

KENT STATE UNIVERSITY

CERTIFICATION OF CURRICULUM PROPOSAL

Preparation Date **12-Sep-17** Curriculum Bulletin _____Effective Date **Fall 2017** Approved by EPC _____*Fall 2018*

Department _____

College **PH - Public Health**Degree **MS - Master of Science**Program Name **Clinical Epidemiology** Program Banner Code **CEPI**

Concentration(s) _____ Concentration(s) Banner Code(s) _____

Proposal **Establish program****Description of proposal:**

This proposal is to establish a MS in Clinical Epidemiology. The program will be a minimum 36 credit hour degree with research-based practicum or thesis options. The program is designed to be completed in two calendar years of study. Classes can be taken 100% online with the practicum/thesis completed under the supervision of an academic advisor and research clinician.

Does proposed revision change program's total credit hours? ☐ Yes ☐ NoCurrent total credit hours: _____ Proposed total credit hours **36**

Describe impact on other programs, policies or procedures (e.g., duplication issues; enrollment and staffing considerations; need; audience; prerequisites; teacher education licensure):

An impact may be to the MPH in Epidemiology as the degrees are in the same field. The difference between the two degrees is that the MS is focused on Clinical Epidemiology methods and is a research degree while the MPH is a more general public health epidemiology and practice based degree. The new degree may impact the Health Policy and Management online MPH program. As the MS grows, we will likely need to add additional NTT faculty (1-2) for classes. Students from the MS degree will be better prepared to lead clinical research teams in hospitals, pharmaceutical companies, medical schools, or contract research organizations. A survey of undergraduate (to gauge interest in the degree) and graduate students (to gauge interest in taking classes as electives) found overwhelming enthusiasm for the degree program. In one week, 214 students completed the survey. The majority were interested in the degree (extremely interested=35%; very interested=18%; and interested=23%). As we have developed a BSPH in Clinical Trials Research that began fall 2016, we are prepared with faculty to offer the MS degree without additional faculty until the program grows (likely in 2019). Current faculty and adjuncts in the BSPH/MPH program can teach these classes with adjunct support as needed; however, as the program grows, we will likely need one to two additional NTT faculty.

Units consulted (other departments, programs or campuses affected by this proposal):

Units on campus that have been consulted include: Colleges of Nursing, EHHS, and Podiatric Medicine

REQUIRED ENDORSEMENTS_____
Department Chair / School Director_____
Campus Dean (for Regional Campuses proposals)**9/25/17**



Transmittal Memo

Date: September 15, 2017

To: Therese Tillett, Director Curriculum Services
Educational Policies Council (EPC)

From: Dr. Sonia Alemagno, Dean College of Public Health



Re: Establish the Mast of Science Degree in Clinical Epidemiology in the College of Public Health

On behalf of the College of Public Health, please find the attached materials to establish the Master of Science Degree in Clinical Epidemiology in the College of Public Health

The focus of the MS in Clinical Epidemiology is epidemiology and biostatistical methods related to clinical trials and clinical research. Students will learn advanced methods of observational and experimental study designs and understand disease prevention, development, prognosis, and treatment. Students will understand and be able to apply good clinical practices, clinical trials design, management, and statistical analysis, study monitoring, pharmaceutical research, and regulations related to clinical research. Depending on background, students who complete the degree will work as part of research teams being largely responsible for the methodology to conduct clinical research studies and analyze clinical data; lead clinical research teams as clinician researchers; or continue their education to pursue doctoral or professional degrees.

It is the hope that this curricular change be approved for fall 2018.

College of Public Health

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VanDomelen, Aimee

From: MILLER, JENNIFER
Sent: Wednesday, September 27, 2017 3:40 PM
To: VanDomelen, Aimee
Subject: New MS Degree

Aimee

We sent over paperwork on Monday for our new MS in Clinical Epidemiology. I am unsure what the process is for requesting CIP codes, but the CIP code that the faculty member feels the program is most connected to is:

Detail for CIP Code 26.1309

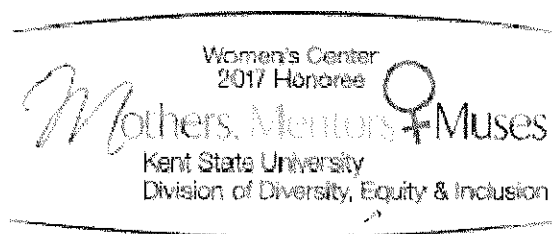
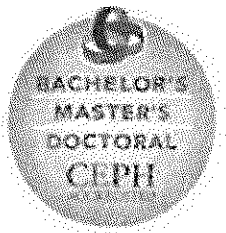
•  [Print](#)

Title: Epidemiology.

Definition: A program that focuses on the scientific study of disease, disability, and trauma patterns within and across populations and the development of health management mechanisms to prevent and control disease outbreaks and injurious behaviors. Includes instruction in biostatistics, biochemistry, molecular biology, immunology, disease and injury determinants, genetic disease and disability factors, behavioral studies, health services research, environmental disease and injury factors, and population studies.

Jen

Jennifer L. N. Miller (Noble); M.Ed., MBA | Assistant Dean, Student and Accreditation Services
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**KENT STATE UNIVERSITY
COLLEGE OF PUBLIC HEALTH
MS IN CLINICAL EPIDEMIOLOGY
FALL 2017**

**Prepared by:
Melissa D. Zullo, PhD, MPH, MA
Associate Professor of Epidemiology
College of Public Health**

New Graduate Degree Program Full Proposal Master of Science in Clinical Epidemiology

The College of Public Health would like to thank the students, faculty, and administration that has supported the development of this degree program. We would also like to thank the Ohio Department of Higher Education members that reviewed the proposal development plan and provided feedback that has helped to improve this proposal.

This proposal will demonstrate the need, curriculum, and experience of faculty in the College of Public Health at Kent State University for a Master of Science in Clinical Epidemiology. The proposal provides the evidence that the CPH is prepared to implement and sustain a graduate program in Clinical Epidemiology for students who are interested in conducting epidemiology research in a clinical setting. The goal of this degree program is to train students to meet the competencies set forth for Schools and Programs of Public Health by the Council on Education for Public Health and the Joint Task Force for Clinical Trial Competency.

Introduction

The Kent State University (KSU) College of Public Health (CPH) was established in 2009 and is fully accredited by the Council on Education for Public Health (CEPH). The CPH offers bachelor, master, and doctoral degrees in a wide range of disciplines. Our Bachelor of Science in Public Health (BSPH) offers nine degree concentrations, the Master of Public Health (MPH) includes five specializations, and the PhD offers three specializations. In spring 2017 the CPH included 640 undergraduate, 215 MPH, and 45 PhD students. Our faculty and students are engaged in research designed to address some of today's most important public health issues including substance abuse, active living, chronic disease, infectious disease, environmental health, clinical research, violence prevention, and management of public health organizations.

The proposed MS degree has developed from expression of KSU CPH students to have focused and advanced training in clinical epidemiology methods. The emphasis of the MS in Clinical Epidemiology is epidemiology and biostatistical methods related to clinical trials and clinical research. Students will learn advanced methods of observational and experimental study designs and understand disease prevention, development, prognosis, and treatment. Students will learn and be able to apply the good clinical practices; clinical trials design; management and statistical analysis; study monitoring; pharmaceutical research; and regulations related to clinical research. Depending on background, students who complete the degree will work as part of research teams being largely responsible for the methodology to conduct clinical research studies and analyze clinical data, lead clinical research teams as clinician researchers, or continue their education to pursue doctoral or professional degrees.

1. Academic Quality: Provide analysis on competency, experience and number of faculty and adequacy of students, curriculum, computational resources, library, laboratories, equipment and other physical facilities, needed to mount the program.

The MS in Clinical Epidemiology is a new degree in an established CPH. Hence, the established faculty, addition of clinical research adjunct faculty, and hire of one non-tenure track faculty in year two of the program will be adequate to meet the demands of the program. There are three faculty designated as core faculty for the program (Zullo, Stephens, and Stedman-Smith) and an additional secondary faculty (Cheruvu). The program director is Melissa Zullo, PhD, MPH, MA. Dr. Zullo has both practical and research experience in the clinical setting and directs the BSPH in Clinical Trials Research concentration.

New Graduate Degree Program Full Proposal

All faculty who will teach in the program have a terminal degree in their specialization (PhD, MD, PhD/RN, or PharmD) and have appointments at Kent State.

Adjunct faculty have years as practicing clinicians and academics. Core faculty and clinical adjuncts are identified in the table below (see appendix for curriculum vitas). In addition, there are other CPH faculty who will teach core classes or electives in the MS who currently teach sections of those courses for the online MPH in Health Policy and Management (Abbey Eng, PhD and Heather Beaird, PhD) or the MPH in Epidemiology (Tara Smith, PhD).

There are no new facilities needed for this program.

