

**Program Proposal Narrative
New Degree Program
Kansas Board of Regents**

Basic Program Information:

Proposing Institution: University of Kansas Medical Center
Title of proposed program: Doctorate in Clinical Laboratory Science Program
Degree to be offered: Doctorate in Clinical Laboratory Science
Anticipated date of implementation: Fall 2019
Responsible department(s) or unit(s): Department of Clinical Laboratory Sciences
Center for Education Statistics (CIP) code associated with the program: 51.1005

A. Program Need and Student Characteristics

1. Is the program central to the mission of the institution?

The University of Kansas Medical Center (KUMC), a major research institution serving the State of Kansas as well as the nation and the world, assumes leadership in knowledge discovery and the development of programs in research, education, and patient care. The KUMC Mission Statement calls for the creation of an environment for instruction that educates health care professionals through high quality educational experiences that are to be offered to a diverse student population through a full range of undergraduate, graduate, professional, postdoctoral and continuing education programs.

KUMC has embraced the goals of the Institute for Healthcare Improvement (IHI) Triple Aim. Those goals are to provide better care for individuals, achieve better outcomes for populations, and reduce per capita costs (Berwick, et al.). The clinical laboratory will play a central role in realizing these goals. Clinical laboratory scientists (CLS) generate seventy to eighty percent of the diagnostic information used by clinicians when making medical decisions (Hallworth). With the rapidly expanding laboratory test menu, there is a need for doctorally-trained clinical laboratory scientists to provide consultation to members of the healthcare team on test utilization and interpretation. This consultation will result in the reduction of unnecessary and inappropriate testing, ultimately decreasing costs.

Additionally, the patient experience will be improved by decreasing the time of diagnosis, decreasing length of stay, increasing continuity of care, and improving access to the interpretation of test results. Furthermore, new Federal requirements mandate test results be available to patients. Laboratory tests are often confusing to those without extensive training in clinical laboratory science. The DCLS will explain what the results mean and how the results relate to health, thereby improving patient education.

The mission of the CLS Department is to do more than train technical health care personnel, but also to educate clinical laboratory professionals who can meet the current and future demands of laboratory medicine. This workforce requires individuals at various levels of education including professionals with advanced degrees such as the DCLS. The proposed program will build upon our existing departmental and institutional strengths and is centrally related to the KUMC mission. This innovative program will prepare individuals to become key members of the interprofessional healthcare team needed by the State of Kansas.

References:

Berwick, D. M., et al. (2008). The triple aim: Care, health, and cost. *Health Affairs*, 27(3), 759-769.
Hallworth, M. J. (2011). The '70% claim': What is the evidence base? *Annals of clinical biochemistry*, 48(6), 487-488.

2. What is the student demand for the program?

Clinical laboratorians are a crucial component of the health care team, and, as described below, there is a current and expanding demand for individuals with specialized training in clinical laboratory science. In 2008, a survey of 299 randomly chosen CLS's indicated that 65% were interested in pursuing a DCLS (Doig & Beck). In 2009, a similar survey was conducted nationally. Out of 1,452 respondents, 61% indicated an interest in pursuing a DCLS with 23% of them indicating a desire to start a program as soon as possible (Nadder). According to the US Bureau of Labor Statistics in May of 2015, there were 163,000

CLS's employed in the US (Bureau of Labor Statistics). This represents an unmet demand of 37,000 individuals who have a desire to start a DCLS program.

Additionally, approximately 3,200 individuals receive MLS(ASCP) certification annually, of which 740 are likely to seek a DCLS degree. There has been strong interest in the program during discussions of our DCLS initiative at statewide and regional meetings, reflecting the trend seen nationally. Graduates of our undergraduate CLS program continually inquire about advanced degree options including the DCLS. Implementing this program will address the growing student demand for doctoral-level training in CLS and therefore meet an unmet demand in the state of Kansas, the Midwest, and nationwide.

The projected annual income for an entry-level DCLS is \$100,000 (based on entry-level salary for professionals of equivalent education, training, and responsibility). Additionally, a DCLS could serve as laboratory director (annual base salary, \$74,000) or as an academic faculty member (starting salary, \$65,000). At current KUMC graduate tuition and fee rates for a Kansas resident, completion of the entire DCLS program on a full-time basis would cost approximately \$31,658. Therefore, receipt of the DCLS degree will provide a substantial financial return to the student.

References:

Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook, 2016-17 Edition*, Medical and Clinical Laboratory Technologists and Technicians. Retrieved from

<http://www.bls.gov/ooh/healthcare/medical-and-clinical-laboratory-technologists-and-technicians.htm>

Doig, K., & Beck, S. (2008). Surveys of support for the doctorate in clinical laboratory science. *Clin Lab Sci*, 21(2), 92.

Nadder, T. (2011). Results from an interest survey on the professional doctorate degree in CLS. *ASCLS Today*, 25(4), 13-14.

3. What is the demand for graduates of this program?

With increasing laboratory test complexity and a rapidly expanding test menu, there is a need for doctoral-level training in CLS to provide consultative services to both patients and healthcare providers. In a survey of physicians, it was found that speed and accuracy of diagnosis was dramatically increased when interpretation was provided with laboratory results for a complex testing panel. Therefore, interpretation provided by those with extensive clinical laboratory expertise will contribute to improved patient outcomes. Furthermore, the Department of Health and Human Services (HHS) has announced a rule that amends the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations giving patients, or a person designated by the patient, access to completed laboratory test reports. Patients can continue to get their laboratory test results from their doctors; however, the HHS rule gives patients a new option to directly contact a laboratory professional.

Nationally, the American Society for Clinical Laboratory Scientists (ASCLS) Doctorate in Clinical Laboratory Science Oversight committee has developed the roles and responsibilities of the DCLS to include: delivery of patient-centered care by providing clinical consultation on laboratory test selection and interpretation; monitoring test utilization on individual patients and populations to reduce diagnostic errors, improve efficiency, and reduce costs; conducting research and apply evidence to improve the quality and safety of diagnostic testing processes; educating the interprofessional health care team, patients, their families, and the general public on matters of clinical laboratory testing; directing laboratory operations to comply with all state and federal laws and regulations; and participating in public and private health policy decision making at all organization and government levels (American Society for Clinical Laboratory Science; Nadder). *These responsibilities require a doctoral-level of education and training.*

Unfortunately, the lack of doctorate-prepared CLS's is a barrier to the availability of interpretations of complex testing panels for both providers and patients. Implementing this program will overcome this barrier, as well as address the state, regional, and nationwide need for doctorate-trained CLS faculty. Included in the appendix materials is a letter of support from Dr. Lyle Noordhoek (President, Kansas Society of Pathologists) in which he outlines the need for the DCLS.

The Clinical Laboratory Integration into the Healthcare Collaborative (CLIHIC) was created by the Centers for Disease Control and Prevention (CDC) Division of Laboratory Science and Standards to develop solutions to optimize the effective use of laboratory services for better patient care. A forty-year review of the literature performed by the CLIHIC revealed an increasing number of reports showing that errors in test selection and interpretation jeopardized patient safety. Furthermore, as summarized by Hickner, et al, "Primary care physicians routinely experience uncertainty and challenges in ordering and

interpreting diagnostic laboratory tests” (pp. 268–274).

Additionally, “With more than 500 million primary care patient visits per year, the level of uncertainty potentially affects 23 million patients per year and raises significant concerns about the safe and efficient use of laboratory testing resources” (Hickner, et al., pp. 268–274).

In 2012, the CLIHC surveyed 1700 internal and family medicine physicians nationally to determine the challenges in utilization of laboratory services. The survey identified the following barriers and challenges associated with laboratory test selection and interpretation: issues accessing and communicating with laboratories, variations in test names, variable and nebulous practice guidelines, inconsistency with laboratory results and clinical presentation, and inadequate and inappropriate laboratory documentation. The CLIHC study also asked clinicians about resources utilized during laboratory test selection and interpretation. It was found that clinicians were most likely to review electronic resources (57%), review paper resources (27%), refer the patient to a specialist (22%), review practice guidelines (21%), wait and see (21%), or ask another clinician for advice (14%) before considering a consultation with a laboratory professional (6%). These findings dramatically emphasize the underutilization of laboratory personnel as a primary resource for healthcare information.

