

**MEMORANDUM**

**To:** Board of Regents  
**From:** Board Office  
**Subject:** Establishment of a Graduate Certificate in Clinical Investigation, SUI  
**Date:** January 6, 2003

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**Recommended Action:**

Approve the University of Iowa's request to establish a graduate Certificate in Clinical Investigation.

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**Executive Summary:**

Three Research Subtracks      The Graduate Training Program in Clinical Investigation in the Carver College of Medicine proposes to offer a Certificate in Clinical Investigation with three distinct subtracks:

1. Patient-oriented research;
2. Clinical epidemiology and behavioral research; and
3. Outcomes and health services research

The number of clinical researchers in the United States continues to decrease. To counter this trend, the National Institutes of Health proposed increased support of clinical research training in academic settings.

National Institutes of Health Funding      The University of Iowa won a coveted NIH K30 Clinical Research Curriculum Award to develop the infrastructure to provide rigorous training in contemporary clinical research. The Iowa K30 Graduate Training Program in Clinical Investigation, under the leadership of Dr. Brad Doebbeling, is considered one of the best programs in the country and has been instrumental in helping SUI obtain several new research training programs and K awards. It is increasingly important that there be a formal Certificate of Clinical Investigation as part of the K30 Program to prepare individuals to compete for grants involving clinical research.

Requires 19 Credit Hours      The proposed certificate will directly target the training needs of clinical investigators by focusing on coursework in methodology, hands-on research experience with clinical research mentors, and an opportunity for interdisciplinary critique of work-in-progress. The certificate will require 19 credit hours. While SUI offers a Master of Public Health degree with an emphasis on clinical investigation, this degree has only minimal focus on clinical research or research methods.

Consistent with  
Strategic Plans

The proposed certificate is in line with the Carver College of Medicine and the University strategic plans. It would be the only such training program in the state. The University of Iowa has one of only 54 NIH K30 Clinical Research Curriculum Award programs nationally. Of those at comparable medical research institutions, at least eight have a certificate program in clinical investigation. These programs find the certificate program is a useful tool in improving retention of clinicians as well as a competitive recruitment tool for clinicians interested in academic careers. Prospective students will have already received a clinical doctoral degree (MD, DO, PhD/RN, PharmD, DDS) and will bring their clinical expertise and interests in clinical research.

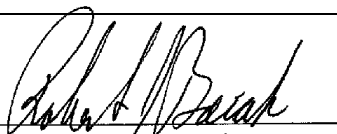
No Additional  
Resources Needed

Required and elective courses are already taught or proposed (irrespective of Certificate approval). No additional program resources for faculty are requested, nor is additional budget support anticipated. The Certificate proposal has been approved by the Dean of the Carver College of Medicine and endorsed by the deans of the health sciences colleges and the Graduate College. It was approved by the Provost.

Program Review  
Questions

Attached to this memorandum are the University's responses to the Board of Regents Program Review Questions.

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Robert J. Barak

Approved:   
Gregory S. Nichols

## 6.05 Academic Review and Program Approval

- A. New Program Approval All new or expanded programs, majors, certificates and minors shall be reported to the Board Office for approval by the Board of Regents, State of Iowa.

New or expanded program proposals are routinely referred to the Interinstitutional Committee on Educational Coordination and the Board Office for review and recommendation. (See § Chapter 1 of this Manual for Committee on Educational Coordination.)

All new programs referred to the Interinstitutional Committee on Educational Coordination and the Board Office shall be submitted to the Iowa Coordinating Council for Post High School Education for appropriate action in accordance with ICCPHSE policy. The Regent institutions are encouraged to submit their new programs to the ICCPHSE well in advance of the Board meeting where it will be considered.

All new or expanded programs submitted to the Board Office for approval by the Board of Regents, State of Iowa, shall include, along with the complete original institution internal approval documents, a complete response to the following program review questions. For proposed minors and certificates, questions 3 - 6 may be omitted, but additional resource needs should be reported.

List contact person for new or expanded programs.

1. Need
  - a. How will this proposed program further the educational and curriculum needs of the students in this discipline?

**Programs currently available to K30 Scholars at The University of Iowa address the need for academic research training with Master of Science (MS), Master of Public Health (MPH), or Doctor of Philosophy (PhD) degrees in numerous basic science fields, translational biomedical research, and population-based epidemiologic and public health research. None of the degrees currently available at the University of Iowa address the training needs of clinicians in patient-oriented clinical research as outlined by the National Institute of Health. Basic science research addresses cellular and molecular events, while translational biomedical research is the study of applying basic science findings to humans, and epidemiology is the study of diseases in populations and is statistically oriented.**

**We propose a certificate program in clinical investigation that requires 19 credit hours and may be completed in one year. This certificate will be extremely attractive to clinicians interested in receiving introductory training in clinical research methods.**

- b. How does it further the educational and curriculum needs of other units in the college or university?

