

AGENDA

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UNIVERSITY
SECRETARIAT
• Board of Governors
• Senate

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**REPORT TO THE UNIVERSITY PLANNING COMMITTEE
from the
UNDERGRADUATE COUNCIL**

FOR APPROVAL

a. NEW DIPLOMA PROGRAM

At its meeting on March 21, 2023, the Undergraduate Council will approve the **Health Information Fundamentals (HIF) Diploma** program. Approval of this item at the University Planning Committee is contingent upon approval at Undergraduate Council on March 21, 2023. Further details are contained within the circulated materials.

It is now recommended,

that the University Planning Committee approve, for recommendation to Senate, the Health Information Fundamentals (HIF) Diploma, as set out in the attached.

b. REVISIONS TO EXISTING CERTIFICATE AND DIPLOMA PROGRAMS

At the same meeting, the Undergraduate Council will approve revisions to the **Diploma in Accounting**, and to the **Applied Clinical Research (ACR) Certificate**. Approval of these items at the University Planning Committee is contingent upon approval at Undergraduate Council on March 21, 2023. Further details are contained within the circulated materials.

i. Revisions to the Diploma in Accounting

It is now recommended,

that the University Planning Committee approve, for recommendation to Senate, revisions to the Diploma in Accounting, as set out in the attached.

ii. Revisions to the Applied Clinical Research (ACR) Certificate

It is now recommended,

that the University Planning Committee approve, for recommendation to Senate, revisions to the Applied Clinical Research (ACR) Certificate, as set out in the attached.

University Planning Committee
FOR APPROVAL: March 22, 2023

Continuing Education Academic Program Submission – For Approval

Department & Program Information	
Program/Plan Name:	Health Information Fundamentals (HIF)
Academic Credential:	Diploma
Name of Representative:	Lorraine Carter
Effective Date:	2023-09-01
Date of Submission:	2023-02-14
Academic Merit (complete all fields; write “not applicable” as needed):	
Program Overview:	<p>Over the past few years, the Canadian Health Information Management Association (CHIMA) and the Canadian College of Health Information Management (CCHIM) consulted with health information industry leaders, federal and provincial policymakers, and healthcare professionals to establish a new set of curriculum standards for education providers. In order to meet these updated curriculum guidelines, MCE is proposing a nine-course diploma called Health Information Fundamentals (HIF).</p> <p>Health Information Fundamentals (HIF) is a diploma program that provides students with the foundational knowledge required for health information professionals. The program will prepare students to work in various health settings as the curriculum focuses on the key practice areas of information governance, data quality, analytics, privacy, technology, and clinical knowledge. Ethics, equity, diversity, and inclusion are included across all practice areas.</p> <p>Graduates of the program will be prepared to challenge the Canadian College of Health Information Management’s national certification examination to earn the designation of a Certified Health Information Management (CHIM) professional.</p>
Learning Objectives:	<p>Upon completion of the program, learners will:</p> <ol style="list-style-type: none"> 1. Describe the Canadian Health Information Management Lifecycle and how it is used to promote data and

	<p>information governance, inform healthcare policy and procedures, and develop leading practices and principles related to managing health information across the continuum of care.</p> <ol style="list-style-type: none"> 2. Apply knowledge of ethical data collection and preparation, quality and conformance, and standards policies and processes to ensure that data is linkable and fit for use in analysis and care and to foster data literacy. 3. Articulate clinical knowledge of medical terminology, anatomical body structures, physiological functions, and pathological conditions for the purpose of identifying risk factors and/or diagnostic interventions and/or treatment options in healthcare. 4. Manipulate and interpret health data and statistics using measurement, analysis, and statistical software systems, and utilize analytics, business intelligence, financial analyses, and informatics to support reporting and decision-making across the healthcare continuum. 5. Interpret federal, provincial, and territorial privacy and health legislation as it applies to policies and processes related to health information, security, privacy, confidentiality, external data sharing and access. 6. Summarize types of healthcare information systems, information flow, health information exchange standards and specifications, and the supporting principles, policies, and processes for health sector technologies. 7. Recognize and articulate how equity, diversity, inclusion, and ethics influence healthcare settings and patient outcomes.
Meeting Learning Objectives:	The HIF program will use a series of courses to achieve the stated program learning objectives. Individual course outcomes are mapped to the program objectives and CHIMA's curricular guidance. The delivery format and teaching methods are structured to have a maximum effect on achieving the learning objectives.
Program Admission Requirements:	<p>The diploma is available to individuals who possess a three-year degree in any discipline and those who are actively pursuing their degrees while taking the HIF program.</p> <p>The following statement for recommended program requirements will be posted on MCE's website:</p>

