

New Graduate Degree Program Development Plan Master of Science in Clinical Epidemiology

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) offers five specializations, and the PhD offers three specializations. In spring 2017 the CPH includes 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, clinical research, violence prevention, and management of public health organizations.

1. Designation of the new degree program, rationale for that designation, definition of the focus of the program and a brief description of its disciplinary purpose and significance.

This proposal is for an online Master of Science (MS) in Clinical Epidemiology in the CPH. The CPH is fully accredited by CEPH and the new MS degree does require CEPH accreditation. 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.¹ This degree is different than the existing MPH specialization in Epidemiology which is practice-based and requires broad education in all areas of public health. While the MPH does provide students the skills to conduct epidemiology research, the proposed degree requires more clinical methodology and research experience. Graduates with the MS will be more competitive in regards to obtaining clinical research jobs in hospitals or medical schools, clinical trials organizations, and pharmaceutical and insurance companies. The MS degree teaches methodological skills that are more advanced than the BSPH in Clinical Trials Research and graduates will be able to obtain entry-level or mid-level positions on research teams in clinical settings.

The focus of the MS in Clinical Epidemiology is epidemiology and biostatistical methods related to clinical trials and clinical research. Students will understand good clinical practices, clinical trials design, management, and statistical analysis, study monitoring, pharmaceutical research, and regulations related to clinical research.

Clinical epidemiology is a subfield in Epidemiology that focuses on research conducted in a clinical setting. The emphasis is on medically defined populations versus epidemiology in public health which studies disease trends in populations.² The field of clinical epidemiology is growing, largely due to our aging population and advances in medical care, and well-trained graduates with a MS in Clinical Epidemiology will be able to find jobs as an Epidemiologist, Research Analyst, Clinical Research Assistant/Associate, Clinical Epidemiologist, Research Scientist, or Research Associate, among other titles. These students are highly employable upon graduation.

2. Description of the proposed curriculum.

The MS in Clinical Epidemiology is a 37 credit hour degree that can be taken 100% online or as a hybrid program. Admissions criteria include a 3.0 minimum undergraduate GPA and submission of

¹ <http://www.careersinpublichealth.net/careers/clinical-epidemiologist>

² Mosby's Medical Dictionary, 9th edition. © 2009, Elsevier

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GRE scores. Students from any undergraduate degree may apply and applicants will be admitted after a comprehensive review of GPA-courses/GRE/recommendations. The coursework is designed around the eight domains of core competencies delineated by the Joint Task Force for Clinical Trial Competency.³ There are classes in this degree that are currently offered fully online and in the traditional format; therefore, students may choose to take classes in either format (100% online or hybrid). There are 7 required classes (22 credits) and 3 electives (9 credits). Included in the curriculum are 6 credits hours of thesis or research intensive practicum. Classes marked with ** are included in the BSPH and MS programs (40/60000 levels). Courses taken at the 60000 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. The courses in Table 1 are included in the curriculum:

Table 1: Courses, credits, course format, and instructor				
Course #	Course Title (term)	Credits	Current course and format	Current or proposed instructor
Required Courses (22 credits)				
BST 52019	Biostatistics in Public Health (fall 1)	4	Currently online and traditional	Abbey Eng, PhD (Biostatistics)
EPI 52017	Fundamentals of Public Health Epi (fall 1)	3	Currently online and traditional	Heather Beard, PhD (Epidemiology)
BST 63014	Applied Regression Analysis (spring 1)	3	Currently taught traditional format will be put online	Vinay Cheruvu, PhD/Peggy Stephens, PhD (Biostatistics/Social Behavioral Sci)
EPI 63016	Principles of Epidemiologic Research (spring 1)	3	Currently taught traditional format will be put online	Madhav Bhatta, PhD (Epidemiology)
EPI 50013	Clinical Epidemiology Basics (sum1 or fall2)**	3	Currently Online	Melissa Zullo, PhD (Epidemiology)
EPI 50014	Clinical Trials Management (sum1 or fall 2)**	3	Currently Online	Jennifer Eaton, PhD (Director of Research at Summa Health System)
BST 63013	Experimental Designs in Public Health Res. (fall 2)	3	Currently online	Vinay Cheruvu, PhD
Electives - pick three (9 credits)				
EPI 50017	Pharmacoepidemiology (spring 2)**	3	Currently online	Martha Blackford, PharmD (Pharmacologist - Akron Children's)
EPI 50015	Scientific Writing for Clinical Research (fall 2)**	3	Currently online	Maggie Stedman-Smith, PhD (EVHS)
EPI 50018	Regulatory Affairs in Clinical Research (Spr 2)**	3	Currently online	Steve Schmidt, PhD (NEOMED)
EPI 63014	Chronic Disease Epidemiology (fall 2)	3	Currently taught traditional format will be put online	Heather Beard, PhD (Epidemiology)
EPI XX	Clinical Database Design and Management (fall 2)	3	TBD	Julie Schaefer, PhD (Research Scientist at Medical Mutual/Kent adjunct)
Thesis or Research-based Practicum (6 credits)				
EPI XX	Thesis (fall 2/spring 2)	6	TBD	Program Director/FTNITT hired in yr 2
EPI XX	Research-based practicum (fall 2/spring 2)	6	TBD	Program Director/FTNITT hired in yr 2

