



CLINICAL RESEARCH FELLOWS' HANDBOOK

Ninth Edition



**Division of Pulmonary and
Critical Care Medicine,
Department of Medicine,
University of Washington**

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PURPOSE OF THIS HANDBOOK

1. To provide fellows considering clinical research with some general guidelines and suggestions about getting started.
2. To answer common questions about clinical research and clinical research training.

GOALS OF THE CLINICAL RESEARCH FELLOWSHIP

Goal: To teach knowledge and skills necessary to conduct independent research and become a successful academic clinician-investigator. This is done in 2 parts:

- 1) Provision of a broad-based introduction to disciplines relevant to research performed by clinical investigators including such method areas as:
 - clinical epidemiology
 - health services research
 - biostatistics
 - health economics research
 - qualitative methods
- 2) Provision of a focused research experience emphasizing 1 or 2 of the above method areas and concentrating on 2-3 research projects with the goal of presenting at National Meetings and publishing in peer-reviewed literature.

The first item is often done largely in the School of Public Health. **The second item is the most important part** and is done in the context of the fellow's research project(s).

COMMON RESEARCH ACTIVITIES

Common research activities can include one or more of the following:

1. Analysis of existing data or meta-analysis
(most likely to be completed within the fellowship)
2. Integration into ongoing research projects
(fellow needs to have unique piece to call her or his own)
3. Independent design and execution of a project
(often can require more than 2 years, but provides opportunity to learn all steps of clinical research – can be very anxiety-provoking)

How is clinical research different than lab research?

1. Fellows generally play a larger role in formulating their early research questions and research design in clinical research. In basic science, a fellow's first research question is usually formulated by her or his mentor.
2. The issues concerning getting formal research training, taking classes in the School of Public Health, and getting a Masters degree are of special concern to the clinical research fellows.

COMMON PATHWAYS FOR CLINICAL RESEARCH TRAINING

There are three common pathways for clinical research training in our Division. Each pathway has some advantages and disadvantages. We will describe each pathway in brief below. There also may be ways to combine or create hybrids of these pathways and occasionally fellows may find the best option for them is another pathway not described here.

1. Mentor is a trained clinical researcher in the Division

This pathway is in some ways the “safest” option, but requires that you find a research mentor in the division who has clinical research training and is doing clinical research in an area that interests you. The advantages are that this person may have a research question and project ready to go that you can pick up. There also may be more resources available to you (office space, computer, statistical help, databases to work on). The disadvantage is that there is a relatively short list of clinical research mentors within the Division who have this training and you may not be interested in working in these areas.

List of some of the mentors and their major research areas as of 1/08:

Randall Curtis: end-of-life care in pulmonary disease and critical illness
 Ken Steinberg: clinical epidemiology of ARDS and sepsis, clinical trials
 Len Hudson: clinical epidemiology and biology of ARDS and sepsis
 Terri Hough: clinical epidemiology of critical illness and long-term outcomes
 Lewis Rubinson: health services of disaster management and response
 David Au: clinical epidemiology of COPD and lung cancer
 Chris Goss: clinical epidemiology of cystic fibrosis
 Margaret Neff: clinical epidemiology of ARDS/ALI and critical illness
 Vishesh Kapur: clinical epidemiology of sleep-disordered breathing
 Vince Fan: clinical epidemiology of COPD

For more information about these or other mentors in the Division of Pulmonary and Critical Care, see the Division website at: <http://depts.washington.edu/pulmcc/>

2. Mentor is a trained clinical researcher outside the Division

There are many epidemiologists or health services researchers at the University of Washington working in areas related to pulmonary diseases including COPD and asthma. Some fellows have worked with these individuals along with a Division co-mentor. Advantages include availability of resources that the Division might not have and topic areas that Division faculty may not cover. Disadvantages include the possibility of “falling between the cracks” as far as being supported within the Division or through national pulmonary and critical care society activities.

3. Mentor in Division has clinical expertise; co-mentor has clinical research training

There are a number of clinical experts within the Division who may have expertise in and access to a specific patient population but who don't have formal training in clinical research methodologies. Fellows interested in a particular clinical entity may be mentored by these experts and also be aided by another clinical investigator in the division. Advantages include the opportunity to do research and to develop additional clinical skills in an area of particular interest to the fellows. Disadvantages include co-mentors providing less than full support of the fellow and the intrusion of clinical expectations into time that should be dedicated to research.

