

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

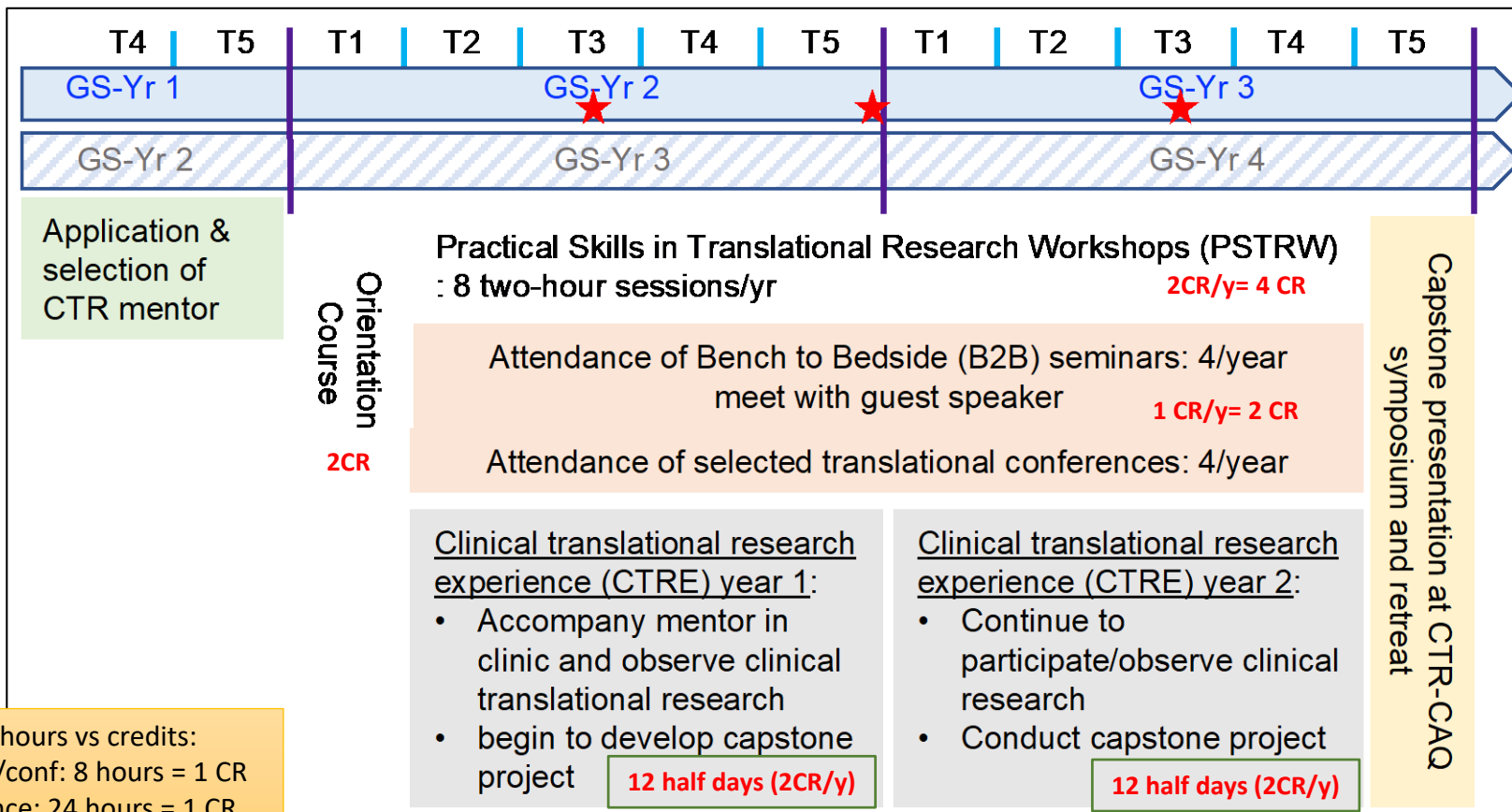
CTR-CAQ Key Components

- **Build upon TBMM “clinical Projects” and dual mentorship experience**
 - Accompany clinical mentor to clinics
 - Attend diagnostic consensus conferences, grand rounds, translational research meetings
 - Observe and participate in clinical research with clinical 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**

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: 2 credits/y → 4 cr total
 - Attend 4 translational conferences/y + 4 B2B Seminars → together = 1credit/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



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	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*, (13: 2 directors, 1 associate director, 4 course directors, 3 committee chairs, 1 (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 & Craigen

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

Mentorship and role of faculty

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
 - 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

