

Clinical Translational Research Certificate of Added Qualification (CTR-CAQ) Program



Information session 4-4-2024

Clinical Translational Research Certificate of Added Qualification Program (CTR-CAQ)

(co-directors: Igna Van den Veyver, MD and Indira Mysorekar, PhD)

Overview

7 PRIMARY GRADUATE PROGRAMS

Cancer & Cell Biology

Chemical, Physical & Structural Biology

Development, Disease Models & Therapeutics

Genetics & Genomics

Immunology & Microbiology

Neuroscience

Quantitative & Computational Biosciences

CLINICAL
TRANSLATIONAL
RESEARCH CAQ

CTR-CAQ Key Components

- Build upon experience with Translational Biology and Molecular Medicine legacy program
- Clinical Projects and dual mentorship experience
 - Accompany clinical research mentor to clinics
 - Attend diagnostic consensus conferences, grand rounds, translational research meetings
 - Observe and participate in clinical research with clinical research mentor
- **Now make this available for all graduate students**
 - Information during recruitment and year 1 in GSBS
 - Up to 30 students accepted per year based on review of application
 - **Application due June 1 → notification July 1 → start in track August 1**
- **T32 training grant**

CAQ requirements: 12 CREDITS

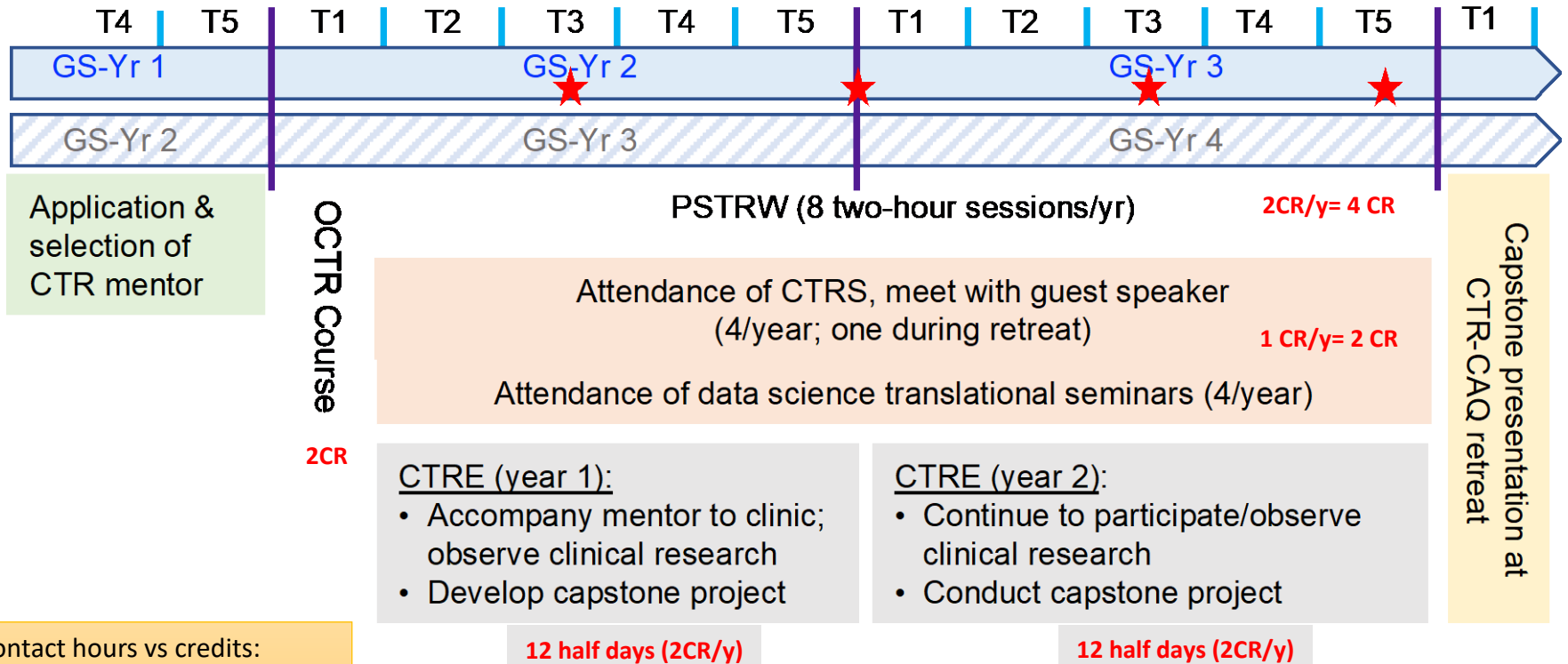
1. Spread out over 2 years (10 terms)