THE RESEARCH QUESTION

The most important feature of any research project is “the research question.” The art of developing good research questions is a learned skill that requires considerable time and energy to develop. The good research question is written in such a way that it is clear how it could be answered.

The best way to develop a research question is to identify a question that have come up during the clinical year or in reading about a particular field and then figure out how to answer it. A less effective way to develop an interesting research question is to identify a database (or worse, to develop a database) and then try to figure out what questions could be asked of the database.

We encourage fellows to have a “start-up” or “secondary” project based on a research question developed by a mentor that uses an existing database. This allows the fellow to “hit the ground running” and offers the opportunity to submit an abstract for the American Thoracic Society during the fellows first research year.

Fellows often consider more than 20 research questions before settling on 1 for a major project. Fellows should keep a list of the notebook or card catalog of potential research questions that occur to them. It is also perfectly reasonable to approach a potential mentor and ask, “Do you have research questions in your area of interest that would be appropriate for fellows?”

The most important criteria of any research question are:

1. The question is interesting to the fellow and others.
2. The question can be feasibly answered during the fellowship.
3. The question is novel.
4. The question can be restated as a testable hypothesis.
5. The question should build on the fellow's and/or mentors experiences.

It is easy to think of interesting questions that aren't feasible and feasible questions that aren't interesting. The trick is to come up with a research question that fulfill both of these criteria. Of the first two criteria, the second is the most difficult.

See the bibliography for two very good articles on picking a research question.

EXPECTATIONS, SUGGESTIONS & DISCOURAGED

Expectations for the Clinical Research Fellows

1. Complete a clinical research study within two years of research training, present the study at at least one national meeting, and write at least one manuscript to be submitted for publication in a peer-reviewed journal.
2. Complete training in clinical research methodology either through the School of Public Health (usually culminating in a Masters degree) or through an organized plan of study to be supervised by a specific mentor.
3. Identify a Primary Mentor, generally in the Division of Pulmonary and Critical Care Medicine, and meet with this individual to review progress and plans at least 12 times a year.
4. Identify a Primary Advisor for the Clinical Investigation Track who has received a Masters degree from the School of Public Health (can be same person as mentor).
5. Attend the Clinical Research Works-in-Progress session and present at this session at least three times a year.
6. Identify an Advisory Committee consisting of at least three faculty members, one of whom is your mentor.
7. Attend the School of Medicine's mandatory lecture series on "The Ethical Conduct of Research."
8. Cocomplete the training in "Ethical Conduct of Research Involving Human Subjects" offered by the UW Human Subjects Committee.
9. Attend the weekly Seattle Area Chest Conference and the Respiratory and Critical Care Conference at Harborview.
10. Act as a teaching assistant for the HuBio course during the 1st or 2nd research year.
11. Actively seek the guidance of mentor(s) and advisors when questions arise and check in with mentors regularly even when there are no questions.
12. Present at Respiratory and Critical Care conference in the 1st and 2nd research year.

Suggested Optional Activities

1. Identifying an additional mentor (often outside the pulmonary division) with expertise in a specific methodologic area and meet with this individual at least 6 times a year.
2. In addition to a major research project, identify and complete 1 (or occasionally 2) secondary research project(s) for which the study design and data collection is usually already completed by a mentor. This often allows submission of an abstract to American Thoracic Society meeting during the first year.
3. Joining appropriate ATS Assembly and attend Assembly business meeting at ATS meeting. Potential Assemblies include Behavior Sciences (BS), Critical Care (CC), Clinical Problems (CP), Microbiology, Tuberculosis & Pulmonary Infections (MTPI)

The following activities are generally discouraged (although special cases exist):

1. Taking too many elective courses in the School of Public Health, especially to the point that it interferes with the fellow's research time.
2. Writing review articles, except when the fellow is reviewing the same literature in preparation for her or his research.
3. Regular teaching (other than HuBio) or clinical activities (other than those required).
4. Auditing courses is generally a bad idea because, unless you are an extremely unusual person, you will get very little out of the course.

MENTORS AND ADVISORS

Fellows should have several advisors and probably only one “main” mentor.

An advisor is someone who provides guidance for the fellow’s research project or career. An advisor can also help decide about getting a Masters degree and choose classes. The advisor role is often relatively passive -- the advisor usually waits for the fellow to call or make an appointment and will often only provide assistance when asked.

Primary Advisor is one of the Clinical Investigation Track faculty familiar with the School of Public Health who will provide some guidance in course work and the balance of course work and research.

A mentor plays a much more direct and active role in the fellow’s research activities and career development. Fellows will usually only have one or, at the most two, mentors.

