Clinical and Translational Science Scholars Program

CLINICAL AND TRANSLATIONAL SCIENCE (CTS)

SCHOLARS PROGRAM

KL2 Handbook

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Welcome

Welcome to the Institute for Clinical Research Education (ICRE) at the University of Pittsburgh, and to your Clinical and Translational Science (CTS) Scholars Program (KL2). This program, offered by the ICRE and the Clinical and Translational Science Institute (CTSI), provides individualized, competency-based training in rigorous research methodologies for the design and conduct of high-quality translational research. The CTS Scholars Program provides courses, seminars, workshops, and experiential training to build essential translational research skills in team science, leadership, community engagement, mentorship, and communication.

This handbook points you to important information that will help you throughout your time at the ICRE. However, it is likely you will have questions that are not answered here. Do not hesitate to contact any of us to let us know how we can be of help.

Contact Information: Program Faculty and Staff

Program Director

Doris M. Rubio, PhD
200 Meyran Avenue, Suite 200
Pittsburgh, PA 15213
dmr18@pitt.edu

Co-Program Director

Kristin Ray, MD, MS, FAAP
Children's Hospital Office Building, Room 108
3414 Fifth Avenue
Pittsburgh, PA 15213-3205
kristin.ray@chp.edu

Statistician

Gretchen White, PhD
200 Meyran Avenue, Suite 300
Pittsburgh, PA 15213
whiteg@edc.pitt.edu

ICRE Administrative Director

Megan Miller, MEd
200 Meyran Avenue, Suite 300
Pittsburgh, PA 15213
messt82@pitt.edu

Responsible for financial, regulatory, and personnel administration of the ICRE.

Program Coordinator

Cynthia Fela
200 Meyran Avenue, Suite 200
Pittsburgh, PA 15213
Cgf31@pitt.edu

Responsible for general administrative support to faculty and trainees.

Technical Writer

Pearl V. Nielsen

200 Meyran Avenue, Suite 300
Pittsburgh, PA 15213
pearl.nielsen@pitt.edu

Responsible for writing and editing support, feedback, and guidance.

Fiscal Specialist

Karin Dillion
200 Meyran Avenue, Suite 300
Pittsburgh, PA 15213
kad19@pitt.edu

Responsible for financial administration of research and career development funds

Multidisciplinary Advisory Committee (MAC)

Kaleab Abebe, PhD
Medicine

Jennifer Brach, PhD, PT
Health & Rehabilitation Sciences, Physical Therapy

Janet M. Catov, PhD, PT
OB-GYN, Epidemiology

Bruce Childers
Computing and Information Sciences

Yvette Conley, PhD
Nursing

Charles Jonassaint, PhD
Medicine

Elizabeth Krans, MD, MSc
Obstetrics, Gynecology & Reproductive Sciences

Deepika Mohan, MD, MPH
Critical Care Medicine

Nader Shaikh, MD, MPH
Health Policy and Management Medicine, Industrial Engineering

Charles Sfeir, DDS, PhD
Dental Medicine

Expectations for the Scholars

The CTS provides an opportunity for Scholars to jump start their careers as multidisciplinary clinical researchers with protected time for research and training. We have developed a set of expectations for the Scholars that will help ensure success.

- **Pursue** individualized training within the ICRE.
- **Attend** all Career Development Seminars. These serve as opportunity for Scholars to communicate with the CTS Leadership and other scholars.
- **Enroll** in and participate in three ICRE courses; Strategic Leadership in Academic Medicine (CLRES 2077) and the Advanced Grant Writing Parts II and II (CLRES 2071 & 2072).
- **Use** the online Customized Career Development Platform (CCDP) to strategically plan their career throughout the program.
- **Participate** in a minimum of eight hours of Responsible Conduct in Research (RCR) training.
- **Participate** in K Club.
- **Attend** the Translational Science conference at least once during your KL2 award period.
- **Attend** monthly advising session with Dr. Rubio or Dr. Ray.
- **Engage** for two years in the Career Development sessions and Advising sessions (even if you receive independent funding prior to your two-year appointment on the KL2 being fulfilled).
- **Take part** in the Transition to Independence Program (TIPS) two years prior to applying for your first RO1 Scholars. For example, you would join TIPS in Y3 of your five-year independent K.

