A PROPOSAL FOR A GRADUATE GROUP IN CLINICAL RESEARCH WITH A MASTER OF ADVANCED STUDY DEGREE IN CLINICAL RESEARCH

Submitted April, 2004

Revised June 4, 2004
Table of Contents

EXECUTIVE SUMMARY ................................................................................................................. 3
SECTION 1: INTRODUCTION AND BACKGROUND .......................................................................... 4
  1.1 Aim and Objectives .................................................................................................................. 4
  1.2 Historical Development ............................................................................................................ 5
  1.3 Timetable for Development ..................................................................................................... 6
  1.4 Relation of proposed program to existing programs ............................................................ 7
  1.5 Interrelationship of the program with other University of California institutions ............ 7
  1.6 Department or group which will administer the program ..................................................... 7
  1.7 Evaluation of program .......................................................................................................... 7
SECTION 2: PROGRAM ...................................................................................................................... 8
  2.1 Preparation for Admission ..................................................................................................... 8
  2.2 Foreign Language .................................................................................................................. 8
  2.3 Program of Study ................................................................................................................... 9
  2.4 Field Examinations ............................................................................................................... 10
  2.5 Qualifying Examinations .................................................................................................... 10
  2.6 Thesis and/or dissertation ..................................................................................................... 10
  2.7 Final Examination .............................................................................................................. 10
  2.8 Special Requirements over and above Graduate Division minimum requirements .......... 10
  2.9 Relationship of Master’s and Doctor’s programs ............................................................... 10
  2.10 Special preparation for careers in teaching ......................................................................... 11
  2.11 Sample Program .............................................................................................................. 11
  2.12 Normative Time from matriculation to degree .................................................................... 11
SECTION 3: PROJECTED NEEDS .................................................................................................... 12
  3.1 Student Demand .................................................................................................................. 12
  3.2 Opportunities for graduates ............................................................................................... 12
  3.3 Importance to the discipline ............................................................................................... 12
  3.4 Ways in which the program will meet the needs of society .............................................. 12
  3.5 Relationship of program to research / professional interests of faculty ........................... 13
  3.6 Program differentiation ...................................................................................................... 13
SECTION 4: FACULTY ..................................................................................................................... 13
  School of Medicine ..................................................................................................................... 14
  UCD Schools, Colleges, Departments & Affiliates ................................................................. 16
SECTION 5: COURSES ..................................................................................................................... 17
  5.1 Additional Curriculum Requirements (workshops and seminars) .................................. 20
  5.2 Staffing plan ....................................................................................................................... 22
SECTION 6: RESOURCE REQUIREMENTS .................................................................................... 22
  6.1 FTE faculty .......................................................................................................................... 22
  6.2 Library acquisition ............................................................................................................. 22
  6.3 Computing costs .............................................................................................................. 23
  6.4 Equipment ......................................................................................................................... 23
  6.5 Space and other capital facilities ..................................................................................... 23
  6.6 Other operating costs ....................................................................................................... 23
SECTION 7: GRADUATE STUDENT SUPPORT ............................................................................. 23
SECTION 8: CHANGES IN SENATE REGULATIONS ..................................................................... 23
SECTION 9: APPENDICES .......................................................................................................... 23
A PROPOSAL FOR A GRADUATE GROUP IN CLINICAL RESEARCH
WITH A MASTER OF ADVANCED STUDY DEGREE
IN CLINICAL RESEARCH

EXECUTIVE SUMMARY

This is a proposal to create a Clinical Research Graduate Group (CRGG) that will offer a Master of Advanced Study (MAS) degree in Clinical Research. The Mentored Clinical Research Training Program (MCRTP) will provide the framework and infrastructure for the CRGG and the MAS degree. The MCRTP has the endorsement and support of the Deans of the School of Medicine (SOM) and the Division of Biological Sciences (DBS) as well as the support of the School of Veterinary Medicine (SOVM), the Department of Biomedical Engineering (DBE) and many regional partner affiliates. The Dean of the School of Medicine and CEO of the Health System has allocated critical funding support for the CRGG MAS degree program. (See Letters of Support, Appendix A)

Prospective students for this program include physicians, pharmacists, biomedical and other scientists, psychologists, and nurses with advanced training. The program will equip its graduates with the knowledge and experience they need to conduct authoritative clinical and translational research, and clinical trials, leading to practical use of scientific and biotechnological advances. The graduates will obtain a set of useful and practical skills for collaborative, team-based research focused on clinical and translational questions.

The University of California, Davis (UCD) has submitted a Clinical Research Curriculum Award (K30) application to the National Institutes of Health (NIH) and review is pending. The K30 is awarded to provide support for institutional infrastructure to inaugurate or expand formal training in clinical research. With the K30, UCD would join 55 institutions nationwide (including UCLA, UCSF, and UCSD) that have received this funding. The K30 grant program reflects the belief, shared by NIH and leaders in the nation’s medical and scientific communities, that highly trained clinical researchers are needed to capitalize on the many new and profound developments and discoveries in basic biomedical science and to translate them into clinically useful therapies. The formation of a CRGG MAS degree in clinical research would respond to this critical need.

This proposal outlines a 48-unit MAS degree curriculum that students can complete in a flexible manner over a period not less than two years. Mandatory course work includes biostatistics, epidemiology, patient-oriented research, health services research, data management / informatics, scientific communication, research management, and career development. These courses, seminars, and workshops will constitute a total of 25 units. Electives (15 units) and a mentored research project (8 units) will increase the unit total to 48. The proposed Masters of Advanced Study in Clinical Research will be awarded by the CRGG upon successful completion of the program.

The overall cost of the CRGG MAS program is expected to be in line with a typical UCD graduate degree. The School of Medicine, Dean’s Office, is underwriting the CRGG MAS degree program. In addition, extramural funding may be derived from other sources such as the K30, and other training grant mechanisms as well as corporate and foundation awards. When appropriate, we envision integrating recent program graduates to participate as instructors and mentors. We estimate that the program will become self-sufficient within the first five years.

UCD’s CRGG MAS program includes a unique collaboration with faculty campus-wide (mentioned above), and with regional partner affiliates including the Veterans Affairs Northern California Health Care System (VANCHS), Shriners Hospital, Childrens Hospital Oakland
The multidisciplinary nature of the program will be captured by the formation of a new Clinical Research Graduate Group (CRGG). The CRGG MAS programs' collaborative, multidisciplinary perspective will role model the type of team-based science that will advance future patient-oriented research. In this manner, the CRGG MAS program will foster a vision of clinical research at UCD that meets the needs of the diverse communities we serve.

SECTION 1: INTRODUCTION AND BACKGROUND

Brief Description of Program

The UC Davis School of Medicine, in cooperation with the Division of Biological Sciences, the School of Veterinary Medicine, and the Department of Bioengineering, propose the formation of a new Clinical Research Graduate Group (CRGG) to award the degree Masters of Advanced Study (MAS) in Clinical Research. The CRGG MAS program will equip its graduates with the knowledge and experience they need to conduct authoritative clinical and translational research, and clinical trials, leading to practical use of scientific and biotechnological advances. The CRGG MAS program's collaborative, multidisciplinary perspective role models the type of team-based science that will advance future patient-oriented research and fosters a vision of clinical research at UCD that meets the needs of the diverse communities we serve.

