Clinical and Translational Research
Fellowship Program (CTRFP)

Program Guidelines
2014-2015

A program sponsored by the Clinical & Translational Science Institute (CTSI)
at the University of California, San Francisco

Updated: June, 2014

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INTRODUCTION/EXPLANATION OF MANUAL
Welcome to the Clinical and Translational Research Fellowship Program (CTRFP), a program of the University of California, San Francisco’s Clinical and Translational Science Institute (CTSI). We are committed to meeting your educational needs and working with you to make your fellowship in clinical research a rewarding and enjoyable experience.

The contents of this manual are provided to familiarize CTRFP fellows with information that is pertinent to their training. The information contained in this manual pertains to all research fellows in the CTRFP, including students funded by the NIH CTSI TL1 grant, the Doris Duke Charitable Foundation, the UCSF SOM Dean’s Office, Promoting Research Opportunities Fully-Prospective Academics Transforming Health (PROF PATH), as well as students who have other funding.

We ask for your full cooperation in abiding by the program’s policies and procedures. If you have any questions or ideas for improving this manual, please contact the program coordinator.

MISSION STATEMENT
The goal of the CTRFP at the University of California, San Francisco (UCSF) is to provide pre-doctoral students with a foundation of skills and knowledge that will enable them to pursue a productive and rewarding career in clinical and translational research and academic healthcare. We strive to attract talented and motivated students with a passion for improving patient care and a thirst for answering relevant and meaningful questions. We do not adhere to a specific research area, but attempt to support fellows in whatever research focus ignites their interest.

Our students’ research topics range from improving health care delivery and disparities to uncovering novel risk factors for diseases, to molecular pathogenesis and identifying and examining new treatments or management strategies. Because of the diverse and experienced clinical research faculty at UCSF, we have access to experienced mentors in almost any area of research. We believe that essential skills are best delivered through a combination of mentored research experience, structured coursework in research methods and epidemiology, and shared experience and evaluation of the work of colleagues (including fellows and faculty).

We strive to provide fellows with a forum in which to develop the key skills that enable success in an academic environment: planning a career, maintaining productivity, writing, obtaining funding, presenting results, working as part of a team, and self-evaluation. We ask that our fellows join us in our mission to create the best possible training program by working hard, supporting their colleagues, providing the leadership with constructive feedback, and having fun.
SECTION I. STUDENT/FELLOW SERVICES

LIBRARIES
UCSF’s main library is the Kalmanovitz Library located at 530 Parnassus Avenue. Newly received journals are located on the first floor; archived journals are in the basement. There are copiers available on both these floors. If you present your ID to the cashier located in the copy center in the basement you can purchase a discounted copy card. UCSF has also purchased electronic access to many journals. You can access these journals from any on-campus computer, or from home if you have set up a VPN account.

Kalmanovitz Library also has a computer lab in the basement, which you can use. To log in to and print from these computers you must set up a Galen account. The Galen account can be established online. The program administration will acquire Galen accounts for the non-UCSF students. To put money on your account to print from library’s computers, see the cashier in the basement. The computers in the library’s computer lab also have Internet Explorer, Stata, Excel, Microsoft Word, and other programs, which you can use.

If you do not have previous experience using PubMed (a portal into the Medline database), the library offers periodic classes. They also host tours of the library. Schedules are available online or at the circulation desk.

The library at the San Francisco Veterans Affairs Medical Center (SFVAMC) is located in Building 6, Room 209 on Floor 2. There is no charge for using the library’s copy machine.

The library at San Francisco General Hospital (SFGH) is located at 1001 Potrero Ave, San Francisco, CA 94110 in Building 30 on the first floor.

PARKING AND TRANSPORTATION
CTRFP does not pay for or reimburse fellows for parking.

All campuses of UCSF suffer from serious traffic and parking congestion. To facilitate travel among campus locations, frequent free shuttle bus service is available. http://campuslifeservices.ucsf.edu/transportation/services/shuttles

Please familiarize yourself with UCSF’s Campus Life Services website for information on parking, vanpools, car share and a host of other transportation options. http://campuslifeservices.ucsf.edu/cls/
STUDENT HEALTH INSURANCE
All yearlong fellows will get health insurance during their fellowship year paid by the CTRFP (if needed). UCSF medical students will have their insurance paid for by the School of Medicine’s Dean’s office.

Non-UCSF students will be able to either continue with their home institution’s coverage or opt to enroll in the UCSF Student Health Plan. The CTRFP will pay the premium in either case.

The contact for issues regarding your student health insurance can be directed either to the program coordinator or Charles McDonough, a Manager in Student Health Services who is familiar with our program (charles.mcdonough@ucsf.edu).

Coverage will begin July 1st and end June 30th.
http://studenthealth.ucsf.edu/

SECTION II. FUNDING AND LEAVE TIME
STIPENDS
CTRFP fellows are funded by the NIH CTSI TL1 grant, the Doris Duke Charitable Foundation, the UCSF SOM Dean’s Office, Promoting Research Opportunities Fully-Prospective Academics Transforming Health (PROF PATH), as well as other funding sources.

