MASTER OF SCIENCE IN CLINICAL AND TRANSLATIONAL SCIENCE

University of Oklahoma Health Sciences Center
Graduate College
Program Director: Dean Anne Pereira
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EXECUTIVE SUMMARY

To complement the mission and research strategic plan of the University of Oklahoma Health Sciences Center (OUHSC), to address the regional and national need for additional independent clinical and translational research investigators, and to satisfy the training requirements of the National Institutes of Health’s (NIH) Clinical and Translational Science Award (CTSA) mechanism, we propose the creation of a Master of Science program in Clinical and Translational Science. The program will be directed through the OUHSC Graduate College. The goal of the interdisciplinary program is to prepare health professionals to become competent in the methodological foundations and conduct of clinical and translational research. The target audience includes junior faculty, residents, and fellows with a professional doctoral degree, including, but not limited to, an M.D., D.D.S., Pharm.D., Doctorate of Nursing, Doctorate of Physical Therapy, or Doctorate of Rehabilitation, who are interested in becoming productive, independent clinical and translational research investigators.

The curriculum consists of didactic study, an experiential practicum, and a mentored research project to be completed over 6 semesters. Program requirements result in a total of 33 credit hours, including 18 core course credit hours (7 courses), 6 elective credit hours (2 courses), and 9 research credit hours. Participants will develop competencies related to principles of qualitative research methods, quantitative research methods, clinical and translational research process and design, informatics, effective oral and written communication, human research ethics and responsible conduct of research, cultural competency, research management, and professionalism and career development.

Oversight of the curriculum occurs by an Executive Committee and an Advisory Committee. The effectiveness of the program will be assessed by an interim evaluation by an independent Board of Visitors and by long-term prospective evaluation based on 12 outcome measures defined a priori.
Program Goal

The goal of the Master of Science degree program in Clinical and Translational Science is to prepare health professionals to become competent in the methodological foundations and conduct of clinical and translational research.

Target Audience

The target audience includes junior faculty, residents, and fellows with a professional doctoral degree, including, but not limited to, an M.D., D.D.S., Pharm.D., Doctorate of Nursing, Doctorate of Physical Therapy, or Doctorate of Rehabilitation, who are interested in becoming productive, independent clinical and translational research investigators.

Program Competencies

Through the proposed curriculum, students will be exposed to and will gain expertise in the following competencies, developed with input from the Clinical and Translational Science MS Program Executive Committee and with reference to existing competencies in related areas and published articles discussing clinical and translational research [1-7].

Qualitative Analysis

• Describe appropriate use and limitations of qualitative data
• Implement appropriate methods for qualitative data sampling
• Utilize appropriate methods for framing queries and defining contexts for qualitative data collection
• Code and interpret qualitative data, with special attention to textual and discourse analysis approaches
• Perform qualitative analyses to identify patterns, themes, and other underlying structures in qualitative data
• Make appropriate inferences from qualitative data
• Use qualitative analyses to construct closed-end quantitative instruments or to frame hypotheses for quantitative investigation

Quantitative Analysis

• Calculate basic epidemiologic measures including prevalence, incidence, and relative or absolute measures of risk, as well as diagnostic test properties including sensitivity, specificity, positive predictive value and negative predictive value and measures of reliability
• Distinguish among different measurement scales (for example, continuous or categorical scales)
• Apply descriptive techniques commonly used to summarize health data
• Describe basic concepts of uncertainty, probability, random variation and commonly used statistical probability distributions
• Identify common statistical methods for estimation and inference including univariate and multivariate methods appropriate for continuous, categorical and time to event data that are appropriate relative to study design
• Utilize software packages for data management and statistical and epidemiologic analyses
• Describe preferred methodological alternatives to commonly used statistical methods when assumptions are not met, such as non-parametric methods
• Make appropriate inferences from quantitative data

Clinical and Translational Research Process
• Explain principles of the scientific method
• Define null and alternative hypotheses as well as specific aims and explicit research questions
• Define clinical research
• Define translational research
• Identify multi- and inter-disciplinary areas of expertise relevant to a particular hypothesis under investigation
• Demonstrate relevant laboratory research skills and identify relevant basic research technologies
• Utilize basic science research findings to inform the design and conduct of clinical research studies
• Describe process of clinical guideline development, including methods of meta-analysis and systematic reviews
• Identify principles of design and conduct for studies investigating the dissemination and implementation of clinical research findings in clinical practice and community settings