With the goal of improving patient outcomes, the CLIHC survey also identified practice changes that would promote better utilization of laboratory tests. These changes included improved access and relationships with laboratory professionals, availability of practice guidelines, and follow-up testing information when appropriate. Hickner, et al., concluded that improving communication with laboratory professionals, particularly access to laboratory consultations, would reduce clinician uncertainty in ordering and interpreting lab tests. The DCLS would provide these consultations thereby enabling meaningful use, appropriate utilization management, and providing interpretation leading to better patient care and safety while also lowering cost and increasing reimbursement.

In addition to providing clinician support, the DCLS will also be a resource for patients. The U.S. health care system is fragmented and uncoordinated resulting in patient disappointment due to redundancy and inadequate communication with providers (Callen, et al.). Improving patient experience is part of the IHI Triple Aim (now the Quadruple Aim). In a 2005 study by Baldwin et al., patients identified several areas where they felt the communication of laboratory results fell short of expectations. Patients typically must wait days to weeks to receive laboratory results from their physicians if they are contacted at all. Oftentimes, the request for results is patient initiated and is met with frustration by leaving frequent messages with a third-party member of the medical staff unnecessarily increasing the administrative complexity of the feedback system.

When results are returned to the patient, there are often follow-up questions that must be relayed back to the physician leading to another round of waiting. Test results are often not personally relayed back to the patient instead they are mailed in the form of a vague letter. The Baldwin study showed that patients asked for more detailed interpretative information even when test results were normal. They wanted to know what their results meant and what potential follow-up testing might be needed. While they understood physicians were busy and difficult to reach, they expressed a desire to have their laboratory results given to them by people “knowledgeable enough to answer questions” (Baldwin, et al.). The DCLS would interpret laboratory values being delivered to the patient. This interpretation could take place outside of the physician’s office thus reducing the number of requests or visits needed to obtain lab results. Additionally, the DCLS would have knowledge of the patient’s history, clinical symptoms and laboratory values, therefore could coordinate additional tests among other providers and prevent unnecessary test duplication. Such coordination by the DCLS would lead to more timely receipt of results, better resource utilization, improved health outcomes, and enhanced patient satisfaction.

The DCLS would have the depth of knowledge and training required to provide real-time clinical decision support thereby reducing the clinicians’ uncertainty and mitigating the challenges to improved patient outcomes. The DCLS will serve as a consistent resource for the patient and other members of the healthcare team. In conclusion, the DCLS will have the advanced training necessary for interpretation of complex testing panels, address appropriate clinical utility, and correlate test results with patient’s symptomology to provide real-time clinical decision support.

References:

American Society for Clinical Laboratory Science. (2013). Advanced practice: doctorate in clinical laboratory science.

- Retrieved from <http://www.ascls.org/position-papers/176-advanced-practice-doctorate-in-clinical-laboratory-science>
- Baldwin, D., et al. (2005). Patient preferences for notification of normal laboratory test results: A report from the ASIPS Collaborative. *BMC family practice*, 6(1), 1.
- Callen, J., et al. (2011). The safety implications of missed test results for hospitalised patients: A systematic review. *BMJ quality & safety*, 20(2), 194-199.
- Hickner, J., et al. (2014). Primary care physicians' challenges in ordering clinical laboratory tests and interpreting results. *The Journal of the American Board of Family Medicine*, 27(2), 268-274.
- Nadder, T. (2013). The development of the doctorate in clinical laboratory science in the US. *The Journal of the International Federation of Clinical Chemistry and Laboratory Medicine*, 24(1).

4. What are the locational and comparative advantages of this program?

There is a long history of Clinical Laboratory Science education at KUMC. The program has been in existence since 1933 and continuously accredited by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) for over 50 years. Our BS in CLS graduates have an outstanding pass rate on national certification exams with scores consistently above the national average. Furthermore, the program has been able to take advantage of the high density of clinical facilities in the Kansas City metropolitan region. The success and reputation of our BS in CLS program will allow for effective establishment of clinical residency partners for the DCLS program. Additionally, the emphasis on interprofessional education amongst the healthcare disciplines at KUMC will provide unique opportunities for collaborative education prior to the clinical residency. Therefore, KUMC is uniquely positioned to offer this Doctoral degree program.

Currently, only two universities in the United States offers the DCLS -- Rutgers, The State University of New Jersey, and The University of Texas Medical Branch. By offering the DCLS, the University of Kansas will be at the forefront of education and training for leadership and delivery of healthcare. The program will attract students from within the state and across the nation because of the University's strong reputation for clinical laboratory education.

5. What are the characteristics of the students who will participate in this proposed program?

Students in this program will hold a Bachelor's degree in CLS or an appropriate life science and have completed a NAACLS-approved CLS program. Additionally, students must already possess national certification as a medical laboratory scientist (MLS[ASCP] or MT[ASCP]), and have a minimum of one year of work experience as a CLS.

Admission to the proposed program. Applications will be considered in accordance with the admission requirements of the Office of Graduate Studies. Applicants should have a minimum grade point average (GPA) of 3.0 (on a 4.0 scale). Graduate Record Examination (GRE) scores will be required for the verbal, quantitative, and analytical writing tests. Applicants must fill out a KUMC Graduate Studies application.

Additional application materials will include official college transcripts, three letters of recommendation from faculty members and/or employers, and a one page personal statement that describes the applicant's educational goals and career objectives. Applications must be received by February 1 for admission to the program for the following Fall semester. Each application will be evaluated by the CLS Admissions Committee. Recommendations for admission will then forwarded to the KUMC Office of Graduate Studies for approval.

B. Curriculum of the Proposed Program

1. What is the curriculum of the proposed program?

Degree requirements overview:

The DCLS is a 76-credit hour program designed to be completed in a three-year time frame if enrolled full time (see program progression below). If completed on a part-time basis, the program would be completed in six years. Course work is divided between advanced theory courses ("Core Curriculum"), research, and clinical residency. The advanced courses encompass the six subspecialties of clinical laboratory science (chemistry, immunology, hematology, immunohematology, microbiology, & molecular diagnostics). In addition to those courses with the CLS prefix, advanced theory courses in the Core Curriculum include content areas from other KUMC departments. Letters of support from those

departments are included with this proposal. Research projects will advance practice in clinical laboratory medicine, such as the development and implementation of diagnostic and interpretive algorithms, clinical practice guidelines, and collaborative interprofessional patient care. The year-long residency places the students in clinical practice environments at program affiliates. During the residency, the students will work with management, laboratory staff, physicians, nurses, and other members of the healthcare team to provide guidance in laboratory utilization and interpretation thereby optimizing patient outcomes. Additionally, this curriculum addresses the competencies established for the profession by the American Society for Clinical Laboratory Science Doctorate in Clinical Laboratory Science Oversight Committee and NAACLS accreditation guidelines for the DCLS.

Proposed curriculum:

<i>Course Name & Number</i>	<i>Credit Hours</i>
<u>Core Curriculum</u>	
CLS 800 Advanced Topics	3
CLS 802 Principles of Healthcare Education or MICR 805 Teaching in Higher Education	3
CLS 805 Advanced Molecular Diagnostics	2
CLS 815 Research Methods in Clinical Laboratory Sciences	2
CLS 820 Evidence Based Practice	3
CLS 830 Advanced Clinical Chemistry	3
CLS 836 Advanced Hematology	3
CLS 838 Advanced Immunology/Transplant	3
CLS 842 Advanced Clinical Microbiology	3
CLS 844 Advanced Immunohematology	3
CLS 851 Clinical Correlations I	3
CLS 852 Clinical Correlations II	3
CLS 880 DCLS Interprofessional Practice	2
CLS 890 Advanced Laboratory Operations	3
BIOS 704 Principles of Statistics in Public Health	3
HP&M 810 Health Care System	3
PHCL 898 Principles of Pharmacology	1
PHSL 843 Physiology of Disease	3
PRVM 800 Principles of Epidemiology	3
PRVM 853 Responsible Conduct of Research	1
CLS 901 DCLS Research I	2
CLS 902 DCLS Research II	3
CLS 903 DCLS Research III	3
CLS 999 DCLS Capstone	1
<u>Research</u>	
<u>Practicum</u>	
CLS 911 DCLS Residency I	4
CLS 912 DCLS Residency II	5
CLS 913 DCLS Residency III	<u>5</u>
 <u>Total:</u>	 77

Proposed DCLS Full-time program progression

Year 1

Fall - 12 credit hours

- CLS 836 Advanced Hematology (3)
- CLS 830 Advanced Clinical Chemistry (3)

- CLS 815 Research Methods in Clinical Laboratory Sciences (2)
- HP&M 810 Health Care System (3)
- PRVM 853 Responsible Conduct of Research (1)

