



**GRADUATE SCHOOL  
OF BIOMEDICAL SCIENCES  
Department of Biomedical Sciences**

**Master of Science Degree Program**

**CLINICAL  
RESEARCH  
MANAGEMENT**

**HANDBOOK 2011-2013**

(available on-line

<http://www.hsc.unt.edu/departments/bmsc/Specialized%20Master's%20Programs.cfm>)

# **Clinical Research Management Master of Science Degree Program**

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## **Program Description**

Clinical Research involves the testing and determination of 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 protection of human rights, prevention and detection of fraud and the use of 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 will provide a strong foundation upon which to build a career. The rigorous curriculum focuses on providing students a broad-based view of the biomedical sciences, as well as in depth knowledge of regulatory requirements (code of federal regulations, good clinical practices), ethical issues, and both the medical writing and administrative skills necessary to conduct clinical research. An IRB/Regulatory Affairs Track will provide additional training to those individuals whose career goal is in regulatory affairs and/or management of IRB committees. Candidates for the degree earn approximately 51 SCH of which 12 SCH are a laboratory Internship Practicum, the latter substituting for a thesis requirement. The program is usually completed in eighteen months (IRB Track is two years). Students are only admitted in the summer semester.

As part of the program, all students will complete a 26-week (40 hours/week) internship practicum in clinical studies and use this experience to write a detailed Internship Practicum Report pursuant to receiving the Master of Science degree. The average time to complete the degree is eighteen months. 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.

### **Opportunities for Graduates in Clinical Research Management**

Well-trained clinical research professionals are in high demand. The tremendous increase in medical technology and information in the last decade has resulted in an explosion of potential new drugs, devices and biologics that must be tested before being released for use by the public. The profession is constantly challenged to improve and streamline the clinical research programs in order to shorten the development timelines and control the cost for new product development.

Clinical research professionals can hold a multitude of positions either in industry, at the investigational site, or in the clinical research service profession either at a contract research organization (CRO) or a site management organization (SMO). Job titles may include, but are not restricted to, clinical research associate, clinical research scientist, clinical research coordinator, medical writer, clinical trial auditor, clinical trial monitor, product safety specialist, clinical research trainer, etc. Industry (sponsor) and service professions (CRO, SMO) usually provide technical and managerial career paths and ample growth opportunities.

Typically a clinical research coordinator who has been involved with the implementation and coordination of a clinical trial at a research site (private, clinic, hospital), will advance his/her career by switching to either industry or one of the service professions. Others make the reverse switch because they prefer the interactions with the patients, or they may want to travel less than what is typically required from a clinical trial monitor. Turnover in all these industries and positions is relatively high because of the growing variety of choices clinical research professionals have, especially after they have accumulated a number of years of experience.

The graduate from the Clinical Research Management program will be qualified to fill a beginning position as a clinical research associate (industry or CRO position) or clinical research coordinator (research site position). These jobs may contain any or all of the following key 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.

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 which the students learn in the program, excellent verbal and written communication skills, organizational skills and interpersonal skills are essential to having a successful career as a clinical research professional. Furthermore, a good dose of diplomacy, flexibility and professionalism will be a must to succeed.

## **Admissions Requirements**

The admissions committee will review all applicants for acceptance into the program. A student must have a bachelor's degree and must meet the general requirements listed in the catalog in effect at the time of application. In addition, the Medical College Admissions Test (MCAT) is required for admission to this program and applicants must have completed the following prerequisites: general or inorganic chemistry (8 SCH), biology (14 SCH), physics (8 SCH), organic chemistry (8 SCH), English (6 SCH), and calculus or statistics (3 SCH).

All applications must be completed and received in accordance with the deadlines published in the academic calendar. Electronic application records will be updated before letters are mailed. Applicants may check their application records online at

<http://my.hsc.unt.edu> for admissions decisions. No admissions decisions will be released by phone.

A bachelor's degree or its equivalent from a regionally accredited institution.

A competitive grade point average; in general, 3.0 or higher.

An official GRE score. There is no minimum GRE score requirement. In general, a composite score of at least 1100 with an analytical writing core of 3.5 is considered competitive (revised GRE – composite score of 310). The GRE is not the only consideration for acceptance into the program; we consider the entire application package. The GRE may be waived if the applicant holds a terminal degree (Ph.D., M.D., D.O., etc.) If the applicant is an M.D. they must be licensed to practice in the U.S.

The UNTHSC at Fort Worth requires an applicant from a foreign country to demonstrate satisfactory proficiency in oral and written English before being granted admission in addition to supplying official documentation of minimum scores for the Test of English as a Foreign Language (TOEFL) or the International Language Testing System (IELTS) exam. Upon acceptance, if it is determined that a student is not proficient in the English language, he/she will be required to complete an approved English as a Second Language (ESL) course at his/her own expense.

## **Support**

In general, master's students do not qualify for teaching assistantships. They are, however, eligible to apply for the Elena and Thomas Yorio Scholarship for First-Year Students and the Rachel Dauphin Memorial Scholarship.

## **Program Requirements**

Each student is responsible for the completion of the core requirements for the Clinical Research Management program according to the procedures that follow. Each item must be completed in the sequence and time period indicated. Forms are subject to revision at any time and should be obtained from the Graduate School of Biomedical Sciences' web site.

The admissions committee will review all applicants for acceptance into the MS program in Clinical Research Management. A student must have a bachelor's degree and must meet the general admission requirements as described in the catalog in effect at the time of application.