Picking advisors is easy. Any faculty member who provides useful advice can fill this role. Picking mentors is a bigger decision and may require the help of several advisors. Fellows should also talk to other fellows mentored by a prospective mentor, but remember that identifying the right mentor is an individual and personal decision that depends not only on the mentor’s mentoring skills, but also on matching the personalities of the mentor and fellow.

Expectations of the Clinical Research Mentors

In general, fellows can expect their mentors to:

1. Help fellow’s determine their goals from the research fellowship and set an individualized time table for accomplishing those goals.
2. Help identify interesting and feasible research questions.
3. Meet on a regular basis (not to be less than 6-12 times a year.)
4. Supervise the design, development, data collection, data analysis, and interpretation of one or more of the fellow’s studies (mentors who meet these expectations should generally be co-authors on the abstract and paper.)
5. Help the fellow choose a mechanism for obtaining research training and help the fellow choose course work and navigate the School of Public Health (some mentors will appropriately delegate this responsibility to the Primary Advisor.)
6. Work with the fellow to find the right balance between supervising the fellow and allowing the fellow independence.
7. Foster the fellow’s productivity and provide some resources when necessary.
8. Help the fellow with choosing appropriate timing and sources for grant applications.
9. Facilitate the fellow’s career advancement and help the fellow find a job.

“Less than ideal” Characteristics of a Mentor

Be aware of the following characteristics in mentors (although nobody’s perfect):

1. The avoider or the over-committed: someone who is not available or accessible.
2. The criticizer: someone who criticizes freely but never makes positive comments.
3. The push-over: someone who compliments but never gives constructive criticism.

QUESTIONS FOR FELLOWS TO ASK POTENTIAL MENTORS**A) Projects**

- 1) What projects are you working on?
- 2) In what stage of completion are they?
- 3) What projects might be good for me to work on with the understanding that I would be first author if I complete the work involved?
- 4) Is there a project that I might work on and expect to be able to have an abstract ready for ATS in my first research year?
- 5) Are you willing to mentor me if I work on data from one of your projects?
- 6) Are you willing to mentor me if I work on a project that is not one of your projects?

B) Practical Matters

- 1) If I work with you, do you have a desk or space where I would work?
- 2) If I work with you, do you have access to a computer for me?
- 3) Do you have additional funding available for travel to professional meetings and additional research expenses?

C) Future Funding Questions

- 1) If I decide to do a 4th year to finish research, when should I write a grant to fund that year and what grants might I write?
- 2) If I decide to do a 4th year to finish research and don't get a grant to fund it, what funding options might be available for me?

Research Advisory Committee

The primary purpose of the Research Advisory Committee is to ensure that the fellow is progressing towards their career goals.

At the beginning of the research year, the fellow should choose an advisory committee. The advisory committee consists of 3-4 individuals including the research mentor, and additional faculty of the fellow's choice. Often times, one member of the committee may be outside the Division of Pulmonary Medicine, particularly if the research project involves collaboration with an outside faculty. Either the Program Director (Mark Tonelli) or the Research Director (Len Hudson) should sit on each committee. Once the composition of the committee is determined, the fellow should forward their names to Leila Armas (lsarmas@u.washington.edu) along with a timeframe for the meeting. Leila will coordinate with committee members to arrive at a time and place for the meeting. The first meeting must be held by the fall of the first research year and meetings should be scheduled approximately every 6 months thereafter.

In addition to advancing the career goals of the fellow, the advisory committee increases the pool of faculty who understand your research project and career goals. This is especially important when it comes time for career counseling and obtaining letters of recommendations for grant applications or jobs.

Expectations of the Research Advisory Committee

1. Help fellows determine their goals from the research fellowship and set an individualized timetable for accomplishing those goals.
2. Help identify interesting and feasible research questions and identify other resources and potential collaborators that may be useful to the fellow's projects.
3. Meet on a regular basis (1-2 times a year.)
4. Foster the fellow's productivity and provide some resources when necessary.
5. Help the fellow with choosing appropriate timing and sources for grant applications.
6. Suggest potential avenues for presentation of data (local or national meetings, etc)
7. Facilitate the fellow's career advancement and help the fellow find a job.
8. Provide a written summary of the meeting for the fellow and the Program Director.