Program Requirements

I. Career Development Seminars

Scholars are required to attend weekly, one- or two-hour Career Development Seminars that take place on Mondays at 4:00pm–5:00pm or 3:00–5:00pm. These will be a combination of in person and virtual sessions throughout the year. Each CDS will have one of the following formats:

- Scholar Progress Report
- Professional Development Presentations
- Writing Group Session
- Advising Session

A. Trainee Progress Report

Scholars are expected to present a progress report on their status to the CTS Program Directors and fellow CTS scholars. The presenting scholars' primary mentor(s) are expected to attend these presentations. The scholar progress report presentation should have the following layout:

- Research Progress – 5 minutes
- Progress on goals in the IDP – 5 minutes
- Mentors report on progress –5 minutes
- Q & A – 10 minutes

B. Professional Development Presentations

Throughout the year, University of Pittsburgh professionals will be invited to attend the CDS and talk about their area of expertise. These meetings will take place one Monday a month from 3:00-5:00pm (unless otherwise noted).
Past topics have included:

- Entrepreneurship
- Time Management
- Managing a Team

C. Writing Group Session

Scholars will be assigned to a small group of peers. On a monthly basis, one member of each group will submit a document for review by their group. Groups are expected to review the Aims in advance of the CDS and come prepared to provide feedback. Statisticians will also be present to review the Aims.

III. Mentoring

Each scholar is expected to have at least two primary mentors from different disciplines who are accomplished independent investigators forming a multidisciplinary team. The team is expected to meet at least monthly. Mentors and mentees will complete a Mentoring Contract (available in appendix) at the start of the program. This will outline the expectations for the mentoring relationship as a mentor and mentee. Mentors are also required to attend their mentee's annual Scholar Progress Report at the Career Development Seminars.

IV. Authorship Agreement

Misunderstandings can happen when researchers collaborate on a manuscript. Some of these misunderstandings revolve around authorship order, people failing to adhere to agreed-upon revision timelines, or disagreements about where to publish the work. These tensions can strain collaborations and delay time to publication. Research indicates that early-career researchers find it difficult to initiate authorship conversations with their mentors.

The NIH encourages collaboration and has an interest in speeding publication and translation of research. To that end, we have implemented an **Authorship Agreement** form. Mentors and mentees are required to execute this written agreement before work begins on any manuscript, regardless of the mentee's position in the authorship order. The document sections are based upon suggestions and surveys of ICRE trainees, and upon the areas of tension most often cited in anecdotes or in the literature. It is editable so that rows can be added as the team working on the manuscript expands or contracts, or if the timeline changes. You can download the Authorship Agreement link https://icre-authorship.garrisonhughes.site/, and update it at mentor meetings.

V. Customized Career Development Platform (CCDP)

Scholars will complete an online Individual Plan using the CCDP at the start of the KL2 program. These plans will identify goals, objectives, and outcomes for the scholar. Once the CCDP is complete, it will be submitted to mentors and program directors for approval. The CCDP will be regularly updated and reviewed throughout the year by the scholar, mentoring team, and program director. The CCDP will be used to evaluate a scholar's success and opportunity for reappointment. https://ccdponline.org/

VI. Course Recommendations

It is **strongly recommended** that trainees take the following courses during their fellowship:

- Strategic Leadership in Academic Medicine (CLRES 2077)
- Advanced Grant writing Parts I and II (CLRES 2017 & 2072)

Course requirements will be tailored to each trainee's individual research background with the help of the CTS Fellowship program directors.

A. Medical Writing and Presentation Skills (CLRES 2141)

Online (generally offered in the Fall and Spring term).

This course is designed for investigators (new and current) to aid in the understanding of conducting research. The course begins with how research projects are implemented and concludes with presenting findings from research. Conducting research is a life-long experiential learning process. As such, we have taken valuable experience from accomplished investigators to aid in the learning process so that new investigators learn from others' experience.

B. Strategic Leadership in Academic Medicine (CLRES 2077)

Wednesdays, 1:00 p.m. to 3:00 p.m., Summer Term.