By the end of the second 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 on the designation of advisory committee form with the GSBS Office of Admissions and Services. A degree plan must also be filed with the GSBS Office of Admissions and Services at this time.

Students must be in good academic standing prior to be allowed to start their internship at a site (cumulative GPA 3.0). Exceptions to this rule can only be granted by the dean or his designee.

During the summer of year one, the student will enroll in BMSC 5697, the Internship Practicum. 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, pharmaceutical or medical device company, a clinical research organization or site management organization.

A formal research proposal describing how the practicum is to be spent must be approved by the advisory committee and submitted to the graduate school early in the summer semester, year one.

At the end of the practicum, the student must submit a report and internship daily notebook to the mentor for his/her approval. The advisory committee will meet with the student at this time and review both the notebook and written report. The student will present his/her work as both an oral and written report. The oral presentation will be open to the public and will then be 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 and the report. If not approved, the student may have a chance to revise the report or repeat the practicum 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 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 GSBS graduation website.

It is strongly suggested that the student and major professor, as well as the major professor and the on-site mentor, communicate on a regular basis to review the student's progress during the practicum.

## **CRM Curriculum**

The following curriculum is required for all students enrolled in the Clinical Research Management program:

**Year 1**

**Summer**

BMSC 5400.002	Biostatistics for Biomedical Science	4 SCH
BMSC 5900.001	Short Course in Health Disparities	1 SCH
MOLB 5201.002	Introductory Biochemistry	2 SCH

**Fall**

BMSC 5301	Integrative Biomedical Sciences CORE I: Principles of Biochemistry	3 SCH
BMSC 5302	Integrative Biomedical Sciences CORE II: Molecular Cell Biology	3 SCH
BMSC 5303	Integrative Biomedical Sciences CORE III: Immunology and Microbiology	2 SCH
BMSC 5310	Scientific Communications	3 SCH

**Spring**

BMSC 5304	Integrative Biomedical Sciences CORE IV: Physiology	4 SCH
BMSC 5305	Integrative Biomedical Sciences CORE V: Pharmacology	2 SCH
BMSC 5165	Introduction to Industry Practice	1 SCH
BMSC 5312	Introduction to Clinical Research & Studies	3 SCH
BMSC 5121	Ethical, Legal and Social Issues for Responsible Clinical Research	2 SCH

**Summer**

BMSC 5697	Laboratory Internship Practicum	6 SCH
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**Year 2**

**Fall**

BMSC 5697	Laboratory Internship Practicum	6 SCH
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**Total Course 51 SCH**

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 and 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.

## Course Descriptions

### CORE Courses:

#### **BMSC 5301. Integrative Biomedical Sciences I: Principles of Biochemistry.**

3 hours. A broad introduction to the fundamentals of biochemistry, especially those relating to thermodynamics, molecular pathways and regulation. Discussion of important techniques that contribute to our present understanding of biochemistry. Offered each Fall. Course restricted to Medical Sciences and Clinical Research Management majors. Letter Grade.

#### **BMSC 5302. Integrative Biomedical Sciences II: Molecular Cell Biology.**

3 hours. The fundamentals of cell and molecular biology, concentrating on understanding of the experimental basis of these disciplines as well as the current state of knowledge. Offered each Fall. Course restricted to Medical Sciences and Clinical Research Management majors. Letter Grade.

#### **BMSC 5303. Integrative Biomedical Sciences V: Immunology and Microbiology.**

2 hours. A general exploration of basic concepts of immunology, microbiology and virology including study of genomics, proteomics and gene therapy. Course restricted to Medical Sciences and Clinical Research Management majors. Offered each Fall. Prerequisites: BMSC 5301 and 5302 or consent of the department. Letter Grade.

#### **BMSC 5304. Integrative Biomedical Sciences III: Physiology.**

5 hours. Emphasis on integrative physiology of human organ systems. Offered each Spring. Course restricted to Medical Sciences and Clinical Research Management majors. Prerequisites: BMSC 5301 and 5302 or consent of the department. Letter Grade.

#### **BMSC 5305. Integrative Biomedical Sciences IV: Pharmacology.**

2 hours. Emphasis on fundamental principles of pharmacology that include pharmacodynamics, pharmacokinetics, ligand-receptor interactions and their consequent biological effects. Course restricted to Medical Sciences and Clinical Research Management majors. Offered each Spring. Prerequisites: BMSC 5301 and 5302 or consent of the department. Letter Grade.

### Additional Courses:

**MOLB 5201.002. Introductory Biochemistry.** This introductory course in biochemistry is intended to provide undergraduate and graduate students with a foundation and in-depth knowledge of biochemistry. This course will cover many aspects of biochemistry including biomolecules and metabolism. The course consists of lectures Letter Grade.

**BMSC 5165. Introduction to Industry Practice.**

1 hour. Introduction to the practice of industry science with an emphasis on good laboratory practice, new drug applications, FDA regulations, clinical trials and biotechnology transfer. Course graded on pass/fail basis. Offered each Spring. Letter Grade.

**BMSC 5121. Ethical, Legal, and Social Issues for Responsible Clinical Research.**

2 hour. Regulations involved with human subject research will be discussed both from an historical and contemporary perspective. Case studies will be presented and students will attend an Institutional Review Board meeting. Offered each Spring. Letter Grade.

