University of Puerto Rico
Medical Sciences Campus

Academic Proposal for the Establishment of a Post-doctoral Master of Science in Clinical Research Program

Submitted by: College of Health Related Professions
and School of Medicine

Dates of approval:

College of Health Related Professions:

School of Medicine:

Deanship of Academic Affairs:

MSC Academics Senate:

MSC Administrative Board:

UPR University Board:

UPR Board of Trusters:

PR Council of Higher Education:

TABLE OF CONTENTS

THEME		PAGE
I.	Introduction	1 – 2
II.	Justificacion	2
III.	Relationship of the program with the strategic plan of UPR and MSC	3 – 4
IV.	Relationship of the new program with other programs in the MSC	4
V.	Description of the program	4 – 19
VI.	Application and Admission Requirements	19 – 21
VII.	Academic requisites for graduation	21
VIII.	Recruitment and faculty development	22
IX.	Learning resources	22
X.	Physical facilities and resources	22 – 27
XI.	Profesional Accreditation	28
XII.	Administration of the program	28 – 33
XIII.	Finantial Aid	33
XIV.	Budget	33
XV.	Evaluation Plan	33 - 35

LIST OF APPENDIXES

1. List of potential mentors and liasons
2. Biographical Sketches of participating faculty, mentors and liasons.

I. INTRODUCTION

A. Title of the Program and academic degree

The proposed academic program is a multidisciplinary, post-doctoral Master of Science in Clinical Research. The program will be offered to candidates holding a doctoral degree in a clinical health care discipline and doctoral candidates. Relevant doctorate degrees include: M.D., D.D.S., D.M.D., D.O., N.D. DNS, Ph.D., ScD. or Pharm.D. The degree will be a joint offering of the School of Medicine and the College of Health Related Professions, Medical Sciences Campus, University of Puerto Rico.

B. Duration of the Program

The program will have a duration of two calendar years. The curriculum has two major components: didactic courses and research experiences.

C. Brief description of the program

The academic program curriculum was developed with the support of a one-year planning grant awarded in 2001 by the National Institutes of Health (NIH) – Planning Grant for Clinical Research Training in Minority Institutions RFA-AR-00-009. The grant proposal to offer a post-doctoral Master of Sciences in Clinical Research was submitted to NIH Clinical Research Education and Career Development (CRECD) in Minority Institution under RFA-AR-01-009 on February 15, 2002. The request was to provide direct costs of up to $500,000 per year. The purpose of the CRECD award is to support the development and implementation of curriculum-dependent programs in minority institutions to train selected doctoral and postdoctoral candidates in clinical research. It is expected that a successful program will produce well-trained clinical researchers who can lead clinical research projects.

The training program will consist of a two-year competency-based curriculum with two major components: didactic courses, and a mentored research project. All components of the training program will be integrated effectively into a balanced program of study designed to produce well-trained researchers able to lead clinical research studies.

The program will focus on training investigators who will be able to lead and expand the clinical research at the UPR-MSC and other partner institutions. During the first 5-year period, the CRECD program will target six specific health conditions of high priority to the Hispanic population as delineated by Healthy People 2010 and the mortality and morbidity trends in Puerto Rico. The conditions are cardiovascular diseases, cancer, HIV, diabetes, respiratory diseases, and oral health. Specific gender considerations will also be targeted in these health conditions. In Puerto Rico, 52% of the population is comprised by females, being the first three causes of mortality for women of all ages cardiovascular diseases, cancer and diabetes. These conditions were also selected because there are sufficient clinical researchers at the UPR-MSC, the SJVAMC or the Mayo Clinic to provide the infrastructure on which to build a viable and productive clinical research program. As the program becomes successful, other health conditions may be added based on priority status and available resources.

Program recruitment efforts will target junior faculty, fellows, residents and doctoral candidates of the participating six academic units of the Medical Sciences Campus (Medicine, Health

Related Professions, Dentistry, Pharmacy, Public Health & Nursing) and the San Juan Veteran's Administration Medical Center. The Medical Sciences Campus, University of Puerto Rico (MSC-UPR), has joined in partnership with Mayo Clinic, San Juan Veteran's Administration Medical Center and the Puerto Rico Department of Health to increase the depth and breadth of training opportunities and improve the overall quality of the educational experience. Training faculty from different disciplines in focused, specific, relevant and critical health issues will allow more research interaction among disciplines, enhance team approach to problem solving and foster interdisciplinary collaboration.

D. Initiation Date

The academic program will be offered only if the University receives NIH funding for its development and implementation. If funded, the program is proposed to begin in January, 2003. Decisions related to the continuation of the post-doctoral Master of Science in Clinical Research after the grant period has ended will be based on the results of the planned evaluation and the availability of fiscal resources.

II. JUSTIFICATION

A. Relationship with the mission, goals and objectives of the University of Puerto Rico and Medical Sciences Campus

The mission of the University of Puerto Rico is to communicate and increase knowledge through teaching, service and research. Therefore, a goal of the Medical Sciences Campus is to become a recognized and well-established research institution through the advancement of science and technology. The proposed post-doctoral Master of Science in Clinical Research will be a multidisciplinary academic offering that will greatly enhance the University's efforts toward the pursuit of this goal.

B. Academic Need for the Program

The University of Puerto Rico, Medical Sciences Campus is a minority institution with ongoing clinical research and a substantial number of faculty members who are engaged in the design and conduct of such research. However, the University does not have a formal didactic program for preparing individuals for careers in clinical research.

C. Demand for the Program

Minority groups are underrepresented in the biomedical sciences, especially in clinical research, so that research teams rarely include minority members. In addition, a growing problem in clinical investigation is the difficulty of recruiting minority groups into clinical trials, which especially limits the study of diseases that exhibit significant variation among ethnic groups. Because of the existing racial and ethnic disparities in health, the difficulties in recruiting minority groups into clinical trials and the scarcity of ethnic minority clinical researchers, NIH has identified the need to support and expand the training of ethnic minority clinical researchers.

D. Opportunities for Career Development

The program is designed for young faculty to enhance their opportunities to succeed in the increasingly competitive funding environment of academic health research and to lead and manage a productive career in clinical research.

III. RELATIONSHIP OF THE PROGRAM WITH THE STRATEGIC PLAN OF THE UNIVERSITY OF PUERTO RICO AND MEDICAL SCIENCES CAMPUS

The development of a new academic post-doctoral program in clinical research is consonant and responds to several key goals and strategic activities of the Strategic Plan of the University system as well as for the Medical Sciences Campus. Some of the most relevant aspects are the following:

A. Human Resources

To continuously develop and train all of the university teaching personnel

The program is designed for young faculty members, fellows, residents, interns and doctoral candidates of each of the participating academic units within the Medical Sciences Campus and the SJVAMC, who have demonstrated interest in pursuing a career in clinical research.

B. Curriculum, teaching and learning

To assure the continuous improvement of the academic offerings

The proposed post-graduate degree program will be a multidisciplinary academic offering of the Medical Sciences Campus, in a joint effort with faculty of the Mayo Clinic, SJVAMC and staff of the Puerto Rico Department of Health. This alliance will enhance the depth of the curriculum, the faculty and improve the overall quality of the educational experience. The curriculum is designed to foster interdisciplinary activities and collaboration to promote teamwork in problem solving, as well as effective health strategic planning based on clinical research outcomes.

To continuously improve teaching – learning strategies

The format of the academic program will address the needs of practicing professionals by providing components of the courses by Internet and videoconferencing, as well as non-traditional scheduling (evenings and Saturdays). In addition, the relationship with outside institutions and faculty will enhance our research and academic capabilities. As an example, current topics will be presented and discussed by invited recognized experts as guest speakers in the course Frontiers in Clinical Research.

C. Research

To increase research activities

The proposed program will provide a 2 year formal didactic and mentored clinical research curriculum that teaches the knowledge, skills and competencies necessary to perform successful clinical investigation and compete for funding.

To improve graduate studies

The propose program will provide the opportunity for health professionals holding a doctoral degree to pursue post-doctoral studies and to advance their research and scientific skills and competencies.

D. Information technology

To incorporate informatics and communication technology to the university system in a continuous and incremental manner

A web site is already available for this program (http://cprsweb.rcm.upr.edu/pdmcr) Web courses will be developed gradually with the goal to have at least half of the required courses with a major component in a distance-learning format at the completion of the NIH funding period.

IV. RELATIONSHIP OF THE NEW PROGRAM WITH OTHER PROGRAMS IN THE MEDICAL SCIENCES CAMPUS

The UPR-MSC graduates are one of the largest number of Hispanic health professionals in Puerto Rico and mainland USA. Traditionally, the institution has focused most of its efforts and resources in the areas of teaching and services provision. However, during the last 10 years, the institution has supported several important initiatives aimed at strengthening its clinical research efforts. Programs such as the RCMI-Clinical Research Center, the Cancer Center, and the Center of Excellence in Women's Health, are among several initiatives funded as part of this effort. In spite of the availability of these and other resources, the number of health professionals that are active in clinical research is still very limited, lagging behind most major academic institutions.

The creation of a post-doctoral Master in Clinical Research will be a unique multidisciplinary academic offering that will contribute to the enhancement of research in our institution and contribute to the need of more minorities in health research, especially patient – oriented research.

V. DESCRIPTION OF THE PROGRAM

A. Philosophy, purpose and objectives

1. Philosophy

The curriculum of the program is designed to offer candidates who have demonstrated an interest to pursue an academic career in their respective disciplines, the learning of methodologies, skills and competencies required to carryout clinical research studies. The program will provide students the opportunity to integrate a didactic curriculum with a mentor-based research experience to become independent, funded and committed clinical investigators.

2. Purpose

To implement an accredited post-doctoral Master of Science in Clinical Research degree. The two-year curriculum will combine intensive didactic and mentored clinical research training that will produce well-trained researchers who can lead clinical research studies addressing health disparities among American people, mainly the Hispanic population.

3. Objectives

The following program objectives below will be developed during the five-year of the grant:

Objective 1.0 Implement a two-year clinical research training program that leads to an accredited post-doctoral Master of Science in Clinical Research degree for junior faculty, post-doctoral trainees and doctoral candidates.

- **1.1** Provide a two-year competency-based curriculum that consists of teaching strategies that include 1) didactics, 2) a mentoring system, 3) a research project, and 4) a

longitudinal seminar series that are integrated effectively into a program of study designed to produce well-trained researchers able to lead clinical research studies.

1.2 Establish a Curriculum Advisory Committee (CAC) to provide oversight and direction to program activities. The role of the CAC will be to advise the program on its development of a sound clinical research infrastructure, including the development of an effective plan to recruit and retain competent clinical investigator faculty and mentors.

1.3 Select faculty who are able to develop and provide electives that will allow trainees from the different targeted disciplines to customize the program to their own needs.

