Bartter Clinical Research Unit (BRU)

U.S. Department of Veteran Affairs
South Texas Veterans Health Care System
Bartter Clinical Research Unit (BRU)

- 7A BCRU is a 8100 sq. ft. clinical facility with both outpatient and inpatient capabilities located at 7a.
- Inpatient/Outpatient care areas that provide visual/auditory privacy (16 rooms/13 beds).
- 24 hour staffing capabilities for extended studies with nurse-patient ratio to meet research intensity.
- Supports clinical research phases and services adult population in all clinical specialties.
FREDERIC C. BARTTER
September 10, 1914 – May 5, 1983

Dr. Bartter was an American endocrinologist best known for his work on hormones affecting the kidney and his discovery of SIADH and Bartter syndrome.

His namesake, The Bartter Clinical Research Unit (BRU), is a collaborative partnership between STVHCS and UTHSCSA supporting diverse, patient-oriented clinical research involving both Veterans and non-veterans in the South Texas Region.
Our Team

**Medical Director** Marzieh Salehi, MD MS, Marzieh.Salehi@va.gov or Salehi@uthscsa.edu

**Nurse Manager** Samantha Elbel, RN, MSN, Samantha.Elbel@va.gov

**Business Administrator (IIMS, CTSA)** Lisa Fleming, MPA, flemingl1@uthscsa.edu
Yolanda Martinez

**Nursing Staff** Amy Thomas MSN, RN, Laura Ramirez BSN,RN, Roxanne Colazo MSN,RN, Katherine DeLeon, BSN RN, Chris Gill BSN,RN, Wendy Dych LVN, Norma Diaz BSN, RN, Hue Mang BSN, RN and Erwin Paleracio BSN,RN

**Investigational Pharmacist** Michael (Tony) Biaglow, PharmD

**Investigational Nutritionist** Tamara Sugarek, RD

**Lab Processing** Nancy Toro, BS,CCRC, Mario Garza Medical Technician

**DXA Technician** Chakradhar Velagapudi, Ph.D., Martha Arroyo, CRC

**Front desk and scheduler** Stephanie Bolan-Reding 210-617-5300 Ext 14720
SPECIALIZED SKILLS/SERVICES

CLINICAL NURSING

- Complex physiologic glucose studies in human, such as oral glucose or meal tolerance test as well as various glucose clamp studies using bedside glucose analyzers
- Intravenous catheter insertion guided by ultrasound for those with poor IV access
- Drug Titration with Algorithms
- Energy expenditure measurement using indirect calorimeter
- Pharmacokinetic Sampling/Processing
- 12 Lead EKGs, limited bedside cardiac monitoring
- Protocol Specific, Nurse developed patient education
- Dynamic Endocrine Testing (MMT, OGT, ACTH test, saline infusion test etc.)
SPECIALIZED SKILLS/SERVICES

OTHER SERVICES
- Anthropometric (fat and lean mass) as well as bone mass measurements using dual energy x-ray absorptiometry (DEXA)
- Metabolic Kitchen & Nutrition Counseling
- Pharmacy services:
  - Ordering & Handling of investigational drug shipments
  - Compounding support for double blind studies
  - Drug storage – ambient & refrigerated
  - Investigational Drug dispensing

SPECIMEN PROCESSING
- Biological specimen processing & shipping
- Refrigerated centrifuge
- Temporary & extended specimen storage
- Storage capabilities
  - -20 Freezer
  - -80 Freezer
The metabolic kitchen is available 6:00 a.m. to 3:00 p.m.
- Hours outside of this timeline are available if needed to support research protocol.
- If you have a specialty request for your study, please contact BRU Nutritionist.
  - Specialty meals must be included in protocol and orders
- Contact information: Tamara Sugarek, RD
  Office: (210) 617-5300 ext. 14755
  Work Cell: (210) 818-3153
High Reliability Organization

- Focus on the Patient/Veteran
- Focus on Safety (Time Out for Procedures)
- Commit to Zero Harm (Stop the Line)
- Clear Communication (Daily Huddles)
- Learn, Inquire, Improve (ACRP, CITI, GCPs, Chemotherapy Certifications)
- Speak up (Daily Huddles)
- Mutual Respect (Teamwork)
- Sensitivity to Operations (Front Line Staff/Processes)
- Preoccupation with Failure (Anticipate Risk)
- Reluctance to Simplify (Root Causes)
- Commitment to Resilience (Bounce Back from Mistakes)
- Deference to Expertise (Empower and Value Expertise/Diversity)
### Patient Encounters/Nursing Hours Worked

<table>
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<tr>
<th>MONTH</th>
<th>SDTU Notes (INCLUDING STIM TESTS, SALINE SUPPRESSION TESTS)</th>
<th>RESEARCH Notes (INCLUDING OGT)</th>
<th>TELEPHONE Notes (APPTS/CONSULTS)</th>
<th>MISC</th>
<th>TOTAL Notes</th>
<th>~Nursing Hours Monthly</th>
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<td></td>
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Collaborative Institutional Training Initiative (CITI)
- Good Clinical Practice (GCP) Guidelines for Biomedical Research
- FDA Regulations of Clinical Trials
- Human Subjects Protection
- International Conference on Harmonisation (ICH) recommendations

Association of Clinical Research Professionals (ACRP)
- Patient-Centered Informed Consent
- Ethics & Human Subject Protection
- Quality Management & Control
- Patient Safety

ONS Chemotherapy Certification Provider Card

SONOSITE Ultrasound Guided PIV Course

Continuous specific Training based on Research study requirements
Defining 7A BRU Research Study Process

1. IRB approved protocol submitted to R&D
2. BRU Nurse Manager
   - Resource feasibility approval
   - BRU Business Admin
   - Cost proposal approval*
3. Pre In-service Questionnaire
   - Assigning study to a specific nurse champion
4. Main In-Service (study team and BRU staff)
5. Investigators are asked to:
   1) present preliminary data
   2) acknowledge BRU support in publication/presentation
6. Study Status review meeting (enrollment closures).

* For non VA-funded studies
7A BRU Research Study Questionnaire  
(Required Prior to Pre-Inservice for New Studies)

- BCRU Contact Information:  
  210 617-5300 Ext 14720
Research Study Communication Strategies

Research Notes/Scheduling

- Attach Wendy Dych (Primary), Katherine Deleon (Secondary) & Stephanie Bolan-Reding to your CPRS notes for future appointments.

- If it is an appointment for the current week, please inform the CHARGE nurse (seated at front desk)/MAS support. Provide the doctor’s orders at least the day (by 12 noon) prior to the visit so all arrangements with pharmacy, lab and dietary can be finalized.

- All new patients require 1010 form which can be sent by staff to registration to be added into our CPRS charting system (if no response in 1 hour, Stephanie will enter data).

- Assigned Study Nurse is the Main point of contact for any study updates, new requests, new protocols, etc. so information can be communicated among all staff involved.
Research Study Communication Strategies continued

**Essential Data before the Visit**

- Research Study Questionnaire completed and turned into Charge Nurse at least the day before the study visit (by 12 noon).
- Ensure all data (including Full Name, DOB, Last 4 of SSN, Study Name, IRB#, Visit#) is present on the doctor’s orders (assigned nurse can review and edit). Ensure the doctor’s orders are signed and dated by the PI. Ensure that Patient’s appointment date & time are indicated.

**Day of Study Visit**

- Check in at the 7A BCRU front desk and then staff will direct you to your patient’s room for the study visit.
- Inform the Charge Nurse of any cancellations, no shows or rescheduled patients. If patient reschedules, study staff should update the orders with the correct date/time of rescheduled visit.
COVID-19 CONTINGENCY PLANS

- COVID-19 pre-screening calls completed 24 hours prior to appointment at 7A BRU.
- Veterans will continue wearing a cloth barrier mask upon entry into area.
- Social distancing of at least 6 feet distance between patients and staff workstations.
- The waiting areas and all clinic spaces require cleaning to include high-touch surfaces and frequently touched areas (chairs, doorways, etc.).
- Clinical staff will utilize appropriate PPE for area. Clinical staff with direct access to patients are to wear reusable face shields or goggles, surgical masks, and gloves.
- Proper hand hygiene must be practiced using either hospital approved hand-gel or soap and water.
Research Collaboration Strategies

- A focus to collectively address unit needs, ensuring safe, patient-centered care, GCP in our research activities, and continuous improvement of the working environment. This will involve nursing staff, nurse manager, unit lab staff, UTHSCSA study coordinators, Chief Nurse for Education and Research, and Associate Chief of Staff Research in addition to the Principal Investigators.

- This will be a dynamic and evolving structure to adapt to the needs of the unit and foster enthusiasm and empowerment in the professionals who work closest to our patients. There will be ongoing training/updates to improve practice throughout our research unit.
Process For Changes In Research Study

After modification to the protocol is approved by IRB and R&D is responsibility of the research team to inform Samantha Elbel and Lisa Fleming so we may improve the entire research experience to the best of our ability.
Questions?