

Student Handbook

University of Pittsburgh School of Medicine Institute for Clinical Research Education

July 2023





PREFACE

Welcome to the Clinical Scientist Training Program (CSTP) of the University of Pittsburgh School of Medicine. This handbook provides information about the policies and procedures pertaining to the programs, the School of Medicine, and the University of Pittsburgh. Although the material contained within the handbook is reviewed and updated once a year, changes may occur during the year and are announced in memos, on the website, and by e-mail so that students are notified in a timely manner. All questions and suggestions concerning the handbook should be directed to:

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University of Pittsburgh School of Medicine
Institute for Clinical Research Education
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Pittsburgh, PA 15213
Phone: (412) 864 - 3324

Fax: (412) 586 - 9672 cstp@pitt.edu (E-mail)

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Table of Contents

I.	Program Overview	3
A	Mission	3
В	Objectives	3
II.	Program Governance	4
A	Clinical Scientist Training Program	4
В	Institute for Clinical Research Education	4
C.	Degree-Granting Programs in Clinical Research	4
III.	Advising and Mentoring	5
A		
В	CSTP Mentors	5
IV.	Program Requirements	6
A	. Overview	6
В	. Academic & Research Integrity	6
C.	Degrees	7
D		
E	Mentored Research	7
F.	Financial Information	8

Appendix A: Guidelines for use of CSTP Funds

Appendix B: CSTP Purchasing Form

Appendix C: Clinical Research degrees - Plans of Study

Appendix D: Mentor-Mentee Contract



I. Program Overview

A. Mission

The mission of the Institute for Clinical Research Education (ICRE) is to offer the highest-caliber training and education in clinical research to all levels of trainees in the Schools of the Health Sciences (SHS) and to enhance collaboration among trainees and researchers from multiple disciplines.

Since 2003, those trainees have included medical students who receive the Clinical Scientist Training Program (CSTP) merit scholarships to pursue clinical research and a dual Doctor of Medicine (MD) and Master of Science (MS) or Certificate in clinical research.

B. Objectives

The CSTP was designed to meet several objectives:

- To provide students with formal training in clinical research methods to support the design and conduct of high quality, ethical clinical research;
- To provide students with career advising to increase their knowledge and understanding of the culture and expectations of academic clinical research environments;
- To decrease student indebtedness and reduce financial barriers to choosing an academic research career.



II. Program Governance & Support

A. Clinical Scientist Training Program

Judy C. Chang, MD, MPH
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B. Institute for Clinical Research Education

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Genevieve McCarthy
Assistant Director of Academic Programs
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gcm19@pitt.edu



III. Advising and Mentoring

A. CSTP Advisors

Dr. Judy Chang will serve as a student's advisor in the CSTP. She will oversee the mentor-mentee relationship and the progress toward meeting CSTP requirements and student-defined annual goals and objectives.

Dr. Chang will meet with each student semiannually. She will prepare annual reports evaluating each student's progress toward his or her specific goals and objectives in the CSTP. These reports are made available to the Dean of the School of Medicine.

B. CSTP Mentors

In the CSTP, students work with UPSOM SP mentors with whom they have a pre-existing relationship. A student's research mentor in the CSTP must be a major investigator, based upon UPSOM criteria. One way to conform the faculty's status is to ask them if they are classified in the "investigator pathway." Typically, they will be currently or formerly funded by the Department of Health and Human Services, Department of Defense, or Veterans Affairs Administration (e.g., "federally funded").¹ To confirm that a faculty member has federal funding, search by name in the Research Portfolio Online Reporting Tool Expenditures and Results (RePORTER)² at:

http://projectreporter.nih.gov/reporter.cfm

An optimal mentored clinical research experience is characterized by at least three features:

- The valued input of an experienced and responsive mentor
- Involvement in an interesting research project of which the student can take ownership
- The opportunity to work as part of a multidisciplinary team that provides exposure to all phases of research: conception, design, grant writing, recruitment and informed consent, data collection and analysis, and dissemination of results.

Mentorship not only provides an opportunity for research collaboration and peer-reviewed publication, but it also contributes to a student's successful research career through career planning, role modeling, and professional networking. The student and mentor will work together to develop a mentoring "contract" to ensure that they have clear mutual understandings concerning

¹ The purpose of this criterion is to ensure that the mentor's research has undergone extensive and rigorous external scientific review.