The program will consist of 48 units and require a minimum of two years of study. The MAS degree by design and definition is meant to offer flexibility in execution and completion. The University of California, San Diego (UCSD) has a similar MAS degree program in Clinical Research and describes the MAS flexibility:

“As defined by the UC Academic Senate, the degree is supplemental rather than terminal; that is, it assumes students have already achieved an advanced medical or scientific degree, are studying towards one, or possess an advanced degree in a relevant healthcare or biotechnical area. Because the students already possess basic scientific and medical knowledge, the MAS degree program supplements this knowledge by showing them how to conduct and manage clinical research and deal with ethical and regulatory issues associated with such research.”

For additional information on the nature of an MAS degree and its place in the University of California educational system, see Appendix B.

The CRGG MAS degree will assist UCD in responding to a national need for highly trained clinical researchers to capitalize on the many profound developments and discoveries in basic biomedical science and to translate them into clinically useful therapies. This need has been recognized by the National Institutes of Health (NIH), which in May 1999 awarded the first of three rounds of Clinical Research Curriculum Awards (K30) to a total of 55 medical schools at major U.S. universities -- 35 in the first round, 20 in the second. UCD’s School of Medicine (SOM) has a strong proposal pending award in the current round of funding -- an acknowledgement of its national stature.

The comprehensive curriculum and mentored research embodied in the proposed MAS degree program capitalizes on strategic initiatives and institutional momentum present at the University of California Davis Health System (UCDHS). This momentum is represented by a consolidated leadership that understands, and actively prioritizes the clinical research mission and the career development of clinical researchers. The positive institutional momentum has formed a
cohesive and collaborative culture which offers a diverse and multidisciplinary environment conducive to clinical and translational mentored research. Within this collaborative atmosphere, prominent senior mentors have emerged and provide an excellent foundation for student career development and advising. In addition, strategic investments have resulted in a growing program of patient-oriented clinical and translational research, providing outstanding opportunities for mentored research experiences for students.

The CRGG MAS program seeks to graduate individuals who will conduct clinical research with full understanding of the best scientific, ethical, regulatory, and management practices. The CRGG MAS degree program is characterized by three core elements:

- **didactic instruction** to extend essential clinical research skills;
- **mentored research** experience; and
- **special experiences**, including integrated workshops which offer students advanced and more directed skills; topical seminars which offer students exposure to the conduct of clinical research in their own research area; and annual retreats during which students present their research.

### 1.1 Aim and Objectives

**Goal 1:** The CRGG MAS program will provide students the didactic training, mentored research experience, and peer support environment needed to complete innovative clinical research.

To accomplish Goal 1, a Clinical Research Graduate Group (CRGG) will offer a formal two-year curriculum leading to a MAS degree in Clinical Research. This program will include:

- A flexible and didactic curriculum tailored to the needs of the student
- Mentored research experiences using a consortium of outstanding mentors in research focus areas (cancer, infectious disease, neurosciences, vascular disease)
- Specialized workshops, seminars, and retreats to augment didactic classes
- Systematic participant evaluation, feedback, and tracking of outcomes

**Goal 2:** The CRGG MAS program will help position UC Davis as a nationally recognized clinical research leader, consistent with the identification of clinical research as a focus in our School of Medicine strategic plan.

To accomplish Goal 2, we will coordinate faculty into a Clinical Research Graduate Group (CRGG) to offer a single, highly visible, consolidated and multidisciplinary training program with significant institutional support. The CRGG MAS program will be flexible and able to respond to individual students career and professional research interests. The result will be a growing cadre of investigators with a patient-oriented research focus. Together with a series of other initiatives to improve clinical research faculty skills, study opportunities, and support infrastructures, the MAS degree of the CRGG will serve as a focal point to achieve our organizational goal of excellence in clinical research. We anticipate that over time the CRGG MAS program will aid in the recruitment and retention of nationally known faculty.

**Goal 3:** The CRGG MAS program will extend the vision and mission of clinical research beyond the School of Medicine (SOM) to other UC Davis programs and to affiliated partner sites.
To accomplish Goal 3, the proposed Clinical Research Graduate Group (CRGG) will build upon established departmental and faculty relationships in the research study areas of preclinical and clinical research, as well as bridge areas that lead to translational research. The CRGG will provide a solid foundation for the core curriculum, workshops and seminars of the MAS degree, and expert mentors for the mentored research component. An outstanding group of faculty mentors from the College of Agricultural and Environmental Sciences (CAES), the School of Veterinary Medicine (SOVM), the Division of Biological Sciences (DBS), the Department of Biomedical Engineering (DBE), Lawrence Livermore National Laboratory (LLNL), and the School of Medicine (SOM) have already been identified. (See Appendix C) The inclusion of faculty and students from these campus programs will provide a unique, multidisciplinary perspective and potential for new approaches to advance our patient-oriented research achievements.

The CRGG MAS program will also interact closely with partners at our affiliated sites, including the Veterans Affairs Northern California Health Care System (VANCHS), Shriners Hospital, Childrens Hospital Oakland Research Institute, (CHORI), and Lawrence Livermore National Laboratory (LLNL), and our Primary Care Network (PCN) to advance our vision of clinical research to meet the needs of the communities we serve. These programs will provide outstanding opportunities for mentored research experiences and will role model the type of team science that will advance future patient-oriented research.

1.2 Historical Development

The CRGG MAS degree responds to a national need for highly trained clinical researchers to capitalize on the many profound developments and discoveries in basic biomedical science and to translate them into clinically useful therapies. This need has been recognized by the National Institutes of Health (NIH), which in May 1999 awarded the first of three rounds of Clinical Research Curriculum Awards (K30) to a total of 55 medical schools at major U.S. universities -- 35 in the first round, 20 in the second. UCD’s School of Medicine (SOM) has a strong proposal pending award in the current round of funding. The NIH K30 program has emphasized the importance of participating institutions awarding a Masters degree to students as a desired priority outcome. The MAS degree appropriately represents the rigor and level of formalized training that our students will receive. The majority of successful K30 awardee institutions, nationally and in the UC system (UCSF, UCSD, UCLA), award a Masters degree. It has essentially become a national standard for Clinical Research Training programs.

1.3 Timetable for Development

2004-2005 First Year Course
- Intensive Summer Session
- Core Courses I-III (IV)
- Workshops, Seminars
- Mentored Clinical Research Project
- Annual Retreat I and Evaluation

2005-2006 Second Year Course
- Elective Courses I-IV
- Workshops, Seminars
- Mentored Clinical Research Project
- Annual Retreat II and Evaluation
1.4 Relation of proposed program to existing programs

The proposed CRGG MAS program will not impact existing campus enrollment. The estimated enrollment of 10-12 students per year will primarily be drawn from UCD post-doctoral students and junior faculty. The CRGG MAS degree program will be available to UCD faculty who wish to pursue a career in clinical research. The unique clinical research focus of the CRGG MAS degree will not significantly impact other UCD programs.