1.4 Assure that a minimum of one-half of the courses are offered with components in distance learning formats by the end of the five-year period.

1.5 Make clinical research training courses available to potential trainees to stimulate interest and build confidence in their ability to succeed in clinical research.

Objective 2.0 Develop a program infrastructure that will support and sustain the UPR MSC post-doctoral Master of Science in Clinical Research degree program beyond the 5-year grant period.

2.1 Continue to a) identify needed expertise, faculty, space, equipment, collaborators, and other resources; b) set goals, objectives, and priorities relative to the curriculum program needs; c) develop and implement strategies to meet the needs identified; and d) evaluate the effectiveness of the strategies implemented.

2.2 Identify internal and external financial support mechanisms to provide institutional encouragement and "protected time" for the present and future clinical investigator faculty.

2.3 Continue to build and strengthen the necessary linkages with key research facilities and groups.

2.4 Encourage student and faculty participation in clinical research and ensure dissemination of information about the prospects of careers in clinical research.

Objective 3.0 Foster clinical research that will seek to reduce health disparities in and improve the overall health of the Puerto Rican and Hispanic population.

3.1 Recruit and select applicants who have demonstrated interest in conducting clinical studies to reduce health disparities, especially in the areas of the six targeted conditions.

3.2 Recruit new faculty to UPR MSC who have demonstrated interest in conducting clinical studies to reduce health disparities, especially in the areas of the six targeted conditions.

3.3 Develop collaborative relationships with clinical researchers from around the country who have demonstrated expertise in clinical research in the six areas being targeted. These collaborators will serve as mentors, co-authors on publications, Visiting Scientists, and/or co-investigators on clinical research projects.

Objective 4.0 Develop and implement a Program Evaluation Plan that systematically and comprehensively a) monitors and provides information to enable continuous quality

Public Speaking – will master public speaking skills in order to communicate effectively in a variety of presentation formats, such as from a ten minute oral presentation to a scientific seminar.

Establishing/management a research project – will be able to prepare budgets, supervise staff and build collaborative networks in his/her research field.

3. Competency-based curriculum

The competency-based curriculum for the CRECD Program is presented below in Table 1. The principles and practices of adult learning theory and of problem-based learning will be applied to better ensure that graduates will become competent lifelong self-directed learners. The six competency domains are: research, professionalism/ethics, leadership communication, interdisciplinary collaboration, and life-long self-directed learning. Traditional graduate training evaluations will be used for all course work, but in addition, outcome evaluation criteria for each competency will be developed by the CAC to determine if the trainees have specifically achieved the competency.

Post-doctoral Master of Science in Clinical Research

COMPETENCIES	LEARNING OBJECTIVES
1. Be able to develop and implement ethnically and culturally appropriate **clinical research** aimed at reducing health disparities in Hispanic populations, especially those served by UPR.	• Develop and adapt approaches to clinical research design and implementation that demonstrates an understanding of ethnicity, culture, gender and aging. • Interact sensitively, effectively, and professionally with persons from diverse cultural, socioeconomic, educational, and professional backgrounds and with persons of all ages and lifestyle preferences. • Identify public health laws, regulations, and policies related to clinical research. • Be able to access, understand, analyze, synthesize, and appropriately apply information pertinent to conducting quality clinical research. • Apply the various research methodologies used in clinical research. • Make relevant inferences from data. • Demonstrate clinical research problem solving skills first by acquiring and interpreting data; next by prescribing, implementing, and monitoring a plan of action based on the data; and lastly, by evaluating the outcomes of the interventions implemented.
2. Conduct ethically responsible clinical research.	• Apply ethical principles in the design and conduct of clinical research. • Identify ethical dimensions involved in the design and conduct of clinical research, especially with disadvantaged and underserved populations.
3. Build and lead effective collaborative networks in one's area(s) of clinical research interest.	• Manage clinical research project, including the budget. • Recruit and supervise necessary staff for clinical research project.
4: Communicate effectively in writing and orally (unless a handicap precludes one of these forms of communication).	• Present accurately and effectively, orally and in writing, demographic, statistical, and scientific information for professional and lay audiences. • Be able to obtain appropriate feedback, consultation, and/or review before, during, and after a research project. • Demonstrate successful scientific writing skills by publishing scholarly works (e.g., books, chapters, peer-reviewed journal articles) and writing an approved clinical research proposal.

5. Be able to work collaboratively, interdependently and effectively with other disciplines on the clinical research team.	• Demonstrate the ability to efficiently and effectively manage research team task assignments. • Demonstrate good interpersonal skills, including the ability to work interdependently with other clinical research team members.
6. Become a lifelong self-directed learner.	• Be a reflective clinical investigator who continuously questions the status quo and seeks better solutions to problems encountered in providing quality care • Acknowledge that health care delivery has gaps and problems that impede the consistent provision of quality care and that each of us must play a role in closing those gaps and resolving those problems. • Use the internet to access clinical research information. • Evaluate the integrity and comparability of data and identify gaps in data sources. • Analyze how data illuminate ethical, political, scientific, economic, and overall public health issues. • Appreciate the need for lifelong learning. • Demonstrate self-directed study by evaluating and determining when there is the need for new and/or improved skills and knowledge, where and how that knowledge and those skills can be obtained, and finally by obtaining them. • Acquire an integrated body of knowledge related to health and continuously update it.

C. Programs Components

1. General description – courses, requisites, all courses titles

The proposed specialized curriculum consists of a total of 36 semester credits to be completed in two years, including both summers. The didactic core component has 24 semester credits and the research component is equivalent to a one-year research project and 12 semester credits. This curriculum has minimal spaces for electives, since its focus is core issues encountered by faculty performing clinical research.

The Curriculum will be comprised of courses in biostatistics, patient-oriented research design and methodology, bioethics and the responsible conduct of research, epidemiology, manuscript/grant writing, seminars in clinical research, a research project, practicums in clinical studies, data management, and study coordination. During the two-year program, trainees will have 50% release time from their academic responsabilities in the first year and 75-100% release time in the second year.

The didactic component is as follows:

Didactic Component (24 credits)	Semester Credits
Introduction to Clinical Research	1
Legal and Regulatory Issues	1
Bioethics and Institutional Review Board	1
Biostatistics in Clinical Research I	2
Biostatistics in Clinical Research II	2
Informatics Application in Research	1
Clinical Epidemiology I	2
Clinical Epidemiology II	2
Introduction to Health Services Research	1
Frontiers in Clinical Research	1
Clinical Trials	2
Clinical Research Protocol Development	2
Scientific Writing	2
Bioanalytical Methods in Clinical Research	2
Electives	2

Note: One semester credit is equivalent to 18 contact hours in a semester.

Research Component (12 credits) - equivalent to one year research. The requirements for completion are the following:

- Approval of a research proposal.
- Completion of clinical research project.
- Preparation and submission of an abstract for an oral or poster presentation in a national/international scientific forum/meeting/congress.
- Preparation of a manuscript ready for submission to a peer-reviewed scientific journal
- Approval of oral presentation of research findings

Research Component

The candidates will submit a one-page research intention letter identifying the health area of interest, which will be chosen from the six priority areas selected for the program, and discuss any specific ideas, hypothesis or problems he/she might want to pursue during the thesis research. At admission to the program, the student will be interviewed by one of the Associate Directors for Clinical Research to discuss his/her research goals and will be provided with a list of possible mentors in his/her health area of interest. The program will

identify liasons in each of the target research areas to serve as initial points of contact and assist both the Associate Director and student in identifying good mentors.

During the first 6 months of the program, the student will talk with several potential mentors in their particular area of interest to discuss possible research projects. Once a mentor is identified, the student and mentor will work together to identify the specific questions to be addressed by the research. After sufficient background reading and literature searching, the student will write a five-page research proposal and submit it to the Research Committee for review, recommendations and approval. It is anticipated that this proposal will be submitted during the first year to the Research Committee.

As in all research training programs, the mentored research project will be the most important vehicle by which students will acquire the skills of a clinical researcher. Throughout this process there will be a balance between guiding the student in design and conduct of their research and expecting the independence needed to succeed in research. To achieve this purpose each candidate will form a Research Committee to guide them throughout their research project.

The Research Committee will be composed of at least three individuals. The primary Mentor will lead the group and will be the person most directly involved with the design and conduct of the research project. The mentor will be an accomplished clinical researcher with the time and expertise to supervise the research. The mentor will be drawn from faculty of the Medical Sciences Campus, the other partner institutions in Puerto Rico, faculty of Mayo Clinic, or, with approval, an outstanding clinical researcher from another academic health center in the U.S. Choice of this mentor will be carefully guided and monitored by the Executive Committee to ensure that only appropriate faculty are chosen as mentors. We recognize that with a broad choice of mentors such as this there could be a concern over issues of distance and time for adequate mentoring. The Executive Committee will take the responsibility to ensure that any mentor chosen will commit the required time and resources. One of the reasons a broad approach has been adopted is to nurture and expand collaborations between Faculty of the Medical Sciences Campus and clinical researchers in the U.S. In this way we will ultimately expand the pool of potential Puerto Rican mentors as well.

The other two members of the Research Committee will be chosen on the basis of their expertise and interest related to the research project. If the mentor is from Puerto Rico it will be expected that one of these individuals be from the U.S. or other country. The role of these other members will be to provide help and guidance to the candidate as needed, as well as monitor research progress and certify when the trainee has met the research requirements of the program. By expecting each Research Committee to include two faculty from Puerto Rico and one from outside we will take a big step toward building collaborations to improve the overall research capabilities of our faculty.

2. Courses

a. Description of new courses

Introduction to Clinical Research, 1 semester credit, REQUIRED

C. Diaz, MD, J. Santana, MD, C. Luciano, MD, JF Rodriguez, PhD (School of Medicine)

This course will be essential to bring to the same level all the students starting the program. The main objectives of the course are to educate students in the essential aspects of clinical research and the basic processes of building patient-oriented research studies. This course provides the basic concepts of Clinical Research starting with the history of fundamental studies and the Researchers that made an impact in the field. In addition, this course will include the fundamentals of study conception (hypothesis), design (research question), and conduct (implementation) of clinical research with emphasis in different clinical settings and analyses. Management, ethics, funding, publications, and regulatory aspects will be also discussed. A brief description of different bio-analytical methods, bio-informatics and genetics will be presented to the students. Resources: Clinical Researchers.

Legal and Regulatory Issues, 1 semester credit, REQUIRED

E. Gonzalez, MD (UPR MSC Compliance Officer)

This course is intended to provide a broad based source of the legal and regulatory issues concerning the clinical research enterprise. Legal aspects of research with human participants will include the development of federal and state rules and regulations promulgation and implementation. Special topics concerning international harmonization and good clinical practice efforts will be discussed. Legal issues such as the participation of children, women, prisoners, and impaired participants in clinical research will be presented. Special attention will be given to stem cell and genetic therapy research.