This course is designed for investigators in the clinical and translational sciences who want to master the basics of research group leadership and management so that they can effectively advance their careers. Topics covered include understanding how academic medical centers function, how to prepare budgets for research projects, how the PI sets the culture of the research group, and how to manage time and personnel. At the completion of the course, trainees should be able to demonstrate an understanding of the basic principles of teamwork, leadership and management, in the context of clinical and translational research endeavors.

C. Advanced Grant Writing Part I & Part II (CLRES 2071 & CLRES 2072)

Weekly, Tuesdays 1:00 p.m. to 3:00 p.m., CLRES 2071 offered in the Fall term, CLRES 2072 offered in the Spring term.

The purpose of the integrated methods course is to build on the skills learned in the methodological core and provide a hands-on research experience. Trainees will learn the phases of the research process from conception to design and, ultimately, to implementation of the research. Through a combination of group seminars and independent work, trainees will use a research topic of their choice to develop their own research proposal in the form of an NIH grant application. The application will include sections on specific aims, background and significance, previous work, and methods. In addition, trainees will review and critique the work of their peers. Mentor must be identified prior to enrollment.

Mock Review Sessions

The purpose of a mock review session is to provide a scientific review of grant applications that trainees plan to submit for external funding.

In order to request a mock review, you must submit an application to our website: http://www.icre.pitt.edu/CRSPMockReview/Default.aspx.

Please Note: Mock review requests must be submitted three months before the award submission due date.

The reviewers for each review session should fit within these guidelines:

1. Two reviewers who are not ICRE faculty are identified with the assistance of the trainee and his or her mentors.
    - At least one of the external reviewers has expertise relevant to the content area of the grant application.
2. One or two reviewers from the ICRE faculty are identified.
    - At least one of these reviewers has expertise in biostatistics or epidemiology.
3. A peer reviewer from an ICRE training program is selected or volunteers.

All reviewers are strongly encouraged to provide written comments to the trainee.

The mock review sessions last about one hour. During the session, the reviewers follow these procedures:

1. For the first 30 minutes of the review, reviewers discuss the grant application.
    - Each reviewer states their initial score.
    - The primary reviewer gives an overall summary of the grant application, highlighting its strengths and weaknesses.
    - The secondary reviewers will offer additional comments.
    - Each reviewer states their final score, which may change based on the comments of other reviewers.
2. For the last half hour, the trainee who submitted the grant application will be permitted to ask the reviewers questions to clarify the points that they made during the mock review.
    - The Reviewers and trainee then brainstorm as to how the trainee can improve the grant application.
3. Mock reviews will be video recorded, and a link will be provided to the scholar for review.

For more information on the mock review sessions, please contact Judy Chang (chanjc@upmc.edu) and Cynthia Fela (cgf31@pitt.edu).

NIH Sample Entries

Other Support

1 KL2 TR001856 (Rubio) 7/12/2017 – 6/30/2018 9.0 CM*
NIH/NCATS $xxxxx*
The University of Pittsburgh Clinical and Translational Science Institute – Clinical and Translational Science Scholars Program

The Clinical and Translational Science (CTS) Scholars Program provides multi-disciplinary career development training, including didactic instruction and mentored research experience, to investigators preparing for careers in clinical and translational science.

NIH Biosketch

1 KL2 TR001856 (Rubio) 7/12/2017 – 6/30/2018*
NIH/NCATS
The University of Pittsburgh Clinical and Translational Science Institute – Clinical and Translational Science Scholars Program

The Clinical and Translational Science (CTS) Scholars Program provides multi-disciplinary career development training, including didactic instruction and mentored research experience, to investigators preparing for careers in clinical and translational science.

Role: Scholar

Note: Ask the CTS Scholars Program staff for dates and funding amounts specific to your KL2 award.

Clinical Trials

- K award funds cannot be used to support clinical trials research beyond **Phase IIA**. Exceptions may be granted for rare diseases but requires NIH prior approval and issuing of a revised Notice of Grant Award.

- Scholars must comply with all NIH data and safety monitoring (SM) requirements for clinical trials. Each clinical trial must have NCATS approved DSM plan / board before any grant resources (funds) used to support clinical trial.