The formation of a new Clinical Research Graduate Group (CRGG) has the potential to enhance the prospect of faculty participation between Graduate Groups through bridging opportunities, e.g., clinical translational perspective for all biomedical science. Examples of potential collaborative groups are: biostatistics, epidemiology, medical informatics, neuroscience, pharmacology & toxicology, microbiology, and biomedical engineering. (See Letters of Support, Appendix A)

1.5 Interrelationship of the program with other University of California institutions

Currently, three University of California institutions (UCLA, UCSD, UCSF) have Master degree programs in Clinical Research. The programs are geographically distant and each contain components specifically tailored to the home UC campus. The UCD proposed CRGG MAS degree program is geographically distant from the current programs and contains components specifically tailored to the local UCD campus environment. For this reason, the CRGG MAS program will not be in competition with exiting programs at UCLA, UCSD, and UCSF. (See Letters of Support, Appendix A)

The proposed CRGG MAS program, similar to other successful programs includes didactic instruction in foundational clinical research skills as well as practical application of these skills through a mentored clinical research project. The UCD CRGG MAS program’s two year mentored research experience is specifically designed to offer an opportunity for practical application of the newly learned skills, and through the mentoring relationship (mentor and advisory committee), will offer the student a team-based, collaborative introduction and approach to clinical research problem-solving, and clinical career development. Additionally, an annual retreat will provide students with an off campus opportunity to practice team-based, collaborative research skills as they present their research to an Internal Advisory Committee and an External Advisory Board in a peer-reviewed format and forum.

1.6 Department or group which will administer the program

The CRGG MAS degree program administrative home will be the Dean’s Office, School of Medicine. The MAS degree program will be administered by the Clinical Research Graduate Group. The proposed Graduate Group chair is the School of Medicine’s Assistant Dean of Research, Dr. Lars Berglund. The administrative staff includes a Program Manager, and Program Representative. The UCD Graduate Council will review the Clinical Research Graduate group academic policies and processes as mandated.

1.7 Evaluation of program

The CRGG Chair will be responsible for preparing an annual report summarizing all of the evaluative measures and assessing any need for modification to the curriculum or other aspects of the MAS program. The annual report will be reviewed by the CRGG before being sent to the
Dean of Graduate Studies. In addition, the CRGG MAS degree program will follow the prescribed review processes as defined by the UCD Graduate Council. The Graduate Council’s Program Review Committee typically reviews new Master’s programs three years after students are first admitted. Thereafter, the MAS in Clinical Research program will be reviewed based on the periodic graduate program review cycle of 7 years.

SECTION 2: PROGRAM

In 1998, President Atkinson characterized the MAS as a degree program that:
- serves specific groups of working professionals with well-defined needs
- offered on a schedule and/or in a location that would increase access for working adults

The proposed CRGG MAS degree program is specifically designed to achieve the characteristic flexibility of the MAS degree. The CRGG MAS degree program’s flexibility is built into the curriculum (didactic instruction, summer session, mentored research, workshops, seminars and annual retreat), and infrastructure specifically to accommodate the needs of our working professional program participants. The time commitment to the mentor meetings and research experience is completely adaptable to the student and mentor schedule. The seminars will be offered on a variety of different days at varying times and in a variety of formats. Students will be able to choose appropriate seminars based on their research interest and available time. The integrated workshops will generally be half-day events offered at a variety of times (mornings and evenings) and days with the possibility of some workshops being offered on Saturday mornings. While the time commitment is greater than a seminar, the student still have the flexibility to choose the appropriate workshop topic and time for their individual interest and schedule. The annual retreat is an off-site weekend event that will not interfere with the student’s work week schedule. The summer session is the most intensive time commitment. Summer classes will take place Mon., Wed., Fri. from 9am to 4pm for 12 weeks. Onsite lunch will be provided to allow students to maximize the use of their time and bond as a cohort. The remaining core course work will take place during the quarter, generally on a Mon/Wed/Fri. or Tues/Thurs. class schedule with a variety of possibilities for times based upon student and instructor availability.

2.1 Preparation for Admission

Candidates must meet the following minimum requirements:
- U.S. citizens, non-citizen nationals, or lawfully admitted permanent residents of U.S.
- Completed one of the following degrees: MD, DDS, DMD, OD, ND, DO, PharmD, DVM, PhD or DNS in nursing.
- High level of interest and potential to pursue innovative pre-clinical/translational or clinical research as a major focus of career plan, and a long-term goal of entering clinical research career.

Preparation for admission to the CRGG MAS degree program includes submission of an application, a 2-4 page research proposal, a description of training plan with identified mentor, and curriculum vitae. Less experienced applicants will be guided through this process, including the choice of mentor if necessary by CRGG advisor. Letters of support from the prospective mentor and Department Chair, and commitment of release time from the candidates’ department chair or division chief will also be required.

2.2 Foreign Language

Not required.
2.3 Program of Study

a.) Specific fields of emphasis

The CRGG MAS program seeks to graduate individuals who will conduct clinical research with full understanding of the best scientific, ethical, regulatory, and management practices. In addition, the CRGG MAS program will emphasize specific fields within the four research strategic focus areas: cancer, neuroscience, vascular, and infectious disease.

b.) Plan: Masters Option II

MAS Option II: The Master’s Option II requires 36 units of graduate and upper division courses and a comprehensive final capstone event in the major subject. The proposed 48 unit CRGG MAS degree program satisfies the unit requirements.

The required final capstone event will be a comprehensive, peer-reviewed, oral and written presentation of the student’s mentored research project. The peer-reviewed written portion will be in the form of a National Institutes of Health (NIH) grant application. The NIH format is a nationally accepted standard for grant submissions and provides an excellent framework for a comprehensive and thorough overview of the student’s work throughout the entire program. The written application will be reviewed and scored by the student’s advisory committee. In addition, the capstone event will include an oral presentation before a group of the CRGG. This evaluative, peer-reviewed presentation will take place at the CRGG MAS program annual retreat.

c.) Unit requirements

<table>
<thead>
<tr>
<th>Course Work</th>
<th>Units</th>
<th>Award</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intensive Summer</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Core Courses (I-IV)</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>Seminar Series</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Workshops</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Mentored Research Project</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Elective Courses (I-IV)</td>
<td>15</td>
<td>Total: 48 Units Masters of Advanced Study in Clinical Research</td>
</tr>
</tbody>
</table>

d.) Required and recommended courses

The 48-unit curriculum can be completed in a flexible manner over a period not less than two years. Mandatory course work includes biostatistics, epidemiology, patient-oriented research, health services research, data management/informatics, scientific communication, research management, and career development. These courses will constitute a total of 25 units. A two year mentored clinical research project (8 units) and second year electives (15 units) will increase the completed MAS degree unit total to 48.

1 Guidelines for CCGA Review of MAS Programs states: “…a capstone requirement does not necessarily have to be a thesis or even a comprehensive exam. As the MAS is primarily vocational in intent, it can be expected that capstone requirements might be different from those expected in a full-time degree program.”
The expected term for completing the CRGG MAS program is two years. The intensive summer session with twelve weeks of full-time instruction will be offered at the beginning of the first year. The required core courses will extend over two years, as will the workshops, topical seminars, and mentored research. The annual retreat will be offered at the end of years one and two.

e.) Licensing or certification requirement
None required.