	<p>In compliance with the Certificates and Diploma admission policy from Undergraduate Council, students who wish to enter the Health Information Fundamentals program should meet the following requirements based on their education and work experience:</p> <ol style="list-style-type: none"> 1) Be a mature student as defined in the Undergraduate Calendar of McMaster University; or be deemed an exceptional case by Continuing Education. 2) Be comfortable using word processing software, spreadsheets, and web browsing tools. 3) Follow University guidelines for English Language Proficiency requirements: Completion of TOEFL exam with a minimum acceptable score of IBT: 86 overall with a minimum score of 20 on each of the four components (Reading, Writing, Speaking, Listening), valid for 2 years.
Program Pre-requisites (if applicable):	Learners will be required to have the necessary computer, software programs and access to the internet to complete all courses.
Program Completion Requirements:	To qualify for a Diploma in Health Information Fundamentals, learners must complete nine courses, 30 units of study.
Program Delivery Format:	Program courses will be delivered online. The online format will include instructor lectures, presentations, group discussions, and practical application activities.
Student Evaluations (Grading Process):	Each course will include several evaluation components. The evaluations will consist of assignments, case studies, presentations, individual or group projects, class participation, or a combination thereof. Where appropriate, evaluations will be structured to evaluate participants' level of competency in achieving overall learning objectives. Grading will adhere to McMaster's academic grading scale.
Course Evaluation:	For each course, students will complete an evaluation to assess content, delivery, materials, evaluation method, and instruction.
Course Instruction:	Instructors for courses will be selected from a pool of qualified external professionals. In compliance with <i>McMaster's Senate and Undergraduate Council Guidelines for Certificates and Diplomas</i> , the selection will be based on academic background and/or experience within the field. Instructors must have a Master's degree (or equivalent) and significant professional experience and teaching within the field.
Credit Towards Degree Programme Studies:	The academic credit courses included in the program may be used for credit towards undergraduate degree studies following the standard academic rules as specified by the Faculty offering

Program Advanced Standing:	<p>the degree.</p> <p>Learners may be eligible to transfer up to twelve units of study. Approved course transfers are based on the following requirements:</p> <ul style="list-style-type: none"> • Courses must have an 80% overlap in content/curricula and a similar number of classroom or contact hours. • Courses must have been taken within the last five years. • Courses must have been taken from an accredited academic institution and listed on an official transcript with a grade. • A final grade of "C-" or better to be eligible. 		
Statement of Financial Viability:			
<p>I have reviewed the business case and financial projections, including enrolment projections and costs. This program's revenue sources include tuition and supplementary fees (MAPS). Expenses are typical and include significant upfront development and marketing costs, as well as typical ongoing delivery costs (such as payment of facilitators, honoraria for other guest facilitators, materials, advertising and administration).</p> <p><i>Lorraine Carter, Director, McMaster Continuing Education</i></p>			
Statement of Administrative Responsibilities:			
<p>Statement of Faculty Alignment:</p> <p>The staffing and systems infrastructure to support the following functions already exists within Continuing Education. Costs will be fully covered by tuition, except for the program's first year, when Continuing Education will subsidize the program start.</p> <p>Continuing Education program responsibilities:</p> <ul style="list-style-type: none"> • Budget development and monetary responsibilities, • Program and course development, • Course registrations/administration, • Supervision of instructors to ensure all required policies and practices are adhered to and courses are taught according to program requirements and standards, and • Marketing and promotions. <p>The Faculty of Health Sciences will act as an academic liaison and is responsible for ongoing academic review and assessment of the curriculum. The Faculty's letter of support is included at the end of this document.</p>			
Listing of Courses			
Course Name	Required/Elective	Unit Value	Content Hours
HIF 101 Introduction to Health Information Management and Records Management	Required	3	48
Course Description:			

This course covers fundamental theories and principles of health information management, including data types, acquisition, repositories, records management, and data collection and use. Principles, frameworks, policies, and processes to manage records and documents will be covered, including an overview of documentation legislation, professional practice guidelines for documentation standards, error detection and correction procedures, and the acceptability of medical abbreviations and acronyms. Concepts of Electronic Health Record (EHR), Personal Health Record (PHR), Electronic Medical Record (EMR), and Electronic Patient Record (EPR) will be introduced. Students will also learn about the overall structure of the Canadian health system—including health data and information repositories—as well as interactions between the Canadian health system and the Ministries, medical research, and public health. Learners will be introduced to Clinical Documentation Improvement (CDI) principles and processes, and the importance of equity, diversity, inclusion, and ethics across the healthcare sector will be discussed throughout the course.

HIF 102 Information Governance, Finance, Research	Required	3	36
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Course Description:
 This course covers three major areas: information governance, finance, and research. Information governance includes information lifecycle management and the relationship between data governance and the HIM lifecycle, which will be discussed in depth. Types of interoperability, the data supply chain, and authoritative sources of routinely collected administrative and population data are also covered, along with principles, frameworks, and policies related to external data sharing and access. The course will introduce provincial funding models, grouping and case weighting strategies, MIS Standards, and resource management. The focus on health-related research in Canada will include the role of epidemiology, the research ethics approval process, qualitative and quantitative approaches and methodologies for research, data collection in research, and data and information collection formats.

HIF 103 Privacy & Health Law	Required	3	36
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Course Description:
 This course will cover privacy and health law, including definitions of common legal terms and key Canadian federal, provincial, and territorial legislation which affect health information and privacy. Learners will be introduced to privacy, security, and confidentiality principles relating to various situations regularly encountered by HIM professionals, such as client privacy, maintaining confidentiality, ensuring security, confidentiality agreements, and external data sharing and access. The course’s focus on key provisions, principles, and definitions will address health information, data protection, and privacy statutes, including access, collection, use, disclosure, and custodian/trustee, and information manager obligations. Tools used to assess and manage privacy risk will also be discussed.

