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





## <u>Clinical Translational Research Certificate of Added</u> <u>Qualification Program (CTR-CAQ)</u>

(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** 

TRANSLATIONAL RESEARCH CAQ

## **CTR-CAQ Key Components**

- Build upon experience with Translational Biology and Molecular Medicine legacy graduate 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 August 1
- [T32 training grant]

## **CAQ** requirements: 12 CREDITS

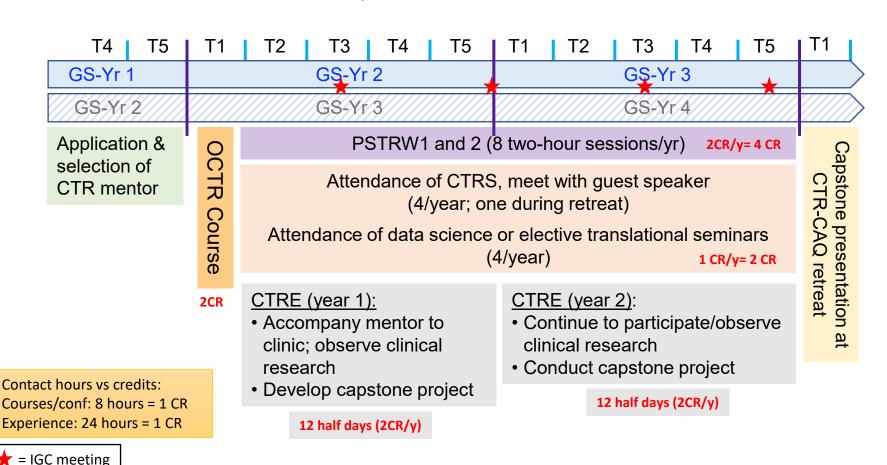
#### 1. Spread out over 2 years (10 terms)

- 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:

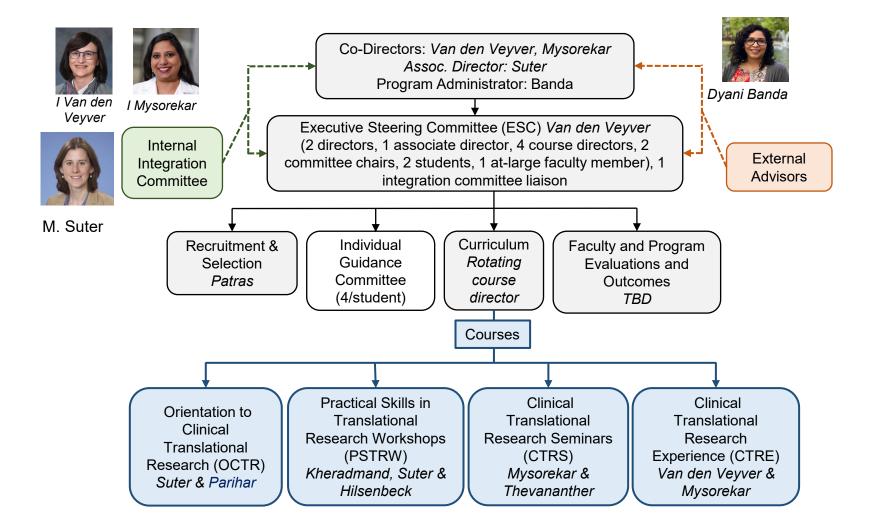
- Written abstract and proposal (by term 5 of year 1); project report (by term 5 of year 2)
- Presentation at CTR-CAQ annual retreat/symposium (~September)

#### **CTR – CAQ curriculum and timeline**



## 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			



## 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)

- Chair: CTR-CAQ faculty advisor (assigned by program)
- Clinical translational research mentor
- Thesis advisor
- Other faculty member
- 4 individual guidance committee (IGC) meetings (~6, 12, 18, 24 months)
- IGC will oversee and advice on progress and completion of the capstone project and progress in the program (CTRE)
- This committee is not another thesis advisory committee!
- The focus is on guidance!

## 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 only 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**

1. T1 to T4 translational research	9. Patents / Licensing	
2. Study Design	10. Epidemiological studies	
3. Team science, mentorship, and academic-industry collaborations	11. The institutional review board	
4. Early-phase clinical trials	12. Clinical trials reporting	
5. Informed consent	13. Research integrity and misconduct	
6. Good manufacturing practice facilities	15. Retrospective study design, working with datasets/databases	
7. Regulatory affairs	16. Correlative Science Analysis	
8. Practical Aspects of Biobanking	17. Clinical ethics overview	

# Practical Skills in Translational Research Workshops (PSTRW1 and 2) 2 Credits/y

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: 4-6 students per break-out group
- 2-4 facilitators for each workshop
- Case-based or project-based skills development
- Active learning and gradual skill building with "hands-on scenarios"



S. Hilsenbeck



F. Kheradmand



M. Suter

# Practical Skills in Translational Research Workshops Format (PSTRW)

- Mostly follows OCTR course lectures
- Pre-workshop assigned reading
- Readiness assurance test (5-10 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** and 2 – Example Topics