CTR mentors

- Faculty who do clinical research / clinical translational research
- They can, but do not have to be, graduate school faculty
- A CTR mentor will be a faculty member of the CTR-CAQ program during the time they are CTR mentors of a CTR-CAQ student
- CTR mentors can apply to become CTR-CAQ core faculty members (for example if they have mentored students and are interested in becoming more involved with the program at other levels)
- TBMM experience: CTR mentor most often is somebody that their thesis advisor already collaborates with
- Role: mostly through CTRE course and individual guidance committee (IGC) (see later slides)

CTR-CAQ core faculty members

- Faculty who do clinical research / clinical translational research
- They are approved graduate school faculty
- A core faculty member will participate in the program as follows:
 1. Course co-directors
 2. Invited) member of a committee:
 1. Recruitment selection and student guidance
 2. Program and student evaluation
 3. Curriculum
 4. Executive steering committee
 3. May be assigned as core program faculty advisor to a student
- Role: most with individual guidance committee (IGC) (see later slides)

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 (with biosketch)
 - (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.
 - 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 as a CTR-CAQ student
 - Dress code!



CTR-CAQ

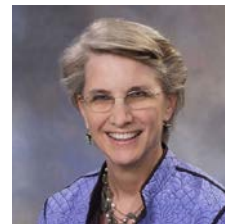
How you present yourself reflects your respect for the privilege of training in a clinical environment

Other preparations before going to clinics

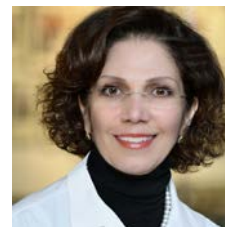
- Insurance
 - same type of malpractice insurance as medical students
 - even though you do NOT participate in care you are covered
- Background checks
- HIPAA and CITI training
- IRB experience (as part of PSTRW course)

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 faculty and students
 - CTR-CAQ students host and participate in faculty selection and invitation
 - CTR-CAQ students meet with guest faculty
 - One of the seminars coincides with annual CTR-CAQ retreat (annual retreat can count for experience credit hours)



S. Thevananther



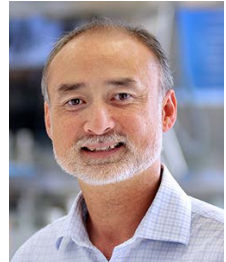
W. Craigen

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



I. Van den Veyver



F. Pereira

CTRE course Year 1: clinical research experience

- Directed by CTR-CAQ mentor (others can help)
- T2 – T5 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 or team launch 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
- 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)

Website - updates in progress

The screenshot shows the top navigation bar of the Baylor College of Medicine website. On the left is the Baylor College of Medicine logo. To its right is the word 'EDUCATION'. Further right is a horizontal menu with links for Healthcare, Community, Research, Education, News, Giving, and Intranet. A blue button labeled 'FIND A PHYSICIAN' is positioned to the right of the menu. Below the navigation bar is a search bar with a magnifying glass icon. A dark grey bar below the search bar contains a left-pointing arrow and the text 'BACK TO PROGRAMS'. The main content area features a large heading: 'Clinical Translational Research Certificate of Added Qualification'. Below the heading is a breadcrumb trail: 'Baylor College of Medicine > Education > Schools > Graduate School of Biomedical Sciences > Programs > Clinical Translational Research Certificate of Added Qualification'. In the bottom right corner of the content area is a 'SHARE' button with a hamburger menu icon. At the bottom left, there is a horizontal line followed by the text 'Baylor College of Medicine's vision is to improve health through science,'. At the bottom right, there is a 'Contact Us' link.

Baylor College of Medicine

EDUCATION

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FIND A PHYSICIAN

Q

← BACK TO PROGRAMS

Clinical Translational Research Certificate of Added Qualification

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Baylor College of Medicine's vision is to improve health through science,

Contact Us

<https://www.bcm.edu/education/schools/graduate-school-of-biomedical-sciences/programs/clinical-translational-research>

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

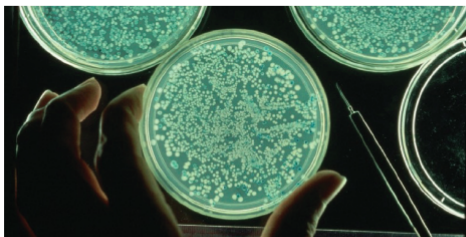
The vision of Baylor College of Medicine is to improve health through science, scholarship and innovation.

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.

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.

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



more →

YOUR 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
 - 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.



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Questions?