Establishing a 5-Year Combined MD/MAS Program in Clinical Research at the UCSF School of Medicine
Final Proposal V.10  September 17, 2009

Background. As part of the Pathways to Discovery Program initiative at the UCSF School of Medicine, the Clinical and Translational (C&T) Research Pathway was established in 2008. One major stated goal of the initiative is to create streamlined, coordinated, accelerated courses of study within both undergraduate and graduate medical education with opportunities for obtaining certificates and advanced degrees.

A two-year Master’s of Advanced Studies (MAS) degree is offered in clinical research as part of the UCSF Training in Clinical Research (TICR) Program. It is sponsored by the Department of Epidemiology and Biostatistics and the Clinical and Translational Research Institute (CTSI). The MAS is intended for advanced pre-doctoral students, post-doctoral fellows and faculty members who wish to master clinical research methods and pursue independent research careers. Course work extends beyond that required for the one-year Advanced Training in Clinical Research (ATCR) Certificate Program to include instruction in advanced epidemiologic and biostatistical methods and specialized topics such as outcomes research, medical informatics, molecular methods in clinical research, clinical trials and decision and cost-effectiveness analysis. In addition to 36 quarter-units, requirements include a comprehensive review of the literature in the scholar's field, presentation of original work at a national scientific meeting and publication of a peer-reviewed manuscript. An abridged but more extensive description of the program is included in the Appendix and a full program description is available at http://www.epibiostat.ucsf.edu/courses/masters.html.

Proposal. Obtaining an MD degree and MAS degree sequentially would require 6 years of training. To achieve our goal of offering accelerated courses of study with opportunities for obtaining advanced degrees in C&T research, we propose offering a combined 5-year MD/MAS degree for select students in the School of Medicine.

Desirability and feasibility. The C&T Research Pathway Directors (Sawaya, Bauer) conducted preliminary meetings with representatives of the SOM Dean’s Office (Loeser, Mitchell, Bell) and TICR Program leadership (Martin) to assess desirability of the combined program and explore “fit” within the envisioned new curriculum. The program was deemed desirable, valuable and in sync with the structure of the new curriculum. One critical component was establishing an on-going clinical experience that would satisfy requirements of the MD degree during the year when students would be focused on MAS coursework. Embedding the clinical experience into existing programs (PISCES: Robertson, Mazzotti, Poncelet and Model SFGH: Vener) was explored, and consultation from leaders of other combined degree programs was obtained (PRIME: Wilson). Ultimately, leaders decided to utilize a more flexible model of enhanced longitudinal enhanced clerkships (LEC). Subsequent meetings (Sawaya, Loeser, Mitchell, Martin, Bauer) focused on program feasibility, ironing out the month-by-month details and assuring that at least one model for course work and clinical experiences, if followed precisely, would translate into awarding of the MD/MAS (assuming satisfactory
(completion of all required elements). This standard template model is included in the attached Table; individualization of schedules is anticipated.

**Longitudinal Enhanced Clerkship (LEC):** The objective of the LEC is to maintain and improve clinical skills during the time the student is primarily learning research methods and conducting research. Currently, MAS classes are offered all day Tuesday and Thursday; electives will likely be offered on Wednesday mornings in the next academic year. The current class schedules are available at [http://rds.epi-ucsf.org/tier/MasterSchedule/MasterScheduleResults.asp?academicyear=2009-2010&quarter=Summer&course=All&selected=1](http://rds.epi-ucsf.org/tier/MasterSchedule/MasterScheduleResults.asp?academicyear=2009-2010&quarter=Summer&course=All&selected=1). To provide an experience equivalent to a 6-week clinical clerkship, the LEC will include a minimum of 60 half-days or 30 whole days. The LCE may be modeled after the PISCES clinical experiences. All work completed as part of the LEC must have prior authorization from the appropriate core clerkship directors to assure adequate granting of credit. The Medicine and Pediatric clerkships may provide this flexibility.