Clinical and Translational Research Design
• Identify an appropriate study design, including experiments, cohort studies, case-control studies, cross-sectional surveys, therapeutic or intervention studies including randomized controlled clinical trials, and field or community trials to test the hypothesis and address the specific aims and research questions
• Identify strengths and weaknesses of different types of study designs
• Identify a relevant study population and develop a sampling plan that addresses concerns of bias, confounding factors, generalizability, and variability
• Develop and test data collection instruments, including questionnaires, medical and other record abstraction, surveys, and data coding.
• Apply epidemiologic principles in health research design
• Appropriately apply concepts in the design and conduct of a clinical trial including comparison group definition and selection, need for and processes of randomization,
endpoint definition, intent-to-treat analysis, sample size justification, adherence, longitudinal follow-up, interim monitoring, and non-inferiority and equivalence hypotheses

Informatics
- Implement principles of database design, management, and storage to ensure high quality, accurate, and secure data
- Merge and extract electronic data files from multiple clinical sources, including medical records, procedure code files, and pharmacy records
- Design and implement patient registry studies
- Compare and contrast informatics requirements for clinical visits, such as scheduling and invoicing, to requirements for research conduct, including data capture and report generation
- Identify principles of web-based data capture to ensure high quality, accurate data
- Access and analyze major US and international health databases and information resources

Oral and Written Communication
- Effectively present study results using appropriate tables and figures
- Effectively present accurate scientific information for professional and lay audiences through written and oral communications, including seminars and lectures
- Prepare and publish high-quality, peer-reviewed manuscripts
- Prepare and submit intramural and extramural grant applications
- Conduct scientific critique of manuscripts and grant applications

Human Research Ethics and Responsible Conduct of Research
- Practice principles of responsible conduct in research including principles related to publication and responsible authorship; data acquisition, management, sharing, and ownership; research misconduct; conflict of interest; and compliance with PHS and institutional policies
- Follow ethical principles in conducting human subjects and animal research
- Discuss basic ethical and legal principles pertaining to the collection, maintenance, use and dissemination of protected health information including principles outlined in the Health Insurance Portability and Accountability Act (HIPAA)

Cultural Competence
- Implement appropriate methods for identifying relevant cultural contexts to be explored
- Develop frameworks for investigating cultural contexts other than your own
- Use ethnographic methods in collecting culturally-specific data
- Apply interpretive analytic frameworks in analyzing culturally-specific ethnographic data
- Make appropriate health-relevant inferences from culturally-specific ethnographic data
• Apply those health-relevant inferences to clinical and/or translational research problems

Research Management
• Apply basic human relation skills to the management of research teams, motivation of personnel, and resolution of conflicts
• Ensure proper training of research staff in the conduct of the planned study and in the responsible conduct of research
• Apply financial and management processes including proposing budget priorities, developing and implementing budget proposals within the constraints of available resources
• Identify and adhere to regulatory guidelines regarding research
• Access funding information and resources available through various intramural and extramural funding agencies
• Develop a research protocol and manual of operations

Professionalism and Career Development
• Define mentoring and implement the giving and receiving of mentoring in the professional setting
• Apply principles of effective time management
• Identify benefits of and process for establishing professional networks
• Identify the value of professional service including active participation in professional organizations and participation in the peer-review of manuscripts and funding applications
• Utilizes a variety of methods of self assessment for professional growth and career development
• Balance demands of academic research positions including clinical service, teaching, research, and professional service and administration
• Discuss the role of a mentor and multi-disciplinary mentoring committee and the process of building effective mentoring relationships
Overview

Curriculum development began by comparing the list of program competencies to the learning objectives of existing OUHSC and OU Norman courses and workshops. In addition to existing courses and workshops, 3 new courses, 1 practicum and Research for Master’s Thesis in Clinical and Translational Science will be developed in order to address the list of program competencies. The new courses and practicum are:

- CTS 5112 Grants Management
- CTS 5133 Foundations of Translational Research
- CTS 5143 Foundations of Clinical Research
- CTS 5231 Practicum in Cross-cultural Research
- CTS 5980 Research for Master’s Thesis

Required credit hours are summarized on page 11 and include 7 required core courses (18 credit hours), 2 elective courses (6 credit hours), and 9 credit hours of research. Required workshops are listed on page 12. Also, students are required to write a research prospectus in a grant proposal format. This prospectus should be completed by the end of their first summer semester and will be approved by their thesis committee. Finally, students are required to write and orally defend a thesis. A sample program of study is given on page 11.

