internship / capstone project Orientation Meeting
	Student contacts internship / capstone project site and committee members; student arranges a committee meeting at the internship / capstone project site or virtually to discuss the internship / capstone project.
Date will vary	Student starts their on-site internship (register for 9 SCH summer/fall/spring and 9 SCH fall/spring/summer) / capstone project for 6 months (register for 3 SCH in each semester).

Within first 2 weeks	Student schedules a committee meeting to present his research topic. Committee approves the topic
After 3 weeks	Major professor and on-site mentor review draft research proposal. Edited draft is sent to other committee members for review.
First 4 weeks	Student prepares research proposal (the student will be working at the site in addition to writing the proposal).
End of Week 5	Advisory committee electronically reviews/approves the final research proposal. Agreement can be obtained via email. IRB application needs to be submitted. Research/ Capstone project Proposals completed and signed by all committee members and filed in the Graduate School
End of the Semester	Major Professor enters Semester Grade (“S” or “U”) Student checks deadline and file for graduation (submit form “Intent to Graduate”)
After 16 weeks	Student meets with major professor to go over proposed practicum / Capstone project report outline and starts drafting actual Practicum / Capstone project Report while continuing to work at the site. Student and Committee sets defense date.
Early to Mid of Week 20	Major professor reviews first draft of report. Other committee members review Practicum / Capstone project Report no later than 2 weeks prior to scheduled defense. Student sets defense date and schedules room and technical services. The “Intent to Defend” form must be filed at least 30 days prior to defense date in the Graduate School. Student focuses 100% on completion of Practicum Report / Capstone project, preparing presentation and practicing presentation with Major Professor.
November/April/July	Student defense of Practicum Report / Capstone project. All members of Advisory Committee MUST be in attendance. Defense must be conducted at least two weeks before the semester end date in order to meet graduation deadline. Immediately following defense Students makes final edits to Internship Practicum / Capstone project Report and submits in the Graduate School and Lewis Library before the end of semester deadline Comply with last day to complete all requirements for confirmation of degree

Internship/ Capstone project Proposal and Final Practicum / Capstone project report

The Internship Practicum / Capstone project Report will consist of a detailed account of the activities performed during the internship / Capstone project as agreed upon in the Internship Practicum / Capstone project Proposal. The students will be briefed before and during the internship / Capstone project as it relates to the required format. Please refer to Section "Guidelines for Final Internship Practicum Report / Capstone project and Defense" in this handout.

Oral Seminar and Defense

The student must file an "Intent to Defend" form in the graduate school no later than one month before the date of the oral defense. Each student must present his/her practicum / Capstone project work to the public in a formal lecture and then defend it in front of the Advisory Committee in private immediately after the public presentation. After submitting the practicum report / Capstone project to the Advisory Committee (at least 2 weeks prior to the defense), it is the student's responsibility to set up his/her oral defense. All members of the Committee must be in attendance. In addition, the student should reserve a room for the oral presentation and defense at least 1 month prior to the defense. Students working in locations outside of Dallas-Fort Worth metroplex can schedule their defenses in a virtual setting using web conferencing tools.

Following the defense, the major professor together with the other members of the committee will assign a Pass/Fail for BMSC 5697 or BMSC-5399 based on guidelines outlined in the *MS Defense Scoring Rubric*. The student must submit the signed *Report of Final Comprehensive Examination (Defense)* form to the SBS office. A copy of the approved Thesis / Capstone project report must be submitted to the graduate school before graduation in accordance with the graduate school rules and time limits for the Master's thesis. (https://www.unthsc.edu/school-of-biomedical-sciences/graduation-instructions-and-forms/)

Research Proposal Guidelines for Internship Practicum / Capstone project Proposal

can be found at https://www.unthsc.edu/school-of-biomedical-sciences/forms-and-guidelines/

Guidelines for the Final Internship Practicum / Capstone project Report and Defense

can be found at https://www.unthsc.edu/school-of-biomedical-sciences/graduation-instructions-and-forms/

Turnitin

The School of Biomedical Sciences supports initiatives that foster students' academic progress. Specifically, the SBS has launched efforts that facilitate mastery of program competencies, while ensuring academic integrity. UNTHSC has contracted with Turnitin.com for plagiarism detection services. Turnitin helps prevent plagiarism by comparing student papers to sources such as commercial databases of online journal articles and periodicals, other student submissions, and current or archived information on the Internet.

Students will be required to submit their Final Practicum Report/ Capstone project report to *Turnitin* (an evaluative software service not affiliated with UNTHSC) to receive feedback on originality of student's work. To facilitate the submission process, the instructor will set up the required written assignments in *Turnitin* which can be accessed through CANVAS. This allows students to submit written assignments and obtain originality reports. The course written assignment set up in *Turnitin* will allow the Instructor to monitor submissions for all required assignments and view results. Students should go to course CANVAS webpage to submit assignments.

The **Similarity/Originality score must be less than or equal to 15%** (not including the Bibliography). The use of this tool is designed to be a formative process, allowing students to gain/improve experience in writing skills and proper referencing. An additional goal allows students to evaluate and synthesize concepts covered in the course that need to be reflected within the written paper. Turnitin compares the content in the paper against text on the Internet, other student submissions, and commercial databases. An Originality Report for each student submission is generated showing any text that appears to be duplicated. The instructor can use this information to determine if the duplicated text is plagiarized. The instructor remains the arbiter of what constitutes plagiarism. Instructions on how to submit the report will be sent to all students.

Criteria for Consideration of the Internship Practicum / Capstone project Grade Assignments

BMSC 5697 Internship Practicum and BMSC 5399 Capstone project are approved courses offered through the Department of Biomedical Sciences, School of Biomedical Sciences and is a requirement for certain Master's degree programs. The student will receive either an "Unsatisfactory (U)" or a "Satisfactory (S)" for all semesters enrolled in the practicum / capstone project, until the semester the student graduates. At the end of this semester, when the student completes all requirements for the practicum / capstone project, he/she will receive a letter grade. Only this letter grade will contribute to the overall GPA. The U/S grades will not be figured into the overall GPA.

The final letter grade is a reflection of performance throughout the internship / capstone project, public seminar, and private oral defense as well as quality of the final practicum / capstone project report. The letter grade is determined by the entire Advisory Committee after conclusion of the defense, whereas the practicum / capstone project grade(s) prior to the final letter grade is (are) determined by the Major Advisor and Onsite Mentor.

- Suggested rating scale for the final practicum semester grade: Excellent = A; Above Average = B; Average-Poor = C; Failing = F

- For the practicum grades prior to the last semester: A "Satisfactory (S)" should reflect A/B/high C work; An "Unsatisfactory (U)" indicates low C and below.

Suggested Criteria

1. Attendance
2. Met all requirements in a timely manner, including filing of appropriate forms
3. Observed accepted standards of professional behavior, e.g. academic integrity, proper behavior in dealing with the public, dress etc.
4. Regularly and actively participated in the activities, both research and educational, of the practicum
5. Commitment, drive, determination, perseverance
6. Creativity, imagination, in terms of problem interpretation as well as problem design
7. Technical ability
8. Keeps up with and understands the literature
9. Effectively completes tasks
10. Ability to write clearly
11. Ability to speak clearly and answer questions knowledgeably
12. Leadership qualities
13. Organizational skills (e.g. good record keeping and well prepared notebooks) and time management skills
14. Appropriate demonstration of independence
15. Overall depth of understanding of the practicum problem and its significance to the general field of study
16. Pays attention to detail