- Clinical trials must be registered at ClinicalTrials.gov

Publication Acknowledgment

"Research reported in this publication was supported by the National Center For Advancing Translational Sciences of the National Institutes of Health under Award Number KL2TR001856. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health."

Press Releases

Prior to issuing press releases concerning KL2 research, contact your CTS Scholars Program advisor. NIH requires advance notice of press releases to allow for coordination.

NIH Public Access Policy

KL2 scholars must comply with the NIH Public Access Policy mandating public access to publications arising from NIH-supported research. For more information: https://publicaccess.nih.gov/

NIH Inclusion Monitoring

Scholars engaged in human subjects research must comply with NIH's requirement for monitoring and reporting inclusion of individuals based on sex/gender, race, and ethnicity.

For general information:
http://grants.nih.gov/grants/funding/women_min/women_min.htm

For a decision tree on types of research to which the policy applies:
http://grants.nih.gov/grants/funding/women_min/Women_and_Minorities_Inclusion_Decision_Tree.pdf

Data will be solicited each year as part of the KL2 annual report to NIH, and scholars will be asked to provide an Inclusion Enrollment Report for each of their applicable protocols, using the form below.

Cumulative Inclusion Enrollment Report

This report format should NOT be used for collecting data from study participants.

Study Title:

Comments:

Racial Categories	Ethnic Categories: Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			Total
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native										0
Asian										0
Native Hawaiian or Other Pacific Islander										0
Black or African American										0
White										0
More Than One Race										0
Unknown or Not Reported										0
Total	0	0	0	0	0	0	0	0	0	0

PHS 398 / PHS 2590 (Rev. 08/12 Approved Through 8/31/2015) Page ___ OMB No. 0925-0001/0002 Cumulative Inclusion Enrollment Report

NIH Prior Approval and Notification – Policies & Procedures

I. Background

In 2012, NIH issued new notices that advised investigators that in certain circumstances NIH prior approval must be obtained before spending NIH research funds on a new or modified research protocol involving human subjects. The full notices are available at:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-129.html

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-130.html

As a scholar or trainee provided with pilot funding through the NIH/NCATS-funded Clinical and Translational Science Institute (CTSI), these polices apply to you.

Note: Human subjects protocols that qualify for an exemption (categories 1-6), and animal studies entailing IACUC approval, require formal NIH notification but not prior approval. Please see table below for more information.

II. Procedures

To comply with these requirements, **all KL2 Scholars are required to notify ICRE Administrator, Megan Miller (messt82@pitt.edu / 412-383-1091) in advance whenever planning to submit a new or modified protocol to the IRB.** New protocols for which you are the Principal Investigator will automatically require NIH prior approval. For modifications, you will be asked for information to determine whether the change constitutes a significant 'change in scope.'

To expedite things as much as possible, it's advisable to prepare your NIH prior approval paperwork in advance at the same time you submit your IRB approval. As soon as you get your IRB protocol approved, the prior approval request can then be submitted to NIH. Expect prior approval to take one to two months to obtain after IRB approval. Please contact Megan Miller for information about the forms to complete and the expected timeline for approval.

A. NIH Prior approval is required:

- When you are named as the Principal Investigator of the IRB protocol (i.e., not your mentor) AND ○ For all newly approved, non-exempt Human Subjects IRB protocols ○ For modifications to ongoing protocols that are deemed to increase risks to subjects (consult ICRE coordinator)

B. NIH Prior approval requires:

- Completion of several forms summarizing your IRB protocol
- Submission of these forms along with your IRB approval form to NIH

C. While waiting for NIH prior approval:

- No CTSI funds may be spent toward the aims of the new / modified protocol under review
- You may begin work on the protocol if no expenses are incurred, or if expenses can be charged to departmental ('hard money') accounts
- Any expenses incurred prior to NIH approval being granted **cannot** be transferred to your CTSI program funds retroactively

D. NIH Notification is required when:

- You are named as the Principal Investigator of the IRB / IACUC protocol (i.e., not your mentor) AND ○ For all newly approved, Human Subjects IRB protocols that qualify for an exemption (see PHS 298 Instructions, Part II, Section 3., Scenario C.