**BMSC 5231. Introduction to Health Disparities Issues in the United States**

2 hours. An examination of the disparities and issues surrounding the treatment of several health problems in the United States, particularly as related to minority populations. Each health condition is approached from the clinical, cultural and scientific aspect so that the student will understand the etiology and treatment of the disease, the cultural characteristics of various populations that may contribute to the disproportionate presence of the disorder in a particular population, and the underlying science involved with each health problem. The latter understanding will aid the student to better approach research, both in the clinical and basic science venues, directed towards better management of the health problems. Offered each Fall. Letter Grade.

**BMSC 5310. Scientific Communications.**

3 hours. The purpose of this course is to develop skills and gain experience in the types of scientific writing required for: submitting articles for publication; grant applications; preparing presentations for lectures and seminars; preparing posters for meetings. Offered Fall and Spring semesters. Letter Grade.

**BMSC 5312. Introduction to Clinical Research and Studies.**

3 hours. Course covers drug development process, ethical and scientific principles of clinical research, clinical trial preparation, study design, informed consent forms, clinical coordinator responsibility and regulatory considerations, and conducting clinical trials from initiation to implementation. Offered each Spring. Letter Grade.

**BMSC 5400. Biostatistics for Biomedical Sciences.**

4 hours. Statistical methods and experimental design; descriptive statistics; data presentation; parametric and non-parametric methods of hypothesis testing including two-sample tests, analysis of variance, regression and correlation analyses; introduction to multivariate statistics. Competency with computer statistical packages is developed. Offered each Summer. Letter Grade.

**BMSC 5697. Internship Practicum**

6 hours. The candidate must complete an internship at an approved site. At the completion of the practicum, the student will write a report detailing the activities of the internship. A copy of the report must be submitted within the appropriate deadlines

to the graduate school according to the guidelines for completing the requirements for graduation. Offered each semester. Satisfactory/Unsatisfactory until semester of graduation. Letter grade for final semester.

## **Current Internship Practicum Sites**

The following sites are currently available for placement of students for their required internship.

**ACRC Trials**

Plano, TX

**Baylor, Dallas (several locations)**

Arlington, Dallas, Plano, and Fort Worth TX

**Texas Health Ben Hogan Sports Training**

Fort Worth, TX

**CRSTI**

Dallas, TX

**Galderma Laboratories, L.P.**

Fort Worth, TX

**Healthpoint**

Fort Worth, TX

**MedTrials, Inc.**

Dallas, Texas

**Reata Pharmaceuticals**

Dallas, Tx

**Mary Kay Cosmetics**

Dallas, TX

**The Center for Cancer and Blood Disorders**

**Dr. Ray Page**

Fort Worth, Texas,

**Texas Research and Education Institute for Texas Health Resources**

Arlington, TX

**Texas Pulmonary & Critical Care Consultants, PA**

**Sleep Consultants**  
**Dr. John Burk**  
Fort Worth, TX

**Dallas VA Medical Center**  
Dallas, TX

**TREI (Texas Research & Education Institute for Texas Health Resources)**  
Dallas, Arlington or Fort Worth

**University of North Texas Health Science Center at Fort Worth**  
Fort Worth, Texas

- Office of Human Subject Protection
- Department of Surgery
- Department of Internal Medicine
- Department of Pediatrics
- Department of Family Practice
- Department of OMM

## **Description of the Student Internship Practicum**

### **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 is an approved course (BMSC 5697) offered through the Department of Biomedical Sciences, Graduate School of Biomedical Sciences. The student will receive either an "Unsatisfactory (U)" or a "Satisfactory (S)" for all semesters enrolled in the practicum, until the semester the student graduates. At the end of this semester, when the student completes all requirements for the 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.

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.

UNTHSC does not offer any remuneration to the student when he/she is enrolled in BMSC 5697 and the student should not expect to be paid as an intern. No student should consider that the internship site has any obligations to pay, hire or in anyway 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.

### **Duration and Time of the Internship**

The internship takes approximately 26-32 weeks (40hrs/week) during which the student will be working under the direct supervision of the Internship mentor at the internship location. If the student does not complete the practicum in the time frame stipulated in his/her program, the student may register for additional hours of BMSC 5697. During the 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.

### **Activities during the Internship**

During the internship, 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 *Research/Practicum Proposal*. Details about the components and formatting of the *Research Practicum Proposal* are outlined in a separate section in this handout. Previous examples can be consulted in Room EAD-824. The practicum proposal must also be submitted to the UNTHSC IRB committee for approval. The student will work under the guidance and direction of an Internship Mentor at the internship site.

As part of the internship, the student will be required to keep a daily diary/log of his/her activities. The Internship Mentor will review and sign-off on the log each week. The diary 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**

If a student is involved with a proprietary study, the exact drug/therapy/devise etc under study will not be identified in either the diary or the practicum report or any other student-generated document, but will be designated by a code as approved by the Internship Mentor. The Internship Mentor will also be a member of the student's advisory committee and will review the practicum report to ensure that the confidentiality of the study under question will be maintained. In addition, before beginning the internship, the student will sign confidentiality agreements required at the internship site.

### **The Student's Advisory Committee and the Internship Practicum Report**

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 Mentor will also be included on the committee, if he/she is not already one of the three required individuals. It is the responsibility of the Advisory Committee to oversee the internship, writing of the practicum report, and defense.

The Internship Practicum Report will consist of a detailed account of the activities performed during the internship as agreed upon in the research proposal. The students will be briefed before and during the internship as it relates to the required format. Previous examples can be consulted in Room EAD-824. Please refer to Section "Guidelines for Final Internship Practicum Report and Defense" in this handout.