APPROXIMATE SCHEDULE FOR FIRST TWO RESEARCH YEARS

Clinical Year:

July-August	Identify a faculty advisor
December	Apply for enrollment in the School of Public Health
Elective and mini-sabaticals	Meet with potential research mentors Identify primary mentor and possible additional research mentor Identify clinical area of research questions Identify a research project (often part of an ongoing project) to be a start-up or secondary project

First Research Year:

July	Celebrate (briefly!) Participate in Research Fellow's Orientation week Make appointments with research mentors Start summer classes Initiate a secondary research project
August	Formulate research questions for major project Present secondary research idea at CRWIP
September	Meet with a few research mentors to go over study designs Work on secondary research project Initiate a major research project
Sept - Oct	<i>Initiate major fellowship research project by this time</i> Present major research idea at CRWIP
Oct	Complete abstract of secondary project for submission to ATS
Jan - July	Work on major and secondary research projects
April or May	Present at ATS
June	Consider beginning to write a fellowship grant (see page 8)

Second Research Year:

July - Dec	Work on major research project and secondary research projects Perform data analysis on at least one of the projects Write up secondary research project Consider writing a grant for further funding (perhaps using major or secondary research project as preliminary data?)
Oct	Submit abstract for ATS from one of the projects
Jan - Mar	Analyze data from major research project
April - June	Write up major research project
April or May	Present at ATS
June	Consider beginning to write a fellowship grant (see page 8)

Third Research Year:

Many fellows interested in going into academic medicine elect to do a third research year. This year is almost a necessity for being competitive in the academic job market. The goals of and funding for this third year should be worked out between the fellow and her or his research mentor well in advance.

WRITING A GRANT DURING THE 1ST OR 2ND RESEARCH YEAR

Fellows are expected to write at least one grant during their research training years. These grants may be to support their salary, to provide funding for research activities, or both. There are many different potential sources for research funding. Some of the common ones are listed below. Fellows should discuss the pros and cons of applying for a grant during the 1st or 2nd research year and the potential grant sources with their mentors.

When writing a grant, be aware that in addition to the deadline for the grant, you need to leave time for:

1. The grant to be taken through the Dept. of Medicine and Grants and Contracts (talk to Monica for a schedule for doing this).
2. Internal review in the following sequence:
 - A. Your mentor(s)
 - B. Other faculty members in the Clinical Research Training Track
 - C. Your Advisory Committee

To complete this sequence in a reasonable timeframe, you should plan to have a first draft of your grant done 2 months prior to the deadline. Notify potential readers well in advance.

Some Grant Options for Salary Support:

1. **American Lung Association Research Training Fellowship:** Stipend support at \$32,500. National level award funds 4th and 5th year fellows; Local level supports fellows at any level. Deadline for National award was October 1st in 2003.
2. **American Heart Association:** Also funded at a National and Local level. Stipend support at \$37,680 for up to 3 years. Deadline for Local was November 20th in 1999. Deadline for National level is June 15th in 2000.
3. **NIH/NRSA Individual Fellowship Awards:** Fund stipend only on NIH pay scale. Deadlines were December 5th, April 5th, August 5th in the 1999-2000 cycle.
4. **Parker B. Francis Fellowship:** Provides stipend and some project support.

WRITING A GRANT TO FUND TRANSITION TO FACULTY

Fellows interested in a career as a physician-investigator in academic medicine will often write a grant during their 2nd or 3rd research year that will bridge them into a faculty position. This type of "career development" grant may come from the NIH (such as a K23 award), the VA, or a foundation. Fellows should be talking with their mentor(s) early in the 3rd research year about such a grant.

CLINICAL RESEARCH WORKS-IN-PROGRESS SESSIONS

The Division of Pulmonary and Critical Care Medicine has its own Clinical Research Works-in-Progress session. Clinical research fellows are expected to attend this conference and to present at this conference at least three times a year. The basic information for the conference is as follows:

What Day: First and third (and occasionally fifth) Thursdays of every month

What Time: 2:30 to 4:00 pm

Where: Harborview, Radiology Library – 1EH107.1

Why: To provide fellows doing clinical research a format to present research proposals and preliminary results and receive feedback and to provide fellows with experience critiquing the work of others.

Format: Projects in any stage of development may be presented ranging from research ideas to preliminary results. Speakers will prepare a one page research outline and specific questions for the group to be distributed prior to the session. Overheads are recommended; slides are discouraged.

If you are ready to present at the CRWIP or you are not on the email list, contact Randy (731-2106; jrc@u.washington.edu) or Leila (731-3356; lsarmas@u.washington.edu).