HIF 104 Quality in Health	Required	3	36
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This course will introduce students to quality in health, including principles, frameworks, policies, and processes to ensure the accuracy, reliability, relevance, timeliness, coherence,

clarity, and accessibility of data against standards and quality criteria. Standards development organizations, the Standards Lifecycle and development, and pan-Canadian standards (e.g., SNOMED CT, LOINC, pCLOCD, HL7, ICD-10-CA, and CCI) will be covered. Learners will be introduced to quality management methodologies such as CQI, LEAN, and TQM, as well as common principles and practices for creating indicators, benchmarks, metrics, and reports. The course will cover clinical indicators (e.g., HSMR and readmission rates) and their role in monitoring health care quality. Organizational practices for maintaining data quality and data integrity will be discussed. Learners will explore tools used for terminology, nomenclature, classification, abstraction, encoding, and data submission.

HIF 105 Information Technology	Required	3	36
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Course Description:
 This course will introduce students to different types of healthcare information systems, systems specifications for interoperability, and the flow of information between these systems. Learners will cover principles, policies, frameworks, and accountability for maintaining data in technology systems, security of technology platforms, access to systems, and personal health information security. Students will learn about standards for data transmission, translation, and transformation, including consideration of natural language processing and transformation between data standards. The course will discuss the development, functional requirements, and maintenance of an MPI and EMPI, as well as personalized information needs and information-seeking behaviour and the development of consumer health portals. Technologies such as cloud storage, blockchain, and virtual care will be highlighted, and the IT Procurement process, project management, change management, and systems implementation will be covered. Policies related to data integrity, disaster recovery, cybercrime, ransomware, and hacking will also be discussed.

HIF 106 Statistics & Analytics	Required	3	36
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Course Description:
 This course will enable learners to apply descriptive statistical theory to analyze continuous and categorical healthcare data. Learners will learn to employ commonly used statistical software systems to relevant data sources, such as DAD, NACRS, RAI, and MIS. The course will introduce common principles and practices for creating performance indicators, standards, benchmarks, metrics, and reports, including different methodologies, definitions, and visualization. Graphical and tabular presentation of healthcare data to facilitate decision-making will also be explored. Learners will examine business intelligence (BI) tools used to locate, store, retrieve, analyze, and present data and information from multiple sources, as well as the policies and processes for those BI tools. The course will also summarize how BI can be utilized for personal information needs and information-seeking behaviour. Additionally, principles and practices for applying machine learning, artificial intelligence, predictive analytics, data modelling, patient flow modelling, and dataflow diagrams will be discussed.

HTH 200 Medical Terminology	Required	3	36
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Course Description:

This course is designed to familiarize students with the relevant clinical terminology to work successfully within the healthcare sector. Upon completion of this course, students will obtain the requisite knowledge of biomedical terminology commonly used in the healthcare environment. Specific topics include the origins and composition of medical words (roots, prefixes, suffixes, abbreviations) relating to major body systems, common disease terms, diagnostic tests, and clinical procedures. This course is geared towards individuals with no previous health education or professional experience within the Canadian healthcare sector.

HTH 300 Anatomy & Physiology	Required	3	36
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Course Description:
 This comprehensive course provides students with an understanding of the anatomy and physiology of the human body. Topics include an overview of the human body in health and disease, including the Skeletal System, Muscular System, Cardiovascular System, Lymphatic and Immune System, Respiratory System, Digestive System, Urinary System, Nervous System, Special Senses, Integumentary System, Endocrine System, and Reproductive System. This course is designed for individuals with little or no educational background in anatomy, physiology, and pathology.

Pathophysiology	Required	6	72
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Course Description:
 This course provides an overview of pathological conditions, disease processes, and their effects on different body systems. Etiology, clinical manifestations, diagnostic tests, and therapeutic interventions for various disorders are studied. The course builds on students' experience with anatomy and physiology.



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DATE: 24 February 2023
TO: Lorraine Carter, Director, McMaster Continuing Education
Members of the Certificates and Diplomas Committee
FROM: Rob Whyte, Vice-Dean, Education, Faculty of Health Sciences
SUBJECT: Evaluation of the Health Information Fundamentals Diploma Program Proposal
for McMaster Continuing Education (MCE)

I have reviewed the revisions document for the Health Information Fundamentals Diploma program offered through McMaster Continuing Education (MCE). I have examined the program's structure and the proposed course descriptions. My finding is that each course meets the standards of an academic course with 3.0 units of advanced credit value.

Based on my examination of the content covered in each course and the teaching and assessment methods, the proposed courses display intellectual rigour comparable to that found in undergraduate degree courses. The revisions document indicates that the courses will be taught by qualified individuals (possessing a Master's degree or equivalent) as defined by Undergraduate Council's Certificate and Diploma requirements. The students taking the courses will meet the minimum requirements set out in Senate's Certificates and Diplomas Policy (2020) for Undergraduate Council.

