3. Analyze, interpret, and present clinical research data.

For more information on objectives and requirements for a Certificate of Program Completion, please see Requirements and Goals.

PREREQUISITES

▲ Top

- 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 ATCR program.
- Supervisor's assurance that at least 70% of time will be available September - June to divide between the activities of this program and the conduct of the trainee's clinical research projects.
- Access to a research mentor in trainee's home department.

TWO TRACKS FOR RECEIVING PROGRAM CREDIT

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Traditional ATCR Program

We offer two options for those seeking admission to the ATCR program. The first is the traditional ATCR Program that we have offered in the past culminating in a Certificate of Program Completion from the Department of Epidemiology and Biostatistics for scholars who successfully complete program requirements. This option is ideal for those who desire to gain the core knowledge and skills needed to become a clinical researcher but who do not feel the need to obtain an official transcript from the University of California listing course credits. This would apply to scholars who do not plan to attempt to transfer credit received for completed ATCR courses to graduate degree programs either at UCSF (e.g., the TICR Master's Degree Program in Clinical Research) or at other universities. This is a lower cost option compared to the credit-bearing ATCR program. In order to apply for this program, please follow the instructions below for Application to Traditional ATCR Program.

Note: Pre-doctoral students who are currently enrolled in a graduate or professional degree program at UCSF should apply for the Traditional ATCR Program, and not the Credit-Bearing Program. This is because UCSF policy does not allow students to enroll in more than one graduate degree/certificate program at a time. If you are accepted into the Traditional ATCR Program, then as long as you formally register (pay fees in the quarter), and file a study list through the UCSF Registar's on-line system for each course you take in the ATCR Program you will receive credit on your graduate transcript for these courses.

Credit-bearing ATCR Program

The second option is a newly approved credit-bearing ATCR Certificate Program offered through the UCSF Graduate Division that offers trainees the opportunity to earn graduate division credit for the courses taken as part of ATCR. Students choosing this option would then have an official UCSF transcript indicating the courses and grades earned, and those who successfully complete the program would receive a Certificate of Program Completion from the University of California. This program is primarily for those who are uncertain about pursuing a formal degree (e.g., the TICR Master's Degree Program in Clinical Research at UCSF) at the beginning of the program and who desire more to time make that decision. Students who elect the credit-bearing ATCR Certificate Program will be able to apply units of coursework credit taken in ATCR in the Summer, Fall, and Winter quarters toward the Master's Degree in Clinical Research if they apply and are accepted into the Master's program. Students would need to decide and apply by the published deadline for the Master's program (typically in late February or early March). Please note that admission into the Master's Program is competitive and that satisfactory completion of courses taken while in the ATCR Certificate Program is not a guarantee of acceptance into the

Master's Program. Please also note that if you intend to apply to the Master's program, you will need to take the ATCR courses on a graded basis following the grading policies for the Master's Program. Finally, since the ATCR credit-bearing program is a UCSF Graduate Division Certificate Program, it necessarily comes with higher fees. In order to apply for the credit-bearing ATCR program, please follow the instructions below for Application to Credit-bearing ATCR Certificate Program.

In summary, the prerequisites, program of study, and mentoring requirements described below are identical for the two tracks. The differences between the tracks are the ability to apply credits toward the Master's Degree in Clinical Research, the nature of the Certificate granted, and cost.

PROGRAM OF STUDY

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REQUIRED COURSES (Summer | Fall | Winter | Spring | Year-long)

Summer

Designing Clinical Research
EPI 202 (S. Hulley, Director; 2 units)
- This course follows the text Designing Clinical Research to provide instruction in developing a research question and creating a 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 produces a 5-page protocol for an actual study, and reviews and supports the work of colleagues.

Responsible Conduct Of Research
EPI 201 (B. Lo, Director; 0.5 units)
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. Each trainee produces a written document resolving the ethical considerations involved in the research protocol developed in the Designing Clinical Research course.

Building a Career in Clinical Research
EPI 227 (M. Whooley, Director; 0.5 units)
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 and career options in industry and foundations as well as NIH and other government agencies. Each trainee produces a detailed 2-year career plan.

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, probabability, 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 (D. Glidden, 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 (E. Hartman, 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 (D. Glidden, 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

ATCR Seminar
EPI 230 (M. Pletcher, Director)
These monthly seminars provide a support group for discussing the design or conduct of trainees' studies and for critique of contemporary clinical research literature.

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.

Grant Writing Workshop
(E. Holly and T. Mitchell, Directors; not for credit)
Instruction in grant writing principles, with specific guidelines for preparing successful grant applications using PHS 398 forms, will be presented with emphasis on federal guidelines and regulations for research with human study participants.

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.

Spring

Clinical Research with Diverse Communities
EPI 222 (E. Perez-Stable, Director; 1 unit)
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; 1.5 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; 0.5 unit)
Introduces practical aspects of the generation of molecular and genetic data from human clinical specimens, including blood and oral cavity specimens.

Outcomes Research
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.

Qualitative Research Methods
EPI 240 (E. Boyd, 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.

