Proposal
Certificate Program in Clinical Research

i. Approved graduate program(s) sponsoring the certificate program

The Clinical Research Certificate program will be sponsored by the existing Clinical Research Scholars Program and administered within the Center for Clinical Investigation. The Center currently manages the Master of Science degree in Clinical Research. The certificate program will be administered by the Center's Academic Program Director, the Center's Academic Development and Training's Executive Committee, and a program coordinator. The Executive Committee will function as a steering committee for the certificate program and will be responsible for oversight of all admissions, academic, and curricular issues that may arise. The Executive Committee consists of a chairperson – the Academic Program Director – and two additional faculty members of the Clinical Research Scholars Program. The Academic Program Director is appointed by the Dean of the School of Medicine, and the additional two members of the Executive Committee are selected by the Program Director and approved by the Dean. The Executive Committee oversees the Master of Science degree program in Clinical Research as well as development of the CCI's other academic and training activities. The Executive Committee will be responsible for approving individuals into the program, handling any student or faculty concerns as arise, and periodic reviewing of the curriculum to assure maintenance of academic standards. The current Academic Program Director and chairperson of the Executive Committee is James Spilsbury, Ph.D.

Administrative aspects of the program will be conducted by the Center's Education Administrator/Manager. This position is currently filled by Natalie Milone, MA.

ii. Need and demand for the certificate program

In its "Roadmap for Medical Research," the National Institutes of Health have highlighted the urgent need to speed biomedical advances and discoveries made in the laboratory to the individual patient and population as a whole. As part of the "Roadmap," the NIH launched the Clinical and Translational Science Awards (CTSA) program to energize clinical translational research and training. Currently, the CTSA program consists of a consortium of 55 medical research institutions located throughout the nation. In 2007, Case Western Reserve University (CWRU), the MetroHealth Medical Center, and the Cleveland Clinic Foundation were awarded one of the CTSA grants (NCRR CTSA Award UL1-RR02498) and formed the Clinical and Translational Science Collaborative, which has as a major goal to accelerate clinical translational research and training in the greater Cleveland area.

The Center for Clinical Investigation is located at CWRU's School of Medicine and serves as the academic home of the Clinical and Translational Science Collaborative. The Center currently directs a number of activities to enhance the clinical translational workforce and infrastructure in greater Cleveland, including a master's program (ongoing) and doctoral program (in development) in clinical research.

Domain	Core Competency	Coursework Supporting Competency

iv. Curriculum for the certificate program.

A total of 4 courses totaling 11 credit hours are required for successful completion of the program. These courses are currently being offered as part of the Master of Science Program in Clinical Research. No new courses are needed. In addition, individuals must successfully complete the Continuing Research Education Credit (CREC) curriculum to complete the certificate program. Descriptions of the courses and CREC requirement follow:

CRSP 401 (3 credit hours) - Introduction to Clinical Research
This course is designed to familiarize students with the language and concepts of clinical investigation and statistical computing, as well as provide opportunities for problem-solving and practical application of the information derived from the lectures. The material is organized along the internal logic of the research process, beginning with mechanisms of choosing a research question and moving into the information needed to design the protocol, implement it, analyze the findings, and draw and disseminate the conclusion(s).

CRSP 402 (3 credit hours) - Study Design and Epidemiologic Methods
This course covers the methods used in the conduct of epidemiologic and health services research. The course begins with how to quantify disease frequency and compare it across populations, often as a way to generate hypotheses about what factors may cause a given condition. The course introduces methodologic issues that need to be considered in the design and conduct of epidemiologic studies, including classification of disease and exposure status, types and consequences of misclassification, effect modification and related concepts. Additional sessions focus on the control of confounding and on the three main types of study designs: randomized trials, cohort studies and case-control studies. Topics include: Measures of disease frequency, measures of effect, classification and misclassification, cross-sectional studies, case-control studies, cohort studies, randomized controlled trials, confounding, bias, and effect modification.

CRSP 431 (3 credit hours) - Statistical Methods I
This course covers the application of statistical techniques in the biomedical sciences. Content includes basic probability theory, random variables, distribution functions, point and interval estimation, regression, and correlation. The course involves the use of packaged statistical programs (e.g., R).