- Orientation to Clinical Translational Research (OCTR) course:
2 credits
- Practical Skills in Translational Research Workshops (PSTRW) 1 & 2:
2 credits/year → 4 credits total
- Attend 4 program + 4 elective translational seminars/year:
1 credit/year → 2 credits total
- Yr 1: Clinical Translational Research Experience + develop capstone project:
2 credits
- Yr 2: CTRE continued + conduct capstone project:
2 credits

2. Completion of capstone project:

- Written abstract and proposal (by term 5 of year 1); project report (by term 5 of year 2)
- Presentation at CTR-CAQ annual retreat/symposium (~September)

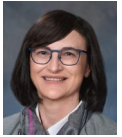
CTR – CAQ curriculum and timeline



Contact hours vs credits:
 Courses/conf: 8 hours = 1 CR
 Experience: 24 hours = 1 CR

Possible co-credits with primary PhD program

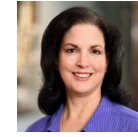
Course	Credit hours	CTR-CAQ Program-specific	Didactic	Count Towards 30 hr Didactic for Candidacy	Possible Contribution To 30 hr
Orientation to Clinical Translational Research	2	No	Yes	Yes	2hr, Elective
Practical skills in Translational Research Workshop	4	Yes	Yes	PSTRW-1 Only	2 hr, Elective
Bench-to- bedside seminars, CTR-CAQ symposium and attendance of translational conferences	2	No	No	No	
Clinical Translational Research Experience	4	Yes	No	No	
TOTAL	12	OPTIONAL CO-CREDIT*			4