2.4 Field Examinations
None required.

2.5 Qualifying Examinations
None required.

2.6 Thesis and/or dissertation
Not applicable.

2.7 Final Examination
Comprehensive capstone event described above under 2.3 Program of Study, Section B.

2.8 Special Requirements over and above Graduate Division minimum requirements

The goal of the CRGG MAS degree program is to produce independent clinical researchers. The NIH format of the capstone requirement assures that graduates are well prepared and well positioned for grant submission and publication. The oral presentation component of the capstone will also prepare students for public presentation of their research. The CRGG MAS degree program graduate will have the skills and tools necessary for a career in collaborative, team-based, clinical research.

The graduates will obtain this set of useful and practical skills for collaborative, team-based research through the CRGG’s modeling of team building and collaborative organization approaches to clinical research. The CRGG MAS degree program infrastructure has built-in opportunities for students to experience and practice a team-based, collaborative approach. The half-day workshop dedicated to team-based science is an introductory event designed to help students identify, explore, and implement the personal and professional skill set necessary to succeed in a clinical research environment that is increasingly dependent upon team-based, collaborative science. Over the course of the two year program students will sharpen their collaborative skills through practical experiences and direct research applications, e.g. Annual Retreat when students present peer-reviewed research to IAC and EAB, and have an opportunity for collaborative mentoring; Advisory Committee Meetings when students present quarterly reviews of research and review career goal achievements; Topical and Journal Seminars Series create collaborative interactions and opportunities for team-based presentations, reviewed and discussed among peers. In addition, the multi-college make-up of the CRGG program and faculty will exemplify other practical aspects of a collaborative organizational, team-based effort as will the integration and utilization of advanced program participants as program teaching assistants, and potentially collaborative mentors.

2.9 Relationship of Master’s and Doctor’s programs
Not applicable.
2.10 Special preparation for careers in teaching
Not applicable.

2.11 Sample Program

Beginning with an intensive summer session, students can complete 25 units of course work (core courses, seminars, and workshops) during the first year. In addition, students will begin a two-year research project with a designated mentor (8 units). The second year students will complete course electives (15 units), and remaining seminar and workshops requirements. Depending on the personal circumstances and professional responsibilities, students may take a reduced course load.

<table>
<thead>
<tr>
<th>Intensive Summer Session (11 units)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Courses</td>
</tr>
<tr>
<td>Clinical Epidemiology and Study Design</td>
</tr>
<tr>
<td>Intro. to Clinical Research</td>
</tr>
<tr>
<td>Medical Statistic 402</td>
</tr>
<tr>
<td>Strategies for Grant Writing</td>
</tr>
<tr>
<td>Responsible Conduct of Research</td>
</tr>
<tr>
<td>Methods in Clinical Research</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Two Year Curriculum Overview</th>
</tr>
</thead>
<tbody>
<tr>
<td>YEAR I</td>
</tr>
<tr>
<td>Summer Session</td>
</tr>
<tr>
<td>Fall Session</td>
</tr>
<tr>
<td>Winter Session</td>
</tr>
<tr>
<td>Spring Session</td>
</tr>
<tr>
<td>Intensive Summer Course*</td>
</tr>
<tr>
<td>EPP 231</td>
</tr>
<tr>
<td>“Biostats. for Preclin. &amp; Trans. Research”</td>
</tr>
<tr>
<td>11 units</td>
</tr>
<tr>
<td>Core Course I</td>
</tr>
<tr>
<td>Epi 232</td>
</tr>
<tr>
<td>“Design &amp; Analysis of Clinical Trials”</td>
</tr>
<tr>
<td>3 units</td>
</tr>
<tr>
<td>Core Course II</td>
</tr>
<tr>
<td>Epi 232</td>
</tr>
<tr>
<td>“Design &amp; Analysis of Clinical Trials”</td>
</tr>
<tr>
<td>3 units</td>
</tr>
<tr>
<td>Core Course III</td>
</tr>
<tr>
<td>Epi 207 (or equivalent)</td>
</tr>
<tr>
<td>“Advanced Concepts in Epidemiologic Study Design”</td>
</tr>
<tr>
<td>3 units</td>
</tr>
<tr>
<td>Elective I</td>
</tr>
<tr>
<td>4 units</td>
</tr>
<tr>
<td>Elective II</td>
</tr>
<tr>
<td>4 units</td>
</tr>
<tr>
<td>Elective III</td>
</tr>
<tr>
<td>4 units</td>
</tr>
<tr>
<td>Elective IV</td>
</tr>
<tr>
<td>3 units</td>
</tr>
<tr>
<td>Core Course IV</td>
</tr>
<tr>
<td>NEW: “Challenges &amp; Opportunities in Clinical Research”</td>
</tr>
<tr>
<td>3 units</td>
</tr>
</tbody>
</table>

| YEAR II                     |
| Summer Session              |
| Fall Session                |
| Winter Session              |
| Spring Session              |
| Annual Retreat              |
| 1 unit                      |
| Seminar Series              |
| 1 unit                      |
| Mentored Research Experience|
| 8 units                     |

2.12 Normative Time from matriculation to degree

The normative time from matriculation to degree is a minimum of two academic years.
SECTION 3: PROJECTED NEEDS

3.1 Student Demand

During the preparation of the CRGG MAS degree program, department chairs and prospective students expressed significant interest in the program. One program participant per year will be sought from each of UCDHS' partners; the majority will be selected from UCDHS. The CRGG MAS program will draw students from several categories of potential candidates: 1) current junior faculty who have identified clinical research as a career goal, 2) junior faculty recruits who demonstrate potential to be exceptional clinical researchers, 3) senior residents and subspecialty fellows in the School of Medicine who have identified clinical research as a career goal, and 4) Ph.D.s or advanced Ph.D. students who have identified pre-clinical/translational or clinical research as a career goal.

The UCD CRGG MAS program is designed to attract senior residents and junior faculty with a commitment to careers in pre-clinical/translational and clinical research. The program will be available to individuals already at the institution and to new recruits as well as candidates from our collaborative partnerships with the School of Veterinary Medicine, the Division of Biological Sciences, the Department of Biomedical Engineering, and Lawrence Livermore National Laboratory.

In the past four years the UCDHS has recruited 434 new faculty, 291 of whom were appointed at the assistant professor level. While 97 have been appointed in a non-research series, 194 would be candidates for the CRGG MAS degree program. Of the 291 assistant professors appointed, 40.5% are women. The recruitment of new faculty is an excellent opportunity to present the CRGG MAS program to potential candidates.

3.2 Opportunities for graduates

There is an ever increasing awareness and need for highly qualified clinical investigators to meet the scientific challenges of collaborative, big team science of the twenty-first century. The CRGG MAS program graduates will be equipped with the knowledge and experience necessary to meet this growing need.

3.3 Importance to the discipline

The proposed CRGG MAS degree program will improve the quality, effectiveness and efficiency of clinical research, and open pathways of collaboration toward the practice of team-based scientific research. The CRGG MAS degree program has the potential to greatly enhance scientific research collaboration through bridging opportunities, e.g. with the pre-clinical, clinical and translational perspectives.