Those students funded by the SOM Dean’s Office will be paid by the Dean’s Office and not CTRFP. Questions regarding stipends from the Dean’s office should be sent to Amineh Helalian at HelalianA@medsch.ucsf.edu or 415-476-2347.

Those students funded by the PROF PATH funds will be paid by the PROF PATH staff and not by CTRFP. Questions regarding stipends from PROF PATH should be sent to Victoria Chen at ChenV@fcm.ucsf.edu.

All CTRFP fellows will receive an annual stipend. The total amount of that stipend will vary by year and funding mechanism.

Taxability of Stipends
Fellow stipends will not have any taxes withheld.

Section 117 of the Internal Revenue Code applies to the tax treatment of scholarships and fellowships.

The interpretation and implementation of the tax law is the domain of the IRS and the courts. Individuals should consult their local IRS office about the applicability of the law to their situation and for information on their tax obligations.
Form 1099
Although stipends are not considered salaries, this income is still subject to Federal and sometimes State income tax. The sponsoring institution may report such income on IRS Form 1099, Statement of Miscellaneous Income, but is not required to do so. **UCSF DOES NOT issue 1099 forms.** However, fellows are still required to report stipends as income.

It is recommended that all Fellows consult an accountant for further details. You will need to call the Stipend Desk at the end of the year to get the total dollar amount that has been issued to you.

**UCSF Stipend Desk Contacts:**

<table>
<thead>
<tr>
<th>Your Last Name</th>
<th>Contact</th>
<th>Telephone</th>
</tr>
</thead>
<tbody>
<tr>
<td>A-L</td>
<td>Erika Sweet</td>
<td>415-502-8205</td>
</tr>
<tr>
<td>M-Z</td>
<td>Maria ‘Cherry’ Lazaro</td>
<td>415-502-8206</td>
</tr>
</tbody>
</table>

**VACATION**
UCSF has approximately 13 paid holidays per year. In addition, full-year fellows can take two weeks of vacation throughout your fellowship. You are required to get this time off approved by your mentor(s) prior to taking the time and you must alert the Program Coordinator of your time off once approved.

**SICK LEAVE**
It is the fellow’s responsibility to communicate time off due to illness or injury to their mentor and immediate work colleagues. If the illness or injury will result in a significant amount of time away from their research, this must be communicated to the CTRFP leadership and program coordinator as soon as possible. This includes notifying CTRFP leadership if you are unable to make the bi-weekly seminar/Works in Progress Sessions.

**EMERGENCY OR FAMILY LEAVE**
In the event that you have a medical or family emergency and need to leave for any length of time, please notify CTRFP program leadership and your mentor as soon as possible.

**CONFERENCES**
The CTR fellowship program has two conferences per year, which some yearlong students will attend. This will depend on how the students are funded.

The first meeting is the National TL1 meeting which is held at different locations each year. This meeting usually happens in May and all TL1 funded students are required to attend and submit abstracts. The second meeting is the National Doris Duke International Clinical Research Fellowship Meeting. The DDCF-funded students are required to attend and submit abstracts. The participation of those
funded by other sources in these meetings varies by year.

Required time traveling to and attending these or other conferences is not counted as vacation time. Participation in other research conferences is at the discretion of the fellow and fellow’s mentor(s) and can be paid for by each fellow’s allotted research funds. All fellows will be required to track their own expenses and make sure there are sufficient funds available prior to committing to attending conferences.

In addition to the two national meetings, all yearlong fellows are required to do an oral presentation at the annual CTRFP Symposium and to create and present a scientific poster at ePosterpalooza! in May. See this website for details from last year’s events: http://ctsi.ucsf.edu/festival. These events are the capstones of the year. Please feel free to invite people from your labs or respective work sites, as well as friends and family.

**RESEARCH FUNDS**

As a part of being a CTRFP fellow, you may receive a pot of money for research expenses. These funds are made available by your funder, so speak to those administrators for your specific details. These research funds are separate and in addition to your stipends. Amounts will vary by funder. The purpose of these funds is to support your research project.

Since CTRFP is an NIH-sponsored program, we are required to follow NIH regulations regarding federal spending. This means that certain types of expenditures are disallowed. These include: food expenses (other than for travel), membership dues, office supplies, purchasing alcohol, purchasing hardware and using the money for incentive payments to research subjects are all expressly disallowed. Please contact the program coordinator before making purchases to ensure they are an allowable expense.

Information about details and processes for payment and reimbursement can be found in Appendix 1.

**SECTION III. FELLOWSHIP PROGRAM CURRICULUM**

**OVERVIEW OF CTRF PROGRAM EXPECTATIONS**

The CTRFP Program requires all fellows to take Designing Clinical Research (DCR) and the Responsible Conduct of Research (RCR) classes in July and August of their research year. There are no other classes required, but all fellows who are doing their research at UCSF must attend Works in Progress sessions (WIPs) and faculty talks every other week at Parnassus campus. They must complete evaluations of the faculty speakers and they must give their fellow students feedback on their WIP presentations. They must also attend (and help host one of) four student-led Inter-School Clinical and Translational Research (CTR) Journal Clubs throughout the year.
There are three check-in meetings with the CTRFP Program Directors (Dr. Joel Palefsky and Dr. Peter Chin-Hong) throughout the year. In May, all students must orally present their research at the Annual CTRFP Research Symposium and, in addition, must create and present a scientific poster at ePosterpalooza! (also held in May). At the end of the year (in May or June) students may be required to attend a national meeting (depending on funding).