Spring – 12 credit hours

- CLS 842 Advanced Clinical Microbiology (3)
- CLS 851 Clinical Correlations I (3)
- CLS 890 Advanced Laboratory Operations (3)
- PHSL 843 Physiology of Disease (3)

Year 2

Fall – 13 credit hours

- CLS 805 Advanced Molecular Diagnostics (2)
- BIOS 704 Principles of Statistics in Public Health (3)
- CLS 838 Advanced Immunology/Transplant (3)
- CLS 802 Principles of Healthcare Education or MICR 805 Teaching in Higher Education (3)
- PHCL 898 Principles of Pharmacology (1)
- CLS 880 DCLS Interprofessional Practice (1)

Spring – 13 credit hours

- PRVM 800 Epidemiology (3)
- CLS 844 Advanced Immunohematology (3)
- CLS 852 Clinical Correlations II (3)
- CLS 820 Evidence Based Practice (3)
- CLS 880 DCLS Interprofessional Practice (1)

Summer – 7 credit hours

- CLS 800 Advanced Topics (1)
- CLS 901 DCLS Research I (2)
- CLS 911 DCLS Residency I (4)

Year 3

Fall – 9 credit hours

- CLS 800 Advanced Topics (1)
- CLS 902 DCLS Research II (3)
- CLS 912 DCLS Residency II (5)

Spring – 10 credit hours

- CLS 800 Advanced Topics (1)
- CLS 903 DCLS Research III (3)
- CLS 913 DCLS Residency III (5)
- CLS 999 DCLS capstone (1)

DCLS Core Course Descriptions (for courses with the CLS prefix)

CLS 800 Advanced Topics (1)

Seminar course that addresses topics and issues relevant to DCLS clinical practice, including ethical and social issues in healthcare practice, health informatics, and communication techniques needed for interaction with healthcare colleagues and patients. Repeatable.

CLS 802 Principles of Healthcare Education (3)

This course will address various aspects of teaching in healthcare settings. This includes educating patients and their families, educating other healthcare professionals, and the more formal area of undergraduate and graduate education. Education theory, pedagogical methods, educational resources, learning objectives, and evaluation techniques applicable to each type of educational situation will be addressed.

CLS 805 Advanced Molecular Diagnostics (2)

This course focuses on the enhancement of scientific and technical knowledge in nucleic acid- based testing for the diagnosis of acquired and hereditary genetic disorders. Topics include: selection of appropriate screening and diagnostic tests and techniques; results interpretation in the context of other laboratory and clinical data; monitoring disease progression, therapeutic efficacy, and follow-up recommendations; communicating results and providing consultation to healthcare practitioners and other stakeholders in a professional manner including ethical considerations. Current scientific literature, clinical scenarios, case studies, and advanced laboratory practice issues will be used to enhance knowledge and skills.

CLS 815 Research Methods in Clinical Laboratory Sciences (2)

A discussion of research methods used in clinical laboratory sciences, with an emphasis on selecting and applying appropriate research designs. Includes an overview of the scientific method and various research models in current used in clinical laboratory science; research ethics and the protection of human subjects; the role of theory in problem formulation; internal and external validity; variable measurement and reliability, and generalizability of findings. Specific approaches covered include experimental and quasi-experimental treatment designs, epidemiologic methods (cohort and case-control studies), survey research, evaluation and outcomes research, methodological studies and qualitative research.

CLS 820 Evidence Based Practice (3)

This course provides foundation skills in research-oriented bibliographic inquiry, with an emphasis on evidence-based review and synthesis of applicable literature in laboratory medicine. Principles of effective scientific communication are also addressed, including how to plan, organize and write structured systematic review articles.

CLS 830 Advanced Clinical Chemistry (3)

This course provides advanced scientific knowledge and technique in clinical chemistry testing for disease diagnosis, monitoring and treatment. Topics will be discussed included but not limited to: updates on cardiac and tumor markers, liver and kidney disease, diabetes, endocrine disorders, nutrition assessment, therapeutic drug management, toxicology, automation and POCT, and advanced case studies in clinical chemistry.

CLS 836 Advanced Hematology (3)

This course focuses on enhancement of scientific and technical knowledge in hematology and hemostasis to consult with other healthcare practitioners on the selection of screening and diagnostic tests for hematological disorders, interpretation of results, and recommendations for follow-up testing. Topics to be investigated include physiology and regulation of the hematopoietic system and hemostasis, and the genetic, molecular and cellular mechanisms underlying the pathophysiology of selected hematological disorders such as anemias, leukemias, lymphomas, and disorders of hemostasis with additional focus on utilization of appropriate hematology and molecular diagnostic tests, and reducing turn-around time. Current scientific literature, clinical scenarios, case studies, and advanced laboratory practice issues will be used to enhance knowledge and skills.

CLS 838 Advanced Immunology/Transplant (3)

This course focuses on enhancement of scientific and technical knowledge in clinical immunology and transplantation to consult with other healthcare practitioners on clinical applications, diagnostic and therapeutic testing of immune-mediated diseases in autoimmunity, pregnancy, anaphylaxis and allergy, immunotherapy and immunotoxicology, transplantation and HLA testing/compatibility, cancer immunology and immunodeficiency. Topics include test methodologies in cellular, humoral, and molecular immunology, selection and interpretation of test results, and recommendations for follow-up testing for patient monitoring. Current scientific literature, clinical scenarios, case studies, and advanced laboratory practice issues will be used enhance knowledge and skills.

CLS 842 Advanced Clinical Microbiology (3)

This course focuses on enhancement of scientific and technical knowledge in clinical microbiology in order to consult with other healthcare practitioners on the selection of screening and diagnostic tests for suspected infectious diseases, interpretation of results, and recommendations for follow-up testing. Topics to be investigated include utilizing molecular diagnostic tests, antimicrobial susceptibility testing and resistance mechanisms, bioterrorism, biofilms, opportunistic and emerging infections, utilization of appropriate microbiology tests, and reducing turn-around time. Current scientific literature, clinical

scenarios, case studies, and advanced laboratory practice issues will be used to enhance knowledge and skills.

CLS 844 Advanced Immunohematology (3)

This course focuses on enhancement of scientific and technical knowledge in clinical immunohematology to consult with other healthcare practitioners on the identification, resolution, and selection of blood products for rare or multiple blood group system antibodies, interpretation of test results, and recommendations for follow-up testing and transfusion recommendations. Additional topics to be investigated include: therapeutic indications for transfusion, transfusion requirements in special situations, the pathophysiology and investigation of adverse transfusion reactions are also examined, blood utilization management, research in blood component collection and storage, and regulatory agency requirements. Current scientific literature, clinical scenarios, case studies, and advanced laboratory practice issues will be used enhance knowledge and skills.

CLS 851 Clinical Correlations I (3)

This course will correlate clinical laboratory testing as it relates to physiological changes associated with representative diseases of major organ systems (e.g., endocrine, muscle, cardiovascular, respiratory, renal, gastrointestinal, immune, nervous, and reproductive). Diseases will be reviewed with focus on changes in laboratory parameters. Class will include lectures, student presentations, evaluations of research papers, and discussions. This course will be taught in parallel with PHSL 843 Physiology of Disease.

CLS 852 Clinical Correlations II (3)

This course will build on CLS851 Clinical Correlations I and will correlate clinical laboratory testing as it relates to physiological changes associated with other diseases of the major organ systems (endocrine, muscle, cardiovascular, respiratory, renal, gastrointestinal, immune, nervous, and reproductive). Diseases will be reviewed with focus on changes in laboratory parameters. Class will include lectures, student presentations, evaluations of research papers, and discussions.

CLS 880 DCLS Interprofessional Practice (1)

This course will build DCLS communication and practice skills within the interprofessional healthcare team. Students will learn with, from, and about other health professions, as well as role of interprofessional collaboration in improving the quality and safety of patient care.

Methods used to develop knowledge and skills may include simulation and group-based activities.

Repeatable.

CLS 890 Advanced Laboratory Operations (3)

This course will explore laboratory quality, utilization, accreditation, regulation, and management topics. Core course content explores the selection, implementation, strengths, and weaknesses of appropriate quality assurance programs to maintain desired quality goals. All aspects of laboratory services will be explored to enhance consultative skills that will be applied in the clinical residency. The use of practice guidelines, critical or clinical pathways, algorithms and reflex testing, direct access testing, evidenced-based practice, and outcomes measurements, as well as initiatives to change the practice of laboratory services in all phases (pre-analytical, analytical and post analytical) are covered.