A summary of the required courses is given in Appendix I.
Credit Hours

Core Course Requirements: 7 courses (18 credit hours) (new courses are identified with an *)

(3 credit hours) * CTS 5143 Foundations of Clinical Research
(3 credit hours) * CTS 5133 Foundations of Translational Research
(3 credit hours) BSE 5013 Application of Microcomputers to Data Analysis (SAS)

Note: Students who plan to take a second biostatistics course as an elective should table BSE 5013 Application of Microcomputers to Data Analysis (SAS). Students who will not take a second biostatistics course may take BSE 5023 Computer Applications in Public Health.

(3 credit hours) BSE 5113 Principles of Epidemiology
(3 credit hours) BSE 5163 Biostatistics Methods I
(1 credit hour) * CTS 5231 Practicum in Cross-cultural Research
(2 credit hour) * CTS 5112 Grants Management

Electives: 2 courses (6 credit hours)

- Any Graduate College approved course offered in OU system approved by the academic advisor may be taken as an elective.

- Students are strongly encouraged to take a second biostatistics course that covers the analysis of multiple factors through regression or analysis of variance (or related non-parametric) methodology:

  BSE 5643 Regression Analysis  BSE 6643 Survival Data Analysis
  BSE 5653 Non-Parametric Methods  BSE 6663 Analysis of Multivariate Data
  BSE 5663 Analysis of Frequency Data  BSE 5173 Biostatistical Methods II

- Additional suggested elective courses are:

  PATH 6053 Mechanisms of Disease  OCTH 7422 Information Management I
  PATH 6024 Principles of Pathobiology  HAP 5873 Health Information Systems
  BSE 5153 Clinical Trials  MI 6401 Bioinformatics – Applications
  HPS 6933 Qualitative Research in Public Health  RADI 5403 Intro to Clinical Biomedical Informatics for the
  NURS 6213 Qualitative Methods in Research  Quantitative Scientists
  OU COMM G5313 Qualitative Research Methods  RADI 5413 Intro to Clinical Biomedical Informatics for
  PHSC 6002 Pharmacogenomics  Biological Scientists
  PATH 6043 Care and Use of Research  BSE 5193 Intermediate Epidemiologic Methods
  Animals

Research Hours: (9 credit hours) CTS 5980 Research for Master’s Thesis
Total Degree Hours: 33 credit hours

Additional Requirements

Required Workshops
Workshops and online short courses related to the following areas are also required.

- Informatics: OUHSC Bird Library Lunch and Learn (selected topics)
- Oral and Written Communication: OUHSC Graduate Research Education and Technology Symposium: Scientific Writing (1 hour), Oral Presentation Skills (1 hour), Poster Presentation Skills (1 hour)
- Human Research Ethics and Responsible Conduct of Research:
  - CITI Online Training: Human Subjects Research
  - On-line IACUC Training (not applicable to all students)
  - OUHSC IRB In-house Workshop
  - OUHSC IRB-sponsored seminar series
    - Professional codes
    - Conflict of interest
    - Regulatory applications
  - CITI Online Training: Responsible Conduct of Research for Biomedical Sciences (a component of the Topics in Research Management course)
- Professionalism and Career Development:
  - OUHSC Faculty Leadership Program
  - OUHSC Faculty Development and Interdisciplinary Programs Workshops
    - Aligning Career Goals
    - Academic Advancement

Research Prospectus

Students are required to write a research prospectus in a research grant proposal format, which will provide an opportunity for students to apply program competencies to their field of interest and will serve as a guide for their thesis research project. Students will receive guidance and feedback from their research committee on effective grant writing and written communication. The research prospectus should be completed by the end of the first summer semester and must be approved by their thesis committee. A summary of the research prospectus will be orally defended by the student.

Mentored Research Project
Students are required to write a thesis on an area of original clinical or translational research under the supervision of a designated faculty mentor and thesis committee. This project will involve 9 credit hours of mentored research. The goal of the project is to generate preliminary data needed for the K23 or K08 grant proposal prepared through the writing and defending of a Masters Thesis. The student will choose a research topic, which will be approved by the student’s graduate committee. The research project will involve literature review, development of an original hypothesis and specific aims to test the hypothesis of interest, research design, data collection and analysis, and written and oral summaries of the research findings. Though program completion is not contingent on the submission of research findings to a professional organization or academic journal, this will be encouraged, as peer-reviewed publication is a critical element in academic success.

