

Graduate Affairs Committee
October 23rd, 2001
3:30 p.m. - 5:00 p.m.
UL 1126

AGENDA

1. Approval of the minutes for September 25th, 2001 Queener
2. Vice Chancellor's Report.....Brenner
3. Associate Dean's Report..... Queener
4. Purdue Dean's ReportPope
5. Graduate Office Report..... Queener
6. GSO Report..... Wagner
7. Committee Business
Curriculum Committee Report O'Palka
Fellowship Committee Pavalko
8. Program Review..... Queener
M.S. in Clinical Research
9. Discussion Queener
Changes in the GRE General Test
10. New Business.....
11. Next Meeting (November 27) and adjournment.....

Graduate Affairs Committee
October 23, 2001
Minutes

Present: Margaret Adamek, Hasan Akay, James Baldwin, Mark Brenner (co-chair), Jon Eller, Karen Johnson, Joyce Mac Kinnon, Chris Miller, Samuel Nunn, Jackie O’Palka, Douglas Perry, Sherry Queener (co-chair), Terry Reed (for William Bosron), Judith Richter, William Schneider, Sharon Sims, Sarah Wagner, Kathryn Wilson, Polly Wolfe

Staff: Monica Ridge

Approval of the minutes - Dr. Queener

The committee approved the minutes from the September 25th, 2001 meeting.

Vice Chancellor’s Report - Dr. Brenner

Dr. Brenner noted that Indiana University will no longer collect indirect fees on those fellowship grants for which the school is not charged indirect but the student is given an institutional allowance to use at their discretion. The students can now utilize this money.

A document titled “Changes to the GRE General Test: CGS Interviews” was handed out at the meeting. The analytical component of the GRE is now a written test. Individuals will be graded on their analytical thinking and the arguments they make, not grammar. There is a second component to this portion where individuals will critique a set of arguments. Two graders will grade this portion of the test. The graders will have taught composition, be a U.S. citizen, and have teaching credentials. They will also go through testing and a training program. There was some talk of making the old analytical portion of the test a stand-alone but the conclusion was that it would not be economically feasible.

Associate Dean’s Report - Dr. Queener

The Digital Signal Processing certificate should be on the November 15th Purdue University Graduate Council Agenda. The Computer Aided Mechanical Engineering certificate has not been sent back to the Purdue University Graduate School from the West Lafayette Mechanical Engineering Department. The procedure, once graduate proposals and course requests are sent by Kim Manlove (IUPUI Academic Policies and Procedures Office) to the Purdue University Graduate School Administration, is as follows:

Proposals and course requests are sent to:

- the corresponding West Lafayette school or department for review by their curriculum committee
- back to the Purdue University Graduate School
- to the area committee of the Graduate Council
- to the Graduate Council
- back to Kim Manlove

The November Graduate Council meeting has been cancelled. The next meeting for the academic year will take place on December 10th. The Curriculum Subcommittee of the Graduate Council will meet on November 8th. The M.A. in Applied Communication should be on the agenda for each meeting, as should the M.S. in Clinical Research if it is approved at today’s meeting.

There is a new initiative between the French Ministry of Foreign Affairs and IUPUI. This could take the form of joint research between IUPUI senior faculty and junior faculty of universities in the Alsace region. Dr. Queener met with individuals from Alsace and the French Consulate of Chicago last week. Dr. Schneider, Dr. Paydar, and Dwight Burlingame were also involved in this meeting. This initiative would include student exchange, exchange of scholars, and research collaborations. Currently, there is some collaboration happening. Dr. Queener is unsure where this new initiative will lead. Dean Isom and Dean Walker are in favor of this collaborative effort. Patrick O'Meara and Greg Lindsey from SPEA had a chance to be involved, and they are also interested in seeing this go forward.

Dr. Queener and Dr. Wilson attended a technology retreat. The main topic of this retreat was distributed learning. There will be a hard copy report and a URL distributed soon. A conversation regarding distributed learning will continue at <http://sws.gjhost.com/>. The strategic plan on distributed learning can be found at the following URL: http://www.indiana.edu/~iude/de_plan/. Erwin Boschmann, the Associate Vice President for Distributed Education at Indiana University, authored the strategic plan. This plan is not slated to go to the Board of Trustees.

Dr. Queener noted that the groundwork is being laid for hosting Ph.D. students on the IUPUI campus. The IUPUI departments of Economics, Geology, and Computer Science are currently working with their corresponding departments in Bloomington to set up an agreement, which would allow Ph.D. students to be hosted on this campus. Guidelines should be established for all departments. Dr. Schneider is unsure if the campus should go this route. He also noted that there should be consistency throughout the campus. Dr. Queener noted that there will be continuing discussion regarding this at future GAC meetings, after consultation with all interested parties.

Graduate Office Report - Dr. Queener

Philip Pope was unable to attend today's meeting, and Joelle Andrew-Mohr is training appropriate staff members in the schools and departments on how to use the WebCenter System of ApplyYourself. Additional training will take place after October 29th, the PeopleSoft go live date. The WebCenter is designed to communicate with applicants and to find applicants in the system using created search criteria. A PeopleSoft Update handout was distributed to the GAC. Graduate applications should now be submitted online. Dr. Queener noted that there has been some resistance by a few schools and/or departments to move to the online application. Dr. Brenner stated that Dean Plater has given permission to charge schools and/or departments who do not utilize the online application for the additional staff hours it will take to manually load applications. There is a web page on the Graduate Office website that each school and/or department will need to link to from their web page so that students can navigate to the online application (<http://www.iupui.edu/~resgrad/grad/apply.htm>). Dr. Akay asked if IUPUI Purdue applicants should continue to apply through the Purdue West Lafayette online application or if they should apply through the new IUPUI application. Dr. Queener stated that Joelle is working on resolving this issue and will be in contact with the Purdue University schools on the IUPUI campus once a decision has been made. The applicant data for these schools will be shared electronically between the IUPUI campus and West Lafayette campus.

Debra Sullivan will be replacing Christina Dooley as the Indiana University Graduate School Secretary. Debra does have experience on campus and will start on Monday, October 29th.

Graduate Student Organization (GSO) Report - Sarah Wagner

Karen Whitney, the Vice Chancellor and Dean of Students, presented information about the new graduate housing at the last GSO meeting. The GSO is to have a report ready by May regarding mandatory programming for residence at the new student housing.

The GSO website is now up and running: www.iupui.edu/~gradstu. Sarah noted that they hope to have a list of contact information for school representatives and officers on the site shortly.

The GSO will co-sponsor the International Banquet this year. It will be held on Saturday, November 10th at the Murat. Previously, the graduate student admission fee was twice as much as the undergraduate fee. This year, due to the co-sponsorship, the admission fees will be equal.

Subcommittee Business

Curriculum Subcommittee - Dr. O'Palka

The Curriculum Subcommittee met on October 16th. Five course change requests and four new course requests were approved; two were sent back to their originating departments for additional information.

Program Review

M.S. in Clinical Research - Dr. Queener

The M.S. in Clinical Research is a 30 credit-hour degree that is geared to health care professionals. This degree is a core part of a 1 million dollar NIH grant (K-30) awarded to Indiana University in October 2000. The NIH now considers a formal clinical research curriculum a core component in funding individual and institutional training grants and career awards. This program is the only K-30 program in the state of Indiana and could potentially bring 3.5 million dollars per year in federal grants to Indiana University. There were three reviewers within the School of Medicine that reviewed this proposal prior to it reaching the GAC. Changes were made in response to those reviews. The first GAC reviewer strongly recommended approval. This reviewer did recommend that those already holding a Ph.D. should pursue post-doctoral training in this program, not the masters' degree. The second reviewer recommended approval with revisions. This reviewer requested clarification regarding the capstone requirements as well as what deans support this proposal. Dr. Reed, who was filling in for Dr. Bosron, noted that these changes could easily be made. He also noted that the issue regarding potential students who already have a Ph.D. has been discussed, and he feels that this would be an uncommon situation. The committee approved the proposal pending the following: revisions made based on the reviewer's comments; delete F835 as an elective (it is no longer taught); somewhere in the proposal the language used in the Mentored Clinical Research course proposal should appear, namely that the required capstone paper is "suitable for publication." Also, there was some interest in seeing this become available also as a PhD minor.

Discussion

Masters Thesis Committee Membership - Dr. Queener

The Indiana University Graduate School has no rules regarding the number of graduate faculty that should serve on a masters thesis committee, but they do for a Ph.D. At the September GAC meeting Dr. Queener requested volunteers to serve on a subcommittee to establish a potential policy regarding this. Dr. Paydar and Dr. Schneider volunteered. Since that meeting Dr.

Schneider has reviewed this issue within the School of Liberal Arts. The school has created a draft policy which contains the following four points: 1) thesis committee should have at least three members, two should be full-time faculty within the relevant department or program, and faculty of adjunct status should be full-time within their home departments; 2) committee membership is subject to approval by the thesis director; 3) the director of the thesis will be a member or adjunct member of the department or program and a full or associate member of the university graduate faculty; 4) a committee member who is not on the faculty of the university may be appropriate, and these appointments must be approved by the SLA associate dean and other appropriate individuals. Dr. Queener asked the GAC if: she should continue working on a document; if this document should be circulated and voted on by the GAC after it has gone through the SLA approval; or is more discussion needed. Dr. Akay suggested that all members of the thesis committee be graduate faculty. Dr. Queener noted that she could prepare a position paper stating that the goal is to move towards having more graduate faculty members serving on the thesis committees. Dr. Queener will work on this draft with Dr. Schneider and bring it back to the GAC. The hope is to move towards uniformity.

Pre-requisite Financial Aid Form - Dr. Queener

The new financial aid form for non-degree students was handed out. According to the federal guidelines, non-degree students who demonstrate intent to pursue a degree are eligible for financial aid. The Financial Aid Office would now like the academic advisor within the school or department where the student intends to pursue a graduate degree to sign the financial aid form. Previously Judy Zent, the Graduate Non-Degree Coordinator, signed this form. Dr. Queener asked the GAC to review the form and to circulate it within their schools. Any feedback should be directed to Barb Thompson. If no feedback is received, the form will be published as is.

Next meeting date

The next meeting will take place on November 27th, at 3:30 p.m., UL1126.

Meeting adjourned at 4:52 p.m.

COURSE SUMMARY

October 16, 2001

COURSE CHANGE REQUESTS

Allied Health Sciences

AHLT	T590	Research in Allied Health Sci / Adv Neurorehab in Occupational Therapy	1-8 Credits / 5 Credits
-------------	-------------	---	--------------------------------

This course is being discontinued for this campus only.

Justification: This course was in MS in OT Program – now discontinued.

School of Engineering and Technology

TECH	581	Selected Topics in Technology	1-6 Credits
-------------	------------	--------------------------------------	--------------------

Change course title to: Workshop in Technology

Justification: To be consistent with Purdue University at West Lafayette.

School of Nursing

NURS C555 Nursing of Children and Families at Risk 6 Credits

Change course title to: Advanced Nursing Care of Children and Families I

Change description to:

P: C550, C661. This course prepares advanced practice nurses for the specialized care of children and their families. Complex, unique, or challenging health issues are examined. Students develop skills in critical thinking, ethical decision making, and facilitating behavioral changes to assume a leadership role in improving health outcomes.