3.4 Ways in which the program will meet the needs of society

The CRGG MAS degree responds to a national need for highly trained clinical researchers to capitalize on the many profound developments and discoveries in basic biomedical science and to translate them into clinically useful therapies. This need has been recognized by the National Institutes of Health (NIH), which in May 1999 awarded the first of three rounds of Clinical Research Curriculum Awards (K30) to a total of 55 medical schools at major U.S. universities.
The collaborative, multidisciplinary nature and perspective of the proposed Clinical Research Graduate Group (CRGG) and MAS program role models the type of team-based science that will advance future patient-oriented research and fosters a vision of clinical research at UCD that meets the needs of the diverse communities we serve. As future networking members of the K30 Consortium the potential importance of this program transcends the local area and places UCD with other national leaders at the forefront of scientific discovery that benefits all of society.

3.5 Relationship of program to research / professional interests of faculty

The expansive and collaborative nature of the development of the MAS program along with the enthusiasm for the proposal to form a new Clinical Research Graduate Group (CRGG) demonstrates the high level of faculty commitment and interest in the CRGG MAS degree program. (See Appendix A for faculty letters of support). The high level of faculty professional interest is also evident in the number of faculty who have agreed to be available as research mentors. (See Appendix C for faculty mentor profiles).

3.6 Program differentiation

The comprehensive curriculum and mentored research training embodied in this MAS degree program capitalizes on strategic initiatives and institutional momentum present at the University of California Davis Health System (UCDHS). This momentum is represented by a consolidated leadership that understands, and actively prioritizes the clinical research mission and the career development of clinical researchers. The positive institutional momentum has formed a cohesive and collaborative culture which offers a diverse and multidisciplinary environment conducive to clinical and translational mentored research. Within this collaborative atmosphere, prominent senior mentors have emerged and provide an excellent foundation for student career development. Strategic investments have resulted in a growing program of patient-oriented clinical and translational research, providing outstanding opportunities for mentored research experiences for students.

There are no California independent university programs in the Sacramento area that offer a MAS degree in Clinical Research. There are three schools in the UC system (UCSD, UCLA and UCSF) that offer Clinical Research programs. The geographically distant locations of the UC campuses makes it highly unlikely that there would be any competition for students among the programs. No existing UC Davis graduate groups provide comprehensive instruction in clinical research.

SECTION 4: FACULTY

The Faculty listed below are interested in belonging to the proposed Clinical Research Graduate Group (CRGG). They are listed according to the four strategic research focus areas of the UCDHS, each with an abbreviated profile of their current research. The majority of these faculty have participated in the development of the proposed MAS degree curriculum and are current members of the proposed CRGG MAS degree Internal Advisory Committee (IAC). Faculty who have committed to serving as Instructors of Record (IORs), Co-Instructors of Record (co-IORs), and session presenters for the core curriculum are marked with an asterisk (*). In addition to the faculty listed below, others will serve as instructional leaders of the workshops and seminars, and be available to mentor students in the research training component. Appendix D contains abbreviated faculty Curriculum Vitae. As noted above, additional faculty who have responded positively to the call for research mentors are listed in Appendix C.
**SCHOOL OF MEDICINE**

**Vascular Biology and Metabolism**

*Lars Berglund*, MD, Ph.D, Assistant Dean for Clinical Research, School of Medicine, and Professor of Medicine. Current research: “Regulation of Lipoprotein (a) metabolism in Humans with special reference to ethnicity” NIH (R01)

*John Rutledge*, MD, Professor and Chief, Division of Endocrinology, Clinical Nutrition and Vascular Medicine. Current research: “Interactions of Lipoproteins with the Artery Wall,” National Heart, Lung and Blood Institute (R01)

*Ann Bonham*, MD, Professor and Chair, Department of Pharmacology. Current research: “Post-exercise hypotension: central sites and mechanisms,” NIH/NHLMI (R01).


*Ishwarlal Jialal*, MD, Vice-Chair for Research, Department of Pathology. Current research: “The effect of high dose vitamin E on carotid atherosclerosis” NIH (R01)


**Cancer**

*Ralph deVere White*, MD, Professor and Chair of Urology, Director, UC Davis Cancer Center, and Chair, Prostate Cancer Research Program. Current research: “Functions of different p53 mutations in prostate cancer,” NIH/NCI (R01).


*Paul Gumerlock*, PhD, Professor of Internal Medicine, Division of Hematology and Oncology. Current research: “Molecular Correlates of a Phase II Study of OSI-774 in Patients with Locally Advanced or Metastatic Papillary Histology Renal Cell Cancer,” (NIH/SAIC-Frederick), “Shed Tumor in S0003 Non-Small Cell Lung Carcinoma Patient Plasma,” (SWOG).

*Primo Lara*, MD, Associate Professor of Internal Medicine, Division of Hematology and Oncology. Current research: “Barriers to Accrual in Cancer Center Trials,” (NCI R21), “Exploiting Novel Molecular Targets in Prostate Cancer Therapy,” (American Cancer Society), “A Phase I, Open Label, Dose Escalation Study of Treatment-Naive or Previously Treated Patients with Advanced Non-Small Cell Lung Cancer or Other Solid Tumors,” (Millennium Pharm.).

*Srinivasan Vijayakumar*, MD, Professor and Chair, Radiation Oncology. Current research: “Chemoprevention of prostate cancer with finasteride [proscar] phase III” PCPT.

*Frederick Meyers*, MD, Professor and Chair, Department of Internal Medicine. Current research: “Simultaneous care: linking palliation to clinical trials,” NIH/NCI (R25)

*Laurel Beckett*, PhD, Professor, Department of Epidemiology & Preventive Medicine, and Head, Division of Biostatistics. Current research: “Alzheimer’s Disease Center, Biostatistics Core” NIH/NIA


Joy Melnikow, MD, Professor, Department of Family and Community Medicine. Current research: “Tamoxifen prevention of breast cancer: acceptance and cost effectiveness” NCI (R01).

Neuroscience

*Randi Hagerman*, MD, Professor of Pediatrics and Medical Director of the M.I.N.D. Institute. Current research: “Genotype-Phenotype relationships in Fragile X families,” NICHD (R01).

David Kilmer, MD, Professor and Chair of Physical Medicine and Rehabilitation. Current research: “Physical Activity and Energy Expenditure in Mobility Impaired Individuals,” (Department of Education pending).


*Stephen McCurdy*, MD, MPH, Associate professor-in-residence, Department of Epidemiology and Preventive Medicine. Current research: Impact of safety education on agricultural injury risk among rural California high school students (a project under the Western Center for Agricultural Health & Safety) NIOSH.


*Peter Yellowlees*, MD, Professor of Psychiatry and Associate Director Center for Health and Technology. Current research: “e-Mental Health Service” (Queensland Health), “Pilot smoking abstinence program for high risk youth,” (UQ Research grant), “Telepediatrics project,” (Queensland Health).

Infectious Diseases

Safety, Tolerability, Pharmacokinetics and Efficacy of Subcutaneous BAY 50-4798 Administration in Patients with HIV.” (Bayer Corp), “A Randomized, Double-Blind Trial of LDT (Telbivudine) Versus Lamivudine in Adults with Compensated Chronic Hepatitis B: NV 02B-007,” (Idenix Pharm.).