**CLASSES**

All fellows are required to take Designing Clinical Research (EPI 150.03) and Responsible Conduct of Research (EPI 201). Usually, these classes are offered between July and September of the research year. Tuition for these classes are paid by the CTRFP or the student’s funder. Registration for the classes will be handled by the program coordinator. More information on DCR can be found [here](#) and information on RCR can be found [here](#).

**ADVANCED TRAINING IN CLINICAL RESEARCH (ATCR)**

ATCR is a four academic quarter program intended for advanced pre-doctoral students, post-doctoral fellows and faculty members who desire rigorous training in the methods and conduct of clinical research. CTRFP offers some students the chance to take this coursework while it pays tuition. For more details on the program visit this site: [http://www.epibiostat.ucsf.edu/courses/ATCR.html](http://www.epibiostat.ucsf.edu/courses/ATCR.html)

There are two types of ATCR, the traditional and the credit-bearing. The credit-bearing ATCR program is the only option for UCSF students interested in doing ATCR while in CTRFP.

If CTRFP fellows decide to take ATCR and are UCSF medical students, they will need to take an official leave of absence from the school of medicine, because enrolling in ATCR will put them in the graduate division of UCSF. UCSF Allied Health students who are interested in taking ATCR should consult the CTRFP program coordinator regarding logistics with the registrar.

Credit-bearing ATCR is identical to the first year of the Master’s program and allows fellows to have access to all of the electives available to the Master’s students. Those in the credit-bearing program have the option to complete the second year of a Master’s degree after their CTR fellowship year. They would do this during their residency or fellowship if they remain at UCSF, or they could apply for a second year of CTR funding to complete the MAS in Clinical Research. See more information about this program below.

**MASTERS IN CLINICAL RESEARCH PROGRAM**

Yearlong fellows matriculated at UCSF are invited to participate in a structured, intensive Masters in Clinical Research Program if they desire. The Masters Program is sponsored by the UCSF Department of Epidemiology & Biostatistics. Coursework and information on the Masters Program is available at:

[http://www.epibiostat.ucsf.edu/courses/ATCR.html](http://www.epibiostat.ucsf.edu/courses/ATCR.html)
Participation in the Masters Program requires a separate application. Admission into the Masters Program cannot be guaranteed by the fellowship.

**WORKS IN PROGRESS SESSIONS**
The bi-weekly CTRFP Works-In-Progress sessions (WIPs) are held every other Wednesday at the Parnassus campus (Schedule may vary slightly) and are mandatory for all CTRFP fellows. This seminar provides an opportunity for fellows to present their research and progress to their peers and an interdisciplinary group of faculty. These sessions allow fellows to both learn from and teach their peers. The environment is relaxed, supportive and open and all types and levels of questions are encouraged. These seminars will include a Faculty presentation on a variety of topics.

**INTER-SCHOOL CTR JOURNAL CLUB**
These Journal Clubs happen 4 times a year. They are student-led (with administrative help provided by program coordinator and program assistant). These Journal Clubs discuss a CTR article with ties to all four schools. The club begins with a presentation from the students who organized the session and then the floor is open to discussion and questions and answers. There is always food offered. Attendance at these evening sessions is mandatory, and it is also required that the fellows get involved and plan at least one of the sessions during the year. More information about the journal club and the expectations for the fellows can be found in Appendix 3.

**FACULTY MENTORS**
The single most important aspect of a CTRFP experience is the designing and conducting research projects under the guidance of a dedicated and outstanding mentor. Great emphasis is placed on finding a good match between the fellow and the mentor that includes not only a common research interest, but also a complementary style that will foster the most productive working relationship.

Mentors have been selected because of their proven track record of commitment and successful mentorship of former clinical research fellows. Faculty members, who are matched with fellows, commit to meeting with their assigned fellow at least weekly, and, in most cases, more frequently to discuss details of designing and implementing research projects, presentations and manuscripts. Fellows are best served by exposure to one primary mentor, who will take responsibility for guiding their main research projects of shared interest, as well as 1-2 secondary mentors, who may advise the fellow about a specific aspect of their work (such as instrument development or a statistical technique). Establishing objectives and goals for the research project with one’s mentors, and a timeline for achieving these goals, is very helpful for ensuring a successful research relationship.
SECTION IV. PROGRAM EXPECTATIONS

**TIME**
CTRFP fellows are expected to spend 40 hours a week (100% effort) at least to their research project with their mentor. Failure to comply with this expectation could affect funding and may require the student to pay back part of or all of their stipend.

