



The University of Georgia

University Council
Athens, Georgia 30602

March 26, 2007

UNIVERSITY CURRICULUM COMMITTEE – 2006-2007

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Dear Colleagues:

The attached proposal to offer the graduate certificate in Clinical Trials Design and Management will be an agenda item for the April 2, 2007, Full University Curriculum Committee meeting.

Sincerely,

Dr. William K. Vencill, Chair
University Curriculum Committee

cc: Dr. Arnett C. Mace, Jr.
Professor Jere W. Morehead

The University Council: Executive Committee, Committee on Facilities, Committee on Intercollegiate Athletics,
Committee on Student Affairs, Curriculum Committee, Educational Affairs Committee, Faculty Admissions Committee,
Committee on Statutes, Bylaws and Committees, Faculty Affairs Committee,
Faculty Grievance Committee, Strategic Planning Committee, University Libraries Committee
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OUTLINE FOR AN INTERDISCIPLINARY CERTIFICATE PROGRAM

I. Basic Information

1. Institution The University of Georgia Date January 31, 2007
2. School / College The College of Pharmacy
3. Department/Division Office of Postgraduate Continuing Education & Outreach
4. Level (undergraduate or graduate) Graduate
5. Proposed starting date for program Fall Semester 2007
6. Abstract of the program for the University Council's agenda:
Provide a one or two page summary of the proposed program that includes an overview and highlights of the response to the criteria in Section II.
7. Submit letters of support from the various academic unit heads involved in developing the program initiative or whose support is vital to its success.

SIGNATURES:

Department Head

Dean of School/College

Abstract

Attached is an application outlining a proposed graduate-level Certificate Program in the area of Clinical Trials Design and Management. This new certificate will be a 16 semester-hour graduate program composed of 5 courses, 3 of which are already approved graduate courses taught by either the College of Pharmacy or the College of Public Health. Application for two new courses has been submitted for approval in the CAPA system.

The Certificate in Clinical Trials Design and Management is designed to help professionals gain a solid understanding of the entire clinical trials process, from drug and device development to monitoring, as well as a foundation in the scientific principles, biostatistics, regulations, and ethics that are vitally important to the conduct of clinical research. Because of its foundational curriculum and its focus on best practices in the clinical trials process, the certificate is appropriate for current professionals--clinical research associates and coordinators, clinical program managers and physicians, biomedical and research scientists, nurses, pharmacists, IRB members and administrators--as well as those new to the field.

The addition of clinical trials management will complement an already existing graduate program in regulatory affairs and will help respond to a growing need in Georgia for biomedical education validated by a report produced by UGA's Selig Center. Efficient management of clinical trials is a significant indicator for biobusiness success and sustainability. When implemented effectively by highly trained managers, clinical trial initiatives can be highly successful in reducing timelines so business targets can be met ahead of schedule. Every day saved in the progression to marketing authorization can equate to millions made in patent-protected sales revenue. At present, many in the biomedical industry recognize there is a critical shortage of trained professionals, especially in the design aspect of new clinical trials. This project prepares clinical trial personnel to manage the clinical trial process for new biomedical products and fills a void in the state of Georgia, which should attract biomedical industries to the State.

Funding for this program is expected through Georgia's Intellectual Capital Partnership Program (ICAPP), which represents the economic development branch of the University System of Georgia. ICAPP is interested in funding this program in an effort to advance the Governor's incentive package for new industries who are considering Georgia for expansion of their operations. Tuition income to sustain the program for subsequent years will be generated from tuition return, and an additional per semester program fee charged to students and returned to the program for ongoing operations. Moreover, portions of existing pharmacy faculty lines will be redirected to this program. The program of study will also apply for entry in the Atlanta Regional Council for Higher Education (ARCHE) and in the SREB Academic Common Market / Electronic Campus status, which will provide expanded educational opportunities for students in Georgia and throughout the southeast.

Applicants to the certificate program in Clinical Trial Management must meet Graduate School admissions requirements and follow Graduate School policies and procedures for non-degree admission. Admission to the certificate program does not guarantee admission to any University of Georgia degree programs.

II. Response to the Criteria

1. The purpose and educational objectives

Due to the rapidly expanding biotechnology industry in Georgia, there is a substantial need for clinical trial experts. The Certificate in Clinical Trials Design and Management is being planned to help professionals gain a solid understanding of the entire clinical trials process, from drug and device development to monitoring, as well as a foundation in the scientific principles, biostatistics, regulations, project management, and ethics that are vitally important to the conduct of clinical research. The proposed Certificate Program consists of 16 semester credit hours and will be delivered through a combination of classroom and distance learning technologies with the face-to-face component located at the Gwinnett University Center.

The broad educational objectives include:

- Describing operational differences and similarities of pharmaceutical, biotechnology and medical device companies.
- Discussing the interrelationships among the different functional or departments involved in the product development and testing process.
- Identifying current principles and practices in medical research and research study design.
- Deciphering regulations, protocols and ethical standards governing clinical trials and testing on human subjects.
- Applying principles to plan and manage a study site.
- Applying statistical concepts to study design and the evaluation of results.
- Describing Good Clinical Practices to assure quality and safety of marketed products.
- Managing a project team.
- Planning timelines and resources.

2. Demonstrated need for the program

Managing clinical trials is one of the most time consuming aspects of the biomedical product development process. Having a trained workforce who can expedite any phase of the clinical trial process can speed time to market leading to greater company profits and improved patient care. Effective clinical trial management must address the issues of monitoring for efficacy and safety, establishing clinical trials inclusion and exclusion criteria, handling voluminous data, determining statistical power for trials, meeting deliverables, and considering ethical and investigating response of subpopulations through genomics.

Georgia's biomedical companies are world leaders in developing new treatments and diagnostics for heart diseases, cancer, central nervous system disorders, metabolic diseases, mental illnesses, HIV and other deadly infections. Since 2000, the growth of Georgia-based biotechnology companies has soared nearly 70 percent, revenues have increased more than 50 percent, and research and development (R&D) spending has surged more than 60 percent. In fact, Ernst and

Young's Report ranked Georgia eighth nationally for the growth in the biotechnology industry, with a predicted rise to fifth by the year 2010.

Yet, competition for attracting and retaining bioscience industries is fierce. According to *Shaping Infinity*, A Georgia Life Sciences Industry Report produced by the University of Georgia's Selig Center, competition for biotech firms is rampant among the states. Among the most valuable enticements that states can provide to life sciences companies is assurance of an educated workforce who can launch new initiatives and expand operations. It cannot be overstated that a readily trained and available workforce is key to the success of bio-business and a strong incentive for location decisions. This need is confirmed in the Selig Report, which notes that the second most serious challenge bioscience companies face with conducting business in Georgia is the shortage of skilled labor (access to capital was ranked as the most serious challenge). Moreover, the majority of companies' officials who were surveyed for this report indicated that they would be interested in hiring graduates of graduate programs in biotechnology to assist them in growing their companies. The reason is that the skilled labor needed must be highly specialized for this industry sector. Personnel must have the appropriate credentials to meet the job demands required for the highly regulated and expensive production of pharmaceuticals, devices, and biologics. This is especially important because organizations are facing drug development life cycles with mounting costs and longer development times. The Selig Report notes that, like other states, clinical trial management is a significant indicator for business success and sustainability. At present, many in the biomedical industry recognize there is a critical shortage of trained professionals, especially in the design aspect of new clinical trials. This is not surprising, because a majority of Georgia biomedical companies are small start-ups and, for start-ups in particular, time is money. The University of Georgia (UGA) is presented with a unique opportunity to fill the immediate industry need by establishing a graduate-level certificate program in clinical trial management that would augment an existing graduate curricula in Biomedical Regulatory Affairs.

Semester/Year of Program Initiation

Because the majority of courses that will make up the certificate program are already approved, the Clinical Trial Management Program is on track to enroll its first students in August 2007 (Fall Semester 2007). This program will follow the traditional academic pace, but will utilize web-based (WebCT) instruction with occasional use of teleconferencing equipment and other technologies for those participants who are unable to commute to Atlanta. Based on present interests, the program expects between eight and sixteen students to enroll for its initial courses. These students will be primarily from within Georgia and currently employed in the pharmaceutical or biomedical industries. It is expected that these working professional students will participate on a part-time basis, while they maintain their current positions, and the number of students will likely increase to 16-25 per semester.

Semester/Year Full Implementation of Program

We anticipate that this program will be fully implemented and underway by Fall Semester 2007.

Semester/Year First Certificate will be awarded

The Certificate Program is geared for working professionals. For this reason, it is not practical to offer this program at an accelerated pace. As such, we expect many of our students to take one

or two courses per semester year-round. With this in mind, we anticipate awarding our first certificate in May 2008.

Annual Number of Graduates Expected

The Clinical Trials Certificate Program expects that it will graduate on average 10-20 students per academic year for the first 5-7 years.

3. Projected Future Trends/Marketing

It is anticipated that the program expects the initial number of student enrollment to be between 8-16 students. As the program develops and information about our program spreads, we expect the number to increase by 5-10 students over the next five years. The program has been developed to meet the human resource needs for clinical trials management in the health products industry within Georgia. As such, our program will recruit potential students and enroll those students based on 1) their current professional position and/or 2) their bachelor's degree in the sciences if they are coming directly from an undergraduate program. Therefore, minority enrollment in the program will be proportionate to 1) minority employment in the health products industry and 2) minority student enrollment in science programs.

Students from other UGA disciplines, such as the College of Public Health, have expressed interest in completing a certificate in clinical trials to enhance skills in biomedical regulatory and clinical science and to increase job prospects. These additional students provide an even greater market for the program of study.

The program of study will also apply for entry in the Atlanta Regional Council for Higher Education (ARCHE) and in the SREB Academic Common Market / Electronic Campus status. ARCHE is a consortium of public and private institutions of Higher Education, libraries, and other non-profit and corporate partners in the Atlanta area. SREB Academic Common Market / Electronic Campus allow students from neighboring states to pay the in-state rate. Both the ARCHE and the SREB Academic Common Market / Electronic Campus provide expanded educational opportunities for students in Georgia and throughout the southeast.

Once the program of study is approved, marketing will occur (1) through national recognition by the Association of Clinical Research Professionals (ACRP); (2) by ICAPP's promotion to bio-business industries, and (3) through the Atlanta Regional Council for Higher Education (ARCHE) and in the SREB Academic Common Market / Electronic Campus, which provide Southeastern regional coverage. Direct marketing materials will also be distributed to key industries through industry newsletters and biomedical clearinghouse businesses that track biomedical careers, like clinical trial design, which are in high demand both nationally and internationally.

4. Design and Curriculum of Program

Detailed Curriculum

Certificate in Clinical Trials Design and Management (16 semester hours)

The following provides a course list and course descriptions of the proposed certificate program:

PHAR 6010 (4 sem hrs): Pharmaceutical, Biotechnology, and Device Industries: Foundational knowledge of the pharmaceutical, biotechnology, and medical device industries. Emphasis on organization, product development, new product applications and commercialization-associated activities, including drug discovery, chemical synthesis, laboratory practices, quality assurance, regulatory affairs, manufacturing, design control, marketing, and post-marketing surveillance.

BIOS 7100 (3 sem hrs): Biostatistical Applications for the Pharmaceutical and Biotechnology Industries: Biostatistical issues regarding the introduction and regulatory agency (FDA) approval of new drugs, biologics, medical devices, and combination products, and their postmarket surveillance are considered. Data quality assurance, experimental design, clinical trials, power and sample size determination, uncertainty assessment, regression, survival analysis, and variable and model selection are considered.

PHRM(HADM) 7230 (2 sem hrs): Ethical Issues in Research: Ethics of research in animals and human subjects, fraud, scientific misconduct, and conflicts of interest.

PHAR 6200 (4 sem hrs): (Course Proposal in Progress) Clinical Trials Design and Management: Fundamentals of the clinical trials environment, study design and management. Emphasis on the initiation, administration, coordination, and management of clinical research studies for the development of new drugs, biologics and other clinical products.

PHAR 6300 (3 sem hrs): (Course Proposal in Progress) Project Management in Clinical Trials: Concepts, practicalities and realities of project management. Providing practical guidance from trial set-up to delivering targets, the problems of performing clinical trials and how to deal with project teams, deadlines, and resources.

Course Identification

Three of the five courses have already been approved in the CAPA system. Course application for PHAR 6200 has been initiated (January 2007). Two of the five courses (PHAR 6010: Pharmaceutical, Biotechnology, and Device Industries and PHRM(HADM) 7230: Ethical Issues in Research) are also required of the regulatory affairs certificate program.

Model Programs

We have benchmarked against similar certificate programs at San Francisco State University, Temple University, and Northeastern University. For instance at Temple University, an advanced Certificate in Clinical Trials Management is 16 semester hours and comprises the following courses.

- *Drug Development*
- *Good Clinical Practices*
- *Bioethics for Pharmaceutical Professionals*
- *Clinical Trial Management for Research Practitioners*
- *Clinical Data Management/Monitoring*

Other programs have similar requirements and many require biostatistics as a separate course. Our program includes the above topics and courses. Additionally, this program of study requires biostatistics in order to cover the important concepts of experimental design, clinical trials, and power and sample size determination. We are positioning our program to focus more broadly in the biosciences and will include application of clinical trials to drug devices and biologics, as well as the traditional pharmaceuticals, which is unique among other certificate programs. This is important because of new combinational compounds that are considered both drug and device and will require a specialized knowledge and skill set.

Accreditation

At present, there is no accreditation required for the Clinical Trials graduate-level certificate programs. There is accreditation of the College of Pharmacy by both the Accreditation Council for Pharmacy Education and SACS, Southern Association of Colleges and Schools. Moreover, the program is being designed using competencies identified by the Association of Clinical Research Professionals (ACRP). ACRP is the primary resource for clinical research professionals in the pharmaceutical, biotechnology, and medical device industries, as well as those in hospitals, academic medical centers, and physician office settings.

5. Faculty Resources

Presently, the core faculty are associated with the College of Pharmacy, the Biomedical and Health Science Institute, and the College of Public Health. Other College of Pharmacy faculty as well as faculty from other university departments and system schools have expressed an interest in participating as the program matures and expands. Additionally, a number of individuals who currently are employed in industry and at the FDA have expressed an interest in teaching in this program of study.

Core faculty for graduate studies:

Paul Brooks, Pharm.D., Senior Public Service Associate and Graduate Coordinator of Regulatory Affairs Graduate Programs, College of Pharmacy (Clinical Administration and Ethics)

C. (Tony) Capomacchia, Ph.D., Associate Professor, Department of Pharmaceutical & Biomedical Sciences, College of Pharmacy (Pharmaceutics)

George Francisco, Pharm.D., Professor, Department of Clinical and Administrative Pharmacy and Associate Dean, College of Pharmacy (Clinical Research and Administration)

Robert Galen, M.D., M.P.H., Professor and Head, Department of Health, Administration, Biostatistics and Epidemiology, College of Public Health (Biostatistics and Epidemiology, Clinical Research)

Saundra Granade, M.S., Instructor for Quality Control, College of Pharmacy (Quality Control/Process Validation)

Johnna Hodges, M.Ed., Public Service Representative and Coordinator, Instructional and Student Resources, College of Pharmacy (Project Management)

Larry Aull, Pharm.D., Clinical Associate Professor, Department of Clinical and Administrative Pharmacy, College of Pharmacy (Clinical Trials Research)

David Mullis, Ph.D., Associate Professor, Department of Pharmaceutical & Biomedical Sciences and Director, Regulatory Affairs Graduate Education Programs (FDA Regulatory Science and Clinical Trials)

Stephen L. Rathbun, Ph.D., Associate Professor of Biostatistics, Department of Health, Administration, Biostatistics and Epidemiology, College of Public Health (Biostatistics and Epidemiology)

Randall Tackett, Ph.D., Professor and Graduate Coordinator, Department of Clinical and Administrative Pharmacy, College of Pharmacy (FDA Clinical Trials and Ethics)

Roseann Termini, J.D., Instructor for Food and Drug Law, College of Pharmacy (Food and Drug Law)

Adjunct and Contract Instructors

A number of individuals who currently are employed in industry and at the FDA have expressed an interest in teaching in the new Clinical Trial Management Program. These include members of the steering committees (listed below) and others who work in the biomedical industry and who have expertise in regulatory science.

Reporting Lines

The Clinical Trials Graduate Certificate program will be headed by Dr. Randy Tackett. The program will be administered through the Office of Postgraduate Continuing Education and Outreach under the head of Dr. Paul Brooks, who reports directly to Dean Svein Øie of the College of Pharmacy. The department offices for this program are located at University of Georgia at Gwinnett (UGA-Gwinnett) with reporting lines through Drs. Jan Sandor and Robert Boehmer for issues related to the Center.

6. Library, computer, and other instructional resources

Critical to the success of the Clinical Trials Design and Management Certificate Programs are library and electronic resources. We plan to utilize resources offered through the Gwinnett University Library, GALILEO, OISD to name just a few. In addition, previous grant funds have provided the necessary monies to purchase reference resources, books, materials, DVDs, and CD ROMs for this program. Moreover, relevant materials are available from the Regulatory Affairs Professional Society, the Food and Drug Law Institute and other publishers. Many of these resources will be housed in the UGA-Gwinnett library. Others will be offered online by UGA-Gwinnett for student access from off-site locations.

As for instructional resources, our program will utilize a blended approach of distance learning and on-site workshop. Our instructional resources include WebCT and Adobe Breeze. The Office of Instructional Support and Development will provide the necessary support to both students and faculty for WebCT assistance. The necessary computer and technology equipment has been purchased with previous funds and is operational. Faculty members have the necessary software, email, and internet access to support the development of this program. There is sufficient infrastructure at UGA-Gwinnett to provide computer technical assistance, wireless network access, and internet access.

7. Physical Facilities

Physical facilities necessary to fully implement the program include facilities at UGA-Gwinnett. Its proximity to Atlanta, which is where our target audience is, makes it an ideal location for conducting face-to-face synchronous instruction. There are many state-of-the art teaching classrooms as well as study areas. It has technology and library support and resources. Select college faculty currently have offices set up at this location. The primary mode of instruction for this program will be through WebCT; therefore, the classroom needs are minimal.

8. Proposed Budget

The program is being supported through funding received from a grant provided by the Board of Regent’s Intellectual Capital Partnership Program (ICAPP) for the purpose of promoting economic development, where education is needed for high-quality, knowledge-based jobs. Also, we anticipate additional 2-3 year funding from ICAPP, with the approval of the certificate program. Tuition income to sustain the program for subsequent years will be generated from tuition return, and an additional per semester program fee charged to students and returned to the program for ongoing operations. Moreover, portions of existing pharmacy faculty lines will be redirected to this program. Additionally, because of the significant shortage of clinical trials personnel, industry officials have indicated tuition assistance reimbursement, classroom space and video conferencing equipment, which will offset indirect costs of running the program.

<u>Year</u>	<u>First Year –FY 07</u>	<u>Second Year-FY 08</u>	<u>Third Year –FY 09</u>
(1) Personnel	\$51,525	\$53,625	\$55,800
(2) Operating Costs	\$12,300	\$12,825	\$13,350
(3) Total	\$63,825	\$66,450	\$69,150

Commitment of Student Financial Support

There are no scholarships or assistantships specific to this program. From our meetings with Industry officials, we have received their assurance that a number of companies will send their employees for this credentialing program. Some businesses offer a reimbursement upon completion of a semester, while others allow for \$5,000 per year in educational expenses.

10. Program/Curriculum Administration

Director: Randall Tackett, Ph.D. Randall Tackett received his undergraduate degree at Jacksonville University in 1975. He then received an M.S. degree in Pharmacology at Auburn University and his doctorate in Pharmacology and Toxicology from the University of Georgia in 1979. Following a two-year postdoctoral fellowship at the Medical College of South Carolina, he returned to the University of Georgia as an Assistant Professor of Pharmacology and Toxicology. He has served as the Director of Graduate Research and as head of the Department of Pharmacology and Toxicology. Currently, he is Professor and Graduate Coordinator of the Department of Clinical & Administrative Sciences. Among his many scholarly pursuits, Dr. Tackett coordinates graduate coursework in advanced therapeutics, drug design, clinical trials, forensic toxicology, and medical ethics. He received the Georgia Psychological Association Distinguished Faculty Award in 1999 and the American Psychological Association Presidential Citation in 2000.

Co-Director: David Mullis, Ph.D. , R.A.C. is Associate Professor and Director, Regulatory Affairs Graduate Education Program at the College of Pharmacy. Dr. Mullis has 25 years of both academic and successful corporate management experience in FDA regulated industry directing US and international programs in regulatory affairs, clinical studies, quality assurance and marketing. Dr. Mullis has served as Vice President, Global Clinical Programs at London International, plc; Vice President of Regulatory Affairs, Clinical Research and Quality Assurance for C.R. Bard, Inc. and has held various corporate positions including Regional Vice President of Corporate Regulatory Affairs, and for Clinical Programs Support. Dr. Mullis has established an outstanding record for obtaining FDA approval for novel products and technologies in medical devices, in vitro diagnostics and biotechnology. He has extensive experience in planning and implementing Investigational Device Studies, developing Investigational New Drug Studies and filing various new product submissions with FDA and international regulatory agencies.

Steering Committees: Two separate advisory committees to be composed of individuals from UGA, industry and FDA. In general, these steering committees comprise faculty and industry leaders, whose wisdom and experience are viewed to be valuable in assisting the administrator of the ICP.

- 1) **Advisory Board:** The function of the Advisory Board is to provide strategic direction for the program. Memberships will consist of senior UGA faculty and administrators, management from local companies, and FDA management.

University of Georgia Representatives:

Bob Boehmer, J.D., Interim Vice Provost for Academic Affairs
Anthony Capomacchia, Ph.D., Associate Professor, College of Pharmacy
J.Griffin Doyle, J.D., Director of Federal Governmental relations
George Francisco, Pharm.D., Associate Dean, College of Pharmacy
Chris Moder, M.B.A., Program Director, ICAPP / UGA Office of Economic Development, USG, Board of Regents

AdHoc:

Paul Brooks, Pharm.D., Director Outreach, College of Pharmacy
David Mullis, Ph.D., Director Regulatory Affairs
Johnna Hodges, M.Ed., Manager for Student and Technical Resources
Randall Tackett, Ph.D., Professor, College of Pharmacy

Industry Representatives:

David Dodd, M.S., CEO, Serologicals
Robert T. McNally, Ph.D., President, Cell Dynamics LLC
Alan Minsk, Esq., J.D., Arnall Goldman Gregory
Gary Dykstra, M.S., Regional Director, Food and Drug Administration
Patty Fritz, M.S., UCB Pharma

- 2) **Curriculum Committee:** The purpose of this committee is to provide input into curriculum development, course content and teaching methodologies. Membership will comprise biomedical professionals working in industry, FDA personnel, consultants, and UGA faculty and staff.

University of Georgia Representatives:

Paul Brooks, Pharm.D., Director Outreach, College of Pharmacy
David Mullis, Ph.D., Director Regulatory Affairs
Johnna Hodges, M.Ed., Manager for Student and Technical Resources
Randall Tackett, Ph.D., Professor, College of Pharmacy

Industry Representatives:

Penny Northcutt, Ciba Vision
Sue Sutton Jones, M.S., VP RA/QA/C/Medical Affairs, Serologicals
Michael Vollmer, J.D., Esq.
Robin Hart, Ph.D., Director RA Merial
Robert Coleman, M.S., Drug Expert, Food and Drug Administration
Don Ruggirello, Ph.D., Solvay Pharmaceuticals
Wayne Wiley, R.Ph., Elan Drugs

Admission, Retention and Administration of Program

Applicants to the certificate program in Clinical Trial Management must meet Graduate School admissions requirements and follow Graduate School policies and procedures for non-degree admission. Additionally, applicants must submit the following program-specific requirements for admission:

1. Submit a supplemental application for admission to the Clinical Trial Management Graduate Education program.
2. Have a working knowledge of required computer software and hardware and daily access to the required computer set-up.
3. Provide a resume and portfolio of experiences in the field.
4. Submit an application to the UGA Graduate School.

Preference for the certificate program will be given to Clinical Trial Management professionals working in Georgia and residents of Georgia initially. This program received its preliminary funding through a competitive grant provided by the Board of Regents' Intellectual Capital Partnership Program (ICAPP) for the purpose of promoting economic development in the State of Georgia. As such, Georgia residents will be given priority initially. Upon completion of the ICAPP grant, this issue will be readdressed.

Admission to the certificate program does not guarantee admission to any University of Georgia degree programs. Application to degree programs requires a separate admission criteria and application process and applicants must complete all admissions requirements as established by the Graduate School and the College of Pharmacy.

In order to remain in the program, students will be required to maintain a minimum grade point average consistent with graduate school requirements. Every effort will be made to support students who are concerned about their academic standing. This includes additional tutoring and mentoring.

11. Conclusion

The College of Pharmacy has completed a number of logistical tasks to implement a new Clinical Trials Design and Management Certificate Program and is in the process of planning course content, detailed program policies, marketing objectives and other needs of this program. The first students are expected to enroll Fall Semester 2007. At that time, we anticipate enrolling eight to sixteen students in one of three available courses. Utilizing a blended approach of web-based instruction, teleconferencing, and live seminars, the Clinical Trial Management Certificate Program will be well suited for working professionals. The feedback that we have received suggests that potential students are highly interested in this format as it is the least intrusive into their professional careers.