Our faculty (Table 1) who will be developing and teaching courses in the program as well as overseeing individual investigations, theses, or research-based practicums have extensive experience in clinical research, epidemiology methods, biostatistics, nursing, rehabilitation, cardiovascular disease, and clinical trials. The faculty have extensive experience developing and teaching online classes. Adjunct faculty will largely be responsible for guest lectures, seminars, and practical experiences in the degree. All adjuncts have experience in practice, teaching, and mentoring.

Table 1: Faculty information including core, secondary, and adjunct faculty in the MS in Clinical Epidemiology

Faculty	Degree	University	Expertise	Years - Profession	Course to be taught
Core and secondary faculty					
Melissa Zullo Associate Professor of Epidemiology	PhD Epidemiology 2009 MPH 2004 MA 1998	Case Western Reserve University NEOUCOM/Kent State Kent State University	Cardiovascular and Pulmonary Epidemiology; Clinical Epidemiology; Outcomes Women's Health	Academics: 8 Clinical: 10	Experimental Designs for Clinical Research Chronic Disease Epidemiology
Margaret Stephens Associate Professor	Ph.D. Sociology 1999 M.A. Sociology 1997 B.A. Sociology 1995 B.S. Education (K-8) 1991	University of Akron	Quantitative Methods Program Evaluation	Academics: 26	Applied Regression Analysis
Maggie Stedman- Smith Assistant Professor	PhD 2009 MSPH RN	University of Minnesota	Clinical Trials Community based trials Nursing Hand Hygiene	Academics: 8 Clinical: 20+	Ethics in Health Sciences Research Scientific Writing for Clinical Research
Vinay K Cheruvu Assistant Professor	PhD – Biostatistics 2011 MS – Statistics 2002 MSc – 1997 Statistics/Econometrics PGD-MISCA 2000	Case Western Reserve University Oklahoma State University Sri Venkateswara University Osmania University	Statistical Consulting Linear / Logistic / Poisson Regression Analysis Longitudinal Data Analysis Survival Analysis Mediation Models Clinical Trial Methods	Academics: 7	Experimental Designs in Public Health Research Advanced Epidemiology and Clinical Research Methods Data Management and Logic using SAS® Software
Adjunct Faculty					
Adjunct Faculty		Employment	Expertise		Courses to be taught or co-advise research
Richard Josephson	MD MS	University Hospitals, Cleveland	Cardiovascular Disease Clinical Trials	Academics: 20+ Clinical: 30+	Individual Investigation Research-based Practicum Thesis
Aditya Khetan	MD	University Hospitals, Cleveland	Cardiovascular Disease Clinical Trials Community based trials	Clinical: 6	Experimental Designs for Clinical Research Research-based Practicum Individual Investigation
Varun Sundaram	MD	University Hospitals, Cleveland	Internal Medicine Cardiovascular Disease Clinical Trials	Academics: 5 Clinical: 8	Individual Investigation Research-based Practicum Thesis

New Graduate Degree Program Full Proposal

Monique Washington	PhD Candidate MSN RN	Cleveland VA Medical Center Spinal Cord Injury/Disorders (SCI) Management of Information and Outcomes (MIO) Coordinator	Spinal Cord Injury Information Outcomes Quality Improvement	Academics: 7 Clinical: 20+	Individual Investigation Research-based Practicum Thesis Observational Designs for Clinical Research
Stephen Selkirk	MD	Cleveland VA Medical Center Department of Neurology - Case Western Reserve Medical School Medical Director, Cleveland ALS Center	Neurology Spinal Cord Injury	Academics: 10 Clinical: 15	Individual Investigation Research-based Practicum Thesis
Mary Dolansky Associate Professor	PhD RN	Case Western Reserve University	Cardiovascular Nursing Cardiac Rehabilitation Transitions of Clinical Care Clinical Trials Heart Failure	Academics: 10+ Clinical: 20+	Individual Investigation Thesis
Steve Schmidt	PhD	NEOMED	Regulatory Affairs Pharmaceutical Sciences	Academics: 30+ Clinical: 30+	Regulatory Affairs Individual Investigation Research-based Practicum Thesis
Martha Blackford	PharmD BCPS	Akron Children's Hospital NEOMED	Pharmacology /Toxicology	Academics: 9 Clinical: 12	Pharmacoepidemiology Individual Investigation Research-based Practicum

Adequacy of Students

Prospective students are those from an undergraduate program in public health, those with a Bachelor of Science in Nursing, practicing clinicians, and Podiatric Medicine graduates, among others. Admissions criteria follow the Kent State Graduate Studies criteria of a 3.0 minimum undergraduate GPA and submission of GRE scores (or other tests where appropriate; e.g., MCAT). Students from any undergraduate degree may apply and applicants will be admitted after a comprehensive review of GPA/prior coursework/GRE/recommendations/goal statement. Our current MPH in Epidemiology and Biostatistics follows the same admissions criteria. Applicants are reviewed by Graduate Studies for minimum GPA and file completeness followed by the department chair/graduate committee and a recommendation is made for admission. This has worked well for this degree. Consideration is given to both GRE and GPA as well as previous coursework at the undergraduate level. As a committee, we look for GRE scores at or above the 50th percentile; however, if an applicant does not meet this guideline, other factors are considered including coursework taken, GPA, and specific grades achieved in science and math/statistics courses. When necessary, we have had interviews with prospective students to gauge their appropriateness for these programs. Applicants to the MS program will be reviewed for appropriateness of previous degree, rigor of science courses, and practical training in a clinical setting. Recommendation for coursework in the MS in Clinical Epidemiology will be made by the program director and academic advisor. Some students may need to take coursework beyond the minimum 36 credit hours identified for the MS in preparation for competency in the field. These courses may include science courses such as anatomy and physiology, biology, basic research methods, or medical terminology. These decisions will be made at the time of admission with the student receiving a conditional admission.

A needs analysis was done of prospective students and this can be found in the upcoming section on **Need**.

Curriculum

The MS in Clinical Epidemiology is a minimum 36 (Individual Investigation allows for variable credit) credit hour degree that can be taken 100% online or as a hybrid program (Table 2). A student completing two to three courses per semester can complete the program in two-calendar years taking classes fall, spring, and summer (Table 3). Courses build upon each other and therefore a student will be required to take many in a specific order (Table 3).

Seven courses (four core courses and three electives) are currently taught in the classroom allowing for a hybrid option for local students. The coursework is designed around the eight domains of core competencies delineated by the Joint Task Force for Clinical Trial Competencyⁱ and the competencies for Schools of Public Healthⁱⁱ. There are 8 required classes (25 credits) and 2 electives (5 to 6 credits). Included in the curriculum are 6 credits hours of thesis or research-based practicum. Students have the option to take an individual investigation in clinical epidemiology as an elective that will be designed in conjunction with the advisor and an external adjunct. The purpose of the investigation will be to provide students with limited experience in a clinical setting additional exposure to the practical side of clinical research. Classes marked with ** are currently included in the BSPH and will be offered in the MS program (40/60000 levels). Courses taken at the 60000 MS level require additional readings and exercises that are aimed at a higher more critical level of learning. Some exercises are semester long projects and others require synthesizing more in depth research materials such as literature on a drug or device.

Table 2: Courses, credits, course format, and instructor				
Course #	Course Title	Credit	Current course and format	Current or proposed instructor
Required Courses (25 credits)				
BST 52019	Biostatistics in Public Health	4	Currently online and traditional	Abbey Eng, PhD
EPI 52017	Fundamentals of PH Epi	3	Currently online and traditional	Heather Beard, PhD
BST 63014	Applied Regression Analysis	3	Currently taught traditional – going online	Peggy Stephens, PhD
EPI 63018	Observational Designs for Clinical Research	3	Currently Online New for MS	Melissa Zullo, PhD or Aditya Khetan, MD
EPI 63019	Experimental Designs for Clinical Research	3	Currently Online New for MS	Melissa Zullo, PhD or Aditya Khetan, MD
BST 63013	Experimental Designs in PH Research	3	Currently online	Vinay Cheruvu, PhD
EPI 63020	Advanced Epidemiology and Clinical Research Methods	3	New for MS	Vinay Cheruvu, PhD
EPI 63021	Ethics in Health Sciences Research	3	New for MS	Maggie Stedman-Smith, RN, PhD
Electives - pick two (5 to 6 credits)				
EPI 50017	Pharmacoepidemiology**	3	Currently online	Martha Blackford, PharmD
EPI 50015	Scientific Writing for Clinical Research**	3	Currently online	Maggie Stedman-Smith, RN, PhD
EPI 50018	Regulatory Affairs in Clinical Research**	3	Currently online	Steve Schmidt, PhD
EPI 63014	Chronic Disease Epidemiology	3	Currently taught traditional – going online	Melissa Zullo, PhD or Varun Sundaram, MD
EPI 63015	Infectious Disease Epidemiology		Currently taught traditional – going online	Tara Smith, PhD
BST 62020	Data Management and Logic using SAS® Software	3	Currently taught traditional – going	Vinay Cheruvu, PhD

			online	
EPI 50196	Individual Investigation	1-3		
Thesis or Research-based Practicum (6 credits)				
EPI XX	Thesis	6		TBD
EPI XX	Research-based practicum	6	TBD	TBD