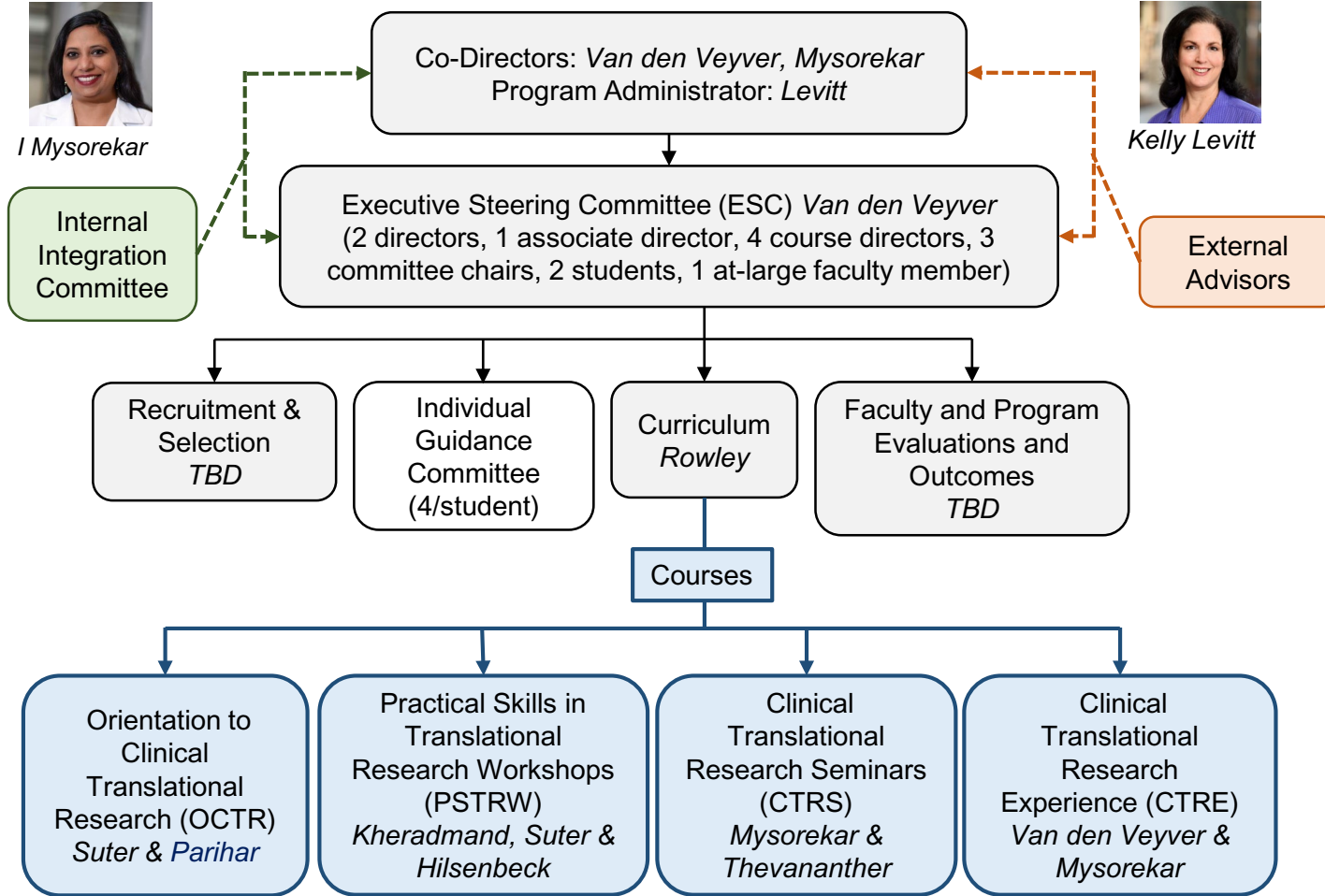
I Van den Veyver



I Mysorekar



Kelly Levitt



Mentorship

1. Clinical Translational Research (CTR) mentor

- Student finds mentor during application process - *Program will help*
- Must be approved by committee that reviews application (modifications may be requested)
- Remains with student throughout time in CTR-CAQ
- Continued interaction post CTR-CAQ is encouraged
- Required mentor orientation will be done in T1 of year 1

2. CTR-CAQ faculty advisor (assigned by program)

3. Individual Guidance Committee (IGC)

- **Clinical translational research mentor**
- **CTR-CAQ faculty advisor (assigned by program)**
- **Thesis advisor**
- **Other faculty member**

- **3 or 4 individual guidance committee (IGC) meetings**

- IGC will also oversee overall progress and defense/presentation of the capstone project

- This committee is not another thesis advisory committee!

Requirements to apply to CTR-CAQ

1. Application package submitted by June 1 for next academic year

- Personal statement (2 pages)
- Student Bio (NIH format)
- Two support letters:
 - (1) thesis advisor
 - (2) clinical translational research mentor (with biosketch)
- Approval from primary graduate program director and thesis advisor

2. Evidence of interest in translational research

- Describe in personal statement
- Describe in advisor's support letter
- Describe in CTR mentor support letter

COURSES

Orientation to Clinical Translational Research (OCTR) course

2 Credits – 16 hours

- Course Director: Melissa Suter, PhD
- Co-director: Robin Parihar, MD, PhD
- 2 credits
- Open to all who are interested (not just CTR-CAQ students)
- Lecture-based with grading for attendance, participation and homework assignments
- Topics and lecturers will be integrated with PSTRWs



M. Suter



R. Parihar

Topics of the OCTR Course Module

T1 to T4 translational research	Good manufacturing practice facilities
Epidemiological studies	Regulatory affairs
Early phase clinical trials	The institutional review board
Team science, mentorship, and academic-industry collaborations	Clinical trials reporting
Study design (RCTs)	Correlative science analysis
Retrospective study design, working with datasets/ databases	Informed consent
Practical Aspects of Biobanking	Research integrity and misconduct
Patents licensing	Clinical ethics overview

Practical Skills in Translational Research Workshops (PSTRW1 and 2)