CRSP 603 (2 credit hours) – Research Ethics and Regulation: Emerging Issues and Ongoing Challenges
This course introduces students to the ethical, policy, and legal issues raised by research involving human subjects. Topics include (among others): regulation and monitoring of research, research in the developing world; research with special populations; stem cell and genetic research; commercialization and conflicts of interest; informed consent; study recruitment; risk-benefit assessment; the use of deception and placebos.

The required courses will be offered every year. CRSP 401 is offered Monday through Friday, 3 hours daily for over a 3-week period in July to accommodate clinician schedules. CRSP 402 and

431 are offered in the Fall semester. CRSP 603 has most recently been offered in the Fall semester, but may move to the Spring semester. Because CRSP 401 is the recommended preparation for CRSP 402, the anticipated order of courses would be: CRSP 401 (summer), with the other CRSP courses taken in subsequent Fall semester(s). However, there is no requirement that the coursework be taken in a specified order or period of time.

Certificate Curriculum for Medical Students

Counterpart courses for CRSP 401, 402, and 431 are currently available to medical students attending either the University Program or the Cleveland Clinic Lerner College of Medicine (CCLCM):

CMED 401 (3 credit hours) - Introduction to Clinical Research
This course is designed to provide an overview of skills necessary to plan and conduct clinical research. The goals of the 15-week course are to learn the basic skills necessary to develop and describe a clinical research project and apply these skills by working with a research mentor to develop a project proposal, which can be submitted for funding. Special emphasis is placed on study design and statistical considerations, ethical and legal considerations of clinical research, and specific methodologies such as cost-benefit studies, analyses of large data sets, outcomes research, qualitative methods in clinical research, and development of the necessary components of a written research proposal. Students and faculty devote the last session of the course to conducting a mock-NIH review of their proposals.

CMED 403 (3 credit hours) - Introduction to Clinical Epidemiology
This course introduces basic concepts of epidemiology, with specific focus on application of these concepts in the clinical research arena. Topics include: measures of disease frequency and the strength of their relationships with possible causative factors; primary observational research designs; clinical trials; interpretation of diagnostic and screening tests, and designs for assessing whether disease screening benefits patients; threats to research validity, including selection and measurement biases and confounding; and ethical and regulatory issues in the conduct of human research.

CMED 402 (3 credit hours) - Statistical Science for Medical Research
This course introduces core concepts and methods of statistical inference for interpreting and precisely communicating information from health science data, with emphasis on clinical research. A comprehensive perspective on statistical modeling unifies several important methods in order to encourage recognition of the breadth and power of modern biostatistics and its role in the health sciences.

CMED 401 is offered in the Spring semester, and CMED 402 and 403 are taught in the Summer.

There is currently no counterpart course for CRSP 603 at the CCLCM; students in the CCLCM will be required to take CRSP 603.

Continuing Research Education Credit (CREC) Certification

CREC is CWRU's program to provide documented training in the protection of human participants in research that is conducted at University Hospitals Case Medical Center, the

MetroHealth System, and CWRU. Researchers from the Louis Stokes Cleveland Department of Veterans Affairs Medical Center and the Cleveland Clinic may also participate. CREC subscribes to the training program that was developed and is currently offered online by the Collaborative Institutional Training Initiative (CITI), an organization founded in 2000 to develop web-based training in human subjects research protections. As of May 2010, the CITI Program has been utilized by over 1130 participating institutions and facilities from around the world. Individuals who complete the CITI Basic Course in The Protection of Human Research Subjects are certified for 3 years to conduct human subjects research, with continuing certification possible through completion of other Office of Research Administration and CITI educational activities. The Basic Course consists of 18 modules and covers the following topics: History and ethical principles; Basic Institutional Review Board (IRB) regulations and review Process; Informed consent; Social and behavioral research for biomedical researchers, Records-based research; Genetic research in human populations; Research with protected populations – vulnerable subjects; Group harms: FDA-regulated research, HIPAA and Human Subjects Research; Workers as research subjects; Conflicts of interest in research involving human subjects. The basic course takes approximately 3 hours to complete.

To obtain the Certificate in Clinical Research, individuals must be CREC-certified. CREC certification is administered through CWRU's Office of Research Administration and equivalent offices at the Cleveland Clinic, University Hospitals, and MetroHealth Center. Individuals who receive CREC certification are provided a certificate to this effect, and their current CREC-certification status is monitored by the institutions' offices of research administration.

v. Justification for the number of credit hours for the certificate program.