RESEARCH OUTLINE FOR CRWIP PRESENTATIONS

Instructions to presenters:

The CRWIP is designed to be a supportive environment where investigators can bring research projects for critical evaluation and discussion. Projects are welcome at every phase from "twinkle in the eye" through implementation and pre-presentation practice. No project can be presented too early or too often.

Presenters are expected to prepare the following for distribution 7-10 days prior to their session:

- 1) A brief research proposal (3 page maximum) with the following outline (bullet points are preferred over prose) :
 - a) Goals of the CRWIP Presenter: What information do you want from the audience
 - b) Background: Why is this an interesting question?
 - c) Research Questions: Primary and secondary questions.
 - d) Study Design: Randomized trial, cohort, case-control, meta-analysis, etc.
 - e) Data: Outcome, predictor, and confounder variables; sources of data; methods of data collection.
 - f) Data Analysis: rephrase each research question as a hypothesis and describe the analytic approach to the data.
 - g) Sample size estimates

Obviously, investigators will be at different stages in their research. "Don't know" is a perfectly acceptable entry - part of the purpose of the CRWIP is to fill these gaps in. Since this written proposal will help your colleagues frame the issues, we would like all presenters distribute a research proposal in some form prior to presentation.

The faculty in the clinical research track are all willing to meet with presenters to discuss any of the sections of their proposal prior to distributing it. You should also review this outline with your mentor prior to distribution.

- 2) A list of questions that you would like answered about your proposal is a key part of preparing for CRWIP. Our experience with these sessions is that your loquacious colleagues will have abundant advice in many areas. Unfortunately, it may or may not cover the specific questions you have. To make sure you walk away with the information that's important to you, carefully consider and distribute a list of questions on which you would like to focus. The questions will depend on the research questions and design and the stage of the project. These questions can range from: "Is this an interesting and feasible research question?" to "Where's the best place to send this manuscript?".

Pulmonary Research Seminar

The Division of Pulmonary and Critical Care Medicine organizes a weekly research seminar where faculty, research fellows, and invited guests present their work. Faculty and trainees from our Division as well as other Divisions and Departments in the University interested in lung research attend this seminar. Research fellows are expected to present their research work yearly at this conference. This allows the fellow to gain experience with formal presentations of their work and practice responding to questions in a more formal environment. The basic information for the conference is as follows:

What Day: Every Monday

What Time: 4:00 to 5:00 pm

Where: UW HSB RR-134

Why: To provide fellows and faculty doing research a forum to present in a more formal, but still local environment and receive feedback as well as to keep the local research community informed of the current research activities in the Pulmonary & Critical Care Division. This is also a venue for presentations by visiting professors.

Format: Although a more formal environment, projects in any stage of development are appropriate for this conference. Slides are the usual presentation format.

Attendance by research fellows at this weekly conference is strongly encouraged in addition to presenting yearly. The schedule for this conference is organized by the training track leaders with administrative support from Donna Schier (dschier@u.washington.edu). The Pulmonary Division conference schedule is available at: <http://depts.washington.edu/pulmcc/Calendar/calendar.htm>.

IMPORTANT QUESTIONS ABOUT A MASTERS DEGREE FROM THE SCHOOL OF PUBLIC HEALTH

1. Should I get a Masters degree?

Maybe. For most clinical research fellows the answer will be yes. The main reason to get the degree is that it will be one way that potential employers can recognize that you have training in clinical research (although it is less important than publications and grants.) Also, for most fellows, once you obtain the basic course work that you need anyway to be a competent clinical researcher, you will be 75% of the way toward the degree.

2. Should I get a Masters of Public Health (MPH) or a Masters of Science (MS)?

Most fellows should get the Masters of Science. The MPH program has a practicum requirement. For physician-fellows, this practicum may not be a good use of your time. However, if you think you might be interested in a job in public health or government (i.e. a state or county TB clinic), the MPH might be better for you.