http://grants.nih.gov/grants/funding/phs398_rev06-2009/phs398.pdf

- For all newly approved IACUC protocols

E. NIH Notification requires:

- Completion of several forms summarizing your IRB / IACUC protocol
- Submission of these forms along with your IRB / IACUC approval form to NIH

F. NIH Notification:

- Does **not** prevent you from starting work on your new IRB / IACUC protocol or spending CTSI funds toward the new protocol

Guidelines for Use of KL2 Career Development Funds

I. Introduction

This guide describes the University of Pittsburgh and NIH polices that govern the use of the $25,000 awarded to you for research and career development costs under the KL2. Please pay special attention to the **HIGHLIGHTED NOTES**. These are common mistakes that have caused prior trainees time, money, and frustration in the past.

A few preliminary Do's and Don'ts:

Please ***DO…***	…and please ***DON'T***
• Use us as a resource! Check with us for advice and help on buying things, arranging travel, hiring people, 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. Pay attention to your monthly reports. Don't wait until the last minute.	• Obtain bio-materials or data without first getting a materials transfer agreement or data use agreement

I. Research Costs: Supplies, Services, and People

A. Computers and Software

WE MUST BUY COMPUTERS AND SOFTWARE FOR YOU.
***The ICRE Fiscal Coordinator must purchase all computers and software. All purchases will be made through University of Pittsburgh purchasing systems.*

- **Computers**: 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 ICRE Fiscal 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 Program Coordinator will find the computer product that most closely matches your request.

- **Software**: The ICRE Fiscal 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 and Services

Please talk to the ICRE Fiscal Coordinator before allowing any individual or any organization to begin working on your research project. This includes services you may seek from individuals or companies for transcription, statistical or specimen analyses, etc. The rules for who may be hired or contracted with are complicated by many factors, and we can help you sort them out quickly.

NO RETROACTIVE PAY
***If you allow an individual or organization to provide effort and services without first working with us to establish the appropriate payment mechanism, we cannot pay them for work done prior to the proper steps being taken to establish payment (e.g., hiring of personnel, written service agreement).*

C. Data and Biomaterial Purchases

The acquisition and/or purchase of data sets (e.g., public health data from the government or a private agency) and biomaterials require execution of a signed **Data Use Agreement (DUA)**, or **Materials Transfer Agreement (MTA)**. These contracts between the University of Pittsburgh and the agency providing the data or materials govern proprietary, confidentiality, and other legal issues, and must be signed off before data or materials are received.

PLAN AHEAD
***Executing a DUA or MTA can take several weeks or even months, so please plan accordingly.*

B. Participant Payments

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. Please allow 4 to 6 weeks for full setup of We Pay services for your research study. Setup includes mandatory training.

C. 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.

D. 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, or for certain types of 'business' meetings. Please check with us.

II. Travel Costs: Registration, Planes, Hotels, and Food

A. $2,500 limit

****The TL1 now limits annual conference travel expenses to $2,500, including registration fees, air fare, lodging and per diem. Please plan accordingly.**

Please Note: *All purchasing, and travel requests must be made by completing a travel request or purchase request form and sending to* sean.reagan@pitt.edu.

B. Receipts

When submitting receipts for your conference travel, include the name of the conference, dates of travel, and an itemized list of all receipts that should be reimbursed. All receipts must be the original and sent as a pdf or dropped off in person. Pictures of receipts will not be accepted.

RECEIPTS
***When submitting receipts for your conference travel, include the name of the conference, dates of travel, and an itemized list of all receipts that should be reimbursed. All receipts must be the original and sent as a pdf or dropped off in person. Pictures of receipts will not be accepted.*

PAY YOUR OWN BILL
***You must pay for your own hotel bill. Do not use your credit card to pay the bill of colleagues, or allow them to pay for you. University travel policy does not permit reimbursement for rooms occupied by anyone other than you.*

Below are important notes about common expenses:

- **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 ICRE Fiscal Coordinator the flight information to purchase the tickets through the University of Pittsburgh travel agent. Although the University of Pittsburgh Travel Agent charges a $25 service fee, the Pitt Travel Agent allows you to charge the cost directly to your TL1 grant funds. If you choose to purchase the flight yourself, reimbursement must wait until after 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 Karin Dillion kad19@pitt.edu before making arrangements.