The thesis option will be a traditional student led research study with active faculty mentoring. The student will work with the faculty advisor to develop their research question and design the study. The student will carry out the study in a setting approved by the advisor. The student will identify a preceptor in the research setting in which the student will conduct the study. The student will defend the thesis upon its completion. The defense will generally take place via videoconferencing technology using Skype or Blackboard Collaborate. Local students will be encouraged to defend the thesis in person.

Students may also choose a research-based practicum rather than a thesis. These practicums must be approved by the practicum coordinator in advance of initiation. Practicum placement must be in a research intensive organization. There must be a faculty advisor and site preceptor who oversees the practicum. The student must play an active role in all aspects of a research study. This includes for example, the Institutional Review Board application, creation of study forms, consent, and data collection, management, analysis, and publication ready manuscript. The practicum will be presented to the CPH in a practicum/research presentation day in person or using videoconferencing.

³ <http://www.coapcr.org/wp-content/uploads/2014/10/Powerpoint-Competencies.pdf>

3. Administrative arrangements for the proposed program: department and school or college involved.

The MS in Clinical Epidemiology will be housed in the Department of Biostatistics, Environmental Health Science, and Epidemiology in the CPH. The program will have a director who is currently the director of the BSPH in Clinical Trials Research

4. Evidence of need for the new degree program, including the opportunities for employment of graduates. This section should also address other similar programs in the state addressing this need and potential duplication of programs in the state and region.

Student Demand

A November 2016 survey of 225 undergraduate and graduate students who were sent a survey through the CPH listserv indicated that 70% (n=50) of responding seniors were extremely/very interested and 44% (n=16) of juniors were extremely/very interested in the MS degree. Overall, 53% of students surveyed were extremely/very interested in the MS while only 5% (n=11) were not at all interested. Of graduate students, 66% (n=56) were extremely/moderately likely to take electives.

Sustainability/Job Growth Projections

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, Research Assistant, and Clinical Epidemiologist, etc. The job outlook from United States Bureau of Labor Statistics for the title “Epidemiologist” with a Master’s degree is a 6% increase from 2014 to 2024.⁴⁵ 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 also depends on the type of organization. For example, data scientist jobs at insurance agencies and pharmaceutical companies typically requires an MS. 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%. Higher level jobs in these organizations require/prefer an MS. The Bureau of Labor Statistics reports an expected rise by 22% from 325,800 positions to 396,500 between 2012 and 2022 for CRA.

Jobs available

Epidemiologist - 623 jobs nationally⁶; 9 in Ohio⁷

Clinical Epidemiologist – 266 jobs nationally⁸, 9 in Ohio⁹

Clinical Data Analyst – 7,614 jobs nationally,¹⁰ 185 in Ohio¹¹

Clinical Research Associate - 480 jobs¹² in Ohio; >16,000 nationally¹³

Health Research Scientist – 7,550 jobs nationally¹⁴; 194 in Ohio¹⁵

⁴ <http://www.bls.gov/ooh/Life-Physical-and-Social-Science/Epidemiologists.htm>

⁵ http://study.com/articles/Clinical_Epidemiologist_Job_Description_Duties_Outlook_and_Salary.html

⁶ <https://www.glassdoor.com/Job/jobs.htm?suggestCount=0&suggestChosen=false&clickSource=searchBtn&typedKeyword=epidemiologist&sc.keyword=epidemiologist&locT=&locId=&jobType=>

⁷ <https://www.glassdoor.com/Job/jobs.htm?suggestCount=0&suggestChosen=false&clickSource=searchBtn&typedKeyword=epidemiologist&sc.keyword=epidemiologist&locT=S&locId=2235&jobType=>

⁸ https://www.glassdoor.com/Job/clinical-epidemiologist-jobs-SRCH_KO0_23.htm

⁹ <https://www.glassdoor.com/Job/jobs.htm?suggestCount=0&suggestChosen=false&clickSource=searchBtn&typedKeyword=clinical+epidemiologist&sc.keyword=clinical+epidemiologist&locT=S&locId=2235&jobType=>

¹⁰ <https://www.glassdoor.com/Job/jobs.htm?suggestCount=0&suggestChosen=false&clickSource=searchBtn&typedKeyword=clinical+data+analyst&sc.keyword=clinical+data+analyst&locT=&locId=&jobType=>

¹¹ <https://www.glassdoor.com/Job/jobs.htm?suggestCount=0&suggestChosen=true&clickSource=searchBtn&typedKeyword=clinical+data+analyst&sc.keyword=clinical+data+analyst&locT=S&locId=2235&jobType=>

¹² <http://www.indeed.com/q-Clinical-Research-Associate-l-Ohio-jobs.html>

¹³ <https://www.indeed.com/jobs?q=clinical+research+associate&l=>

¹⁴ <https://www.glassdoor.com/Job/jobs.htm?suggestCount=0&suggestChosen=false&clickSource=searchBtn&typedKeyword=health+research+scientist&sc.keyword=health+research+scientist&locT=&locId=&jobType=>

Research Assistant/Associate – 376 in Ohio¹⁶

Similar programs in the State of Ohio and region

- Case Western Reserve University offers a MS in Epidemiology (not focused on clinical research).¹⁷ 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.¹⁸
- The Ohio State University offers a Master of Applied Clinical and Preclinical Research in combination with the Colleges of Nursing, Pharmacy, and Medicine.¹⁹ 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 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).²⁰ 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.²¹ This program is for clinicians who want research training.

The CWRU, OSU (1 of 2), Pitt, and UM programs differ from the Kent State program in that they are geared towards clinicians who want additional training to conduct and lead research studies in a clinical setting. The Kent State 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.

5. Prospective enrollment.

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 a 3rd year cohort of 40 students, capping at 40. A student enrolling fulltime will take 7.5 classes per year.

6. Special efforts to enroll and retain underrepresented groups in the given discipline.

It is a goal of the CPH to enroll and retain underrepresented students. This is particularly important in clinical research fields. The National Science Foundation report on *Women, Minorities, and Persons*

¹⁵<https://www.glassdoor.com/Job/jobs.htm?suggestCount=0&suggestChosen=false&clickSource=searchBtn&typedKeyword=health+research+scientist&keyword=health+research+scientist&locT=S&locId=2235&jobType=>

¹⁶<https://www.indeed.com/jobs?q=health+research+coordinator&l=OH>

¹⁷<http://casemed.case.edu/CRSP/eligibility.cfm>

¹⁸<http://casemed.case.edu/CRSP/Certificate.cfm>

¹⁹<https://macpr.osu.edu/about-degree>

²⁰<https://www.icre.pitt.edu/degrees/degrees.aspx>

²¹<https://www.michr.umich.edu/mscr-application-instructions>

*with Disabilities in Science and Engineering (2013)*²² 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. A major priority of Kent State is to put students first which includes the initiative of strengthening diversity and the cultural competence of students, faculty, and staff system wide. The CPH is particularly sensitive to the issue of recruitment, retention, and graduation of underrepresented student populations and now of developing clinical research professionals that are from these groups. Our graduate student body is composed of approximately 30% from underrepresented groups. The college has a comprehensive Strategic Diversity Plan. The plan includes addressing diversity through curriculum; competencies; practicums and internships that offer experiences to work with diverse individuals/groups; self-assessment of diverse experiences by students/staff/faculty; an annual diversity symposium; and recruitment of underrepresented students through targeted recruitment events. The diversity rate in the CPH is higher than that of the University. In addition, the CPH Diversity and Inclusion Committee meets every semester to review diversity measures, discuss concerns/make suggestions to the CPH for programs, policies, and procedures. The committee assures regular evaluation of diversity goals.

7. Availability and adequacy of the faculty and facilities available for the new degree program.

The faculty who will teach the courses and mentor students on their research are all current FTTT, FTNTT, or adjunct faculty (n=3) who teach in Epidemiology/Biostatistics or Clinical Trials Research. All faculty have a terminal degree in their specialization (PhD or PharmD) and have appointments at Kent State (see Table 1). The faculty who will teach in the program have extensive experience developing and teaching online classes. The college has extensive experience in online education with four online undergraduate degrees and one current and one new (fall 2017) online graduate degree. All online courses follow the standards set forth in the Quality Matters™ rubric. The college also employs two online educational technologists 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.

There are no new facilities requirements.

8. Need for additional facilities and staff and the plans to meet this need.

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.

9. Projected additional costs associated with the program and evidence of institutional commitment and capacity to meet these costs.

Budget projections are for 20, 30, 40, and 40 students over the first 1, 2, 3, and 4 years of the program. Revenue is estimated at \$156,400 in years 3 and 4. The director of the program will teach 2 classes in the degree. The table on page 2 lists the faculty who currently teach the courses for this degree. Currently all classes except two required and two electives are offered online. This degree program is capitalizing on what is already in existence. The Dean of the CPH is committed to offering the online degree program as it meets student needs and demand as well as the needs of local and regional employers.

²² https://www.nsf.gov/statistics/wmpd/2013/pdf/nsf13304_digest.pdf