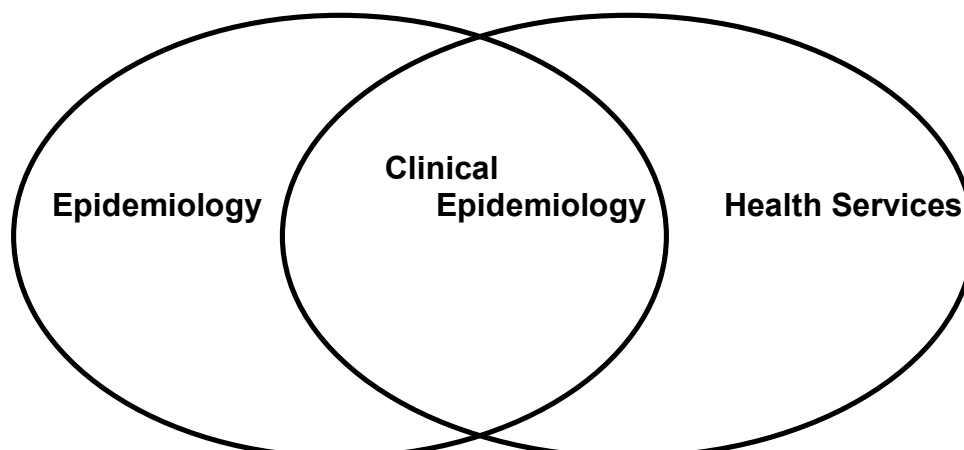
3. Should I get a degree from the Department of Epidemiology or Health Services?

The choice of a department depends on your interests. While most fellows do research that fits into the category of clinical epidemiology which is the intersection of these two departments, it is important to make sure that your department will value the kind of research you want to do. If measuring the incidence of a disease in a population lights your fire, join Epidemiology. If studying the way health care is delivered is up your alley, join Health Services. If you are in the middle, talk it over with your mentor and advisor.

4. Who pays the tuition?

The Division has a set amount of money from the Training Grant to pay for tuition. So far, the Division has been able to cover most or all tuition for fellows for **2 years**. If there are a lot of fellows wanting to get the Masters degree, the Division may not have the funds to pay the entire cost. You may be asked to apply for the K30 Program as another option that will pay for your tuition. Also, if individuals don't finish the degree within two years, they will be responsible for tuition in the third year.

Figure 1:



2008-2009 Academic Calendar

	AUTUMN 2008	WINTER 2009	SPRING 2009	SUMMER 2009		
				Full term	A term	B term
Instruction Begins WAC 478-132-030	September 24	January 5	March 30	June 22	June 22	July 23
Last Day of Instruction	December 5	March 13	June 5	August 21	July 22	August 21
Final Examination Week	December 8-12	March 16-20	June 8-12	Typically the last class day	Typically the last class day	Typically the last class day
Commencement			Seattle, June 13			



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Modified: December 28, 2001*

EXAMPLE OF SOME OF THE CORE COURSES FOR PHYSICIAN-FELLOWS

HSERV 510 or HSERV 583 or *HSERV 590E	Theory & Meth. in Social & Behav. Sci (<i>Grade:3/5 credits</i>) Society, Chronic Illness, and Disability (<i>Grade:3 credits</i>) Social & Behav. Science Seminar (<i>Cr/NC:3 credits</i>) (Qualitative Research Methods)	Winter Spring Autumn/every other year (even years)
HSERV 592B ⁺	Clinical Scholars Program Seminar (CSP) (<i>Grade:2 credits</i>) (Needs to be taken 6 times for a total of 12 credits)	Aut,Win,Spr.
HSERV 511	Intro. Seminars in Health Serv. (<i>Grade:3 credits</i>)	Sum/Aut(1st year)
BIOSTAT 511 and BIOSTAT 512 and BIOSTAT 513	Medical Biometry I (<i>Grade:4 credits</i>) Medical Biometry II (<i>Grade:4 credits</i>) Medical Biometry III (<i>Grade:4 credits</i>)	Summer(1st year)
EPI 512 and EPI 513	Epidemiologic Methods I (<i>Grade:4 credits</i>) Epidemiologic Methods II (<i>Grade:4 credits</i>)	Autumn Winter

*Course generally taken by physician-fellows

⁺The CSP courses require EARLY sign-up.

COURSE REGISTRATION AND OTHER COURSE RELATED ACTIVITIES

Applying to the School of Public Health

If you are interested in the Masters degree, you need to formally apply to the Department that you are most interested in (Epidemiology or Health Services.) You should call the number for the department listed below on page 17 or check their websites listed below. You will need get an application during the winter of your first (clinical) year as a fellow. Ask some of your senior fellows for an example of their application the prior year or two. **Application deadlines are usually in November or December for the following summer quarter.**

<http://depts.washington.edu/epidem/>

<http://depts.washington.edu/hserv/>

Registering for courses

Toward the end of each quarter, you will receive a course registration form that will ask you to list courses you wish to take for the following quarter. Refer to the MPH requirement sheet for a list of required courses. General course information is also available from the UW catalog, the UW Time Schedule (published quarterly), and your faculty advisors.