On behalf of the Faculty of Health Sciences, I am pleased to support the revisions to this program.

Sincerely yours,

A handwritten signature in blue ink, appearing to read "Rob Whyte".

Rob Whyte, MD, MEd, FRCP(C)
Vice-Dean, Education
Faculty of Health Sciences
McMaster University

Cc: Kathleen Geelen, Program Manager
Daniel Piedra, Assistant Director



DATE: 14 February 2023
TO: Dr. Rob Whyte, Vice-Dean, Education, Faculty of Health Sciences
FROM: Lynn Martin, Teaching Professor , McMaster School of Nursing, Faculty of Health Sciences
SUBJECT: Evaluation of the Health Information Fundamentals Diploma Program Proposal for McMaster Continuing Education (MCE)

At your request, I have reviewed the academic submission document for the Health Information Fundamentals Diploma program to be offered through McMaster Continuing Education (MCE). I have examined the program's structure and the proposed course descriptions. My finding is that each course meets the standards necessary to be an academic course with 3.0 units of advanced credit value.

Based on my examination of content covered in each course as well as the teaching and assessment methods, the proposed courses display intellectual rigour comparable to that found in undergraduate degree courses. The submission document also indicates that the courses will be taught by qualified individuals (possessing a Master's degree or equivalent) as defined by the Undergraduate Council's Certificate and Diploma requirements. The students taking the courses will meet the minimum requirements set out in Senate's Certificate and Diploma Policy (2020) for Undergraduate Council.

Sincerely,

A handwritten signature in cursive script, appearing to read "Lynn Martin".

Lynn Martin
Teaching Professor
Faculty of Health Sciences

Cc: Kathleen Geelen, Program Manager
Daniel Piedra, Assistant Director

Certificate & Diploma Committee - Course Cancellation

Department & Program Information (complete all fields):	
Department:	McMaster Continuing Education
Program Name:	Diploma in Accounting
Name of Representative:	Lorraine Carter, Anne Dwyer
Nature of Submission:	Course Cancellation/Removal
Effective Date:	23-May-1
Submission Date:	23-Feb-21
Course Details (complete all fields):	
Course Title & Unit Value: ACC 920 Effective Communication (3 units)	
<p>Course Description: Canada's business environment requires that business people communicate effectively, persuasively and ethically in written and verbal communication. During this course, students will learn how to plan, write and review business communication, using different methods and strategies. Using a combination of teaching methods, including discussion, peer review, writing and editing projects, this course will help develop participant's critical thinking and analysis, research, writing, editing and presentation skills. Special emphasis will be placed on developing appropriate business language skills (spelling, grammar, punctuation, voice and tone). Students will review various writing styles and learn strategies for writing effective summaries and reports. <i>Effective Communication will also provide students with the tools, techniques and strategies for successful testing and examination preparation.</i></p>	
<p>Rationale for Cancellation: Course is no longer needed, as MCE offers a near identical course under Business Administration (BUS 850 Business Communications). The only difference between ACC 920 and BUS 850 was the added testing and examination preparation module that was added to ACC 920 out of need for those pursuing a CGA designation. With the merger of the various professional accounting associations, this requirement is no longer needed. As such, students needing to take Communications as part of their Diploma in Accounting requirements can take BUS 850 Business Communications.</p>	



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DATE: 26 February 2023
TO: Certificates and Diplomas Committee
FROM: Dr. Sue McCracken, Associate Dean (Academic), DeGroote School of Business
SUBJECT: Course Cancellation for the Diploma in Accounting, McMaster Continuing Education

I have reviewed McMaster Continuing Education's proposal for the cancellation of the course, ACC 920 Effective Communication, from the program of Accounting (Diploma). I support this proposal based on the rationale provided. The proposed change to the program is appropriate, and the program continues to meet the standards set out in the Senate's Certificate and Diploma Policy (2020) for Undergraduate Council.

In conclusion, I support the removal of ACC 920 Effective Communication (3 units of study) from the Diploma in Accounting.

Sincerely,

Susan McCracken | Associate Dean (Academic), PhD, FCPA, FCA
Professor in Accounting
DeGroote School of Business | McMaster University
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BRIGHTER WORLD



Continuing Education Academic Program Submission – For Approval

Department & Program Information	
Program/Plan Name:	Applied Clinical Research (ACR)
Academic Credential:	Certificate
Name of Representative:	Lorraine Carter
Effective Date:	2023-09-01
Date of Submission:	2023-03-07
Academic Merit (complete all fields; write “not applicable” as needed):	
Program Overview:	<p>Applied Clinical Research (ACR) is a certificate program consisting of five 3-unit courses offered by McMaster Continuing Education. As an outcome of the COVID-19 pandemic, there has been a transformation in the field of clinical trials and research which fueled a review of the program in Fall 2022.</p> <p>The proposed changes (program description, program learning objectives, course descriptions) are outlined in Appendix A at the end this document.</p> <p>Clinical research professionals contribute to research studies that have a major impact on health care. Significant advancements in these areas and expanding regulatory requirements have increased the demand for trained clinical research professionals. As such, a comprehensive program review of this certificate program was conducted in the Fall of 2022. The review incorporated feedback from industry professionals, ACR instructors, and students. The results have informed the proposed revised program learning objectives and course descriptions presented in this proposal.</p> <p>The revised program learning objectives and course learning outcomes align with the Association of Clinical Research Professionals (ACRP) and the Society of Clinical Research Associates (SORCA) competency domains.</p> <p>The Certificate in Applied Clinical Research (ACR) prepares students to be integral members of a clinical research team by adhering to research ethics, best practices, and regulations, which protect patient safety and ensure trial integrity.</p>