² The database, maintained by the Office of Extramural Research at the National Institutes of Health (NIH), includes projects funded by the NIH, the Substance Abuse and Mental Health Services Administration (SAMHSA), the Health Resources and Services Administration (HRSA), the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Agency for Healthcare Research and Quality (AHRQ), and the Office of the Assistant Secretary of Health (OASH). Although investigators funded by the Department of Veterans Affairs or the Department of Defense also are eligible to be program mentors, these investigators are not searchable in the database.



their roles, responsibilities, and educational goals. The mentor-mentee contract is available in the orientation packet and should outline:

- Expectations for the program and the mentoring experience
- Expectations regarding time commitments and the frequency of meetings
- Expectations regarding skills that will be developed
- Expectations regarding collaboration on research projects
- Commitment to the mentor-mentee relationship

IV. Program Requirements

A. Overview

The CSTP requirements include mandatory seminar attendance, passing all coursework for the MD degree, maintenance of a B average in coursework for the Master of Science (MS) or Certificate in Clinical Research, including a B or higher in all required courses, completion of Responsible Conduct of Research training and mentored clinical research with a University of Pittsburgh faculty member in the investigator pathway (see III B).

CSTP Scholars pursuing the MS must additionally complete the Comprehensive Competency Review (more information available here) and their research must produce a thesis or substantive research project (more information available here).

Certificate students must produce a submission-ready first authored publication.

Please note, you are not allowed to return to Medical School early or register for any Medical School clerkships during your year in the CSTP Program.

B. Academic and Research Integrity policy

Violation of academic or research integrity will be grounds for immediate program dismissal and scholarship revocation. Investigation and sanction in response to allegations regarding academic and research integrity violations will follow existing ICRE, UPSOM, and University policies and procedures.

Concerns about students on leave of absence from the first professional program of UPSOM to pursue graduate Certificate or MS coursework will be lodged by the CSTP program director to the first professional program using a "behavioral concern form."

Formal CSTP performance reviews will be twice during the research year (December and June). Students judged non-compliant with program requirements will not be eligible to receive the scholarship towards the fourth year of medical school. These decisions will be made by the CSTP program director and adjudicated by a sub-committee of the CSTP Advisory Committee.



C. Degrees

CSTP students typically earn a Certificate in Clinical Research (18 credits), although with the program director's approval, the student may opt for a Master of Science (MS) in Clinical Research (30 credits). The Certificate and MS are conferred by the Graduate Studies Office of the School of Medicine. Certificate and MS students must complete the CSTP core curriculum.

D. CSTP Core Curriculum

The CSTP core curriculum is outlined below.

Summer	Fall	Spring		
CLRES 2010 Clinical Research Methods (3 credits)	CLRES 2140 Medical Writing and Presentation Skills (1 credit) or NROSCI 2014 Speaking of Science (3 credits)	Electives		
CLRES 2020 Biostatistics (4 credits)	Electives			
CLRES 2005 Computer Methods in Clinical Research (1 credit, 1 week only)	CLRES 2075 Seminar for the Understanding of Principles and Practices of Research	CLRES 2075 Seminar for the Understanding of Principles and Practices of Research		
CLRES 2040 Measurement in	Techniques: SUPPORT	Techniques: SUPPORT		
Clinical Research	(0.5 credit)	(0.5 credit)		
(1 credit)				
Total credits: 9	Total credits: 4.5	Total credits: 4.5		
Ethics Requirement (2 options)				
1. Enroll in CLRES 2050 Ethics and Responsible Conduct of Research (1 credit)				
2. <u>Responsible Conduct in Research Training</u> (8 sessions)				

E. Mentored Research

The mentored research project must:

1. Meet the National Institutes of Health (NIH) definition of clinical research: "Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a)



mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies."

- 2. Be primarily independent work by the trainee.
- 3. Be approved in proposal form by the CSTP Director in the winter/spring prior to the research year.