*Claire Pomeroy*, MD, Executive Associate Dean, School of Medicine, and Professor, Microbiology and Immunology. Current research: “Mechanisms of exacerbation of GVHD by Murine CMV in BMT” Department of Veterans Affairs.

David Asmuth, MD, Assistant Professor of Internal Medicine, Division of Infectious and Immunologic Diseases. Current research: “Multicolor Flow Users Network Study,” (NIAID R01), “A Study of Safety, Tolerability and Immunogenicity of Human Immunodeficiency Virus Type I (HIV-1) GAG DNA Formulated with CRL 1005 Adjuvant Followed by the Adenovirus Serotype 5 HIV-1”, (Merck & Co.), “Effects of Pegylated Interferon-Alpha 2A on Innate and Adaptive Immunity in SIV-Infected Macques,” (Roche Diag.), “A Phase I Dose Ranging Study of the Safety, Tolerability and Immunogenicity of the Merck Trivalent Adenovirus Serotype 5 HIV-1 GAG/POL/NEF Vaccine in a Prime Boost Regimen in Healthy …,” (Merck & Co.).


*Richard Sweet*, MD, Professor and Program Director, UC Davis, Women’s Center for Health. Current research: “Effectiveness of outpatient treatment for PID” NIH/AHCPR (R01).

*Barbara Shacklett*, PhD, Assistant Professor of Medical Microbiology and Immunology. Current research: “Modeling Lymphocyte Trafficking into the CNS in Aids,” (NIMH/UCSF Pending).

**UCD SCHOOLS, COLLEGES, DEPARTMENTS & AFFILIATES**

*Phyllis Wise*, PhD, Dean, Division of Biological Sciences and Professor Neurobiology, Physiology and Behavior. Current research: “Neurochemical and neuroendocrine function during aging,” NIH (R01)

*Faith Fitzgerald*, MD, Assistant Dean of Humanities and Bioethics (UC Davis School of Medicine). Current publications: “Dark Rounds. Annals of Internal Medicine,” “Principalism at the Bedside,” and “Preventive Medicine and the Road to Hell”

Fitz-Roy Curry, PhD, Associate Dean of Research, Chair, Department of Human Physiology. Current research: “New approach to endothelial cleft structure” NIH (R01).

*Jesse Joad*, MD, Assistant Dean, Faculty Development and Diversity, Professor of Pediatrics. Current research: “ETS worsens RSV bronchiolitis by cysteinyl lenkotrienes” (Flight Attendan Medical Research Institute) “ETS effects on breathing patterns” (California Tobacco Related Diseases Research Program), “Pulmonary effects of environmental oxidant pollutants” (NIEHS PPG, project leader)

School of Veterinary Medicine

*Kent Lloyd*, DVM, PhD, Associate Dean, Research and Graduate Education. Current research: “sst2 receptors and regulation of gastric secretion” NIH (R01)

Phillip Kass, DVM, PhD, Associate Professor, Department of Population Health and Reproduction (School of Veterinary Medicine). Current research: non-experimental inferences, epidemiologic methodology and analysis, epidemiology of environmental hazards of animals and humans, companion animal epidemiology of cancer.

Peter Moore, BVSd, PhD, Professor, Department of Pathology/Microbiology and Immunology (School of Veterinary Medicine). Current research: immunopathology, leukocyte adhesion molecule biology, leukocyte antigen biology, canine/feline hemolymphatic neoplasia, feline immunodeficiency virus induced disease.

Erik Wisner, DVM, PhD, Professor, Department of Surgical and Radiological Sciences (School of Veterinary Medicine). Current research: Tissue specific contrast media development, targeting mechanisms for contrast media delivery, and molecular imaging.
**Katherine Ferrara**, PhD, Professor and Chair, Biomedical Engineering. Current research: “High Resolution Blood flow mapping in Ocular tissues,” NIH (R01).

**Julie Sutcliffe-Goulden**, PhD, Assistant professor, Department of Biomedical Engineering and visiting scientist, LBNL, Berkley. Current research: “A preliminary assessment of the role of fluorothymidine in the evaluation of tumors and infection with PET”

**Lawrence Livermore National Laboratory**

**Dennis Matthews**, PhD, Professor, Department of Neurological Surgery. Current research: Center for Biophotonics Science and Technology, NSF. Goal: To develop applications of photonic technology to life sciences in medicine with education outreach and knowledge transfer components.


**Stavros Demos**, PhD, Scientist and Adjunct Associate Professor (UC Davis School of Medicine). Current research: “Spectroscopic Evaluation of Tissue Injury,” (NSF), “Laser Induced Damage in Optical Materials,” (LLNL LDRD ER).

**SECTION 5: COURSES**

**Existing courses for Year I:**

**Introduction to Clinical Epidemiology and Study Design Epi 250** This long established course provides the skills to conduct epidemiologic research relevant to the student’s field of clinical research. The course includes both didactic and hands-on workshop sessions. The student will understand the anatomy and physiology of conducting clinical epidemiologic research, be familiar with three basic study designs (cross-sectional, case-control, and cohort including experimental trials) and be able to discuss their conduct, strengths, and limitations, identify sources of secondary data and discuss their strengths and limitations, including meta-analysis, discuss principles of measurements in clinical epidemiological studies, including the use of questionnaires, precision, accuracy, sensitivity, specificity, and predictive accuracy, discuss basic methods for analyzing data, including descriptive and analytic statistical approaches and discuss ethical issues involved in conducting clinical epidemiologic research. Instructors of Record (IOR): P. Romano, Professor of Medicine and Pediatrics; S. McCurdy, Associate Professor of Epidemiology and Preventive Medicine. They have teamed to teach this course for many years.

**Medical Statistics 402** This is an established UC Davis course in biostatistics. Course content includes statistics in clinical, laboratory, and population medicine; graphical and tabular presentation of data; probability, binomial, Poisson, normal, t-,F-, and chi-square distributions, elementary non-parametric methods, simple linear regression and correlation, life tables. Microcomputer applications of statistical procedures in population medicine. This course emphasizes biomedical applications of statistical methods. 3 hours lecture 2 hours lab per week, 6 weeks IOR : Jacob Wegelin, Asst. Professor of Epidemiology and Preventive Medicine.

**Biostatistics for preclinical and translational research EPP 231:** This is a new UC Davis course in biostatistics. The prerequisite is Medical Statistics 402 or the equivalent. Course content includes introductions to design of preclinical and translational experiments and design
of correlative studies; multivariate linear regression; analysis of variance and other techniques for nested, factorial and repeated measures designs; pharmacokinetic and bioassay models; multivariate data. Special topics will include construction of data summary measures, the analysis of genomics data such as microarrays, and graphical representations of complex data. The course is designed to provide a foundation for research design, collaboration with biostatisticians, and routine analysis of quantitative measurements in medical research. IOR: A. Tsodikov.

**Advanced Concepts in Epidemiologic Study Design Epi 207** This course or an equivalent course provides the student with in-depth integration of advanced concepts in study design, with theory and examples, including confounding, effect modification under additive and multiplicative models, internal and external validity, bias, misclassification etc. The course is designed to provide the student with a thorough knowledge and understanding of the theory and practice of designing experimental and non experimental epidemiologic studies. IOR: P. Kass.