	<p>Graduates are prepared to apply clinical research protocol requirements, as well as good clinical practice (GCP) guidelines, standard operating procedures (SOPs), research ethics board (REB) requirements, and federal regulations (Health Canada and FDA).</p> <p>In addition, graduates have acquired project management, self-directed research, communication, and ethical decision making skills through completion of a real-world team-based capstone project.</p>
Learning Objectives:	<p>Upon completion of the program, learners will be able to:</p> <ol style="list-style-type: none"> 1. Summarize clinical research principles and study design concepts 2. Identify the sequential steps, milestones, processes, and deliverables for conducting a clinical trial across a study's start-up, maintenance, and close-out phases 3. Describe study conduct in compliance with clinical research protocol requirements, as well as good clinical practice (GCP) guidelines, standard operating procedures (SOPs), research ethics board (REB) requirements, and federal regulations (Health Canada and FDA) 4. Create study documents and forms that are essential for clinical trial conduct 5. Explain how quality management processes are implemented in clinical trials to ensure participant safety and data integrity 6. Apply core principles when examining ethical issues in clinical research 7. Demonstrate teamwork, leadership, communication, and project management skills needed to work effectively with multidisciplinary study teams
Meeting Learning Objectives:	<p>The methods of delivery and evaluation in each course are structured to ensure students achieve the course learning outcomes which are mapped to the program learning objectives and ACRP and the SOCRA domains. The capstone course simulates real-world experiences as students work in teams to apply theoretical knowledge and skills gained from previous courses in the program. In addition to meeting the</p>

	learning objectives, students are required to demonstrate successful study conduct through self-directed research, project management, and professional communication.
Program Admission Requirements:	The following statement for recommended program requirements will be posted on MCE's website: In compliance with the Certificates and Diplomas admission policy from Undergraduate Council, students who wish to enter the Applied Clinical Research program should meet the following requirements based on their education and work experience: <ol style="list-style-type: none"> 1) Be a mature student as defined in the Undergraduate Calendar of McMaster University; or be deemed an exceptional case by Continuing Education. 2) Be comfortable using word processing software, spreadsheets, and web browsing tools. 3) Follow University guidelines for English Language Proficiency requirements: Completion of TOEFL exam with a minimum acceptable score of IBT: 86 overall with a minimum score of 20 on each of the four components (Reading, Writing, Speaking, Listening), valid for 2 years.
Program Pre-requisites (if applicable):	Learners will be required to have a computer, software programs and access to the internet to complete all courses.
Program Completion Requirements:	To qualify for a Certificate in Applied Clinical Research, learners must complete five courses, 15 units of study.
Program Delivery Format:	Courses will be delivered online. The online format will include instructor lectures, presentations, group discussions, and practical application activities.
Student Evaluations (Grading Process):	Each course will include several evaluation components. The evaluations will consist of assignments, case studies, presentations, individual or group projects, class participation, or a combination thereof. Where appropriate, evaluations will be structured to evaluate participants' level of competency in achieving overall learning objectives. Grading will adhere to McMaster's academic grading scale.
Course Evaluation:	For each course, students will complete an evaluation to assess content, delivery, materials, method of evaluation and instruction.
Course Instruction:	Instructors for courses will be selected from a pool of qualified external professionals. In compliance with <i>McMaster's Senate and Undergraduate Council Guidelines for Certificates and Diplomas</i> , the selection will be based on academic background and/or experience within the field. Instructors must have a Master's Degree (or equivalent) and significant professional experience and teaching within the field.

Credit Towards Degree Programme Studies:	The academic credit courses included in the program may be used for credit towards undergraduate degree studies following the normal academic rules as specified by the Faculty offering the degree.
Program Advanced Standing:	Learners may be eligible to transfer up to three units of study to the program. Approved course transfers are based on the following requirements: <ul style="list-style-type: none"> • courses must have an 80% overlap in content/curricula and a similar number of classroom or contact hours • courses must have been taken within the last five years • courses must have been taken from an accredited academic institution and listed on an official transcript with a grade • a final grade of "C-" or better to be eligible

Statement of Financial Viability:

I have reviewed the business case and financial projections which include enrolment projections and costs. Sources of revenue for this program include tuition and supplementary fees (MAPS). Expenses are typical and include significant upfront development and marketing costs, as well as typical ongoing delivery costs (such as payment of facilitators, honoraria for other guest facilitators, materials, advertising and administration).
Lorraine Carter, Director, McMaster Continuing Education

Statement of Administrative Responsibilities:

Statement of Faculty Alignment:
The staffing and systems infrastructure to support the following functions already exists within Continuing Education. Costs will be fully covered by tuition, except for the first year of the program, when the startup will be subsidized by Continuing Education.
Continuing Education program responsibilities:

- budget development and monetary responsibilities
- program and course development
- course registrations/administration
- supervision of instructors to ensure all required policies and practices are adhered to and courses are taught according to program requirements and standards
- Marketing and Promotions

The Faculty of Health Sciences will act as an academic liaison and is charged with the responsibility of ongoing academic review and assessment of the curriculum. The Faculty's letter of support is included at the end of this document.