**PERFORMANCE**
As with most things in life, trainees will get out of the fellowship what they put into it. Experience shows that providing extra attention to defining one’s research questions, methods and data sources up-front can make a big difference in enhancing a smooth transition into data collection and analysis. A brief review of the current literature in one’s area of interest is a good idea, in that it helps the faculty and fellows provide more effective feedback and guidance. Regular and frequent presentation of one’s progress on defining the research question, collecting the data, analyzing the data and interpreting the results is critical for fellows to learn about and participate in research projects. Yearlong fellows will present approximately 2-3 times per year to the rest of the CTRFP participants. For the benefit of your own training as well as that of your peers who rely upon your feedback and insights, it is expected that fellows will attend all of the fellowship-related seminars.

In addition, all fellows are expected to fully participate in and achieve passing grades in all Master’s Program, ATCR, or other fellowship-supported coursework in which they have enrolled. Fellows who are experiencing difficulty with the coursework should bring this to the attention of the program director so that steps can be taken to assist them in taking corrective action. Failure to do so could jeopardize on-going financial support from the fellowship program.

**EVALUATIONS & PROGRESS REPORTS**
Both students and mentors will be required to complete online evaluations three times during the year. *Evalue, an online evaluation tool, will be used in evaluating the program as well as both mentor and student. Fellows will also be required to submit quarterly progress reports and complete evaluations on the faculty speakers. In-person meetings will also be scheduled three times a year with the program directors to provide a forum to receive feedback from fellows. There may also be additional surveys to complete during the year in other tools.

SECTION V. HIPAA/DATA SECURITY/MALPRACTICE INSURANCE
Federal regulations, state laws and UCSF policy state that each computer user is **personally responsible** for data stored on any device, including laptops, thumb drives, CDs and DVDs, home computers and portable hard drives. Password protection on any device is not sufficient for protecting data. When protected data are compromised by theft or other occurrence, the notification process is
lengthy and expensive as well as publicly embarrassing for all parties. Please refrain from storing non-deidentified data on any local device. Please refer to the UCSF Privacy Training website: http://www.epibiostat.ucsf.edu/courses/schedule/clin_research_predocs.html.

**HEALTH INSURANCE PORTABILITY & ACCOUNTABILITY ACT (HIPAA)**

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 mandated significant changes in the legal and regulatory environments governing the provision of health benefits, the delivery and payment of healthcare services, and the security and confidentiality of individually identifiable, protected health information. The law is composed of two major legislative actions: provisions for health insurance reform and requirements for administrative processes. Complying with all aspects of HIPAA has required that providers and all entities within the healthcare industry (including clinical research) to comply with certain standards in information systems, operations policies and procedures, and business practices.

Failure to comply with the electronic data, security or privacy standards can result in civil monetary penalties up to $25,000 per violation per year. Violation of the privacy regulations for commercial or malicious purposes can result in criminal penalties of $50,000 to $250,000 in fines and one to ten years of imprisonment. The Civil Rights Division of the DHHS is charged with enforcement and is recognized as a stringent “enforcer.” Providers who fail to comply also run the risk of violating public trust, which can have profound impact on public relations.

All fellows are expected to read and complete three modules online, located at http://hipaa.ucsf.edu/education/student/default.html. They are the following:

1. Advanced HIPAA Healthcare Provider Module
2. Advanced HIPAA PHI Management Module
3. Advanced HIPAA Security Module

In addition, students must:

1. Review of the UCSF Privacy and Confidentiality Handbook
2. Complete the UCSF Confidentiality Statement

All of this must be completed **NO LATER THAN AUGUST 1st of your research year.** A secure environment to store student data will be made available as needed.

***“MYRESEARCH” SECURE DATA ENVIRONMENT***

The Academic Research Systems group within the Information Technology Services department provides a secure data hosting service for research called MyResearch (https://myresearch.ucsf.edu). Research data can be housed in a
professionally staffed data center with the highest level of data security standards and accessed over a secure encrypted connection. See the website for more details.

**MALPRACTICE INSURANCE**
CTR Fellows are expected to spend 100% of their time doing research. It is understood that students may sometimes need to have direct patient contact either for collecting primary data or to enhance the learning process directly related to a student’s research project. **Non-UCSF students are required to maintain their home institution’s malpractice coverage and provide proof of coverage to the program administrator prior to any patient contact at any UCSF facility.**

**SECTION VI. LOAN DEFERMENT**
Students doing a yearlong fellowship and taking a leave of absence from their school of matriculation, must contact your Financial Aid Advisor for loan deferment policies and procedures. Some universities require the completion of a specific form verifying your participation in the CTRFP.

**SECTION VII. PUBLICATIONS**
It is appropriate for you to acknowledge the funding source on publications with the agency name and funding number.