**Student funding.** Funding for the MAS program is currently provided by the PACCTR Program, an NIH-funded program housed within the UCSF CTSI. Currently, two PACCTR students are enrolled in the MAS program (total length of training for the MD/MAS degree: 6 years); the PACCTR Program covers tuition and stipends. The precise funding for the 5-year combined program has not yet been determined; use of federal sources as currently used in the 6-year program may not be applicable to the 5-year program as conceived. Other potential sources include grants, loans and scholarships and are to be determined.

**Administrative structure, stewardship and budget.** The Program will be administered by a Program Director with administrative support from the Pathways to Discovery Program (as has been designated for the C&T Research Pathway). Administrative support for student enrollees will be provided by the current MAS support structure from the CTSI; stewardship of Pathways-specific administrative needs (e.g., coordination of the students’ longitudinal enhanced clerkships) will be coordinated through the administrative funding provided by Pathways program. In addition to the program leadership, an advisory council will be established. Current and former students involved in research programs at UCSF (e.g., C&T Research Pathway, PACCTR) will be invited to participate to assure feasibility and responsiveness to student concerns and curricular goals.

**Evaluation and tracking.** Students will be evaluated and tracked by the same mechanisms that have been established for the PACCTR and MAS Programs.

**Timeline.** This program will be advertised in the Fall to first- and second-year medical students; applications will be accepted from second-year medical students in January 2010. Successful applicants will be informed of their acceptance in February 2010 and will begin course work in August 2010.

**Contact:** The contact person for this proposed program is C&T Research Pathway Director George Sawaya, MD ([sawayag@obgyn.ucsf.edu](mailto:sawayag@obgyn.ucsf.edu)).
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Italicized items are optional or informational program elements; bolded items are MD/MAS-specific courses and curricular elements.
LEC refers to a longitudinal enhanced clerkship. One 6-week clerkship will be replaced with an LEC and will involve 60 half-days or 30 whole days throughout the clerkship years.
*Flexible start date: August or September
†optional
Appendix

Master's Degree Program in Clinical Research
abridged from http://www.epibiostat.ucsf.edu/courses/masters.html

OVERVIEW
The Master's Degree Program in Clinical Research is a two-year course of study intended for advanced pre-doctoral students, post-doctoral fellows, and faculty members who wish to master clinical research methods and pursue independent research careers. The Program Director is Jeffrey N. Martin, MD, MPH. Course work extends beyond that which is required for the ATCR Certificate Program to include instruction in advanced epidemiologic and biostatistical methods and specialized topics such as outcomes research, medical informatics, molecular methods in clinical research, and decision and cost-effectiveness analysis. Requirements include a comprehensive review of the literature in the scholar's field, presentation of original work at a national scientific meeting, and publication of a peer-reviewed manuscript. Scholars will work closely with mentors in their home departments and preceptors chosen from the TICR faculty.

OBJECTIVES
- Acquire a mastery of a broad set of clinical research methods.
- Plan and implement one or more clinical research projects.
- Present research findings at a national meeting.
- Write a comprehensive literature review and publish one or more first-authored peer-reviewed original research papers.
- Obtain experience in the instruction of clinical research methods.

PREREQUISITES
- Possession of a MD, PhD, DDS or PharmD degree, or currently enrolled as a medical, dental, or pharmacy student and will have completed at least two years of training in respective professional school prior to enrollment in the Master's program.
- Ability to devote at least 70% of time to this program and to the conduct of the scholar's own research during August to May in at least two academic years.
- Established relationship with a research mentor.
- Affirmation of the Professional Conduct Statement (signed during orientation).

PROGRAM OF STUDY
This is a two-year course of study. 36 quarter units are required. Trainees will take the majority of their coursework in the first year allowing for focus on independent research in the second year. Grading policy is determined by the UCSF Graduate Division. In particular, scholars should note that UCSF graduate students must maintain at least a 3.0 (B average). It is the policy of the TICR Program that one "C" grade or less (or one "U" grade) will trigger a discussion between the program director and the student about the expected level of performance in the program; two "C" grades or less (or two "U" grades) will trigger a formal review by the TICR Internal Advisory Committee and may result in the student being dismissed from the program.

Other policies and procedures governing graduate study at UCSF may be found at the Graduate Division website.