Example Plan of Study

<table>
<thead>
<tr>
<th>Semester</th>
<th>Course</th>
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<tbody>
<tr>
<td>Fall</td>
<td>Foundations of Clinical Research</td>
<td>3</td>
<td>App of Computers in Analysis</td>
<td>3</td>
<td>Grants Management</td>
<td>2</td>
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<tr>
<td>Spring</td>
<td>Biostat Methods I</td>
<td>3</td>
<td>Foundations of Translational Research</td>
<td>3</td>
<td>Research (complete research prospectus)</td>
<td>3</td>
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<td></td>
<td>Principles of Epi</td>
<td>3</td>
<td>Elective</td>
<td>3</td>
<td></td>
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<tr>
<td>Year 1</td>
<td>Elective</td>
<td>3</td>
<td>Cultural Practicum</td>
<td>1</td>
<td>Research</td>
<td>2</td>
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<tr>
<td>Year 2</td>
<td>Research</td>
<td>2</td>
<td>Research</td>
<td>2</td>
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Alternate plans of study are given in Appendix II.

New Course Development

The following table lists the faculty members who will develop and direct the new courses.

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<thead>
<tr>
<th>Course</th>
<th>Lead Faculty</th>
<th>Semester</th>
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<tr>
<td>Foundations of Clinical Research</td>
<td>Julie Stoner, Associate Professor</td>
<td>Fall (beginning 2009)</td>
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<td></td>
<td>Toby Hamilton, Assistant Professor</td>
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<tr>
<td>Foundations of Translational Research</td>
<td>Michael Burton, Professor</td>
<td>Spring (beginning 2010)</td>
</tr>
<tr>
<td>Practicum in Cross-cultural Research</td>
<td>Lancer Stephens, Assistant Professor</td>
<td>Fall (beginning 2010)</td>
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<tr>
<td>Grants Management</td>
<td>Morris Foster, Professor</td>
<td>Summer (beginning 2010)</td>
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Accreditation or Certification Standards

Currently, there are no established accreditation or certification standards related to programs in clinical and translational research.

Summary

The following table summarizes the relation between program competency domains and curricular requirements. The program provides content and experiential learning opportunities in each of the competency domains and is therefore expected to achieve the program goal of preparing health professionals to become competent in the methodological foundations and conduct of clinical and translational research. The program will be evaluated relative to the program goal and competencies as described in the Program Review and Assessment section of this document.

<table>
<thead>
<tr>
<th>Competency Domain</th>
<th>Curricular Component</th>
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<tbody>
<tr>
<td>Qualitative Analysis</td>
<td>• Foundations of Clinical Research</td>
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<td></td>
<td>• Practicum in Cross-cultural Research</td>
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<td></td>
<td>• Research Prospectus</td>
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<td></td>
<td>• Mentored Research Project</td>
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<tr>
<td>Quantitative Analysis</td>
<td>• Biostatistical Methods I</td>
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<td></td>
<td>• Computing Course</td>
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<td></td>
<td>• Principles of Epidemiology</td>
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<td>• Research Prospectus</td>
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<td>• Mentored Research Project</td>
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<tr>
<td>Clinical and Translational Research Process and Design</td>
<td>• Foundations of Clinical Research</td>
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<td></td>
<td>• Foundations of Translational Research</td>
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<td></td>
<td>• Principles of Epidemiology</td>
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<td>• Research Prospectus</td>
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<td>• Mentored Research Project</td>
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<tr>
<td>Informatics</td>
<td>• Foundations of Clinical Research</td>
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<td></td>
<td>• Foundations of Translational Research</td>
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<td></td>
<td>• Computing Course</td>
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<td>• Library Workshops</td>
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<td>• Research Prospectus</td>
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<td>• Mentored Research Project</td>
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<tr>
<td>Oral and Written Communication</td>
<td>• All Courses</td>
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<td>• GREAT Symposium</td>
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<td>• Research Prospectus</td>
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<td>• Mentored Research Project</td>
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<tr>
<td>Human Research Ethics and Responsible Conduct of Research</td>
<td>• CITI, IACUC and IRB training</td>
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<td>• Grants Management</td>
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<td></td>
<td>• Research Prospectus</td>
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<td>• Mentored Research Project</td>
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<tr>
<td>Cultural Competence</td>
<td>• Practicum in Cross-cultural Research</td>
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<td>• Research Prospectus</td>
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<td>• Mentored Research Project</td>
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<tr>
<td>Research Management</td>
<td>• Grants Management</td>
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<tr>
<td>Professionalism and Career Development</td>
<td>• Professional Development and Leadership Workshops</td>
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<td></td>
<td>• Research Prospectus</td>
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<td></td>
<td>• Mentored Research Project</td>
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ACADEMIC STANDARDS