F. Financial Information

All students who are admitted to the CSTP will receive a full tuition scholarship covering the tuition costs of the Certificate in Clinical Research, a NIH-level predoctoral stipend, and health insurance during the research year. Students satisfactorily completing their CSTP research year will additionally receive a partial tuition scholarship of \$25,000 toward the fourth year of medical school tuition. This scholarship recognizes students with exceptional promise and decreases their debt burden, so they have the flexibility to pursue academic careers in the future. For a complete description of CSTP funding and guidelines for allowable use of funds, please see the handout *Guidelines for Use of CSTP Funds*.



Guidelines for Use of CSTP Funds

V. INTRODUCTION

The Clinical Scientist Training Program (CSTP) supports costs associated with your University of Pittsburgh tuition, books, research project, conference travel, and health insurance during your one year period of appointment, July 1^{st} – June 30^{th} . This guide will help you understand the University of Pittsburgh and CSTP program rules that govern allowable costs and the procedures we follow to pay for supplies, services, and personnel. It also explains how to manage your health insurance coverage during your CSTP research year.

A. Award summary

Expense	Award	Notes
	amount	
Tuition	100%	100% of tuition costs to obtain the Certificate in Clinical Research.
		NOTE: CSTP does <u>not</u> pay student fees (\$590 / term)
Health insurance	\$4,800	Reimbursed monthly when you submit receipts
Stipend	\$27,144	Direct deposit paid last day of each month (\$2,262.00 / mo.)
Research & Travel	\$6,200	Supports research related costs and travel to scientific conferences

Do's and Don'ts of using your funds

DO	and please DON'T		
 Use us as a resource - check with us for advice and help on buying things, arranging travel, and purchasing services. Save yourself money, time, and frustration 	Buy anything with your own money before checking with us; some things are not allowable and can't be reimbursed		
Keep original receipts and turn them in promptly for reimbursement	Allow someone to work on your research and try to figure out how to pay them later. Always talk to us first about options for hiring and paying people – it can be complicated.		
Plan your spending to use funds effectively throughout the year. Don't wait until the last minute.	Obtain bio-materials or data without first getting a materials transfer agreement or data use agreement		



VI. STIPEND PAYCHECKS

- You will receive a stipend payment on the last day of each month by direct deposit). Your first paycheck will be 7/31/2023.
- Accessing your Paystub for your records You may wish to retrieve record of your paystub monthly. To access your pay stub, login to http://my.pitt.edu. From the navigation menu on the right side of the page, click PRISM Login. Click PHR Employee Self Service and click Pay Statement. If you cannot access PRISM, please let the ICRE Program Coordinator know as soon as possible. Your access to PRISM will start 7/1/2022 and will be discontinued on the last day of your CSTP appointment.

VII. RESEARCH FUNDING

<u>Please note</u>: when submitting purchasing requests, please complete the **ICRE Purchasing Form** (pg. 16). Purchase requests can be sent to: cdj16@pitt.edu.

A. Computers and Software

- The CSTP Program Coordinator must purchase all computers and software. All purchases will be made through University of Pittsburgh purchasing systems.
- **Computer** You must provide a written justification explaining why the computer (e.g., laptop, iPad), including any requested hardware features, is required to complete the specific aims of your proposed research. Approval will **not** be given to purchase computers for general purposes (e.g., web access, writing papers). The CSTP Program Coordinator, who must make this purchase through University of Pittsburgh purchasing systems, has limited access to models, features, and brand names. If your justification is approved, the ICRE Fiscal Coordinator will find the computer product that most closely matches your request but please make sure to send the desired model and configurations in justification and order form.
- **Software** The CSTP Program Coordinator must order any software that is required for your research. You must provide a research justification, description, and web link to the requested software.

B. Research Personnel (Temps, Student Workers, Research Staff, etc.)

• You need prior approval before you can use research funds to pay for any research staff or services (e.g., statistical analysis, transcription, data entry). Please talk to the CSTP Fiscal Specialist before starting any research work.



C. Data Set Purchases

• The acquisition and/or purchase of data sets (e.g., public health data from the government or a private agency) require execution of a signed **Data Use Agreement (DUA)**, which is a contract between the University of Pittsburgh and the agency providing the data. The DUA governs proprietary, confidentiality, and other legal issues. Executing a DUA can take several weeks or even months.

D. Payments for Study Participants

• We can set you up in the University's online 'We Pay' system that allows you to pay research participants using pre-loaded debit cards, however, this can't be listed as a Study Aide. Please allow 4 to 6 weeks for full setup of We Pay services for your research study. Setup includes mandatory training.