Justification: Revision of Pediatric Clinical Nurse Specialist Major

NURS	C670	Role of Nurse Specialist in Parent-Child Nursing	3-6 Credits
-------------	-------------	---	--------------------

Change course title to: Advanced Nursing Care of Children and Families II

Change credit hours to: fixed at 3

Change non-lecture contact hours to: fixed at 10

Change course description to:

P: C555. This course prepares advanced practice nurses to function effectively in leadership roles within multi disciplinary health care systems / organizations specifically focused on children and their families. Critical issues that impact the practice environment are explored. Students develop skills in facilitating evidence-based practice for specific populations of children and their families.

Justification: Revision of Pediatric Clinical Nurse Specialist major

School of Science

BIOL 568 Wound Repair, Regeneration, and Artificial Tissues 3 Credits

Change title to: Regenerative Biology and Medicine

Change description to:

This course examines first, the mechanisms of natural regeneration (regenerative biology) and second, the application of these mechanisms to the development of therapies to restore tissues damaged by injury or disease (regenerative medicine).

Justification: To reflect current use of terminology

NEW COURSE REQUESTS

School of Medicine

GRAD G532 Neural Substrate for Sensory-Motor Control 3 Credits

This is an advanced graduate course that will build upon the neuroanatomic foundation established in ANAT-D527. The goal is to give functional meaning to the neural systems involved with acquiring behaviorally relevant information and transforming this information into signals that guide behavior. The emphasis will be on neuronal signal processing.

Justification: Knowledge of integrative neuronal mechanisms is a foundation for neuroscience research.

GRAD G660 Clinical Research Methods 3 Credits

This course provides an introduction to core topics in clinical research, including various types of study design, principles of measurement, and health services and database research. The course is required for the M.S. in Clinical Research degree and is intended primarily for health care professionals desiring a career in clinical research.

Justification: Required course for proposed M.S. in Clinical Research.

GRAD G661 Clinical Trials 3 Credits

This course is intended to provide comprehensive coverage of clinical trials, including design, subject recruitment, data collection, and interpretation and report of results. The course is required for the M.S. in Clinical Research degree and is intended primarily for health care professionals desiring a career in clinical research.

Justification: Required course for proposed M.S. in Clinical Research.

GRAD G664 Mentored Clinical Research 3-9 Credits

This course consists of original clinical research conducted under the mentorship of an established faculty scientist. Presentation and defense of the student's results before a Mentor Panel and a first-authored paper suitable for publication in a peer-reviewed journal constitute the capstone experience in lieu of a thesis for the M.S. in Clinical Research.

Justification: Required course (capstone project in lieu of a thesis) for proposed M.S. in Clinical Research.

SUMMARY OF NEW DEGREE PROGRAM PROPOSAL

- I. **Campus** IUPUI
- II. **Proposed degree** Master of Science in Clinical Research
- III. **Projected date of implementation** Fall 2002

IV. List the major objectives of the proposed program. and describe its chief features.

The Master of Science in Clinical Research is the formal degree that would be awarded to individuals who complete all course and degree requirements for the Indiana University Clinical Investigator Training Enhancement (CITE) Program. This is a federally-funded innovative training program aimed at increasing both the number and quality of clinical investigators emanating from one of the premier biomedical research universities in the Midwest. The CITE Program is an interdisciplinary Tri-School (Medicine, Nursing, and Dentistry) initiative comprising a two-year *formal clinical research curriculum* that includes training in 6 components needed to be a successful clinical investigator, specifically clinical research methods, biostatistics, clinical trials, research ethics, scientific writing, and grant preparation.

V. Why is the degree needed? (Rationale)

For the past several decades, there has been a decline in young clinician-scientists embarking on research careers. Although there has been a perception that clinical research is at a competitive disadvantage compared to basic research in terms of priority scores and funding success, it appears that much of the quantitative difference lies in the fact the National Institutes of Health (NIH) receives far fewer clinical research proposals. Because of the recognized need for formal research training of clinical investigators, the NIH has initiated the K-30 Clinical Research Curriculum Award (CRCA) program which awards training grants on a competitive basis to applicant medical schools throughout the United States. Indiana University applied for and successfully received one of these prestigious CRCA grants. There are 55 funded K-30 programs throughout the U.S., many of which award a Masters degree to students who complete the training requirements. The CITE program funded at IU is the only K-30 program in the state of Indiana.

VI. Describe the student population to be served.

This degree is designed for certified/licensed health care professionals seeking advanced training in clinical research. The students will have completed (or be in the process of completing) a doctoral degree (e.g., MD, DNS, DDS, PhD) and be certified or licensed to practice in a specific health-care profession, e.g., as physicians, nurses, dentists, or allied health care professionals. Indiana University has more than 30 institutional and individual federally-funded training grants in the T, K, and F series which support more than 80 postdoctoral training positions. Most of these training grants fund a minimum of 50 to 70% of the research trainee's time to be explicitly devoted to conducting research and to participate in formal research training. There are also a number of fellows funded locally as well as junior faculty, some of whom may elect to enroll in the CITE Program. Since approximately half of those on training grants are involved in bench (rather than clinical) research, we estimate, conservatively, there will be 6-10 new enrollees in the CITE Program each year. Since this is a 2-year Masters degree program, this means there will be approximately 12-20 students enrolled in the CITE program at any one time.

VII. How does this program complement the campus or departmental mission?

As described in section VI above, IU has a large cadre of fellows currently supported by training grants, as well as junior faculty funded by or intending to apply for career awards in clinical research. Because of the large number of departments involved and the small number of eligible individuals in each department, it is more efficient and effective to provide a single, centralized curriculum and concomitant Masters degree on a campus-wide basis. This facilitates pooling of faculty time and resources to provide the optimal interdisciplinary training that is integral to successful clinical research education. Supported by the Deans of the Schools of Medicine, Nursing, and Dentistry and partnering with the IU General Clinical Research Center, the CITE program establishes a strong, campus-wide partnership for formal clinical research education.

VIII. Describe any relationship to existing degree programs within the IU system.

This program neither duplicates nor conflicts with any other degree programs within the IU system.

IX. List and indicate the sources (including reallocation) of any new resources (personnel, financial, learning, etc.) required to implement the proposed program.

Indiana University received a 5-year, 1 million dollar K-30 award from the NIH for funding of this program. This will cover faculty costs, equipment, supplies, and other personnel. As described in section VI above, students in this program will be fellows or faculty members assigned to departments in the School of Medicine, Nursing, and Dentistry. As such their stipends or salaries will be provided by these Departments. No new resources will be required.

X. Describe any innovative features of the program (e.g., involvement with local or regional agencies, offices, etc.; cooperative efforts with other institutions; opportunities for students, etc.).

The proposed M.S. in Clinical Research would link Indiana University as a partner in the national effort to increase the quantity and quality of clinical researchers. The shortage of formally trained clinical researchers has been recognized at the federal level which in turn has prompted the NIH to fund, on a competitive basis through the K-30 mechanism, Clinical Research Curriculum Awards (CRCA) for qualifying universities. As a recipient of one of these competitive K-30 CRCA grants, Indiana University will be able to not only train a large number of clinical researchers but also benefit from networking with this national initiative. There is an annual meeting of all K-30 Program Directors to foster such networking and dissemination of innovative approaches to clinical research education. During the first 2 project years, the CITE Program will be developed and refined. Once established, the curriculum will be made available to a wider audience through making selected components available in a web-based, CD-ROM format. This will allow selected components of the curriculum to be used for medical student or resident research electives. Having such trainees complete selected modules of the curriculum in a self-study fashion would complement “hands-on” research they participate in with a faculty mentor. Also, the Residency Review Committees (RRC) for most clinical subspecialty training programs mandate that certain core topics in clinical research be covered in order to meet accreditation requirements. Having core topics available in several formats would assist IU’s clinical training programs to meet this RRC requirement. Finally, IU has a unique system of campuses located throughout the state, and collaboration is encouraged through the Intercampus Research Program (IRP). The modular aspects of certain curricular components could enhance clinical research training state-wide.

Mentoring enhancement is incorporated as an integral component of the CITE program, because a formal curriculum by itself may be inadequate to launch a successful research career. Key components include monthly meetings with a *primary mentor*, monitoring and evaluation of the capstone experience by a *mentor panel*, and formal feedback from program enrollees.

COVER PAGE

INSTITUTION: Indiana University

COLLEGE: University Graduate School

DEPARTMENT: Medicine

DEGREE PROGRAM TITLE: Clinical Research

FORM OF RECOGNITION TO BE AWARDED/DEGREE CODE: M.S.

SUGGESTED CIP CODE:

LOCATION OF PROGRAM/CAMPUS CODE: Indiana University-Purdue University Indianapolis

PROJECTED DATE OF IMPLEMENTATION: August 2002

**DATE PROPOSAL WAS APPROVED BY
INSTITUTIONAL BOARD OF TRUSTEES:** _____

**SIGNATURE OF AUTHORIZING
INSTITUTIONAL OFFICER** _____

DATE _____

**DATE RECEIVED BY COMMISSION
FOR HIGHER EDUCATION** _____

COMMISSION ACTION (DATE) _____

ABSTRACT

Master of Science in Clinical Research
to be offered by
University Graduate School, Indiana University,
Indiana University-Purdue University Indianapolis

Objectives:

To prepare health professionals to conduct clinical research and successfully compete for funding within their own fields as well as at an interdisciplinary level.

Clientele to be served:

This degree is designed for certified/licensed health care professionals seeking advanced training in clinical research. The students will have completed (or be in the process of completing) a doctoral degree (e.g., MD, DNS, DDS, PhD) and be certified or licensed to practice in a specific health-care profession, e.g., as physicians, nurses, dentists, or allied health care professionals. We anticipate that most students will be fellows or junior faculty in the Schools of Medicine, Nursing, and Dentistry. Their stipends or salary support will typically be provided by training grants, career awards, other research funds, or departmental resources. IU currently has more than 80 postdoctoral research positions funded through federal training grants and career awards, most of which protect a minimum of 50-70% of the trainee's time for at least two years. This protected time is to be explicitly devoted to research and formal coursework. The M.S. degree will generally represent the formal training needed to prepare students for careers in clinical research.

Curriculum:

A total of 30 semester hours is required to complete the M.S. in Clinical Research. The requirements are distributed as follows:

Course Title	Course Number	Credits
• Biostatistics	G 651	3
• Research Ethics	G 504	2
• Grant Writing	N802	3
• Research Communication	G 655	2
• Clinical Research Methods	New course *	3
• Clinical Trials	New course *	3
• Independent Research	New course	8-9
• Electives	IUPUI	5-6

* Course has been taught for four years, but not for credit as a university course

Employment possibilities:

This degree should enhance a graduate's employment as a clinical investigator in the university, industry, or government research setting. Advising prior to application will clearly indicate that this is not an entry-level, professional degree to secure employment. The students will be health professionals who are committed to conduct independent as well as collaborative research following graduation from the program. Graduate education generally increases the potential for organizational advancement.