Dropping and adding courses

If you wish to drop or add a course after you have registered, please notify the person in the front office in charge of registration immediately. Fees to add and drop courses increase as the quarter progresses, and you may not add or drop a course after the deadline.

Applying for Satisfactory/Not Satisfactory (S/NS) grading option

If you are registered for a course that is graded (4.0-0.0), you may apply to take the course Satisfactory/Not Satisfactory. With the S/NS option, any grade above 2.7 will be converted to an "S" and any grade below that will be converted to an "NS". An "S" is passing. In order to apply for the S/NS option you need to:

- 1) Be sure that you will meet your requirement of 18 graded credits, if you choose this option (check with the person in the office responsible for course registration to make sure).
- 2) Go to Schmitz Hall, Rm. 225, **before** the 10th day of class and submit a non-STAR transaction form (***If you make the change after the first week of class, you will be charged \$20 by the Registrar's office**)

<http://depts.washington.edu/registra/forms/nonstar.pdf>

Elective Courses

You should take any elective courses (i.e. not required for the Program or your degree) in the quarters preceding your final quarter (usually Spring quarter of your second research year). Your last quarter you will be registered for only 2 credits. Be sure that elective courses do not interfere with your research.

Graduation

Students must apply for their master's degree at the Graduate School (Administration Building at upper campus, 2nd floor) within the first two weeks of the quarter in which they expect to complete their degree requirements. The filing of the application is the sole responsibility of the student. The Graduate School will approve the application as long as all requirements for the School have been met. If there are discrepancies, the applicant will be notified, otherwise the application will be forwarded to the appropriate graduate program. Master's degree applications are valid for two consecutive quarters, and if requirements for the degree are not completed during the quarter of the initial application, the student's application may be retained by the graduate program coordinator for the quarter immediately following. Upon completion of departmental requirements, the master's degree application is signed by the Supervisory Committee and returned to the Graduate School.

Thesis

Your thesis will be one of your research projects in a format very similar to the way you would submit it for publication. However, there are VERY picky format requirements. When you have completed your thesis, before having your committee sign off on it, you will need to take it to the Graduate School and have it checked for correct formatting by the thesis advisors.. They are picky about the EXACT format of the thesis and it is worth doing this well in advance. Once the thesis has met all format requirements it will be accepted by the Graduate School. **Do not wait until the last day that theses are due or you will have to wait in a long line.**

PHONE NUMBERS

ACADEMIC

Graduate Student Counselors and Admissions Applications

Health Services	543-8778
Epidemiology	685-1762

Information about course registration

Registrar's office	543-4000
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Information about graduation

Graduate School	543-5900
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COMPUTER

General Questions (UW Help line)

MCIS – Computer Support	543-7012
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Software Questions

Apple Assistance Center (Mac Users)	1-800-996-1010
Microsoft Word for Windows (DOS Users)	462-9673

LIBRARIES

Business Administration	543-4360
Health Sciences	543-3390
Odegaard	543-1947
Social Work	685-2180
Suzzalo	543-0242
KKSherwood – HMC Library	341-4124

MISCELLANEOUS

Student Loan Deferment (Libby Sando)	543-0065
Fiscal Services for Students	543-4694
Benefits Office (Health/life insurance)	543-2800
Center for Educational Resources (Slides)	543-6114
Andy Blair – HMC Media Specialist	731-3470
Publication Services - Graphics (Posters)	543-5680

EXAMPLE OF RESEARCH OUTLINE

Investigators

William Bollinger, MSII and J. Randall Curtis, MD, MPH

Title

Factors that Predict which Patients with a Negative Induced Sputum for *Pneumocystis carinii* Pneumonia Undergo Bronchoscopy

Research Questions

Primary Research Questions:

1. What factors are associated with the decision to pursue diagnostic bronchoscopy after a negative sputum induction for *Pneumocystis carinii* pneumonia (PCP)?
2. Is the patient's insurance status associated with the performance of bronchoscopy?

Secondary Research Questions:

1. What is the current sensitivity of induced sputum for PCP at Harborview Medical Center?
2. Is there a difference in a) survival from an episode of PCP or b) late hospitalization rate between patients treated empirically for PCP after a negative induced sputum and patients with a bronchoscopically-confirmed diagnosis of PCP controlling for severity of disease?