Graduate Research Committee

Each student will have a Graduate Committee consisting of at least four Graduate Faculty members. Three of the faculty members on each committee will be Graduate Faculty members in the Clinical and Translational Science program. The remaining member of the graduate committee will be chosen by the student with concurrence by those faculty members and the approval of the Program Director and should have expertise in the student’s chosen area of specialty. The Chair of the Graduate Committee must be a Graduate Faculty member of the Clinical and Translational Science program and will be the primary mentor for the research project. The Chair must be identified prior to program admission. The remaining three members of the graduate committee must be identified by the end of the second semester. At least two of the members must have had prior experience serving on or chairing a graduate MS thesis or PhD dissertation committee and at least two of the members must be from departments other than the home department of the Chair. Students are strongly encouraged to include a faculty member with expertise in research design methods, either quantitative methods such as biostatistics or epidemiology, or qualitative research methods, as appropriate for the proposed thesis research project.

Core Clinical and Translational Science program faculty are listed in Appendix III.

MS in CTS Executive Committee

The Executive Committee will meet quarterly to review progress on implementation and conduct of the curriculum, to address any problems or issues that arise, to review the progress of all participants, and to determine annual program admission.

Members of this committee include:

James Tomasek, Ph.D., Professor, College of Medicine; Dean of the Graduate School
Doris Benbrook, Ph.D., Professor, College of Medicine
Michael Burton, Pharm. D., Professor, College of Pharmacy
Linda Cowan, Ph.D., Professor, College of Public Health
Carol Dionne, PT, PhD, OCS, Cert MDT, Assistant Professor, College of Allied Health
John Dmytryk, D.M.D., Ph.D., Associate Dean for Research, Professor, College of Dentistry
Kathleen Dwyer, Ph.D., R.N., Professor, College of Nursing
Morris Foster, Ph.D., Professor, OU Norman, College of Arts and Sciences
Mark D. Fox, MD, PhD, MPH, Associate Dean for Community Health and Research Development, College of Medicine, Tulsa
James George, M.D., Professor, College of Medicine, College of Public Health
Gene Hallford, M.A., A.B.D, College of Medicine
Judith James, M.D., Ph.D., Professor, Oklahoma Medical Research Foundation, College of Medicine
John Mulvihill, M.D., Professor, College of Medicine
Lester Reinke, Ph.D., Professor, College of Pharmacy
Julie Stoner, Ph.D., Associate Professor, College of Public Health, College of Medicine
Sara Vesely, Ph.D., Associate Professor, College of Public Health
MS in CTS Advisory Committee

The Advisory Committee will meet monthly and will include senior faculty with broad multidisciplinary representation who have an excellent track record of success in clinical and translational research and extensive experience as mentors, as well as a portfolio of ongoing funded projects to support research training and mentoring. Members of the Advisory Committee will review the content and progress of the curriculum, will review progress of the students, and will make recommendations for any necessary revisions to the curriculum or changes in its process or content. This committee will review applicants for the program and make recommendations for acceptance to the Executive Committee. They will also serve as advisors for the participants until they select a mentor and thesis committee.

The members of this Advisory Committee must be Graduate Faculty members in the Clinical and Translational Science program and must have at least the authority to chair Masters Thesis committees as determined by the Graduate Faculty Appointment Committee of the Graduate Council. One member from each of the six participating professional Colleges will serve on the Advisory committee. Members of the Advisory Committee will be appointed by the CTS Executive Committee.

Members of this committee include:

- Graduate College: Julie Stoner, Ph.D. (Liaison)
- College of Medicine: Doug Drevets, M.D.
- College of Allied Health: Carol Dionne, P.T., Ph.D., O.C.S., Cert. M.D.T.
- College of Nursing: Kathleen Dwyer, Ph.D., R.N.,
- College of Dentistry: John Dmytryk, D.M.D., Ph.D.,
- College of Pharmacy: Lester Reinke, Ph.D.
- College of Public Health: Sara Vesely, Ph.D.