DCLS Research Requirement

A three-course series (CLS 901/902/903)

A prospectively planned and approved translational research project which is advisor-guided, student-directed, and designed to support and enhance students' ability to apply their graduate knowledge and achieve tangible outcomes for the CLS profession. DCLS Research Project is a series of three courses taken consecutively (CLS 901, CLS 902, CLS 903). The three-course series includes all aspects of the translational research project, including the planning, data collection, analysis/interpretation of results, preparation, and presentation of the research project, both oral and written. The three-course series outcome is the preparation of a manuscript suitable for publication. Research projects will advance practice in clinical laboratory medicine, such as the development and implementation of diagnostic and interpretive algorithms, clinical practice guidelines, and collaborative interprofessional patient care. Examples of DCLS research projects include: reducing unnecessary test orders by implementing a physician education program in hemostasis testing for stroke patients; cost savings following test utilization review for commonly inappropriately ordered tests; assessing the transfusion criteria for select populations (oncology, liver

transplant, refractory platelet, etc.).

DCLS students actively working on their research project will be guided by a five-member committee consisting of four CLS Department Graduate Faculty and one external member of the KUMC Graduate Faculty. The students must maintain active enrollment in applicable coursework each semester while in the research phase. Each student enrolls in the research project courses CLS901, CLS902, and CLS903 only once. If additional enrollment is required to complete the research project, the student must enroll in a suitable and repeatable course such as CLS800 Advanced topics for each additional semester.

DCLS Clinical Residency

A three-course series (CLS 911/912/913). This year-long clinical residency is designed to develop the DCLS professional to meet the national DCLS professional responsibilities (See appendix). The clinical residency will prepare DCLS candidates for the practice of clinical laboratory consultation in a variety of settings –such as hospitals, reference laboratories, insurance providers, pharmaceutical companies, public health laboratories, and community health organizations.

Training includes laboratory administration, laboratory information systems, internal medicine, oncology, critical care, pediatrics/geriatrics, emergency and trauma, infectious disease and antibiotic stewardship, and community health. This experience is provided in structured clinical rotations occurring at clinical affiliates. Skills and knowledge will be evaluated through competency-based assessments and portfolio development. This portfolio will contain documentation of experiences and work products developed during the DCLS candidate’s residency rotations. This may include de-identified summaries of consultations, papers and abstracts published or submitted, PowerPoint presentations, method evaluation data and/or written procedures from utilization projects. Development and assessment of the portfolio will be directed by competencies and guidelines necessary to sit for DCLS-associated national certification examinations.

An example of a residency rotation schedule is provided below:

Duration	Rotation
5 weeks	Hospital Laboratory Administration <ul style="list-style-type: none"> • Internal procedures associated with the hospital laboratory, Electronic Health Record (laboratory access), Laboratory Information Systems, and utilization issues.
4 weeks	Hospital Information System <ul style="list-style-type: none"> • Lab test order guidelines and current algorithms, coverage and reimbursement for laboratory services (Policy/insurance)
28 weeks	Subspecialties of clinical practice <ul style="list-style-type: none"> • Internal medicine • Family medicine • Obstetrics and gynecology • Pathology • Emergency/Critical Care • Pediatrics
6 weeks	Reference laboratory <ul style="list-style-type: none"> • Laboratory information systems, laboratory testing order guidelines and current algorithms, coverage and reimbursement for laboratory services in a non-hospital clinical laboratory.
5 weeks	Community Health <ul style="list-style-type: none"> • Public health departments • Health clinic/ambulatory outpatient medicine • Senior care/Nursing home/Skilled care

DCLS Degree Completion

Comprehensive Examination. Upon completion of the core curriculum, a comprehensive examination, written and administered by Graduate Faculty in the Department of Clinical Laboratory Science, will be required of all degree candidates. Students will demonstrate their command of the clinical laboratory science body of knowledge, as well as their ability to statistically analyze data, and their expertise in the broad scope of clinical practice. Students must be in good academic standing with the KUMC Office of Graduate Studies (i.e. hold a minimum 3.0 cumulative GPA) to be eligible for the comprehensive examination. The examination must be completed prior to enrollment in residency courses with a minimum score of 80% to be considered successful. Students who fail to obtain a successful score will be allowed to repeat the examination one time with the recommendation of the Departmental Graduate Curriculum Committee. The repeat examination may not be scheduled within two months of the unsuccessful attempt. Under no circumstances will students be allowed to take the comprehensive examination more than twice. There is no cost associated with the exam.

Research Project Capstone. Defense of the research project described above. The capstone is completed during the final semester of the program and consists of a written and an oral examination. The written component consists of a manuscript suitable for publication based on the research completed as described above. The final oral defense will be scheduled once the final draft of the manuscript is accepted by the student's five-member Graduate Committee. The oral examination is a defense of the manuscript and can include questions regarding general knowledge of clinical laboratory science concepts and applications.

Performance on the oral defense will be rated as "Honors," "Satisfactory" or "Unsatisfactory" and this rating will be forwarded to the Office of Graduate Studies. If the rating is "Unsatisfactory," the student may be allowed to repeat the defense, with the recommendation of the Department. The repeat defense may not be scheduled sooner than two months after the first attempt. Under no circumstances will the student be allowed to take the final defense more than twice. If a rating of at least "Satisfactory" is not achieved after the second attempt, the student will be dismissed from the program.

Residency Portfolio. This portfolio will contain documentation of experiences and work products developed during the DCLS candidate's residency rotations. This may include de-identified summaries of consultations, papers and abstracts published or submitted, PowerPoint presentations, method evaluation data and/or written procedures from utilization projects.

Development of the portfolio will be directed by competencies and guidelines necessary to sit for DCLS-associated national certification examinations. The portfolio will be assessed by the student's five-member Graduate Committee per the National competencies and guidelines.

C. Program Faculty

1. Faculty qualifications

All faculty involved in the proposed program possess advanced degrees with specializations that are directly associated with their teaching responsibilities. Courses in the DCLS Core curriculum designated with a 'CLS' prefix will be taught by faculty from the Department of Clinical Laboratory Sciences (CLS). A description of the CLS Department faculty involved in the DCLS program is included below. Seven of the core courses have a prefix other than 'CLS'. These courses are offered by other departments and are taught by KUMC Graduate Faculty from those departments. Collectively, there will be a minimum of 14 KUMC Graduate Faculty involved in teaching the courses associated with the DCLS Core curriculum. Letters supporting the enrollment of DCLS students in courses offered by other departments are included in the appendix materials.

Department of Clinical Laboratory Sciences (CLS) Faculty.

The CLS Department currently has nine faculty members, most of whom hold nationally recognized clinical laboratory certification. The CLS faculty who will teach in the DCLS program are: Eric Elsinghorst, PhD, MPH, MLS(ASCP)MB^{cm}, Research Associate Professor; Renee Hodgkins, PhD, MT(ASCP), Clinical Assistant Professor; Jan Hudzicki, PhD, MLS(ASCP)SM^{cm}, Clinical Associate

Professor; and WenFang Wang, PhD, C(ASCP)^{cm}, Clinical Assistant Professor. Currently, the faculty identified above are non-tenure track.

New faculty recruitment. In December of 2016, two CLS Department faculty members left the department (one person who retired and one person who resigned for personal reasons). The CLS Department is currently recruiting two new faculty members to fill these positions with a Summer 2017 start date. The salary lines for these hires are currently in the CLS Department budget.

In addition to filling these two replacement positions, the CLS Department will be recruiting two additional faculty members: one with an anticipated Summer 2018 start date and one with an anticipated Summer 2019 start date. A letter showing institutional support for the cost of these hires is included in the appendix materials. Each of these new faculty members will be recruited as an Assistant Professor (non-tenure or tenure-track, depending on experience and potential to maintain independent scholarly activity). Minimum qualifications for the positions include: a doctoral degree in an appropriate discipline; MLS(ASCP)^{cm} or MT(ASCP) certification, and expertise in a hospital-based clinical laboratory discipline (Hematology, Clinical Microbiology, Clinical Chemistry, Clinical Immunology, Immunohematology, Molecular Diagnostics).

Teaching responsibilities will represent at least 40% effort for each of the positions, with those teaching responsibilities being in the DCLS program.

Other teaching assignments. Eric Elsinghorst, Renee Hodgkins, Jan Hudzicki, and WenFang Wang, also teach in the CLS Department's undergraduate BS in CLS degree program. Participation in the DCLS program will represent about 50% of the teaching responsibilities for these faculty members.

