

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

(co-directors I Van den Veyver and C. Smith)

Overview

7 NEW PROGRAMS

Cancer & Cell Biology

Chemical, Physical & Structural Biology

Development, Disease Models & Therapeutics

Genetics & Genomics

Immunology & Microbiology

Neuroscience

Quantitative & Computational Biosciences

CLINICAL
TRANSLATIONAL
RESEARCH CAQ

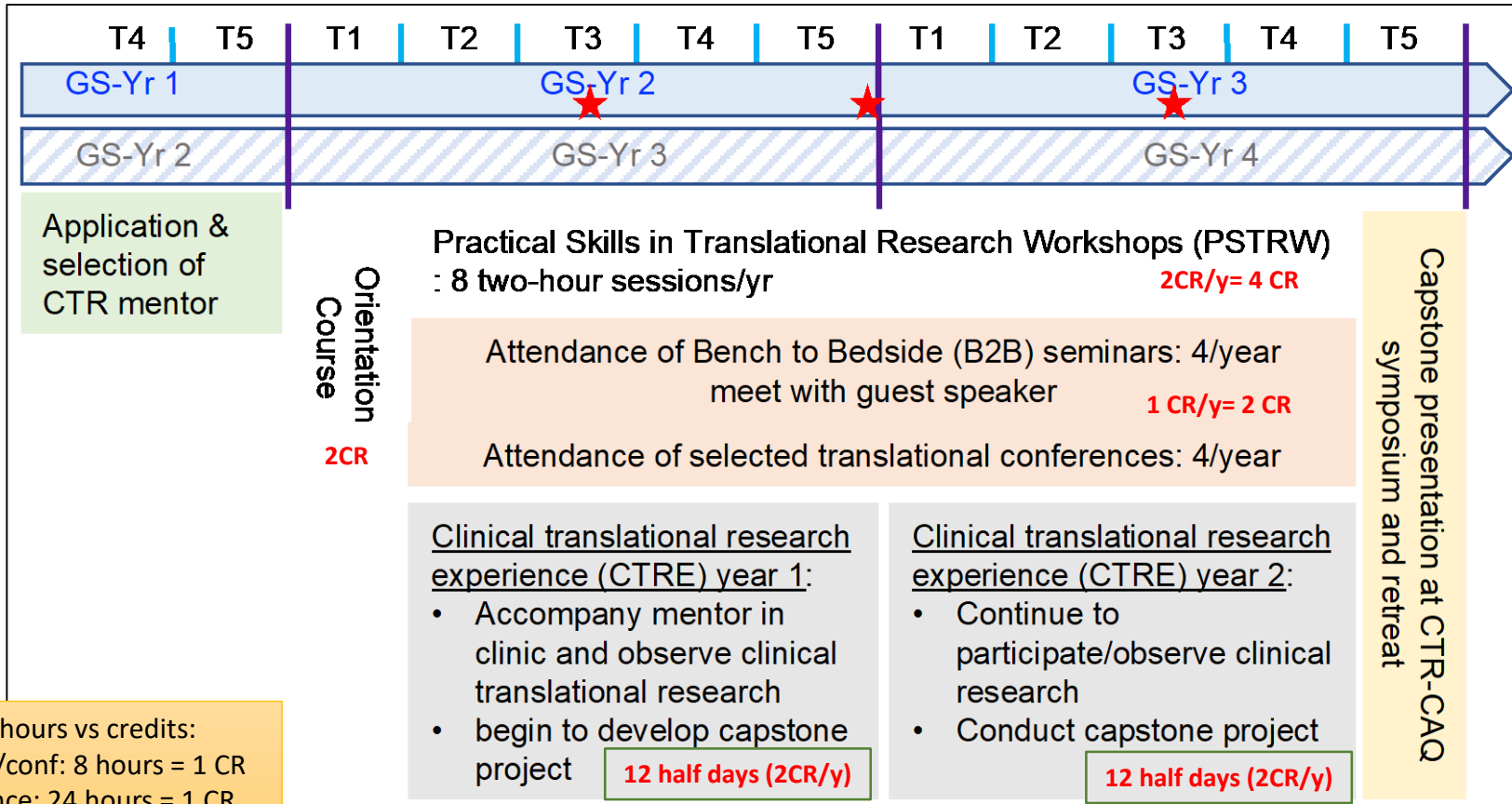
CTR-CAQ Key Components

- **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) and if approved by program you can co-credit for elective credits**
 - Orientation to Clinical Translational Research course: 2 credits
 - Practical Skills in Translational Research Workshops 1 & 2: 2 cr/y → 4 cr total
 - Attend 4 translational conferences/y + 4 B2B Seminars → together = 1cr/y → 2 credits total
 - Year 1: Clinical Translational Research Experience and observing clinical research: 2 credits
 - Year 2: CTRE continued plus Capstone project: 2 credits
- 2. Completion and presentation to CTR-CAQ committee of capstone project at CTR-CAQ annual retreat/symposium (term 5 of year 2)**

CTR – CAQ curriculum and timeline



Possible co-credits with primary PhD program

Course	Credit hours	CTR-CAQ Program -specific	Offered BCM (GSBS)-wide by CTR-CAQ program	Offered by grad program	Co-credit hours
Orientation to Clinical Translational Research	2	No	Yes	variable*	2
Practical skills in translational research workshop	4	Yes	No	variable*	4
Bench-to- bedside seminars, CTR-CAQ symposium and attendance of translational conferences	2	No	Yes	variable*	2
Clinical Translational Research Experience	4	Yes	No	No	No
TOTAL	12	OPTIONAL CO-CREDIT*			8