E. Supplies

- **Lab** We can buy lab supplies at special contracted prices from companies such as Fisher Scientific, R&D Systems, and many others. We can review supplier options with you.
- **General research supplies** We can purchase limited stock and brand supplies at discount prices. If you need a general supply product, we can order from one of the brand names available.

F. Meals/Food

• Meals and other food purchases are generally not paid or reimbursed from research funds. An exception can be made if food is provided to a gathering of research study participants.

VIII. CONFERENCE TRAVEL

<u>Please note</u>: when submitting receipts or requesting travel please complete the **ICRE Travel Request and Reimbursement Form** (pg. 17). All receipts must be the original and sent as a pdf or uploaded into the Concur System. Pictures of receipts will not be accepted. Travel Requests can be sent to: ICRETRVL@pitt.edu.

- Registration Fee- we can pay for registration fees in advance. If you choose to pay the
 registration fee personally (i.e. use your own credit card), you will be reimbursed only
 after the event is complete.
- **Flights** You must find your flight online and give the CSTP Program Coordinator the flight information to purchase the tickets through the University of Pittsburgh travel agent. Although the University of Pittsburgh Travel Agent charges a fee approximately \$30 more than the online price, the Pitt Travel Agent allows you to charge the cost directly to your CSTP grant funds. If you choose to purchase the flight yourself, reimbursement must wait until <u>after</u> the event is complete. **You will only be reimbursed for flights out of Pittsburgh International Airport, directly to and from the event. If you are flying to another event before flying back to Pittsburgh, please notify me before making arrangements.



- **Hotel** You can be reimbursed for conference stays only after travel is complete. You must provide an <u>itemized</u> hotel checkout slip or zero balance print out. Allowable charges are limited to room charges, taxes, and internet service only. ** Room service is unallowable unless there is an itemized receipt detailing the charges. Hotel stays that extend beyond the conference time frame will not be reimbursed.
- **Food and incidentals** For reimbursement of the cost of your food and other incidentals (e.g., tips, taxi fare), you have a choice. You may either submit receipts for your exact out of pocket costs, or request Government set 'per diem' reimbursements that vary by city. For government per diem rates, see www.gsa.gov/mie. If you choose to be reimbursed for exact receipts, your total daily reimbursement cannot exceed the government per diem limit. You must keep your original itemized receipts to receive reimbursement for all meals, taxi fares, tolls, and public transit fees.
- **Parking** With original receipt, you can be reimbursed for parking outside of Pittsburgh City Limits when traveling to conferences.
- Personal Car Use If you use your car for conference travel, we can pay a mileage rate
 based on federal guidelines. Distance to the destination will be based on departing from
 the University of Pittsburgh Oakland campus. We cannot pay for gasoline costs on
 personal cars.
- **Vehicle Rental** All vehicle rentals must be pre-approved. Check with us for discount codes that can be applied to rentals.

IX. ACADEMIC COSTS: TUITION & BOOKS

A. Tuition

- We will pay your tuition bill each semester after you register for classes. The CSTP award funds 100% of the tuition cost for you to obtain the Certificate in Clinical Research.
- Trainees pursuing a Masters in Clinical Research must pay the added cost from personal funds or another source. Note that you may re-budget your CSTP research or travel funds to pay for additional credits of tuition beyond the 18 credits required for the Clinical Research Certificate degree.
- If you add or drop a class, please email us and let us know so we can pay the extra bill and keep a record of refunds.
- The CSTP program does **not** pay for graduate school fees. You must use your personal funds to pay all fees charged by the University (e.g., *Wellness fee, Graduate Activity fee, Security, Safety, and Transportation Fee* and *Computing/Network Services Fee*).

B. Books

• To be eligible for reimbursement, you must purchase books directly from the Pitt Book store. Alternately, we can purchase the books for you directly from your CSTP funds. You will **not** be reimbursed for books purchased from other sources, such as Amazon. However, books purchased at scientific conferences can be reimbursed. Book purchases are reimbursed from your \$4,200 research funds.