Adjunct faculty. Faculty serving as preceptors for DCLS students while in residency will be affiliated with the program through adjunct faculty appointment in the Department of Clinical Laboratory Sciences. These appointments will be made at a level appropriate with the education and experience of the preceptor.

2. How many graduate assistants will serve the program?

As currently envisioned, no graduate assistants will serve the proposed program. Should enrollment in the proposed program rise substantially above the anticipated level, graduate teaching assistants may be required to support the core faculty.

D. Academic Support

1. What additional academic support is needed?

No additional academic support is required for this program.

2. What new library materials and other forms of academic support are required beyond normal additions?

No new library materials or academic support services are required.

3. What new supporting staff will be required beyond normal additions?

No new support staff is needed at the current time.

E. Facilities and Equipment

No new equipment will be needed for the proposed program. The new faculty member will need an office. The Dean of the School of Health Professions has submitted a request for space for all departments in the School. For the CLS Department, this request includes five faculty offices and a conference room. Financing for the SHP space will come from the School or the University, and therefore is not reflected in the financing of the DCLS program.

F. Program Review, Assessment and Accreditation

1. What program review process or evaluation methods will be used to review the program?

To ensure its effectiveness, the proposed program will be systematically reviewed and evaluated through survey and evaluation instruments that incorporate feedback from students, graduates, residency

sites, and employers.

Students: For each course (including clinical residencies) in which they are enrolled, students will provide feedback through faculty and course evaluations. At the completion of the degree program, students will complete an overall program evaluation survey aimed at identifying strengths and weaknesses of the program. This survey also seeks constructive feedback and recommendations to help improve the program for each of the DCLS competencies.

Graduates: At one and three years post-graduation, graduates will receive program evaluation surveys that seek feedback and recommendations to help improve the program. Because the DCLS is an emerging profession, these surveys will also serve to identify new content areas and skills that impact professional practice and should be incorporated into the curriculum. Residency sites. Adjunct faculty at each clinical affiliate will evaluate student and program performance. For students, clinical site faculty will evaluate student performance. For program evaluation, clinical site faculty will evaluate the strengths and weaknesses of the program as exemplified by the overall preparedness of students for clinical residency, and make recommendations to help improve the program. Employers. One year after graduation, the employer of a graduate (when known) will be sent a survey to evaluate the overall preparedness of the graduate for the workplace and make recommendations to help improve graduate preparedness.

The overall effectiveness of the program and its faculty will be evaluated on an ongoing basis by the Clinical Laboratory Science Curriculum Committee. This evaluation will incorporate responses from the various surveys and evaluation instruments described above, student coursework grades, outcomes of the comprehensive qualifying exams and research projects required for degree completion, and the national certification exam taken by program graduates (when a DCLS exam becomes available). Based on these effectiveness measures, curricular change will be implemented. The effectiveness of those changes will be monitored through continued evaluation of student outcomes. In addition to this internal effectiveness evaluation, the educational efforts of the program undergo periodic evaluation by the KUMC School of Health Professions, the Kansas Board of Regents Institutional Program Review and by NAACLS.

3. What are the institution's plans regarding program accreditation?

The program will seek accreditation from NAACLS for the doctorate in clinical laboratory science. The accreditation process consists of five steps: Self-Study Report, Paper Review process, Site Visit process, review by the Doctoral Review Committee (DRC) and review by the NAACLS Board of Directors. The NAACLS guidelines state that the Self-Study Report be submitted within 12 months of the graduation of the third student from the program. The Self-Study Report is then evaluated within 2 months, and the review is submitted as a written report (i.e. Paper Review). The program's response must be submitted with supporting documentation within one month of receipt of the Paper Review. A Site Visit will then be scheduled, and a Site Visit Report will be forwarded to the program within 45 days of the Site Visit. The program will have one month to respond to the Site Visit Report. All documentation will then be reviewed by NAACLS DRC and a recommendation for accreditation is submitted to the NAACLS Board of Directors who is then responsible for awarding the program its initial accreditation.

The current NAACLS accreditation fees are: initial application, \$600; approval, \$1,829; site visit preparation, \$500; site visit, actual cost; annual accreditation (after initial approval), \$2,009. These fees will be supported by the CLS Department budget; therefore, they are not included on the financial proposal.

Appendix

DCLS Professional Responsibilities

Support letter from Dr. Abiodun Akinwuntan, Dean, School of Health

Professions Support letter from David Vranicar, Vice Chancellor for Finance, KUMC

Support letter from Dr. Lyle Noordhoek, President Kansas Society of Pathologists

Support letter from Dr. Gustavo Blanco, Interim Chair, Department of Molecular and Integrative Physiology

Support letter from Dr. Won Choi, Executive Director, MPH Program

Support letter from Dr. Robert Lee, Chair, Department of Health Policy and Management

Support letter from Dr. Ken McCarson, Co-Director, Graduate Committee, Department of Pharmacology and Toxicology

Support letter from Dr. Michael Parmely, Professor, Department of Microbiology, Molecular Genetics and Immunology

Support letter from Dr. Jo Wick, Associate Director, Graduate Education, Department of Biostatistics

DCLS Oversight Committee
A Subcommittee of the ASCLS Education Scientific Assembly

Doctor of Clinical Laboratory Science (DCLS) Professional Responsibilities
Approved 6/27/16

1. Provide patient-centered, customized consultation services on appropriate test selection and interpretation for the purpose of clinical decision-making among the interprofessional healthcare team and for the patient.
(/OM Core Competencies¹: patient-centered care, interprofessional teams)
2. Monitor laboratory data, test utilization, and diagnostic testing processes for individual patients and populations using informatics and analytics to reduce diagnostic errors, improve efficiency, and reduce costs.
(/OM Core Competencies: quality improvement, informatics)
3. Conduct research and apply evidence to demonstrate clinical utility of laboratory tests and algorithms and to improve the quality, efficiency, and safety of the overall diagnostic testing process².
(/OM Core Competencies¹: evidence-based practice, quality improvement, patient-centered care, informatics)
4. Educate health care providers, patients, their families, and the general public on the indications, patient preparation, and interpretation of clinical laboratory testing, including home self-testing.
(/OM Core Competencies¹: patient-centered care, interprofessional teams)
5. Direct laboratory operations to comply with all state and federal laws and regulations, as well as guidelines determined by professional boards of licensure, and certification/accreditation agencies.
(/OM Core Competencies¹: quality improvement)
6. Participate in public and private health policy decision making at all organization and government levels.
(/OM Core Competencies¹: quality improvement, interprofessional teams)

¹From Institute of Medicine. *Health Professions Education: A Bridge to Quality*. Washington, DC: National Academies Press, 2003

²Diagnostic testing processes includes those used for screening, diagnosis, prognosis, and monitoring disease states.

September 20, 2016

Robert Klein, PhD

Vice Chancellor for Academic Affairs Kansas
University Medical Center

Dear Vice Chancellor Klein,

This letter is to express my strong support for the Doctorate in Clinical Laboratory Sciences (DCLS) degree program that is being proposed by the Department of Clinical Laboratory Sciences (CLS) in the School of Health Professions (SHP). Clinical laboratories generate the data used by physicians to make medical decisions. The clinical laboratory test list is rapidly increasing in complexity, particularly with the addition of molecular diagnostic testing. Consequently, there is a need for individuals with highly specialized knowledge and training to provide consultative services to physicians and healthcare providers. The level of consultation provided by these professionals will further improve patient outcomes and reduce costs by reducing unnecessary and inappropriate testing, decreasing the time to diagnosis, decreasing length of stay, and increasing continuity of care. In line with Federal regulations which require that test results be available to patients, DCLS-trained professionals will provide consultation to physicians, other healthcare providers, and patients regarding outcomes of laboratory testing.

We have a unique opportunity here at the University of Kansas Medical Center (KUMC) to develop this much needed program as it will be built upon existing strengths in the CLS Department, the SHP, and KUMC. The CLS Department is highly-regarded with a well-established network of clinical affiliates, and is an ideal department for the creation of a DCLS program. Currently, there are only two other DCLS programs nationwide. Therefore, this program would place KUMC in a leadership position during the emergence of a new cohort of professionals who will be critical members of the interprofessional healthcare team needed by the State of Kansas and the country.

I am aware that as part of the new degree approval process, our School will undergo a review by external consultants to evaluate our ability to deliver the proposed program. Since the DCLS degree proposal is considered high priority for the SHP and KUMC, SHP will bear the expenses associated with the review visit.