BST=biostatistics; EPI=epidemiology; TBD=to be determined

Table 3: Example of program timeline for full-time and part-time students			
Course #	Course title	Semester taken by full-time students	Semester taken by part-time students
BST 52019	Biostatistics in Public Health	Fall semester 1	Fall semester 1
EPI 52017	Fundamentals of PH Epi	Fall semester 1	Fall semester 1
EPI 63021	Ethics in Health Sciences Research	Fall semester 1	Fall semester 4
BST 63014	Applied Regression Analysis*	Spring semester 2	Spring semester 2
EPI 63018	Observational Designs for Clinical Research**	Spring semester 2	Spring semester 2
XXX	Elective	Spring semester 2	Spring semester 5
EPI 63019	Experimental Designs for Clinical Research**	Summer semester 3	Summer semester 3
BST 63013	Experimental Designs in PH Research***	Summer semester 3	Summer semester 3
EPI 63020	Advanced Epidemiology and Clinical Research Methods****	Fall semester 4	Fall semester 4
XXX	Elective	Fall semester 4	Spring semester 5
EPI XX	Thesis or research-based practicum	Fall semester 4	Summer semesters 6
EPI XX	Thesis or research-based practicum	Spring semester 5	Fall semester 7
EPI XX	Thesis or research-based practicum	Summer semester 6 if needed	Spring semester 8

*pre-requisite=BST52019; **pre-requisite=EPI52017; ***pre-requisite=EPI63019; ****pre-requisite=EPI63018 AND EPI63019

ONLINE DEGREE INFORMATION

Because your degree will be offered online, you will also need to incorporate the following information into this section:

i. Instructor qualifications for online instruction (e.g., Quality Matters, university training)

The CPH faculty have extensive experience in online education with four online undergraduate degrees and one existing and one new (fall 2017) online graduate degree. Faculty who are new to the online format can attend education sessions in how to teach effectively online and informational sessions on use of Blackboard™. All online courses follow the standards set forth in the Quality Matters™ rubric. The college also employs two online educational technologists and instructional designers and utilizes the Office of Continuing and Distance Education which has online technologists who have worked extensively with our faculty and staff in online curricular development.

ii. Will the program be offered in partnership with a third-party commercial on-line service provider? If yes, please provide name of provider and describe their responsibilities (e.g., recruitment, admissions, advising)

Yes, the program will be offered in partnership with Everspring, Inc. Everspring will be responsible for marketing; initial advising of students who are interested in the program; and monitoring to ensure that students are engaged in a course. Everspring also provides support to faculty to resolve student engagement issues as needed.

- iii. ***If applicable, describe how program faculty will oversee and direct original research performed by students in the program. At a minimum, address the following areas:***
- ***how students will gain access to required facilities and resources***
 - ***how students will be trained in necessary procedures***
 - ***how students will present their progress***
 - ***how the progress and quality of student projects will be assessed***

Students will work with an academic and clinical advisor to develop their research (individual investigation, research-based practicum, or thesis). Students in northeast Ohio will be able to access clinical advisors in a variety of local hospitals. (See Appendix C for letters of support). Students who reside outside of the local area will receive assistance in finding a clinical setting in which to do their research. For example, we have worked with our online BSPH concentration in CTR and HPM students to find internship and practicum placements and have obtained memorandums of understanding (MOU) from over 300 sites across the country. As students find their own placement, this registry grows.

Students will obtain research training through their coursework and if they choose to perform an individual investigation. They will apply this training in the research-based practicum or thesis.

When a student is engaged in the research component of the program, they will be required to work with their academic and clinical advisors to develop a timeline for completion of the study. Progress of the research will be monitored by the advisors according to the timeline students develop. Quality will be determined by the thesis advisor and the thesis committee - which at KSU consists of the advisor, who chairs the committee, two additional faculty members from the CPH (one will be the clinical advisor), and one or more members from other departments or college if appropriate. The majority of the committee will be from the CPH. Students choosing the thesis option will complete the notification of approved thesis topic required by graduate studies and certified by the advisor, committee, graduate coordinator, and the CPH Dean. Students will prepare an oral defense of their thesis that will be open to the university community. Local students will present on campus. Students who do not reside in the area will be encouraged to come to campus for the defense, otherwise they will present over videoconference.

- iv. ***If applicable, describe how program faculty will mentor students, and how students will participate in the socialization that is necessary for the effective scholarly exchange of ideas at the level appropriate for the degree sought. At a minimum, address the following areas:***
- ***how students will select a primary mentor and members of any required oversight committee frequency of any mandatory interactions between program faculty and students***
 - ***opportunities that exist for students to develop and refine ideas through scholarly exchange with faculty and others in the field***
 - ***career development opportunities will be provided***

Students in the online program will identify a clinical advisor/mentor from the MOUs described above or on their own and will work with their KSU faculty advisor either as their research mentor or to identify another faculty member who is aligned with their research interest. The thesis committee will be identified with the faculty advisors direction. Students will be required to interact with their advisors according to the timeline they develop.

Students who choose the research-based practicum will have less interaction with the faculty advisor and more with the clinical advisor. Students will be given guidance on what are considered appropriate activities in the research-based practicum. They will check in with their advisor at minimum twice per semester. Students will prepare a report at the end of their practicum describing their activities, what they have learned, etc. Our current BSPH in CTR students perform this activity and report to the program

Students in the program will enroll in courses in sequence as identified in Table 3 above. Students work with Everspring to determine when courses are offered and register using the Kent State system. If a student needs access to a class that has a pre-requisite or needs approval attached they will work with their advisor. Everspring manages and tracks student activity to identify students who are considered inactive and those who have dropped from the program. The program director will work with Everspring to monitor student progress.

Scholarly exchange is an important component of a graduate research degree. The CPH offers a no credit seminar series during the semester. These are presented traditionally and synchronously to students online. Online students also engage in discussion boards in each class during which they interact asynchronously with other students and faculty. The CPH also hosts a spring seminar that students can attend physically or virtually.

Students will be encouraged to work with their advisor and the CPH career ambassadors to identify career development opportunities.

In addition to this analysis, for entry-level graduate degree programs, academic quality assessment will focus on the adequacy of the answers provided in response to the following questions:

i Is the program distinctly different, both conceptually and qualitatively, from the undergraduate degree programs in the same or related disciplines? If so, is there a detailed listing of the specific differences?

The MS in Clinical Epidemiology is substantially different from the BSPH in Public Health with a concentration in Clinical Trials Research (CTR). The BSPH offers students comprehensive training in Public Health. The BSPH concentration in CTR introduces clinical research methods including experimental designs principles and practical experiences appropriate at the undergraduate level. Students graduating with this degree are trained to work as research assistants and clinical research associates at the entry-level for research entities including hospitals and contract research organizations. They will not have the skills to design or lead clinical studies. BSPH students take five courses in the concentration and a practice-based internship at a hospital or other research entity. Coursework includes: Clinical Epidemiology Basics; Clinical Trials Management; Scientific Writing for Clinical Research; Pharmacoepidemiology; and Regulatory Affairs in Clinical Research (See Table 4 for comparison of first courses offered in the BSPH and MS core relating to clinical study designs). BSPH students graduate with the ability to work on a team primarily doing the recruitment, consenting participants, performing data collection/abstraction, and data entry. They will not be tasked with designing or leading a research study or analyzing data. Job responsibilities are related to data collection and study management.

The MS in Clinical Epidemiology is an advanced degree that trains students in the epidemiology methods of clinical research. Students will graduate with the ability to think critically and carry out an epidemiology study from the point of conceptualizing the research questions and designing the study methodology, creating valid and reliable study documents, training and overseeing research staff, ensuring study fidelity, and analyzing the data. These concepts are more advanced than the BSPH. The rigor of a graduate degree in epidemiology is clear in the types of courses that students take but it is not only the coursework that sets it apart from the BSPH, it is the immersion in a research-based practicum experience or intense design and investigation of a thesis. See four courses developed for the MS in Clinical Epidemiology for a list of class topics (Appendix E).

Table 4: Comparing topics in clinical methods classes offered in the BSPH (1 course) and the MS (2 courses)		
Level	Class	Topic

BSPH	Clinical Epidemiology Basics	<ul style="list-style-type: none"> • What is Clinical Research • Reviewing the Basics of Epidemiology Methods • Ethical and Legal Issues in Clinical Trials Risk Prognosis • Formulating Research Questions • Who is the Study Population? • Study Designs • Randomization • Blindness • Participant Recruitment • Baseline Participant Assessment • Adverse Events – what are they?
MS	Observational Designs for Clinical Research	<ul style="list-style-type: none"> • Clinical Epidemiology Basics and History • Observational Epidemiology Study Designs: A Review • Understanding Causation in Observational Studies • Basics of Risk in the Cohort Study • Concepts of Time: Time, Exposure, and Outcomes • Bias • Understanding Risk Using the Case-control Study Design • Nested Studies in Cohorts: Case-control and Case-cohort Designs • Disease and Prognosis • Formulating Research Questions • Data for Epidemiologic Research • Defining the Study Population • Measurement and Validity
MS	Experimental Designs for Clinical Research	<ul style="list-style-type: none"> • Randomized Control Trial Studies and Alternative Designs • Randomization Techniques • Blinding • Sample Size Theory • Meta-analysis • Evidence-based Medicine • Clinical Prediction Rules and Risk Scores • Instruments and Measurements • Quality Control and Data Issues • Participant Recruitment and Adherence • Baseline Participant Assessment • Adverse Events • Response Variables • Clinical Trials in Varying Modalities

ii Does the program emphasize the theoretical basis of the discipline as expressed in the methods of inquiry and ways of knowing in the discipline?