The Clinical Research Certificate program is a 11 credit hour program. Students who successfully complete the required coursework will receive a Certificate in Clinical Research issued by the Center for Clinical Investigation. Based on consideration of the critical competency-knowledge areas described above, the required 11-credit hour coursework for the Certificate program was identified: Introduction to Clinical Research; Study Design and Epidemiologic Methods; Statistical Methods 1, and Research Ethics and Regulation. Required CREC certification takes approximately 3 hours to complete. Credit hour requirements and the breadth of curricula of several existing certificate programs in clinical research were also considered (Appendix 2). The examined programs range from 6 to 24 required credit hours and cover similar information.

vi. Entrance, performance, and exit standards for the certificate program.

Entrance Standards: Entrance to the Certificate program will be administered by the Center for Clinical Investigation. Individuals who want to participate in the program will complete an application form that includes a brief personal statement describing the reason(s) for seeking clinical research training and a recent CV or resume.

members of research teams working at CTSC institutions, who already have a baccalaureate degree or higher, will be interested in the certificate program. Thus, to include all these individuals, we will require that applicants must have already attained a baccalaureate degree to be admitted to the certificate program. Per CWRU School of Graduate Studies requirements, individuals who are not already graduate-degree-seeking students at CWRU must submit to the School of Graduate Studies a completed non-degree application form. Individuals who are not faculty, staff, or employees of CWRU must also submit a transcript or copy of their diploma, documenting completion of a baccalaureate degree. Per School of Graduate Studies requirements, non-degree-seeking individuals will not need to provide their Test of English as a Foreign Language (TOEFL).

Individuals will be accepted into the program based on the Executive Committee's review of the personal statement and any supporting documentation required by the School of Graduate

Steven A. Lewis, MS, MBA
Research Biostatistician, MetroHealth Medical Center. Research interests consist of: categorical data analysis, generalized linear models, multivariate methods, sample size determination, and data visualization.

Thomas Love, PhD
Associate Professor, Department of Medicine, CWRU School of Medicine; Director, Biostatistics and Evaluation Unit, Center for Health Care Research and Policy, MetroHealth Medical Center. Research interests include: biostatistics, observational studies and propensity methods, risk adjustment, health information technology, education.

Joe Sudano, PhD
Assistant Professor, Department of Medicine, CWRU School of Medicine; Senior Researcher, Center For Health Care Research and Policy, MetroHealth Medical Center; Associate Director of Education, Center for Reducing Health Disparities, MetroHealth Medical Center. Research interests include: health care disparities; social determinants of health; measurement equivalence, validity, and item-response theory in cross-cultural health status measurement; health outcomes research.

Tracy J. Wilson-Holden
Director, Research Integrity and Education, Office of Research Compliance, CWRU. Area of expertise: ethical conduct of research, especially management of research data.

Mark Votruba, PhD
Associate Professor, Department of Economics, Weatherhead School of Management; Director, Health Economics Research Unit, Center For Health Care Research and Policy, MetroHealth Medical Center. Research Interests include health economics (allocation of medical resources, incentives for care, insurance markets) and public economics (social program participation, social interactions effects).

CRSP 402 – Study Design and Epidemiologic Methods
Doug Einstadter, MD, MPH
Professor, Department of Medicine, CWRU School of Medicine; Member, Center for Health Care Research and Policy; Staff Physician, Department of Medicine, MetroHealth Medical Center. Research interests include: use of large databases in health services research; application of geographic information systems to health services research; use of informatics to improve quality of care.

CRSP 431 – Statistical Methods I
Ralph O'Brien, PhD
Professor, Department of Epidemiology & Biostatistics, CWRU School of Medicine. Areas of expertise include: statistical science, especially sample-size analysis and robust tests for assessing variability differences.

CRSP 603 – Research Ethics and Regulation

Nicole Deming, JD, MA
Assistant Professor, Department of Bioethics, CWRU School of Medicine; Center for Biomedical Ethics at MetroHealth Medical Center. Research interests include: informed consent process, patient/physician communication, professionalism, research regulations, and living organ transplants.