MENTORING

▲ Top

Structured mentoring by faculty members experienced in the scholar's chosen academic discipline is an essential element of becoming an accomplished clinical researcher. While the ATCR curriculum and faculty will provide the methodologic guidance to enable the scholar to plan and implement clinical research, this does not substitute for the benefits derived from a relationship with mentors who work primarily in the scholar's field. Hence, we require that each student receive guidance from:

- A home Department Chair (or Division Chief) or Fellowship Program Director: This is the person in the home Department or Division who assures that the scholar has sufficient time allotted for clinical research and provides resources for the research.
- A research mentor: This is an established scientist who meets regularly with the scholar, reviews progress, provides scholarly guidance, and monitors whether facilities and resources are adequate.

APPLICATION TO TRADITIONAL ATCR PROGRAM

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The ATCR application is available in a ready-to-use Microsoft Word format (created on Word for Office 97 for the PC). To use this, click on the "Microsoft Word Format" button below. The word document should then appear in your browser. Next select "File > Save As" from the menu bar and save a local copy of the document to your computer. **Make sure to save a copy of the file on your computer before attempting to use the file.**

If you are not able to access the application in the Microsoft Word format, please download the .pdf version of the application by clicking on the pdf button below. This can then be printed out and completed by typing where indicated.

ATCR APPLICATION ATCR APPLICATION

Completed ATCR applications in MS Word format should be sent by email to Allison Deneen, Program Assistant (adeneen@psg.ucsf.edu). A signed hard copy of the application should also be sent to:

Allison Deneen
Program Assistant, Advanced Training in Clinical Research Certificate Program
University of California, San Francisco
UCSF Box 0560
185 Berry St, Suite 5700
San Francisco, CA 94107
415-514-8135 (telephone)

Deadline: Applications for the ATCR Certificate Program for 2006-2007 are due . Notice of admission decisions will be made by early July.

Cost: The current fee for 2006-2007 is $7425 for University of California Fellows and Faculty. This includes fees for all four quarters (Summer, Fall, Winter, and Spring). Fees do not include books, supplies, or software. Fees in subsequent years are subject to change.

Scholars are also strongly encouraged to own a wireless-capable laptop computer for use in computer labs in various courses and to take advantage of the wireless internet network at the TICR Program's facility at the China Basin Landing Building.

The statistical software package Stata (Stata Corporation, College Station, Texas) is used in the program. The TICR Program has arranged for a sizeable discount for UCSF-affiliated personnel via the Stata GradPlan program.

APPLICATION TO CREDIT-BEARING ATCR PROGRAM

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To apply to the credit-bearing ATCR Certificate program you must complete the one-page UCSF Graduate Division application available in PDF format below and send it to Allison Deneen with a $60 non-refundable processing fee by June 1, 2006. When completing the application check the box "Cert" and write in "Advanced Training in Clinical Research" in the blank space following "Graduate Program". Please note that transcripts, GRE scores and TOEFL scores are not required for admission into the program.

GRADUATE DIVISION APPLICATION

Send to:

Allison Deneen
Program Assistant, Advanced Training in Clinical Research Certificate Program
University of California, San Francisco
UCSF Box 0560
185 Berry St, Suite 5700
San Francisco, CA 94107

In addition to the Graduate Division application, you must also complete the ATCR application. The ATCR application is available in a ready-to-use Microsoft Word format (created on Word for Office 97 for the PC). To use this, click on the "Microsoft Word Format" button below. The word document should then appear in your browser. Next select "File > Save As" from the menu bar and save a local copy of the document to your computer. **Make sure to save a copy of the file on your computer before attempting to use the file.**

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Program Assistant, Advanced Training in Clinical Research Certificate Program
University of California, San Francisco
UCSF Box 0560
185 Berry St, Suite 5700
San Francisco, CA 94107
415-514-8135 (telephone)

Deadline: Applications for the credit-bearing ATCR Certificate Program for 2006-2007 are due Notice of admission decisions will be made by early July.

Cost: The fee for the credit-bearing ATCR Certificate Program in 2006-07 is $10,758. This includes the $7,425 ATCR program fee for University of California fellows or faculty plus the estimated UCSF student services fees of $3,333. The latter fees are required for all persons in credit-bearing certificate or degree programs and at this time are only estimated for 2006-07. This includes fees for all four quarters (Summer, Fall, Winter, and Spring). In addition there is a $60 non-refundable application processing fee that must accompany the one-page UCSF Graduate Division Application.

Fees do not include books, supplies, or software. Fees in subsequent years are subject to change.

Scholars are also strongly encouraged to own a wireless-capable laptop computer for use in computer labs in various courses and to take advantage of the wireless internet network at the TICR Program's facility at the China Basin Landing Building.

The statistical software package Stata (Stata Corporation, College Station, Texas) is used in the program. The TICR Program has arranged for a sizeable discount for UCSF-affiliated personnel via the Stata GradPlan program.