Bioethics and Institutional Review Board, 1 semester credit, REQUIRED

E. Gonzalez, MD (UPR MSC Compliance Officer)

This course is intended to provide a broad based source of the bioethical issues concerning the participation of human subjects in the clinical research enterprise. Bioethical aspects of research with human subjects will include the development and implementation of regulations from the historical perspective of specific cases that resulted in laws promulgation. Special topics concerning international harmonization and good clinical practice efforts will be discussed. Ethical issues such as voluntary participation, minimal risk, justice, and beneficence attached to research will be presented.

Biostatistics in Clinical Research I, 2 semester credits, REQUIRED

J. Guzman, PhD (Graduate School of Public Health) and Staff

This course presents the fundamentals of biostatistical analysis as applied to clinical research. Topics include: measures of central tendency and dispersion; basic probability concepts; probability distributions; sampling; estimation; hypothesis testing; Student's t-test; analysis of variance; regression and correlation; the Chi-square test, and non-parametric and distribution-free statistics. Text: Zar JH. Biostatistical Analysis. Prentice-Hall

Biostatistics in Clinical Research II, 2 semester credits, REQUIRED

J. Guzmán, PhD (Graduate School of Public Health) and Staff

This course presents more advanced topics on biostatistical methods. These include multiple linear regression; conditional and unconditional logistic regression; log-rank test; Cox proportional hazards; management of time-dependent covariates; Poisson regression; tests for interaction; Mantel-Hanzel procedure to control confounding; Mantel-Hanzel Chi-Square; statistical power and sample size calculation. Texts: Selvin S. Statistical Analysis of Epidemiologic Data. Oxford University Press. Kahn HH and Sempos CT. Statistical Methods in Epidemiology. Oxford University Press. Zar JH. Biostatistical Analysis. Prentice-Hall

Informatics Applications in Research, 1 semester credit, REQUIRED
Rubén García, PhD and Carlos Ortiz, MS (College of Health Related Professions)
This course provides basic computational and informatic tools necessary for the practice of clinical research. These include statistical software such as: web applications and research resources such as MEDLINE, MD Consult, NLM, CDC and NIH sites; use of search engines; use of the PDA; judicious use of computer technology, the Internet; and principles for the visual display of quantitative information and presentation tools (PowerPoint, SigmaPlot). Resources: Software, on-line Internet resources.

Clinical Epidemiology I, 2 semester credits, REQUIRED
C. Nazario, PhD (Graduate School of Public Health)
This course presents the fundamentals of clinical epidemiology: the application of epidemiologic principles and methods to problems encountered in clinical medicine. Topics include: measures of morbidity and mortality; direct and indirect adjustment of rates; relative risk; attributable risk; relative odds; validity and reliability; evaluation and application of screening and diagnostic tests; actuarial life tables; Kaplan-Meir estimates; design of prevalence studies; clinical trials; cohort studies; case-control studies; cohort effect; confounding and effect modification; bias; causation; statistical significance versus clinical significance. Text: Hennekens CH, Buring JE and Mayrent SL. Epidemiology in Medicine. Little, Brown and Company.
Additional readings: List of recently published papers.

Clinical Epidemiology II, 2 semester credits, REQUIRED
C. Nazario, PhD (Graduate School of Public Health)
The intermediate course builds on concepts presented in the course Introduction to Clinical Epidemiology, and presents issues in the design, implementation and analysis of validation studies, observational studies and clinical trials. Topics include: principles of ROC analysis; measures of agreement; measures of validity and reliability; bias; observational versus experimental epidemiologic studies; misclassification; secondary data analysis; design-specific issues on sample size; effect of non-participation; matching in case-control studies; selection strategies of cases and controls; strengths and weaknesses of case-control studies; strengths and weaknesses of cohort studies; recruitment and sources of cohorts; issues in follow-up of longitudinal studies; management and analysis of censored data; application of univariate and multivariate adjustment techniques; identifying and dealing with effect modification in case-control and cohort studies; the drug approval process; efficacy vs. effectiveness studies; randomization; blinding; compliance to intervention; contamination of the control group; generalization of results, and issues on the establishment of causality in observational and experimental epidemiologic studies. Texts: Rothman KJ (Editor) and Greenland S. Modern Epidemiology. Little, Brown and Company. Friedman LM, Furberg

CD and Demets DL. Fundamentals of Clinical Trials. Springer-Verlag Kelsey JL, Whitmore AS and Evans AS. Methods in Observational Epidemiology

Introduction to Health Services Research, 1 semester credit, REQUIRED
M. Marquez, PhD (School of Medicine and Graduate School Public Health)
This course presents the basic concepts, theory, and methods associated with health services research. The following topics are covered: health care economics, technology assessment, health care financing, outcome measurement and analysis, evidence-based medicine, risk adjustment, severity measurement, economic analysis (including cost-effectiveness analysis), quality of care measurement, disease management, managed care, and continuous quality improvement. The lectures will focus on the foregoing topics, particularly as they relate to the organization and delivery of health care services. Students will be required to prepare a final report for presentation and discussion.

Frontiers in Clinical Research, 1 semester credit, REQUIRED
J.F. Rodríguez, PhD (School of Medicine)
This is a seminar series for the dissemination of the latest issues in Clinical Research. Distinguished Clinical Researchers from around the world will be invited to present their work. The Speaker will provide a list of publications and the students will be required to read at least two of them. This course will also teach students how to interpret and critically appraise research articles. The first day at the University, the Speaker and the students will have a 3 hours interactive session. During this session, the Speaker will provide his/her vision on Clinical Research and the appropriate direction that students should take to be successful. In addition, the student will be required to ask at least two questions regarding the articles that they read prior to the arrival of the Speaker. During the second day, the Speaker will present the seminar and the students are required to attend. They will also be required to ask at least one question regarding the topic presented. After the seminar, the Speaker will meet with the Mentors and the Students to have an informal discussion regarding issues pertaining to Clinical Research such as, study design, ethics, funding opportunities, collaborative efforts, among others.

Clinical Trials, 2 semester credits, REQUIRED
J. Guzmán, PhD (Graduate School of Public Health) and staff
This course provides in-depth discussion on the design, analysis and implementation of clinical trials. Topics include: history of clinical trials; cost issues; planning a clinical trial; design principles such as sample size, power analysis, randomization, masking and selection of end points; issues in the execution of clinical trials including data collection, patient recruitment/follow-up, compliance to intervention, and quality assurance; data management and analysis including survival analysis and interim analysis; study management and reporting procedures including patient safety monitoring and administrative committees, and coordination of multicenter studies. Text: Meinert CL and Tonascia S. Clinical Trials: Design, Conduct, and Analysis. Oxford University Press.

Clinical Research Protocol Development, 2 semester credits, REQUIRED
R. McGee, PhD and G. Poland, MD (Mayo Clinic)
This course will present the principles and methodological concepts relevant to the design of prospective and retrospective clinical research. The focus will be on developing a protocol which successfully translates research questions into feasible study designs that allow specific hypotheses to be tested. Topics to be addressed include: identifying appropriate research questions, generating testable hypotheses, specifying the research design, developing and validating measurement instruments, discussing sample size and power, planning and describing the data analysis, and addressing study limitations. Specific examples of actual protocols from ongoing studies will be used to illustrate the concepts. This course will consist of 18 90-minute lectures and classroom discussions. The students will be required to develop their own abbreviated clinical research proposals for constructive review by the instructors and peers.

Scientific Writing, 2 semester credits, REQUIRED
M. Fanchon Rouce Hamilton, PhD (Proposal Writing and Publications Consultant)
The Scientific Writing course will provide experience and improvement in both written and oral technical communication. Sentence level topics will include sentence parts and word functions, phraseology, sentence fragments, run-on-sentences, punctuation, tense sequence among verbs, infinitives, and participles, compound nouns and modifiers, capitalization, parallel structures, using italics, using numbers, etc. At the paragraph level, the instruction will address sentence variety, tense/pronoun consistency, sentence-combining skills, coherence and transition, and paragraph development. Students will know all of the elements of a scientific research proposal, including abstracts, introduction, statement of the problem, material and methods or experimental methods, analyses, figure-table-text links, references, and special sections such as list of abbreviations, list of symbols, and appendices. Students will learn to write with clarity, accuracy, comprehensiveness, accessibility, conciseness, and correctness, using the computer as a writing assistant. The student will apply the knowledge acquired by preparing a well-written, sound research proposal during the course. The course objective is to impart the skills necessary to obtain funding and get their work published in prestigious journals that are read by international audiences.

Bioanalytical Methods in Clinical Research, 2 semester credits, REQUIRED
J.F. Rodríguez, PhD (School of Medicine) and C. Flexner, MD (John Hopkins University)
This course will offer a review of the most relevant and popular methods applied today in clinical research studies. It will be focused on the scientific basis, rationale, potential applications and limitations of current analytical methodology. Some of the areas that will be covered include: techniques for genetic analysis, metabolic studies, immunoassays, application of molecular biology methods, physiologic studies, kinetic analysis (including an introduction to pharmacokinetics), essentials of quality control and normative values.

Seminar Series, 0 credits, REQUIRED
J.F. Rodríguez, PhD (School of Medicine) and E. Estape, PhD (College of Health Related Professions)
The School of Medicine Graduate School currently offers seminar series in most of the biological sciences (e.g., Immunology, Neurosciences, Pharmacology, Anatomy,

Pharmacology, Biochemistry etc.). Students in the post-doctoral Master in Clinical Research are required to participate in these seminars.

Surveillance systems, 1 semester credit, ELECTIVE
Juan C. Orengo, MD, PhD (Puerto Rico Department of Health) and Johnny Rullán, MD, MPH (Puerto Rico Secretary of Health)
This course will focus on the characteristics of some systems for chronic and infectious diseases. It will also provide detailed descriptions of data collection, management and how specific data with help in the development of clinical research or identifying areas in need of clinical research. As examples, the behavioral risk factors surveillance system (BRFSS) and the HIV-AIDS surveillance system will be discussed.

Observational Studies, 2 semester credits, ELECTIVE
M. Rosa, PhD, DrPH (School of Nursing) and Staff
The clinical trial is the most powerful clinical study design due to its experimental nature. However, observational analytical studies are widely used to assess etiology of disease. This course provides in-depth discussion on the design, analysis and implementation of cohort and case-control studies. Topics on cohort studies include: methodological issues for biomarkers, exposure measurement, retention and tracking of cohorts; quality assurance and quality control; population-based cohort studies; occupational cohort studies; use of computerized record linkage in cohort studies. Topics in case-control studies include planning and execution; selection of cases and controls; sample size; measurement in case-control studies; basic and advanced methods of statistical analysis in case-control studies; sources of bias; limitations of the case-control methodology, and applications of the case-control methodology in evaluation of treatment and program efficacy, outbreak investigations, genetic epidemiology and occupational epidemiology.