**Required and elective courses in the proposed Certificate curriculum include courses already offered or proposed irrespective of Certificate approval, taught by current faculty members. Rather than taking random courses with no formal curricular advising or concrete outcome, clinicians will have an organized curriculum and infrastructure for research support within the proposed Certificate. Therefore, no additional program resources for faculty are requested.**

2. Duplication and Collaboration

- a. What programs in this field of study are available in other colleges and universities in Iowa?

**The University of Iowa would be the only Regents institution to offer a training program as outlined in the proposed Certificate.**

(Identification of other programs available in this field at other institutions should be made within a broad definitional framework. For example, such identification should not be limited to programs bearing the same title, the same degree designation, having the same curriculum emphasis, or purporting to meet exactly the same needs as the proposed program.)

- b. With what representatives of these programs has there been consultation in developing this proposal? Provide a summary of the responses of each institution consulted.

**N/A**

(The complete text of responses should be included.)

- c. In what ways is this proposed program similar to those mentioned in 2a? In what ways is it different or does it have a different emphasis?

**N/A**

(In describing program similarities and differences, consider such factors as curriculum, prospective student groups to be served, and career or other types of goals to be emphasized.)

- d. How does the proposed program supplement the current programs available?

**N/A**

(In some instances, this question should go beyond how the program will supplement others within the state. If the justification for the program involves special regional or national needs, a description of existing programs within the region or the nation and the relation of the proposed program to these should be provided.)

- e. Has the possibility of some kind of interinstitutional program or other cooperative effort been explored? What are the results of this study?

**N/A**

(Consider not only the possibility of a formally established interinstitutional program, but also how special resources at other institutions might be used on a cooperative basis in implementing the proposed program solely at this institution.)

- f. Please list the Iowa institutions in which articulation agreements are being developed for the proposed program (NOTE: This applies only to community college degree programs which may transfer students to this program).

**N/A**

- g. Please provide the Classification of Instructional Program (CIP) Code for the proposed program.

**51.9999**

Additional Resource Needs

Either question one or question two requires a “yes” answer. In addition to a “yes” response to one of the first two questions, question three and question four should be answered. If applicable, question five should be answered.

1. Will the program require new resources? Yes \_\_\_ No X  
If “yes,” what is the plan to obtain new resources?
2. Will the program require reallocated resources? Yes \_\_\_ No X  
If “yes,” what is the university’s reallocation plan to fund this program?
3. At what level of enrollment will additional resources be required for the program?
4. Estimate the total costs (or *incremental increases in expenditures*) that may be necessary as a result of the new program for the next three years.
5. For programs planning to use external grants, what would be the effect of the grant termination?

**At this time, we do not anticipate needing any additional budget support to offer the proposed certificate program to 5 - 8 students per year. The K30 Graduate Training Program in Clinical Investigation and the Roy J. and Lucille A. Carver College of Medicine offers administrative support for the program. With demonstrated success, the program will continue to be supported if the grant funds are terminated.**

	First Year	Second Year	Third Year
a. Faculty			
b. Graduate Assistants			
c. General Expense			
d. Equipment			
e. Library Resources			
f. New Space Needs [estimated amt. & cost of new and/or remodeled space)			
g. Computer use			
h. Other resources			
TOTAL(S)			

6. How does this program relate to the college’s/university’s strategic plan?

**The proposed Certificate is perfectly aligned to address Strategic Plan Goal #2 of the Roy J. and Lucille A. Carver College of Medicine subgoal #2.9: “Adopt a collegiate plan to support the future of patient-oriented research by the College’s faculty in cooperation with the UIHC.” Training in clinical research will position fellows and junior faculty to be**

highly successful in obtaining NIH funding, which will address subgoal #2.1: “Increase NIH extramural research support to rank in the top ten public medical schools.” Other health sciences colleges at The University of Iowa include similar strategic initiatives supported by the proposed Certificate – to increase research productivity and quality, enhance interdisciplinary activities within the University of Iowa, and improve research infrastructure.

New program proposals for programs that are currently offered at one or more Regent University must also complete the Board of Regents questions on potential program duplication contained in §6.09 of this Policy Manual.

N/A

#### **6.09 Principles and Standards for Program Duplication**

- A. The Board of Regents, State of Iowa, recognizes that program overlap or duplication cannot be evaluated in absolute terms. Some duplication is desirable, appropriate, and essential. Other duplication is inappropriate.
- B. Policy decisions concerning the appropriateness of new programs or the expansion of existing programs that appear to duplicate activities in other institutions shall be based on such considerations as the following:
  - 1. Does the institution have personnel, facilities, and equipment adequate to establish and maintain a high quality program or should the program be located in another institution where adequate resources are available?