- Find more information/details of acknowledgements here: [http://accelerate.ucsf.edu/cite](http://accelerate.ucsf.edu/cite).
  - All students who are or were a part of CTRFP (formerly PACCTR) must acknowledge the program with the following statement:
    - "This publication [or project] was made possible in part by the Clinical and Translational Research Fellowship Program (CTRFP), a program of UCSF’s Clinical and Translational Science Institute (CTSI) that is sponsored in part by the National Center for Advancing Translational Sciences, National Institutes of Health, through [UCL-CTSI Grant Number TL1 TR000144](http://accelerate.ucsf.edu/cite) and the Doris Duke Charitable Foundation (DDCF). The contents are solely the responsibility of the authors and do not necessarily represent the official views of the NIH, UCSF or the DDCF."
- If the details of your acknowledgement aren’t included on the website above, contact your funding agency.
SECTION VIII. PROGRAM CONTACTS

Joel Palefsky, MD, CM, F.R.C.P.(C) Program Director
513 Parnassus Avenue, S420
Campus Box 0654
San Francisco CA 94143-0654
Tel: 415-476-1574
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As of February 2015:
Mark Dorshkind
CTRFP Financial Analyst
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Email: mark.dorshkind@ucsf.edu
CTRFP Fellows
Finance Guidelines
2014-2015

Some CTRFP Fellows have funds to spend on research and travel to their national meeting.
Details of funding are specific to funding stream, so please check with Program Coordinator for details of your specific case.
Students paid by ProfPath or the Dean's office should check with their funding office for details.

1. If you have been notified that you have these funds, you can spend your Research Funds on:
   a. Travel (required to pay for attendance at national meeting)
   b. Research materials (All expenses must be directly related to your research)
      i. Software
      ii. Lab supplies

2. Please get Program Coordinator (Kim Woodhouse) approval before you spend

3. You cannot spend your Research Funds on:
   a. Hardware (computers, etc)
   b. Memberships or subscriptions
   c. Alcohol
   d. Office supplies (poster printing is allowable)

4. All receipts must be submitted for payment by June 25th (unless you are DDCF funded, which gives you until June 30, 2015 to submit for payment)

TRAVEL
1. Book your travel early (we recommend 6-8 weeks ahead of time but that is just a suggestion)
2. Before you book your flight:
   a. Review policies and procedures (http://controller.ucsf.edu/travel)
   b. Get approval from Program Coordinator
3. Payment options:
   a. Use Connexxus (UCSF travel portal, requires set-up through MyAccess): http://controller.ucsf.edu/travel/
   b. Pay out of pocket and get reimbursed via MyExpense
4. When you return from your trip, submit your reimbursements within five business days!

RESEARCH MATERIALS
1. MyExpense: Online tool to reimburse out of pocket expenses
   a. Process
      i. Send PDF of receipts to Mark Dorshkind or upload to MyExpense Receipt Store yourself
         1. Receipt must show proof of payment
         2. Itemized receipt for all applicable purchases
         Please remember:
         - A receipt that doesn’t show actual payment is NOT proof of payment. Proof of payment includes anything that shows a paid balance
         - If requesting reimbursement for a conference, please include the conference agenda with your receipts.
         - Keep in mind food and meals can be reimbursed up to $71 per day per person.
ii. Email Mark Dorshkind, notifying him that you have a reimbursement request in the pipeline
iii. He will prepare the reimbursement request and submit it on your behalf to the approver
iv. He appraiser reviews and approves (assuming no questions)
v. Once approved, reimbursement is usually distributed within 5 business days

2. Bearbuy: Purchasing system used by UCSF
   a. Mentor’s department typically handles purchasing supplies (if any)
   b. SAVE packing slips and get them to Mark Dorshkind (once you are sure the item is not defective and is what you ordered)
      i. Give to Kim during a WIP meeting
      ii. Send via intercampus mail (Box: 0558)
      iii. Scan and email pdf to Mark (good option for international fellows)

CTR Fellowship Program Administrative Contacts:
Kim Woodhouse, Program Coordinator: Kim.Woodhouse@ucsf.edu
Mark Dorshkind, Finance Analyst: Mark.Dorshkind@ucsf.edu

Getting Started – One Time Activities
MyExpense: Assign Mark Dorshkind as Delegate
   a. Log in to MyExpense at www.myexpense.ucsf.edu using your MyAccess unique ID
   b. Go to Profile
   c. Then to Expense Delegates
   d. Then Add Delegate
   e. Add "Dorshkind, Mark" and click all four boxes

Set up Direct Deposit:
   a. Complete this Direct Deposit form.
   b. Follow the instructions and submit to Freddie Robinson (frobinson@accounting.ucsf.edu) in Student Accounts.

NOTE: UCSF students may have already completed direct deposit and won’t need to re-submit as long as your banking information remains unchanged.
APPENDIX 2: Fellow’s Advice

Some previous fellow advice for a productive and enjoyable fellowship:

• Be sure to pick a project that is feasible and in which you are interested. It sounds like a no-brainer, but it’s easy to be led astray by the promise of publication.
• Try to work on more than one project, if possible. If your primary project doesn’t pan out, you’ll have something to fall back on.
• If you are considering taking the ATCR sequence, be sure you’re aware of the time commitment these courses impose. It will affect the amount of time you have for research, but you’ll receive great training in basic epidemiology and biostatistics.
• Ultimately, try to figure out what your goals are for the year and do your best to attain those. They need not all be publication-oriented.
• The summer session of TICR is a good time to explore project ideas. You will be part of a small group in which you can discuss ideas for your proposal.
• The fall quarter of ATCR or the Master’s program is tough. You should expect to devote most of your time to coursework, leaving little time for research. This is frustrating. Prioritizing is essential. Keep in mind that the workload decreases substantially after the first semester.
• Once you start programming in Stata, do ALL your work in Do files. It will save you huge amounts of time later.
• The STATA statistical coursework is during winter and spring quarter of ATCR. In spring quarter, you will be asked to select a dataset to analyze. This is a good time to incorporate one of your own projects and get statistical assistance.
• UCSF provides resources for assisting you with writing grants and preparing manuscripts. When it comes time, inquire with the program director about the appropriate people to contact. This is a helpful resource.
• Use the Works-In-Progress sessions to get and give as much constructive feedback as you can. When you present, your main goal should be to make the session work for you. There are no rules on how or what you should present. New fellows often feel deflated after the first or second time they present. Remember a room full of people can make suggestions for how to improve EVERY project. All feedback is given to help you. In order to fully take advantage of your Works-In-Progress, consider doing the following:
  o Email materials out to the group over the weekend before the meeting so that people are already familiar with your project when they arrive. Background is essential, but if people come prepared you can spend your time discussing your project rather than informing people about it.
  o By the same token, be sure to read materials distributed by your colleagues prior to coming to Works-In-Progress. It is true that you get as much out of giving feedback as you do from presenting, but you have to be prepared.
  o Write down for yourself or distribute to the group specific questions you want addressed during your time. This makes sure that you get out of the session the feedback you really wanted, rather than the group’s ideas for the eventual million-dollar project you should implement when you are an assistant professor.
• Enjoy SF (especially for those from other areas) and be sure to some take time for yourself!
UCSF Inter-School Journal Club General Information and Procedures

Committee composition: at least 2-3 student representatives from each professional school (dentistry, medicine, nursing, pharmacy), as well as faculty representatives

Events: 3-4 per year, including one during the week of the Research Festival in May. Usually Wednesday nights, 5-7 pm. First hour is journal club presentation/discussion, second hour is drinks, snacks and mingling.

Event planning

1. Planning meetings: first meeting 4-6 weeks prior to event; some decisions may be made over email but aim for at least 3 in-person meetings, especially with presenters
2. Choose a journal article*
   a. Goal is to choose a subject of interest to all 4 schools, but if not possible, a subject of broad appeal to health professional students
   b. Timely (last 6 months), well-designed, high-impact studies preferable
3. Choose presenters
   a. 3 or 4 total, at least one from each school
   b. Decide who will present at least 3 weeks in advance
4. Plan presentation*
   a. Divide responsibility to cover major areas: background, study design (study type, subjects, intervention/predictor, outcome variables), results, discussion
   b. May start with a fictional case to introduce clinical question
   c. Goal is to have powerpoint slides ready one week prior to presentation in order to have last meeting be dry-run
5. Presentation schedule
   a. 5 minute welcome and introduction
   b. 10 minutes background (including case if applicable)
   c. 10-15 minutes study design, major findings
   d. 30 minutes guided discussion—write on the board!
   e. Second hour: mingling and refreshments

*See following pages for Tom Newman’s excellent, detailed suggestions for choosing an article, planning and leading a journal club.
SUGGESTIONS FOR LEADING A JOURNAL CLUB

Tom Newman
June 11, 2007

Note: There are many different ways to lead a journal club. The format suggested here is aimed at helping participants learn how to read articles critically. I've found it works well, but it does require more effort from the learners than they may initially be used to. If this format can be used for a regular (e.g., monthly) journal club, participants can get used to preparing and contributing more. This handout was developed to help UCSF "Senior Consulting Residents" in the Pediatric Clinic lead a monthly journal club lasting about 50 minutes.

I. Select a provocative article

A. Two good choices are articles that you pulled as a result of an encounter with a particular patient and articles that have been published recently dealing with a clinical problem we commonly encounter.

B. It should report original research. Reviews are out -- the article needs to have a methods section. Meta-analyses, decision analyses and cost-effectiveness analyses are OK, but they are harder to assess critically because the results often depend on whether you can trust the authors and their underlying assumptions. I usually don't bother with them if they are industry sponsored.

C. If the methods are valid, it would change the way we diagnose, treat, or conceptualize the clinical problem or would clarify management of something currently controversial. (It's hard to excite people about critically reading an article which, if valid, would mean that we shouldn't do anything differently.)

D. Sometimes a pair of articles with opposite conclusions, as long as they are not too long or difficult. (For example, back to back articles on coin ingestions in children, with opposite conclusions and recommendations made a good journal club.)

II. Prepare yourself

A. Read the article critically. Write out what the authors did, what results they got, and what they concluded according to the outline below.

B. Think about each of the decisions the investigators made in designing the study, and what they concluded from the results. Were these good design decisions? Were the conclusions reasonable? What are possible problems with the design, sampling, measurements, and so on? How likely are these problems? How would they impact on the results and conclusions?

C. Pick out a few MAIN POINTS OR CONCEPTS that you think are most important in reading this study critically. Examples of these sorts of concepts are: bias in
measurement of outcome, loss to follow-up, unrepresentative subjects, effect size/number-needed to treat, confidence intervals for negative studies, etc.

D. Meet with a preceptor who can go over (or help you identify) some of the main points. Provide the preceptor with a copy of the article before the meeting.

E. There are lots of annoying things that can happen and detract from the conference. Try to anticipate and prevent them. Although I generally discourage PowerPoint, if you are going to use a computer, pre-test anything you are going to project. Projecting images from Mac computers is often problematic. Make sure there is enough chalk or dry-erase markers, you and the participants know where the room is, that it has enough chairs, that it is reserved and no one else will be in there, etc.

III. Prepare the participants. A journal club is better if people show up having read the article!

A. Distribute the article about 7 days in advance. It’s easiest for you to e-mail pdf files, but easiest for participants if you hand them the article on paper (obtaining a commitment to read it and come to the journal club when you do so).

B. If possible, make sure all participants have received the article and know that you are looking forward to their participation. If you send a pdf out by e-mail, it may be possible to choose “Return Receipt” so you know everyone got it.

C. Bring extra copies of the article to the session. Several people usually forget to bring it with them, even if they have read it, and it helps if everyone has a copy in front of them. Use 2-sided copies.

D. MAKE SURE EVERYONE KNOWS DATE, TIME, AND PLACE!

IV. Leading the discussion

A. Basic rules and tips

1. Start and end on time! (Of these, ending on time is most important!)

2. The more key points the participants make themselves (rather than you pointing them out) the better. Avoid lecturing and answering your own questions!

3. Try to make sure everyone is involved and interested. It is OK to call on people who are keeping quiet, including faculty members, if you do it in a nice way. If people fall asleep, wake them up; it is distracting to others to have anyone clearly not participating. Similarly, if one or two people are dominating the discussion, say, "I want to hear from some other people now" and try to get others into the discussion. If people are engaged in a separate
conversation, stop and bring them back to the group by asking what they are saying.

4. Use the board, NOT PowerPoint. The trouble with PowerPoint is that it gives the message that you have already decided what will be covered, and that you going to be the one making the important points. This tends to make your audience more passive. When you use the board, it makes it much easier to let the participants decide what points are most important to cover, and to keep track of points participants bring up, that you want to come back to later. (Write things you want to come back to in a “Parking Lot” section of the board.) A good sized chalk- or whiteboard lets you keep the basic “H&P” of the article on the board while talking about possible biases. Finally, putting stuff on the board helps keep the people who come late from slowing things down by asking stuff that has already been covered. It is helpful to think in advance about what you will put where on the board, so you don’t erase stuff you wish was still up there.

B. Format for discussion: Just as with a clinical case presentation, it is helpful to review the factual information before proceeding to discussion of judgment and interpretation. Plan on spending the first few minutes explaining why you chose the article, perhaps by a brief presentation of a relevant case. Then take about 20 minutes going through what the authors of the study did, what results they got, and what they think the implications for clinical practice are, using the outline below. Then the second half of the discussion can center on whether the design and results justify their conclusions, and what to do with the patient that led to your pulling the article.

C. Tips on timing: A common problem is to run out of time just as the discussion is getting interesting. This can result from spending too much time on the more boring stuff at the beginning. You don't want the discussion of what the article says (as opposed to what it means) to last more than half the session. You can speed up by reducing the number of things you ask the group or the number of chances or amount of time you give them to answer. For example, you can just write straightforward aspects of the study design (e.g., the inclusion and exclusion criteria) on the board yourself, rather than asking participants to find them and read them to you. Similarly, if you are afraid things are going too fast, you can slow things down by involving the participants more.

V. **Outline of the content of the article:** The same sort of learning that allows one to get better at obtaining relevant information from a patient, organizing it, and presenting it to others applies to reading journal articles as well. After using the structure below to review the article yourself, lead the journal club participants through it. Write the main headings one at a time on the board, explain what they mean, and get the participants to fill in the data from the paper. The elements of a study, analogous to the Chief Complaint, HPI, and so on are:

   A. **Authors and funding source:** This is analogous to the "identifying information and source of history" you're taught to put at the very beginning of your H & P.
It's a good idea to start with these items so you don't forget them later. Who are the authors? Do you know of any of their previous work, and has it been reliable? Who paid for it? It's not that research sponsored by industry is necessarily untrustworthy, but knowing who sponsored it, just like knowing the study design, gives you a head start at knowing what sorts of biases to look for. For example, if a study sponsored by a drug company finds that their drug is unsafe or inferior to others, you can probably assume that the results have been carefully scrutinized, and any possible threats to their validity have been evaluated!

B. Research Question: What is the question this study was designed to answer? Sometimes it helps to picture a clinical situation you'll be better able to handle if the study is valid. Examples of research questions are: "Does oral amoxicillin reduce morbidity in infants 6-24 mos old with fever > 39 degrees and no source?" or "Does passive smoking increase hospital admissions for respiratory disease in children?" Often the last line of the abstract gives the author's answer to the research question.

C. Study Design: What type of study is this? Randomized blinded trial? Cohort study? Case-control study? Cross-sectional study? Case series? If you are having trouble remembering the differences between them, you can Google them. If you want more depth, if you Google "Users Guides to the Medical Literature" you can find a series of articles that discusses different types of studies in greater depth, using a study-design specific approach that complements the approach I take here. Your preceptor can also help you with this.

D. Study subjects: Who was in the study? How were they selected? Who was excluded? How many subjects were there? Knowing how they selected the subjects is important in order to know whether the study results are valid (sometimes called "internal validity") and whether they are generalizable to the sort of patients you are likely to see ("external validity").

E. Predictor variable(s):

1. What they are: Sometimes called "independent variables," predictor variables are what the authors think might cause or predict changes in the outcome variable. For example, in a randomized trial, the main predictor variable is group assignment: i.e., whether the subjects were randomized to get the test drug or the placebo. In a study of passive smoking and respiratory tract disease, it would be some measure of passive smoking. In the studies of coin ingestions, predictor variables were all the things the authors thought might predict whether the coin would pass spontaneously into the stomach—things like what size of coin, how long ago the ingestion occurred, and whether it was causing difficulty swallowing.

2. How they are measured: For example, passive smoking may be measured crudely by asking the number of adults in the house who smoke or the
amount the mother smokes. Sometimes problems with how the variables are measured invalidate the study.

F. **Outcome variables:**

1. What they are: the clinically significant phenomena the investigators are trying to predict, prevent, or treat. Examples are presence or absence of disease, measures of symptom burden, survival time, etc. Watch for studies that show an effect on an outcome variable that is only marginally interesting. For example, moderate jaundice affects neonatal BAER’s but has no effect on their hearing. Some studies of cough suppressants compare cough latency (the amount of time it takes a dog to cough when his trachea is irritated); these studies have little clinical relevance.

2. How they are measured: If it’s a disease, what are criteria for diagnosis? Are those determining clinical improvement blinded to the treatment group of the subjects?

Sometimes it takes some effort to figure out exactly what the authors were measuring. For example, in studies of drugs for asthma, a common outcome measure is the percent improvement in peak flow or FEV1. If a child comes in with FEV1 = 50% of predicted, and improves to 75%, that could be considered a 25% improvement (75% - 50%). Or, it could be considered a 50% improvement, since the reduction in FEV1 below predicted was cut in half. It is important to clarify this, to know what the results mean.

G. **Results:** What did they find? Usually the key results are summarized in tables or figures—it may be helpful to walk the group through the most important tables to make sure everyone can see what results were obtained. If there’s a lot and you don’t want to put it on the board, you can make a couple of transparencies.

Make sure you consider not just statistical significance, but the **effect size** — that is, the magnitude of the difference between groups. *Relative* effect size is measured using the **risk ratio (RR) , odds ratio (OR) or relative risk reduction (RRR)**. It is important for assessing causation but less relevant clinically than the **absolute** effect size, measured by the risk difference, or **absolute risk reduction (ARR) and the number needed to treat (NNT)**. It’s probably easiest to illustrate these with a simple example. If the rate of a bad outcome in the treated group is 15% and in the control group is 20%, then the RR is 15%/20% = .75 and the RRR = 1-RR = 25% and the ARR = 20%-15%=5% and the NNT=1/ARR=20.

H. **Conclusions:** What do the authors think the results mean? At this point don’t discuss yet whether you agree with them.

VI. Discussing the validity of the study. The first part of the discussion dealt with facts, all of which were in the paper. The second half of the discussion deals with interpretation. There are no longer clear right and wrong answers—judgement comes into play.
A. Identify possible biases or flaws in the study. Was the sampling scheme reasonable? Were the measurements valid? Is the study design appropriate to answer the research question? Listing possible biases is akin to listing the differential diagnosis.

B. For each one, estimate how likely it is to have affected the validity of the results, and figure out in what direction it would affect the results. This step is crucial. In a case presentation, it's not that helpful just to throw out a lot of obscure possible diagnoses. You need to see whether the features of the case make these diagnoses likely enough that it's worth doing a test for them. Similarly, no study is perfect. When someone suggests a possible problem, you need to discuss whether this is something that is really important, and how it would affect the results. A COMMON error is to dismiss a study because of "flaws" that are unlikely to account for the results or would have biased the study in the opposite direction from what was found. (This is particularly true for randomized double-blind trials, in which most errors will bias the results towards finding no difference between groups.)

VII. Wrapping up: The most important part of the discussion is the "bottom line." Make sure you leave enough time for this! If the journal club started with an actual case, go around the room and see whether the article has changed how people would manage that case. If you don't have a specific case in mind, make one up. For example, at the end of the discussion on coin ingestions you could ask: "OK. You get a telephone call from the mother of a two-year old who has swallowed a quarter 10 minutes ago, but is asymptomatic. How many would have them come in? [Show of hands.] How many would do an X-ray?" Then you can spend the last 5 minutes or so having people justify their answers.
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Tom Newman         June 11, 2007

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**H. Conclusions:** What do the authors think the results mean? At this point don't discuss yet whether you agree with them.

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I have received the Program Guidelines for CTRFP and I agree to read them and abide by the rules and expectations set out in this document for the entirety of my time in the program (July 1, 2014-June 30, 2015)