X. HEALTH INSURANCE COVERAGE & REIMBURSEMENT

A. Terms and conditions

- Your current coverage from the medical school will continue through August 31, 2023.
 You do not need to take any action for this coverage to continue as you begin the CSTP program.
- CSTP funds may only be used to reimburse you for the cost of Pitt-sponsored health insurance. CSTP funds <u>cannot</u> be used to reimburse you for the cost of coverage under private or family insurance (e.g., CSTP trainee remains covered under parent's plan, plans through the ACA).
- CSTP funds do <u>not</u> reimburse the cost of vision or dental insurance costs, although you may sign up for them and pay out of pocket.
- During August, you will need to enroll in new coverage through the University benefits office to cover your from September 1, 2022 to August 31, 2023. The UPMC health plan offered by the benefits office is essentially the same as that offered by the medical school; it's just the administrative process for enrollment and payments that is different.
- The CSTP award provides funds to reimburse you the out of pocket monthly cost of health insurance. The monthly premium is deducted from your bank account, and you must submit receipts to be reimbursed. You can seek reimbursement for the two month (July & August 2022) beyond your CSTP appointment.
- Although you may sign up for dependent or family plans, monthly reimbursement will be limited to the cost of individual health insurance (currently \$370.25 / month but will increase as of September 1, 2022. The new monthly premium costs have not been released yet).

		September 1, 2023 – August 31, 2024	September 1, 2023 – forward	
Source	Coverage from medical school automatically continues	New graduate student coverage from University HR office	Return to coverage through medical school	
Monthly premium	Cost included in MS tuition bill or billed separately to student	Monthly deduction from personal bank account	Cost included in MS tuition bill or billed separately to student	
What you must do	When contacted by the School of Medicine to enroll in health insurance for the upcoming year, 'WAIVE' your insurance coverage through the medical school.	Enroll for new coverage during open enrollment in August to be effective September 1 -AND- Submit receipts for reimbursement of monthly premium from CSTP funds	Re-enroll for coverage through medical school to become effective September 1	



Medical School - Continuing Coverage – From *July 1, 2022 – August 31, 2023*, you will continue to receive your ongoing, pre-paid health insurance coverage through the University of Pittsburgh School of Medicine – Office of Student Affairs (SOM). For these two months, there is no cost to you and no reimbursement to seek. <u>However, when you are contacted by the SOM to renew your med school health insurance for the upcoming year 2022-2023, you will need to waive coverage.</u>

Graduate School - Open Enrollment – To sign up for graduate student coverage beginning *September 1, 2022 through August 31, 2023*, you must enroll during August for new health insurance coverage through the University of Pittsburgh Benefits office.

- You are eligible for plans available to "Health Sciences Fellows, Pre and Postdoctoral Fellows, Certificate Trainees" http://www.hr.pitt.edu/student-in/graduate-s/medical
- For enrollment instructions see http://www.hr.pitt.edu/benefits/student-be/how-enroll
- UPMC Health Plan customer service can be reached at (888) 499-6885.
- University benefits office can be reached at (412) 624-8160.

Coverage Period – Your coverage through the University of Pittsburgh benefits office will continue through *August 31, 2022*. Your insurance will no longer be active as of *September 1, 2022*. It is your responsibility to arrange for your coverage options through the School of Medicine following this date.

B. Reimbursement Procedures

• When you sign up for health insurance, your share of premium costs will be charged to a bank account of your choice on the 3rd of every month. To be reimbursed, provide your health insurance receipt (email) or bank/credit statement showing the line-item charge to the CSTP Program Coordinator each month.



XI. CSTP FUNDS AND TAXES

Students often ask our office if a stipend is taxable. This can be a difficult question, and our office cannot provide advice regarding your tax situation. Each student's situation can be unique; therefore, we recommend reviewing IRS Publication 970 http://www.irs.gov/pub/irs-pdf/p970.pdf and/or consulting with a professional tax advisor.

Please also see the attached letter from the Payroll Department which outlines the following:

- Scholarships, fellowships, and training grants are taxable unless the amount is a "qualified scholarship."
- "Qualified scholarship" would include the amount used for tuition and fees.
- Any amount that is not a "qualified scholarship" is taxable income, which must be reported on your IRS form 1040 and may require tax payments.