B. Program Description

1. Proposed Program and Stated Objectives

Background

In the 1990's, the National Institute of Health (NIH) recognized that while basic science research was flourishing, there was a shortage in qualified clinician-scientists (e.g., physicians, nurses, dentists, and allied health care professionals). This was reflected both in an inadequate number of individuals embarking on careers in clinical research as well as an insufficient number of clinical research grant proposals submitted and funded. One strategy devised to remedy this was to enhance the formal training of clinical researchers. As a result, the NIH issued a request for applications for a new program – Clinical Research Curriculum Award (CRCA) – to be funded as K-30 grants. The request for CRCA proposals provided the following background and rationale:

The NIH recognizes that highly trained clinical researchers are needed in order to capitalize on the many profound developments and discoveries in fundamental science and to translate them to clinical settings. This RFA is intended to stimulate the inclusion of high-quality, multidisciplinary didactic training as part of the career development of clinical investigators. The CRCA supports the development and/or improvement of core courses designed as in-depth instruction in the fundamental skills, methodology, theories, and conceptualizations necessary for the well- trained, independent, clinical researcher. While many NIH programs support research experiences for new clinicians, not all of these trainees have the opportunity to receive formal course work in the design of clinical research projects, hypothesis development, biostatistics, epidemiology, disease mechanisms, medical technology, human genetics, and the legal, ethical and regulatory issues related to clinical research. This award is intended to support the development of new didactic programs in clinical research at institutions that do not currently offer such programs or, in institutions with existing didactic programs in clinical research, to support and expand their programs or to improve the quality of instruction. The goal of this program is to improve the training of the participants, so that upon completion of their training, they can more effectively compete for research funding.

For the purpose of this award, clinical research includes: patient-oriented research, epidemiologic and behavioral studies, and outcomes or health services research. The NIH defines patient-oriented research as research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) that requires direct interactions with human subjects. Patient-oriented research includes the development of new technologies, understanding mechanisms of human disease, therapeutic interventions and clinical trials.

Indiana University submitted a K-30 CRCA proposal and was approved for funding in October 2000. The IU program is entitled: "Clinical Investigator Training Enhancement" (CITE). A formal curriculum addressing requisite competencies in clinical research is planned, eventuating in a new Master of Science in Clinical Research. The NIH has now funded 57 CRCA programs, the majority of which provide either a required or optional Masters degree (see Appendix A). The IU CITE program is the only K-30 funded program in the state of Indiana.

Proposed Program and Objectives

This proposal describes a Master of Science degree program in Clinical Research. Its focus is on formal training in clinical research for health care professionals who desire to make clinical research either the predominant focus or a substantive part of their long-term career goals. It is expected that the Master of Science degree program in Clinical Research will not only fulfill the aims of the K-30 training program for which IU has been funded by the NIH, but will also play a central role in achieving the mission of Indiana University, which is to be a nationally recognized leader in clinical research. This proposed M.S. program will prepare a cadre of trained clinical

investigators who will be able to: (a) successfully compete for federal, foundation, and industry funding; (b) conduct clinical research and publish their findings, thereby further enhancing the stature of IU as a leader in biomedical research; and (c) conduct research that will enhance the health of residents of the state of Indiana.

By participating in the proposed program, CITE trainees will accomplish two primary objectives:

1. Complete a two-year formal clinical research curriculum, at the end of which they will receive a Master of Science in Clinical Research degree.
2. Conduct clinical research under the mentorship of a faculty scientist whose discipline or area of clinical investigation corresponds to the research interests and career aims of the CITE enrollee. A mentor panel will be established for each enrollee to monitor progress.

Health care professionals committed to a career in clinical research are ideal candidates for the CITE program. Over the past several decades, it has been increasingly recognized that a cadre of clinician-scientists committed to and trained in patient-centered research is essential to complement the numerous advances emanating from the basic biomedical and laboratory sciences. There are substantial needs as well as funding opportunities for investigators interested in conducting clinical trials, epidemiological studies, translational research, health services and outcomes research, studies involving large databases, and other types of clinical studies. Employment possibilities for trained clinical investigators include research positions in academics, industry, and government. Most participants will already have a doctoral degree (e.g., MD, PhD, DNS, DDS) or be in training for a doctoral degree.

Substantial time for completing the CITE program is required in that there are two main components: completion of the formal curriculum and active involvement in clinical research under the mentorship of a faculty scientist. Both elements are critical to preparation of the candidate for successful research following graduation. CITE is an integrated program where the formal classroom curriculum complements and parallels the ongoing clinical research that is relevant to each enrollee's career. This differs from a "sequential" program in which individuals might focus predominantly on formal coursework for several years, deferring their actual research until they have attained their degree. The rationale is two-fold. First, CITE coursework is most meaningful when applied to research in which the enrollee is engaged and hopes to continue following program completion. Second, success in clinical research requires not only formal training but several primary outcomes, particularly publications and grants. In addition to the M.S. degree, CITE graduates will have completed a grant proposal for funding as well as one or several manuscripts for publication. The combination of a degree plus the products of successful research will substantially enhance the likelihood of sustained success as an externally funded clinical investigator following program completion.

In the state of Indiana, there has been no formal attempt to consolidate the educational opportunities in clinical research for clinician-scientists. All of the expertise necessary to deliver a Master of Science in Clinical Research already exists in the School of Medicine and in other schools on the IUPUI campus. The proposed new program will build on this expertise to provide a curriculum that will meet the educational needs of clinician-scientists. The impetus for this proposal has been the federally-initiated CRCA program which has considerable national stature: the NIH has provided K-30 funding for 55 CRCA programs to leading U.S. research universities. The CITE program is the only CRCA awarded in the state of Indiana.

To accomplish these objectives, students must:

- Complete the required coursework;
- Conduct data-driven research under the direction of a research advisor;
- Based upon these research, complete a capstone experience consisting of: a first-authored scientific paper deemed of publication quality, as well as oral presentation and defense of the research before the student's Mentor Panel

2. Admission Requirements, Anticipated Student Clientele, and Student Financial Support

a. Admission requirements

Students accepted into the program must complete the standard admission requirements of the University Graduate School. Under exceptional circumstances, the School of Medicine Graduate Studies Committee may ask the University Graduate School to conditionally admit individuals as special students.

b. Prerequisite coursework and/or degrees

Students must possess at least a bachelor's degree and the professional education necessary for certification or licensure to practice in a specific health profession.

c. Anticipated clientele

The M.S in Clinical Research is designed to advance the research training of health professionals currently working or trained to work in patient care settings. Most participants will already have a doctoral degree (e.g., MD, PhD, DNS, DDS) or be in training for a doctoral degree. Potential applicants include, but are not limited to, the following:

- Fellows or other health care professional trainees who have substantial protected time for clinical research
- Junior faculty who have career awards or support from their division or department for participation in the CITE program
- Other faculty who previously have focused on basic research or other academic activities but now are committed to pursuing a career in clinical research.

CITE constitutes the formal didactic requirements for certain types of federal training grants (such as K-23's) and other career awards. Individuals in these programs would be expected to participate in CITE unless they were enrolled in some other type of formal degree program.

d. Selection criteria

The minimum admission requirements are: 1) undergraduate baccalaureate degree; 2) current and appropriate credentials in a health-care discipline, such as medicine, nursing, dentistry, or an allied health care field; 3) letter from an established faculty scientist who agrees to provide the mentorship for the student's clinical research; this mentor must have a track record of funded clinical research; 4) letter from the student's division head or department chair assuring at least 50-70% protected time for a minimum of 2 years; 5) potential for developing the skills to conduct independent clinical research as evaluated by the M.S. in Clinical Research Education Committee.

e. Student financial support available

Fellowships: Indiana University has 13 institutional and 21 individual federally-funded training grants which fund 86 postdoctoral training positions, including T32 (n = 37 positions), T15 (n = 8), F32 (n = 7), KO1 (n = 3), KO2 (n = 1), KO8 (n = 8), K14 (n = 1), K15 (n = 1), and MCJ (n = 20) grants. Additionally, there are 4 junior investigators funded by CAPS awards, 3 on K-24 awards, and 17 individuals on nonfederally funded training grants. Thus, the potential pool of individuals on training grants alone (including CAPs) is over 100 postdoctoral trainees. These training grants provide stipends to support the costs of living, and some also provide tuition, fees, and other training-related costs. Students apply for these fellowships directly to the major department.

Educational Opportunity. The K-30 grant provides funding for tuition and fees for a limited number of students who have come from a background that has hampered their chances to develop fully their scholastic capabilities.

Employer Assistance: Many hospitals and other health-care facilities offer employee incentive programs to further employee education and advancement. These programs can include reimbursement for tuition, textbooks, and fees.

3. Proposed Curriculum

a. Curriculum requirements

The minimum course requirements total 30 credit hours divided into three areas;

Clinical Research (16 cr.)
Electives (5-6 cr.)
Mentored Clinical Research (8-9 cr.)

The core courses in clinical research equip the student to become an independent clinical investigator. Curricular electives are focused on content areas relevant to the student's research discipline to gain added mastery in that area. The capstone experience is the writing of a first-authored publication-quality paper originating from the student's mentored clinical research, submission of an abstract to a scientific meeting, and oral presentation and defense of these results before the student's Advisory Committee.

The curriculum listed by content area is listed below. All courses except electives are required.

<u>Clinical Research</u>	16 cr
Biostatistics G651.....	3 cr
Research Communications G655.....	2 cr
Research Ethics G504.....	2 cr
Grant Writing N802.....	3 cr
Clinical Research Methods New course	3 cr
Clinical Trials New course	3 cr
<u>Electives</u> [in consultation with graduate advisor]	6 cr
<u>Mentored Clinical Research</u> New course.....	8 cr
<u>Total Minimum Credits</u>	30 cr

b. Sample curriculum sequence - two years

Most or all of the courses necessary to deliver the curriculum will be offered on an annual basis. Generally, students will average about 6 credit hours in each of the fall and spring semesters and 3-4 credits in the summer. The table below details a likely course sequence over a 2-year period:

Course Title	Course Number	Credits
Fall (Year 1)		
• Clinical Research Methods	New course 1	3
• Biostatistics	G 651	3
Spring (Year 1)		
• Clinical Trials	New course 2	3
• Research Communication	G 655	2
• Mentored Clinical Research	New course 3	2
Summer (Year 1)		
• Mentored Clinical Research	†	3
Fall (Year 2)		
• Research Ethics	G 504	2
• Grant Writing	N 802	3
• Elective	IUPUI	3
Spring (Year 2)		
• Mentored Clinical Research	†	3
• Elective	IUPUI	3

† Continuation of new course 3.

c. Existing courses

Biostatistics G651

This course covers the use of computers and statistical software for data analyses, fundamental statistical concepts including probability and distributions, and application of parametric and nonparametric statistics on continuous and categorical data. Individuals who also want training in more complex statistical techniques, such as multivariate analysis and survival analysis, are encouraged to take a second course in biostatistics.

Research Ethics G504

This course provides an introduction to both the theory and practice of research ethics and covers the key ethical principles and concepts. Topics covered include the history of science and misconduct, mentoring and laboratory supervision, data management and ownership, human subjects research (including safety compliance), animal rights and welfare, research writing, authorship and mentorship, conflict of interest and industry relationships, intellectual property and copyright, and genetic technology.

Grant Writing

N802

This course combines a core didactic set of classes along with the requirement for completion of a grant to be submitted for intramural or external funding. Topics covered include specific aims and hypotheses, background section and previous work, study design and methods, statistical analysis and sample size determination, budget preparation, and other special issues. Identifying federal and nonfederal funding sources will be addressed. Elements of a successful grant are further reinforced through grant review and mock study sections.