Survey Research, 2 semester credits, ELECTIVE
M. Rosa, PhD, DrPH (School of Nursing) and Staff
Surveys are a major source of information on populations, and clinical investigators should become familiar with the fundamental elements of good survey research. This course covers topics such as survey planning; calculating and drawing samples; designing of questionnaires; conducting interviews; fieldwork coordination, and issues in data storage, security and processing.

Biological/Medical Infomatics applied to Clinical Research, 2 semester credits, ELECTIVE
R. González, PhD (School of Medicine)
This course provides an overview of computational science and biological/medical informatics applied to state of the art clinical research. Topics may include: introduction and applications of image analysis and/or signal processing; nucleic acid and protein sequence analysis and genomics; data visualization and advanced applications of data presentation and graphics for research; modeling of biological systems, data or processes using advanced techniques such as non-linear fitting, Monte Carlo simulations, etc.; design and applications of biomedical databases for research. The overall strategy for the course will be that of an advanced research seminar tailored to the profile and needs of the students taking the course.

The teaching strategies will involve a mixed model of seminars/lectures and distance/electronic education. The evaluation process will be based on rigorous scientific analysis of applications of informatics to clinical research in the scientific literature, hands on exercises, and a small research project in an area of interest to the student where an application of informatics is essential to completion of the work. The research project outcome will be based on evaluation of a research report similar to a research publication.

Gender Considerations in Clinical Research. Elective. 2 credits.
Delia M. Camacho, PhD (CHRP and Puerto Rico Center of Excellence in Women's Health)
The rationale for the course is based on the need for clinical evidence on gender-specific issues related to manifestation of illness, treatment, and outcomes, leading to understanding the importance of women's health research. A global perspective on women's health will be presented, giving students the opportunity to assess the status of research on gender differences. The course will discuss the differences in the composition of diseases between men and women; underrepresentation of women in clinical trials; define gender-related analysis; gender framework for health research and the gender variables that must be taken into account; how to incorporate women in studies; and NIH guidelines on including women and minorities in clinical trials. Strategies for course offering will include lectures, seminars, literature review and student presentations.

Program Curriculum Model

	Year 01	Year 02
Spring	Introduction to Clinical Research (1) Legal and regulatory issues (1) Bioethics and Institutional Review Board (1) Biostatistics in Clinical Research I (2) Informatics Applications in Research I (1) Clinical Epidemiology I (2) Introduction to Health Services Research (1) Seminar Series (0)	Clinical Research Component (4) Frontiers in Clinical Research (1) Seminars in Clinical Research (0)
Summer	Biostatistics in Clinical Research II (2) Clinical Epidemiology II (2)	Clinical Research Component (4)
Fall	Clinical trials (2) Clinical Research Protocol Development (2) Scientific Writing (2) Bioanalytical Methods in Clinical Research (2) Seminars Series (0)	*Clinical Research Component (4)* Seminar Series (0)

	Electives (Any two credits) Surveillance System (1) Observational studies (2) Survey Research (2) Biological/Medical Informatics (2) Gender Consideration in Clinical Research (2) Courses offered at the Medical Sciences Campus with the approval of the Program (1,2)	

Curricular Sequence of the Program

First year

Spring				
January	***February***	***March***	***April***	***May***
Introduction to Clinical Research (3wk; 6 hrs per wk) Legal and regulatory issues (3wk; 6 hrs per wk)	Introduction to Health Services Research (3 wk; 6 hrs per wk) Bioethics and IRB (3 wk; 6 hrs per wk)	Biostatistis in Clinical Research I (6 wk; 6 hrs per wk) → Informatics Applications in Research (6 wk; 3 hrs per wk)	Clinical Epidemiology I (6 wk; 6 hrs per wk) →	
←——Seminar Series——→				

Summer	
June	***July***
Biostatistics in Clinical Research II (4 wks; 9 hrs per wk)	Clinical Epidemiology II (4 wks; 9 hrs per wk)

Fall				
August	***September***	***October***	***November***	***December***
Clinical trials (6 wk; 6 hrs per wk) → Bioanalytical Methods in Clinical Research (6 wk; 6 hrs per wk) →	Clinical Research Protocol Development (6 wk; 6 hrs per wk) →		Scientific Writing (6 wk; 6 hrs per wk) → Electives (6 wk, 6 hrs per wk) →	
←——Seminar Series——→				

Second year

Spring				
January	*February*	*March*	*April*	*May*
Clinical Research	Clinical Research	Clinical Research	Clinical Research	Clinical Research
←----------Frontiers in Clinical Research----------→				

Summer	
June	*July*
Clinical Research	Clinical Research

Fall				
August	*September*	*October*	*November*	*December*
Clinical Research	Clinical Research	Clinical Research	Clinical Research	Clinical Research
←---------- Seminar Series ----------→				

D. Educational Methodology and Teaching Strategies

The proposed program is designed to meet the need for a formal academic training in the quantitative qualitative and other methodological principles of clinical research, including patient-oriented research, epidemiologic and behavioral studies, outcome research and health services research. Planned for persons who have completed a doctoral degree or are in the final phase of completing a doctoral degree, the proposed program will require a minimum commitment by prospective students of at least 2 years for didactic and clinical research training. Students who complete the course of study will be awarded a post-doctoral Master of Science in Clinical Research degree by the University of Puerto Rico, School of Medicine and College of Health Related Professions. Graduates will be qualified to plan original clinical investigations with adequate sample size, sampling methods, well-defined diagnostic criteria, and effective control of confounding variables. Graduates will have sufficient knowledge of statistical principles and methods to recognize when additional advice is necessary. Successful completion will result in an improved level of competency in the preparation of competitive research proposals and grant applications for funding and effective presentation and communication of scientific knowledge and findings. They will also learn various advanced methodologies and pharmacological concepts that are used routinely in clinical research. Finally, graduates will have substantive knowledge and skills to design and implement research studies about major research questions or problems in one or more of six priority health areas (cardiovascular diseases, diabetes, cancer, HIV, respiratory diseases and oral health) and will be adept with medical and epidemiologic tools for studying these problems.

Effective teaching aims to change learner competencies by means of particular methodological approaches. The overall conceptual framework that will be used by this Program will be a balanced integration of the principles and practices of adult learning theory or andragogy, problem-based learning, pedagogy, and interdisciplinary team training. The explosion in medical information and technology that has occurred during the past several decades and the rapid obsolescence of such information makes it essential that we develop clinical investigators

able to manage information and become life-long, self-directed learners. In addition, it is imperative that all professionals working in health-related fields, including research, are able to work effectively with professionals from multiple disciplines. Trainees in this program will be recruited from multiple disciplines at the rate of three to five per year for a total of 10-17 trainees in a 5 year period. They will have a longitudinal seminar series experience with scientific literature appraisal over the entire two-year period. This interdisciplinary training should facilitate the enhancement of interpersonal skills and the ability to effectively collaborate with professionals from other disciplines.

This program will minimize the use of the pedagogical lecture. However, some didactic courses are necessary, largely for the sake of efficiency, but when used, at least 50% allocated time will be for interactive discussion. The use of distance learning strategies will not only support the principles of problem-based learning by allowing trainees to study and work on assignments at their own convenience, but they will also enhance the mentoring system by enabling the faculty to spend less time on pedagogical, passive learning activities, such as lectures, and more time in small group interactive teaching and one-to-one discussions. Additionally, the use of distance-learning strategies will facilitate communication with experts and expand the availability of resources. One of the curriculum goals is to develop at least half of the required didactic courses with components in a distance learning modality by the completion of the first NIH funding period. The format for web-course development selected is "Blackboard". The infrastructure for faculty training and course development will be provided by the Office of Informatics and Educational Resources of the CHRP. On-line materials and conferences will be available to students through the Internet – web page of the program. To facilitate communication, an e-mail system will allow interactive dialogues and group discussions through chat or forum. The net will also provide access to other library resources. Video conferencing will also be utilized as a teaching strategy. Other educational methodologies utilized in the courses will include conferences, reading assignments, problem-based learning, group discussions and seminars. At present, both the School of Medicine and CHRP are using technology to support teaching.

VI. APPLICATION AND ADMISSION REQUIREMENTS

A. Application requirements and general norms of admission

1. Candidates

The recruitment of candidates for the first four groups that will be admitted to the program will be according to the NIH guidelines for selection of students as described in the RFA-AR-01-009 –clinical Research Education and Career Development in Minority Institutions:

- Junior Faculty – 7 years of their first faculty appointment or 7 years as of the date they received their doctoral degree
- Fellows
- Interns and Residents
- Doctoral candidates in their third or fourth year of study

2. Application requirements

- Hold a doctoral degree in a health field, such as MD, DDS, DMD, DO, Ph.D., ScD., Pharm D from a recognized academic institution

- Minimum doctoral (or accumulated for the doctoral degree) general grade point average of 3.0
- Two Formal Commitment Letters from Dean / Director of Unit and Immediate Supervisor (Department Chair, Division Director, Program Director) for release time to attend this program
- Submission of the official application and all required documents prior to the deadline established by the program
- Curriculum Vitae
- Transcript from the institution granting the doctoral degree
- Two letters of recommendation from individuals familiar with the applicants science – research related activities
- Personal statement detailing how this program will contribute to the candidate career goals
- A one-page research intention letter in one of the clinically relevant health areas

3. Admission Requirements

All applicants will be screened administratively for completeness and adherence to requirements. Applicants meeting all requirements will be interviewed by three members of the Admissions Committee. The Committee will then meet as a body to discuss and rank applicants. The Admission Committee will recommended the top ranked candidates to the Executive Committee.

Admission Formula

The admission formula considers three aspects, the Performance Based Interviewed (PBI), the Grade Point Average (GPA) in a 4.00 point scale and Personal and Professional Characteristics (PPC).

The recommended weight for three aspects are as follows:

45% Performance Based Interview
10% Grade Point Average (GPA)
45% Personal and Professional Characteristics

100% Total

The Personal and Professional Characteristics will be obtained form the following submitted documents:

Curriculum Vitae
Letters of recommendations
Personal statements
Research Intention Letter

The Performance-based interview (PBI) questions are based on the competencies needed by the applicant to successfully complete the program and will be the same for all applicants. Evaluation criteria is designed to measure the knowledge, skills, attitude, abilities and experience of the candidate that will help him/her to achieve a successful training performance.

Projected registration for the first five years
The program will run on a 2 year schedule with 3-5 students/class starting on January 2003. The expected total trainees for the NIH funded period will range from a minimum of 10 to a maximum of 17 students, depending on the cost for the student's training. This cost will depend on the candidate's positions at the time of her/his admission.