Recruitment

Students will be recruited from colleges and institutions across the OUHSC campus, public and private universities in Oklahoma and from other states. Students who are interested in the program will initially be referred to the program staff support member, Nicole Yi-Wohlers, MS, for general program information. Ms. Yi-Wohlers will then refer students to Dr. Julie Stoner, Liaison to the Dean for the MS in CTS program. Dr. Stoner will provide additional information about the program and admission requirements. Interested students who have not identified a research mentor will be referred to a member of the MS in CTS Advisory Committee, depending on the student’s area of interest, who will work with the applicant to identify a potential mentor and corresponding departmental chair, whose support is necessary for program admission. This process will help
to facilitate recruitment and admission of students who are not currently working or engaged in research at OUHSC.

**Admission Application**

**Application Material:**

Individuals applying for acceptance into the Master of Science program in Clinical and Translational Science will possess a wide variety of educational and work-related backgrounds, but must possess a professional doctoral degree.

Required application materials include:

1. OUHSC Admission Application form
2. Official Transcripts from all universities attended
3. Current curriculum vitae or resume
4. Three letters of reference
   - One letter of reference must be from the proposed primary research mentor and should address the mentor's commitment to the planned research project, including funding if available
   - One letter of reference must be from the applicant's program director, department chair, or current employer ensuring sufficient, dedicated time necessary to successfully complete the degree program, including continued salary support and time off for didactic course work (course work up to 9 clock hours per week during normal business hours or other agreed upon limit plus additional time for research)
   - One letter of reference may be from any individual who is familiar with the applicant's academic and professional experience and can comment on the applicant's qualifications, character, and ability to successfully complete the degree program
5. A one-page typed (single-spaced, 12 point font with 1 inch margins) personal summary describing:
   - The applicant's interest, background, and experience in clinical and translational research that qualifies the applicant to successfully complete the program and to be successful in clinical and/or translational research
   - Career goals related to clinical and translational research, indicating how the MS in CTS program will help the candidate meet the career goals
6. A one-page (single-spaced, 12 point font with 1 inch margins) research summary briefly describing:

- The planned research project including the research objectives and a general summary of the project. If possible, the hypotheses to be tested, specific aims, background and significance, and research study design could instead be included. The research summary should be based on discussions of the research project with the research mentor but should reflect the student's writing and understanding of the proposed project.

- A brief discussion of how the proposed project supports career goals

- Identification of a primary research mentor

Note: the Graduate College will waive the requirement for these students to take the Graduate Record Examination for admission to this program.

International Applicants (including Non-Native Citizens of the United States):

- Any international applicant who has not been accepted into a residency program at a regionally accredited U.S. medical school AND does not have an undergraduate or master's degree from a regionally accredited U.S. school is required to have a minimum score of 570 on the Test of English as a Foreign Language (TOEFL) paper test, a minimum TOEFL score of 230 on the computerized version, or a minimum score of 88 on the iBT version. The student must take the test within the two years immediately preceding the semester of admission; an original score report is required.

- Formal admission requires that international transcripts be reviewed by World Education Services (WES). The Advisory Committee will evaluate applications and make an admission decision without WES; applicants provisionally accepted in this manner will then be required to complete the WES evaluation.

- Any international applicant who is a resident alien should submit a copy of the resident alien card along with the application for admission.

Application Review

Based on a review of the applications received, the Advisory Committee will choose the most qualified applicants for personal interviews. Applicants selected for interviews will meet with members of the Advisory Committee. The Advisory Committee will discuss each prospective student in regard to their application materials and interview to identify applicants most likely to successfully complete
the program. Admission recommendations will be submitted to the MS in CTS Executive Committee for their final approval.

Fall admission is preferred. Applications are due May 1 for August (fall) program admission. Spring admissions will be considered on a case-by-case basis. Applications are due September 1 for January (spring) admissions. Summer admissions will not be considered.

Final permission for your admittance into the CTS program rests with the Dean of the Graduate College.

Minority Student Recruitment

An effort will be made to recruit minority students into the emerging profession of Clinical and Translational Science. The number of minority students accepted will depend on applicants and their qualifications, although it is hoped that at least 20% of each year's cohort will belong to a minority population.