Course Registration: All students matriculated in the Master's in Clinical Research Degree program must follow the registration process established by the UCSF Office of Admissions and Registrar. Please refer to the Office of Admissions and Registrar website for further information about the registration process, deadlines for filing study lists, adding/dropping courses, and other matters.
REQUIRED COURSES

YEAR 1

Summer
Scholars who have taken and passed summer courses prior to enrollment in the Master's program will be excused from taking these courses if accepted into the program. However, in accordance with Graduate Division policy, retroactive course credit units cannot be granted, and hence scholars will need to take additional coursework in other quarters to compensate for not receiving credit for these summer courses.

Designing Clinical Research  EPI 202 (S. Hulley, Director; 2 units)  This course provides instruction in developing a clinical research question and creating a concise protocol that includes a literature review, study design, subject sampling and recruitment, instruments and other measurement approaches, sample size, consent form, budget and timetable. Each trainee reviews and supports the work of colleagues. The course closely follows the textbook *Designing Clinical Research*, by S. Hulley and other TICR faculty, now in its third edition.

Building a Career in Clinical Research  EPI 227 (M. Whooley, Director; 0.5 unit)  Trainees learn about choosing a mentor, time management, generating finished projects, getting grants and getting a job; about how UCSF administration works; and about sources of clinical research funding including industry and foundations in addition to NIH and other government agencies.

Responsible Conduct Of Research  EPI 201 (B. Lo, Director; 0.5 unit)  Trainees learn through case discussions how to identify and resolve common ethical dilemmas that arise in clinical research, how research on human subjects is regulated by the federal government, and what constitutes research misconduct. Trainees resolve the ethical considerations involved in the research protocol they develop in the Designing Clinical Research course. This course meets the NIH requirements for training in research ethics.

Introduction to Statistical Computing in Clinical Research  BIOSTAT 212 (M. Pletcher, Director; 1 unit)  Instruction in use of computer software for managing and analyzing clinical research data; roles of spreadsheet and relational database programs; use of STATA for managing, cleaning, describing, and analyzing data.

Fall

Epidemiologic Methods  EPI 203 (J. Martin, Director; 3 units)  Instruction in clinical research study design; measures of disease occurrence and disease association; the different mechanisms of bias in clinical research (selection, measurement, and confounding); and a conceptual approach to multivariable analysis.

Clinical Epidemiology  EPI 204 (T. Newman, Director; 3 units)  Instruction in the research implications of evidence-based clinical medicine, including the specifications of diagnostic tests, screening tests, and prognostic tests.

Biostatistical Methods for Clinical Research I  BIOSTAT 200 (B. Jersky, Director; 3 units)  Introduction to descriptive statistics, distributions, probability, exploratory data analysis, and selected variable parametric and non-parametric inference. The STATA software package will be used throughout to implement concepts learned in class and to allow scholars to begin to explore their own data.

Winter

Clinical Trials  EPI 205 (D. Grady, Director; 1.5 units)  Instruction in experimental design options; methods of randomization; blinding, interventions and controls; measuring outcomes and adverse effects; follow-up, compliance and postrandomization problems; ethical issues; and working with pharmaceutical companies.
Database Management Systems for Clinical Research  EPI 218 (M. Kohn, Director; 1 unit) Instruction in choosing the appropriate data management system; design of research databases; options in data entry; form and report generation; computer security; and budgeting for data management personnel and equipment.

Biostatistical Methods for Clinical Research II  BIOSTAT 208 (S. Shiboski, Director; 3 units) Instruction in multiple predictor analyses as a tool for control of confounding and for constructing predictive models. Topics will include linear regression and logistic regression. The STATA statistical package will be used throughout.

Spring

Systematic Reviews (Meta-Analysis)  EPI 214 (S. Bent, Director; 1 unit) Instruction in the methods of systematic and unbiased identification of primary research studies; abstraction of data; determination of summary estimates and evaluation of heterogeneity.

Publishing and Presenting Clinical Research  EPI 212 (W. Browner, Director; 1 unit) Instruction in preparing abstracts, posters, all aspects of manuscripts, and oral presentations; instruction in oral presentations includes videotaping and critique of trainees' presentations.