	PSTRW 1		PSTRW 2	
1	Clinical research proposal development	1	Writing an IRB protocol (practical aspects) and NIH application Human Research Section	
2	Sample size and power calculation	2	Data Wrangling: Research with large clinical datasets and electronic medical records (EMR)	
3	Biobanking research	3	Developing an industry-sponsored project	
4	Observational studies	4	Developing, validating, and implementing a new diagnostic test	
5	Intervention early clinical trials	5	Bringing a new therapeutic to market	
6	Databases and data management	6	Applying for patents and intellectual property	
7	Randomized controlled trials	7	Community outreach & engagement, communication & investigator responsibility to engage stakeholders	
8	ATTEND AN IRB MEETING (assigned slots throughout year) and write short report (following prompts)	8	ATTEND AN IRB MEETING (assigned slots throughout year) and write short report (following prompts)	

#### 1 Credit/year

# Clinical Translational Research Seminars (CTRS)

- 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



Mysorekar

## Clinical Translational Research Experience (CTRE) course 2 Credits/y-12

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

Individualized Flexibility



I. Van den Veyver

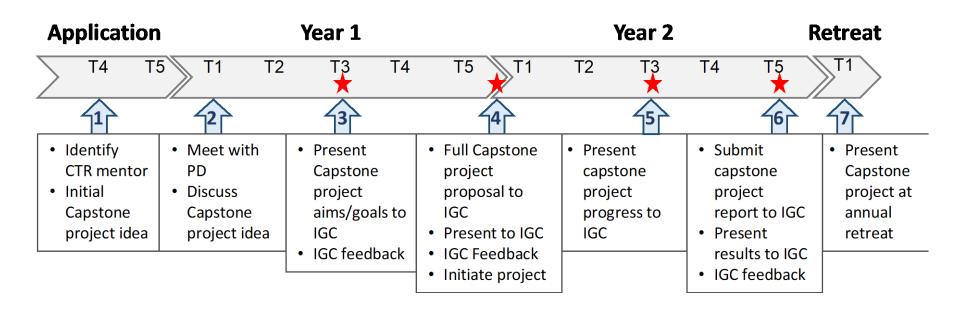


I. Mysorekar

## **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



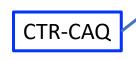
## CTR-CAQ program "CRISP" event Clinical Research Initiation for Science Professionals



"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



## 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)
- Rubric to evaluate progress
- Present summary to IGC at scheduled meetings (~ every 6 months)

# Annual program retreat

- September 15, 2025
- One day; in person
- 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 short talks
- Leadership opportunity: retreat committee
- Students recommend and invite speaker
- Career breakout session

## Website

#### https://www.bcm.edu/education/schools/graduate-school-ofbiomedical-sciences/programs/clinical-translational-research

#### Graduate School of Biomedical Sciences

Programs and Admissions Certificates

Current Research Ourrigulum. Students

Faculty **Postrioctoral** 

Affairs

Mentoring Resources

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Baylor College of Medicine > Education > Graduate School of Biomedical Sciences > Degree Programs and Certificates > Clinical Translational Research

#### Graduate School of Biomedical Sciences

Faculty

#### Contact

Dyani Banda: Program Administrator ctr-cag@bcm.edu

#### Program Information

- Application
- · Video: Student Information Session
- · Slides: Student Information Session
- Frequently Asked Questions

Program Leadership

Igna Van den Veyver, M.D. CTR-CAO Co-Director

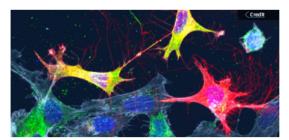
Indira Mysorekar, Ph.D. CTR-CAQ Co-Director

Melissa Suter. Ph.D.

CTR-CAO Associate Director

Credit

#### 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-CAO 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.

Read Ph.D. Candidate Kelsey Mauk's Journey To Complete The Program



#### Connect with us

#### CTR-CAO 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 quest 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
- . 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

#### Meet Our Students



Meet Brittany Jones



Mentoring

More +

Meet English Laserna

#### 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

#### Baylor College of Medicine

#### GRADUATE SCHOOL

OF BIOMEDICAL SCIENCE

#### 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.

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more →

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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

For a full listing of BCM

research centers, visit

For a full listing of BCM

healthcare/care-centers.

healthcare clinics and centers, visit

www.bcm.edu/

research/centers.

www.bcm.edu/

USDA Children's Nutrition Research Center

Vaccine Research Institute

And many more clinical research centers and clinics.



## Small-group in person Q&A sessions **Alkek Building** Watch for calendar invitation

#### Monday, April 21 – Noon in Alkek N317

 Cancer & Cell Biology (CCB) and Neuroscience (NE), and Quantitative & Computational Biosciences (QCB)

#### Tuesday, April 29 – 1:00pm in Alkek N311

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

#### Wednesday, May 7 – Noon in Alkek N302

 Development, Disease Models & Therapeutics (DDMT) and Genetics & Genomics (GG)

#### **Contact:**

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Indira Mysorekar indira.mysorekar@bcm.edu

Dyani Banda Dyani.Banda@bcm.edu

## **Questions?**

We look forward to receiving your application!