Research Communication

G655

This course focuses on the conceptualizations and writing of research communications in a variety of formats including but not limited to abstracts, peer-reviewed original publications, and grant submissions. Approximately half of the class time is spent in lecture sessions. In the remaining class time, students meet with a section director from their discipline who guides them in using their communication skills in their personal research programs.

d. New courses

Clinical Research Methods

This course covers the major types of study design (other than clinical trials) used in clinical research, including cohort, case-control, cross-sectional, survey, and secondary database studies. Fundamental themes in clinical research – and how to appropriately investigate them –are also addressed, such as diagnostic tests, therapy, etiology, and prognosis. Other topics include questionnaire design, meta-analysis, economic analysis, health status measurement, qualitative research, computerized searching, and health services and outcomes research.

Clinical Trials

This course covers core topics in conducting clinical trials, including design, recruitment, informed consent, randomization, blinding, data collection and analysis, safety monitoring, study closeout, and alternative designs such as cross-over and nonrandomized trials. Also, regulatory and special topics are covered including drug trials phase I through IV, patenting and other legal issues, institutional review boards, cancer trials, cells and human tissue, and trials involving special populations

Mentored Clinical Research

This course consists of the student's major research project conducted under a structured mentorship program directed by a faculty scientist. There are a series of benchmarks built into this course, including (1) monthly meetings with the primary mentor; (2) mentor panel meetings at established intervals with evaluation reports to the M.S. Program director; (3) submission of a first-authored abstract to a regional or national scientific meeting; (4) oral presentation and defense of the research before the student's Mentor Panel; and (5) completion of a scientific paper -- first-authored by the student and for which a major portion of the research was done by the student – which is deemed of publication quality by the Mentor Panel. These last two components comprise the capstone experience for the M.S. degree, in lieu of a thesis.

e. Recommended electives

In addition to the core courses, students will take 5-6 credits of electives toward completion of the requirements for the M.S. degree. Recommended electives include the following:

- G 652 Biostatistics II
- H 517 Fundamentals of Epidemiology
- G 865 Fundamentals of Molecular Biology
- G 890 Methods in Molecular Biology & Pathology
- G 817 Eukaryotic Cell Biology (2 Credits)
- J 805 Molecular Immunology
- J 828 Virology
- Q 580 Basic Human Genetics
- F813 Clinical Pharmacokinetics
- F 809 Neuropharmacology
- F 835 Molecular Mechanisms of Drug Action
- F 836 Physiological Disposition of Drugs
- CSCI 436 Principals of Computer Networking
- CSCI 541 Database Systems
- CSCI 542 Distributed Database Systems

f. Courses at another institution

Students are not required to take courses at other institutions, although electives may be accepted, pending approval by the University Graduate School.

4. Form of Recognition

a. Type of degree to be awarded

Students who complete the graduate requirements will receive a Master of Science degree in Clinical Research from Indiana University.

b. Indiana University CIP Code

The classification of Instructional Programs (CIP) code for the M.S. in Clinical Research is pending.

c. Program, organizational and site information on diploma

All students completing the degree requirements will receive the Master of Science in Clinical Research. The M.S. is appropriate given the research thrust of the degree. The M.S. in Clinical Research will be housed in the University Graduate School. There will be ongoing review of curricular and admissions criteria by the M.S. in Clinical Research Education Committee, and by the University Graduate School. The Indiana University Graduate School will award the M.S. degree in Clinical Research.

5. Program Faculty and Administrators

a. Current faculty

Core faculty (all full members of IU Graduate School)

Kurt Kroenke

Rank: Professor.

Specialization: Health services research.

Appointment: Senior Research Scientist, Regenstrief Institute for Health Care

Full-time, tenured faculty; full member of IU Graduate School faculty.

Highest degree: M.D.

Professional and scholarly accomplishments, publications, etc.: See attached CV (Appendix E)

Siu Hui

Rank: Professor.

Specialization: Biostatistics

Appointment: Senior Scientist, Regenstrief Institute for Health Care;

Full-time, tenured faculty; full member of IU Graduate School faculty.

Highest degree: Ph.D.

Professional and scholarly accomplishments, publications, etc.: See attached CV (Appendix E)

Hugh Hendrie

Rank: Professor of Psychiatry

Specialization: Geriatric psychiatry (dementia and depression).

Appointment: Senior Scientist, Regenstrief Institute for Health Care

Full-time, tenured faculty; full member of IU Graduate School faculty.

Highest degree: M.D..

Professional and scholarly accomplishments, publications, etc. See attached CV (Appendix E).

Neil Oldridge

Rank: Professor of Physical Therapy and Medicine

Specialization: Outcomes assessment in rehabilitation sciences and geriatrics.

Appointment: Associate Director, IU Center for Aging Research;

Full-time, tenured faculty; full member of IU Graduate School faculty.

Highest degree: Ph.D.

Professional and scholarly accomplishments, publications, etc. See attached CV (Appendix E).

Charles Clark

Rank: Professor of Medicine.

Specialization: Diabetes clinical and health services research

Appointment: Associate Chief of Staff for Research and Development, VA Hospital

Full-time, tenured faculty; full member of IU Graduate School faculty.

Highest degree: M.D.

Professional and scholarly accomplishments, publications, etc.: See attached CV (Appendix E)

David Crabb

Rank: Professor of Medicine

Specialization: Gastroenterology and hepatology

Appointment: Chair, Department of Medicine

Full-time, tenured faculty; full member of IU Graduate School faculty.

Highest degree: M.D.

Professional and scholarly accomplishments, publications, etc.: See attached CV (Appendix E).

David Wilkes

Rank: Associate Professor of Medicine

Specialization: Pulmonary medicine

Appointment: Vice-Chair for Research, Department of Medicine

Full-time, tenured faculty; full member of IU Graduate School faculty.

Highest degree: M.D.

Professional and scholarly accomplishments, publications, etc.: See attached CV (Appendix E).

***Potential Core Faculty (School of Medicine) – pending submission and approval of
Graduate School Faculty status (will apply fall of 2001)***

Munro Peacock

Rank: Professor of Medicine

Specialization: Clinical and basic research in disorders of bone.

Appointment: Director of General Clinical Research Center;

Full-time, tenured faculty [to apply for IU Graduate School faculty appointment by Oct 2001]

Highest degree: M.D.

Professional and scholarly accomplishments, publications, etc.: See attached CV (Appendix E).

Scott Denne

Rank: Professor of Pediatrics

Specialization: Clinical and basic research in pediatric metabolism

Appointment: Associate Director of General Clinical Research Center;

Full-time, tenured faculty; [to apply for IU Graduate School faculty appointment by Oct 2001].

Highest degree: M.D.

Professional and scholarly accomplishments, publications, etc.: See attached CV (Appendix E).

Clement McDonald

Rank: Distinguished Professor of Medicine

Specialization: Medical informatics and health services research.

Appointment: Director and Senior Research Scientist, Regenstrief Institute for Health Care

Full-time, tenured faculty; [to apply for IU Graduate School faculty appointment by Oct 2001].

Highest degree: M.D.

Professional and scholarly accomplishments, publications, etc.: See attached CV (Appendix E).

Support faculty (in School of Medicine or other IUPUI schools/centers):

Joan Austin

Rank: Distinguished Professor of Nursing

Specialization: Behavioral and chronic disease research

Appointment: Director, Center for Enhancing Quality of Life in Chronic Diseases

Full-time, tenured faculty; full member of IU Graduate School faculty

Highest degree: DNS

Professional and scholarly accomplishments, publications, etc.: See attached CV (Appendix E).

Stephen Bogdewic

Rank: Associate Professor of Family Medicine

Specialization: Qualitative research and faculty development

Appointment: Vice-Chair, Department of Family Medicine

Full-time, tenured faculty; full member of IU Graduate School faculty.

Highest degree: MD

Professional and scholarly accomplishments, publications, etc.: See attached CV (Appendix E).

Christopher Callahan

Rank: Associate Professor of Medicine

Specialization: Clinical and health services research

Appointment: Director, IU Center for Aging Research; Research Scientist, Regenstrief Institute;

Full-time, tenured faculty.

Highest degree: M.D.

Professional and scholarly accomplishments, publications, etc.: See attached CV (Appendix E).

Thomas Imperiale

Rank: Associate Professor of Medicine

Specialization: Clinical epidemiology and health services research.

Appointment: Research Scientist, Regenstrief Institute for Health Care;

Full-time, tenured faculty

Highest degree: M.D.

Professional and scholarly accomplishments, publications, etc.: See attached CV (Appendix E).

Barry Katz

Rank: Professor of Medicine

Specialization: Biostatistics

Appointment: Director, Division of Biostatistics

Full-time, tenured faculty; full member of IU Graduate School faculty.

Highest degree: Ph.D.

Professional and scholarly accomplishments, publications, etc.: See attached CV (Appendix E)

Lawrence Lumeng

Rank: Professor of Medicine

Specialization: Gastroenterology

Appointment: Director, Division of Gastroenterology

Full-time, tenured faculty; full member of IU Graduate School faculty.

Highest degree: M.D.

Professional and scholarly accomplishments, publications, etc.: See attached CV (Appendix E).

Christopher McDougale

Rank: Professor of Psychiatry

Specialization: Child and adolescent psychiatry

Appointment: Chairman, Department of Psychiatry

Full-time, tenured faculty; full member of IU Graduate School faculty.

Highest degree: M.D..

Professional and scholarly accomplishments, publications, etc. See attached CV (Appendix E).

Colleen McHorney

Rank: Professor of Medicine

Specialization: Health services research and psychometrics

Appointment: Senior Scientist, Regenstrief Institute for Health Care;

Full-time, tenured faculty.

Highest degree: Ph.D.

Professional and scholarly accomplishments, publications, etc.: See attached CV (Appendix E).

Sharon Moe

Rank: Associate Professor of Medicine

Specialization: Clinical research in nephrology; clinical trials.

Appointment: Director, IU Clinical Trials Program; Assistant Dean for Research Support

Full-time, tenured faculty

Highest degree: M.D.

Professional and scholarly accomplishments, publications, etc.: See attached CV (Appendix E).

Stanley Spinola

Rank: Professor of Medicine

Specialization: Infectious diseases

Appointment: Director, Division of Infectious Diseases

Full-time, tenured faculty; full member of IU Graduate School faculty.

Highest degree: M.D..

Professional and scholarly accomplishments, publications, etc. See attached CV (Appendix E).

George Stookey

Rank: Professor of Preventive Dentistry

Specialization: Preventive dentistry

Appointment: Executive Associate Dean, Indiana University School of Dentistry

Full-time, tenured faculty; full member of IU Graduate School faculty.

Highest degree: Ph.D

Professional and scholarly accomplishments, publications, etc. See attached CV (Appendix E).

William Tierney

Rank: Professor of Medicine

Specialization: Health services research and medical informatics.

Appointment: Chief, Division of General Internal Medicine and Geriatrics, School of Medicine;

Full-time, tenured faculty

Highest degree: M.D.