Finally, I endorse the proposal for your approval and that of the Council of Chief Academic Officers, the Council of Presidents and the Board of Regents.

Sincerely yours,



Abiodun Akinwuntan, PhD, MPH, MBA
Dean and Professor
KU School of Health Professions

Office of the Dean, School of Health Professions

Mail Stop 2007 I 390 I Rainbow Blvd. I Kansas City, KS 66160 I Office 913-588-5235 I Fax 913-588-5254 I
TTY 71 I
healthprofessions.kumc.edu

Eric Elsinghorst

From: David Vranicar
Sent: Friday, April 28, 2017 11:14
To: AM Eric Elsinghorst
Cc: Abiodun Akinwuntan
Subject: Support For Doctorate in Clinical Laboratory Sciences
Importance: High

Dr. Elsinghorst,

We have recently discussed and reviewed your plans for your proposed new Doctorate in Clinical Laboratory Sciences. I am writing to confirm my support for your proposal. Please let me know if you need any additional information from me to advance your plans. I wish you all the best as you pursue this new degree and am available to assist in any way I can.

The Department of Clinical Laboratory Sciences in the University of Kansas Medical Center's School of Health Professions is proposing a new degree option - the Doctorate in Clinical Laboratory Sciences ("DCLS"). This program would provide the University with a unique opportunity to take a leading role in the training of a new group of healthcare professionals that we expect to significantly impact patient outcomes.

In order to offer the DCLS program, the Department of Clinical Laboratory Sciences will require two additional faculty members. I have reviewed the budget request for the new program and commit to support the ongoing cost of salary and benefits for the two faculty members as requested in the proposal.

Thank you,
David

David Vranicar
Chief Financial Officer & Vice Chancellor for Finance
University of Kansas Medical Center
Cell: 913-522-7196 I Office.: 913-588-0442
dvrnicar@kumc.edu I www.kumc.edu
3901 Rainbow Blvd., Mailstop 2015
Kansas City, KS 66160

Lyle J. Noordhoek, MD, FCAP
2509 Felten Drive
Hays, KS 67601

May 2, 2016

University of Kansas Medical Center Clinical
Laboratory Sciences
ATTN: Eric Elsinghorst, PhD, MPH, MB(ASCP)cm
3901 Rainbow Blvd. MS 4048
Kansas City, KS 66160 Dear

Dr. Elsinghorst,

It is my pleasure to write a letter of support in regards to the development of Doctorate in Clinical Laboratory Sciences (DCLS) at the University of Kansas School of Medicine Department of Clinical Laboratory Sciences. I believe the creation of this program is timely and will be of great benefit to the citizens of the state of Kansas and provide an avenue for clinical laboratory scientists to actively participate in optimizing healthcare for patients.

As a board certificate pathologist practicing anatomic and clinical pathology and working both within hospital-based locations and as an independent pathology laboratory providing laboratory services and consultative services to as many as 60 hospitals throughout the state of Kansas and the adjacent states of Nebraska, Colorado, New Mexico, Texas, Oklahoma, Missouri, Arkansas, Illinois, Tennessee and Ohio, I have seen many instances where it would be possible to dramatically reduce adverse patient outcomes and improve the accuracy of diagnosis, the speed of diagnosis, and increase the efficiency of physicians, nurses and allied health support organizations within a hospital by having the active assistance of a clinical laboratory scientist with doctorate level training.

One of the crucial elements in patient care is a rapid diagnosis using the available information and applying selectively laboratory testing and other modes of testing that result in confirmation or elimination of suspected diagnosis early in the admission and treatment of the patient. This facilitates the elimination of wasted resources, wasted time, inaccurate diagnosis and harmful outcomes due to delayed diagnosis or broad interpretations in treatment due to poorly refined diagnosis. The addition of a doctorate level clinical laboratory scientist who is knowledgeable in available test methodologies would greatly assist physicians, nurse practitioners, ER doctors and others on the healthcare team in selecting the correct test and diagnostic algorithm based on clinical impression. As laboratory sciences are evolving faster than many other areas of medicine, there is frequently a lack of knowledge or incomplete knowledge of available test methodologies, appropriateness of test methodologies, and errors in interpretation of results. By integrating laboratory professionals with an extensive knowledge of clinical chemistry, hematology, immunology, microbiology, transfusion medicine and advanced methods of molecular diagnosis into the diagnostic team early in patient evaluation, it is possible to greatly decrease time in the hospital, decrease costs associated with hospitalization and eliminate redundant testing, unnecessary testing and adds an additional layer of knowledge in advanced testing methodology that would not yet be known or readily available to other individuals in the healthcare team.

Among the key factors that may also be considered is the integration of DCLS specialists into the management pathway and decision pathway of hospital administration, not only at large institutions, but at the numerous rural healthcare settings prevalent throughout the Midwest. This may be on-site

consultation on a regular basis, telemedicine-based consultation, or consultation services based within a hospital network or a distributed care model. This has the net effect of greatly multiplying the effectiveness of any one DCLS specialist to a degree that may not be anticipated initially.

It has been my experience that, although most pathologists are trained in both anatomic and clinical pathology, pathologists have their daily workloads closely tied to the demands of anatomic pathology which usually results in curtailing their participation in clinical laboratory consultation with clinicians, nurses, administrations or remote locations. Frequently the highest time demand and workloads for the anatomic pathologists is at the time that the clinical laboratory decisions need to be made by the other practitioners within the hospital. Because of the complex and very expensive team within the anatomic pathology component of medical care (the examination of tissue specimens and direct diagnosis of disease processes), there is frequently a necessity for the individual to be wholly involved intellectually in an undisturbed manner for protracted periods to adequately diagnose, analyze results and consult with clinicians for anatomic pathology treatment throughout the day with surgical specialists and oncologists. This again greatly limits the availability of the pathologist for providing clinical laboratory consultation services.

It is my belief that the implementation of a Doctorate in Clinical Laboratory Sciences with the addition of those individuals into the healthcare team will greatly increase the success of the hospitals and healthcare networks where they participate. During the process of quality improvement and risk management, early investigation of sentinel events with evaluation of critical pathways, best practices and adjustment of those practices based upon local factors, it would be possible to optimize healthcare in **ways** that are not addressed by blanket policy or practices established at other locations that do not have the same constraints of finances, patient demographics or reimbursement pathways.

The interplay of molecular diagnostics with antibiotic stewardship will become a primary function at many hospitals to provide optimal treatment. Decreasing errors of commission or omission are both important to both decrease length of stay in the hospital and increase effectiveness of the healthcare team. The Doctorate in Clinical Laboratory Science will provide a critical resource for optimization.

I consider the development of this program to be one of the most important activities that the Department of Clinical Laboratory Sciences should pursue, both in the short term and long term. Adequate support and funding of this activity should be greatly encouraged by the School of Health Professionals, the University of Kansas School of Medicine, and the State of Kansas.

Please feel free to share my letter with anyone who is involved in the decision process for this critically important program.

Thank you for allowing me the opportunity to comment on this program, and the opportunity to review the proposed curriculum for the DCLS degree. I believe you will have great success in this endeavor.

Sincerely,



Lyle J. Noordhoek, MD, FCAP
Consulting Pathologist
President **Kansas** Society of Pathologists
President Kansas Medical Society
LJN/kas



Department of Molecular and Integrative Physiology

August 3rd, 2016

Dr. Elsinghorst, PhD, MPH, MB(ASCP)
Chair, Department of Clinical Laboratory Sciences
The University of Kansas Medical Center

Dear Dr. Elsinghorst:

This letter is to confirm that the Department of Molecular and Integrative Physiology strongly supports the enrollment of students from your Clinical Laboratory Sciences doctorate program in the Physiology of Disease (PHSL 843) Course that our Department offers. As you know, this course covers physiological changes associated with representative diseases of major organ systems (endocrine, muscle, cardiovascular, respiratory, renal, gastrointestinal, immune, nervous, and reproductive).

We look forward to your new program. Please do not hesitate to contact me if you have any further questions.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Gustavo Blanco'.

Gustavo Blanco
Professor and Interim Chair
Department of Molecular and Integrative Physiology

Department of Molecular and Integrative Physiology
Mail-Stop 304313901 Rainbow Blvd, I Kansas City, KS 66160 I (913) 588-7025 I Fax (913)
588-7430 I www.kumc.edu

July 25, 2016

To: Eric A. Elsinghorst, PhD, MPH, MB(ASCP)
Chair, Department of Clinical Laboratory
Sciences The University of Kansas Medical
Center
3901 Rainbow Boulevard, MS 4048
Kansas City, KS 66160

Re: Letter of Support for new Doctorate in Clinical Laboratory Sciences

Dear Dr. Elsinghorst,

The Department of Clinical Laboratory Sciences is proposing a new doctorate in Clinical Laboratory Sciences and as part of the required coursework; your program will require 2 of our courses in the Department of Preventive Medicine and Public Health.