2 Credits/y – 8 x 2 hours/y

- Course Director: Susan Hilsenbeck, PhD
- Co-directors: Farrah Kheradmand, MD (PSTRW1) and Melissa Suter (PSTRW2)
- **Over two years: PSTRW1 and PSTRW2**
- For CTR-CAQ students only – small group approach!
- Up to 30 students: 8-10 students per break-out group
- Two facilitators for each workshop
- Case-based or project-based skills development
- Active learning and gradual skill building



S. Hilsenbeck



F. Kheradmand



M. Suter

Practical Skills in Translational Research Workshops Format (PSTRW)

- Follows OCTR course lectures
- Pre-workshop assigned reading
- Readiness assurance test (10 minutes)
- Introduction of topic and task 1 by faculty facilitator (10 minutes)
- Break-out groups work and discuss for ~15-30 minutes
- Present to entire group, receive feedback, discussion (presenters rotate)
- [Repeat with task 2 (depending on topic)]
- Ethics, rigor and reproducibility, and responsible conduct of research aspects are integrated in each workshop.

PSTRW1 – example topics

YEAR 1	
1	Clinical research proposal development – PHI and HIPAA
2	Sample size and power calculation
3	Study design – retrospective studies
4	Study design – prospective early clinical trials
5	Biobanking research
6	Databases and data management
7	Randomized controlled trials
8	ATTEND AN IRB MEETING (assigned slots throughout year)

Clinical Translational Research Seminars (CTRS)

1 Credit/year

- Course Director: Sundararajah Thevananther, PhD
- Co-director: Indira Mysorekar, PhD
- **4 one-hour translational research seminars of choice / clinical data science seminars**
- **4 times per year School-wide CTR-CAQ seminar**
 - Open to all and required for CTR-CAQ students
 - Translational researcher guest faculty invited by CTR-CAQ students and faculty
 - CTR-CAQ students host and participate in guest speaker selection and invitation
 - CTR-CAQ students meet with guest speaker
 - One of the seminars coincides with annual CTR-CAQ retreat (annual retreat can count for experience credit hours)



S. Thevananther



I. Mysorekar

Clinical Translational Research Experience (CTRE) course

2 Credits/y – 12 half days/y
Total 4 credits

- Course Director: Igna Van den Veyver, MD
- Co-director: Indira Mysorekar, PhD
- 12 half days “experience” per year – starts term 2 of year 1
- Guided by CTR-CAQ mentor
- Exposure to **clinical medicine** and **clinical research** in field of research interest
 - Mostly year 1
- Capstone project
 - Mostly year 2
- BCM affiliate locations