VII. ACADEMIC REQUISITES FOR GRADUATION

A. Total credit/hours required
The post-doctoral Master of Science in Clinical Research requires a minimum of 24 didactic semester credits and 12 semester credits equivalent to one year of effort devoted to research. The research component requires the completion of a clinical research project, preparation and submission of an abstract for an oral or poster presentation in a national/international scientific forum/meeting/congress, preparation of a manuscript journal and the approval of an oral presentation of research findings.

B. Minimum academic grade point average
The minimum grade point average required for courses will be 3.0 (on a 4.0 scale). At least one-half of the credits included in the degree program must be graded the A – through – F system.

C. Total transferred credits accepted
Participants wishing to transfer credit for equivalent graduate courses will formally request the transfer of credit to the Executive Committee. The students will also provide the course syllabus for content evaluation. A maximum of 4 semester credits will be accepted for transfer.

D. Other requisites
During the first year of the program, students will dedicate 50% of their time to courses and literature search for the writing of a five-page research proposal. It is expected that students work during the mornings of the five-day week and dedicate the rest of the week and some Saturdays to the didactic component. The research component is equivalent to one year research and entails a 75-100% time commitment to research and attendance to a series of seminars. A full-time commitment to research is preferable. For those students that need to provide clinical services as part of their duties, a 75% commitment will be allowed, with only one day/week for clinical duties. The clinical research project must be completed during the second year of the program.

E. Time required to complete requisites for graduation
The didactic component should be completed within the first year and the completion of the research project by the end of the second year. An additional year can be approved by the Executive Committee when requested by the student with the approval of the mentor for the following graduation requisites: submission of the abstract, preparation of manuscript and oral presentation of research findings.

VIII. RECRUITMENT AND FACULTY DEVELOPMENT

A. Available faculty

The available faculty for courses is detailed in the description of new courses of this proposal. (pages 11 - 16)

The mentor will be an accomplished researcher who is actively engaged in clinical investigation in the priority health area selected by the student and will be the chairperson of the student's Research Committee. The mentor will help the students in the design and conduct of the research project and supervise the student's progress. The mentor will maintain close communication with the Research and Executive Committees in relation to the student's performance and training plan so as to complete the research requirements on time. Potential mentors have been identified for the six health priority areas stated in this grant. In addition, liaisons have been at appointed the Mayo Clinic to assist in the selection of mentors. (See Appendix 1)

B. Faculty projection in five years

All faculty participating in this program will be on a part-time basis according to their responsibilities in courses and research mentoring. The number of faculty participating will be flexible and will vary according to the model of the curriculum proposed and number of students admitted each year.

C. Faculty Qualifications

See appendix 2 for Biographical Sketches of participating faculty, mentors and liasons.

IX. LEARNING RESOURCES

The educational resources and services currently available at the Medical Sciences Campus Library and at the program level are adequate in quality and quantity to support program objectives and teaching methods. The MSC Library is the main health sciences information resource for the Island and the Caribbean. The Library collection comprises 42,092 book titles and 1,296 journal subscriptions. As a health sciences library, it offers books and journals in clinical research, as well as in other areas that support knowledge in the field.

Services provided at the MSC Library meet faculty and student needs for information in a variety of formats. These include interlibrary loans, document delivery services of materials not found in the collection, bibliographic instruction, and librarian mediated literature searches. The Health Education Information Resources Services (HEIRS) area is equiped with personal computers that provide access to the Internet, campus information, management systems, and information bases data.

X. PHYSICAL FACILITIES AND RESOURCES

The University of Puerto Rico, Medical Sciences Campus has a very strong research infrastructure to support basic sciences research. Some of these are the MBRS SCORE/RISE Program, RCMI Basic Research Program, Animal Resources Center and Caribbean Primate Center. One of our goals is to expand and enhance infrastructure that supports clinical research. The Medical

Sciences Campus is located in the Puerto Rico Medical Center. Extramural facilities include departmental, research and clinical areas located for example, at the Adult and Pediatric Hospitals, as well as the Oncology Hospital, San Juan City Hospital and Cardiovascular Center of Puerto Rico and the Caribbean. Within walking distance of the campus is the VA Hospital and Health Department. In addition, the University of Puerto Rico owns the Carolina University Hospital. The Clinical Research Center and the University Hospital, along with the collaboration partnerships with the VA Hospital, Health Department and the Medical Center teaching hospitals will guarantee an excellent access to potential study participants and specific populations at risk or affected by the health conditions under study.

Over the last decade, there have been important accomplishments in the support and development of research at the UPR-MSC. It is estimated that 40% of the efforts of the basic and clinical faculty are dedicated to research. In addition to time spent in direct scientific investigation, a significant amount of effort is spent in administrative, educational, and other activities related to research, such as grant and manuscript preparation. Principal investigators are supported by an appropriate mix of case managers, research nurses, physician assistance, nurse practitioners, data managers, and computer programmers. In 1984, the Minority Biomedical Research Support (MBRS) was funded to enhance the basic research infrastructure and facilitate the interaction between basic and clinical faculty in scientific projects of clinical relevance. In 1986, the Research Centers in Minority Institutions (RCMI) Program was established with funding from the National Center for Research Resources, NIH. The purpose of the RCMI is to develop a strong infrastructure for conducting research related to health disparities in the Puerto Rican population. Research approaches to address this goal range from the molecular to the clinical level. The specific aims of the program are to: Develop infrastructure and provide support services to facilitate the conduct of research related to health disparities; Target specific areas of research related to health disparities and provide a focal point for these research activities on campus; and Promote the professional development of research faculty and technical personnel working on this area.

To achieve these objectives, the RCMI has established the **Health Disparities Research Program**, which has three components: the **Division of Research Resources**, the **Division of Research Development**, and the **Division of Advancement in Research**. The **Division of Research Resources** includes all activities that provide research support services in the areas of molecular genetics, information architecture, and image analysis. The Molecular Genetics Core Facility enhances institutional biomedical research capability by supporting basic and clinically oriented projects with strong molecular biology and molecular genetics components. The Molecular Neurobiology Unit expands the capability of MSC Institute of Neurobiology investigators for conducting research on the regulation of gene expression in neurobiological system. Established in 1996, the Cell Image Analysis Resource Center provides training to researchers in the use of Image Analysis. The goal of the Center for Information Architecture in Research is to improve collaboration between researchers at the UPR MSC and researchers in other institutions within and outside Puerto Rico through the application of computing and telecommunications technologies.

The **Division of Research Development** supports research activities addressing health disparities in the Puerto Rican population such as AIDS, women's health (breast cancer,

osteoporosis), emerging infectious diseases, and blood disorders. The purpose of the **Disparities in Women's Health Program**, is to strengthen research in women's health at the UPR MSC National Center of Excellence in Women's Health by supporting two projects in the major causes of morbidity and mortality in women's health in Puerto Rico focusing on health disparities in women. The **AIDS and Emerging Infectious Diseases Program** serves to enhance the capabilities of the UPR MSC to conduct research in the areas of AIDS and infectious diseases. These focus areas were chosen due to the high incidence of HIV in the Island as well as the real threat that emerging or re-emerging diseases pose to Puerto Rico, a tropical Caribbean island. The multidisciplinary program allows the integration of the resources and expertise needed by our basic and clinical scientists to accomplish their goals. The program consists of two components: a core facility providing state-of-the-art equipment and a training component for faculty, post-doctoral fellows and students.

The face of the HIV epidemic is being defined as affecting women, young people and ethnic/racial minorities. The intervention approaches developed for other populations, such as gay men, upper socioeconomic class and non-minority populations might not be as effective in particular for Hispanic women living with HIV. The **Women's HIV Empowerment Program** enables investigators to determine the role of personal empowerment on better adherence to HAART and its consequence on improving immune status and prolonging survival in women living with HIV. The **Division of Advancement in Research** provides opportunities for strengthening research skills, obtaining specialized services on biostatistics, epidemiology and scientific editing, rewarding role models, protecting and commercializing ideas, and accessing research-related databases. The Division of Advancement in Research consists of two components: the Specialized Research Services Program and the Faculty and Technical Research Development Program, both programs will be under the umbrella of the Research Resources.

A brief description of the research infrastructure and facilities accessible for the development of this program follows.

RCMI Clinical Research Center (CRC) – Both the Director and Associate Director of the CRC are active participants in the development of this training program. The main office of the Master of Science in Clinical Research will be located in the CRC facilities to assure and facilitate collaborative work. The CRC also has a meeting room which will be utilized for seminars, classes or meetings. The CRC has 14,000 sq. feet of space in the University Hospital and was constructed by the MSC with institutional funds at a cost of over $900,000. The facility has 9 examination rooms, 3 nursing stations, 2 procedure rooms, 2 infusion areas, two isolation rooms, one record room, pharmacy and administrative areas. The Core lab has capability for storage and initial processing of laboratory samples. Its support personnel include: One head nurse, 3 research nurses, one patient coordinator, one administrator, one administrative secretary, Biostatistical consulting services, one computer manager/biostatistician, one core lab director and one dental assistant. Medical equipment includes; EKG, Pulmonary function meter, pediatric and adult emergency carts with defibrillators. As part of the research support services the CRC provides supplies for examination and sampling of human subjects. Among these, disposable gowns, gloves, masks, vials, surgical and procedure trays, Lumbar puncture trays, IV fluids, medical examination equipment. The CRC also provides computer support and communications to the MSC and On-line services as Internet, On-line Library, and biostatistical software.

During the past two years, the center has taken a central role in coordinating and sponsoring the participation of the UPR-MSC, as a satellite site in a clinical research training course developed by the Clinical Center of the National Institutes of Health and entitled *Introduction to the Principles and Practice of Clinical Research*. This course was first given by the NIH in 1995 and represents one of the few national programs for training and education in clinical research principles and methodology. The institution is now one of only four sites in the nation to receive all 33 lectures via videoconferences. The course offers an intensive series of lectures and seminars covering diverse topics related to clinical research, grouped under 4 modules: 1) epidemiologic methods; 2) ethical issues and regulation of human subject research; 3) monitoring patient-oriented research and regulatory issues; 4) preparing and funding a clinical research study. The lectures are received via videoconferences in the long-distance learning facilities of the Medical Sciences Campus. This is expected to be a continuing activity, with the course being offered each year during the first semester of the academic year.

Research Center: The Research Center of the School of Dentistry was established to aid faculty and students in the design of scientific research in the field of dentistry in Puerto Rico. The mission of the Research Center is to advance the search for scientific knowledge and improve the practice of the profession through research in the dental sciences. The ultimate goal of the office is to encourage research activities for publications in peer review journals. A highly qualified team of human resources advises and trains faculty and students in the area of design and methodology of scientific research. The Center is fully equipped with microcomputers, videodiscs, audiovisual aids, and terminals connected to the Medical Sciences Campus Center. The Center has a full-time demographer, a half-time epidemiologist, and a statistician among its human resources. They are in charge of teaching the statistics and research design courses to the dental and post-graduate students as well as mentoring the graduate students in their research projects.