**Design and analysis of clinical trials EPP 232**: This is a new UC Davis course in biostatistics. The prerequisite is Medical Statistics 402 or the equivalent. Course content includes Phase I, II and III clinical trials; sample size, power, stopping rules and interim analyses; sources of bias and error in clinical trials; analysis when outcome is survival, response, or measured change; monitoring, audits, and reports; safety and regulatory issues; and writing the clinical trial paper. The course parallels STA/BST 225, a course for doctoral students in the Graduate Groups in Biostatistics and Statistics, developed by Dr. Beckett and faculty in the Department of Statistics, with an emphasis on rigorous treatment of the statistical methodology. The parallel coursework offers the opportunity for joint lectures on common topics and for pairing biostatistics students and clinical researchers for projects and possible subsequent collaboration during mentored research projects (required for clinical research students) and applied internships (required for biostatistics doctoral students.) IOR: L. Beckett.

**New courses for Year I:**

**Introduction to Clinical Research** The purpose of this new course is to provide an introduction to the CRGG MAS degree program and an overview of major clinical research topics that will be taught in further depth during the two year curriculum. The course will combine didactic lectures (“Approach to Clinical Research”) and presentations by successful clinical researchers describing practical experiences (“Experiences in Clinical Research”). Students will understand the expectations and goals of the program and their role in the program. Students will acquire basic knowledge needed to pursue clinical research training, including the mentored research project. Students will meet successful role models and understand the opportunities and challenges of clinical research. IOR: F. Meyers, Professor and Chair, Department of Medicine; C. Pomeroy, Professor and Executive Associate Dean.

**Strategies for Grant Writing** This is a well established course at UC Davis. The purpose of this course is to provide the student with the skills and strategies to write a successful career development proposal and eventually an independent research award. The course will combine interactive presentations with assignments that will result in a completed proposal by the end of the summer. IOR: J. Rutledge, Professor and Vice Chair for Research Department of Internal Medicine.

**Responsible Conduct of Clinical Research** The object of medical research is to extend knowledge and improve the prevention and treatment of human disease. Progress in medicine is critically dependent on the validity of the research and the integrity of the researchers. There are several core elements to the responsible conduct of medical research, and it is imperative
that researchers have a clear knowledge and understanding of these elements. This ten-week course includes the nine NIH-mandated modules: Data Acquisition and Reporting (Beckett), Mentor Training (Pomeroy / Gandara / Rutledge), Publication Practices and Authorship (Lloyd), Peer Review/Grant Process (Rutledge / Curry), Collaborative Science (Lloyd), Human Subjects (Wun / Hobbs), Research with Animals (Cardiff), Conflict of Interest/Commitment (TBD), and Research Misconduct (Gilad). A tenth module, Entrepreneurship/Industry Collaborations / Intellectual Property/Technology Transfer (Lam) has been added.

Class sessions will have the following format: An in-depth introduction of the topic, defining relevant terminology, legislation, and major issues. This presentation is followed by an active class discussion engaging participants to share case-based applications of the theme topic to example derived from either personal experience and/or journal texts. The open debate will lead participants to reflect and review upon their own positions and personal views with regard to the complex research topic applications. The course will be based on the content of journal articles and material from the following textbook: *Responsible Conduct of Research*, A.E. Shamoo and D.B. Resnik, Oxford University Press, 2003, IOR: T. Wun, Associate Professor of Medicine and Chief Division of Hematology, VAMC; J. Hobbs BSN Director of the UC Davis Clinical Trials Support Unit

**Methods in Clinical Research** The purpose of this new course is to provide an overview of major approaches to clinical research, including health services research techniques, informatics, using the General Clinical Research Center (GCRC), and preclinical methodologies available to enhance clinical projects. The course will provide an overview of the clinical research support infrastructure available at UC Davis. The course is designed to serve as a framework for CRGG MAS program students as they pursue mentored clinical research projects. Students will understand the range of methodologies that can be applied to clinical research. Students will meet key individuals that they can contact for assistance/guidance during the mentored research experience. Students will acquire a multi-disciplinary perspective about clinical research. The course will be divided into 3 blocks as outlined below.

- **Health Services Research and Informatics** The objective of this module is to provide the student with the understanding of the interaction between patient characteristics, physician/provider characteristics, the process of delivering care and outcome measurements. Quality of life and quality of care outcomes will be emphasized. Barriers to care in large populations and individual doctor – patient communication will be taught by example. The use and pitfalls of electronic medical record systems will be modeled. IOR: R. Kravitz, Professor of Medicine; P. Yellowlees, Professor of Psychiatry and Associate Director Center for Health.

- **Clinical Research Support Facilities** This module will provide the student with didactic and experiential knowledge in the successful completion of clinical research. Students will tour and be provided demonstrations of the value of the UC Davis Clinical Research Investigator Services Program (CRISP) and the General Clinical Research Center (GCRC). Didactic presentations during the module will include data base management, sequential development of clinical trials and laboratory based correlates of clinical investigation. Case based discussions will be emphasized in the didactic sessions. IOR: I. Jialal, Professor; L. Berglund, Professor and Director of GCRC; J. Hobbs, BSN, Director, Clinical Trials.

- **Pre-Clinical Models to Support Clinical Research** This section will provide the student with didactic and experiential experiences in the use of pre-clinical models of clinical research. Tour and demonstrations of the Microarray Facilities/ Genomics/ and Imaging
Specific topics to be covered include primate models of human disease (Solnick, Dandekar, Tarantal), use of mouse models to study human disease (Cardiff), molecular pharmacology and diagnostics (Gumerlock, Knowelton), genomic analyses (Dandekar, Mitchelmore), and imaging techniques (Ferrara, Carter). IOR: K. Lloyd, Associate Professor and Associate Dean for Research; S. Dandekar.

**Challenges and Opportunities in Clinical Research**

This course uses case studies to challenge the student to critique and analyze patient oriented research. Emphasis will be placed on either large epidemiologic studies e.g. Hormone Replacement Therapy and CV risk or molecular epidemiologic correlates e.g. molecular markers of breast cancer to predict recurrence. The student will be expected to read the assigned study, understand the scientific underpinnings and design and provide a critique including an alternative plan. A written as well as oral presentation is expected. IOR: F. Meyers, Professor and Chair, Department of Medicine; C. Pomeroy, Professor and Executive Associate Dean.

In addition to these Year I courses, the student is required to participate in a minimum number of workshops and seminars that will be offered throughout the two year program. Another required component of the CRGG MAS program is the on-going mentored clinical research project. The mentored clinical research project requires regular mentor meetings and 4 written reports over two years. In addition the student will meet with an advisory committee and prepare a comprehensive capstone event as described above in section 2.3 Program of Study.

Year II of the CRGG MAS degree program will consist of four graduate level elective courses. The student, with the assistance of his/her mentor and advisory committee, will choose these electives based on research experience and interest, expertise and clinical study career growth. The same mentored research, seminar, and workshop requirements apply to Year II.

Year II course elective options include new CRGG MAS program courses in development and existing courses from other graduate group programs.