I. Van den Veyver



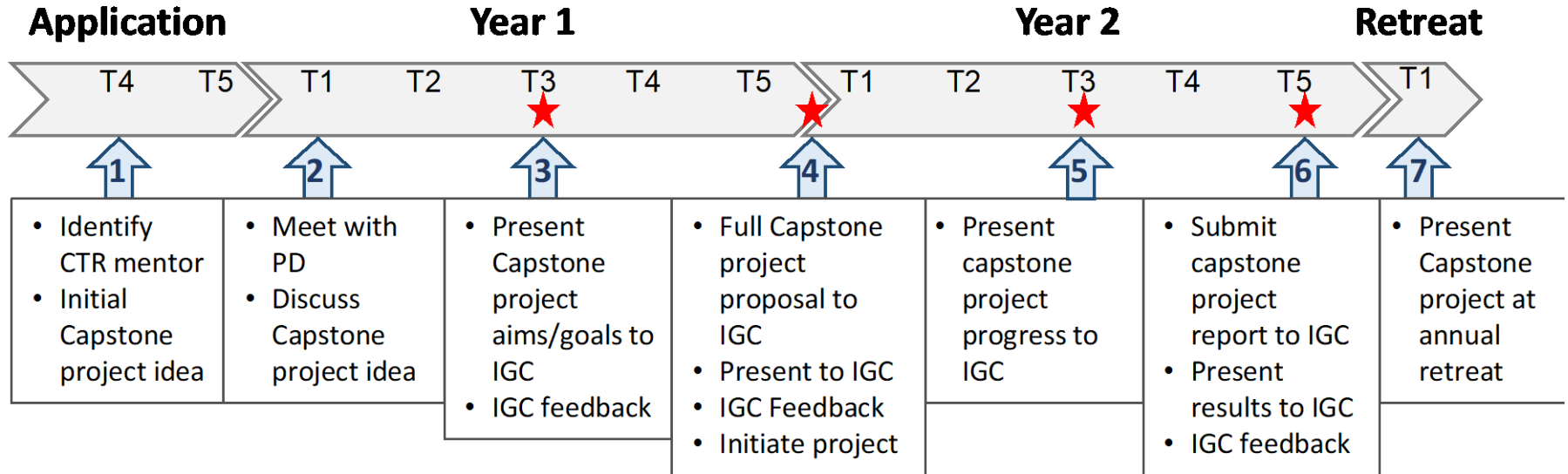
I. Mysorekar

**Individualized
Flexibility**

Preparations before going to clinics

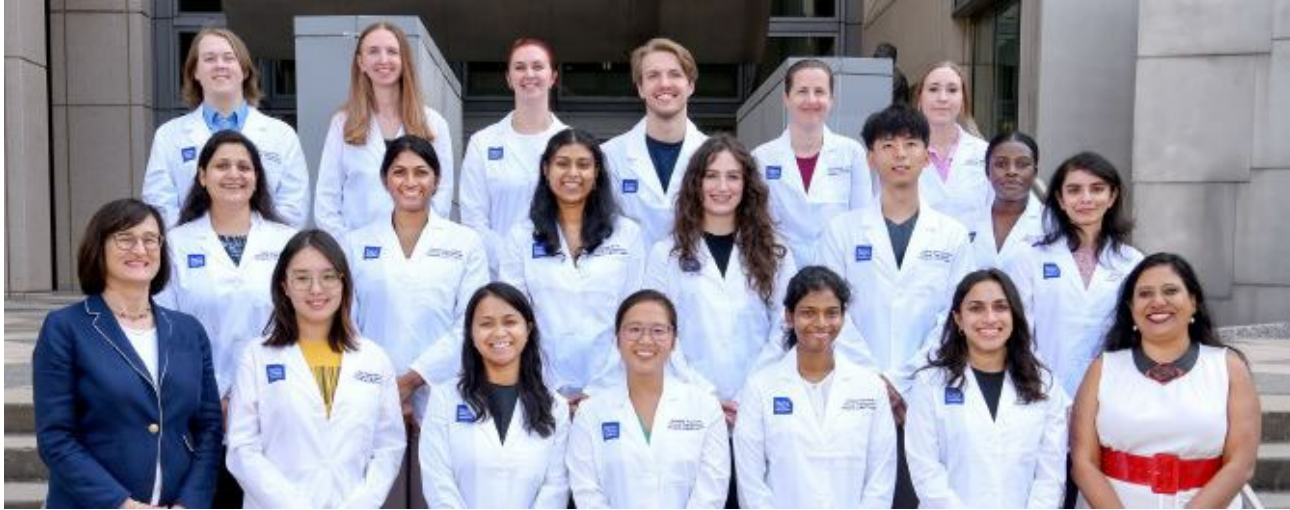
- Starts once student is admitted to CTR-CAQ
- Insurance
 - same type of malpractice insurance as medical students
 - even though you do NOT participate in care you are covered
- Background checks
- HIPAA and CITI training
- IRB experience (as part of PSTRW course)

Timeline for capstone project



CTR-CAQ program “CRISP” event

Clinical Research Initiation for Science Professionals



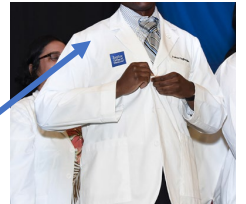
“MINI”

White coat ceremony

CTR-CAQ CRISP event

- After term 1 (~end of OCTR course)
- Before the start of CTRE Clinical Activities
 - ***Celebrates your entry into clinical research environment***
 - Privilege to train in clinical learning environment
 - Representing the program and knowing your role and responsibilities
 - Professionalism in clinical learning environment
 - The do's and don't's in clinics as a CTR-CAQ student
 - Dress code

CTR-CAQ



CTRE course Year 1: clinical research experience

- Directed by CTR-CAQ mentor (others can help)
- Term 2 – Term 5 year 1 (can overflow to year 2)
- **Exposure to clinical medicine in area of interest**
- **Exposure to clinical research**
- Observe clinical research activity and *begin to develop* "capstone project"
- Guided flexibility – role of IGC and CTR-CAQ mentor
- Varies depending on mentor and student experience
- Experiences can transition in focus as student progresses

CTRE course Year 2: capstone project

- Directed by clinical translational research mentor (others can help)
- Capstone project proposal (short -- not a thesis proposal or QE proposal!)
- Conduct capstone project
- Varies depending on mentor, research field and setting, and prior student experience
- Options:
 - Can vary from case series to participation in trials
 - Must be feasible in allotted time
 - Oversight by IGC

CTRE course Oversight

- Graded as: pass – incomplete – fail
- Brief proposal of activities is required for Term 1 year 1
- Clinical activity reports - other terms
 - Reviewed by CTR-CAQ mentor and course directors
- Evaluation forms for student and mentor (twice per year)
- Present summary to IGC at scheduled meetings (~ every 6 months)

Cancer & Cell Biology	+
Chemical, Physical & Structural Biology	+
Clinical Translational Research	
Development, Disease Models & Therapeutics Graduate Program	+
Genetics & Genomics	+
Immunology Microbiology	+
Neuroscience	+
Quantitative & Computational Biosciences	+
Diversity	+

Contact

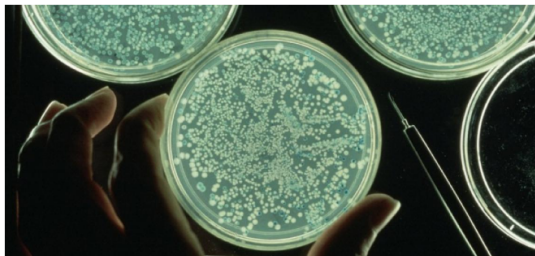
Kelly LeVitt Program Administrator
ctr-caq@bcm.edu

Program Information

Application deadline: June 5, 2020

- [Application](#)
- [CTR-CAQ Student Biosketch Template](#)
- [Video: Student Information Session](#)
- [Video: Faculty Information Session](#)
- [Slides: Student Information Session](#)
- [Frequently Asked Questions](#)

Clinical Translational Research Certificate of Added Qualification



Prepare to Lead Translational Research Teams

Baylor graduate students in their first or second year who are interested in a career focused on translating biomedical discoveries into molecular medicine advances to benefit human health are invited to apply for the Clinical Translational Research Certificate of Added Qualification (CTR-CAQ) program. Participants will acquire the foundational knowledge and professional skills required of effective leaders of translational research teams.

The CTR-CAQ is a two-year program run in coordination with our [seven interdisciplinary Ph.D. programs](#) so that it will not slow down your progress with your thesis research. You and your mentors will design your clinical translational research work so that it integrates with or complements your thesis research. Each year, 30 students will be selected to participate.

The CTR-CAQ program will be supported by an NRSA Institutional Predoctoral Training Grant (T32) from the National Institute of General Medical Sciences. We anticipate funding for eight students beginning in the summer of 2020. See the application for information on eligibility and to apply for support by the T32.

CTR-CAQ Courses

- [Session](#)
- [Slides: Student Information Session](#)
- [Frequently Asked Questions](#)



America's fourth largest city is a great place to live, work and play. Find out why.

[Get To Know Houston](#)

CTR-CAQ Courses

Orientation to Clinical Translational Research (OCTR): Topics covered include T1-T4 translational research, study design for randomized clinical trials and retrospective studies, Good Manufacturing Practice facilities, informed consent, regulatory affairs, Institutional Review Board.

Practical Skills in Translational Research Workshops (PSTRW): Case-based or project based skills development pertaining to clinical research proposal development, sample size and power calculations, retrospective studies, prospective early clinical trials, biobanking research, databases and data management.

Clinical Translational Research Seminars (CTRS): translational research seminars given by guest faculty invited by CTR-CAQ faculty and students. Students have opportunity to interact with guest faculty in small, informal group setting.