Faculty Expertise for Counterpart Medical School Courses

CMED 401 – Introduction to Clinical Research

Course Director
Matthew Karafa, PhD
Assistant Professor, CCLCM; Quantitative Health Sciences Project Staff, Cleveland Clinic Foundation.

Lecturers
Carolyn Apperson-Hansen, Mstat
Director, Research Concierge, Clinical and Translational Science Collaborative, CWRU. Ms. Apperson-Hansen provides support in all phases of clinical and translational sciences in the regulatory and technology areas as well as assists inexperienced investigators to understand research study needs and navigate multi-disciplinary research processes. She has extensive experience in statistical analyses and database management.

Alex Fu, PhD
Assistant Professor, CCLCM; Associate Staff, Quantitative Health Sciences, Cleveland Clinic Foundation. Dr. Fu's research interests include: pharmacoeconomics, utility assessment, health policy evaluation, propensity score method, and econometrics, particularly in the areas of diabetes and mental illness.

Gretchen Hallerberg, Medical Library Director, Cleveland Clinic Foundation

Michael Kattan, MBA, PhD
Professor, Department of Medicine, CCLCM; Chairman, Department of Quantitative Health Sciences, Cleveland Clinic Foundation.

Amy Moore, Scientific Publications, Cleveland Clinic Foundation

Nancy Obuchowski, PhD
Professor, CCLCM; Vice Chair, Quantitative Health Sciences, Cleveland Clinic Foundation. Research interests include: design and analysis of studies of screening and diagnostic tests; extension of Receiver Operating Characteristic (ROC) analysis to nominal, ordinal, or continuous outcomes; testing the equivalence of diagnostic tests.

Ralph O'Brien, PhD

Professor, Department of Epidemiology & Biostatistics, CWRU School of Medicine. Areas of expertise include: statistical science, especially sample-size analysis and robust tests for assessing variability differences.

Carmen Paradis, MD
Clinical Assistant Professor, CCLCM; Center for Ethics, Humanities and Spiritual Care, Cleveland Clinic Foundation; Member, Institutional Review Board, Cleveland Clinic Foundation; Research Subject Advocate, Clinical and Translational Science Collaborative Research Unit, CWRU. Research interests include: research ethics, informed consent, and ethics education.

Shannon Morrison, MS
Statistical Programmer, Quantitative Health Sciences, Cleveland Clinic Foundation.

CMED 402 – Statistical Science for Medical Research
Amy Nowacki, PhD
Assistant Professor, CCLCM; Assistant Staff, Department of Quantitative Health Sciences, Cleveland Clinic Foundation. Research interests include: clinical trial design and randomization schemes, prediction, validation, and statistical education.

CMED 403 – Introduction to Clinical Epidemiology

Course Directors
Peter Imrey, PhD
Professor, Department of Medicine, CCLCM; Staff, Department of Quantitative Health Sciences, Cleveland Clinic Foundation. Research interests include: analysis of multivariate categorical data; linear models; sample survey methods; quantitative epidemiology.

Daniel Sessler, MD
Professor, Department of Anesthesiology, CCLCM; Chair, Department of Outcomes Research, Cleveland Clinic Foundation. Dr. Sessler coordinates more than a hundred studies, including large, multi-center outcome trials.

viii. New resources, courses, etc., if any, necessary to support certificate program.

Managerial and administrative tasks necessary for the proposed Certificate program will be added to Tc-.1n eo7g
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Appendix 1

Table 1: Annual Enrollment in CRSP 401 "Introduction to Clinical Research"

Year	Number
2002	44
2003	26
2004	47
2005	40
2006	55
2007	62
2008	45
2009	49
2010	78
Total:	446

Appendix 2

Example Certificate Programs

Institution	Required Coursework Topics	Credit Hr Requirements
Columbia (pre-doc)	• Principles of Epidemiology • Biomedical Informatics • Research Ethics • Clinical Trials • Biostatistics • Practicum	6 semester hrs
University of Pennsylvania	• Research methods/study design • Biostatistics • Database management • Ethical Scientific-Research conduct	9 semester hrs
University of Tennessee	• Fundamentals of Clinical Investigation • Biostatistics • Principles of Epidemiology • Ethical and Legal Issues in Clinical Research	12 semester hrs