### **The Oral 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 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 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 contact Ms Amanda Griffith in the graduate school to set up a lecture room and advertise the oral presentation. This should be done 2 weeks prior to the defense.

## **Expectations and Focus of the Internship Practicum**

### **Expectations**

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/Device 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 or the graduate school.**

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.

# Role of the Committee Members

## Major Professor

Each student will be assigned a major professor. The student should be made to feel that he/she may come to this mentor for advice/mentoring as needed. 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 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 grades after consulting with the internship mentor and, along with the rest of the advisory committee, determines the final letter grade for the internship practicum.

## Advisory Committee

Each student will be assigned an advisory committee. 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 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 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 before the completion of 24 SCH. 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.

\* Individuals at the internship site with master's degrees or higher may be designated Category I graduate faculty in order to become members of the advisory committee.

## **Internship Mentor**

The student will work under the guidance and direction of an Internship Mentor at the internship site and thus, the Internship Mentor plays a critical role in the success of the internship experience. The Internship 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, the student will be required to keep a daily diary/log of his/her activities. The Internship Mentor will review and sign-off on the log each week. The diary will form part of the basis for the student's practicum report and must be turned in to the student's advisory committee along with the practicum report.

The Internship 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. The Internship 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 Mentor remains responsible.

## **Timetable for the Internship Practicum (Students not on IRB/Regulatory Affairs Track)**

**The internship will take 26 consecutive weeks (40 hrs/week)**

**NOTE: If internship is begun later than below start date, conferral of degree (graduation) will not occur until spring 2011 (All dates will be revised to fit start date). Any change in the internship practicum dates requires previous approval from Program Director and Graduate Advisor.**

### **Summer Start:**

<b><u>Date</u></b>	<b><u>Task</u></b>
April	Assignment of internship site and advisory committee
Early May	Pre-Internship Orientation Meeting
End of May	Student contacts internship site and committee members; student arranges a committee meeting at the internship site to discuss internship and

	<p>practicum project. Student can start on-site as soon as day after this meeting took place.</p>
June 1 - November 30	<p>Student starts their on-site internship for 6 months (register for 6 SCH summer; 6 SCH fall).</p>
First 4 weeks	<p>Student prepares research proposal (the student will be working at the site in addition to writing the proposal).</p>
Middle of June	<p>Major professor and on-site mentor review draft research proposal. Edited draft is sent to other committee members for review.</p>
End of June	<p>Advisory committee meets to review/approve final research proposal. Agreement can be obtained via email. IRB application submitted</p>
By June 30	<p>Research/Practicum Proposals completed and signed by all committee members and filed in the Graduate School</p>
End of Summer Semester	<p>Major Professor enters Fall Semester Grade (“S” or “U”)</p>
September 1	<p>Student checks deadline and file for graduation (submit form “Intend to Graduate”)</p>
October	<p>Student calls an advisory committee meeting early in October to go over his/her proposed practicum report outline (or may meet with members individually). Student starts drafting actual Practicum Report while continuing to intern at the site. Student and Committee sets defense date.</p>
Last Week October	<p>Major professor reviews first draft of report. Other Committee Members review Practicum 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 1 month prior to defense date in the Graduate School.</p>

Early November	Student focuses 100% on completion of Practicum Report, preparing presentation and practicing presentation with Major Professor.
Last 2 weeks of November	Student defense of Practicum Report. All members of Advisory Committee MUST be in attendance (remember, Thanksgiving falls in this period).
Immediately following defense	Students makes final edits to Internship Practicum Report and submits in the Graduate School.  Major Professor files letter grade
First week December	Comply with last day to complete all requirements for fall confirmation of degree
<b>Fall Start:</b>	
August - January	Start On-Site Internship 6 months (6 SCH summer; 6 SCH fall). NOTE:
Week prior to Fall Semester	Student, On-Site mentor and Committee Members meet at the site to discuss internship and research/practicum proposal. Student can start on-site as soon as day after this meeting took place.
First 4 weeks	Student prepares research proposal (the student will be working at the site in addition to writing the proposal).
September 15-19	Major professor and on-site mentor review draft research proposal. Edited draft is sent to other committee members for review.
By September 30	Advisory committee reviews/approves final research proposal. Agreement can be obtained via email.
Mid-October	Research/Practicum Proposals completed and signed by all committee members and filed in the Graduate School

	Check deadline and file for graduation (Intend to Graduate form)
December	Student asks advisory committee members to review his/her proposed practicum report/thesis outline. Student starts drafting actual Practicum Report while continuing to intern at the site.
Early January	Student sets defense date and schedules room and technical services.  Student files Intent to Defend form with Graduate Office
January	Student focuses 100% on completion of Practicum Report with Major Professor.
Mid-to late-January	Major professor reviews draft of report (get help from other committee members as well). Other Committee Members review final draft of the Practicum Report/Thesis no later than 2 weeks prior to scheduled defense. Student works on preparing presentation and practicing presentation with Major Professor.
Mid-February	Student defends Practicum Report. All members of Advisory Committee MUST be in attendance (remember, Thanksgiving falls in this period).
Immediately following defense	Students makes final edits to Internship Practicum Report and submits in the Graduate School.
May	Comply with last day to complete all requirements for fall confirmation of degree
<b>Spring Start:</b>	
Jan -July	Start On-Site Internship 6 months (6 SCH Spring; 6 SCH Summer).
Jan – 1 <sup>st</sup> week of semester	Student, On-Site mentor and Committee Members meet at the site to discuss internship and research/practicum proposal.