The certificate program will be led by **Bradley N. Doebbeling\***, MD, MSc, who is a Professor of Internal Medicine and Epidemiology, University of Iowa Colleges of Medicine and Public Health, and Co-Director, Iowa City Veterans Administration Medical Center REAP, Program for Interdisciplinary Research in Healthcare Organizations. He was Co-Principal Investigator of the landmark Centers for Disease Control and Prevention-funded Iowa Gulf War Study and is Principal Investigator for an ongoing 6 year Department of Defense-funded Case Validation Study. He also is currently PI on two Merit Review grants from Veterans Administration (Health Services Research and Development and Epidemiology). He is Program Director of the University of Iowa National Institute of Health-funded K30 Graduate Training Program in Clinical Investigation, and Associate Director of the Doris Duke Clinical Research Fellowship. His research has been funded by the National Institute of Health, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, and Robert Wood Johnson Foundation. He serves on research advisory committees for Institute of Medicine, Veterans Administration, Centers for Disease Control and Prevention, National Institute of Health, and Department of Defense.

Required and elective courses in the proposed Certificate curriculum will be taught by current University of Iowa faculty with expertise in the subject areas.

The most important training experience will be the mentored or preceptored research experiences with established, active investigators. Participants in the program will meet with potential mentors and will be introduced to their programs of research early during the summer program. The University of Iowa is a teaching hospital with many well-funded established researchers to serve as mentors to the trainees and provide meaningful projects for them to work on.

**A Steering Committee has been formed to include a broad base of representation from the clinical and basic science departments of the health sciences colleges. This committee plays an important advisory role to the Program Director and Steering Committee Chair, Dr. Doebbeling, in policy formulation, admissions, certification of students, and total program evaluation. The committee currently meets on at least a quarterly basis to advise the Program Director on program policy and administration, curriculum needs, and review of student academic progress.**

**The Executive Committee is a subset of the Steering Committee that includes senior faculty with specific methodological expertise, exceptionally strong clinical research training experience, and a strong commitment to the training program. These individuals participate in the weekly research conferences and provide critiques of students' research efforts. They are also readily available to the Program Director and trainees and provide input regarding the certificate program and its direction. The Executive Committee also serves as the program admissions committee and is chaired by Dr. Doebbeling.**

2. Does student demand for the proposed program justify its development or expansion?

**Clinicians and postdoctoral trainees have repeatedly requested focused training in clinical investigation research methods and skills. The proposed certificate will directly target the training needs of clinical investigators by focusing on coursework in methodology, hands-on research experience with clinical research mentors, and an opportunity for interdisciplinary critique of work-in-progress.**

3. Do adequate employment opportunities for graduates exist, and is it likely that they will continue to exist?

**The University employs most, if not all, of the students in the proposed certificate program as junior faculty or clinical fellows. Training in the certificate program will enhance prospects for obtaining tenure within the University or research positions at other academic medical institutions by teaching and developing clinical research skills, promoting and supporting work on preliminary studies that facilitate obtaining R01 funding from the National Institute of Health, and fostering a strong community of clinical research scholars. This training will support the University's investment in junior faculty by making them more likely to obtain funding, publish in peer-reviewed journals, and secure tenure.**

4. In fields in which one university already offers a substantial program, but in which another university is proposing a new or expanded program, could the first institution reasonably accommodate the necessary expansion or would its resources and facilities be so taxed that such an expansion would reduce educational quality?

**N/A**

5. Would a comparable program development or expansion at the first university (see Point 4) require new capital construction producing a higher cost alternative to that proposal?

**N/A**

6. Would the proposed program enhance other programs already in place at the university?

***Required and elective courses in the proposed Certificate curriculum include courses already offered or proposed to be taught by current faculty members. Rather than taking random courses with no formal curricular advising or concrete outcome, clinicians will have an organized curriculum and infrastructure for research support within the proposed Certificate. The certificate may be of interest to trainees in other research training programs, such as the Translational Biomedical Research program, or trainees on NIH T32 or other research training grants.***

7. Is the proposed program consistent with the institutional mission statement?

**The proposed Certificate supports initiatives outlined in The University of Iowa's strategic plan, including 1) achieving premier graduate and professional programs and 2) fostering distinguished research, scholarship, and artistic creation. The establishment of the proposed Certificate will allow for excellence in education, mentoring, training in specialized patient-oriented clinical research, and scholarship among clinicians at University of Iowa.**

**The proposed certificate program wholly supports the mission of the University of Iowa.**

8. Do other colleges in Iowa offer programs similar to the one proposed and at comparable quality and cost?

**The University of Iowa would be the only Regents institution to offer a training program as outlined in the proposed Certificate.**