Puerto Rico Cancer Center: The Puerto Rico Cancer Center is comprised of programs in basic and clinical research, medical care, education, and community services. It also includes the Island wide Cancer Management System. The Center is part of the School of Medicine and receives funding from the government of Puerto Rico. In 1999, faculty from the PR Cancer Center at the MSC was successful in obtaining a Minority Institutions/Cancer Centers Partnership Program to collaborate with MD Anderson Cancer Center in Houston, Texas. More recently, a collaborative agreement was signed with the Lee Moffitt Cancer Center in Tampa, FL to exchange information and support interactions between clinical, basic and epidemiologist scientists in both institutions.

The Pharmacokinetic-Pharmacodynamics Laboratory: was established to characterize the pharmacokinetics and pharmacodynamics of selected drugs in the Puerto Rican population. It performs several analytical procedures for the identification of antiretroviral drugs, as well as pharmacokinetic-pharmacodynamic modeling using different software such as RSTRIP, PCONLIN and ADAPT. **The RCMI Image Analysis Resource Center:** It houses specialized equipment for performing qualitative and quantitative image analysis. Special services provided include real time image analysis, morphometry, bone histomorphometry, cell counting, grain counting for *in situ* hybridization and densitometry. **The RCMI Central Electron Microscope**

Unit: (CEMU): An additional 200 sq. ft. were added to the space occupied by the CEMU to house a JEOL 1200 transmission and scanning electron microscope. The instrument is also equipped with an x-ray fluorescence detector, which allows determination of the elemental composition of intracellular structures. All images are captured digitally, and thus, can be transferred electronically for further processing and analysis. **The RCMI Flow Cytometry Facility:** A recent upgrading of the facility includes the acquisition of a new flow cytometer with the capacity of performing four-color immunophenotyping analysis. The equipment will be available for investigators conducting clinical studies. The Flow Cytometry Facility, located on the third floor of the main building of the MSC continues to offer a variety of analyses to its users, including immunophenotyping, DNA analysis, detection of interleukins and other cytokines, analysis of cellular ploidy and analysis of mixed lymphocyte reactions, as well as sorting and cloning of cells and hybridoma production and cloning.

The Institute for Humanistic Studies and Bioethics: The goals of the Institute are to: 1) develop and strengthen the humanistic perspective within the health professions, with emphasis on Bioethics; 2) train health professionals in the comprehension, analysis, evaluation, and application of methods used in humanistic disciplines; and 3) collaborate with the MSC faculty in the promotion and development of ethical principles among students and health professionals.

The Women and Health Center, DHHS National Center of Excellence in Women's Health: The Women and Health Center of the Medical Sciences Campus was established in March 1996 in an effort to contribute to the well being of women in Puerto Rico by integrating and coordinating the incorporation of issues relevant to women and their health in the academic endeavors of the MSC. The Center is one of 16 model Centers funded by the Office of Women's Health to provide integrated and comprehensive women's health services. It operates under three major components: Education, Clinical Services and Research. The Center's objectives include: integration of faculties and programs of the Campus committed with the well being of women throughout their life cycle; offering information, orientation and educational services to the academic community and to the Puerto Rican community in general; promoting research studies of multi and interdisciplinary nature and the development of integrated services sensitive to women's needs; promoting the inclusion of issues relevant to women in the training of health professionals; stimulation of the development of female leaders in the health sciences; and fostering collaboration with similar organizations within and outside Puerto Rico.

Hispanic Center of Excellence – provides critical support required to produce fundamental changes and strengthen the creation of stimulating environment for the training of medical students and faculty development. It integrates Hispanic health issues into the curriculum of the School of Medicine, without increasing the number of hours required for the MD degree.

FILIUS Institute - FILIUS is the first and only multi-disciplinary and multi-campus research organization of the University of Puerto Rico- President's Office. The Institute conducts research and training in childhood autism, neurological disorders, correctional rehabilitation, violence prevention, mental disorders, assistive technology, and hearing loss. It has a broad array of human and physical resources that engage in interdisciplinary research on prevalence, diagnosis, treatment, and rehabilitation of Hispanic individuals with disabilities.

Puerto Rico Diabetes Data Management Center – The Puerto Rico Diabetes Control, Prevention, Research and Evaluation Project (PRDCPREP) is a Contractual Agreement between the Centers for Disease Control and Prevention (CDC) and the University of Puerto Rico, Medical Sciences Campus, Graduate School of Public Health, Department of Biostatistics and Epidemiology (Contract #200-2000-10045). Under this contract, the University of Puerto Rico offered technical assistance to the Puerto Rico health Department Diabetes Control Program (PRDCP) in order to evaluate the Puerto Rico Diabetes Surveillance System (PRDSS) and developed a plan to create the Puerto Rico Diabetes Data Management Center (PRDDMC) as a repository of surveillance plus other relevant data related to diabetes mellitus. The goal of the Puerto Rico Diabetes Data Management Center (PRDDMC) is to become a repository of information and data related to diabetes mellitus in Puerto Rico. This goal will be met by gathering, analyzing and disseminating the ongoing epidemiological information of diabetes-related areas such as prevalence, health care costs, and complications in Puerto Rico. This will promote and increase the analysis of primary and secondary diabetes data in relation to its associated risk factors, diabetes-related complications, and patterns of care of the population living with and/or at risk for diabetes in Puerto Rico.

XI. PROFESSIONAL ACCREDITATION

The proposal for the creation of this program will be submitted to the Council of Higher Education of Puerto Rico for their evaluation and approval. There is no professional accreditation.

XII. ADMINISTRATION OF THE PROGRAM

The Program Leadership/Management for the first five years of the program will be as follows:

Principal Investigator: Dr. Estela S. Estapé will serve as the Principal Investigator and Director of the UPR MSC CRECD program. She will be responsible for overall program leadership and direction. In that capacity, she will be responsible for budget management, program planning, organization, implementation, and evaluation. She will be assisted in these duties and responsibilities by the program key personnel described below and will use the organization structure also described and shown below. Dr. Estapé will be assisted in program management by the Co-Director, Dr. José Rodríguez-Orengo, and by the two Associate Directors for Clinical Research, Drs. Julio Benabé and Clemente Díaz. These four leaders will work in close communication and in collaboration with other members of the Executive Committee, the Admissions Committee, the Evaluation Committee, the Curriculum Advisory Committee and the External Advisory Committee. The Director, Dr. Estapé, will be directly responsible for the academic administration of the program, and Dr. Rodríguez-Orengo, the Co-Director, will be responsible for the coordination and implementation of the curriculum. The two Associate Directors for Clinical Research, both physicians and established clinical researchers, will provide additional breadth in patient-oriented research.

The Program Director, Dr. Estela S. Estapé, is the Dean of the College of Health Related Professions at the Medical Sciences Campus. Her position as a Dean of the institution will provide her leadership to motivate her colleagues to collaborate in this program. She has a doctorate degree in pharmacology/toxicology, with post-doctoral training in electrophysiology at Mt. Sinai School of Medicine. Dr. Estapé conducted research as a Merit Review Investigator of the Veteran's Administration for 13 years studying the relationship between cataractogenesis and salt-sensitive hypertension. This experience will facilitate communication and collaboration with SJVAMC. In addition, during her tenure as Dean, Dr. Estapé completed a clinical research pilot project to measure human serum digoxin-like immunoreactive factor (DLIF) as a potential marker for stroke-proneness. This study protocol was approved by the SJVAMC and MSC Human Subcommittees and funded by RCMI-CRC for a one-year period. She has also successfully mentored and graduate 5 master and 3 PhD's students during the last seven years. She has developed a Master of Science Program in Clinical Laboratory Sciences, which is specially tailored to practicing health professionals and initiated the development of a proposal to create a new PhD program in Health Related Sciences with specializations in Clinical Laboratory Sciences, Speech Pathology, Audiology and Physical Therapy. She created the Office for Research and Development at the College of Health Related Professions, which led to the first research institute at the UPR, named the FILIUS Institute. Dr. Estapé is also active in health policy-making and research advocacy locally in Puerto Rico and nationally as well. She has been an active member of the Research Committee of the American Heart Association, Florida/Puerto

Rico Affiliate and member of its Board of Directors for the past three years. One of her contributions was to help create a pilot project for the American Heart Association to increase the participation of women and minorities in research. Dr. Estapé is member of the Board of Directors of the Association of Schools of Allied Health Professions and was invited by the U.S Secretary of Health to serve on an Advisory committee for the Division of Interdisciplinary, community-based program, HRSA. Dr. Estapé has committed 25% of her time to this grant.

The Program Co-Director, Dr. José F. Rodríguez is Associate Professor at the Department of Biochemistry, School of Medicine. He has been actively involved in clinical research for nine years, when he was named Site Pharmacologist for the Pediatric AIDS Clinical Trials Unit (PACTU) at the Medical Sciences Campus. He is also Site Pharmacologist for the Adult AIDS Clinical Trials Unit (AACTU). He has trained at NIH and St. Jude Children's Research Hospital. He was named Director of the Biochemical Pharmacology Laboratory and has developed several trials in collaboration with Dr. Clemente Díaz, Director of the PACTU. One of the pediatric trials under the supervision of Dr. Rodriguez was Pediatric AIDS Clinical Trials Group study 153, a pharmacokinetic interactions study of IFN-alpha with zidovudine in HIV-infected children. Dr. Rodriguez has been a member of the PACTG Pharmacology Committee and the Adolescent Committee since 1997 and recently elected to the AACTG Pharmacology Committee. In 1995, Dr. Rodríguez was awarded an RO1 to perform clinical studies in the intracellular pharmacologic aspects of nucleoside reverse transcriptase inhibitors active metabolites in the HIV-infected population. Recently, Dr. Rodriguez has conducted several clinical trials in partnership with Dr. Jorge Santana, Director of the Adult-ACTU (AACTU). Drs. Rodriguez and Santana have performed intensive pharmacokinetic studies of zidovudine-trphosphate (ZDV-TP) and lamivudine-triphosphate (3TC-TP) in HIV-infected adults. In addition, the team recently completed the clinical trial to determine if previous exposure to zidovudine has an effect in the phosphorylation of stavudine-triphosphate. They have begun another clinical trial to determine the effect of ribavirin in the phosphorylation process of zidovudine in HIV-HCV co-infected patients. Another RO1 was awarded last year to Dr. Rodriguez and Dr. Santana to perform this clinical study. GlaxoSmithKline has recently contacted Dr. Rodriguez to perform a pharmacokinetic study: COD 10001.