First 4 weeks	Student prepares practicum proposal (the student will be working at the site in addition to writing the proposal).
By 1 <sup>st</sup> week of February	Major professor and on-site mentor review draft practicum proposal. Edited draft is sent to other committee members for review.
By 2 <sup>nd</sup> week of February	Advisory committee approves final practicum proposal. Agreement can be obtained via email.  Research/Practicum Proposals completed and signed by all committee members and filed in the Graduate School  Check deadline and file for graduation
May- Early June	Student focuses on completion of Practicum Report, preparing presentation and practicing presentation with Major Professor.  Student meets with advisory committee members if necessary in early May to go over his/her proposed practicum report outline (can be done via E-mail). Student starts drafting actual Practicum Report while continuing to intern at the site. Last week in May or early June, Major professor reviews first drafts of report. Other Committee Members review Practicum Report no later than 2 weeks prior to scheduled defense. Student sets defense date and schedules room and technical services.
By 1 <sup>st</sup> week of May	Student files Intent to Defend form in the Graduate School
By the first week July	Student defends Practicum Report. All members of Advisory Committee MUST be in attendance
Immediately following defense	Students makes final edits to Internship Practicum Report and submits in the Graduate School.
By 2 <sup>nd</sup> week of July	Last day to complete all graduation requirement

# Research Proposal Guidelines for Internship Practicum Reports

Many studies end in futility or waste considerable amounts of time because the student begins the project with only a meager understanding of the area under consideration and no real plan or road map. To be successful, the student should have a detailed plan as well as an overall conceptualization of the study. The research proposal for the internship practicum allows the student to specify the problem/activities that will be pursued during the internship; to elaborate on the significance of the study to a particular profession; to review related literature; and outline the appropriate methodology employed in the study within a reasonable time-frame. The proposal serves as a “road map” for the activities to follow. The student has 4 weeks to finalize the proposal after starting the internship.

The Internship practicum is an opportunity for the intern to observe and learn the day-to-day activities, processes and responsibilities involved in conducting clinical trials at a site or in the industry. In addition, the student will be required to have a special focus on particular aspects of clinical trial management in that environment that will be agreed upon prior to starting. All this needs to be captured in the Research Proposal. In general, the proposal will contain the following components:

- I. **Summary:** Provide one or two paragraphs which describe what the research project will do and how it will be conducted.
- II. **Problem/Hypothesis:** Provide one or two paragraphs listing the seminal observations which lead one to the STATED problem or hypothesis.
- III. **Significance:** Provide one paragraph which describes why the project is important.
- IV. **Background:** For a thesis or dissertation, provide a review of the salient literature which directly supports or opposes the state hypothesis. For a PILOT, provide a review of the recent observations or opposing arguments which support the larger review of the problem or methods development.
- V. **Research Design and Methodology:**
  - ◆ Present clearly and concisely the research design and proposal statistical analysis
  - ◆ Describe the data to be collected
  - ◆ Describe methods, data collection and sampling techniques to be employed
  - ◆ Describe briefly any new methods or tools which will be developed

- ◆ Describe briefly any populations which will be sampled
  - ◆ Describe briefly any data bases which will be sampled
- VI. **Limitations:** Describe any key factors which will limit the interpretation of the data collected or arguments presented.
- VII: **General Internship Experience:** Provide insight into the broad range of tasks, including administrative or managerial responsibilities observed or conducted during the internship, also the ones that are not immediately related to the main focus of the internship experience.
- VIII. **Chapters:** List projected chapter titles
- IX. **Bibliography:** List all references cited in the proposal using an accepted form of scientific citation. Choose whether you will use the name system, e.g. (Miles et al, 2004), or the number system, e.g. (1) through (n). Then be consistent! Unless the idea is totally your own, cite a source. Failure to do so is plagiarism!

**NOTE:** The student should read the requirements, consult examples for writing the practicum report and work closely with the Major Professor before beginning to actually write either the proposal or the final document. They are highly encouraged to ask assistance in the library for properly and efficiently conducting on-line searches and to use a citation software program such as END-NOTES, Stat-Ref or RefWorks.

## Obtaining UNTHSC IRB Approval

All practicum projects conducted by students at the UNTHSC **must** be approved by the UNTHSC IRB committee through the Office for the Protection of Human Subjects prior to the study being conducted. The Office for the Protection of Human Subjects oversees human subjects' protections through program oversight, education, policy setting, and outreach. The OPHS conducts initial review for all research projects involving human subjects and refers their findings and recommendation to the UNTHSC IRB for formal in-depth review and approval. The OPHS monitors all research involving human subjects under their Federal Wide Assurance (FWA) jurisdiction. OPHS will provide assistance to students who are preparing IRB applications. All forms and guidelines for preparation of documents that must be submitted to the IRM can be found on the OPHS website:

<http://www.hsc.unt.edu/sites/ophs-irb/>

# Guidelines for the Final Internship Practicum Report and Defense

At the beginning of the summer term of the first year, the student will enroll in BMSC 5697 (6 SCH), the Internship Practicum. The Internship will continue in the fall semester of the second year (6 SCH) so upon completion, the student will have spent a total of 26 weeks in the internship.