Listing of Courses: The course descriptions provided below reflect the changes based on the Fall 2022 review. The titles of the courses have not changed.

Course Name	Required/Elective	Unit Value	Content Hours
ACR 101: Principles of Clinical Research	Required	3	36
Guided by the lens of Good Clinical Practice (GCP) and pertinent regulations, this introductory course examines how to conduct safe and successful clinical trials. Clinical trial phases, study			

design, and the roles and responsibilities of various stakeholders will be explored. Emphasis will also be placed on the foundational skills needed for successful trial management including project management and communication skills.

ACR 102: Research Ethics	Required	3	36
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This course analyzes the professional guidelines and codes of ethics applicable to the clinical research process. Situations presenting ethical dilemmas as well as scientific integrity and the responsibilities of the clinical investigation team as defined by Good Clinical Practice (GCP) guidelines are explored.

ACR 103: Clinical Trial Design	Required	3	36
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This course reinforces the key fundamentals of clinical trial design and methodology including protocol development, participant recruitment, and data management and analysis while adhering to regulatory frameworks and guidelines. Students evaluate clinical study designs that explore relevant research questions using data-driven analysis.
Pre-requisite: ACR 101 Principles of Clinical Research.
Pre-requisite: ACR 101 Principles of Clinical Research.

ACR 104: Clinical Trial Management	Required	3	36
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Strategies for planning and managing clinical trials, including operational complexities in clinical research projects are examined. Effective methods used for the preparation of scientific documents, data management, quality assurance, safety reporting, and end of trial practices are explored. Students will also apply real-world skills of leadership, project management, and risk management in clinical research.
Pre-requisite: ACR 103 Clinical Trial Design.

ACR 105: Clinical Research Capstone	Required	3	36
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This capstone course is intended to simulate real-world experiences in the areas of clinical research protocols and study management. Working in teams, students will apply the theoretical knowledge and skills gained from previous courses in the program. Students will also be required to demonstrate successful study conduct using self-directed research, project management, and professional communication.
Pre-requisite: ACR 104 Clinical Trial Management.

Insert Faculty Support Letter:

Attach a letter of support from the Associate Dean of the Faculty. **All documentation must be included in one file.**

Appendix A: Proposed Updates to the Certificate in Applied Clinical Research, Winter 2023

The Certificate in Applied Clinical Research offered by McMaster Continuing Education (MCE) was reviewed in the Fall of 2022. Based on recommendations from the review, changes are proposed to the program description, program objectives, and course descriptions. There are no changes recommended for course titles.

PROGRAM DESCRIPTION	
Current	Proposed
<p>The Applied Clinical Research certificate program will consist of five, three (3) unit courses (15 units). Program content is based on common areas of knowledge and skills for clinical research associates and managers as identified by a North American Advisory Board and the competencies of the Internationally-focused Association of Clinical Research Professionals (ACRP)</p> <p>Upon successful completion of the required five courses, participants will receive the McMaster University Certificate in Applied Clinical Research. Students are given a three-year period to complete all required components of the certificate program. This requirement is based on the need to remain current with legal, regulatory and ethical considerations in the field of work.</p> <p>Each course will bridge theory and practical experience through a combination of experiential learning (i.e. case studies, discussions, and presentations) and traditional teaching methods. There will be considerable emphasis on the application of content in each course to ensure students are well prepared for employment in this field. In addition, students will complete a capstone project/practicum placement as the final course in the program, which provides a concentrated opportunity to apply the clinical research methods, techniques and strategies to a real-world situation/case. Emerging trends, theories and practices will be incorporated into coursework to ensure that program content is current and relevant.</p>	<p>The Certificate in Applied Clinical Research (ACR) prepares students to be integral members of a clinical research team by adhering to research ethics, best practices, and regulations, which protect patient safety and ensure trial integrity.</p> <p>Graduates are prepared to apply clinical research protocol requirements, as well as good clinical practice (GCP) guidelines, standard operating procedures (SOPs), research ethics board (REB) requirements, and federal regulations (Health Canada and FDA).</p> <p>In addition, graduates have acquired project management, self-directed research, communication, and ethical decision-making skills through completion of a real-world team-based capstone project.</p>

PROGRAM OBJECTIVES	
Current	Proposed
<ol style="list-style-type: none"> 1. Describe GCP (Good Clinical Practice) requirements and explain the legal and regulatory issues in clinical research (Bloom's: Understanding) 2. Construct a clinical research protocol and critique flawed and exemplary studies (Bloom's: Evaluate and Creating) 3. Differentiate the key elements of successful study and site management (Bloom's: Analyze) 4. Examine ethical issues in clinical research and select appropriate approaches strategies to navigate(Bloom's: Analyze) 5. Practice the leadership and communication skills needed in a clinical research setting.(Bloom's: Apply) <p>The following objectives will be threaded within each course: Students will be able to:</p> <ol style="list-style-type: none"> 1. Demonstrate an awareness of ethical practices and professional standards applicable to the field of clinical research 2. Exemplify the skills, attitudes and behaviours required to effectively communicate with various stakeholder groups engaged in clinical trials 3. Demonstrate personal management, leadership and project management skills 	<ol style="list-style-type: none"> 1. Summarize clinical research principles and study design concepts 2. Identify the sequential steps, milestones, processes, and deliverables for conducting a clinical trial across a study's start-up, maintenance, and close-out phases 3. Describe study conduct in compliance with clinical research protocol requirements, as well as good clinical practice (GCP) guidelines, standard operating procedures (SOPs), research ethics board (REB) requirements, and federal regulations (Health Canada and FDA) 4. Create study documents and forms that are essential for clinical trial conduct 5. Explain how quality management processes are implemented in clinical trials to ensure participant safety and data integrity 6. Apply core principles when examining ethical issues in clinical research 7. Demonstrate teamwork, leadership, communication, and project management skills needed to work effectively with multidisciplinary study teams.

COURSE DESCRIPTIONS	
Current	Proposed
<p>ACR 101: Principles of Clinical Research This introductory course explores the terminology, as well as roles and responsibilities involved in a clinical research project. Good Clinical Practice (GCP) procedures will be examined, as well as an overview of legal considerations of clinical trials. Emphasis will be placed on the foundational skills needed for successful trial management including project management and communication skills.</p>	<p>ACR 101: Principles of Clinical Research Guided by the lens of Good Clinical Practice (GCP) and pertinent regulations, this introductory course examines how to conduct safe and successful clinical trials. Clinical trial phases, study design, and the roles and responsibilities of various stakeholders will be explored. Emphasis will also be placed on the foundational skills needed for successful trial management including project management and communication skills.</p>
<p>ACR 102: Research Ethics Professional guidelines and codes of ethics that apply to the conduct of clinical research will be analyzed. Situations presenting ethical dilemmas including vulnerable populations will be explored as well as scientific integrity, and the responsibilities of the clinical investigation team as defined by GCP guidelines.</p>	<p>ACR 102: Research Ethics This course analyzes the professional guidelines and codes of ethics applicable to the clinical research process. Situations presenting ethical dilemmas as well as scientific integrity and the responsibilities of the clinical investigation team as defined by Good Clinical Practice (GCP) guidelines are explored.</p>
<p>ACR 103: Clinical Trial Design Scientific and statistical concepts related to the design and analysis of clinical trials will be examined, as well as the regulatory framework and guidelines that govern clinical trials. Emphasis will be placed on the concepts in the design of a clinical trial including the process of protocol development and effective use of Case Report Forms.</p>	<p>ACR 103: Clinical Trial Design Strategies for planning and managing clinical trials, including operational complexities in clinical research projects are examined. Effective methods used for the preparation of scientific documents, data management, quality assurance, safety reporting, and end of trial practices are explored. Students will also apply real-world skills of leadership, project management, and risk management in clinical research. Pre-requisite: ACR 103 Clinical Trial Design.</p>
<p>ACR 104: Clinical Trial Management Strategies for conducting and managing clinical trials, as well as operational issues of a clinical research project will be examined. Effective methods for organizing data and quality assurance will be explored as well as end of trial practices, safety reporting, and the preparation of scientific documents. Topics in leadership will also be examined including management of resources, risk and professional conflicts.</p>	<p>ACR 104: Clinical Trial Management Strategies for planning and managing clinical trials, including operational complexities in clinical research projects are examined. Effective methods used for the preparation of scientific documents, data management, quality assurance, safety reporting, and end of trial practices are explored. Students will also apply real-world skills of leadership, project management, and risk management in clinical research. Pre-requisite: ACR 103 Clinical Trial Design.</p>

ACR 105: Clinical Research Capstone

This course is intended to simulate a real-world experience that offers an applied synthesis of learning in the areas of clinical research protocols, and study and site management principles. Participants will also be expected to demonstrate a solid grasp of competencies in leadership, and communication skills that are also needed to ensure a successful clinical trial. This course is designed to offer students the opportunity to apply the theoretical knowledge and skills gained from the Applied Clinical Research program to a capstone project

ACR 105: Clinical Research Capstone

This capstone course is intended to simulate real-world experiences in the areas of clinical research protocols and study management. Working in teams, students will apply the theoretical knowledge and skills gained from previous courses in the program. Students will also be required to demonstrate successful study conduct using self-directed research, project management, and professional communication. Pre-requisite: ACR 104 Clinical Trial Management.