Professional and scholarly accomplishments, publications, etc.: See attached CV (Appendix E).

b. Administrators:

Kurt Kroenke, M.D.
Director, CITE Program

David Crabb, M.D.
Chair, Department of Medicine

D. Craig Brater, M.D.
Dean, School of Medicine

George Walker, Ph.D.
Vice President for Research and
Dean, Indiana University Graduate School

Gerald Bepko, J.D.
Chancellor, Indiana University-Purdue University Indianapolis

c. New faculty positions required:

No new faculty positions are required

6. Needed Learning Resources

a. Library holdings, equipment, laboratories, clinical and research facilities available

Indiana University has an extensive array of learning resources and facilities that will be available to the proposed Master of Science in clinical research in support of its educational and research mission. These include system, campus and participating school resources. State-of-the-art data, video and voice technologies are present to create a sophisticated learning environment.

Library holdings: The libraries on the Bloomington and Indianapolis campuses will be important resources for students in graduate health programs. The collections in Bloomington number 5.6 million volumes and over 40,000 journals. The IUPUI campus, meanwhile, has a new, state-of-the-art library completed in 1993. There are more than 300,000 volumes, including subscriptions to over 3,000 journals. The library has two networked classrooms as well as both faculty and student networked study rooms and over 600 individual study carrels. Students have access to several databases for bibliographic searches. It houses the Robert Payton Philanthropic Studies Library, which has an extensive collection of references and volumes about the nonprofit or third sector. The Ruth Lilly Medical Library, located in the Medical Research Building, serves the Schools of Medicine, Nursing, and Allied Health Sciences. This library houses over 194,000 volumes. Through MEDI ARS, BRS and Dialog, students have access to over 400 databases such as Medline, CINAHL, HEALTH, CANCERLIT, and the Cochrane Library. There is a History of Medicine special collection.

Individual school libraries with specialized collections in business, dentistry, law, optometry and public affairs are also available to graduate students.

The IUPUI University Library has a media library room, and both the University and Medical Libraries have audiovisual materials and other special collections.

The IU system's library holdings are available to all students through interlibrary loan and on-line searches. In addition, students have access to library collections in Indiana, at Big Ten Universities, and at institutions around the country.

Special Equipment & Collections: The Bloomington and Indianapolis campuses have state-of-the-art electronic technologies for instructional design and distance learning. There are facilities for special classroom set-ups and video production. The University is part of the Indiana Higher Education Telecommunication System (IHETS), a consortium of universities in the state that provides distance learning programs at over 300 locations around Indiana. Computer laboratories on the campuses give students access to databases for bibliographic searches and to statistical packages for research. There are eighteen such learning centers on the IUPUI campus, including centers in the Ruth Lilly Medical Library, the University Library, and the business, dental, and nursing schools. Within the School of Medicine, Medical Educational Resources Program (MERP) and Medical Illustrations are additional sources of visual and electronic equipment and resources. The campuses and schools are linked by local area networks that facilitate communication and sharing of materials with people in different departments and schools.

General Clinical Research Center: The GCRC opened at IU in July 1962 and, apart from a brief period from 1969 to 1971, has had continuous federal funding. In 1987 the first CAPs were funded. A supplement to incorporate clinical research in AIDS was awarded in July 1988. This expanded the Center to 10 beds and completely renovated the Center. As part of the 1989 renewal, 1.5 additional FTEs in nursing were funded to support research in Neonatology in the Riley Hospital for Children. A supplement was funded on December 1991 to update the Computer Database Management and Analysis System. As part of the 1994 renewal 2 adjacent inpatient rooms were remodeled to provide extensive bedside space for monitoring and performing intensive protocols. The FTEs in nursing were also increased from 18 to 19 with 0.5 FTE adding to the 1.5 FTE in Neonatology. The Program Director, Munro Peacock, M.D., was appointed in July 1987, and the Principal Investigator, Stuart Kleit, M.D., in July 1997. Dr. Kleit is also Executive Vice President of Academic and Medical Affairs for Clarian Health. In 1998, an additional 3000 square feet of outpatient space was committed by Clarian to the GCRC. The GCRC was site-visited for competitive renewal in 1998 and is funded through November 2004, grant year 32.

Clinical Facilities: The State of Indiana has a population of over 5,000,000. Indiana University Medical Center acts as a primary care center for metropolitan Indianapolis with a population of about 800,000, the nation's 12th largest city. In 1997 University Medical Center comprising University Hospital with 332 beds, Riley Hospital for Children with 243 beds, and Methodist Hospital with 760 beds merged to form Clarian Health. In 1997 Clarian Health had 63,622 admissions with 351,529 total patient days and 948,194 total outpatient visits. This merger more than doubled the number of beds, tripled the number of admissions and doubled the number of outpatient visits of the original Indiana University Medical Center. In addition, Wishard Hospital has 473 beds and 17,574 inpatient admissions annually, with 21 clinics handling 165,000 outpatient visits. Veterans Hospital has 176 beds, 60 nursing home beds, 5,967 inpatient admissions and 284,271 outpatient visits annually. LaRue Carter Psychiatric Hospital has 145 beds, 203 inpatient admissions and 6,250 outpatient visits per year. Clarian Health acts as the major secondary and tertiary referral center for the State of Indiana. It has the patient population and the resources to withstand changes induced by managed care to support clinical research at the highest level.

Laboratories: In 1992, a new wing of University Hospital, (150,000 square feet dedicated to Ambulatory Care) was opened, and the contiguous Lilly Pharmaceuticals Clinical Research Center of 82,334 sq. ft. was opened in April 1998. In 1996 the Clinical Cancer Pavilion of 120,000 gross

square feet contiguous with Indiana University Hospital was opened and in 1997 the Cancer Research Institute of 63,950 net square feet was completed. The Institute houses the 5 key groups that make up the laboratory research arm of the IU Cancer Center: the National Gene Vector Laboratory, the Experimental Therapeutics Program, the Adult Hematology/Oncology Research Program, the Herman B Wells Center for Pediatric Research and the Walther Oncology Center. Also in 1997, the Children's Cancer Center of 18,622 net square feet within the James Whitcomb Riley Hospital for Children was opened. The Medical Science Center of 84,000 sq. ft. of laboratory space is the most recent addition.

Current Assets for Research: The number of faculty in the School of Medicine currently stands at 999 full-time and 68 part-time with 33% spending over 50% of their effort on research. In Clinical Medicine the total hours of effort is 559,928 with 183,779 of these devoted to research. Corresponding figures for Clinical Surgery are 118,980 and 24,423 and for basic science, 217,485 and 116,441. School of Medicine Research funding for 1997-98 amounted to \$109,027,965 of which \$67,179,528 were Federal, \$35,634,807 were Non-Government, and \$6,213,630 were State and Local Government. Approximately two-thirds of the School's extramural support comes from the NIH, over a third of which is multidisciplinary funding to Centers, Program Projects and Co-operative Studies. The two tables on the next page list 20 research centers or program projects supported by PHS/NIH or other federal funds, as well as 14 supported by nonfederal funds.

In 1989 the Research Investment Fund was established and commits approximately 22% of recovered indirect costs to research development at IUPUI. This Fund supports fellowship stipends in the graduate school, development of research resources, and new initiatives in interdisciplinary research. A second program, the Research Venture Award, also supports initiatives in research. Beginning in 1998, the newly formed Clarian Health Research Committee recommended that \$3,000,000 be available to support clinical research in the form of infrastructure and direct support. The GCRC supports a substantial proportion of the faculty holding PHS/NIH funding at IU School of Medicine. The grant support of GCRC users for 1996-1997 was over \$45,000,000 (direct) with over \$32,000,000 from federal sources, over \$9,000,000 from industry and over \$1,500,000 from foundations. Over the last 3 years the extramural funding for the School of Medicine rose from \$75 million to \$105 million. It ranks 34th among schools of medicine in PHS/NIH funding, while its Department of Medicine ranks 15th among all departments of medicine nationwide. During 1998, the IU School of Nursing received about \$4 million in grants for research conducted by 30 nurses, and it ranks 11th among nursing schools nationwide.

Regenstrief Institute for Health Care (RIHC): The RIHC was established in 1969 and is maintained by the philanthropic Regenstrief Foundation. The RIHC houses 18 full-time investigators (including 3 PhD biostatisticians), and an additional 9 full-time investigators hold affiliated scientist positions. RIHC provides substantial in-kind support for a fellowship program that includes 12 trainees in health services research, medical informatics, and geriatrics. The Regenstrief Institute also houses two major research centers. The Diabetes Research and Training Center is one of six such federally-funded centers in the country, and the Center for Aging Research is a campus-wide multidisciplinary consortium. The Regenstrief Medical Record System (RMRS) is one of the largest general medical data systems in the world. Established in 1974, The RMRS has registered more than 1 million patients, has over 2 million dictated records, and is accessed nearly 5 million times each year. Currently, the RMRS is used at more than 40 inpatient and outpatient facilities in Indianapolis and surrounding counties and is the largest coded, continuously operated medical records system in the United States.

Federally-Supported (entirely or partially) IU Research Centers and Program Projects	
AIDS Clinical Trials Group	General Clinical Research Center
Alcohol Research Center	Germ Cell Tumor Research Center
Alzheimer's Disease and Related Disorders Center	Metabolic Regulation in Neoplasia and Chemotherapy
Biomechanics and Biomaterials Center	Multipurpose Arthritis Center
Determinants of Bone Mass in the Elderly	National Center of Excellence in Women's Health
Diabetes Research and Training Center	Neurology and Genetics of Alcohol Seeking Behavior
Dose Intensification by Gene Transduction in Cancer	Neurology of the Weaver Mutant Mouse (Alzheimer's)
Enzyme-pattern Targeted Cancer Center	Radiology Planning Grant for Functional MRI
Gene Replacement Therapy in Hematopoietic Stem Cells	Role of SWL in Renal Injury and Stone Commutation
Genetic Modification/Alternate Source of Stem Cells	Sexually Transmitted Disease Research Center

IU Research Centers and Program Projects Supported by Local or Nonfederal Funds	
Center for Medical Genomics	Krannert Institute of Cardiology
Indiana Diabetes Center	Methodist Research Institute
Institute of Psychiatric Research	Otis Bowen Research Center
Indiana University Breast Cancer and Research Program	Regenstrief Institute for Health Care
Indiana University Center for Aging Research	Veterans Administration Center
Indiana University Center for Patient-Oriented Research	Walther Oncology Research Center
Indiana University Center for Vascular Biology & Medicine	Wells Center for Pediatric Research

b. Need for additional learning resources

No additional resources are necessary to support the degree.

7. Other Program Strengths.

a. Special Features

The proposed Master of Science in Clinical Research is unique at both state and regional levels. While there are a variety of health professions graduate education programs, there is currently no one program that offers education clinical research for the allied health professions.

There is a coalescence of resources at IU that make it a particularly desirable setting for a Master of Science in clinical research. These include:

- Clinical Research Curriculum Award. The recent notification by the NIH that IU has been approved for this K-30 grant provides 1 million dollars of federal funding over the next 5 years (2000-2005) in support of the development and implementation of this program. Like many federal training grants, it likely there will also be a process for competing renewals.
- Interdisciplinary participation in this program by the only Medical and Dental schools in the state, and the largest Nursing school in the nation;
- A large and diverse patient population that includes primary, secondary and tertiary care; a wide spectrum of sociodemographic characteristics; varying health care systems including 1500 beds in public and private hospitals, Veterans, and managed care patients;
- A large number of federal and nonfederal research training grants;
- A large number of research faculty with an extensive portfolio of funded projects;
- A successful GCRC which has been funded for over 35 years;
- A Division of Biostatistics with a strong commitment to teaching;
- A Clinical Trials Unit as well as a federally-funded Clinical Pharmacology training grant, which further enriches the research training environment at IU for clinical trials;
- The Regenstrief Medical Record System (RMRS) which has registered more than 1 million patients since 1972, has over 2 million dictated records, and is accessed nearly 5 million times each year. Currently, the RMRS is used at more than 40 inpatient and outpatient facilities in Indianapolis and surrounding counties and is the largest coded, continuously operated medical records system in the United States. It provides innumerable opportunities for data-base research, computer-based interventions, and training in medical informatics.

b. Anticipated Collaborative Arrangements with Other Parties

One obvious collaboration is the utilization of courses offered by the Master of Public Health program (e.g., Biostatistics, Epidemiology) and the potential of MPH and other university graduate students to take the new courses to be offered by the Master of Science in Clinical Research program (Clinical Research Methods, Clinical Trials, Grant Preparation).

Two of the new courses (Clinical Research Methods, Clinical Trials) have been taught for the past 4 years as a series of classes (not for credit) by faculty scientists of the Regenstrief Institute. During this period, a number of IU fellows and junior faculty have attended. Once these new courses are submitted and receive official approval, it is expected that certain fellows and junior faculty will enroll as students in the courses. Also, certain graduate students from other degree programs, particularly those related to the health sciences, are likely to enroll.

Faculty from numerous schools, departments, centers, and hospitals on the IUPUI campus will most likely be recruited to deliver lectures on selected topics pertaining to patient-centered outcomes, participate on student advisory committees, and serve as adjunct faculty.

Because the program is focused on clinical research, the students' capstone experience (scientific paper for publication and oral defense of research) will typically involve patient-centered

investigations. Therefore, graduate students will use patient information from health-care settings throughout central Indiana. This will require research affiliation agreements and approval of appropriate human subjects committees.

Clinical research education is considered a high priority by the NIH, which hosts an annual K-30 program director meeting, which the IU program director will regularly attend. In fact, Dr. Kroenke attended the second annual K-30 directors meeting in March, 2001. At this meeting, there are workshops and group discussions focusing, among other things, on how courses may be shared nationally through distributive education. To the extent this collaboration is successful, students at other U.S. universities may access portions of the curriculum for the M.S. in Clinical Research.

C. Program Rationale

1. Institutional Factors

a. Compatibility with the institution's mission

The M.S. in Clinical Research is compatible with the strategic goals of Indiana University at several levels of its organizational structure, including 1) the Indiana University System, and 2) the Indiana University-Purdue University Indianapolis campus.

Indiana University System

Under the direction of President Myles Brand, and as a result of the work of more than 250 members and friends of the university, Indiana University published its Strategic Directions Charter: Becoming America's New Public University. That strategic planning process resulted in 30 recommendations within 3 principal areas (Community of Learning, Responsibilities of Excellence, Accountability and Best Practices). The M.S. in Clinical Research is particularly relevant to 5 of the 30 recommendations:

3. *Encourage and support excellence in learning through the refinement of traditional teaching methods and the use of new technologies of learning.*

One aim of the grant is to make core elements of the curriculum available in formats that could be used in a flexible fashion, such as CD-ROM, audiotapes, and other self-study materials. One benefit would be that students enrolled from clinical departments with different schedules can gain certain competencies outside the traditional classroom setting. Another benefit would be the availability of curricular components to other students doing research electives, as well as to faculty and studies from other campuses in the IU system.

8. *Increase access to the university through nontraditional programs and courses.*

This program will be available to students from many different departments and schools. A number of individuals who are not enrolled in the full M.S. program are likely to enroll in single or several courses relevant to their clinical research. Certain core components of the clinical research curriculum will be available in self-study formats (CD-ROMS, audiotapes, written syllabi) for undergraduate or graduate students taking research electives.

19. *Establish a research organization and increase external research collaboration.*

This program involves multiple schools and will foster interdisciplinary research training and collaboration. IU's program will also be part of a network of over fifty K-30 programs at medical

schools throughout the U.S. The faculty who teach classes and mentor students in this program will be research scientists from multiple divisions, departments and schools.

20. *Ensure that Indiana University reflects the diversity of American society and supports the achievements of minorities in all aspects of university life.*

One priority specified in the K-30 grant funding this program is recruitment of minority students. Indeed, one benchmark of success specified in the grant proposal is the number of minority students who matriculate and complete the program.

21. *Ensure that women are recruited, appointed, and retained in all areas of the university, and that women students are encouraged to enter all academic fields.*

Historically, a third or more of the clinical research trainees in the Regenstrief Institute have been women. In this new M.S. in Clinical Research program, we will continue to make recruitment of women students a priority, thus preparing them for successful academic and scientific careers.

Indiana University-Purdue University Indianapolis

In 1996 IUPUI integrated its mission, vision, values, aspirations, goals, and strategic initiatives with Indiana University's Strategic Directions Charter through publication of its Strategic Directions for IU and Indiana University-Purdue University Indianapolis. The M.S. in Clinical Research will enhance the following IUPUI strategic initiatives:

1. Providing excellent academic programs that emphasize the interconnections among teaching, research, and service.
2. Providing strong programs in research and graduate education that complement undergraduate programs and serves local, state and national constituencies.
3. Achieving regional and national recognition as a center of excellence in professional education and health-related research.
4. Ensuring that the campus population reflects the diversity of American society and that minorities and women are recruited, supported, and advanced in all aspects of campus life.
5. Supporting centers of excellence in defined areas of research and practice.
6. Reviewing and enhancing infrastructure for research and graduate program support, including fellowships.
7. Achieving excellence in providing postdoctoral research training in health-related areas.
8. Developing graduate and graduate professional programs that meet merging needs by building on our existing programs.
9. Establishing policies/procedures/strategies/incentives for effecting multidisciplinary collaboration.

It is apparent from the strategic directions, goals, and strategies cited above that the M.S. in Clinical Research is relevant to the mission of Indiana University at several organizational levels.

b. Planning process resulting in this proposal

Department of Medicine Core Research Curriculum for Fellows. In 1996, the Department of Medicine began an ambitious core curriculum that all fellows (research and clinical) were expected to attend. It would meet for an hour every Tuesday morning (7:00 to 8:00) and covered a variety

of topics in 44 one-hour sessions, including computer science, molecular biology, measurement tools, drug development, teaching skills, research ethics, biostatistics, diagnostic test development, health administration, academic issues, and quality management. Fellows completed an evaluation form after each lecture (or module of lectures). Also, during the second year that the curricular sessions were held, an assigned faculty member would audit the session and provide written feedback to the Department Chair with a copy to the lecturer. Fellows from several departments other than Medicine also attended because these lectures on topics salient to clinical research were not provided elsewhere on campus. Several lessons emerged from these preliminary steps toward a research curriculum. Although the sessions typically received high ratings by the faculty auditor, a number of the sessions were lightly attended by trainees. Feedback indicated this may have resulted from several factors: (1) all department fellows were required to attend, both clinical as well as those more committed to research; (2) the time of the day was not convenient; (3) most importantly, the coverage of topics may have been too introductory and brief. However, this core curriculum provided an initial template (as well as institutional experience and demonstrated faculty participation) for a more intensive, interdisciplinary, research-oriented curriculum.

Regenstrief Institute Research Curriculum. The Regenstrief Institute for Health Care comprises full-time IU faculty who focus on health services, medical informatics, and aging research. The Institute's fellowship program has developed an introductory Clinical Research Methods course, consisting of over fifty 90-minute seminars which will serve as the template for the Clinical Research Methods and Clinical Trials courses in the proposed M.S. in clinical research program. Taught by MD and PhD clinical researchers and biostatisticians, curricular topics include grant writing; budgeting; funding; evidence-based medicine and critical appraisal of the medical literature; study designs including clinical trials; social science techniques (surveys; focus groups; health status measurement; instrument development); database research; practice guidelines, quality improvement, report cards; patient satisfaction; meta-analysis; and economic analyses.

Grant Preparation Course. Through the cooperative efforts of the Offices of Research & Sponsored Programs and Faculty & Senior Staff Development, a Proposal Development/Grant Writing course has been offered to full and associate faculty at Indiana University. The curriculum covers a minimum of 15 major topics over the course of one semester, and draws upon professionals in fields relevant to the enrollees. These include Types of Funding Options, Approaching Funders, Private Foundations and Budgets, Perspectives of a Senior Scientist, Utilizing the World Wide Web, Electronic Research Administration, Proposal Preparation Basics, Federal Budgeting, Time Management, Humans and Animals in Research, Corporate-funded Opportunities, Peer Review, Awards and Grant Accounting, Assessment, Final Report Preparation. This course was popular but budgetary constraints limited attendance to only selected individuals based upon peer reviewed preliminary proposal submissions. Limited funding also made it difficult to provide adequate faculty time for proposal review and feedback. With federal funding provided by the K-30 CRCA award, it will be possible to build upon the original curriculum for the 2-credit Grant Preparation course for the M.S. in Clinical Research program.

General Clinical Research Center (GCRC) Resident Elective. A one-month elective in clinical research for 2nd-3rd internal medicine year residents was started in 1994 has been completed by 21 residents to date. Beginning in 1999, a similar one-month elective has been offered to MD/PhD students in the fourth year of their degree program. Core elements include: (1) critiquing a clinical research protocol along with a primary faculty reviewer and attending a GCRC Advisory Committee or IRB meeting; (2) critically reviewing a manuscript submitted for publication for originality; sample size; controls; methods and variables; confounding variables; statistics; presentation; literature; (3) statistics: twice a week meetings with the GCRC statistician (a

member of the Division of Biostatistics) to discuss selected readings and self-study assignments; (4) data management: regular tutorials on data management and software with the GCRC system manager; (5) laboratory: regular tutorials on laboratory methods with the GCRC laboratory staff; (6) nutrition: regular tutorials on dietary variables in clinical research with the GCRC dietician; (7) research apprenticeship: resident selects (preferably several months before taking the rotation) an active protocol, performs a literature search in the field of research of the protocol, and works closely with the principal investigator during the rotation; (8) elective GCRC workshops, including a 1-day Essentials of Patient Research workshop and a 1-week Designing and Implementing Clinical Nutrition Research (the latter covers many generic issues in clinical research).

Mentoring Enhancement Program. Beginning in July 1997, a Mentoring Enhancement Program was initiated for fellows in the Regenstrief Institute research training program. This consists of the following: (1) creating a Mentor Panel that meets quarterly with each fellow, after which the primary mentor submits a report to the Program Director; (2) Development of mentoring guidelines by the Fellowship Advisory Committee, including a 2-year time-line with explicit benchmarks to monitor a fellow's progress; (3) Mentoring Satisfaction Survey administered to each fellow at the mid-point of their first year; (4) Mentoring Quality Improvement Meeting of all primary mentors.

Postdoctoral Training Steering Committee. This committee, chaired by Craig Brater, MD and involving all training program directors in the Department of Medicine, was convened in January 1998. It met 9 times over several years to plan and advise on the Clinical Research Curriculum Award proposal. This process facilitated input of key stakeholders in the program planning.

Clinical Research Curriculum Award. A proposal for federal funding through the K-30 mechanism was submitted by Kurt Kroenke, MD, Professor of Medicine, in November 1998. Based upon the critiques, revisions to the proposal were made and the grant was resubmitted in May 2000 during the second cycle of NIH solicitation for CRCA proposals. IU was notified by the NIH in the fall of 2000 that funding had been approved, with the start date being 30 September 2000.

Stakeholder Meetings with Campus Leaders. The CITE program director has conducted a series of stakeholder meetings with key IU leaders in clinical research and graduate education, in order to determine the number and types of potential students, curricular and scheduling needs, mentoring capacity; institutional resources; and priorities of divisions, departments and schools. These 30 separate meetings with 40 campus leaders are summarized in Appendix B.

Review of NIH-funded CRCA Programs. The CITE program director has reviewed the general curriculum, structure, and degree status of CRCA programs currently funded through the NIH K-30 mechanism. A list of all 57 funded programs was obtained from the NIH. The abstract of each program was downloaded from the NIH website. Further information was obtained by examining program-specific websites as well as requesting more detailed information of specific programs. The results of this data-gathering are summarized in Appendix A. Of note, the majority of these programs have a Masters degree as either a requirement or option for CRCA trainees.

c. Impact of the proposed program on other programs

Although the principal focus of this degree is on the clinical sciences traditionally housed in the Departments of Medicine, Nursing, and Dentistry, there are no other M.S. degrees in Indiana that specifically deal with clinical research. Because of this, other health professionals may choose to enter the degree program. This will not be a large number due to the substantial amount of protected time needed for the program (70% over two years) and the requirement for a committed

faculty research mentor. Alternatively, students in other graduate-degree programs may elect to take specific courses as electives to complete their individual degree requirements.

Four courses from other Departments are core courses for the M.S. in Clinical Research degree. An agreement has been reached with all four course directors as well as their Department Chairs that students from the M.S. in Clinical Research degree program will have access to those courses. Letters of support from these course directors and their Department Chairs are included in Appendix C. Also, letters of support from the Deans of the Schools of Medicine, Nursing, and Dentistry are included in Appendix D.

Our students will be drawing linkages with previously mentioned research centers and laboratories on the IUPUI campus to conduct their own research. This interdisciplinary thrust will foster greater research collaboration.

2. Student Demand

a. Description of enrollment projections

Enrollment projections were estimated in several ways:

- The number of IU training grant positions, career awards, and other sources of potential students were determined. These are summarized above in section B.2.e (pp. 7-8).
- The CITE program director conducted a series of campus stakeholder meetings from January through April 2001; these are summarized in Appendix B.
- The CITE program was advertised to potential students beginning in January 2001. A total of 18 individuals were interviewed to determine whether program participation would be feasible. Interviews showed that 14 individuals were interested and qualified.
- Student enrollment in the K-30 funded CRCA programs at other U.S. medical schools was reviewed, and this is summarized in Appendix A.

Based upon this, we anticipate that the M.S. in Clinical Research will have an ongoing enrollment of 12-20 graduate students at any one time (6 to 10 in each class of a two-year program).

b. Enrollment and completion data

See Table 1 on p. 30.

3. Transferability

Transfer of graduate credits from other institutions will be in accordance with the regulations established by Indiana University Graduate School.

4. Access to graduate and professional programs

This degree is not preparing students for entry into graduate or professional schools.

5. Demand and employment factors

This degree will be marketed to enhance existing employment potential, particularly in clinical research positions. Advising prior to application will clearly indicate that this is not an entry-level,

professional degree to secure employment. The students will be certified/licensed health professionals who, as a result of this degree, will be better trained for clinical research. Moreover, the completion of this degree may enhance one's competitiveness for clinical research positions in academic institutions, foundations, industry, or government agencies. Graduate education generally increases the potential for organizational advancement.

6. Regional, state, and national factors

a. Comparable programs in region or state

The proposed MS in Clinical Research is unique to Indiana. Several other medical schools in states surrounding Indiana also have CRCA grants funded by the NIH. However, the student pool for the IU program as well as those elsewhere is predominantly fellows and junior faculty supported by training grants or career awards specific to the institution. Therefore, relocation to other institutions for the requisite training is not feasible.

b. External agencies

There are no regional, accrediting, professional association or licensing requirements that have shaped the program's curriculum or other aspects of the program.

D. Program Implementation And Evaluation

Program Implementation

The School of Medicine will be able to implement the program within a semester following final approval for several reasons: (1) The faculty is already in place; (2) 6 of the 8 courses are existing courses (4 core courses, 2 electives); (3) Of the 3 new courses, 2 have already been taught (without formal credit toward a degree) for the past four years, so that the curriculum is already well established; (4) The one new course not previously offered for credit is Mentored Clinical Research, but its core components (formal Mentor Panels and benchmarks) have been in place for clinical research fellows at the Regenstrief Institute since 1997.

The table below outlines the projected time line for obtaining approvals from Indiana University and the Indiana Commission for Higher Education. We anticipate that final approval will be obtained by the spring 2002 semester. The program director working in conjunction with the M.S. in Clinical Research Education Committee, will be responsible for the general administration of the program, admitting students to the program, monitoring student progress, and assisting students in the selection of their advisory committees. In addition, the program director will establish linkages in the community for teaching, research and practice activities. The M.S. in Clinical Research Education Committee will begin recruiting students in March 2002 and complete the admissions process by July 2002. An Advisory Committee will be formed, consisting of key faculty members from the Schools of Medicine, Nursing and Dentistry, as well as student representatives. Several external advisors (Charles Lewis, MD, Professor of Medicine, UCLA School of Medicine, and Robert Fletcher, MD, Professor of Medicine, Harvard School of Medicine) have agreed to evaluate and provide feedback on the program. The program director will be responsible for the daily administration of the degree.

Timeline of reviews and approvals	
School of Medicine Graduate Studies Committee	fall 2001
IU Graduate Affairs Curriculum Subcommittee	fall 2001
IU Graduate Affairs Committee	fall 2001
Vice Chancellor for Research and Graduate Education	fall 2001
University Graduate School Curriculum Committee	fall 2001
IU Graduate School	fall 2001
Dean of the Faculties and Chancellor	fall 2001
Academic Officers Committee	fall 2001
Vice President for Academic Affairs	fall 2001
IU Board of Trustees	spring 2002
Indiana Commission for Higher Education	spring 2002
Timetable of program implementation:	
Final approval from IU/ICHE	spring 2002
Vice President for Academic Affairs	spring 2002
Formation of Graduate Program Committee	spring 2002
Formation of Advisory Committee	March 2002
Recruitment of students	March 2002
Admission of first class	August 2002

Program Evaluation

General Principles

The evaluation process will be a continuous one, as we note the progress of students and consider their reactions to the program. The School of Medicine and University Graduate School will monitor course enrollments, students' grades and progress, timely completion of the student's capstone experience (scientific paper, abstract, and oral defense), quality of the research, and students' successful transition to careers in clinical research. In the fourth year after implementation, an evaluation team from the core faculty will study the program in depth and submit a report to the Deans of the Schools of Medicine, Nursing and Dentistry and the University Graduate School. Overall responsibility for evaluation of the degree resides in the University Graduate School and in the School of Medicine. The school dean, program director, and Graduate Studies Committee will evaluate the curriculum based on assessment of learning outcomes. The advisory committee will provide guidance based on input from community leaders and employers. The Graduate Studies Committee will periodically review course materials to determine whether the content is focused on the goals of the program. Student course evaluations will also be closely monitored. In addition, students will complete surveys at the beginning and end of their enrollment in the program to measure student expectations, knowledge, and satisfaction. Based on competencies developed by the faculty, student learning outcomes will be assessed by oral and written examinations. Program staff will keep a computerized database of all graduates with respect to employment, research, publications, and other professional activities.

Benchmarks for Assessing Effectiveness

Benchmarks for Assessing Effectiveness of M.S. in Clinical Research and CITE Program		
Benchmark	Minimum	Target
<u>Abstracts</u> <ul style="list-style-type: none"> Submitted for presentation at national scientific meeting Accepted as poster or oral presentation 	1 per trainee 0 per trainee	2 per trainee 1 per trainee
<u>Papers</u> <ul style="list-style-type: none"> Submitted for publication in peer-reviewed journal Accepted for publication in peer-reviewed journal 	2 per trainee 0 per trainee	2 per trainee 1 per trainee
<u>Academic/Research Career</u> (% of class) <ul style="list-style-type: none"> Any academic or research job immediately post-training Any academic or research job 4 years post-training At least 50% research time immediately post-training At least 50% research time 4 years post-training 	80% 65% 40% 25%	90% 80% 60% 50%
<u>Grants</u> (% of class) <ul style="list-style-type: none"> Submitted within 1 year of finishing training Funded within 3 years of finishing training Total funding (direct) 	50% 30% no limit	75% 50% no limit
<u>Honors</u> <ul style="list-style-type: none"> Career award (funded) within 3 years of finishing training Research award (regional or national) within 3 years of finishing training 	1 per class 0 per class	2 per class 1 per class
<u>Minority</u> trainees	1 per class	2 per class

Important benchmarks to assess the effectiveness of a formal curriculum for training clinical researchers include abstract presentations, publications of original research papers, retention in academics in any capacity but particularly a research position, grant submissions and funding, honors such as research awards, funded career awards, and leadership roles in scientific organizations. Another benchmark would be successful recruitment of trainees from underrepresented minority groups. The table above summarizes minimum and target goals for the M.S. in Clinical Research and CITE Program. Benchmarks not represented in the table because the outcome period is typically longer than 5 years include: (1) the proportion of faculty who eventually attain promotion to associate professor and full professor; (2) the advancement of trainees to major leadership positions either locally (e.g., department chair; director of a research programs, center or institute) or nationally (officer or major committee chairman in a scientific or other professional society; study section member; etc.); (3) research position in industry or research-leadership positions in government, foundations, or other organizations.

Trainee Evaluation

(a) The *primary mentor* will meet at least *monthly* with a trainee to review research progress, address goals and concerns, and provide feedback.

(b) Trainees will meet with their *Advisory Committee* (consisting of 3-5 faculty members) 5 times over the two years of their program. The trainee will prepare the agenda, and the committee will review current progress, provide advice and guidance, and identify "next steps" in the trainee's research and other goals for the next quarter.

(c) Following each Advisory Committee meeting, the primary mentor will prepare a

summary report that will be forwarded to the Program Director. The Program Director will review the report initially to identify any issues that need immediate attention, and also keep a copy on file for review at the trainee's semi-annual meeting with the Program Director.

(d) There will be *monthly* meetings of the CITE *Education Committee*, which will discuss current courses, trainee progress, and other curricular and administrative issues.

(e) There will be an annual meeting of the CITE *Advisory Committee*. This committee (a) establishes *policies and procedures* for the training program; (b) approves *curriculum*; and (c) discusses any *needs or concerns* regarding particular trainees that have been identified by the primary mentor, the Education Committee, or the trainee.

(f) The Program Director will meet separately with each trainee for one-hour *semi-annual Progress Report meetings* (August and December). At this meeting, he will review their files (which includes quarterly Mentor Panel reports, research reports, and other items). He will provide feedback and address particular trainee concerns.

Program Evaluation

(a) Trainees will complete a *curriculum evaluation form* for each course, providing an overall rating, as well as specific comments on what would further improve the course.

(b) Trainees will also complete a *mentoring satisfaction questionnaire* each year in December. The results will be used to improve the mentoring process.

(c) Fellows who take *elective courses* at the University will be asked to complete a postcourse evaluation form, which will be maintained in a central fellowship file.

(d) A formal review of this new M.S. program will be conducted after 3 years by external reviewers identified by the CITE Education Committee and approved by the School of Medicine Graduate Studies Committee.

Economic Projections

Table 2A estimates program costs and revenues. Since there is currently a K-30 grant that provides funding from October 2000 through September 2005, the annual support from this grant is listed under Revenues, and the Expenses (which match the grant Revenues) are listed under Expenses. Although it is likely the NIH will renew these K-30 grants in 5-year cycles, this M.S. program will not be dependent upon such funds but rather is expected to be self-sustaining through tuition and fees.

It is also important to emphasize the economic benefits of this program, which include:

(a) Career awards. This program will be a core component of federal career award applications (K-23, VA, etc.), and it is expected that a minimum of 3 new career awards will be funded each year. This would bring in an estimated \$350,000 of grant money annually.

(b) Center grants. Several center grants are being submitted, of which the formal curriculum proposed with this new degree is a core component of research training and faculty development. These include a Pepper Center from the National Institute of Aging, an international Child-Maternal Health grant from the Fogarty Center, and several other center grants. These center grants would bring in an estimated \$2,000,000 annually.

(c) Training grants (e.g., T-32's). This research curriculum will be a core component of new or competing renewals for NIH individual and institutional training grants, bringing in an estimated \$750,000 annually.

(d) Similar K-30 programs are funded in neighboring states, including at 3 Illinois medical schools, 2 Ohio medical schools, 2 Michigan medical schools, 2 Wisconsin medical schools, and 1 Kentucky medical school. Approval of this degree for IU's program will keep Indiana competitive with neighboring states in attracting new faculty and clinical investigators who in turn will obtain federal grant money for medical research in Indiana.

Program: Master of Science in Clinical Research
Date: 14 July, 2001

**TABLE I:
PROGRAM ENROLLMENTS AND COMPLETIONS
Annual Totals by Fiscal Year (Use SIS Definitions)**

	Year 1 2002-03	Year 2 2003-04	Year 3 2004-05	Year 4 2005-06	Year 5 2006-07
A. PROGRAM CREDIT HOURS GENERATED					
1. Existing Courses	164	196	176	176	176
2. New Courses	92	108	64	64	64
TOTAL	256 *	304 *	240	240	240
B. FULL-TIME EQUIVALENTS (FTE's)					
1. Generated by Full-time Students	16	16	16	16	16
2. Generated by Part-time Students	0	0	0	0	0
TOTAL	16	16	16	16	16
3. On-Campus Transfer FTE's	0	0	0	0	0
4. New-to-Campus FTE's	16	16	16	16	16
C. PROGRAM MAJORS (Headcount)					
1. Full-time Students	16	16	16	16	16
2. Part-time Students	0	0	0	0	0
TOTAL	16	16	16	16	16
3. On-Campus Transfers	0	0	0	0	0
4. New-to-Campus Majors	16	16	16	16	16
5. In-State	14	14	14	14	14
6. Out-of-State	2	2	2	2	2
D. PROGRAM COMPLETIONS	4	12	8	8	8

* Total credit hours higher for first several years because some candidates will take several existing courses (e.g., biostatistics) in 2001-02.

Program: Master of Science in Clinical Research
Date: 14 July 2001

TABLE 2A:
TOTAL DIRECT PROGRAM COSTS AND SOURCES OF PROGRAM REVENUES

(See text on p. 29, “Economic Projections”, for further explanation of costs and revenues)

	Year 1 FTE: 2002-03	Year 2 FTE: 2003-04	Year 3 FTE: 2004-05	Year 4 FTE: 2005-06	Year 5 FTE: 2006-07
A. TOTAL DIRECT PROGRAM COSTS					
1. Existing Departmental Faculty Resources *	160,231	161,117	158,393	140,000	140,000
2. Other Existing Resources	27,973	28,426	29,026	48,000	48,000
3. Incremental Resources (Table 2B)	0	0	0	0	0
TOTAL	188,204	189,543	187,419	188,000	188,000
B. SOURCES OF PROGRAM REVENUE					
1. Reallocation	0	0	0	0	
2. New-to-Campus Student Fees	0	0	0	0	0
3. Other – Federal Grant †	188,204	189,543	187,419	188,000 †	188,000 †
4. New State Appropriations	0	0	0	0	0
a. Enrollment Change Funding	0	0	0	0	0
b. Other State Funds	0	0	0	0	0
TOTAL	188,204	189,543	187,419	188,000	188,000

* Includes both faculty cost and non-faculty program manager costs funded by NIH K-30 grant from October 2000 – Sept 2005. Although likely to be reviewed, the degree program is expected to be self-sustaining at that point through tuition and fees.

† Funded by NIH K-30 grant from Oct 2000 through Sept 2005. There likely will be a competing renewal available then.

**TABLE 3:
NEW ACADEMIC DEGREE PROGRAM PROPOSAL SUMMARY**

14 July 2001

1. Prepared by Institution

Institution/Location: Indiana University School of Medicine/IUPUI
 Program: Master of Science in Clinical Research
 Proposed CIP Code:
 Base Budget Year: 2002-03

	Year 1 2002-03	Year 2 2003-04	Year 3 2004-05	Year 4 2005-06	Year 5 2006-07
Enrollment Projections (Headcount)	16	16	16	16	16
Enrollment Projection (FTE)	16	16	16	16	16
Degree Completions Projection *	4	12	8	8	8
New State Funds Requested (Actual)	0	0	0	0	0
New State Funds Requested (Increases)	0	0	0	0	0

* Some students are taking up to 12 credits in a non-graduate degree program in 2001-02. Thus, some of these would be able to complete the M.S. degree (if approved) in 2002-03 (an estimated 4 students), and the rest in 2003-04 (thus leading to more graduates – namely 12 – that year). In Years 3 onward, it is expected the program will reach a steady state of approximately 8 graduates per year.

2. Prepared by Commission on Higher Education

New State Funds to be Considered for Recommendation (Actual)	0	0	0	0	0
New State Funds to be Considered for Recommendation (Increases)	0	0	0	0	0

CHE Code:
 Campus Code:
 County Code:
 Degree Level:
 CIP Code:

Comment:

New Graduate Program Review

(October 6, 2001)

Document reviewed: Master of Science in Clinical Research proposal

Summary: The proposed program would award an MS degree in clinical research to health care professionals who complete a two-year 30 credit-hour curriculum involving clinical research methods, biostatistics, clinical trials, research ethics, scientific writing and grant preparation. Applicants for the program would have completed or would be in the process of completing a doctorate degree (e.g., MD, DDS, DNS, PhD). The majority of applicants would come from the postdoctoral fellows already supported by other training grants at the University. The degree would be housed in the Department of Medicine, at the School of Medicine, and be organized through the federally funded Indiana University Clinical Investigator Training Enhancement (CITE) Program. This 5-year grant provides the administrative funding for the program, and the CITE program director would also be the MS degree program director. Students would be guided by a graduate advisory committee, and the curriculum would include two new didactic courses that are currently taught but not for credit. In addition, one new research course would be developed and the remainder of the courses would involve current graduate courses. In lieu of preparing a thesis, students would submit an abstract of their research for presentation at a research meeting, prepare a manuscript for a peer-reviewed journal, and give an oral defense of their research before the their advisory committee. The program would be periodically evaluated by the School of Medicine Graduate Studies Committee, the students and the CITE Education Committee.

Recommendation: Accept with discussed revisions

Discussion:

There is a need for this proposed program. It does not duplicate other programs at the University. The applicants, faculty and resources appear to be in place. The curriculum is sound. The new courses to be developed are at an appropriate level. The program director is qualified and capable of administering the program. The program description provides high quality detailed information and strongly suggests that the new program will be educationally sound and will be successful. Comments for consideration are as follows:

1. Page 7, line 15 from top: certification or licensure – PhD's usually do not have certifications or licenses but may still be applicants for the program.

2. Page 9 of the 1998-2000 IU Graduate Bulletin states that “Departure from the traditional thesis requirements prescribed by the individual departments must be approved by both the department and the Dean. I presume Dr. Crabb and Dr. Brater approve this, but there is no specific documentation provided.

3. There is confusion about the requirements of the capstone experience needed in lieu of the thesis. Page 10, line 2 from bottom states: “These last **two** components comprise the capstone experience...” These are the oral defense and completion of a scientific paper. **Page 27, line 15 from bottom states:** ...the capstone experience consists of **three** areas (scientific paper, abstract, oral defense).

Course description for Mentored Clinical Research: that **three** areas will be involved (oral defense, preparation of an abstract, and completion of one or more first-authored publications)

4. There is confusion about the required scientific paper(s) for publication. The requirement needs to be clear and specific.

Page 10, line 2 from bottom states: that *a* scientific paper must be *completed*

Page 27, line 15 from bottom: just indicates “scientific paper” as part of the capstone experience

Page 28, Table: indicates that *two* papers must be *submitted* as a minimum requirement

Course description for Mentored Clinical Research: indicates *completion of one or more* first-authored publications

5. Page 28, Table: This indicates that an abstract must be submitted to a *national scientific meeting* while **page 10, line 5 from bottom** indicates that the abstract may be submitted to a *regional or national meeting*

6. It might be helpful if the directors of specific training grant programs would provide specific approvals stating that they will allow their students to enroll in the new MS program. Table 1 suggests that at least three such directors may have agreed (Drs. Crabb, Fuqua, Lemons). Maybe such letters were included in an Appendix that I did not see (?).

7. Suggest changing the phrase “mentor panel” to “advisory committee” on pages 2, bottom line; page 6, line 10 from top; page 7, line 6 from top; page 10 lines 2, 4 and 7 from bottom; page 26, line 16 from bottom; page 29 line 12 from top.

Reviewer:

Review of the Master of Science in Clinical Research

This is a very carefully constructed degree program that has already been reviewed once and revised with great care. The program is a response to an NIH initiative to increase the number of clinical research proposals it receives. The IU School of Medicine with the Schools of Nursing and Dentistry has responded to the NIH K-30 request for proposals and has received a renewable five-year Clinical Research Curriculum Award. This is one of 55 awards in the United States and the only award in Indiana.

This degree program is designed to serve practicing, licensed health care professionals who seek advanced training in clinical research. Students must hold some type of doctoral degree or be nearly completing such a degree. Degrees specified in the proposal include the MD, DNS, DDS and PhD. As the program is described this would seem reasonable for all candidates but those who have actually completed the PhD. The PhD is considered a terminal research degree. Additional work in clinical research to learn the special skills and address the special issues in this area would necessarily (it seems to me) be a post-doctoral activity. Receiving a Masters Degree after a PhD seems unusual. In fact, special permission must be obtained to pursue a second PhD as far as I know and, at Purdue University, where I have experience, is almost never granted. This problem might be solved by noting that those already holding a PhD would pursue post-doctoral training in this program. As noted by other reviewers I still do not see how junior faculty hired on tenure track could pursue this option early in their career and expect to gain tenure. It seems that excluding this population would not diminish the necessary demand for the program however.

The authors of the program may be unaware of the PhD in Clinical Rehabilitation Psychology in the School of Science. Graduate level courses offered through this program offer an array of courses in clinical psychology that would broaden and enrich the set of recommended electives listed in section e of the Proposed Curriculum.

This program is strongly recommended for approval by the IUPUI Graduate Affairs Committee.