

MISSOURI DEPARTMENT OF HIGHER EDUCATION

FORM NP: NEW PROGRAM PROPOSAL FORM

Sponsoring Institution(s): Washington University

Program Title: Graduate Certificate in Clinical Research Management

Degree/Certificate: Certificate

Options: _____

Delivery Site(s): Washington University, Danforth Campus

CIP Classification: 51.0711

Implementation Date: July 1, 2009

Cooperative Partners: University College in Arts & Sciences, Washington University School of Medicine

Expected Date of First Graduation: December, 2010

AUTHORIZATION

Name/Title of Institutional Officer:

Edward S. Macias, Provost

Signature _____ Date _____

Person to Contact for More Information:

Susan E. Hosack, Director, Office of Student Records/Registrar

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Form SE: STUDENT ENROLLMENT PROJECTIONS

Year	1	2	3	4	5
Full Time					
Part Time	10	10	10	10	10
Total	10	10	10	10	10

Form PS: PROGRAM STRUCTURE

A. Total credits required for graduation: 21

B. Residency requirements, if any: _____

C. General education: Total credits: _____

Courses (specific courses OR distribution area and credits):

_____ cr. _____ cr. _____ cr.

D. Major requirements: Total credits: 21

- Fundamentals of Clinical Research Management 3 cr.
- Medical Writing for Clinical Research 3 cr.
- Drug and Device Development 3 cr.
- Trends in Health Care Policy 3 cr.
- Compliance, Legal, and Regulatory Issues 3 cr.
- Designing Outcomes of Clinical Research 3 cr.
- Epidemiology 3 cr.

_____ cr. _____ cr. _____ cr.

E. Free elective credits: _____ (Sum of C, D, and E should equal A.)

F. Requirements for thesis, internship or other capstone experience: _____

G. Any unique features such as interdepartmental cooperation:

Course work largely from University College in Arts & Sciences, several cross-listed courses from master's programs in clinical investigation and health care services (Washington University School of Medicine).

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Form PG: PROGRAM CHARACTERISTICS AND PERFORMANCE GOALS

Institution Name: Washington University

Program Name: Graduate Certificate in Clinical Research Management

Date: July 1, 2009

(Although all of the following guidelines may not be applicable to the proposed program, please carefully consider the elements in each area and respond as completely as possible in the format below. Quantification of performance goals should be included wherever possible.)

Student Preparation

- Any special admissions procedures or student qualifications required for this program which exceed regular university admissions, standards, e.g., ACT score, completion of core curriculum, portfolio, personal interview, etc. Please note if no special preparation will be required.

No special preparation other than experience in clinical research.

- Characteristics of a specific population to be served, if applicable.

The Certificate in Clinical Research Management is designed primarily for individuals with clinical research responsibilities, drawn largely from academic research centers and the pharmaceutical industry.

Faculty Characteristics

- Any special requirements (degree status, training, etc.) for assignment of teaching for this degree/certificate.

No formal requirement, though majority of faculty hold the PhD, MD, or MA.

- Estimated percentage of credit hours that will be assigned to full time faculty. Please use the term "full time faculty" (and not FTE) in your descriptions here.

Approximately ten faculty, all adjunct in University College, each to carry three credit hours (single course). Several may teach two courses (six credit hours). Faculty drawn largely from Washington University School of Medicine administrative and clinical staff.

- Expectations for professional activities, special student contact, teaching/learning innovation.

Enrollment Projections

- Student FTE majoring in program by the end of five years.
- Percent of full time and part time enrollment by the end of five years.

Student and Program Outcomes

- Number of graduates per annum at three and five years after implementation.
- Special skills specific to the program.

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The program targets key processes for managing research protocols that develop and use drugs, devices, and treatments for patient care. The program focuses on the scientific methods of clinical research, good clinical practice, research ethics, and the regulatory guidelines that protect human subjects. Specific course work and overall program objectives for all clinical research management programs of study offered through University College reinforce “good clinical practices” published by the Association of Clinical Research Professionals.

- Proportion of students who will achieve licensing, certification, or registration.

In addition to strengthening participants’ overall marketability in clinical/academic research and related industry settings, the program will provide necessary skills for certification, all clinical research management programs of study offered through University College reinforce “good clinical practices” published by the Association of Clinical Research Professionals

- Performance on national and/or local assessments, e.g., percent of students scoring above the 50th percentile on normed tests; percent of students achieving minimal cut-scores on criterion-referenced tests. Include expected results on assessments of general education and on exit assessments in a particular discipline as well as the name of any nationally recognized assessments used.
- Placement rates in related fields, in other fields, unemployed.
- Transfer rates, continuous study.

Program Accreditation

- Institutional plans for accreditation, if applicable, including accrediting agency and timeline. If there are no plans to seek specialized accreditation, please provide reasons.

Alumni and Employer Survey

- Expected satisfaction rates for alumni, including timing and method of surveys
- Expected satisfaction rates for employers, including timing and method of surveys