ADVANCE PAYMENT
***Registration fees and flight costs are allowable costs only for conferences that will be attended during the same budget year (ending May 31). TL1 funds cannot be used to pay in advance for conferences that will occur after the end of the current TL1 budget period, except in cases when a scholar will be reappointed for a subsequent year.*

- **Hotel**: You can be reimbursed for conference stays only after travel is complete. You must provide an **itemized** hotel checkout slip or zero balance print out. Allowable charges are limited to room charges, taxes, and internet service only.

- **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.

ROOM SERVICE
***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.*

- **Parking**: With original receipt, you can be reimbursed for parking outside of Pittsburgh City Limits when traveling to conferences.
- **Personal Car Use**: The university prefers that you rent a car for business.

III. Academic Costs: Tuition & Books

A. Tuition

- We can pay your bill for tuition and fees directly from your KL2 funds. Please let us know when you register for classes that you want to use your KL2 funds to pay for them.

- 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.

- KL2 funds cannot be used to pay the 'Graduate Activity Fee' (typically $6-$12). You must pay this with a personal credit card.

A. Books

- You can receive reimbursement for books purchased directly from the Pitt Book Store, as well as books you purchase at scientific conferences.

- We can also purchase the books on your behalf from the Pitt Book store or Amazon; just send us the book information to request this assistance.

ONLINE BOOKS

***You **cannot** be reimbursed for books purchased from other stores or online sources, such as Amazon.*

CITI Modules: Human Subjects Research Training Modules

NOTE: Please allow 3-5 hours to complete all of the modules.

Step 1: Create an HSConnect Account

- Click: www.hsconnect.pitt.edu
- Create HS Connect account; use your Pitt or other email address as a log-in and create a password.

Step 2: Complete 3 CITI Training Modules

- Click: http://www.citi.pitt.edu/citi/
- Log in with your HSConnect Account login and password
- Follow the prompts to create your CITI account affiliated with the University of Pittsburgh
    - Click *'Add a course or update your learner groups'*
    - Make the following selections and complete the following training modules:
        - **Question 1 – Conflict of Interest training**: Answer 'Yes' to choose the *Conflict of Interest (COI) Training Course for PHS-funded researchers*
        - **Question 2 – Responsible Conduct of Research**: Choose the module most relevant to your area of research, either *Biomedical or Social and Behavioral* responsible conduct of research
        - **Question 3 – Human subjects research**: Choose *Biomedical or Social & Behavioral* research

Step 3: Complete HIPAA training module (if required)

If you will be accessing the medical records for any research purpose (recruitment, screening, obtaining lab values, etc.), you will also need to take "HIPAA Researchers Privacy Requirements."

- Go to the Studies in Education and Research page: http://cme.hs.pitt.edu/
- Log in with your HSConnect Account
- Under *Module Listings*, click the *HIPAA* subfolder
- Select and complete: *HIPAA Researchers Privacy Requirements*

Step 4: Send us your certificates

Email or fax (412-586-9672) copies of each certificate

Notes

- CITI Modules will expire after three years.
- CITI Modules are transferable between other institutions that utilize CITI.

- The HIPAA module does not expire.

Animal Research – Training Modules

Step 1: Create an HSConnect Account

Click: www.hsconnect.pitt.edu

- Create HS Connect account; use your Pitt or other email address as a log-in and create a password.

Step 2: Complete relevant Internet-based Studies in Education and Research (ISER) training modules

- Go to the Studies in Education and Research (ISER) page: http://cme.hs.pitt.edu/ ○ Log in with your HSConnect Account ○ Under *Module Listings*, click the *Animal-Based Research Modules* subfolder ○ Select and complete the following modules:
  - *Research Integrity*
  - *Use of Laboratory Animals in Research & Education – Update*
  - *Other species specific modules that apply to your research (see IACUC Training Chart at http://www.iacuc.pitt.edu/training)*

Step 3: Complete CITI training modules

- Click: http://www.citi.pitt.edu/citi/
- Log in with your HSConnect ○ Follow the prompts to create your CITI account affiliated with Pitt
- Click *'Add a course or update your learner groups'*
- Make the following selections:
  - **Question 1 - Conflict of Interest training:** answer 'Yes' to choose and complete the *Conflict of Interest (COI) Training Course for PHS-funded researchers* course
  - **Question 2 – Responsible Conduct of Research:** choose the module most relevant to your area of research, either *Biomedical or Social and Behavioral* responsible conduct of research
  - **Question 3 – Human subjects research:** choose *'No, not at this time'* to skip out.