Note: Pre-doctoral students who are currently enrolled in a graduate or professional degree program at UCSF should apply for the Traditional ATCR Program, and not the Credit-Bearing Program. This is because UCSF policy does not allow students to enroll in more than one graduate degree/certificate program at a time. If you are accepted into the Traditional ATCR Program, then as long as you formally register (pay fees in the quarter), and file a study list through the UCSF Registar's on-line system for each course you take in the ATCR Program you will receive credit on your graduate transcript for these courses.

TICR Home | TICR Master Schedule | TICR Courses | TICR Programs | TICR Rosters
Department Home

September 19, 2006!

This is the day that your complete concise protocol is due. Please note the following things:

1. We have an absolute limit of 5 pages of text, single space and size 12 font(!), plus up to an additional 5 pages of references and appendices. The reason for these constraints is not so much to reduce the size of your creative task (although our students' welfare is always a priority with the faculty) as it is to make the task of critiquing each other's protocols a manageable one. The 5 page limit makes for a considerably more concise protocol than an NIH submission, but is not so different from what is expected for a small intramural grant. The need to be concise will discipline your approach to planning your study. If necessary you can summarize the ways you would flesh some parts of the text out in a longer version.

2. We cannot make exceptions to the due date. The logistics of sending out the protocols in time for them to be read and critiqued mean that we have no flexibility on this one. Just give us whatever you have on September 19, even if you still plan further improvements.

   Please e-mail the protocol as a Microsoft word attachment to Olivia DeLeon at olivia@epi.ucsf.edu . She will use the return address to email your assignments for the final session back to you about a week later.

The next page provides you with a suggested outline indicating a good way to allocate the five pages (to help avoid such things as spending too much space on the significance and then neglecting key nitty-gritty aspects of the methods).

5 Page Protocol
Suggested Outline

Title
Abstract
Specific aims
Significance (limit this to 1/2 page)
Methods

- Overview of design
  - time frame and nature of control
- Study subjects
  - selection criteria, target and accessible populations
  - plans for sampling and for recruiting subjects
- Measurements
  - predictor variables (intervention, if an experiment) and potential confounders
  - outcome variables
- Pretest plans
- Statistical issues
  - hypotheses and sample size estimates
- Quality control and data management

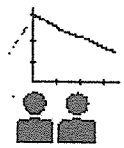
Administrative

- Personnel
- Timetable

Ethical considerations
References (not included in the 5-page limit)
Appendices (not included in the 5-page limit)

臨床研究修士課程のプログラム

Department of Epidemiology and Biostatics



Training In Clinical Research

Master's Degree Program in Clinical Research

Director: Jeffrey N. Martin, MD, MPH

Note:

- China Basin Landing
-

OVERVIEW

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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. 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.

Other Programs

OBJECTIVES

▲ Top

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

PREREQUISITES

▲ Top

- 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.

PROGRAM OF STUDY

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1. COURSES

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, probabability, 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 (D. Glidden, 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.

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. (Note: This required course can also be taken during the second year.)

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 (E. Hartman, 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 (D. Glidden, 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

Fall

Biostatistical Methods for Clinical Research IV
BIOSTAT 210 (J. Neuhaus, 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.

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.

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.

Grant Writing Workshop
(E. Holly and T. Mitchell, Directors; not for credit)
Instruction in grant writing principles, with specific guidelines for preparing successful grant applications using PHS 398 forms, will be presented with emphasis on federal guidelines and regulations for research with human study participants.

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.

Spring

Clinical Research with Diverse Communities
EPI 222 (E. Perez-Stable, Director; 1 unit)
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; 1.5 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; 0.5 unit)
Introduces practical aspects of the generation of molecular and genetic data from human clinical specimens, including blood and oral cavity specimens.

Outcomes Research
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.

Qualitative Research Methods
EPI 240 (E. Boyd, 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.

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

Intercampus Exchange
The University of California Intercampus Exchange Program allows graduate students to take courses on another campus of the University while remaining registered on the home campus. The student pays fees only to the home campus and grades for courses taken at the host campus are reported to the Registrar for inclusion on the student's UCSF transcript. Application forms for the intercampus Exchange are available in MU200W. A similar program exists with Stanford University. Forms for cross registration with Stanford are also available in MU200W.

SAMPLE COURSE SCHEDULE

2. 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.

3. 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.

4. 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.

The "Completion of Degree Requirements" form is available in a ready-to-use Microsoft Word format (created on Microsoft Word 2000 for the PC). To use this, click on the "Microsoft Word Format" button below. The word document should then appear in your browser. Next select "File > Save As" from the menu bar and save a local copy of the document to your computer. **Make sure to save a copy of the file on your computer before attempting to use the file.**

COMPLETION REQUIREMENTS COMPLETION REQUIREMENTS

If you are not able to access the application in the Microsoft Word format, please download the .pdf version of the form by clicking on the pdf button above. This can then be printed out and completed by typing where indicated.

MASTER'S COMMITTEE

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

1. **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.
2. **An epidemiologist/clinical researcher faculty member 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.
3. **A biostatistician faculty member 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 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