If you have questions about receiving a W2, a 1099, a 1098-T or other tax document from the University of Pittsburgh, please review the following information http://www.cfo.pitt.edu/payroll

How to access your paystub if you will not be receiving a W2 or 1099: If the Payroll Office advises that you will not be receiving a W2 or a 1099, log in to www.my.pitt.edu to view a copy of a year-end paystub to provide to your tax advisor. Go to www.my.pitt.edu, and on the right hand side, click on "PRISM Login." In the "Main Menu" section, you should be able to locate "Pay Statement." You can then change the year and the month to the last month of the calendar year to see your cumulative stipend amount for the year.

XII. RE-BUDGETING OF FUNDS

The CSTP allows you to use research (\$4,200) and travel (\$2,000) funds interchangeably. You may also use research or travel funds to pay for additional credits of tuition beyond the 18 credits required for the Clinical Research Certificate degree.

**You are NOT able to re-budget research or travel funds to pay for additional credits of tuition beyond the 18 credits required for the Clinical Research Certificate degree. The additional credits and costs will have to be paid out-of-pocket or by another funding source.



CSTP Purchasing Form

Purchase requests should be sent to cdj16@pitt.edu

Purchasing Order Form								
Requested By:								
Is order > \$5000?					Y or N	Ship t	o Address:	
If less expensive items can be found, can it be purchased elsewhere? **If the item ordered is a computer, laptop, or piece of								
	ent, justification o							
Order Date	Company Name/Website	University Supplier Y/N	Qty	Unit	Item # (Catalog #)	Item Description	Price/Unit	Total Price



ICRE TRAVEL REQUEST AND REIMBURSEMENT FORM

All travel requests should be submitted to ICRETRVL@pitt.edu DATE SUBMITTED (DD/MM/YYYY): REQUESTING (PLEASE TICK): Travel Booking: ☐ Flight booking ☐ Hotel booking (Expedia Only) ** If sending receipts, please make ☐ Conference registration sure to only send clear PDF Reimbursement: documents. You may also upload all Flight ☐ Hotel ■ Baggage Fees receipts into the Concur System as ☐ Per Diem ☐ Car Rental ☐ Tolls you receive them. ■ Mileage □ Parking ☐ Taxi/Car Service ☐ Poster printing Abstract submission Conference Registration Please Note: You may only be reimbursed after the ☐ Trainee Health Insurance ☐ Supplies/Books☐ Group Business Meal conference/meeting has ended. Other: NAME: CELL PHONE NUMBER: TRAVEL/CONFERENCE DETAILS NAME AS IT APPEARS ON ID: DATES OF TRAVEL: REASON FOR TRAVEL: CONFERENCE/MEETING NAME: CONFERENCE/MEETING DATES: CONFERENCE LOCATION: URLS FOR CONFERENCE/MEETING: FREQUENT FLYER MILES: WINDOW/AISLE PREFERENCE: FLIGHT AND HOTEL OPTIONS (Please provide your desired flight/hotel information below - make sure to include dates, flight numbers, desired airports, and desired hotel room type) FUGHT OPTION 1: FUGHT OPTION 2: HOTEL:



Clinical Scientist Training Program Mentor Commitment Contract 2023

This contract is designed to facilitate communication between medical student mentees and their faculty mentors. Open communication about expectations is critical to the success of the mentormentee relationship. This contract serves as a guide; mentees and mentors can adapt it for their own needs. Please provide a signed copy of this contract to CSTP Program Coordinator Lindsay Bell as soon as possible.

Expectations regarding time commitments, frequency of meetings, and attendance at research presentations

We expect CSTP trainees to meet with their mentors for approximately an hour weekly, outside of group "lab" meetings, during 12 months of the research year. CSTP trainees will present a Research in Progress to their fellow CSTP scholars and Dr. Chang during this year. Mentors do not attend the "Research in Progress" but should provide feedback to their trainee prior to the date of their presentation.

"Laboratory" or Team Meeting Day/Time	
"One-on-one" Meeting Day/Time	
"Research in Progress" Day/Time	
Mentee's expectations of the mentor	
Mentor's expectations of the mentee	
	_



We, acting as team mentors and mentee, agree to enter into a team mentoring relationship based on the expectations described above.

Mentee's Name (Please print name)	Mentor's Name (Please print name		
Mentee's Signature	Mentor's Signature		
Date	Date		