Retention

Consistent with Graduate College policy, students must maintain a 3.0 cumulative GPA. Any student who falls below this standard will be placed on academic probation and counseled by his or her committee chairperson and the Program Director. The student will also be referred to the Advisory Committee to determine what additional assistance can and should be offered to the student. Remediative coursework and/or special instruction may be offered to assist the student in achieving the required academic standard required by the program and the Graduate College. Students with a cumulative GPA less than 3.0 for 2 consecutive semesters will be discontinued from the program.

Graduation Standards

Students must complete at least 24 hours of didactic coursework, 9 hours of Masters Thesis Research, and defend their thesis research. All students must meet the standards of the OUHSC Graduate College to graduate as defined in the Graduate College Bulletin.

THE FACULTY

The MS in Clinical and Translational Science program is an interdisciplinary degree granting program. Faculty participating in this program must have a primary appointment in one of the health professional colleges at OUHSC. Faculty wishing to participate in the program must be approved initially by the Advisory and Executive Committees and subsequently be approved by the Graduate Faculty Appointment Committee following the guidelines of the OUHSC
Faculty approved to chair MS thesis committee must demonstrate research activity according to OUHSC Graduate College guidelines and must have documented resources, funding, space, and support. There are currently more than 50 faculty who have been approved to participate in the MS in CTS program all of who could potentially chair a MS thesis committee for a student in this program. Core faculty are listed in Appendix III.

REFERENCES

Appendix I: Required Core Course Descriptions

* CTS 5143 Foundations of Clinical Research (3 hrs)

This course will provide an overview of qualitative research methods, observational clinical research methods, and clinical trials methods. Topics in clinical research informatics also will be covered with an aim to raise awareness of informatics tools to implement research projects and manage data, as well as common pitfalls.

CTS 5143 Foundations of Clinical Research will include learning objectives that cover the following competencies:

Informatics:
- Apply principles of database design, implementation, management, and storage to ensure high quality, accurate, and secure data
- Merge and extract electronic data files from multiple clinical sources, including medical records, procedure code files, and pharmacy records
- Discuss principles of patient registry design and implementation
- Compare and contrast informatics requirements for clinical visits, such as scheduling and invoicing, to requirements for research conduct, including data capture and report generation
- Identify principles of web-based data capture to ensure high quality, accurate data
- Access and analyze major US and international health databases and information resources

Qualitative Research:
- Describe appropriate use and limitations of qualitative data
- Implement appropriate methods for qualitative data sampling
- Utilize appropriate methods for framing queries and defining contexts for qualitative data collection
- Code and interpret qualitative data, with special attention to textual and discourse analysis approaches
- Perform qualitative analyses to identify patterns, themes, and other underlying structures in qualitative data
- Make appropriate inferences from qualitative data
- Use qualitative analyses to construct closed-end quantitative instruments or to frame hypotheses for quantitative investigation

Clinical Research Design Including Clinical Trial Design:
- Explain principles of the scientific method
- Define null and alternative hypotheses as well as specific aims and explicit research questions
- Define clinical research
- Utilize basic science research findings to inform the design and conduct of clinical research studies
- Identify an appropriate study design, including basic science laboratory experimental studies, cohort studies, case-control studies, cross-sectional surveys, therapeutic or intervention studies including randomized controlled clinical trials, and field or community trials, and instrumentation to test the hypothesis and address the specific aims and research questions
- Identify strengths and weaknesses of different types of study designs
- Identify a relevant study population and develop a sampling plan that addresses concerns of bias, confounding factors, generalizability, and variability
- Develop and test data collection instruments, including questionnaires, medical and other record abstraction, surveys, and data coding.
- Apply epidemiologic principles in health research design
- Appropriately apply concepts in the design and conduct of a clinical trial including comparison group definition and selection, need for and processes of randomization, endpoint definition, intent-to-treat analysis, sample size justification, adherence, longitudinal follow-up, interim monitoring, and non-inferiority and equivalence hypotheses

This course will include a series of seminars and lectures focused on the above competencies. Ongoing related projects across OU campuses will be highlighted. Potential speakers and topics include the following:

- Dr. James George and Dr. Sara Vesely, College of Public Health: thrombotic thrombocytopenic purpura epidemiologic data registry
- Dr. Graca Dores, VA: SEER Data
- Dr. Johnathan Wren, OMRF: data mining
- Dr. Elgene Jacobs, College of Pharmacy: Health Care Authority data, SAS, SQL
- Karen Evans, Cancer Institute: Velos
- Dr. Kimberly Ernst, electronic medical information management

* CTS 5133 Foundations of Translational Research (3 hrs)