Background

1. PCP remains one of the most common opportunistic infections among patients with HIV infection.
2. The role of empiric therapy for PCP is controversial and practice patterns for PCP vary in different care settings and different geographic regions.
3. A randomized, controlled trial comparing empiric therapy to early definitive diagnosis for PCP is not feasible.
4. Decision analyses have concluded that empiric therapy and early definitive diagnosis are likely to be equally efficacious, but conditions effecting these decision analyses, such as the prevalence of PCP among patients evaluated for PCP, are changing with the widespread use of PCP prophylaxis and the changing demographics of HIV infection.
5. Analysis of current practice patterns for diagnosis of PCP will provide insight into a) practice variation in the diagnosis and management of PCP, b) the prevalence of PCP among those patients evaluated for PCP, c) an update of the sensitivity and negative predictive value of induced sputum, d) question of whether quality improvements efforts should target PCP diagnostic strategies.

Design

Retrospective cohort study.

Subjects

Selection criteria:

HIV-infected individuals referred for sputum induction to establish the diagnosis of PCP.

- Cohorts:
- a) individuals with a negative induced sputum who receive bronchoscopy.
 - b) individuals with a negative induced sputum with no bronchoscopy.

Sampling design:

A consecutive sample of individuals referred for sputum induction.

Variables

Predictor variables:

Age, gender, insurance status, initial alveolar-arterial oxygen difference, LDH, albumin, total lymphocyte count, CD4 cell count, history of previous PCP, CDC HIV classification, primary care clinic affiliation.

Outcome variables:

Survival from the episode of PCP, late hospitalization, late bronchoscopy, health care charges.

Statistical Issues

Hypothesis and analytic approach:

1. What factors are associated with bronchoscopy after a negative sputum induction for PCP?

Hypothesis: Individuals who undergo bronchoscopy will have more severe PCP (increased alveolar-arterial O₂ difference and LDH), and less severe HIV infection (higher CD4 count, total lymphocyte count, and albumin).

Analysis: T-tests or Wilcoxon rank sum for continuous variables, chi square for categorical variables.

2. Is the patient's insurance status associated with the performance of bronchoscopy?

Hypothesis: There is no association between insurance status and bronchoscopy.

Analysis: Chi square.

3. What is the sensitivity of induced sputum for PCP at Harborview Medical Center?

Hypothesis: Descriptive.

Analysis: The numbers of patients with a positive induced sputum for PCP will be the numerator and the number of patients diagnosed with PCP by induced sputum and bronchoscopy (after a negative induced sputum) will be the denominator. In addition, patients treated empirically for PCP after a negative induced sputum will be added to the denominator in a secondary estimate of the potential range of sensitivity.

4. Is there a difference in survival from an episode of PCP or late hospitalization rate between patients treated empirically for PCP after a negative induced sputum and patients with a bronchoscopically confirmed diagnosis of PCP?

Hypothesis: Patients treated empirically may have a higher survival rate than those with a confirmed diagnosis, but this will disappear after controlling for severity of disease. Patients treated empirically will be more likely to require late hospitalization and late bronchoscopy.

Analysis: This is an exploratory analysis to determine the feasibility of assessing the outcome of empiric therapy using medical record databases. The study will not be powered to answer this question. Chi square test will be used to compare survival from an episode of PCP in the two groups. Logistic regression will be used to assess survival from an episode controlling for severity of illness variables.

Sample size estimates:

Pending.

RECOMMENDED BIBLIOGRAPHY

Choosing a research questions and general career advice:

1. Kahn RC. Picking a research problem: the critical decision. *NEJM* 1994; 330:1530-3.
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3. Goldman L. Blueprint for a research career in general internal medicine. *J Gen Intern Med* 1991; 6:341-4.

Writing research papers:

1. Welch HG, Froehlich GW. Strategies for writing for a physician audience. *J Gen Intern Med* 1996; 11:50-55.

Mentors and Mentoring:

1. Applegate WB, Williams ME. Career development in academic medicine. *Am J Med* 1990; 88:263-7.
2. Luft R, Low H. Excellence and creativity in science. *Clin Res* 1980; 28:329-33.
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1. DeAngelis CD, Johns ME. Promotion of women in academic medicine. *JAMA* 1995; 273:1056-7.
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3. Tesch BJ et al. Promotion of women physicians in academic medicine: glass ceiling or sticky floor? *JAMA* 1995; 273:1022-5.

General study design and biostatistics papers

1. Browner WS, Newman TB. Are all significant P values created equal? *JAMA* 1987;257:2459-63.
2. Concato J, Feinstein AR, Holford TR. The risks of determining risk with multivariable models. *Annals Int Med* 1993; 118:201-10.
3. Mills, JL. Data torturing. *NEJM* 1993; 329:1196-9.