The Department of Preventive Medicine and Public Health and our Master's programs strongly support the enrollment of Doctorate of Clinical Laboratory Science students in PRVM 800 (Principles of Epidemiology) and PRVM 853 (Responsible Conduct of Research).

We look forward to your new program and please do not hesitate to contact me if you have any further questions.

Sincerely,



Won S. Choi, PhD
Professor, Preventive Medicine and Public Health
Executive Director, MPH Program
Co-Director, MS-CR Program

July 28, 2016

Eric A. Elsinghorst, PhD, MPH, MB(ASCP) Chair,
Department of Clinical Laboratory Sciences The
University of Kansas Medical Center
3901 Rainbow Boulevard, MS 4048 Kansas
City, KS 66160

Dear Dr. Elsinghorst:

I am pleased to offer my support for your proposed Doctorate in Clinical Laboratory Sciences. The state and the region will benefit from this program, and there is a growing need for advanced training in clinical laboratory sciences, and I predict that students will take advantage of this program. Furthermore, KUMC's commitment to provide innovative, high quality care to a broad range of patients with complex problems makes it an ideal location for your department's program.

In particular we welcome enrollment of your students in HP&M 810, The Health Care System. This will afford them an overview of the system and offer them an introduction to health policy issues. The course brings together students from diverse backgrounds, and I am confident that it will prove valuable to your students. Of course our Master of Health Services Administration students will also benefit from learning about how the system looks from the perspective of people who work in clinical laboratories. Should space considerations ever arise, we have other courses that should meet the needs of some of your students and we will work with you to place students appropriately. I welcome this initiative and look forward to working with you.

Sincerely,



Robert H. Lee, PhD Professor
and Chair



Kenneth E. McCarson,
Ph.D. Co- Director, Biobehavioral
Measurement Core (BMC) Director, R.L. Smith
IDDRC Rodent Behavior Facility Kansas
Intellectual and Developmental Disabilities
Research Center (KIDDRC)
Professor

Department of Pharmacology, Toxicology and
Therapeutics
3901 Rainbow Boulevard, MSN IO 18
Hemenway Life Sciences Innovations Center 2069
Kansas City, KS 66160
Office Telephone: (913) 588-7519
Laboratory Telephone: (913)
588-7595
E-mail: kmccarson@kumc.edu

Eric A. Elsinghorst, PhD, MPH, MB (ASCP)
Chair, Department of Clinical Laboratory Sciences
The University of Kansas Medical Center
3901 Rainbow Boulevard, MS 4048
Kansas City, KS 66160

August 18, 2016

Dear Dr.

Elsinghorst:

The Graduate Committee of the Pharmacology & Toxicology Graduate Programs met recently to discuss your request to list our PHCL 898 - Principles of Pharmacology as part of your proposed core curriculum for the new Doctorate in Clinical Laboratory Sciences degree program. We agree that there is the need for the inclusion of principles of Pharmacology and Toxicology in such a program, and that this course would provide the needed content for your students. While this would significantly increase the numbers of students we service in this course, the Graduate Committee unanimously agreed to support your plans to have your DCLS students enroll in our course. We understand that inclusion of this course in your DCLS curriculum would increase our number of enrolled students by 3 - 10 students over the 2019 - 2022 period of predicted growth of your program.

We look forward to the opportunity to contribute to your degree program and wish you success in bringing it to fruition!

Sincerely,

A handwritten signature in black ink, appearing to read 'Ken McCarson', written over a white background.

Kenneth E. McCarson, Ph.D.
Professor of Pharmacology
Co-Director, Graduate Committee, Pharmacology & Toxicology Graduate Programs

Pharmacology, Toxicology & Therapeutics
Mail-Stop 1018 | 3901 Rainbow Blvd. | Kansas City, KS 66160 | (913) 588-7140 | Fax (913) 588-7501 |
<http://www.kumc.edu/pharmacology/>



July 27, 2016

Eric Elsingerhorst, Ph.D.
Chair
Department of Clinical Laboratory Sciences
KUMC

Dear Eric,

It was good to hear of your plans for a new degree program for the Doctorate in Clinical Laboratory Sciences and your intention to include teacher training in the curriculum. The program objectives in the Education Principles of Health Care domain of your program description match well with the stated course outcomes of our Teaching in Higher Education course (MICR 805). This is a 3-credit graduate course in teacher training designed for doctoral candidates in various biomedical fields and I have taught for the past three years; primarily in the School of Medicine basic science departments. The educational principles and practice experiences contained in the course should address most of your program's educational goals. The course is offered in both the Fall and Spring semesters.

I look forward to hearing more about your new program and working with your faculty to meet your training needs.

Sincerely,

A handwritten signature in black ink that reads 'Michael'.

Michael J. Parmely, Ph.D.
Professor



Department of Biostatistics

August 4, 2016

Eric A. Elsinghorst, PhD, MPH
Chair
Department of Clinical Laboratory Science
University of Kansas Medical Center
390 I Rainbow Blvd., MS 4048
Kansas City, KS 66160

Dear Dr. Elsinghorst,

I am writing on behalf of the KUMC Department of Biostatistics to confirm our enthusiastic support for the proposed Doctorate in Clinical Laboratory Sciences (DCLS). This new program will include the Biostatistics course *BIOS 704: Principles of Statistics in Public Health* as part of its required coursework. We are willing and able to accommodate enrollment of DCLS students in this course.

Please feel free to contact me directly at (913) 588-4789 or at jwick@kumc.edu if I can provide any more information regarding the Department of Biostatistics' support of your proposal.

Sincerely,

A handwritten signature in black ink that reads 'Jo A. Wick'.

Jo Wick, PhD
Associate Director
Graduate Education
Department of Biostatistics
University of Kansas Medical Center

**Program Summary
New Degree Program
Kansas Board of Regents**

New Degree Request – University of Kansas Medical Center

<u>Criteria</u>	<u>Summary</u>
1. Program Identification & CIP	Doctorate in Clinical Laboratory Science CIP: 51.1005
2. Academic Unit	School of Health Professions, Department of Clinical Laboratory Sciences
3. Program Description	<p>Open to individuals holding a national certification as medical laboratory scientists, graduates from this program will provide consultative services to patients and healthcare teams, or they may choose to enter academic positions in clinical laboratory science. Clinical laboratory scientists are a crucial component of the health care team, as seventy to eighty percent of a physician’s medical decisions are based on data generated by the clinical laboratory, and new Federal requirements mandate that test results be available to patients.</p> <p>Working with a rapidly expanding laboratory test menu and increasing test complexity, clinical laboratory scientists provide consultation to patients, physicians, and other members of the healthcare team. The proposed program is designed to address these needs by providing doctoral-level training and advanced practice in Clinical Laboratory Science (CLS), as well as by building upon the existing strengths of our nationally-accredited CLS program.</p>
4. Demand/Need for the Program	<p>With intensified analyses and a rapidly expanding test menu, there is a need for doctoral-level training in Clinical Laboratory Science (CLS) to provide consultative services to both patients and healthcare providers. In a survey of physicians, it was found that speed and accuracy of diagnosis was increased in 70-80% of their cases when interpretation of laboratory results was provided (Hickner, et al.).</p> <p>Individuals with extensive clinical laboratory expertise will dramatically improve patient outcomes and reduce costs. Unfortunately, the lack of doctorally-prepared clinical laboratory scientists is a barrier to the availability of interpretation of complex testing panels. Implementing this program will overcome this barrier, as well as address an unmet need in the state of Kansas (and nationwide) for doctorally-trained CLS professionals.</p> <p>In 2008, a survey of 299 randomly chosen early career CLS’s indicated that 65% were interested in pursuing a doctorate in clinical laboratory science (DCLS) (Doig & Beck). In 2009, a similar survey was sent nationally. Out of 1452 respondents, 61% indicated an interest in pursuing a DCLS with 23% of them indicating a desire to start as soon as possible (Nadder). Implementing this program will address both the need and demand for doctoral-level training in CLS.</p>