Once a student has enrolled in BMSC 5697, he/she must maintain continuous enrollment until the graduate school has accepted the final internship report. Failure to maintain continuous enrollment will either invalidate any previous BMSC 5697 credit or will result in the student's dismissal from the degree program, unless granted an official leave of absence by the graduate dean for medical or other exceptional reasons.

At the end of BMSC 5697, the student must submit the internship report and notebook (daily journal) to the major professor, advisory committee including the internship mentor for their approval. The advisory committee will meet with the student to approve the work of the internship and the report. Corrections may be suggested at this time. The completed/corrected internship report should be submitted to the advisory committee **at least two weeks prior to the defense.**

Just prior to the defense (same day), the student will present a formal public seminar pertaining to the report. The advisory committee (and internship mentor) will administer the final oral defense of the internship report and related work in private immediately following the seminar.

The internship report/thesis must be prepared for digital submission according to GSBS Guidelines (Preparation and Electronic Filing of Dissertations, Theses and Internship Practicum Reports at UNTHSC) for Filing Theses, Internship Practicum Reports and Dissertations (available online at <http://hsc.unt.edu/education/gsbs> under Forms). Specific format requirements for the Internship Practicum Report for the Clinical Research Management students will be communicated clearly during the internship. The body of the Internship Practicum Report in general will contain the following chapters:

Chapter I: Introduction

Chapter II: Internship Subject  
Background and Literature Review  
Specific Aims  
Significance

Materials and Methods  
Results and Discussion  
Summary and Conclusions  
Bibliography

Chapter III: Internship Experience  
Internship Site  
Journal Summary (refer to addendum for complete day-today log  
of activities)

Appendix

Examples of past Internship Practicum Reports are available in Lewis Library.

Note: If the student includes figures, images, tables from publications (books, journal articles, etc.) they **must obtain copyright permission** from the appropriate editor/publisher in order to publish it in their practicum report. This permission is attached as an appendix to the practicum report.

### **The Oral Defense**

The student must file an “Intent to Defend” form in the graduate school approximately one month before the date of the oral defense. Each student must present his/her practicum 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. The student should plan on a minimum 45 minute presentation, allowing an additional 15 minutes for questions from the audience. The student should plan for an additional 2 hours for the private defense. It is the student’s responsibility to set up his/her oral defense and private defense. All members of the Advisory Committee must be in attendance. The student must contact Ms Amanda Griffith in the graduate school to set up a lecture room and advertise the oral presentation. This should be done at a minimum of 1 month weeks prior to the defense. In addition, the student must contact the graduate secretary in the Department of Cell Biology and Genetics to arrange for public advertisement of the defense seminar date and time.

## **Criteria for Consideration of the Internship Practicum Grade Assignments**

The internship is an approved course (BMSC 5697) offered through the Department of Biomedical Sciences, Graduate 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, until the semester the student graduates. At the end of this semester, when the student completes all requirements for the 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.

The final letter grade is a reflection of performance throughout the internship, public seminar, and private oral defense as well as quality of the final practicum report. The letter grade is determined by the entire Advisory Committee after conclusion of the defense, whereas the practicum 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

## **Forms Required Prior/During the Internship Practicum**

### **Internship Practicum Advisory Committee Meetings and Required Forms**

#### **Advisory Committee Meetings**

It is the student's responsibility to schedule and coordinate dates, times and meeting rooms for Advisory Committee meetings. The student should schedule his/her oral defense date, time and place at least 4-5 weeks prior to the planned date, to make sure ALL committee members can be present.

#### **Required Forms and Signatures**

There are several Forms that must be completed and filed with the Graduate School office during the course of the program. The required Forms (see attached) can be obtained on the website. The names and degrees of the individuals who will sign the form need to be TYPED IN under their respective signature lines, prior to printing the forms out and collecting the signatures.

Students, who have been assigned 4 rather than 3 Advisory Committee members, need to ADD a signature line on the forms for this additional member. For any given form, the students are only responsible to obtain the signatures of their committee members. The signatures from the Dean, Graduate Advisor, Practicum Coordinator or GSBS office representative will be collected internally after the student drops off the forms. All Forms are to be submitted to the Graduate Office.

Dr. Vishwanatha's and Dr. Gwartz's signatures will be collected by a representative of the Graduate Office, **after** all other required signatures have been collected by the student.

**Who signs where? (type in the names and degrees before you require processing):**

Graduate Advisor: Patricia Gwartz, Ph.D., FACC

Program Director: Patricia Gwartz, Ph.D., FACC

GSBS Approval: Carla Lee

GSBS Office: Carla Lee

Department Chair: Jamboor Vishwanatha, Ph.D.

Graduate Dean: Jamboor Vishwanatha, Ph.D.

**Forms Required:**

Pre-Internship agreement

"Master of Science-Degree Plan"

If not already submitted (before completion of 24 SCH), student brings this form to first committee meeting and obtains signatures prior to dropping the forms off in the Graduate Office.

"Master of Science- Designation of Advisory Committee"

Student brings this form to first committee meeting, collects signatures of all committee members and drops off in the Graduate Office for internal processing.

"Master of Science- Research Proposal"

Student collects all committee members' signatures, attaches approved final research proposal, and drops the documents off in the Graduate Office for internal processing.

"Declaration of Intent to Graduate"

Form to be completed and filed by student in Graduate Office after collecting required signatures. To be filed **no later than date** listed on website for semester student plans to graduate.