Dr. Rodríguez is Co-chair of a PACTG clinical study P1012 with Dr. Pat Flynn and Dr. John Rodman, both of St. Jude Children's Research Hospital. The group will compare the steady-state pre-dose amounts of ZDV-TP and 3TC-TP in peripheral blood mononuclear cells when the same total daily dose of combivir is administered once versus twice daily. At the present time the Puerto Rico site had accrued 4 patients for this particular study. In addition, Dr. Rodriguez is the Protocol Pharmacologist for PACTG 369, the first international Phase I/II collaboration study between the PACTG and the Republic of South Africa. This study will determine the maximum tolerated dose and the pharmacokinetics of nitazoxanide for cryptosporidium treatment in HIV-infected children. Dr. Rodríguez has also performed clinical trials to determine the glutathione levels in HIV-infected children. Recently, he performed studies to determine the homocysteine levels in Puerto Rican patients with presumptive cardiovascular problems and began collaborations with Dr. Norma Anderson in Jamaica to study homocysteine concentrations in women with pre-clampsia. In 1999, Dr. Rodríguez was Associate Dean for Biomedical Sciences at the School of Medicine. Through his efforts, a working relationship was established between the Mayo Clinic Graduate Program, directed by Dr. Richard McGee, and the UPR-School of

Medicine. The first UPR-medical student was accepted in Mayo's M.D.-Ph.D. program in 1999. The student will undertake his M.D. studies at the University of Puerto Rico and the Ph.D. coursework at the Mayo Clinic. The applicant anticipates that the UPR-Mayo Clinic partnership formed to plan a Master of Clinical Research degree program will be an ideal extension of the existing relationship between the institutions. Dr. Rodríguez will share administrative responsibilities with Dr. Estapé and has committed 25% of his time to this grant.

Associate Directors for Clinical Research

Dr. Julio E. Benabé did his fellowship in Internal Medicine/Renal in Washington University, School of Medicine. He is an experienced clinical researcher and Director of the RCMI Clinical Research Infrastructure Initiative. He is also Chief of the Hypertension Section at the SJVAMC and Professor of Medicine, UPR School of Medicine. Dr. Benabé has committed 5% of his time to this grant.

Dr. Clemente Díaz received training as a clinician (Pediatrics) at the University of Maryland School of Medicine (1973-76), and in Clinical Research at the Johns Hopkins School of Medicine (Robert Wood Johnson Scholar: General Pediatric Academic Development Program (GPAD) at The Johns Hopkins Hospital 1980-83. He is an experienced clinical researcher and founding member of the Care and Research in Children with HIV.AIDS (Pediatric ACTG), and in the Multi Center Study of Perinatal Transmission of HIV, The Women and Infants Transmission Study (WITS) He has served as reviewer in the Chartered AIDS Review Committee of the National Infectious Diseases Institute (NIAID), as well as invited lecturer at the University of Maryland, and the Medical College of Virginia. He has been invited Plenary Speaker, and Faculty at National and International Meetings. Dr. Clemente Díaz has committed 10% of his time to this grant.

Executive Committee:

Selected members of the Curriculum Advisory Committee (CAC) will join the Director, Co-Director, and two Associate Directors to form the Executive Committee. This committee will consist of nine (9) members and will meet bi-monthly by conference calls, monthly when necessary and once a year as part of the CAC. The Executive Committee will be advised by the CAC and the External Advisory Committee and will serve as the body responsible for day-to-day implementation of Program policies and procedures. For the day-to-day management of the Program, they will be assisted by a 50% Administrative Coordinator and a Secretary. Some of its specific responsibilities will be to:

- Monitor and evaluate the overall effectiveness of the CRECD Program.
- Monitor and implement the specialized curriculum.
- Oversee the preparation of the Annual Summary Report of all program activities.
- Monitor and evaluate the progress of each candidate and decide whether candidates will continue or be terminated from the program.
- Review and approve the research training plans (research experience and mentors)
- Identify and recruit mentors for each of the targeted health areas.

The members of the Executive Committee are:

- Director - Estela S. Estapé, PhD

- Co-Director - José Rodríguez-Orengo, PhD
- Associate Directors - Julio Benabé, MD and Clemente Díaz, MD
- Representative from CRC – Carlos Luciano, MD
- Representative from School of Medicine – Miriam Marquez, PhD
- Representative from CHRP – Rubén García, PhD
- Representative from Mayo Clinic – Richard McGee, PhD
- Representative from SJVAMC – Francisco Muñiz, MD

Admissions Committee:
The Admissions Committee will consist of five members, also from the CAC, and will meet as necessary to interview and recommend candidates to the CAC for admission to the program.

The responsibilities of the Admissions Committee are:
- Recruitment of candidates.
- Selection of candidates.

The members of the Admissions Committee are:
- Co-Director - José Rodríguez-Orengo, Ph.D.
- Representative from the School of Medicine – Walter Silva, Ph.D.
- Representative from the CHRP – Delia Camacho, Ph.D.
- Representative from the School of Dentistry – Augusto Elias Boneta, DMD
- Representative from VA – William Rodríguez, MD

Program Evaluation Committee:
The responsibilities of the Program Evaluation Committee are:
- Systematic collection, analysis and reporting of detailed information regarding program structure process and outcomes.
- Provide pertinent information for decision making and reporting purposes.
- Detailed information is provided under the section of Program Evaluation Plan.

The members of the Program Evaluation Committee are:
- Director - Estela S. Estapé, PhD
- Program Evaluation Consultant – Veronica J. Scott, MD, MPH
- Representative from School of Medicine – Miriam Marquez, PhD
- Representative from College of Health Related Professions – María Rodríguez Frau, EdD
- Representative from Department of Health - Juan Carlos Orengo, MD, PhD
- Program Administrative Coordinator – María T. San Martín, MS

External Advisory Committee will be formed to help identify areas of strengths and weaknesses, assist in the monitoring and evaluation of the overall effectiveness of the program and provide recommendations. It will consist of three members, who will be recognized clinical researcher. The External Advisory Committee will meet once a year with the CAC.

The proposed membership for the External Advisory Committee is as follows:
- Dr. Edward D. Frohlich, MD, Alton Ochsher Clinic Foundation

- David F. Ransohoff, MD, University of North Carolina at Chapel Hill (K-30 Director)
- William E. Wilkinson, PhD, Duke University Medical Center (K-30 Director)

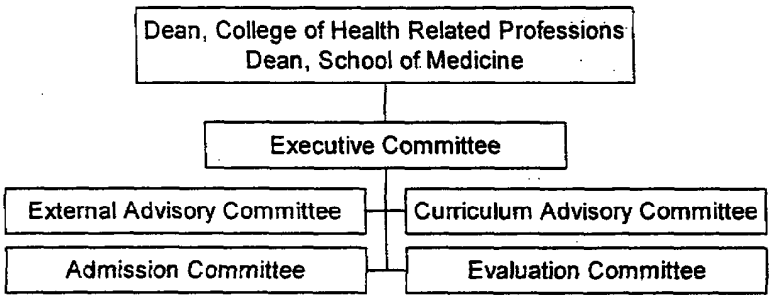
Curriculum Advisory Committee (CAC)

The Curriculum Advisory Committee will be a permanent multidisciplinary committee and will consist of academic administrator of the Medical Sciences Campus, directors of various patient oriented research programs and representatives from the Veterans Administration Medical Center, Mayo Clinic Graduate School and Department of Health. The members are listed below. The CAC will be chaired by the Director and all its members will meet at least once a year to discharge its responsibilities. As stated in the RFA, the CAC will be responsible for the recruitment and selection of candidates for the CRECD Program; the establishment and review of effectiveness of the curriculum; the approval of the education and training plans (e.g., curriculum, research experiences, mentors) for each candidate; interim monitoring and evaluation of each candidate's progress with recommendations for changes in the plan, if necessary, or termination of a candidate who is not making adequate progress; and monitoring and evaluation of the overall effectiveness of the CRECD Program. The CAC will provide a summary report with each annual progress report that describes the Committee's actions, and discusses progress of the CRECD Program, including evaluation of areas of strengths and weaknesses. As is evident from the foregoing discussion of Program Leadership and Organization Structure, most of these responsibilities will be delegated on a day-to-day basis to CAC members who form subcommittees so that program management can proceed efficiently and effectively. However, policies that determine each committee's functioning and authority will be established by the CAC operating as a single body.

The members of the CAC will be:

- Chancellor, Medical Sciences Campus, José Carlo-Izquierdo, MD
- Dean, Academic Affairs, Medical Sciences Campus, José Hawayek, MD
- Dean, School of Medicine, Francisco Joglar, MD
- Associate Dean, College of Health Related Professions – Milagros N. Vélez, EdD
- Dean, School of Dentistry, Angel Pagán, DMD
- Dean, Graduate School of Public Health, Rosa Pérez, PhD, MPH
- Dean, School of Pharmacy, Ilia Oquendo, PhD
- Dean, School of Nursing, María Rosa, PhD, DrPH, RN
- Chief, Department of Medicine, VA, Carlos Ramirez-Ronda, MD
- ACOS/Research, VAMC, Edwin Mejias, MD
- Program Director/K30ProgramMayo Clinic, Sherrine E. Gabriel, MD
- Director, Puerto Rico Department of Health, Johnny Rullán, MD, MPH
- Director, RCMI Program, MSC – Emma Fernández, PhD
- Director, FILIUS Institute, UPR - Nicolas Linares, PhD
- Members, Executive Committee
- Members, Admissions Committee
- Members, Evaluation Committee

The organization structure of the program is as follows:



XIII. FINANCIAL AID

If funded by NIH, this grant will provide salaries/stipends of up to $20,000 per year plus fringe benefits for pre-doctoral students and up to $75,000 per year plus fringe benefits to post-doctoral/faculty trainees. The amount provided will be commensurate with the institution's scale for persons of equivalent qualification, experience and rank. Up to two years of support will be provided. In addition, the grant will provide support for direct costs per year per trainee adjusted to the actual percent effort for the following types of expenses: (a) research expenses (b) tuition, fees and books (c) travel to research meetings or training (d) statistical services.

XIV. BUDGET

If the program is funded by NIH, there is no need for institutional support for the first five years.

XV. EVALUATION PLAN

The Program Evaluation Committee will assist the Director with the systematic collection, analysis, and reporting of detailed information about the implementation and outcomes of the overall CRECD program. The CRECD Director remains ultimately responsible for evaluation of the program. In order to review and revise the evaluation plan and to select/develop data gathering tools and processes, the committee will meet bi-weekly during the first three months of Year 01, and monthly through the remaining 9 months of year 01. Thereafter, meetings will be held quarterly. Local committee members will convene in a meeting room and will be joined via telephone conference call by the Evaluation Consultant. Face-to-face meetings with all members, including the Evaluation Consultant, will be held twice a year for the first two years and once yearly thereafter. One of these meetings will coincide with the CAC and EAC meeting.