CTS5133 Foundations of Translational Research will include learning objectives that cover the following competencies:

- Define translational research
- Identify multi- and inter-disciplinary areas of expertise relevant to a particular hypothesis under investigation
- Demonstrate relevant laboratory research skills and identify relevant basic research technologies (will be further developed in an elective)
- Identify principles of building on basic science research findings to inform the design and conduct of clinical research studies
- Identify principles of design and conduct for studies investigating the dissemination and implementation of clinical research findings in clinical practice and community settings

The course will include a seminar/discussion session where overview seminars, and seminars highlighting ongoing clinical and translational research projects across OU campuses, are presented by faculty. Multi- and inter-disciplinary relationships will be highlighted. The course also will include an experiential component. Students will attend working group meetings of a clinical and translational research project and will write a paper describing multi- and inter-disciplinary research principles observed through the project and will discuss how these principles will be integrated into their
own research projects. Oral presentations summarizing student experiences also will be given.

**BSE5013 Application of Microcomputers to Data Analysis (3 hrs)**  Lecture  
Prerequisites: BSE 5163 or permission of the instructor. Introduction to the use of data management and processing equipment and 1 package (SAS) readily available on this campus. Storage, manipulation, and retrieval of data and statistical summaries are emphasized.

**BSE5113 Principles of Epidemiology (3 hrs)**  Lecture, Laboratory  
Prerequisites: None. This course provides an introduction to epidemiology for students majoring in any aspects of Public Health. The principles and methods of epidemiology investigation, both of infectious and non-infectious diseases are discussed.

**BSE5163 Biostatistics Methods I (3 hrs)**  Lecture, Laboratory  
Prerequisites: College algebra and ability to use computer spreadsheet or instructor permission. Fundamental concepts and applications of statistics.

* **CTS 5231: Practicum in Cross-cultural Research (1 credit hour)**

CTS5231 Practicum in Cross-cultural Research will need to include learning objectives that cover the following competencies:

- Describe appropriate methods for identifying relevant cultural contexts to be explored
- Describe frameworks for investigating cultural contexts other than your own
- Use ethnographic methods in collecting culturally-specific data
- Apply interpretive analytic frameworks in analyzing culturally-specific ethnographic data
- Make appropriate health-relevant inferences from culturally-specific ethnographic data
- Apply those health-relevant inferences to clinical and/or translational research problems

This course will provide the student an opportunity to apply knowledge and skills of clinical research in the context of an ongoing project that involves participants who have cultural backgrounds different from those of the student. Projects will vary depending on the faculty preceptors who teach the practicum each year. Each student will work with a preceptor to develop and carry out his or her own mini-study within the context of the parent project. Practicum projects should rely primarily on qualitative methods, but may have mixed-method designs.
* CTS 5112: Grants Management (2 credit hours)

CTS5980 Topics in Research Management will need to include learning objectives that cover the following competencies:

- Applies basic human relation skills to the management of research teams, motivation of personnel, and resolution of conflicts
- Ensures proper training of research staff in the conduct of the planned study and in the responsible conduct of research
- Applies financial and management processes including proposing budget priorities, developing and implementing budget proposals within the constraints of available resources
- Identifies and adheres to regulatory guidelines regarding research
- Accesses funding information and resources available through various intramural and extramural funding agencies
- Develop a research protocol and manual of operations


CTS 5980: Research for Master’s Thesis

This course will provide the student with the opportunity to assimilate didactic knowledge and apply it to the development and completion of a master’s thesis in Clinical and Translational Science.
Appendix II: Example Program Plans of Study

The following provides example plans of study for the MS in CTS program. The following criteria are met in all of the examples:

- Foundations of Clinical Research is only taught in the fall semester
- The cultural practicum is only taught in the fall semester
- Foundations of Translational research is only taught in the spring semester
- Foundations of Clinical Research must be taken before the Cultural Practicum so that students have background information regarding qualitative research methods
- The research prospectus should be written after taking Foundations of Clinical Research so that students have a background in research design
- Biostat Methods I and Principles of Epi should be taken before Application of Computers in Analysis, or instructor permission must be granted
- Students are strongly encouraged to take a second biostatistics course that covers the analysis of multiple factors through regression or analysis of variance (or related non-parametric) methodology as an elective. One of the two electives is scheduled after Biostat Methods I and Application of Computers in Analysis are scheduled.

Courses taught during normal business hours are highlighted in the attached tables.
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Appendix III: Core Faculty