Biostatistical Methods for Clinical Research III  BIOSTAT 209 (S. Cheng, Director; 3 units) A continuation of the Winter Quarter course in multivariable statistical analysis that includes instruction in survival analysis and analysis of repeated measures and clustered data. The course culminates with student presentations of statistical analyses of their own research projects.

Year-Long

Master's Seminar I  EPI 220 (T. Newman, Director; 1 unit each quarter) The seminar provides a forum for presenting scholar's projects, and for evaluating controversies in clinical research.

YEAR 2

Winter

Biostatistical Methods for Clinical Research V  BIOSTAT 226 (J. Hilton, Director; 2 units) Instruction in advanced topics in biostatistics in two subject areas: 1) issues in the design and analysis of randomized clinical trials; and 2) bioinformatics.

Spring

Biostatistical Methods for Clinical Research IV  BIOSTAT 210 (D. Glidden, Director; 2 units) Instruction in advanced topics in biostatistics including individualized instruction in biostatistical methods pertaining to the scholars’ research projects. Topics are in part suggested by the class and include, but are not limited to: analysis of health surveys, nonparametric regression techniques, and survival and repeated measures analyses.

Year-Long

Master's Seminar II  EPI 221 (J. Martin (Fall); J. Witte (Winter); R. Hiatt (Spring), Directors; 1 unit each quarter) The seminar provides a forum for scholars to present their projects and specialized methodologic topics.

ELECTIVE COURSES
Fall

**Measurement in Clinical Research**  EPI 225 (A. Stewart, Director; 1.5 units)  Instruction in the critical importance of measurement to clinical research including: defining concepts prior to selecting measures; evaluating the conceptual and psychometric adequacy of measures; and locating, reviewing, selecting potential measures.

**Translating Evidence Into Practice**  EPI 245 (A. Auerbach, Director; 2 units)  An introduction to the different target audiences and approaches needed to translate biomedical evidence into practice. The course is the gateway for scholars who plan for additional study within this discipline but also suffices as cross-exposure for scholars from other disciplines. In addition to didactic work, scholars are guided through the creation of a research protocol aimed towards translating their particular choice of evidence into practice.

Winter

**Decision & Cost-Effectiveness Analysis**  EPI 213 (J. Kahn, Director; 2 units)  Instruction in creating decision trees and other analytic models; obtaining appropriate probabilities, utilities and costs; and completing analyses using customized software.

**Medical Informatics**  EPI 206 (I. Sim, Director; 1 unit)  Instruction in the core concepts of medical informatics: vocabularies, interchange standards, decision support systems, and how computers are used to manage information in health care and to support clinical research.

**Molecular and Genetic Epidemiology I**  EPI 217 (J. Witte, Director; 1.5 units)  Introduction to the concepts, principles, and use of molecular and genetic methods in epidemiologic and clinical research and how to develop a framework for interpreting, assessing, and incorporating molecular and genetic measures in research.

**Qualitative Research Methods**  EPI 240 (D. Dohan, Director; 1.5 units)  Introduces basic qualitative research methods used in clinical settings: question design and interviewing techniques; focus group analysis; ethnographic fieldwork, notes and narrative analysis; and audio and video data collection and analysis.

Spring

**Health Disparities Research Methods**  EPI 222 (E. Perez-Stable, Director; 1.5 units)  Instruction in the meaning of race, ethnicity, social class, and culture, and how these constructs affect the conduct and interpretation of clinical research.

**Molecular and Genetic Epidemiology II**  EPI 219 (S. Sen, Director; 2 units)  Instruction in selected statistical aspects of population-based and family-based candidate gene association studies, quantitative trait mapping in model organisms, and methods for dealing with multiple comparisons.

**Lab Practicum for Molecular and Genetic Epidemiology**  EPI 223 (J. Wiemels, Director; 1 unit)  Introduces practical aspects of the generation of molecular and genetic data from human clinical specimens, including blood and oral cavity specimens.