PREREQUISITES

Current	Proposed
ACR 101: None ACR 102: Completed ACR 101 ACR 103: Completed ACR 102 ACR 104: Completed ACR 103 ACR 105: ACR 104 as Co-requisite	ACR 101: None ACR 102: None ACR 103: Completed ACR 101 ACR 104: Completed ACR 103 ACR 105: Completed ACR 104



Dr. Robert Whyte
Vice Dean, Education
Faculty of Health Sciences

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Fax: 905.528.4727
Email: rwhyte@mcmaster.ca

DATE: 24 February 2023
TO: Lorraine Carter, Director, McMaster Continuing Education
Members of the Certificates and Diplomas Committee
FROM: Rob Whyte, Vice-Dean, Education, Faculty of Health Sciences
SUBJECT: Evaluation of the Applied Clinical Research Certificate Program Proposal for McMaster Continuing Education (MCE)

I have reviewed the revisions document for the Applied Clinical Research Certificate program offered through McMaster Continuing Education (MCE). I have examined the program's structure and the proposed course descriptions. My finding is that each course meets the standards of an academic course with 3.0 units of advanced credit value.

Based on my examination of the content covered in each course and the teaching and assessment methods, the proposed courses display intellectual rigour comparable to that found in undergraduate degree courses. The revisions document indicates that the courses will be taught by qualified individuals (possessing a Master's degree or equivalent) as defined by Undergraduate Council's Certificate and Diploma requirements. The students taking the courses will meet the minimum requirements set out in Senate's Certificates and Diplomas Policy (2020) for Undergraduate Council.

On behalf of the Faculty of Health Sciences, I am pleased to support the revisions to this program.

Sincerely yours,

A handwritten signature in blue ink, appearing to read "Rob Whyte".

Rob Whyte, MD, MEd, FRCP(C)
Vice-Dean, Education
Faculty of Health Sciences
McMaster University

Cc: Kathleen Geelen, Program Manager
Daniel Piedra, Assistant Director



DATE: 23 February 2023
TO: Dr. Rob Whyte, Vice Dean, Faculty of Health Sciences
FROM: James D. Douketis, Professor, Department of Medicine, Faculty of Health Sciences
SUBJECT: Evaluation of Proposed Revisions for the Applied Clinical Research Certificate Program for McMaster Continuing Education (MCE)

I have reviewed the revisions document for the Applied Clinical Research Certificate program which is offered through McMaster Continuing Education (MCE). I have examined the program's structure and the proposed revisions. My finding is that each course meets the standards of an academic course with 3.0 units of advanced credit value.

Based on my examination of the content covered in each course as well as the teaching and assessment methods, the proposed courses display intellectual rigour comparable to that found in undergraduate degree courses. The submission document also indicates that the courses will be taught by qualified individuals (possessing a Master's degree or equivalent) as defined by the Undergraduate Council's Certificates and Diplomas requirements. The students taking the courses will meet the minimum requirements set out in Senate's Certificates and Diplomas Policy (2020) for Undergraduate Council.

Sincerely,

A handwritten signature in black ink that reads "James D. Douketis" with a horizontal line underneath.

J. Douketis MD, FRCPC
Professor
Department of Medicine, Faculty of Health Sciences



DATE: February 21, 2023
TO: Dr. Rob Whyte, Vice Dean, Faculty of Health Sciences
FROM: Dr. Bram Rochweg, Faculty of Health Sciences
SUBJECT: Evaluation of Proposed Revisions for the Applied Clinical Research Certificate Program for McMaster Continuing Education (MCE)

I have reviewed the revisions document for the Applied Clinical Research Certificate program which is offered through McMaster Continuing Education (MCE). I have examined the program's structure and the proposed revisions. My finding is that each course meets the standards of an academic course with 3.0 units of advanced credit value.

Based on my examination of the content covered in each course as well as the teaching and assessment methods, the proposed courses display intellectual rigour comparable to that found in undergraduate degree courses. The submission document also indicates that the courses will be taught by qualified individuals (possessing a Master's degree or equivalent) as defined by the Undergraduate Council's Certificates and Diplomas requirements. The students taking the courses will meet the minimum requirements set out in Senate's Certificates and Diplomas Policy (2020) for Undergraduate Council.

Sincerely,

A handwritten signature in black ink, appearing to be "BR" or similar initials.

Dr. Bram Rochweg
Associate Professor, Medicine
Associate Member, Health Research Methods, Evidence, and Impact (HEI)



DATE: 20 February 2023

TO: Dr. Rob Whyte, Vice Dean, Faculty of Health Sciences

FROM: Mark Crowther, Professor and Chair, Medicine, Faculty of Health Sciences

SUBJECT: Evaluation of Proposed Revisions for the Applied Clinical Research Certificate Program for McMaster Continuing Education (MCE)

I have reviewed the revisions document for the Applied Clinical Research Certificate program which is offered through McMaster Continuing Education (MCE). I have examined the program's structure and the proposed revisions. My finding is that each course meets the standards of an academic course with 3.0 units of advanced credit value.

Based on my examination of the content covered in each course as well as the teaching and assessment methods, the proposed courses display intellectual rigour comparable to that found in undergraduate degree courses. The submission document also indicates that the courses will be taught by qualified individuals (possessing a Master's degree or equivalent) as defined by the Undergraduate Council's Certificates and Diplomas requirements. The students taking the courses will meet the minimum requirements set out in Senate's Certificates and Diplomas Policy (2020) for Undergraduate Council.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark Crowther".

Mark Crowther
Professor and Department Chair
Faculty of Health Sciences