* Must be approved by PhD program – will propose up to 4 chosen from 8 co-credits available

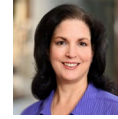


I Van den Veyver



C Smith

Co-Directors: VdV, Smith
Associate director: TBD
Program Administrator: K Levitt



Kelly Levitt

Executive Steering Committee (ESC) *Van den Veyver*, directors,
course directors, committee chairs, 2 students, 1 at-large faculty
member

Internal Advisory / Integration
Committee



D Burrin

Trainee
recruitment,
selection &
guidance (6)
D. Burrin

Individual
Guidance
Committee (4)



D Rowley

Curriculum (5)
D. Rowley

Courses

Faculty and
program
evaluation &
outcomes (3)

Core Training
Program Faculty
and CTR
mentors

Orientation to
Clinical
Translational
Research (OCTR)
Suter & Parihar

Practical Skills
Workshops in
Translational
Research (PSWTR)
*Kheradmand &
Hilsenbeck*

Bench to
Bedside
Seminars (B2BC)
*Thevananther &
Craig*

Clinical Translational
Research Experience
(CCTRE)
*Van den Veyver &
Pereira*

Mentorship

1. Clinical translational research 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
 - Required mentor orientation will be done in T1 of year 1
2. Assigned faculty advisor from CTR-CAQ core faculty
3. 2 x / y: individual guidance committee (IGC) meeting

Individual Guidance Committee (IGC) meeting

- Student
- Clinical translational research mentor
- CTR-CAQ faculty advisor
- Thesis advisor
- Other CTR-CAQ faculty member

This committee is not another thesis advisory committee!

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

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 clinical mentor support letter

COURSES

Orientation to Clinical Translational Research (OCTR) course

- 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
- Course will end with a CTR-CAQ “mini white coat ceremony”



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

What is the mini white coat ceremony?

- Has been done in TBMM for the last several years before the start of clinical projects.
 - 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

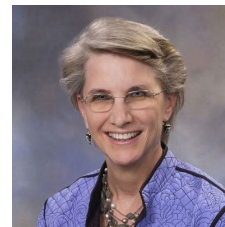


Other preparations before going to clinics

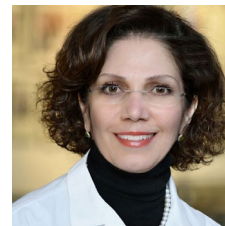
- Insurance
 - same type of malpractice insurance as medical students
 - even though you do NOT participate in care you are covered
- Background checks
- HIPAA and CITI training
- IRB experience (as part of PSTRW course)

Practical Skills in Translational Research Workshops (PSTRW)

- Course Director: Susan Hilsenbeck, PhD
- Co-director Farrah Kheradmand, MD
- **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 (standardized scenarios)
- Active learning and gradual skill building



S. Hilsenbeck



F. Kheradmand

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 minutes
- Present to entire group, receive feedback, discussion (presenters rotate)
- Repeat with task 2, etc... up to 2-4 tasks (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)

Bench to Bedside Seminars (B2B)

- Course Director: Sundararajah Thevananther, PhD
- Co-director William Craigen, MD, PhD
- **4 one-hour translational research seminars of choice**
- **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



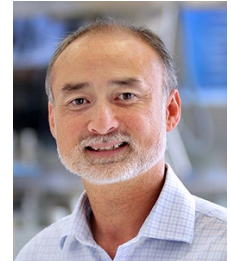
W. Craigen

Clinical Translational Research Experience (CTRE) course

- Course Director: Igna Van den Veyver, MD
- Co-director: Fred Pereira, 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



F. Pereira

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

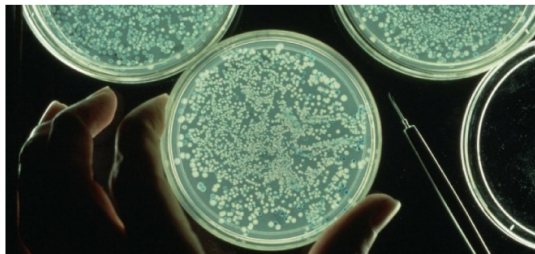
- Directed by clinical translational research mentor (others can help)
- Capstone project proposal (short -- not a thesis proposal or QE proposal!)
- Conduct capstone project
- Varies depending on mentor, research field and setting, and prior student experience
- Options:
 - Can vary from case series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

CTRE Oversight

- Graded as: pass – incomplete – fail
- Brief proposal of activities is required for Term 1 year 1
- Clinical activity report - 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 +

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

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](#)

ADMISSIONS

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

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**FOR MORE
INFORMATION,
CONTACT**

Rashieda Hatcher
Program Administrator
✉ ctrcaq@bcm.edu

CLINICAL TRANSLATIONAL RESEARCH CERTIFICATE OF ADDED QUALIFICATION

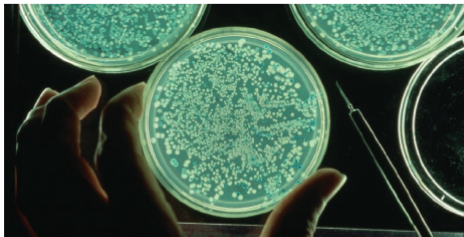
The vision of Baylor College of Medicine is to improve health through science, scholarship and innovation.

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.



Contact:

Igna Van den Veyver
iveyver@bcm.edu

Levitt, Kelly
klevitt@bcm.edu

Questions?