Systematic and comprehensive evaluation activities will be done throughout the planning, development and implementation of the CRECD Master's Degree Program utilizing three broad program dimensions: program structure, process and outcomes. However, the major thrust of the program's evaluation will be on measuring outcomes. The overall program evaluation will focus on the administrative arrangements, plans, efforts, approaches taken, methods and procedures as well as the changes that occur over time. The evaluation information will thus enable the CRECD Director and staff to:

- document and monitor program structure, process and outcomes;
- justify budget expenditures;
- revise, update and/or prioritize program goals, objectives, and implementation approaches, as the need for modification becomes apparent;
- promote and seek continued local and national support for the CRECD Master's Degree Program; and
- ascertain the extent to which the CRECD activities contribute to the attainment of program goals, objectives, and outcomes.

Program Structure

The evaluation of program structure will fully describe the local environments and social context in which the training and other program activities take place and will provide the baseline from which the program is planned, developed, and further evaluated. Such information will help ensure that appropriate program activities eventually implemented are feasible and realistic given current levels of interest, funding, facilities, and other resources. The specific objectives for the evaluation of program structure will be to:

- clarify and prioritize the immediate and long-term program outcomes;
- specify the standards (criteria) of success for the outcomes;
- identify specific program events on which to focus during evaluation;
- develop specific evaluation procedures and instruments to study critical program events and outcomes;
- establish a timetable for specific program evaluation activities; and
- obtain baseline information on pertinent people and events.

Program Process

Specific objectives for process evaluation will be to:

- document the events and progress leading to the implementation and design;
- determine the consistency between the program's implementation and design;
- document the immediate and short-term results of the program;
- screen for new and unanticipated problems or side effects;
- establish feedback loops to modify current objectives/methodology or create new ones to achieve specific program goals; and
- facilitate communication and participation in decision-making between the CRECD Director and other program participants.

Program Outcomes

The overall program outcomes that will be evaluated are:

- Whether the development of a program infrastructure that will support and sustain the UPR post-doctoral Master of Science in Clinical Research degree program beyond the 5-year grant period occurs.
- Whether the development of a program infrastructure that will support and sustain the UPR post-doctoral Master of Science in Clinical Research degree program beyond the 5-year grant period occurs.
- Whether clinical research that seeks to reduce racial and ethnic health disparities among

the American people, especially those served by the University of Puerto Rico, is being fostered by the Program.

Trainees will not only be evaluated on the traditional dimensional changes of knowledge, skills, and attitudes, but also on other outcomes specified in advance by the CRECD program staff. The trainee outcome evaluation will determine the extent to which the implementation of the competency-based curriculum, the mentoring system, and the overall program enable the trainees to achieve the stated trainee outcomes stated below and others that may be selected during the first six months of program funding.

- Traditional trainee outcomes such as knowledge, skills, and attitudes identified by course directors, the trainee's mentors, and the trainees' research committees will be evaluated.
- Trainees will be evaluated to determine if they have achieved the competencies delineated.
- Trainees individually, and the Program overall (including faculty when appropriate), will be evaluated for the following outcomes: number of scholarly publications completed each year (both in peer-reviewed journals and books), the number of externally funded clinical research projects (especially peer-reviewed funding), the total amount of extramural clinical research funding, the number and quality of national and/or international presentations to peers on clinical research.
- Trainees will be tracked post-completion of the Program for career outcomes using the Mayo Graduate School database tracking system (e.g., track the percentage of program completers in full-time academic positions and/or the percentage of program completers in government or nonprofit research positions performing clinical research).

Health outcomes data for the six conditions will be monitored, using the HP2010 tracking databases. All six conditions are monitored to some extent in the Puerto Rican population by HP2010. During the first six months of funding, the Evaluation Committee will 1) explore the adequacy of these databases in tracking these six conditions in Puerto Rico, and 2) determine whether additional data elements need to be monitored. If the latter is found to be the case, then the Program staff will seek additional funding to collect this data. Though this Program alone will not be able to claim to have the only impact on reducing health disparities in this population, it may be possible to determine to what extent this Program does impact those outcomes.

APPENDIX 1

TABLE 3

POTENTIAL MENTORS
POST DOCTORAL MASTER PROGRAM IN CLINICAL RESEARCH
2002

CANCER			
Reynold Lopez	MD		Director Puerto Rico Cancer Center Medical Sciences Campus
Edna M. Mora	MD	Associate Professor	Director, Cancer Biology Laboratory Department of Surgery and Pathology Medical Sciences Campus
Luis Baez	MD	Professor	Chief Hematology Oncology Section San Juan Veterans Affairs Medical Center Oncologic Hospital, U. P. R.
Lesbia Hernandez	Pharm. D	Associate Professor	School of Pharmacy Medical Sciences Campus, MSC, University of Puerto Rico
Jorge Miranda	Pharm. D	Professor	School of Pharmacy Medical Sciences Campus, MSC, University of Puerto Rico
Elsa Cora	PhD	Professor	Department of Biochemistry School of Medicine, MSC, University of Puerto Rico
Adriana Baez	PhD	Professor	Department of Pharmacology School of Medicine, MSC, University of Puerto Rico
Santiago Borrero	MD	Professor	Department of Biochemistry School of Medicine, MSC, U.P.R.
HIV			
Irma Febo	MD	Associate Professor	Director Gamma Project, Department of Pediatrics, School of Medicine, MSC, U.P.R.
Jorge Sanatana	MD		Director AIDS Clinical Trials Unit School of Medicine, MSC, U.P.R.
Carmen Zorilla	MD	Professor	Director CEMI Project School of Medicine, MSC, U.P.R.
Clemente Diaz	MD	Professor	Director Department of Pediatrics School of Medicine, MSC, University of Puerto Rico

Jose F. Rodriguez	PhD	Associate Professor	Department of Biochemistry School of Medicine, MSC, University of Puerto Rico
Carlos Ramirez Ronda	MD	Professor	Chief Medical Services San Juan Veterans Affairs Medical center School of Medicine, MSC, University of Puerto Rico
Guillermo Vazquez	MD	Professor	Director Department of Microbiology and Medical Zoology School of Medicine, MSC, University of Puerto Rico
Adeline M. Nyamathi	PhD	Professor	Associate Dean of Academic Affairs University of California, School of Nursing, Los Angeles, CA
DIABETES			
Rosa Perez	MD, PhD	Professor	Dean School of Public Health Medical Sciences Campus, MSC, University of Puerto Rico
Julio Benabe	MD	Professor	Director Clinical Research Center School of Medicine, MSC, University of Puerto Rico
Emma Fernandez	PhD	Professor	Director RCMI Program School of Medicine, MSC, University of Puerto Rico
Carlos Luciano	MD	Associate Professor	Associate Director CRC School of Medicine, MSC, University of Puerto Rico
Edwin Mejias	MD	Associate Professor	Associate Chief of Staff for Research Development Chief Rheumatology Section San Juan Veterans Affairs Medical Center School of Medicine, MSC, University of Puerto Rico

CARDIOVASCULAR DISEASES			
Walmor De Mello	MD, PhD	Professor	Chairman Department of Pharmacology School of Medicine, MSC, University of Puerto Rico
Miguel A. Rivera	PhD	Associate Professor	Laboratory of Human Genomics School of Medicine, MSC, University of Puerto Rico
Luis Rodriguez	MD		Chief Cardiology Section San Juan Veterans Affairs Medical Center School of Medicine, MSC, University of Puerto Rico
Jose L. Cianchini	MD	Professor	Director Hypertension Clinic San Juan Veterans Affairs Medical Center School of Medicine, MSC, University of Puerto Rico
Pablo I. Altieri	MD	Professor	Physiology Department and Cardiology Section School of Medicine, MSC, University of Puerto Rico
Hector Banch	MD	Associate Professor	Cardiology Section School of Medicine, MSC, University of Puerto Rico
Rafael Cox	MD	Professor	Cardiology Section School of Medicine, MSC, University of Puerto Rico
Mario Garcia Palmieri	MD	Distinguished & Emeritus Professor	Director Cardiology Section School of Medicine, MSC, University of Puerto Rico
Teresa C. Juarbe	PhD	Assistant Professor	Department of Family Health Care Nursing, School of Nursing, University of California, San Francisco, CA
RESPIRATORY DISEASES			
William Rodriguez	MD	Assistant Professor	Chief Pulmonary Section & Critical Care Medicine San Juan Veterans Affairs Medical Center School of Medicine, MSC, University of Puerto Rico

Alfonso Torres	MD	Associate Professor	Staff Pulmonologist San Juan Veterans Affairs Medical Center School of Medicine, University of Puerto Rico
Edwin Alicea	MD	Assistant Professor	Staff Pulmonologist San Juan Veterans Affairs Medical Center School of Medicine, University of Puerto Rico
Sylvette Nazario	MD	Assistant Professor	Staff Allergist and Immunologist San Juan Veterans Affairs Medical Center School of Medicine, University of Puerto Rico
Jesus Casals	MD	Assistant Professor	Staff Pulmonologist San Juan Veterans Affairs Medical Center School of Medicine, University of Puerto Rico
Homero Monsanto	PhD	Professor	School of Pharmacy Medical Sciences Campus, MSC, University of Puerto Rico
ORAL HEALTH			
Augusto Elias Boneta	DMD, MSD	Professor	Director of Research School of Dentistry, MSC, University of Puerto Rico
Lydia Lopez	DMD	Associate Professor	Surgical Sciences department Oral Diagnosis Section and research Office School of Dentistry, MSC, University of Puerto Rico
Kathleen Crespo	EdD	Associate Professor	Ecological Sciences Department School of Dentistry, MSC, University of Puerto Rico
Eleuterio Bravo	DDS	Professor	Program Director Oral Cancer Education Program School of Dentistry, MSC, University of Puerto Rico
Walter Psoter	DDS, PhD	Assistant Professor	Department of Epidemiology and Health Promotion New York College of Dentistry, New York University, N.Y.
Cristina Claudio	PhD	Professor	Community Dentistry, Ecological Sciences Department School of Dentistry, MSC, University of Puerto Rico

Table 4

LIAISONS
POST DOCTORAL MASTER PROGRAM IN CLINICAL RESEARCH
2002

Rose D. Sheats	DMD	Professor	Chairman Research Committee Dental Health Specialties Mayo Foundation, Rochester, MN
James R. Cerhan	MD	Associate Professor	Health Sciences Research Department Cancer Epidemiology Mayo Foundation, Rochester, MN
Robert A. Rizza	MD	Professor	Chair Division of Endocrinology, Metabolism & Nutrition Mayo Foundation, Rochester, MN
Véronique L. Roger	MD	Associate Professor	Research Chair Division of cardiovascular Diseases Mayo Medical School Mayo Foundation, Rochester, MN
Andrew H. Limper	MD	Professor	Thoracic Diseases Research Unit Mayo Clinic, Rochester, MN