**Clinical Performance and Health Outcomes Measurement**  EPI 211 (A. Bindman, Director; 1.5 units)  Instruction in types of questions that can be addressed with large administrative and clinical databases; gaining access to these databases; determining validity of information; risk adjustment; linking datasets; and building registries.
Translating Evidence Into Practice: Individual-Centered Implementation Strategies  EPI 246 (M. Handley, Director; 2 units)  Instruction in developing interventions for individual health behavior change, including behavior change strategies at the individual, interpersonal, and system/community level; developing practical frameworks to integrate principles of behavior change theory.

Translating Evidence Into Practice: System-Centered Implementation Strategies  EPI 247 (L. Schmidt, Director; 1.5 units)  Instruction in translational tools at health care system level to promote the adoption of evidence-based medicine by the public and providers through mechanisms that influence health care delivery systems.

TICR Policy Regarding Academic Credit for Courses Taken in the Past.

Scholars may also choose from a diverse array of other graduate level courses at UCSF.

ACCOMPLISHMENT OF THE FOLLOWING PRODUCTS OF CLINICAL RESEARCH

Preparation of a comprehensive literature review: For this requirement, the scholar will compose a comprehensive review of the literature pertinent to his or her research question. This review should take the form of a three to five page single-spaced report, similar in format to the "Background and Significance" section of an NIH proposal, that demonstrates the scholar’s mastery of the field’s literature and provides the rationale for his/her proposed project. Emphasis should be placed not only in describing the findings of prior work but also providing a methodologic critique of sentinel studies. If numerous other studies have been performed on the scholar’s research question, the scholar should explain why further work (which may include a formal meta-analysis) is needed. If little or no prior work has been performed, the scholar should focus on background work just proximal to the question posed, again with an emphasis on methodologic critique. It is expected, although not required, that this requirement be completed by the end of the first year in the program.

First-authored oral or poster presentation at a national or international meeting: This requirement involves submission of a first-authored abstract to a nationally or internationally recognized scientific meeting/conference within the scholar's academic field and acceptance of that abstract for either poster or oral presentation. The abstract should describe a study of a comparative nature (not simply a case report or case series) using data analyzed (but not necessarily collected) during residence in the Master's program. It may be acceptable in selected cases, with pre-approval by the scholar's Master's Committee, to present work that was started prior to enrollment in the program. It is expected that the work represent a substantive contribution to the scholar's research field.

Submission as first author of a peer-reviewed manuscript: Using data analyzed (but not necessarily collected) during residence in the Master's program, the scholar will prepare and submit a first-authored manuscript for publication in a peer-reviewed journal that is approved by the Master's Committee. It may be acceptable in selected cases, upon approval of the scholar's Committee, to submit work that was started prior to enrollment in the program. The manuscript should describe a study of a comparative nature and not simply a case report or case series. The manuscript may be a comprehensive extension of the work submitted in abstract form to a national meeting. It is expected that the work represent a substantive contribution to the scholar's research field. The format should follow that suggested by the journal to which submission is intended. Achievement of this requirement will be considered complete upon satisfactory review by the scholar's Master's Committee and upon written correspondence indicating receipt of the manuscript by an approved peer-reviewed journal. Of note, it is not acceptable for a scholar to present an already submitted, accepted, or published manuscript to his/her committee and expect automatic approval. The final arbiters of the soundness of the work will be the Master’s Committee members and not the journal editors or its reviewers.

INSTRUCTIONAL EXPERIENCE IN CLINICAL RESEARCH

All scholars will be required to serve as instructional assistants (typically in their second year) for one or more courses in the TICR program. This experience will typically involve leading a weekly small-group discussion.
section of 10 to 15 students, holding office hours for students, and grading homework assignments and projects. Scholars will receive feedback on their performance both from the Course Director and from students, who are polled anonymously using the TICR Program's web-based course evaluation system.

FILING FOR GRADUATION
The UCSF Graduate Division’s ‘Completion of Degree Requirements’ form should be used to document the completion of the required number of course units and the three required products of clinical research. Scholars should use this form to have their Master's Committee members mark their signatures attesting to the satisfactory completion of each written requirement. Scholars must be registered for the quarter during which they complete the last of their requirements, whether it is coursework or any of the written products. The "Completion of Degree Requirements" form must be completed and submitted to the Program Coordinator by the end of the quarter during which the scholar plans to graduate.