Yes. The coursework is designed around the eight domains of core competencies delineated by the Joint Task Force for Clinical Trial Competency and the Council on Public Health Education competencies for Schools of Public Health.

iii Does the program place emphasis on professional decision making and teach the use of critical analysis in problem solving?

Yes, the MS in Clinical Epidemiology emphasizes professional decision making and critical analysis of problem solving through both coursework and practical experiences (Individual investigation, thesis, or research-based practicum). A major competency in the field of epidemiology is critical thinking and this is emphasized and reinforced in all core coursework. Further, the practical experiences will allow students to apply decision making and critical analysis through application of clinical epidemiology methods in the field.

iv Is the program designed to educate students broadly so that they have an understanding of the major issues and concerns in the discipline or professional area?

Yes. The MS is housed in the CPH. The CPH is fully accredited by CEPH and the new MS degree does require CEPH accreditation. Hence, the competencies addressed in the MPH will be addressed and expanded in the MS. This degree will provide students with advanced methodological training in clinical epidemiology with a focus on the skills that are needed to conduct health research in a clinical setting. To become a Clinical Epidemiologist, students need to pursue a Master's degree. The coursework focuses on methods used in clinical epidemiology and allows students with less exposure to the clinical setting to take courses in chronic disease epidemiology, infectious disease epidemiology, and ethics in clinical research. Further, the practical experiences under the supervision of clinical practitioners will provide hands on experiences that enhance understanding of clinical research.

v Is there an adequate description of the required culminating experience such as an exit project (which would not necessarily be a research experience)?

Students have two options that can act as a culminating experience. One is practical but research-based and the other is a traditional thesis. The research-based practicum will allow students to immerse themselves in a clinical study acting as a member of a research team. For example, our BSPH students in CTR currently complete an internship in a clinical research setting. These students are integrated into a research team and perform activities appropriate for an undergraduate student. For example, participating in research team meetings, helping write IRB applications, performing medical records abstractions, reviewing documentation, and consenting patients. The MS in Clinical Epidemiology students will engage at a level appropriate for a graduate student – providing input on the study design, developing research instruments, being responsible for the IRB process, recruiting and consenting participants, maintaining study documents, troubleshooting, validity checks, data collection and management, data cleaning and analysis, and report/manuscript writing. These are the activities they will be expected to perform in the occupation. The second option is the traditional thesis. Students will work with a faculty advisor and clinical research mentor to complete a clinical epidemiology thesis.

All students will be required to present their research-based practicum or thesis to the CPH in a practicum/research presentation day either in person or using videoconferencing technology.

vi Does the proposed program identify faculty resources appropriate for the research component of the program?

Yes. All faculty have extensive research experience to oversee the research-based practicum or the thesis. Faculty have published in peer-review journals and made presentations at national and international conferences. Adjunct faculty are all established or emerging researchers with histories of grant funding and publications in clinical settings and clinical trials. Students will have access to clinical research settings in which to conduct the individual investigations, practicums, or thesis.

vii Does the program curriculum offer what students need to know for competence at the expected level of professional expertise?

Yes. The curriculum is designed around competencies in the field of Clinical Trials Research and Public Health. These competencies come from the Joint Task Force for Clinical Trial Competency and the Council on Public Health Education competencies for Schools of Public Health. Students receive these competencies through each of the core courses with reinforcement in the electives and practical

experiences. Students will be able to sit for and pass the certification exam for clinical researchers (see section below).

viii What plans have been made to address standards and guidelines for professional accreditation, if applicable? What are the core courses required for the program?

Professional accreditation is not required for the field of clinical epidemiology. However, the Association of Clinical Research Professionals offers three levels of certification. Each level requires a minimum standard of educational degree plus hours of experience. The experience is generally not obtained until the individual has worked for at minimum 1.5 years in the field. Job announcements sometimes desire accreditation or corresponding education/years of experience. There is no set standard for clinical researchers. Core courses in the program identified above in Table 2 meet the competencies set forth by the Joint Task Force – which offers the certification. Students choosing to become certified will have the knowledge to be successful in the process.

2. Need. Examples of potential metrics of program need include:

a Student interest and demand; potential enrollment; ability to maintain the critical mass of students.

As this degree is an online program, it has the potential to reach students outside of Northeast Ohio. However, the explanation of potential and identified sources of students for the program is limited to the northeast Ohio geographic area.

Student Demand

Our needs assessment included three groups of Kent State University students (see Appendix B: Student Surveys): CPH undergraduates and graduate students; College of Nursing (CN) undergraduate students; and College of Podiatric Medicine (CPM) students. A survey was administered to CPH students in November 2016 to determine if there was interest in the degree and in electives that will be offered in the degree. Separate surveys were administered to students in the CN and CPM in August 2017 to determine interest in a graduate research degree after completion of their current degree. These two groups were chosen because they will be practicing clinicians who work directly with patients and there is demand for employees with this combination of training.

CPH Student Interest

The CPH has a large undergraduate student body that has shown interest in the new degree. Currently, only 5% (n=21) of our undergraduates have entered the MPH since 2014 (Table 5) with the majority of students being recruited from outside of The CPH and Kent State University. Based off the response to the survey administered to CPH undergraduates, we anticipate increased enrollment into the MS from the BSPH.

Table 5: Undergraduates by semester and BSPH students by AY who transitioned to MPH						
BSPH by semester	Fall 2014	Spring 2015	Fall 2015	Spring 2016	Fall 2016	Spring 2017
Enrollment	550	614	562	596	528	552
BSPH Graduates	42	99	63	93	62	84
BSPH Graduates entering MPH by AY	4		8		6	3

The survey administered to students in the CPH in November 2016 included 225 undergraduate and graduate respondents (Seniors = 33%; Juniors = 16%; Sophomores = 10%; Freshman = 2% graduate students = 39%). Undergraduates were included to identify those who will be likely to enroll in the MS degree. Graduate students were included to identify those likely to take courses as electives in their current

concentration. Results indicated that 59% (n=42) of seniors were extremely/very interested and 67% (n=24) of juniors were extremely/very interested in the MS degree. Overall, 59% of students surveyed were extremely/very interested in the MS while only 5% (n=11) were not at all interested. Of graduate students, 66% were extremely/moderately likely to take electives in the Clinical Epidemiology degree. The new BSPH with concentration in CTR that began in summer of 2015 was an opportunity to measure interest in an MS in Clinical Epidemiology and hence these courses were offered to both undergraduate and graduate students. Graduate students have only two electives to fit their MPH curriculum; therefore, high enrollment was not anticipated. Graduate student enrollment between the two courses (Clinical Epidemiology Basics and Clinical Trials Management) was as follows: Summer 2015: n=9; Summer 2016: n=10; Fall 2016: n=7; and Summer 2017: 5.

College of Podiatric Medicine Student Interest

A survey was administered to students in the CPM in August 2017. There were 130 students who responded to the survey. Students were asked if they were interested in a graduate research degree after they completed their Podiatric Medicine degree and how interested they were in the specific Clinical Epidemiology degree. Over half of respondents (57%) indicated they were interested in a research degree (28% yes; 29% maybe). Of those interested, 80% (n=59) indicated they were somewhat (35%) to very interested (45%) in the specific degree.

College of Nursing Student Interest

A similar survey was administered to undergraduate students in the CN in August 2017. These students were asked if they were interested in a graduate degree after completion of their BSN, if they were interested in doing nursing research (working as a clinical nurse researcher), and how interested they would be in the specific Clinical Epidemiology degree. There were 160 students who responded to the survey. The majority were interested (yes = 74%; maybe = 23%) in obtaining a graduate degree after the BSN. Of these students, 29% (n=45) were interested in working as a clinical nurse researcher while 52% (n=80) indicated they might be interested. The students who expressed interest were asked how interested they would be in a MS in Clinical Epidemiology. Of these students (n=124), 31% (n=38) were very interested and 41% (n=51) were somewhat interested (21% were unsure and 7% were not interested).

Projected Student Enrollment

A new online MPH degree option with concentration in Health Policy and Management was initiated in summer 2015. This degree was an addition to the traditional face to face degree already offered in the College of Public Health. While this degree is not the same as an MS in Clinical Epidemiology, its

Table 6: Health Policy and Management Online MPH	
Cohort Start	N Enrolled
Summer 2015	5
Fall 2015	21
Spring 2016	15
Summer 2016	12
Fall 2016	28
Spring 2017	24
Summer 2017	10
Fall 2017	35
Spring 2018	15

enrollment data can be used to project the MS enrollment (Table 6).