5. Comparative/ Locational Advantage	<p>Nationally, only two universities (Rutgers University, NJ; University of Texas Medical Branch, TX) offer the DCLS. As a leading academic medical center that focuses on patient outcomes with a team-based health-care delivery approach, KUMC is an ideal location for this innovative program.</p> <p>The CLS program at KUMC has been in existence since 1933 and continuously accredited by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) for over 50 years. Our BS in CLS graduates have an outstanding pass rate on national certification exams, and the program benefits from the high density of clinical facilities in the Kansas City metropolitan region. The success and reputation of our BS in CLS program will allow for effective establishment of clinical residency partners for the DCLS program. Additionally, the emphasis on interprofessional education amongst the healthcare disciplines at KUMC will provide unique opportunities for collaborative education prior to the clinical residency. Therefore, KUMC is uniquely positioned to offer this Doctoral degree program.</p>
6. Curriculum	<p>The 76-credit hour program consists of advanced graduate core courses, a research project, and a clinical residency. The core courses provide foundational knowledge needed for professional practice, including clinical correlations, test utilization, evidence-based practice, and quality assurance. The advanced courses encompass the six subspecialties of clinical laboratory science (chemistry, immunology, hematology, immunohematology, microbiology, & molecular diagnostics). The research project requires students to synthesize and integrate knowledge and apply theories and principles learned across the curriculum, and will include a written thesis as well as an oral defense. In the clinical residency, the students are provided the opportunity for professional practice by delivering consultative services to patients and healthcare teams.</p>
7. Faculty Profile	<p>All faculty involved in the proposed program are certified clinical laboratory scientists and/or possess advanced degrees in disciplines that are directly associated with clinical laboratory science. The CLS Department currently has nine faculty members, most of whom hold nationally recognized clinical laboratory certification. The CLS faculty who will teach in the DCLS program are: Eric Elsinghorst, PhD, MPH, MLS(ASCP)MB^{cm}, Research Associate Professor; Renee Hodgkins, PhD, MT(ASCP), Clinical Assistant Professor; Jan Hudzicki, PhD, MLS(ASCP)SM^{cm}, Clinical Associate Professor; and WenFang Wang, PhD, C(ASCP)^{cm}, Clinical Assistant Professor. Due to two vacancies, the CLS Department is currently recruiting new faculty members to fill these positions with a Summer 2017 start date.</p> <p>The faculty, and their departmental affiliation, currently identified as instructing DCLS core curriculum courses offered by other departments are: Glendon Cox, MD, MHSA, BA. Department of Health Policy & Management; Gregory Reed, PhD. Department of Pharmacology, Toxicology & Therapeutics; Steven LeVine, PhD. Department of Molecular & Integrative Physiology; Babalola Faseru, MD, MPH. Department of Preventive Medicine & Public Health; and Christopher Crenner, MD, PhD. Department of History & Philosophy of Medicine.</p> <p>Professionals mentoring students at clinical sites will be affiliated with the program through adjunct faculty appointments in the Department of Clinical Laboratory Sciences.</p>

8. Student Profile	The proposed program requires that applicants possess national certification as a medical laboratory scientist (MLS[ASCP]) and Bachelor's degree in CLS or an appropriate life science. It is required that applicants have work experience as a medical laboratory scientist.
9. Academic Support	Students enrolled in the program will be assigned to a five-member advising committee which will be responsible for guiding each student through the program requirements. Students will meet with these advisors on a regular basis. The current academic support services available at KUMC are sufficient to support the proposed program.
10. Facilities & Equipment	New facilities or equipment will not be needed for the proposed program.
11. Program Review, Assessment, Accreditation	Accreditation of the program will be sought through the National Accrediting Agency for Clinical Laboratory Sciences. The proposed program will be systematically reviewed and evaluated through survey and evaluation instruments that solicit feedback from students, graduates, residency sites, and employers. Program assessment will incorporate responses from the various evaluation instruments, as well as student coursework grades and outcomes of the thesis defense required for degree completion. Based on these measures, curricular changes will be implemented. The effectiveness of any change will be monitored through continued evaluation of student outcomes. A national certification exam for the DCLS is currently being developed. Graduates' performance on this exam will be included as part of the program process improvement.
12. Cost, Financing	Operating expenses for the proposed program will come from the existing budget of the Department of Clinical Laboratory Sciences, KUMC School of Health Professions. Two additional doctoral-level faculty are required in addition to the two vacancies. The two vacancies will be funded by the existing budget for the Clinical Laboratory Sciences Department. The salaries for the two additional faculty will be provided by the University.
<p>References</p> <p>Hickner, J., et al. (2014). Primary care physicians' challenges in ordering clinical laboratory tests and interpreting results. <i>The Journal of the American Board of Family Medicine</i>, 27(2), 268-274.</p> <p>Doig, K., & Beck, S. (2008). Surveys of support for the doctorate in clinical laboratory science. <i>Clin Lab Sci</i>, 21(2), 92.</p> <p>Nadder, T. (2011). Results from an interest survey on the professional doctorate degree in CLS. <i>ASCLS Today</i>, 25(4), 13-14.</p>	

**Curriculum Outline
New Degree Program
Kansas Board of Regents**

- I. Identify the new degree: Doctorate in Clinical Laboratory Science
- II. Provide courses required for each student in the major:

<u>Course Name & Number</u>	<u>Semester Credit Hours</u>
<u>Core Courses</u>	
CLS 800 Advanced Topics	3
CLS 802 Principles of Healthcare Education (3), or MICR 805 Teaching in Higher Education (3)	3
CLS 805 Advanced Molecular Diagnostics	2
CLS 815 Research Methods in Clinical Laboratory Sciences	2
CLS 820 Evidence Based Practice	3
CLS 830 Advanced Clinical Chemistry	3
CLS 836 Advanced Hematology	3
CLS 838 Advanced Immunology/Transplant	3
CLS 842 Advanced Microbiology	3
CLS 844 Advanced Immunohematology	3
CLS 851 Clinical Correlations I	3
CLS 852 Clinical Correlations II	3
CLS 880 DCLS Interprofessional Practice	2
CLS 890 Advanced Laboratory Operations	3
BIOS 704 Principles of Statistics in Public Health	3
HP&M 810 Health Care System	3
PHCL 898 Principles of Pharmacology	1
PHSL 843 Physiology of Disease	3
PRVM 800 Principles of Epidemiology	3
PRVM 853 Responsible Conduct of Research	1
<u>Research</u>	
CLS 901 DCLS Research I	2
CLS 902 DCLS Research II	3
CLS 903 DCLS Research III	3
CLS 999 DCLS Capstone	1
<u>Practica</u>	
CLS 911 DCLS Residency I	4
CLS 912 DCLS Residency II	5
CLS 913 DCLS Residency III	5
 Total:	 <u>76</u>

**Fiscal Summary
New Degree Program
Kansas Board of Regents**

Proposed Program: Doctorate in Clinical Laboratory Science

Implementation Year: Academic Year 2019-2020, Fiscal Year 2020

Part I. Anticipated Enrollment	Implementation Year		Year 2		Year 3		Year 4		Year 5	
	Full-Time	Part-Time	Full-Time	Part-Time	Full-Time	Part-Time	Full-Time	Part-Time	Full-Time	Part-Time
A. Full-time, Part-time head-count:	2	2	6	6	11	10	14	14	15	18
B. Total SCH taken by all students in program:	74		236		412		537		618	

Part II. Program Cost Projection

A. In implementation year one, list all identifiable General Use costs to the academic unit(s) and how they will be funded. In subsequent years, please include only the additional amount budgeted.

	Implementation Year	Year 2	Year 3	Year 4	Year 5
Costs:					
Salaries/Fringe	\$93,100	\$93,100	NAAB	NAAB	NAAB
OOE	\$1,200	NAAB	NAAB	NAAB	NAAB
Total	\$94,300	\$93,100	NAAB	NAAB	NAAB

NAAB = No additional amount budgeted.

Indicate source and amount of funds if other than internal reallocation:

Salaries/Fringe: As described in the “Program Faculty” section of this proposal, the CLS Department is filling two vacancies, the funds for which are in the current CLS budget. In addition to filling these vacancies, two additional new faculty will be required to support the program. The salary and fringe costs associated with new faculty hiring will be supported by KUMC (letter of support from David Vranicar, KUMC Vice Chancellor for Finance, is included in appendix materials). By the fourth year of the program, the net income realized through tuition will more than offset the cost of new faculty salary and benefits. OOE. The OOE costs will be supported by the reallocation of existing resources. OOE costs will be ongoing each year, but without requiring additional amounts budgeted, so are shown in the “Implementation Year” only.