

Update: General Research Updates

December 17, 2020



UT Health
San Antonio

During the Forum:

- The session will be recorded
- Mute your mics to avoid echoing or background noise
- Do not activate your camera to preserve bandwidth
- In lieu of voicing your questions, use the chat function, a moderator will respond to your question

Overview

VPR Website Demo

IIMS First Program

CTO – Introduction of New Staff

UT Health Learns

Updates Regarding Emailing and Texting subjects

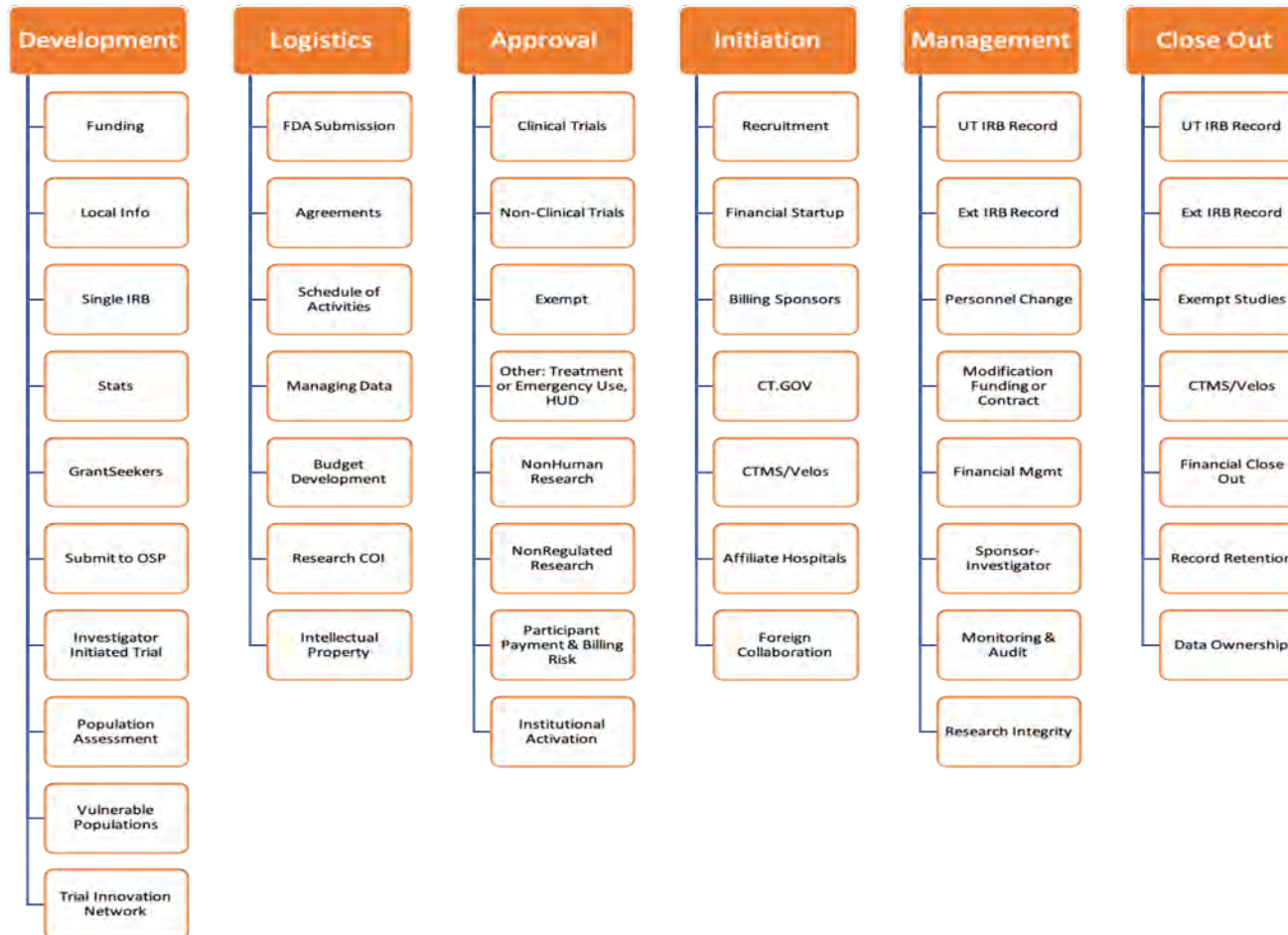
Updates to Research Forum Registration

VPR Website Demo

Kimberly Summers, PharmD

RPP Director

Human Protocol Life Cycle Topics

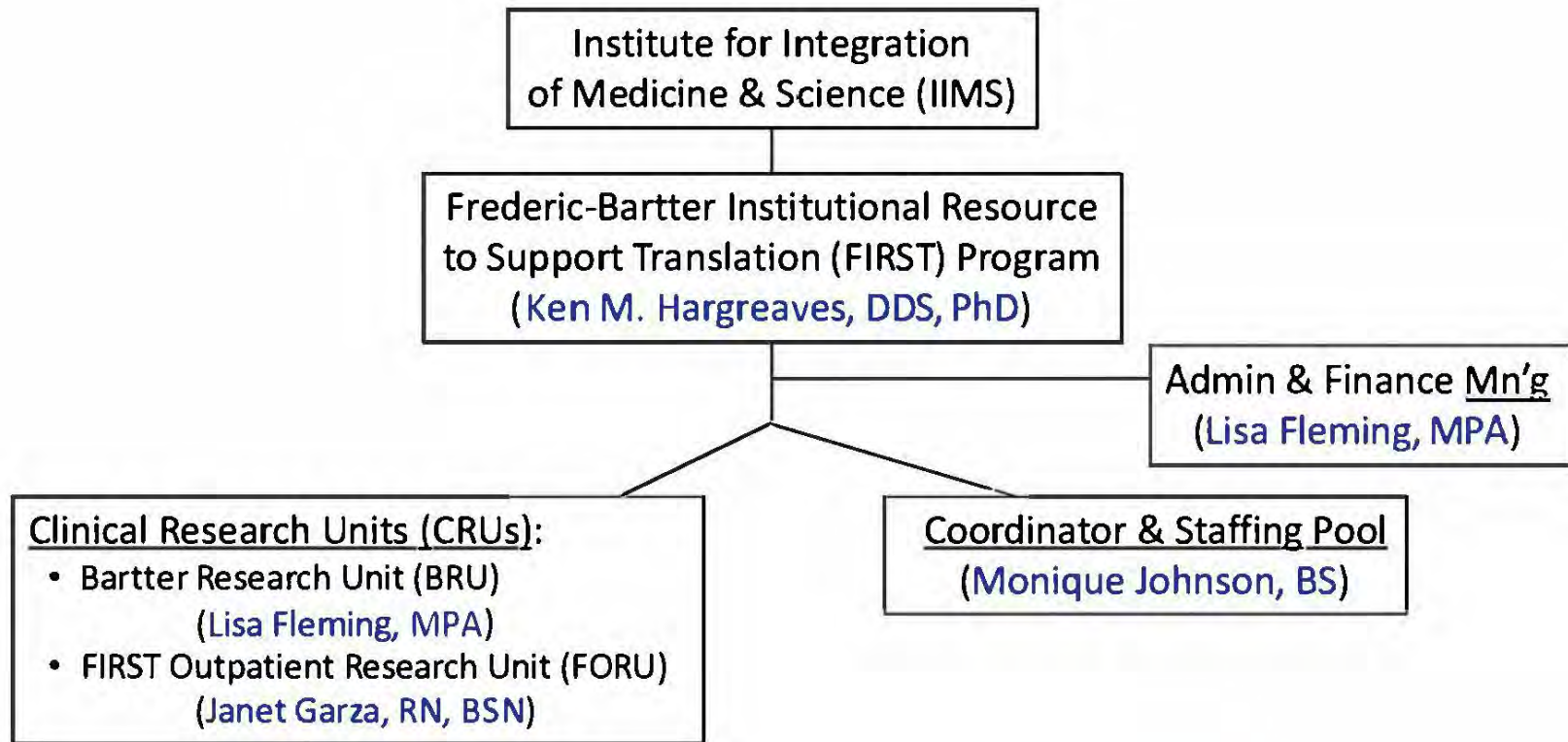


IIMS First Program

Lisa Fleming – Program overview

Janet Garza – FORU Opportunities

Monique Johnson – Coordinator & Staffing Pool



The **FIRST** Program ...to support your research
Frederic-**B**artter **I**nstitutional **R**esource to **S**upport **T**ranslation

FIRST Program

Frederick Bartter *I*nstitutional *R*esource to *S*upport *T*ranslation (FIRST)

The FORU and BRU provide controlled environments with highly experienced research nursing staff to support a broad range of services for clinical trials.

The staff of the CSP are available to investigators to complement or expand the capacity and capabilities of their research teams with research coordinators and nurses.

Participant safety is the highest priority.

How to Begin:

- Contact Lisa Fleming, MPA, Business Administrator, to initiate service request (flemingl1@uthscsa.edu)
 - For research conducted in the BRU, contact the Research & Development Office to complete a resource evaluation form and determine other VA-specific steps
- Provide Protocol, Lab Manual, etc.
- Participate in study team meeting
- Sign cost proposal agreement

Bartter Research Unit (BRU)

South Texas Veterans Health Care System (STVHCS)

Audie L. Murphy Memorial VA Hospital - Medical Center
7400 Merton Minter (7th Floor), San Antonio, TX 78229

- ~6,000 sq. ft. Clinic
- Phase I-IV study support
- Visit-related Cost (\$) Charge (invoiced monthly)
- Contact: Lisa Fleming, MPA for additional service details
 - Fleming1@uthscsa.edu

BRU: Inpatient/Outpatient Clinical Research

BRU Staff Services

- VA Nurses
- Nurse Assessments/Monitoring
- Drug Administration/Infusions

Research Pharmacy

- Drug Receipt Dispensing, Storage & Destruction
- Drug Accountability
- Drug Temperature Monitoring

Clinical Laboratory Services

- Safety – Specimen Processing (IATA Certified)
- Short/Long Term Specimen Storage for Batch Shipment

Other Study Support Services

- DXA Scans
- Nutritional Counseling
- Food Services
- Exam Room Usage by Study Teams
- Conference Room Space

FIRST Outpatient Research Unit (FORU)

UT Health San Antonio

Medical Arts & Research Center (MARC) - Medical Center
8300 Floyd Curl Drive (103.01), San Antonio, TX 78229

- FORU - ~2,500 sq. ft. Clinic
- Phase II-IV study support
- Visit-related Cost (\$) Charge (invoiced monthly)
- Contact: Janet Garza, RN, BSN for additional service details
 - garzaj37@uthscsa.edu

FORU: Outpatient Clinical Research

FORU Staff Services

- Staffed with Research Nurses & Research Assistants
- Drug Administration
- Phlebotomy
- IV Infusions
- Nurse Assessment/Monitoring
- Collaborates with study monitors
- BLS Certified
- Supported by the Coordinator & Staffing Pool (CSP)
- Mobile Nursing

Research Pharmacy

- Drug Receipt, Dispensing, Storage & Destruction
- Drug Accountability
- Drug Temperature Monitoring

Clinical Laboratory Services

- Safety – Specimen Processing & Shipping (IATA Compliant)
- Short/Long Term Specimen Storage for Batch Shipment

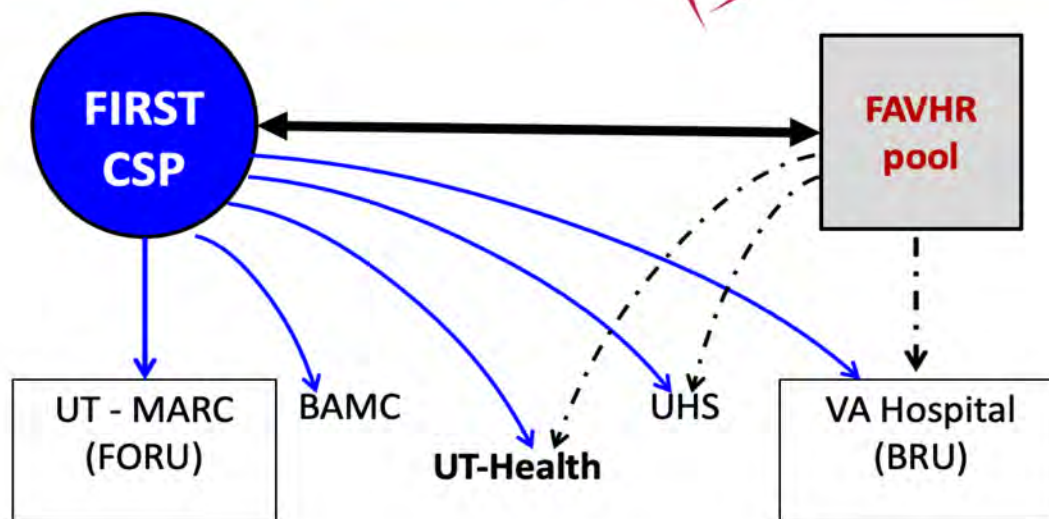
Other Study Support Services

- ECGs
- MARC Café Meal Vouchers
- Exam Room Usage by Study Teams
- Parking Validation Available for Research-Related Visits

Coordinator & Staffing Pool (CSP)



Coordinator & Staffing Pool (CSP)
(a UTHSCSA Service Center)



Coordinator & Staffing Pool (CSP)

UT Health San Antonio & Surrounding Affiliates (VAH, UHS, Other)

- Combined Research Coordinators and Research Staff Pool:
 - UT Health San Antonio
 - Foundation for Advancing Veterans' Health Research (FAVHR)
 - Michelle M. Trimble - CEO
- Flexible Pool Work on (%FTE) needs with \$/hour charges (invoiced monthly)
- Coordinator & Staffing Pool (CSP) Agreement with initiate support services
 - Agreements are Study specific
 - Department & PI must acknowledge level of study support
 - Requires PID or Department ID prior to CSP agreement execution
- Contact: Monique A. Johnson, BS for additional service details
 - JohnsonM13@uthscsa.edu

Coordinator & Staffing Pool (CSP)

Experienced Coordinators & Research Staff

- PhD, RN, BSN, BS, BA, ACRP Certified & Technician levels.
- Affiliations: UHS, VAH, BAMC, and others.
- EMR, eVelos, ClinCard & RedCap access.
- Data Management Systems: EDC, IWRS/IRT, e Pro & Other CTMS Programs

Clinical Research Support

- Industry Sponsor & PI Initiated Studies.
- Phase I-IV including device trials.
- Pre-Award, Post-Award, Regulatory, Study Transfer, & Study Closeout Support.

Coordinate Clinical Research Studies

- Collaboration between PI, Department(s), Sponsor, Hospitals/Clinics/Pharmacy, CTO, IRB(s)/CRO & Other support research staff.
- Track Study Progress: Recruitment, Enrollment, Study conduct, Source documentation & Data management.

Questions?

CTO Updates

*Jason Bates, MBA
Director, CTO*

CTO Staff Announcement

NEW Team Member – Christie Bryant – Billing Analyst

Jason Bates – Director, Clinical Trials Office

Patricia Miranda – Manager, Research Operations

Brandi Weaver – Manager, Clinical Trials Development

Cathy Haegelin - Budget Analyst – Senior

Anna Stewart, Budget Analyst – Intermediate

Lynda Schrack – Clinical Trials Specialist

Cristina Morales – Clinical Trials Specialist

Laura Martinez – Administrative Assistant



UT Health
San Antonio

Clinical Trials Office



UT Health Learns



VPR Research Trainings previously in Knowledge Center have been transferred to UT Health Learns.

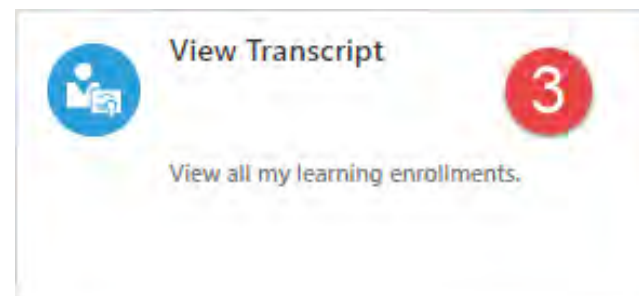
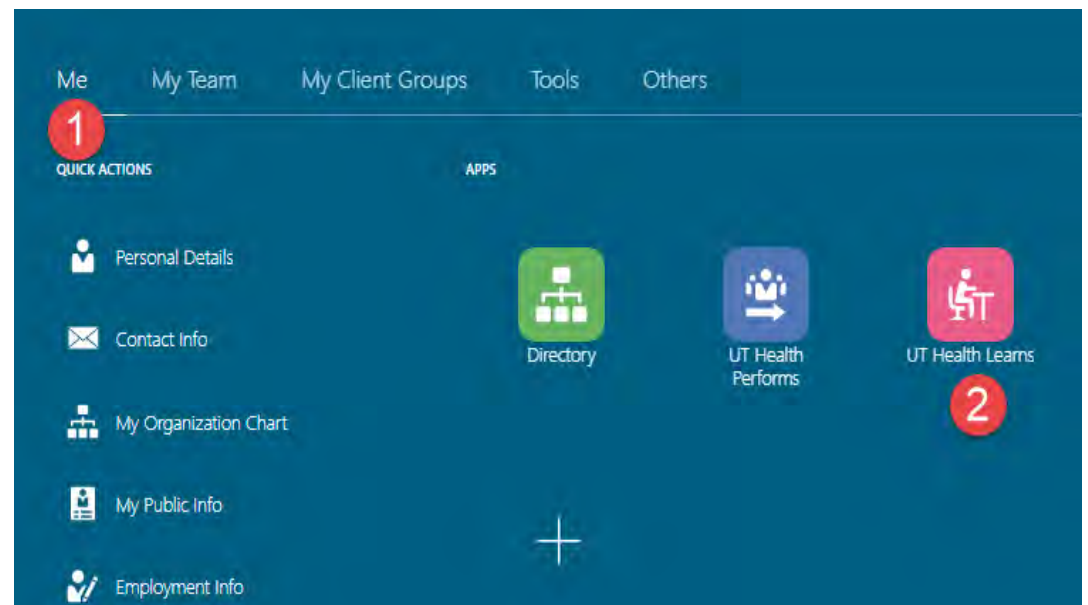


CTO will now make assignments within UT Health Learns for required training, users will be given 30days to complete.

UT Health Learns cont.

Access and Review past Trainings:

1. Log into UT Health Learns and Select Me
2. Select UT Health Learns
3. Select View Transcript



UT Health Learns cont.

Access and Review past Trainings:

4. Find and select course you want to review

The screenshot displays the 'Enrollments' interface. At the top, there is a search bar labeled 'Search by learning item title' and a 'Hide Filters' button. Below the search bar, there are 'Filters' and 'Reset' options. The 'Filters' section includes 'Expand All' and 'Collapse All' buttons, and three date selection fields: 'Completed Date', 'Enrolled Date', and 'Due Date', each with a date picker and an 'OK' button. The 'Sort' dropdown is set to 'Completed on - Most Recent'. The main content area shows two course entries, each with a blue icon and a red circle containing the number 4. The first course is 'CTO Velos eResearch [WBT]', completed on 12/8/20, enrolled by Clinical Trials Office, due 12/31/20. The second course is 'CTO Management of Research Billing Risk [WBT]', completed on 12/8/20, enrolled by Clinical Trials Office, due 1/8/21.

UT Health Learns cont.

Access and Review past Trainings:

5. Select Review Content Under Completion Status

Completion Status

Search... Show Filters

View By Completed Activities

Completed on 12/8/20

eLearning Required

Self-Paced Online

5 Review Content

Updates on Emailing/Texting Research Subjects

*Meyad Baghezza, BA CIP
Associate Director, IRB*

Emailing Subjects

- Prior to emailing subjects, they will need to sign the UTHSA's Email Authorization



- Research consent template has been updated to include language and a link to the Email Authorization

E-mail Authorization Agreement *Insert the language below if study will use email to communicate with the research team members – include the information below. The Email Authorization Agreement is found here: [English version](#) and [Spanish version](#).*

The research team would like to communicate with you regarding your research visits via email. In order to do this, we will ask that you sign a separate Email Authorization Agreement.

Initial Recruitment Emails on Hold

Confirmation that
subject authorized
email method of
communication

A plan to handle
recruitment data
from University
Health is
established

**This includes recruitment emails using data from CIRD for recruitment purposes*

Texting



- Use of personal cell phones remains prohibited



- Subjects waiting to be seen must call lieu of texting personal cell phones



- Must use a platform approved by the institution- Compliance and IMS



- BAA will be need to be in place prior to use of the approved platform

Texting

- The institution is currently evaluating potential options that would allow texting from University numbers across campus
- Goal is to **not** require researchers to obtain Compliance/IMS approval each time there is a proposal to include the texting of subjects
- Draft guidance is being reviewed and will be shared once it has been finalized

Questions?

Changes to Research Forum Registration


The Research Forum is moving to Zoom

After clicking Submit, enter your email address into the **Confirmation Message** field on the next screen

[Close survey](#)

Thank you for your registering for the Research Forum.

To receive the Zoom meeting invitation, insert your email in the field below. **You must do this before you close the survey or this window.**

 **Enter your email to receive confirmation message?**
A confirmation email is supposed to be sent to all respondents that have completed the survey, but because your email address is not on file, the confirmation email cannot be sent automatically. If you wish to receive it, enter your email address below.

[Send confirmation email](#)

* Your email address will not be stored

Download your survey response (PDF): [Download](#)

Virtual Concierge

January 5, 2021	1pm - 4pm
January 13, 2021	9am - 12pm
January 27, 2021	9am - 12pm

Research Forum

- Thursday, January 28, 2021
- 1:00 pm – 2:00 pm
- Zoom