Based off projections from the HPM online MPH, we anticipate a 1st year cohort of 20 students, a 2nd year cohort of 30 students, and 3rd – 5 year cohorts of 40 students each, capping between 20 and 30 per class. A student enrolling fulltime will take 7.5 classes per year (see Budget Projections). The majority of HPM online students are enrolled full-time (101) with only 20

students taking courses part-time.

b Institutional need; plan for overall development of graduate programs at the proposing institutions.

At the graduate program level at KSU, students engage in exceptional research opportunities through more than 50 master's programs with over 100 areas of specialization. According to the Carnegie Commission on Higher Education, KSU is one of 77 public research universities that maintain "high research activity." The Carnegie Foundation has designated KSU as Doctoral/Research University Extensive, one of only 90 public institutions nationwide in this category. This designation recognizes KSU as a leader in selected areas of research and creative activity. With our eight-campus network in Northeast Ohio, KSU serves the state and the nation with excellence through our many graduate programs. Graduate education at KSU is part of the strategic plan which is supported by the university as a whole. Kent State's Strategic Roadmap demonstrates our commitment to students, global competitiveness, the growth and prosperity of our region, and providing cutting-edge knowledge and ideas while offering high-quality innovative education.ⁱⁱⁱ

c Societal demand; intellectual development; advancement of the discipline; employment opportunities and d. Scope; local, regional and national needs; international need.

Due to the increase in complexities of clinical trial designs and protocols, there is a growing need for trained clinical researchers. Further, northeast Ohio is rich with world renowned hospitals that conduct cutting edge research. The job titles for a graduate with a MS in Clinical Epidemiology are diverse and a job search requires entering multiple titles. These titles include: Epidemiologist, Research Scientist, Clinical Research Associate, Clinical Data Specialist, Clinical Data Manager, Research Investigator, Research Assistant, and Clinical Epidemiologist, among others. Entry level jobs in the field are generally at the Bachelor's level while director and manager jobs typically require or prefer a MS or PhD. Degree requirement for a job also depends on the type of organization. For example, data scientist or research investigator jobs at insurance agencies and pharmaceutical companies typically require an MS and sometimes a PhD. The job title Clinical Research Associate (CRA), which typically is an entry level job for a BSPH student, was ranked 9th in Best Jobs in America with ten-year projected job growth of 36%. There is a demand for these positions; however, they often require experience which is where the advanced degree^{iv} can help secure employment.

Labor statistics are not collected specifically on Clinical Epidemiologist; hence, data for this needs analysis was obtained on multiple job titles for which a Clinical Epidemiologist would be qualified. According to the Ohio Labor Market Industry Snapshot report,^v in the Business Functions cluster - Environmental Scientists and Specialists including Health will allow 44 annual opening while across all industries there are 115 annual openings. The Bureau of Labor Statistics report for the timeframe between 2014-2024, predicts 6% growth for Epidemiologists^{vi} (Master's), 12% growth for Survey Researchers^{vii} (Master's), and 34% growth for Statisticians^{viii} (of which 25% work in universities and 15% work in scientific research and development services^{ix}). While CRAs can enter the field with a Bachelor's degree, a Master's^x degree can assist with employment and advancement in this challenging field. The Bureau of Labor Statistics reports an expected rise by 22% from 325,800 positions to 396,500 between 2012 and 2022 for CRA.

Table 7 presents examples of job titles, companies, and locations of jobs in Ohio for which a Master's level Clinical Epidemiologist would qualify. The abundance of jobs throughout the country supports the needs for the online MS degree.

Table 7. Examples of available Ohio jobs which a graduate of the MS in Clinical Epidemiology would be qualified

Job Title	Company	Location
Clinical Research Manager	Hemex Health	Cleveland
Biostatistician	Cleveland Clinic Foundation QHS	Cleveland
Senior Research Scientist	Charles River	Spencerville
Research Scientist I	Charles River	Ashland
Data Scientist	Ascend	Dayton
Clinical Research Coordinator III	Cincinnati Children's Hospital	Cincinnati
Biostatistician	Cleveland Clinic Foundation	Cleveland
Director Research Operations	OhioHealth	Columbus
Clinical Trial Manager – Oncology	Medpace	Cincinnati
Research Associate - Epidemiology	Nationwide Children's Hospital	Columbus
Research Project Coordinator	Nationwide Children's Hospital	Columbus
Research Associate RI Behavioral Health	Nationwide Children's Hospital	Columbus
Research Coordinator- Plastic Surgery	Nationwide Children's Hospital	Columbus
Clinical Research Manager	Ohio State University	Columbus

Examples of jobs (count) available nationally and in Ohio

Epidemiologist - 623 jobs nationally,^{xi} 9 in Ohio^{xii}
 Clinical Epidemiologist - 266 jobs nationally^{xiii}, 9 in Ohio^{xiv}
 Clinical Data Analyst - 7,614 jobs nationally,^{xv} 185 in Ohio^{xvi}
 Clinical Research Associate - >16,000 nationally^{xvii}, 480 jobs^{xviii} in Ohio
 Health Research Scientist - 7,550 jobs nationally^{xix}; 194 in Ohio^{xx}
 Research Assistant/Associate – 376 in Ohio^{xxi}

Northeast Ohio Employer Support

Clinical researchers/research directors at Northeast Ohio Hospitals have indicated need for graduates trained in clinical epidemiology methods. Letters of support from these individuals can be found in Appendix C (Letters of Support). Titles and hospitals are listed below. A survey (Appendix D: Survey Responses) indicating need, number of open positions, and starting salaries was completed by five clinical researchers/research directors at these hospitals.

- Vice President, Research, Sponsored Programs & Innovation at **Summa Health Akron City Hospital**
- Professor of Medicine, Harrington Heart & Vascular Institute at **University Hospitals Cleveland**

- Emergency Medicine Research Director, **Cleveland Clinic Akron General**
- Chief Research Officer, Rebecca Considine Research Institute, **Akron Children's Hospital**
- Vice President for Research & Dean of College of Graduate Studies, **NEOMED**
- Department Chair, Quantitative Health Sciences, **Cleveland Clinic Foundation**
- Director, University Partner Collaborations, St. **Vincent Charity Medical Center**
- Director of Clinical Research, **University Hospitals**
- Director ALS Center of Excellence, **Cleveland Veteran's Administration**
- Director of Research, **Cleveland Clinic Akron General**

3. Access and Retention of Underrepresented Groups

a Plan to ensure recruitment, retention and graduation of underrepresented groups within the discipline.

It is always a goal of Kent State University and the CPH to enroll and retain underrepresented students. This is particularly important in clinical research fields. The CPH is particularly sensitive to the issue of recruitment, retention, and graduation of underrepresented student populations and developing clinical research professionals that are from these groups. Our graduate student body is composed of approximately 30% from underrepresented groups. The CPH has a comprehensive Strategic Diversity Plan. Highlights from the Diversity Plan are found in the tables below (Tables: 8 - 9). Recently, the CPH has hired an Academic Diversity Outreach Specialist to work with underrepresented and international students on retention and graduation success as well as other areas of concern to these students. Kent State University has six goals embedded in its strategic framework. The CPH Strategic Diversity Plan focuses on three of the six goals. As noted below and following each of the three university goals are the CPH strategic focus areas:

1. Ensuring Student Success (University goal)
 - A Diverse Community
 - Equitable Retention
 - A Welcoming Environment
2. Developing and Recognizing Our People (University goal)
 - Equitable Progress for All
3. Enhancing Academic Excellence and Innovation (University goal)
 - Embracing Cultural Diversity Competencies

Table 8: CPH Diversity Scorecard Final Report

Metric	Baseline Year 2009-10	Goal Year 2015-16	Goal 2016-17
Access Goal 1: Increase access for African American, Native American, & Latino faculty, staff and students			
Full-Time/First-Time Freshmen	16.7% (AY2010-11)	20.4%	25%
Tenure track Faculty -New Hires	0%	33.3%	5%
Non-Tenure track Faculty - New Hires	0%	20%	5%
Unclassified Staff - New Hires	0%	50%	5%
Classified Staff - New Hires	n/a	n/a	6%
Retention Goal 2: Increase retention of African American, Native American, & Latino faculty and students			
Student first year retention rate	n/a	72.7%	70%
Student second year retention rate	n/a	41.7%	70%
Tenure Track Faculty Annual Retention	n/a	n/a	100%
Non-Tenure Track Faculty Annual Retention	n/a	n/a	100%
Excellence Goal 3: Increase graduation rate and degrees awarded to African American, Native American, & Latino students			
Masters Degrees Awarded	n/a	20%	30%

Doctoral Degrees Awarded	n/a	0%	10%
Special note: The CPH is a fairly new college to Kent State University with its inception in 2009. Therefore, there was no data available during the baseline year for most of the categories examined. Further, goals were not set until AY2016-17 and the table below reflects both of these special circumstances.			

b Provide as background a general assessment of:

i Institution and departmental profiles of total enrollment and graduate student enrollment of underrepresented groups within the discipline.

Table 9: College and concentration underrepresented student enrollment, September 2017					
	Total n=832 (%)	Graduate Students (n=277)	Undergraduate Students (n=555)	BSPH in Clinical Trials Research (n=36)	MPH in Epidemiology or Biostatistics (n=57)
African-American	142 (17.1)	42 (15.2)	100 (18.0)	9 (25.0)	7 (12.2)
Hispanic-Latino	9 (1.0)	1 (0.4)	8 (1.4)	1 (2.8)	0 (0)
International*	45 (5.4)	30 (10.8)	15 (2.7)	0 (0)	16 (28.0)
Multi-Racial ALANA/other	38 (4.6)	10 (3.6)	18 (3.2)	1 (2.8)	2 (3.5)
Native American	1 (0.1)	1 (0.4)	0 (0)	0 (0)	0 (0)
Total	235 (28.2)	84 (30.3)	141 (25.0)	11 (30.6)	25 (43.9)

*We chose to include international students in this presentation of data as they are a group that may currently have a difficult time seeking and completing a degree.

Highlights from the CPH Diversity Scorecard – 2016 (note that 2016-2017 data is not yet available)

- The CPH increased underrepresented full-time/first-time freshmen enrollment from 16.7% during AY2010-11 to 20.4% during the goal year. The AY2016-17 goal is 25%.
- During AY2015-16, underrepresented tenure track faculty hires for the CPH were 33.3%. The AY2016-17 goal is 5%.
- During AY2015-16, underrepresented non-tenure track faculty hires for the CPH were 20%. The AY2016-17 goal is 5%.
- During AY2015-16, underrepresented unclassified staff hires for the CPH were 50%. The AY2016-17 goal is 5%.
- During AY2015-16, underrepresented student first year retention rates for the CPH were 72.7%. The AY2016-17 goal is 70%.
- During AY2015-16, underrepresented student second year retention rates for the CPH were 41.7%. The AY2016-17 goal is 70%.
- During AY2015-16, underrepresented masters degrees awarded decreased for the CPH and were at 20%. The AY2016-17 goal is 10%.

ii Compare underrepresented groups degree recipients from the department and university at all levels compared to national norms. Supply data by group where available.

The National Science Foundation report on *Women, Minorities, and Persons with Disabilities in Science and Engineering (2013)*^{xxvii} shows that in 2010 only 13% of Master's degrees were granted to underrepresented minorities in social science and engineering fields and black women made up only 2% of employees in the science and engineering fields. As noted in the highlights section above, our 2015-2016 underrepresented masters degrees awarded decreased; however, our current enrollment data for

underrepresented and international students for the sciences of public health (biostatistics and epidemiology) are 44% with 31% of the Clinical Trials Research concentration at 31%. The recent hiring of the Academic Diversity Outreach Specialist will help us to obtain our diversity goals.

4. *Statewide Alternatives*

a Programs available in other institutions.

Similar programs in the State of Ohio and region

- The University of Cincinnati offers the MS in Clinical and Translational Research designed to prepare clinical professionals with the skills to become independent researchers.^{xxiii} The degree is geared towards practicing clinicians and is designed to be completed in two years with a 2 credit thesis. Applicants must have a bachelor's degree and a minimum 3.0 GPA.
- Case Western Reserve University offers a MS in Epidemiology (not focused on clinical research).^{xxiv} CWRU also offers a MS in Clinical Research for those with a MD, DDS, doctorate in nursing or allied sciences such as Pharmacy, or Biomedical Engineering. This program is for clinicians who want research training. CWRU offers a graduate certificate in Clinical Research with four classes.^{xxv}
- The Ohio State University offers a Master of Applied Clinical and Preclinical Research in combination with the Colleges of Nursing, Pharmacy, and Medicine.^{xxvi} The degree is 100% online. While this program is the closest to the proposed MS degree at KSU, the OSU program is practice based (requires a capstone) while the KSU program is research focused (students take methodological courses that will allow them to design and carry out research studies and requires a thesis or research intensive practicum). The OSU program is a 36 credit hour program. There are four specializations: Clinical Research Management, Regulatory Affairs, Safety Pharmacology, and Clinical Pharmacology.
- The Ohio State University CPH also offers a MPH in Clinical and Translational Science which is directed at clinicians (e.g., MD, DO, DDS, DVM, PharmD) who want additional training in clinical research.
- The University of Pittsburgh offers a MS in Clinical Research that is geared towards medical students, fellows, and faculty (i.e., must have a terminal degree).^{xxvii} This program is for clinicians who want research training.
- The University of Michigan offers a MS in Clinical Research that requires students to be currently enrolled in a professional or doctoral program in Medicine, Nursing, Pharmacy, Dentistry, or other health-related degree.^{xxviii} This program is for clinicians who want research training.

This program at the University of Cincinnati is the most similar in design to the proposed MS in Clinical Epidemiology at KSU and is also a hybrid program. The CWRU, OSU (1 of 2), Pitt, and UM programs differ from the KSU program in that they are geared towards clinicians who want additional training to conduct and lead research studies in a clinical setting. The KSU program is geared towards students coming out of a bachelor's degree who want a graduate degree to be able to work on a team conducting clinical research.

b Appropriateness of specific locale for the program.

KSU is situated in northeast Ohio and has access to several large institutions for placement of our students in research organizations. We have the support for this degree from the major hospitals in Akron as well as those in Cleveland.

c Opportunities for inter-institutional collaboration.

KSU willingly supports inter-collegiate collaborations and enjoys the partnerships we have with regional hospitals and research organizations. It is best for students to gain practical experiences and educational opportunities from different institutions and organizations. Opportunities that arise with our state-wide partners will be welcome. Our students also have the support of local hospitals/researchers who enthusiastically support this new degree.

d Institutional Priority and Costs

i Support and commitment of the proposing institution's central administration.

The MS in Clinical Epidemiology has the support of the faculty and administration in the CPH as well as the University Provost.

ii Adequacy of available resources committed for the initiation of the program.

There are no new facilities needed as this is an online program. Current faculty levels meet the needs of the new degree for the first year. In year two we have budgeted for a FTNTT faculty.

Budget Projections are presented in the table below. Projections are for 20, 30, 40, and 40 students over the first 1, 2, 3, and 4 year of the program with class sizes capped at 30. Revenue is estimated at \$386,483 in years 3 and 4.

Budget Projections

Kent State University					
Fiscal Impact Statement					

5. External Support

- This program has enthusiastic support from our clinical partners in northeast Ohio. Please see Appendix C.

SUPPLEMENTAL INFORMATION TO ACCOMPANY FULL PROPOSAL

1. Clarification and revisions based upon the reviews of the program development plan (PDP).

We appreciate the feedback from our colleagues at Cleveland State University, University of Toledo, The Ohio State University, Ohio University, and The University of Cincinnati and hope that your feedback and recommendation have been addressed.

Review by The Ohio State University College of Public Health: *Development Plan Submitted by Kent State University College of Public Health for the Master of Science in Clinical Epidemiology*

Kent State University submitted a Proposal Development Plan indicating the intent, pending further review and approval, to develop and implement an *Online Master of Science in Clinical Epidemiology Degree*. A review from The Ohio State University College of Public Health follows:

1. Potential conflicts with any existing program at the RACGS member's own institution:

The Ohio State University offers a Master of Applied Clinical and Preclinical Research in combination with the Colleges of Nursing, Pharmacy, and Medicine. The degree is 100% online. While this program is the closest to the proposed MS degree at KSU, the OSU program is practice based (requires a capstone) while the KSU program is research focused (students take methodological courses that will allow them to design and carry out research studies and requires a thesis or research intensive practicum). The OSU program is a 36 credit hour program. There are four specializations: Clinical Research Management, Regulatory Affairs, Safety Pharmacology, and Clinical Pharmacology.

The Ohio State University College of Public Health (OSU COPH) also offers a MPH in Clinical and Translational Science which is directed by faculty within the college in collaboration with faculty of other colleges (e.g., MD, PhD, DO, DDS, DVM, PharmD). This program is designed for professionals in training (MD/PhD, Residents, Fellows) who want additional training in clinical research. The program requires 45 credits of coursework including a field practicum and a culminating research project. Course sequences in epidemiology, biostatistics, and clinical research are taught by COPH faculty. Culminating research reports are evaluated by the student's advisory committee and must be suitable for submission for peer review and publication.

No response required.

2. Possible cooperation or collaboration:

Ohio State, including its College of Public Health, engages in interuniversity cooperation and collaboration involving universities inside and outside Ohio. From the proposal, it is uncertain what specific cooperation and collaboration can occur as a result of the proposed program, but there is certainly possibility. Indeed, there is always strong interest for mutually beneficial and manageable projects that lead to positive outcomes.

Yes, we agree. There is always an interest in collaboration with our university partners inside and outside of Ohio. Specific collaborative opportunities may arise down the road and these are welcome.

3. Concerns with substantive elements of the program development plan:

The number of semester credits to earn the proposed degree is acceptable. However, it is unclear that the proposed curriculum would provide the necessary training to conduct clinical research. For example, it is unlikely that single courses in “applied regression analysis” and “clinical trials management” will be adequate to cover the complexities of planning, conducting, analyzing and interpreting clinical trials (e.g., power calculations, recruitment, randomization, blinding, compliance, monitoring, adverse events, analysis, logistic regression, Cox regression, repeated measures ANOVA, closeout, etc.) and a variety of other logistic issues that are routinely encountered by investigators. Furthermore, it will be essential to identify a cadre of clinicians actively engaged in conducting human clinical investigations who are willing to teach and monitor students in the program to help assure that enrolled students receive successful training and experiential activities.

Thank you for this feedback; we have addressed the curricular concern by changing the content of some of the core classes and adding an advanced epidemiology methods course and a data management and logic using SAS® software. We have also identified clinician researchers in our local partner hospitals who are enthusiastic about mentoring these students. We have added an individual investigation option as variable credit that will give students with less clinical exposure the opportunity to immerse themselves in this environment under the supervision of a clinical researcher.

See question #4 for more information on clinician mentors.

4. Suggestions for strengthening the proposal or sharpening its focus:

The proposal must identify individuals with practical experience in conducting clinical investigations to serve as advisors and mentors of students enrolled in the program. As stated in the proposal, “*clinical epidemiology is a subfield in Epidemiology that focuses on research conducted in a clinical setting.*” And yet, no specific clinical resources are identified in the proposal that would be a sustainable resource for experiential training in the field. Furthermore, the proposal is designed as an online program that offers no specific activities by which enrolled students can interact with faculty engaged in clinical investigations.

Thank you for this comment. The full proposal contains information on clinicians and local hospitals that are interested and willing to support graduate students in this degree. Letters of support are in the appendix. These hospitals include: Akron Children’s Hospital, Cleveland Clinic Akron General, Summa Health Akron City Hospital, Cleveland Clinic Foundation, St. Vincent Charity Medical Center, University Hospitals Cleveland, and the Cleveland Veteran’s Administration.

Applicants for enrollment are students from any undergraduate degree program with at least a 3.00 GPA plus GRE scores and recommendations. However, no specific thresholds have been established as criteria for enrollment. Given the complexities of clinical investigations involving medicine, biology, biostatistics, epidemiology, etc., it would seem advisable to establish a more stringent set of requirements for admission into the program that would ensure that enrolled students have a high likelihood of success.

This is an understandable concern; however, our current MPH in Epidemiology and Biostatistics follows the same admissions criteria. Applicants are reviewed by the department chair/graduate committee and a recommendation is made for admission. This has worked well for this degree. Consideration is given to GRE and GPA as well as previous coursework at the undergraduate level. As a committee, we look for GRE scores at the 50th percentile; however, if an applicant does not

meet this guideline other factors are considered including coursework taken, GPA, and specific grades achieved in science and math/statistics courses. When necessary, we have interviewed prospective students to gauge their appropriateness for these programs. Applicants to the MS degree will be reviewed for appropriateness of previous degree, rigor of science courses, and practical training in a clinical setting. Recommendation for coursework in the MS in Clinical Epidemiology will be made by the program director and academic advisor. Some students may need to take coursework beyond the minimum 36 credit hours identified for the MS in preparation for competency in the field. These courses may include science courses such as anatomy and physiology, biology, basic research methods, or medical terminology.

Students are given the option of completing a research-based practicum instead of a thesis. No specific details for this option describe how students are connected with a “site preceptor” who oversees the research-based practicum. This option includes IRB protocol development and approval, creation of study forms, attaining informed consent, data collection, management, analysis and writing a “publication-ready” manuscript. Since this comprehensive profile of tasks may be overwhelming for a beginning graduate student with little prior training, it would seem prudent to tailor this option to only professional students who have already achieved significant training in a particular health-related field.

The program is designed so that students receive the proper training to be able to perform activities such as IRB, development and approval, creation of study forms, attaining informed consent, data collection, management, analysis and writing a “publication-ready” manuscript. Even at the undergraduate level, our BSPH in Clinical Trials Research students receive practical training in how to carry out these tasks, albeit at a less rigorous level. When MS students are ready to do their practicum or thesis, they will be assisted in the process of either conducting their research with a faculty member or clinical researcher, or finding a site for the research-based practicum. We have a network of research sites available for these placements (see letters of support) and experience with clinical internship placement at the undergraduate level.

A major element of human clinical investigations is the collegial nature of the field. Faculty with expertise in medicine, molecular biology, pharmacology, biostatistics, epidemiology, medical ethics, and other health-related disciplines are required in order to provide valuable insights on the planning and successful conduct of clinical studies. Broadening the teaching faculty of the proposed program will be important to its success.

In anticipation of this need, we have added multiple clinical researchers as adjuncts and received support from our clinical partners for additional adjuncts as needed. Specifically, we have added MDs and RNs with clinical research experience to the list of faculty. Each of these faculty work in a clinical setting and/or conduct clinical trials research.

Cleveland State University

1. Market need for the proposed program and the distinctions or differences between the proposed program and other similar programs across the state;

For this particular type of program, the state market is not saturated and KSU has done a good job in their proposal in describing how their program will be differentiated from those across the state.

No response required.

2. Opportunities for collaboration with the CCGS member's own institution;

KSU may wish to consider possible dual degree options with CSU's clinical programs or offering this degree to alumni of these programs, especially for those clinical practitioners with a strong interest in research. Clinical practitioners could especially benefit from this type of program since they have already trained in and may even be practicing within a clinical setting and would understand the strengths and limitations of conducting epidemiological research in such settings.

Thank you for this suggestion. One step we took was to do a survey of Kent State Undergraduate Nursing students and Podiatry students to determine if there was interest in a graduate Clinical Epidemiology research degree after they completed their current degree. There was overwhelming support as you will read in the full proposal. We anticipate that there will be strong interest from students in a similar program or recent graduates of a similar program, such as students from the CSU clinical programs.

3. Concerns with substantive elements of the proposed degree program;

Given that this program has a very specific focus on clinical epidemiology, I would encourage KSU to offer this as a hybrid program and ideally one where its graduate students can gain some hands-on experience within a clinical research setting. Especially with undergraduate students, few of them would have experience working within a clinical context and reading about this research environment is very different from effectively working in it.

We have added an individual investigation option for students who may not have appropriate clinical exposure to be able to step into a clinical research environment. These students will work with an adjunct faculty member who is a clinician. Additionally, students will complete a research-based practicum or thesis option in a clinical setting.

4. Suggestions that might help the submitting institution strengthen the proposal or refine its focus;

A practicum or internship component would greatly help to strengthen the program and provide opportunities for students to experience a clinical research environment, ideally as a means to help them develop their theses for the degree.

This option is now included as both an individual investigation and a research-based practicum.

University of Cincinnati Review of Kent State PDP – MS in Clinical Epidemiology

1. Market need for the proposed program and the distinctions or differences between the proposed program and other similar programs across the state;

Overall the proposed program of MS in Clinical Epidemiology at Kent State University College of Public Health has a market need as health care research, including clinical trials, post-marketing monitoring, and health care quality research, is increasing in the nation. The distinction between the proposed program and other programs described in the plan mostly lies at the target students: BS or potential MS students, not health care professionals with terminal degrees. The overlap with Ohio State University MS program is possible, but the training demand is probably large in the state of Ohio.

No response required.

2. Opportunities for collaboration with UC or other universities;

The collaboration with UC has not been mentioned, and UC/CCHMC Clinical & Translational Science and Training program was not described at all. There is a possibility for future collaborations between Ohio universities to enhance clinical epidemiology training.

Thank you for identifying this program that we overlooked adding to the proposal. It has been described in the full proposal. Future collaborations are welcome by Kent State University.

3. Concerns with substantive elements of the proposed degree program; and

The proposed degree program targets a future labor force of clinical research associates, which are in high demand in premier clinical research centers. The concepts taught in epidemiology, biostatistics, clinical research management, and experimental design are generally sufficient for students in this degree program. The faculty listed in Table 1 has taught similar courses. The limitations include no MD clinicians listed as faculty instructor, insufficient physiology/pathophysiology basis for the training, and online setting without enough hands-on experience.

We have identified a strong list of local clinical researchers to serve as adjuncts in the online component as well as to oversee individual investigations, research-based practicums, or theses. These faculty will also serve as seminar presenters for face to face seminars that can be put online for online only students.

Students who apply to the program may be advised to take additional science based courses that prepare them for the field. Determinations will be made by the admissions committee when the student is admitted to the program.

4. Suggestions that might help the submitting institution strengthen the proposal or refine its focus.

Involvement of clinical faculty into the training program is needed as this will strengthen the direct experience of the students with sufficient exposure to real-world clinical trials. The pharmacoepidemiology course can probably be designated as a required course instead of being elective. Students with insufficient knowledge about anatomy/physiology may need some background to be familiar with human disease

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origins and treatments.

Thank you for your review of the program. Clinical faculty have been added to the program as adjuncts. Some of these with greater education and practice in clinical epidemiology designs will be able to teach core classes (Washington and Khetan). They will also oversee the practice based components of the degree.

The University of Toledo

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May 16, 2017

University of Toledo Review of Kent State University Program Development Plan Master of Science in Clinical Epidemiology

Our reviewer had no concerns with this proposal and agrees that the degree could be very useful for students interested in doing clinical research.

No response required.

Ohio University

Feedback on the KSU preproposal for an MS in Clinical Epidemiology

#1: Market need for the proposed program and the distinctions or differences between the proposed program and other similar programs across the state.

Undoubtedly, there is a market need for graduate-level educated Clinical Epidemiology professionals. This need is anticipated to be growing further, due to (1) increasing numbers of consumers of health care and public health services being a result of the population aging, and (2) continuous introduction of newer, more complex and expensive diagnostic and treatment modalities that necessitate putting more emphasis on scientifically-grounded, evidence-based approaches in clinical decision-making ensuring the best possible patient-centered health care.

Employment opportunities for these professionals extend beyond “hospitals or medical schools, clinical trials organizations, and pharmaceutical and insurance companies” and “insurance agencies and pharmaceutical companies” indicated in the proposal (pp.1 and 3). They also include research divisions of healthcare systems and plans (e.g., Kaiser Permanente, Henry Ford Health System, Geisinger Health System); government agencies (the FDA, the CDC, the AHRQ); non-government organizations and foundations (e.g., PCORI, American Cancer Society); research corporations and consulting firms (e.g., Booz Allen Hamilton, Batelle, Westat) that conduct research in various areas, including health-related, for various clients, ranging from federal agencies and state governments to foundations and businesses; clinical research centers at university hospitals; and even pharmacy chain corporations.

The preproposal misses some of the job titles for graduates with an MS in Clinical Epidemiology, such as Research Investigator (e.g., Kaiser Permanente uses this job title) and Assistant Director Epidemiology (may be a minimum qualification requirement in some circumstances in the industry if coupled with a significant experience, in lieu of a doctorate degree). Also, the preproposal lists some jobs and job titles which are not appropriate as permanent full-time jobs for graduate-educated professionals because they are over-qualified for them, e.g., “Clinical Research Assistant” (p.1.) and “Research Assistant” (p.3) positions should be filled by undergraduate-educated employees.

It is unclear why in their introduction of the concept of clinical epidemiology the authors chose to refer to a non-commonly-known web site CareersInPublicHealth.net that is not affiliated with any recognizable institution of higher education or epidemiology professional organization or government agency, but rather appears to have been created and maintained by two enthusiastic public health devotees – “Rafa & Ann” - for the purpose of providing “the information that people need to know who want to work in the exciting, dynamic field of public health”¹ [sic]. While this web site is an applaudable activity in educating lay public and prospective students about careers in public health, its discussion of Clinical Epidemiology misses the essential point that *Clinical Epidemiology* involves applying epidemiology methods to *clinical decision making*. This crucial characteristic, differentiating Master’s in Clinical Epidemiology from Master’s in Epidemiology or Master’s in Clinical Trials, is stated strongly on the web sites of well-recognized and highly respected Clinical Epidemiology programs, such as UCSF Division of Clinical Epidemiology (“Clinical Epidemiology is the application of principles of epidemiology to clinical medicine. While classical epidemiology is the study of the distribution and determinants of diseases in populations, clinical epidemiology is the application of the principles and methods of epidemiology to conduct, appraise or apply clinical research studies focusing on prevention, diagnosis, prognosis, and treatment of disease. Clinical Epidemiology is the basic science of Evidence-based Medicine”)² or University of Toronto Clinical Epidemiology & Health Care Research (“Clinical epidemiology is the study of the determinants and effects of clinical decisions”).³ It is also emphasized in a renowned, classical book *Clinical Epidemiology: The Essentials* by R. Fletcher and S.

Fletcher: **“The term ‘clinical epidemiology’ is derived from its two parent disciplines: clinical medicine and epidemiology. It is ‘clinical’ because it seeks to answer clinical questions and to guide clinical decision making with the best available evidence” (p.3)4.**

Based on the limited description of the programs listed in the “Similar programs in the State of Ohio and region” section of the preproposal, it appears that the major distinction of the proposed program would mostly be in the course delivery mode and the type of the students enrolled; it is difficult to make a definitive conclusion without reviewing the curricula of the other programs first. However, the difference in the type of students to be enrolled, with the proposed program targeting students coming out of non-clinical bachelor’s degrees, unlike the other programs, raises concerns discussed in #3 below.

Thank you for these suggestions. We have modified the proposal to address these concerns.

#2: Opportunities for collaboration with the CCGS member’s own institution.

No opportunities for collaboration with other CCGS member institutions have been proposed in the preproposal document.

No response required.

#3: Concerns with substantive elements of the proposed degree program.

It is concerning that all the required courses in the proposed MS in Clinical Epidemiology program geared towards students without any clinical background would be taught by faculty with no clinical degree (MD, DO, DNP, PA, PharmD), but rather by PhD faculty only. The only faculty with professional clinical background (PharmD) would be teaching one elective course only (Pharmacoepidemiology). If the proposed Clinical Epidemiology program enrolled health professional students with clinical experience, having the faculty with such qualifications would be adequate. But if the proposed curriculum is completed by students coming out of non-clinical bachelor’s degrees, as this program proposes, it will not be an MS in Clinical Epidemiology, but rather an MS in Epidemiology with the concentration in Clinical Research or MS in Clinical Research or MS in Clinical Trials, preparing professionals with necessary skills to conduct clinical research, but who have no command or at least basic understanding of clinical decision-making process (based on the understanding of the pathological basis of disease, the diagnostic process, and the choice of treatment modalities) – a distinctive characteristic of Clinical Epidemiology programs by definition, differentiating them from Epidemiology or Clinical Research programs. By analogy, mastering lancet manipulation and tissue cutting techniques is not sufficient to make an individual a surgeon.

Thank you for this comment. We have identified the faculty who have clinical degrees and experience and the areas in which they will serve in the program in table 1 and 2 of the proposal. These faculty will teach, provide seminar lectures (in our CPH seminar series that can be broadcast online), and oversee the practical experiences in the program.

#4: Suggestions that might help the submitting institution strengthen the proposal or refine its focus.

This concern discussed in #3 above can be corrected by either changing the name of the program to a more accurate, such as MS in Clinical Research or MS in Clinical Trials, or by enrolling students with clinical background only. Alternatively, adding at least 20-25 credit hours of the fundamentals of human anatomy, physiology, pathology, and the basics of the clinical aspects of health and disease may possibly allow enrolling students without clinical background.

The proposal has identified clinical faculty who will serve in varying capacities described above in the degree program. The students who are admitted to the program will be evaluated for appropriateness of

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undergraduate degree and clinical experiences. Courses will be recommended by the admissions committee and academic advisor. This will be sufficient to admit students from differing backgrounds. Students who have limited clinical or science background may be advised to take additional courses, take the chronic disease and infectious disease epidemiology courses, enroll in individual investigation, and complete a research-based practicum versus a thesis; however, these decisions will be made on a case by case basis.

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- ⁱ <https://www.acrpnet.org/professional-development/competency-domains-clinical-research-professionals/>
 - ⁱⁱ <http://www.aspph.org/educate/models/mph-competency-model/>
 - ⁱⁱⁱ <http://strategicroadmap.kent.edu/contents/>
 - ^{iv} <http://blog.proclinical.com/how-to-get-a-job-as-a-clinical-research-associate-cra>
 - ^v <http://ohiolmi.com/proj/JobsOhioInd.htm>
 - ^{vi} <https://www.bls.gov/ooh/life-physical-and-social-science/epidemiologists.htm>
 - ^{vii} <https://www.bls.gov/ooh/life-physical-and-social-science/survey-researchers.htm>
 - ^{viii} <https://www.bls.gov/ooh/math/statisticians.htm>
 - ^{ix} <https://www.bls.gov/careeroutlook/2008/summer/art03.pdf>
 - ^x <http://blog.proclinical.com/how-to-get-a-job-as-a-clinical-research-associate-cra>
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 - ^{xxi} <https://www.indeed.com/jobs?q=health+research+coordinator&l=OH>
 - ^{xxii} https://www.nsf.gov/statistics/wmpd/2013/pdf/nsf13304_digest.pdf
 - ^{xxiii} <https://med.uc.edu/eh/divisions/epi/programs/ms-clinical-translational-research>
 - ^{xxiv} <http://casemed.case.edu/CRSP/eligibility.cfm>
 - ^{xxv} <http://casemed.case.edu/CRSP/Certificate.cfm>
 - ^{xxvi} <https://macpr.osu.edu/about-degree>
 - ^{xxvii} <https://www.icre.pitt.edu/degrees/degrees.aspx>
 - ^{xxviii} <https://www.michr.umich.edu/mscr-application-instructions>