Clinical Translational Research Experience (CTRE): Students learn about clinical aspects of their area of research interest through exposure to clinical medicine and clinical research, and develop a short capstone project in consultation with their CTR mentor.

You will:

- Gain knowledge of the ethics, regulatory aspects and practical conduct of clinical research
- Conduct hands-on work with peers in small groups to use this knowledge in simulated scenarios
- Master the skills necessary to work in and lead teams of researchers
- Participate in clinical/translational conferences and meetings where you will learn from and interact with experts in translational research
- Complete a capstone project with mentorship from your chosen clinical translational research mentor who will introduce you to clinical research

Clinical Translational Research Mentors

Baylor College of Medicine Graduate School of Biomedical Sciences is embedded within a leading health sciences university with a top-ranked medical school and located in the heart of the world's largest medical complex. This provides access to many exceptional clinical translational research mentors for our students. You will have the opportunity to select mentors from the:

- [Asthma Clinical Research Center](#)
- [Center for Cell and Gene Therapy](#)
- [Dan L. Duncan Institute for Clinical and Translational Research](#)
- [Lester and Sue Smith Breast Center](#)
- [Pediatric clinics at Texas Children's Hospital](#)
- [Tropical Medicine Clinic](#)
- [Children's Nutrition Research Center](#)
- [Vaccine Research Center](#)
- And many more clinical research centers and clinics

ADMISSIONS

Admission to the CTR-CAQ is open to BCM Ph.D. candidates in their first or second year.

Each year, 30 students will be selected to participate.

The two-year program is run in coordination with our seven interdisciplinary Ph.D. programs so that it will not slow down your progress with your thesis research. You and your mentor will design your CTR-CAQ work so that it integrates with or complements your thesis research.

**FOR MORE
INFORMATION,
CONTACT**

Rashieda Hatcher
Program Administrator
✉ ctrcaq@bcm.edu

CLINICAL TRANSLATIONAL RESEARCH CERTIFICATE OF ADDED QUALIFICATION

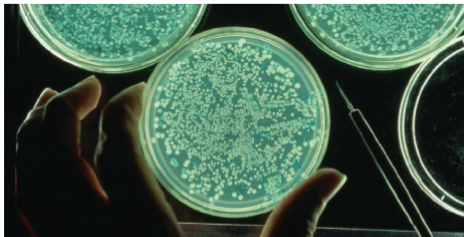
The vision of Baylor College of Medicine is to improve health through science, scholarship and innovation.

Realizing this vision requires providing the next generation of translational research leaders with the knowledge, skills and experience necessary to apply the knowledge gained from the basic sciences to address clinical and community healthcare needs.

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more →

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BCM adult outpatient clinics

Center for Cell and Gene Therapy

Dan L Duncan Institute for Clinical and Translational Research

Lester and Sue Smith Breast Center

Texas Children's Hospital Fetal Center

Texas Children's Hospital pediatric clinics

Tropical Medicine Clinic

USDA Children's Nutrition Research Center

Vaccine Research Institute

And many more clinical research centers and clinics.

For a full listing of BCM research centers, visit www.bcm.edu/research/centers.

For a full listing of BCM healthcare clinics and centers, visit www.bcm.edu/healthcare/care-centers.



Small-group in person Q&A sessions

Alkek N302

Watch for calendar
invitation

Monday, April 22 - Noon

- Cancer & Cell Biology (CCB) and Neuroscience (NE)

Tuesday, April 23 – 1:00pm

- Chemical, Physical & Structural Biology (CPSB) and Immunology & Microbiology (IY)

Wednesday, April 24 - Noon

- Development, Disease Models & Therapeutics (DDMT), Genetics & Genomics (GG), and Quantitative & Computational Biosciences (QCB),

Annual program retreat

- September 17, 2024
- One day
- Students who finished the two years must present
- Other CTR students can present
 - Student submits abstract (end of term 5; with project summary)
 - All will have posters; some selected for talks
- Leadership opportunity: retreat committee
- Students recommend and invite speaker
- Planned in person

Contact:

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Questions?

**We look forward
to receiving your
application!**