"Declaration of Intent to Defend"

To be completed and dropped off in Graduate Office by student, **no later than 30 days prior to actual defense date.**

"Master of Science- Report of the Final Comprehensive Examination (Defense)"

Student brings this form to the defense for Advisory Committee members to sign. Student must file this signed form with the Graduate School after the committee has assigned a Pass, Repeat or Fail grade, based on recommendation of all committee members. Student is allowed to turn in the signed form along with the other graduation materials.

“UMI Publishing Agreement”. Students completing a practicum reports, thesis or dissertation, must upload your document to UMI. You are responsible for submitting an electronic document that is EXACTLY the same as that approved by your advisory committee

“UNTHSC Electronic Document Filing Form”

Hard (paper) copy of your thesis/practicum report manuscript complete with signature page (without Dean's signature).

“Graduation Clearance Form” - requires signatures from Campus Police, ITS, Graduate Advisor, Student Financials, Office of Financial Aid.

“Degree Candidate Information Form”

“Confirmation of Survey of Graduating Students”

## PREVIOUS INTERNSHIP PRACTICUM TOPICS

The following are examples of titles from past students’ Internship Practicum Reports. Also indicated are the sites where the internship took place. Copies of these entire reports as well as the initial research proposal and others may be viewed in the Gibson D. Lewis Health Science Library or in the Graduate School.

<b>Clinical Internship Site</b>	<b>Project</b>
Department of Family Medicine, UNTHSC	A Review of DPP-IV Inhibitors in the Treatment of Type 2 Diabetes Mellitus and a Look at Patient Adherence to Overall Care Plans During and After Clinical Trials
Department of Family Medicine, UNTHSC	Implications Of Clustering On Sample Size Calculations In Randomized Controlled Trials
Department of Internal Medicine (Rheumatology), UNTHSC	Safety and Efficacy of a Novel Xanthine Oxidase/Xanthine Dehydrogenase Inhibitor in the Treatment of Gout
Department of Internal Medicine (Rheumatology), UNTHSC	A Study To Determine Improved Compliance Of Bisphosphonate Treatment In Subjects With Osteoporosis

Department of Internal Medicine (Rheumatology), UNTHSC	Financial Management And Budget Development Within Academic Clinical Research: Identifying Critical Needs And Creating Useful Tools For Clinical Trial Negotiations
Department of Internal Medicine (Rheumatology), UNTHSC	Analyzing The Scientific Debate Of Coxibs And The Ethics Impact Of Vioxx's Withdrawal On Drug Regulation And An Ongoing Phase Iii Clinical Trial With A New Cox-2 Inhibitor
Department of Internal Medicine (Geriatrics), UNTHSC	Using a Database to Facilitate the Accrual of Geriatric Subjects with Dementia for Clinical Research Studies
Department of Internal Medicine (Geriatrics), UNTHSC	Analysis Of Effective Subject Retention Methods In An Alzheimer Disease Clinical Trial And Evaluating The Preference Of Caregivers And Subjects Towards Taking Alzheimer Medication Daily At Home Versus In A Clinic On A Timed Schedule
Department of Internal Medicine (Geriatrics), UNTHSC	A Retrospective Medication Chart Review of Patients Clinically Diagnosed With Alzheimer's Disease, Vascular Dementia and Mild Cognitive Impairment Disease Patients
Department of Internal Medicine (Geriatrics), UNTHSC	Level Of Understanding Of Participation In A Clinical Trial By Alzheimer's Subjects And Its Correlation To Their Neuropsychological Test Scores: A Pilot Study
Department of Internal Medicine (Diabetes), UNTHSC	Analysis Of Recruitment Methods To Understand Efficient Enrollment Into A Study Which Is Attempting To Discover A New Risk Factor For The Preventive Treatment Of Cardiovascular Disease With Rosuvastatin
Department of Surgery, UNTHSC	A Specimen Acquisition Trial for Assessment of Human Antibody Response to Urolinase in Subjects Treated for Acute Lower Extremity Ischemia
Department of Surgery; UNTHSC	Implementation of a Pain Management Protocol in Abdominal Surgery Patients Involving an Investigational Fentanyl Patient-Controlled Transdermal System---Issues Involving Patient Enrollment
Department of Surgery; UNTHSC	A Phase II Clinical Study to Evaluate The Efficacy and Safety of rhThrombin in Subjects Undergoing Arterial Bypass Surgery and AV Graft Formation for Hemodialysis
Department of Surgery; UNTHSC	Compare and Contrast Traditional (Paper) and New (Electronic) Clinical Data Collection Systems-Perspective of the Investigative Site
Department of Surgery; UNTHSC	Gaining New Insights on Improving the Current System of Institutional Review Boards Research Site Interaction: A Novel Approach
Dept.OMM UNTHSC	Implications Of Demographics On Perceived Treatment Options
Dept.OMM UNTHSC	A Standardized Protocol for Emerging Hypertension among Subjects of a Randomized Controlled Trial of