MASTER'S COMMITTEE
Each scholar selected for the Program will be asked to form a Master's Committee, which will consist of three faculty members:

- **A representative from the scholar's academic field** (e.g., cardiology). This individual should be conducting primary research in the scholar's chosen field and will typically be a faculty member at UCSF. Upon approval from the TICR Steering Committee, individuals from outside of UCSF (e.g., UC, Berkeley; Stanford; or Biotechnology/Pharmaceutical Industry) may serve in this capacity. To request to include an individual outside of UCSF, scholars should provide the Master's Program Director with the individual's curriculum vitae and a letter of justification.

- **An epidemiologist/clinical researcher faculty member (primary or secondary/affiliated appointment) from the UCSF Department of Epidemiology and Biostatistics.** If possible, a faculty member with working knowledge of the scholar's substantive interests should be chosen.

- **A biostatistician faculty member (primary or secondary/affiliated appointment) from the UCSF Department of Epidemiology and Biostatistics.** If possible, a faculty member with working knowledge of the scholar's substantive interests should be chosen.

The purpose of this committee is both to provide mentorship and to evaluate the achievement of the requirements for graduation. Scholars should select and submit committee members to the Master's Program Director by the end of the Winter Quarter in the first year. One committee member should be selected as the Chairperson, whose role is to arbitrate when there is significant disagreement among committee members or to advocate for the scholar if he/she is experiencing difficulties gaining access to other committee members or scheduling meetings of the committee. The Chairperson must hold either a primary or secondary/affiliated faculty appointment in the Department of Epidemiology and Biostatistics. It is expected that scholars will meet with their committees at least quarterly to review progress and set future objectives.

By the end of their first year, scholars will be required to complete the "Initial Committee Review" form indicating, 1) that they have had at least one meeting with all 3 members of their Master's Committee present and, 2) that the committee members and scholar agree that the scholar is making satisfactory progress toward meeting the program requirements (i.e., the comprehensive literature review, first-authored presentation and manuscript).

At no less than 6 months prior to the date that scholars anticipate completing the last of their original research research products (i.e., the comprehensive literature review, first-authored presentation and manuscript), scholars are required to complete the "Pre-Graduation Review" form indicating that they have had at least one meeting with all 3 members of their Master's Committee present where the content and timeline were agreed
upon regarding the completion of the three research products. For example, if the scholar plans to graduate at the end of the Spring quarter of the second year (the minimum length of stay in the program), then he/she will need to file for graduation by approximately June 7 and thus should complete the "Pre-Graduation Review" form by no later than December 7. The purpose of this "Pre-Graduation Review" meeting is to ensure that the Committee is well aware of the exact projects the scholars have chosen to fulfill their requirements.

At no less than 3 months prior to the date that scholars anticipate completing the last of their original research products (i.e., the comprehensive literature review, first-authored presentation and manuscript), scholars are also required to complete the "Final Graduation Review" form indicating that they have had at least one meeting with all 3 members of their Master's Committee present where a final plan and timeline were agreed upon regarding the content and completion of the three research products. For example, if the scholar plans to graduate at the end of the Spring quarter of the second year (the minimum length of stay in the program), then he/she will need to file for graduation by approximately June 7 and thus should complete the "Final Graduation Review" form by no later than March 7. The purpose of this "Final Graduation Review" meeting is to ensure that the Committee is well aware of and agrees with the final plans the scholar has made to fulfill the program's research product requirements. The objective is to avoid last minute submissions to Committee members, which defeat the purpose of obtaining the members' well-reasoned advice. It is, however, anticipated that the scholar will continue to meet with Committee members, either together or individually, after this required "Final Graduation Review" meeting for further mentoring and review of the scholar's work. When planning for final approval of products by Master's Committee members, scholars should expect that Committee members may require as long as three weeks to return comments to the scholar. Therefore, Committee members should be presented with drafts of the required products well before the scholars' anticipated graduation.

At all required Committee meetings (and any other meetings held with the full committee), the scholar should take the responsibility for setting the agenda for the meeting, including sending out the agenda and accompanying materials (e.g., drafts of products) by e-mail at least one week prior to the meeting.