**New Course(s) for Year II [in development]:**
- Statistical Genetics
- Clinical Pharmacology
- Clinical Trials
- Molecular Methods in Clinical Research
- Outcomes Research
- Clinical Research with Diverse Communities
- Ethical Issues in Clinical Research

**Existing Courses for Year II:**
- MDI 210: Introduction to Medical Informatics (2 units, TBA)
- MDI 209: Clinical Data Acquisition (4 units, Malyj)
- MDI 289F: Medical Applications of Databases (3 units, Staff)
- MDI 290: Special Topics in Medical Informatics (Cardiff)
- GGG 296: Scientific Professionalism and Integrity (2 units)
- EPP 273: Health Services Administration (Dr. Leigh and Dr. Troidl)
- EPP 499: Research in Community and International Health (Staff)
- PHR 404: Medical Statistics III (Farver)

**5.1 Additional Curriculum Requirements (workshops and seminars)**
In addition to the mentored clinical research project, students must complete 8 workshops (4 required and 4 elective) and attend 20 seminars over the course of the program.

The following workshops are required:

<table>
<thead>
<tr>
<th>Workshop Topic</th>
<th>Instructor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Team Science</td>
<td>Matthews</td>
</tr>
<tr>
<td>Research Project Management/Conflict Management/Team Building</td>
<td>Crumley</td>
</tr>
<tr>
<td>Strategic Clinical Research Career Development</td>
<td>Meyers/Pomeroy</td>
</tr>
<tr>
<td>Biomedical Ethics</td>
<td>Rich</td>
</tr>
</tbody>
</table>

The following workshops are elective:

<table>
<thead>
<tr>
<th>Workshop Topic</th>
<th>Instructor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Qualitative Research Methods</td>
<td>Paterniti</td>
</tr>
<tr>
<td>Clinical Research Aspects of Bioengineering</td>
<td>Ferrara</td>
</tr>
<tr>
<td>Medical Pharmacogenomics and Developmental Therapeutics</td>
<td>Lam/Gumerlock</td>
</tr>
<tr>
<td>Nutritional and Metabolic Analysis</td>
<td>Berglund/Jialal</td>
</tr>
<tr>
<td>Advanced Medical Informatics and Database Management</td>
<td>Yellowlees</td>
</tr>
<tr>
<td>Technology Transfer and Academic-Industry Partnerships</td>
<td>Chronister</td>
</tr>
<tr>
<td>Working with the Media/Public Relations</td>
<td>Hyatt</td>
</tr>
<tr>
<td>Drug Discovery: Preclinical Phase I, II, III, IV</td>
<td>Bonham</td>
</tr>
<tr>
<td>Clinical Research at Community Partners</td>
<td>Seigel(VA), King (CHORI), Matthews (LLNL), Greenhaugh (Shriners)</td>
</tr>
</tbody>
</table>

The student, in discussion with their advisory committee, will choose the most appropriate seminar series based on their particular research interest and clinical career growth needs.

Seminars (existing series at UC Davis)

- Cancer Center Seminar Series
- Center for Neurosciences Seminar Series
- Treadwell Vascular Seminar Series
- Microbiology/Infectious Disease Seminar Series
- Center for Comparative Medicine Seminar Series
- Stem Cell/Regenerative Medicine Seminar Series
- General Clinical Research Center Seminar Series
- Basic Sciences New Faculty Seminar Series

A new seminar series is being developed entitled, “Hot Topics in Clinical Research,” and will review topics of general interest in clinical research.

Annual Retreat

At the end of each year, the CRGG MAS program students will participate in a two day, off-campus, retreat. The annual retreat will offer students an opportunity to gather and reflect upon their experience and present their research to the External Advisory Board (EAB) and the Internal Advisory Committee (IAC). As mentioned above, this forum will provide students the opportunity to practice and experience collaborative mentoring with their peers and the CRGG program faculty. The retreat presentations will allow students to learn about clinical research in
other areas, and provide an environment for them to engage in multi-disciplinary cross-talk with peers and mentors.

The retreat also provides the opportunity for a formal and extensive program evaluation. The EAB, IAC, and CRGG students and faculty will evaluate all aspects of the program. In addition, each student will have an opportunity to review and evaluate their career development goals, and discuss them with their mentor and/or member of their advisory committee. Lastly, the CRGG faculty will review student progress as independent researchers and provide recommendations for each student.

5.2 Staffing plan

The proposed curriculum for the CRGG MAS program is a combination of new courses and current courses. The expansive and in-depth nature of the CRGG MAS program curriculum with ongoing seminars, workshops and mentored research project, warrants and requires the formation of a new Clinical Research Graduate Group (CRGG). The proposed Chair of the CRGG is the Assistant Dean of Research in the School of Medicine, Dr. Lars Berglund.

The proposed CRGG will be responsible for the content and quality of the MAS program curriculum. In addition to our core instructors who have primary appointments in a variety of different departments, we plan to employ teaching assistants (most of whom will be recent students) to assist in homework correction and seminar preparation. The CRGG MAS program will also have the support of a program manager.

SECTION 6: RESOURCE REQUIREMENTS

No additional new resources from campus will be required for the CRGG MAS degree program. Program costs, including but not limited to faculty instructional costs, program support costs, student services costs, and overhead will be covered by student fees and other non-state funds. The CRGG MAS program has been identified as a priority area of investment for the School of Medicine and the UCD Health System. The School of Medicine, Dean’s Office and UCDHS will provide funding for the program. The major institutional commitment to the CRGG MAS degree program includes both in-kind and actual dollar support as well as important release time for potential student participants (see Letters of Support, Appendix A). Students will pay regular graduate fees and tuition. The student fees will not fully cover the CRGG MAS program costs. The remaining costs will be absorbed by a combination of non-state funds (School of Medicine, Dean’s Office and UCDHS), and recruitment packages and department support. Additional support will be sought from corporate and foundation awards (common at other campuses).

The School of Medicine Dean’s Office will be the administrative home for the CRGG MAS program. The CRGG MAS program administrative support and overhead (personnel, equipment, space, etc.) will be supported by the Dean’s office.

6.1 FTE faculty
No new faculty required.

6.2 Library acquisition
No new library acquisitions required. The current Health Sciences Library holdings will support the needs of the CRGG MAS program.
6.3 **Computing costs**
No new computing costs required.

6.4 **Equipment**
No new equipment required.

6.5 **Space and other capital facilities**
None required. The CRGG MAS will make use of existing classroom and laboratory facilities.

6.6 **Other operating costs**
The CRGG MAS program administrative support and overhead (personnel, equipment, space, etc.) will be supported by the Dean’s office.

**SECTION 7: GRADUATE STUDENT SUPPORT**

It is anticipated that most of our students will be supported by their clinical home departments through release time, training grants and other internal and/or extramural training grants.

**SECTION 8: CHANGES IN SENATE REGULATIONS**

No changes in Senate Regulations will be required.

**SECTION 9: APPENDICES**

Appendix A: Letters of Support
Appendix B: Nature of MAS degree in the UC educational system
Appendix C: Faculty Mentor Profiles
Appendix D: Faculty Abbreviated Curriculum Vitas