	OMT/UPT for Chronic Low Back Pain
UNTHSC, Office of Human Subject Protection	Getting Lost In Translation: The Dangers Of Literal Translations In The Informed Consent Process.
UNTHSC, Office of Human Subject Protection	The State of IRB Staff in America
Texas Cancer Care (The Center for Cancer and Blood Disorders)	Pilot Study to Determine the Effects of Marinol on Hot Flash Relief in Breast Cancer Patients
Texas Cancer Care (The Center for Cancer and Blood Disorders)	Gender Differences in Hemoglobin Level at the Onset of Symptoms of Cancer-Related Anemia
Texas Cancer Care (The Center for Cancer and Blood Disorders)	Medicare 2005 Demonstration Project: Patient Reporting of Nausea and Vomiting symptoms and Its Impact on Improving Quality of Patient Care
Texas Oncology	Determining the Validity to Qualitatively Standardize the Conceptualization and Measurement of Cancer-Related Fatigue through Patient Documentation
TREI	Misscare Nursing Survey: A Secondary Data Analysis
TREI	Structure and Function of an Interdisciplinary Research Committee at a Hospital-Based Non-Academic Institution
CRSTI	Factors Responsible For Loss To Follow Up In A Longitudinal Study Comparing Coronary Artery Bypass Surgery And Percutaneous Coronary Intervention
Baylor Research Institute, Dallas, TX	Electronic Management of Multi-Site Clinical Research: Identifying and Overcoming Obstacles in the Uses of Clinical Trial Management
Baylor Research Institute, Dallas, TX	A Review of Dendritic Cell Vaccines in Cancer Treatment With An Analysis of Issues Related to Subject Enrollment in a Clinical Research Trial
Baylor Research Institute, Dallas, TX	Evaluation Of The Systematic Clinical Trials Protocol Approval Process At A Matrix Cancer Center
Baylor All Saints Research Institute, Fort Worth, TX	The Role of Patient Education in the Patient's Familiarity and Understanding of Treatment
Baylor All Saints Research Institute, Fort Worth, TX	An Analysis Of Subject Recruitment Issues For An HCV Investigational Drug Clinical Trial
Baylor All Saints Research Institute, Fort Worth, TX	The Role of Patient Education in the Patient's Familiarity and Understanding of Treatment
Baylor All Saints Research Institute, Fort Worth, TX	Analysis Of The Informed Consent Process In Pancreatic Islet Cell Transplantation
Baylor, Plano	Managing a Multicenter Clinical Research Study: The CABANA Trial: Catheter Ablation Versus Drug Therapy for the Treatment of Atrial Fibrillation
Baylor, Plano	Bone Marrow Aspirate vs. Bone Morphogenetic Protein (rhBMP-2) in Multilevel Adult Spinal Deformity Surgery

	and the Feasibility of Using Adult Mesenchymal Stem Cells.
Baylor, Plano	Comparing Site Management Of A Nih Versus Industry Sponsored Study: Ctsn (Surgical Interventions For Moderate Ischemic Mitral Regurgitation) Trial Versus Deep (Dual Epicardial Endocardial Protocol For Persistent And Longstanding Atrial Fibrillation) Trial
Tarrant County Health Department; Turberculosis Control Clinic, Fort Worth, TX	Evaluation of a New Blood Test for Tuberculosis Diagnosis
Tarrant County Health Department; Turberculosis Control Clinic, Fort Worth, TX	A Study of the Effectiveness and Tolerability of Weekly Rifapentine/Isoniazid for three months versus daily isoniazid for nine months for the treatment of Latent Tuberculosis Infection
UT Southwestern	Identifying And Overcoming Barriers In Clinical Research Management: A Review Of Clinical Trials Within An Academic Medical Center
Texas Health Resources; TREI	Evaluation Of The Temporal Artery Thermometry To Assess Accuracy When Compared With Body Core Temperature In The Operative Environment
USOncology	Design and Implementation of a Phase 1 Study of Curcumin in Multiple Myeloma (MM) and Monoclonal Gammopathy of Undetermined Significance (MGUS)
Mary Kay	Evaluation Of Sensitive Skin In The Asian Population
Reata Pharmaceutical	Industry Perspective On Clinical Investigative Sites: Maximizing Sponsor Return On Investment
Texas Pulmonary & Critical Care	Factors Affecting Referrals from Primary Care Physicians to Clinical Research Trials
Alcon Research, Ltd., Fort Worth, TX	Use of Prostaglandin Analogues (PGAS) in the Treatment of Patients with Open-Angle Glaucoma (OAG) or Ocular Hypertension (OHT)
Alcon Research, Ltd., Fort Worth, TX	Electronic Data Capture (EDC) Approach vs. Paper-Data Approach to Data Management
Alcon Research, Ltd., Fort Worth, TX	Development of a Subjective Comfort Questionnaire for Hydrogel Contact Lens Wearers
Alcon Research, Ltd., Fort Worth, TX	Ergonomic Efficiency Field Evaluation of the C-03-35 Intraocular Lens Delivery System
MedTrials, Inc., Dallas, TX	Long Term Compliance and Withdrawal Rates in Gynecologic Oncology Clinical Research Studies
MedTrials, Inc., Dallas, TX	Analysis of Regulatory Document Management in a Contract Research Organization Setting
MedTrials, Inc., Dallas, TX	Project Management in View of Increasing Sponsor

	Demands
MedTrials, Inc., Dallas, TX	Adverse Event Capturing and coding Using the Medical Dictionary for Regulatory Activities (MedDRA)
MedTrials, Inc., Dallas, TX	Refining a CRO's Standard Operating Procedures Through the Review and Analysis of FDA Warning Letters and Industry Literature
MedTrials, Inc., Dallas, TX	Developing a Strategic Approach to Drive Training Excellence for Clinical Research Professionals
Galderma, Fort Worth, TX	Presentation of Sample Case Studies from a Phase 4 Clinical Trial, "Community-Based Research Assessment Investigating Clobetasol Propionate 0.05% Spray for the Treatment of Chronic Plaque Psoriasis - The COBRA Study"