Step 4: Send us your certificates

Email or fax (412-586-9672) copies of each certificate to your designated ICRE Program Coordinator.

Notes

CITI Modules are transferable between other institutions that utilize CITI. ○ The Research Integrity module does not expire. All other modules expire after 3 years.

Association for Clinical and Translational Science

The Association for Clinical and Translational Science (ACTS) (http://www.actscience.org/) is the premier organization in the field, and is active in the realms of:

- **Research** – improving the efficiency with which new therapies may reach the public
- **Education** – serving as the academic home for all educational activities for the full spectrum of translational sciences
- **Advocacy** – engaging at all levels with other professional organizations
- **Mentoring** – facilitating collaboration and professional relationships between trainees and mentors

ACTS holds an Annual Meeting that brings together all of the disciplines involved in clinical and translational research and all of the participants in the field—including trainees, investigators, educators, as well as representatives from industry and government. Due to the multidisciplinary and multidimensional nature of the field, collaboration and interfacing is practically a prerequisite for success—and the Annual Meeting provides an ideal opportunity for networking and advancement.

TL1 Fellows are required to attend the annual meeting, unless a compelling reason not to attend is provided. Trainees can apply for a travel award to assist with the conference expenses.

Our fellows consistently return from these meetings full of praise for how helpful the conference is for their careers:

- **Inspiring** – Participants are inspired by stories of success in clinical and translational research and its positive impacts on people's lives
- **Informing** – Attendees learn of the most up-to-date and valuable information in the field
- **Supporting** – Trainees are provided with a supportive forum to present their research to a broad array of investigators
- **Providing resources** – Participants are presented with novel methods, best practices, and resources to achieve successful translation
- **Developing** – The meeting offers high-quality career development programs for trainees and mentors to progress in their roles

Recent plenary presentations have featured directors of CTS Institutes at universities across the country, and officials in the Department of Health and Human Services, the National Institutes of Health, the FDA, as well as advocacy organizations for pharmaceutical research companies.

Save the Date!

ACTS Translational Science Conference

Washington, DC, from April 15-17, 2025, with pre-meeting activities starting on April 14.

Association for Clinical and Translational Science (actscience.org)

Evaluation/Tracking

I. Purpose of Evaluation/Tracking

The ICRE takes several steps to continuously evaluate the CTS Scholars Program. Through year round evaluation and tracking, we are able to identify strengths and weaknesses of the program, chart career progress of Scholar outcomes, determine appropriate modifications to the program, and comply with NIH requirements for rigorous evaluation. **Timely Scholar participation in the evaluation process is greatly valued and crucial to the continued success of the program.**

II. Evaluation Mechanisms

The ICRE has several mechanisms to help ensure that evaluation is thorough and multi-faceted. These include:

- **A detailed web-based tracking portal**: this system helps us track Scholar progress as they advance in the program and their careers
- **Annual surveys of Scholars and mentors**: these surveys are critical to the evaluation of the program and help us evaluate completed milestones and objectives of Scholars, mentor-mentee relationships, academic productivity, and any appointments or promotions obtained by Scholars
- **Course and seminar evaluation**: evaluation of courses and seminars developed for this program are important for determining what aspects are most beneficial during Scholar training

III. Example Outcomes

The ICRE tracks a number of short- and long-term outcomes. Below is a list of some examples that highlight the main goals of our evaluation strategy:

A. Short-Term Outcomes

- Scholars' satisfaction with the program (didactic training and mentored research)
- Percentage of Scholars submitting grant applications to NIH or other agencies
- Percentage of Scholars dedicated to careers in multidisciplinary clinical/translational research

B. Long-Term Outcomes

- Percentage of current effort in multidisciplinary research
- Grant funding on multidisciplinary projects
- Number of core faculty positions held at a multidisciplinary center or institute

- Number of presentations and publications produced by Scholars

IV. IRB & Informed Consent

IRB approval has been obtained for our data collection and evaluation of the CTS Scholars Program. Some of the data we collect from our evaluation surveys are used to inform our research concerning successful education, training, and careers of clinical/translational scientists. For this reason, informed consent is obtained from Scholars prior to completing their initial survey.

Appendix A. Clinical and Translational Science Fellowship Mentoring Expectations and Contract

Mentoring is critical to career success in research. Each fellow will have a primary mentor who will be an accomplished independent investigator and committed to the career development of their mentees. The fellow will have at minimum weekly contact and meetings with their primary mentors (often more frequently) since the fellow will be working in the laboratory of the primary mentor or work on a related project. In addition, each fellow may have additional one or more co-mentors, preferably from different disciplines, forming a multidisciplinary team. We will obtain written commitments from all of the mentors to have continuous involvement with the fellows throughout the program. Because the fellowship is promoting team science through the conduct of multidisciplinary research and the use of team mentoring for mentees, the entire mentoring team will meet with the mentee at least monthly to design and plan the research projects, complete or update, discuss progress, provide advice on project management, and to help guide data collection, analysis, and manuscript preparation. https://teamsciencetools.icre.pitt.edu/

Expectations for Mentors

1. **Team meetings with the mentee**. There should be a minimum of one hourly meeting of the primary mentors and the mentee per week, and one hourly meeting per month of the entire mentoring team and the mentee.
2. **Attending fellow's presentations.** The mentoring team is expected to attend meetings and seminars in which the mentee is presenting.
3. **Evaluation.** The mentoring team will participate in biannual evaluations and assessments of mentoring relationships.
4. **Confidentiality.** The content of all exchanges between the team mentors and the mentee are subject to the expectations of professional confidentiality.
5. **Customized Career Development Plan (CCDP).** The mentors are expected to review, approve, and monitor progress of mentee's CCDP.

Expectations for Mentees

1. **Team meetings with mentors**. There should be a minimum of one hourly meeting with the primary mentors per week and at least one hourly meeting twice a year with the entire mentoring team.
2. **Training.** The mentees participate in the half-day training to obtain skills in working in with mentors in a team science environment.
3. **Fellow's presentations.** The fellows present their work at research-in-progress meetings and at seminars with the mentoring team in attendance.

4. **Evaluation.** The mentee will participate in biannual evaluations and assessments of the mentoring relationships.
5. **Confidentiality**. The content of all exchanges between the team mentors and the mentee are subject to the expectations of professional confidentiality.

Customized Career Development Plan (CCDP). Develop CCDP, review CCDP with mentor and TL1 director, and review progress.

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

_____ (mentor's signature) date____/____/____

_____ (mentor's signature) date____/____/____

_____ (mentee's signature) date____/____/____

_____ (KL2 director's signature) date____/____/____

Purchasing Order Form - Submit to sean.reagan@pitt.edu

Requested By:

Is order >$5000? _____ Y or N

If items can be found less expensive can it be purchased elsewhere? _____ Y or N

Ship to Address:

****If the item ordered is a computer, laptop, or piece of equipment, justification of the purchase is needed. (detailed**

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

Submit Form to sean.reagan@pitt.edu

Date Submitted (dd/mm/yyyy):	
Requesting (Please Tick): ** If sending receipts, please make sure to only send clear PDF documents. You may also upload all receipts into the Concur System as you receive them. Please Note: You may only be reimbursed after the conference/meeting has ended.	Travel Booking: ☐ Flight booking ☐ Hotel booking (Expedia Only) ☐ Conference registration Reimbursement: ☐ Flight ☐ Hotel ☐ Baggage Fees ☐ Per Diem ☐ Car Rental ☐ Tolls ☐ Mileage ☐ Parking ☐ Taxi/Car Service ☐ Poster printing ☐ Abstract submission ☐ Conference Registration ☐ Trainee Health Insurance ☐ Supplies/Books ☐ Group Business Meal ☐ Other:
Name & DOB:	
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:	Username & Password (if applicable): Username: Password:
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)

Flight option 1:

Flight Option 2:

Hotel: