The Madison VA Clinical Trials Task Force: A model for leveraging partnerships between research and patient care to maintain feasibility in clinical research

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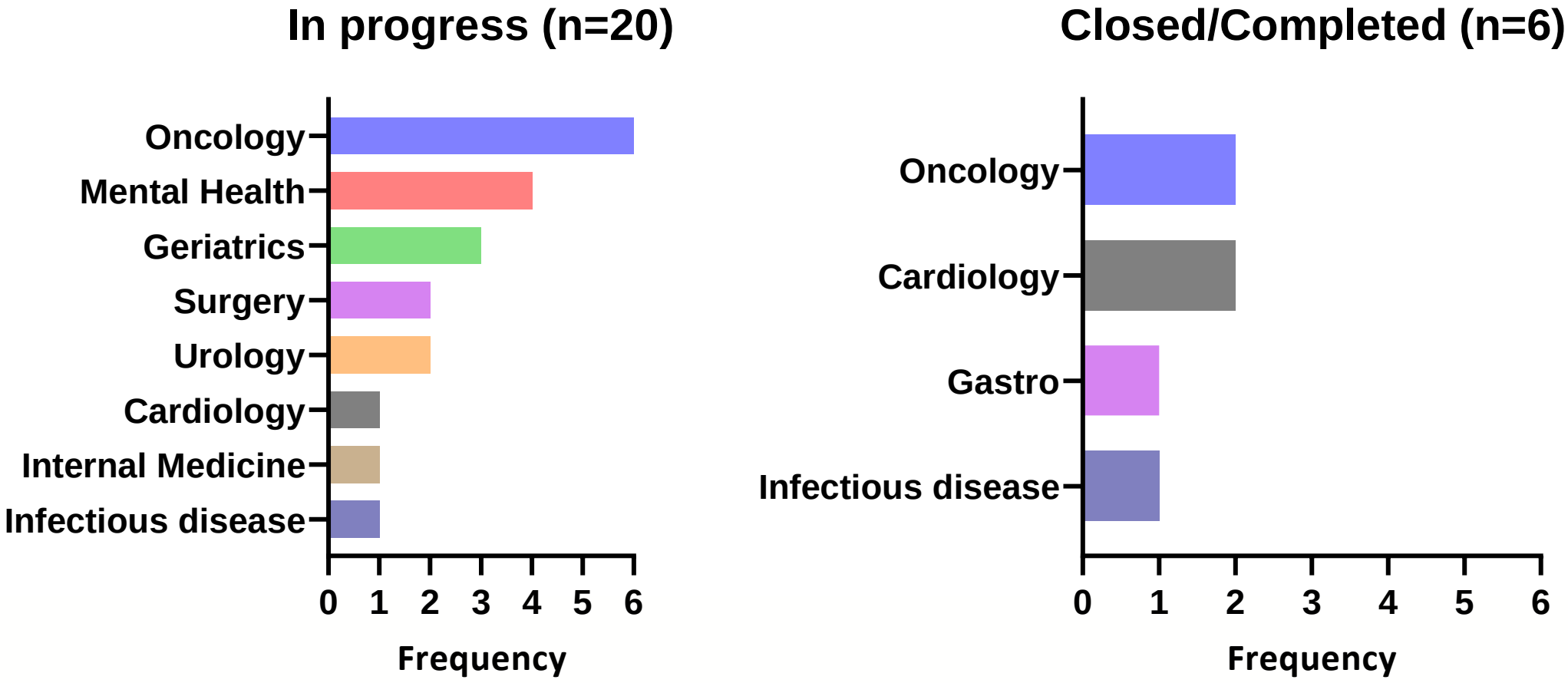
University of Wisconsin-Madison, Madison, WI, USA

The Clinical Trials Task Force (CTTF)

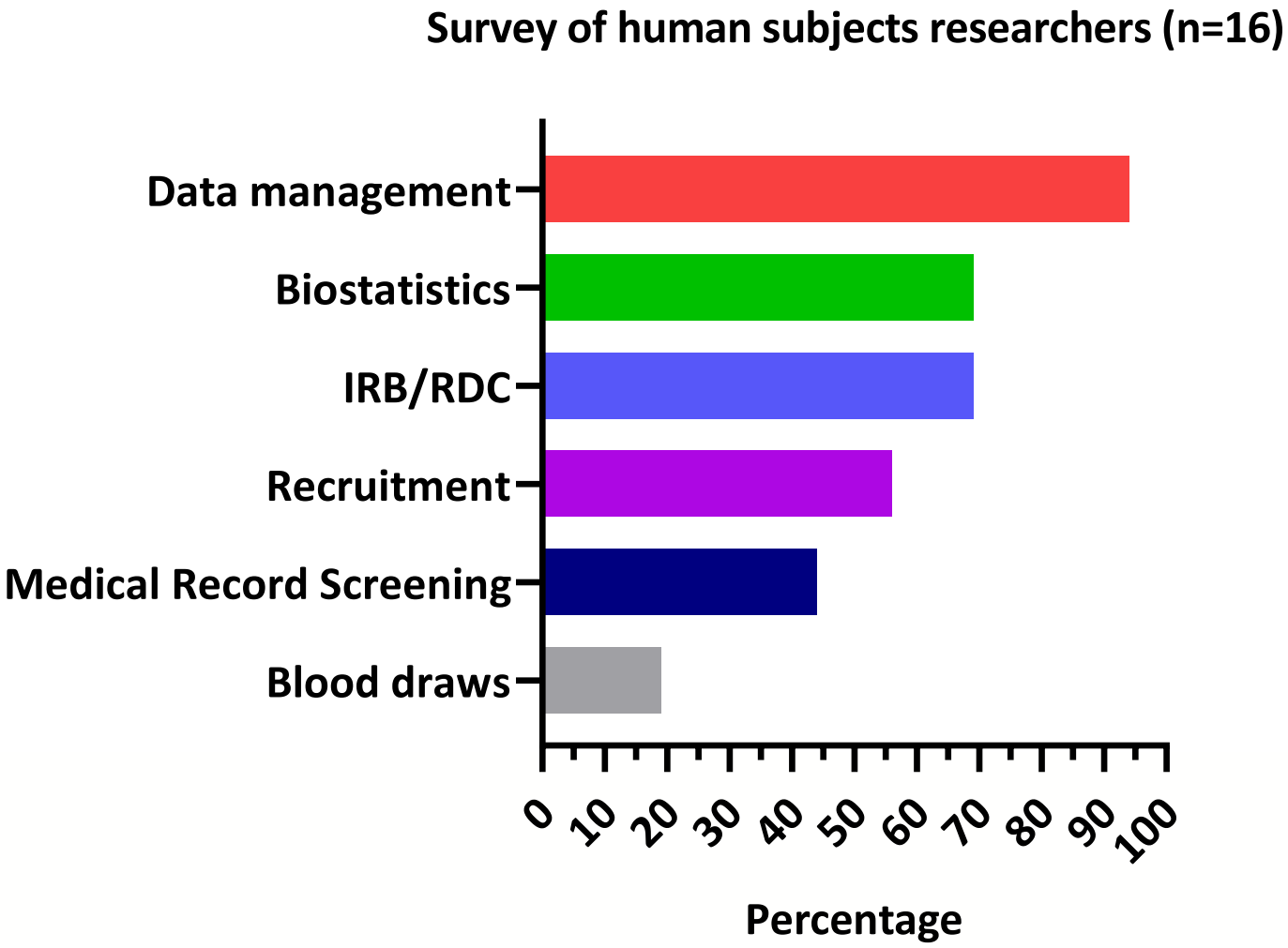
- A group of administrators, scientists, and patient care providers who meet monthly to discuss new protocols and general issues facing clinical researchers (est. August 2021)
- **Goal 1:** Identify feasibility issues and solutions as early as possible (e.g., protocol development, regulatory review)
- **Goal 2:** Connect researchers with available resources within the facility
- **Patient care representation:** oncology, nursing, pharmacy, pathology/clinical lab, radiology, CPRS, GRECC, infectious disease
- **NPC representation**: Kevin Hull, Chief Development Officer and Director of Education, CARES

Step 1: Clinical trials at the Madison VA

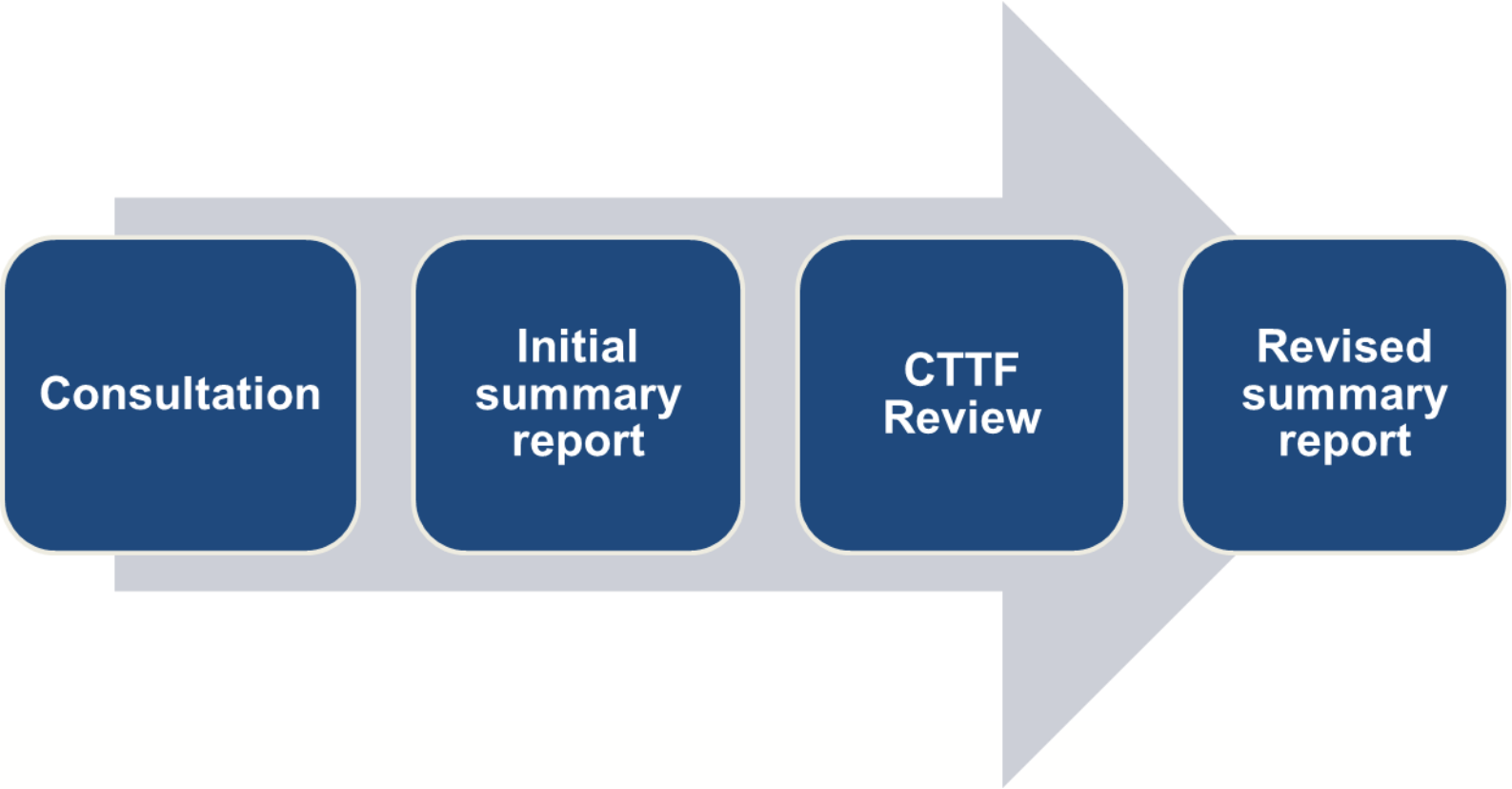


Note. Data limited to trials that were ongoing or opened since formation of CTTF (August 2021)

Step 2: Identify feasibility barriers



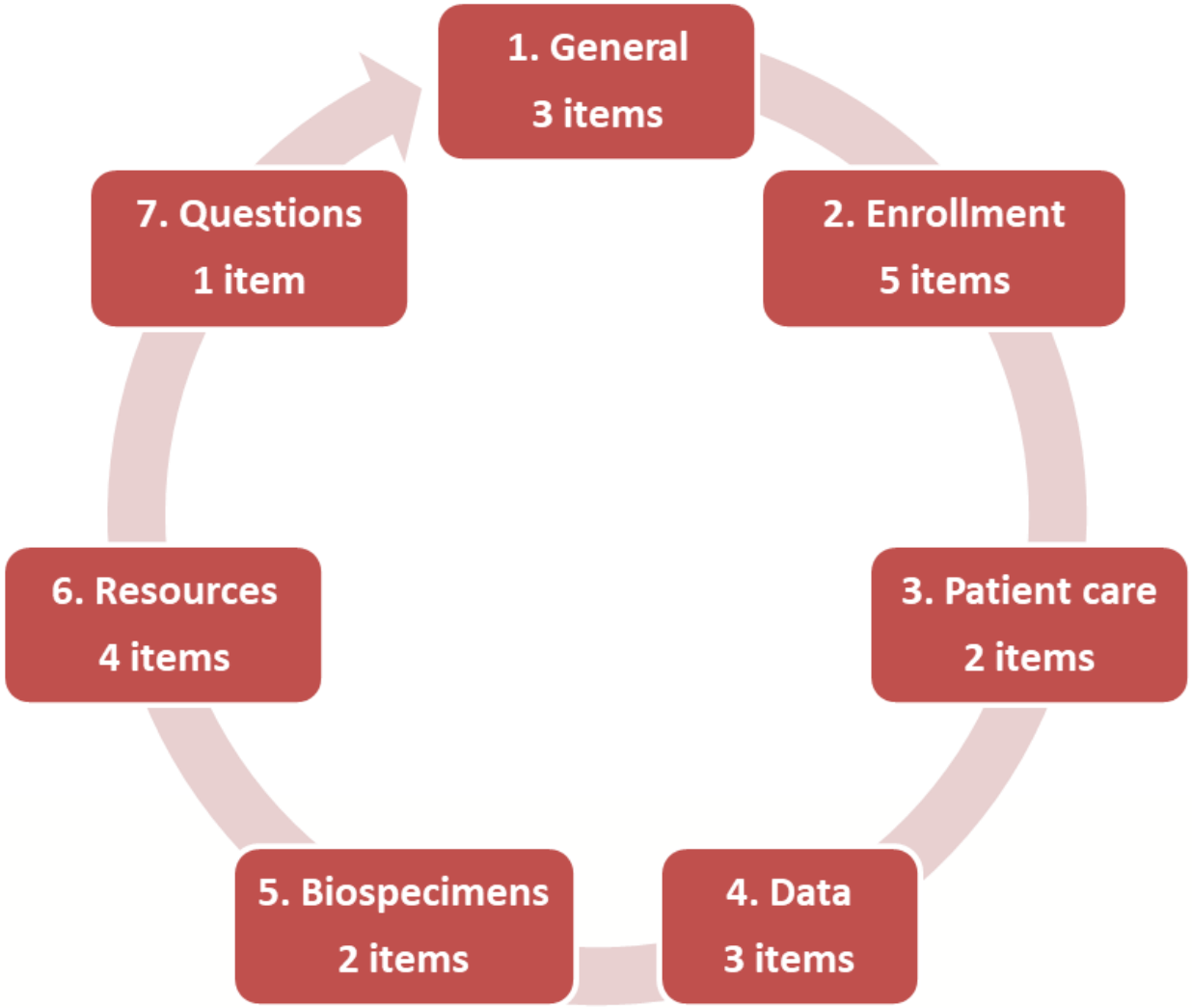
Step 3: Develop process for gauging feasibility of individual studies



How do consultations work?

- Madison VA Research office or non-profit affiliate staff member alerts the study team about the consultation process
- 30-minute consultation meeting scheduled with task force chair
- 20-item structured interview to identify feasibility issues
- Initial summary report with comments, concerns, and recommendations sent to study team within 1-5 business days

The 7 consultation elements



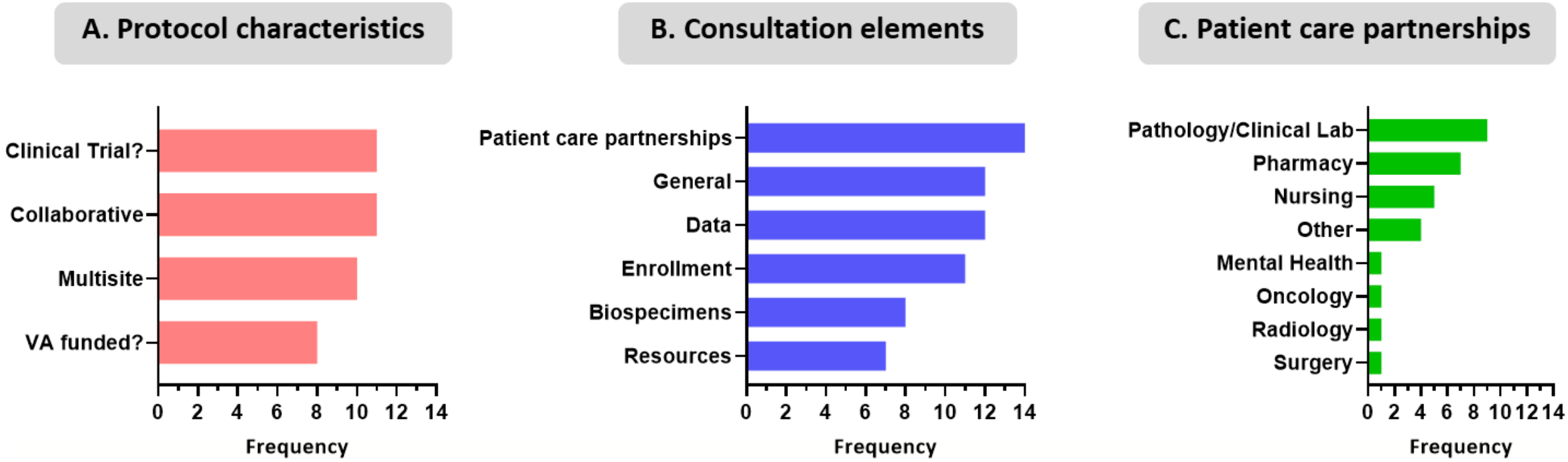
How do CTTF meetings work?

- Monthly meetings held virtually
- Consultations are summarized by the Chair, concluding with comments, concerns, and recommendations made to study team
- CTTF members provide additional feedback
- Service specific updates on successes and challenges
- Meeting minutes sent to CTTF members for record keeping purposes
- Revised summary report sent to the study team (and also R&D)

Consultation data (n=14)

PI Department/Patient focus	
1. **Rheumatology** - Long-COVID	8. **Urology** - Non-muscle invasive bladder cancer
2. **Mental Health** - Major Depressive Disorder	9. **Cardiology** - Hypertension
3. **Surgery** - Surgical wounds	10. **Dermatology** - Melanoma
4. **Radiology** - Liver Cirrhosis	11. **Infectious disease** - C. difficile infection
5. **Oncology** - Head and Neck cancer	12. **Surgery** - Liver Transplant
6. **Pulmonary and Critical Care** - Idiopathic Pulmonary Fibrosis (IPF)	13. **Oncology** - Prostate cancer
7. **Infectious disease** - Organ Transplant	14. **Infectious disease** - Gulf War Illness

Consultation data (n=14)



A unique challenge at the Madison VA

- The Wm S. Middleton VA Hospital is physically connected to the University of Wisconsin-Madison Hospital
- VA institutional knowledge
- Patient care partnerships

Acknowledgements

Name (Service)		
Nasia Safdar (Res/ID)	Emily Hennes (Res/Pharm)	Kevin Hull (CARES)
Aaron Heneghan (Res)	Jennifer Piccolo (Res/Pharm)	Jim Combs (Radiology)
Chris Fletcher (Res/Onc)	Emily Zentz (Nursing)*	Michelle Peters (CPRS)
Jamie Swanlund (Res)*	Carrie Norton (Lab/Path)	Ruth Roller (GRECC)
Karen Hoffman (Res)	Christina Yerges (Lab/Path)	
Dyan Lesnik (Res)	Ryan Laughlin (Lab/Path)	

***Supported by the Chicago Association for Research and Education in Science**

VA SOUTHERN NEVADA HEALTHCARE SYSTEM








Expansion of Clinical Research: Focus on Facility and Community Strengths

Alicia M. Brown, Ph.D., ACOS-R

Date 08/02/2022

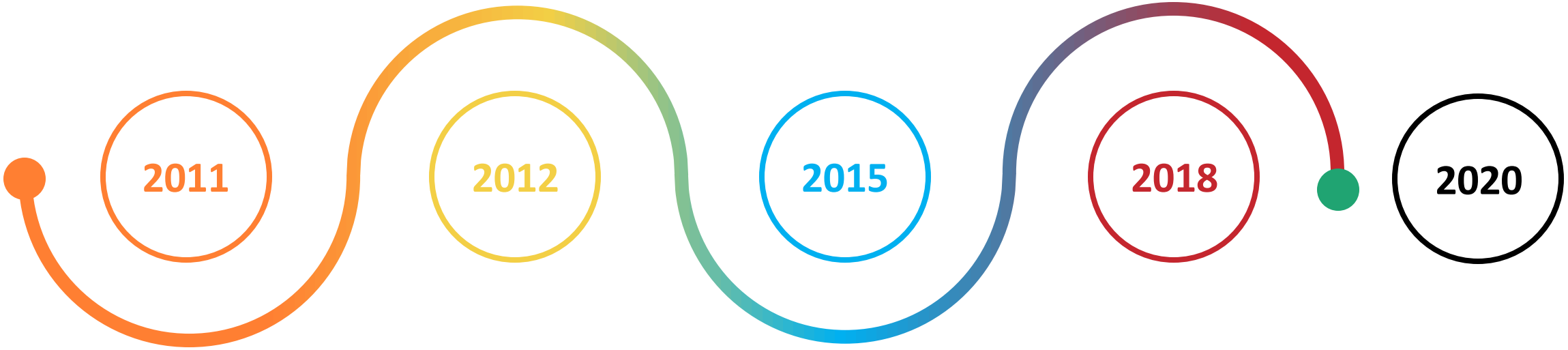
VA
U.S. Department of Veterans Affairs
Veterans Health Administration
Southern Nevada Healthcare System

PATHWAY DESIGNATED
AMERICAN NURSES CREDENTIALING CENTER

VA Southern Nevada Healthcare System (VASNHS) - 2022

- Level 1B Complexity
- Serves 71,000 Veterans
- Medical Center, 5 CBOCs, 1 Outreach Clinic, 1 IOP (addictions)
- Clinical care focus
  - 10 years of Veteran enrollment growth

VA Southern Nevada Healthcare System – A Decade in Review



LEVEL 2 COMPLEXITY

16 locations across the valley and 1 outreach clinic in Pahrump; small research service with a handful of clinical trials

1C LEVEL COMPLEXITY

Medical Center opened; Change in Leadership; research expanded, then contracted through attrition

1B LEVEL COMPEXITY

Change in Leadership; New Research Service team hired; focus on collaboration between VA and University affiliate; attrition

GOAL 1A LEVEL COMPLEXITY

Change in leadership.

COVID OPERATIONS PROTOCOLS

I CARE

VA HEALTH CARE Defining EXCELLENCE in the 21st Century

PATHWAY DESIGNATED

Inspire Interest within VA Southern Nevada Healthcare System

- Entertain ***any* and *all*** ideas
- Partner with facility Education Department, Office of Academic Affiliates, and Nursing Education
- VASNHS Pilot Program
- Research Week Poster Presentations
- VISN 21 Early Career Award Program

Develop Partnerships (Within and Outside VASNHS)

- Pair University researchers with VA Clinician Scientists
- Identify interested researchers and match their interests with studies from various databases
- Mentorship model with VA San Diego Healthcare System (VASDHS)
  - Rely on VASDHS committees as committees of record
  - VASDHS Research Compliance Officer (RCO) = VASNHS RCO
- Integrate Research Service annual Business Plans with those of other services
- Recharge and Salary Agreements with Nonprofit Corporation

Build on Strengths of Las Vegas Community

- Collaborations
  - VA - Clinical expertise
  - UNLV - Academic research
- Hire talent – Involvement in selection of clinical staff
- Create promotional ladders - Grow our own

Education

- VASNHS Research Strategic Plan 2021 - 2025
- Research Eligibility Form
- Grand Rounds
- In-services and brown bag luncheons
- One-to-One meetings
- Grant writing consultant

Adapt To/Create Positive Change

- Flexibly implement shifts in business practice to meet challenges of worldwide change (e.g., pandemic)
  - Integrate Incident Command into daily operations
  - Create SOPs
  - COVID (ORDCOVID19@va.gov)
- Equipment/software purchases (TRM)
- QUERI
  - Support transition from QI to research
- Informal NODE program

Thank you!

Use of the Office of Research Agreements Management (ORAM) group in fiscal for clinical reimbursements

Gerhard Schulteis, PhD
Associate Chief of Staff/Research
VA San Diego Healthcare System, VISN-22

VA San Diego
HEALTHCARE SYSTEM

VA San Diego ORAM: Office of Research Agreements Management

- Nurse (RN) hired by Fiscal Service, analyzes all research protocols that indicate use of clinical facilities/services (from a checklist in IRB application)
- Establishes appropriate billing for clinical services and staff effort supporting research, funded by VA or extramural sources, including industry-sponsored
  - Works with PIs to establish cost estimates for grant submissions
  - Reviews IRB protocols and advises on applicable costs before committee approval
  - Completes service agreements with Clinical Services to ensure the service agrees to all services to be provided for a given research study
  - Facilitates agreements and invoicing for use of the VA San Diego Research Pharmacy
  - Works with VA Research Budget Office and Non-Profit Foundation Post-Awards Group to establish appropriate billing and invoicing for projects
- Also processes reimbursement agreements for research-protected time for VA-paid investigators supported by extramural awards administered by NPC
  - Industry Sponsored (this is our most frequent case)
  - Private Foundation Awards
  - Federal Sponsors where permitted (e.g. DoD)*

*NIH does NOT permit reimbursement of career clinician VA effort

VA San Diego ORAM: Office of Research Agreements Management

IRB#_____ VA R&D #

VA San Diego Healthcare System Research Application for Use of Medical Resources

IRB #

Research Study/Project Title:

PI: **Coordinator or Contact:**

Funding Source (Commercial, NIH, etc.): **Funds Administered by:** ☐ **VMRF** ☐ **UCSD** ☐ **VA** #_____

IF UCSD IS ADMINISTERING FUNDS, THE FOLLOWING INFORMATION IS REQUIRED IN ORDER TO ENTER INTO BILLING CONTRACT: **Please use the Sharing Agreement Request Template**

Brief description of project (or old protocol # if renewal) :

Anticipated start date: **If a research study, how long will the study last?**

# of subjects @ THIS SITE: **Are non-veterans included? Y** ☐ **N**☐

Please copy and paste "costs" section of consent form here:

Please complete the following in order to process request and receive estimate for billable services:

Physician: Will any providers, other than study staff using protected research time, be involved in providing research-related care to subjects? (ex: anesthesiologist, psychiatrist consult, etc.) Y☐ N☐, if yes, specify: _____

Labs: Who will draw bloods and/or collect urine for lab tests? _____
Will the VA lab run/provide results? Yes ☐ No ☐: For Ammonia labs only _____
Will VA lab be involved in processing labs/kits for shipment? Y☐ N☐ _____

Nursing: Will VA RN's be utilized for study visits (check in, charting, V/S, blood draw, etc) and/or data collection for the study? No ☐ Yes ☐: specify _____

Radiology: Will VA provide x-ray, CT, MRI, DEXA, ultrasound or other services? No ☐ Yes ☐: specify:
- MRI, 4/subject_____
_____

Nuclear Med: Will VA provide nuclear medicine services? No☐ Yes☐, specify_____

Space: Will require additional designated clinic space @ VAMC. No☐ Yes☐ specify:_____
_____

Pharmacy: Will study require the services of the research pharmacist? No☐ Yes☐ IF YES, PLEASE CONTACT STEVE FUNK, RESEARCH PHARMACIST AT EXT. 3646.

Please check if any of the following additional ancillary services will be utilized for this project:

☐ Cardiology: research ECG
☐ Inpatient Unit: ICU, DOU, Medicine
☐ Neurology (EEG)
☐ Other: please specify: _____
☐ SDTU (3 E):
☐ Pulmonary (PFT) NA
☐ VA space, specify:

VA San Diego ORAM: Office of Research Agreements Management

For Alternative Revenue Stream Use Only:

Based on the above information provided on page 1, MOU/Sharing Agreement for billing of study procedures and visits:

WILL/MAY be required for the following services:

	CPT code (if applicable)	Estimated #/frequency	Fee per unit

Additional charges may apply for services provided in treatment of study-related adverse events or for services that were not included on this form at the time of study initiation. Rates subject to annual adjustment dependent upon VA cost of providing service and length of study.

PI agrees that this agreement includes all Research services/procedures for study purposes. PI and study staff are responsible for adhering to CPRS ordering/consult and charting guidelines provided by ARS and for monthly update of research activity log on W: ORAM Research Subject Logs to facilitate accurate workload tracking and billing.

Service chief signature below certifies that staff providing services will have access to communications stating scope of tasks and that VAMC is able to provide service to the study without delaying clinical care to eligible veterans:

Requested Approvals

SIGNATURE FIELDS HERE

ARS Review completed: CKD
R&D Committee Notified of ORAM Approval:

Research Service Review completed: ____

VA San Diego ORAM: Office of Research Agreements Management

 For Alternative Revenue Stream Use Only:

VA San Diego
Healthcare System

Investigational Drug Service Fees

The Investigational Drug Service

The Investigational Drug Service through the Research Service and Pharmacy Service will assist investigators in conducting clinical research. All investigational drugs at the VA Medical Center **MUST** go through the Pharmacy. Services that the Investigational Drug Service Provides:

- Meeting with company sponsors for protocol review and pharmacy procedures.
- Ordering and handling shipments of investigational drugs.
- Ordering and handling shipments of controlled substances.
- Compounding support for double blind studies.
- Patient randomization schedules for study protocols.
- Investigational drug dosing adjustments based on drug levels (Non-blinded investigator).
- Record keeping for investigational drugs (dispensing, inventory control).
- Drug information sheet (VA Form 10-9012)
- Unit dose with Bar code and Omnicell preparation for inpatient services
- All pharmacy investigational drug requirements to Meet Hospital Policies

Fees:

Protocol Set-Up: $1700
(One time fee for preparing pharmacy notebook, meeting with sponsor, setting up procedures, preparing drug information sheet, computer drug entry)

Annual Maintenance Fee $800
(Up-date approvals, checking out dates, temperature logs, monitor visits, billed on anniversary of date from initial Set Up)

Closure Fee $450
(Final accountability, drug destruction or return, document storage)

Dispensing Charges per Dose: (does not include cost of drug)

Outpatient Prescription	$25
IV Preparation	$25 to $50
Chemotherapy	$50 to $100
Viral Vectors	$100
Ordering and handling controlled substances	$15 / Green Sheet
Special compounding	$100 per hour

Drug budget for grant submission No Charge

VA San Diego ORAM: Office of Research Agreements Management

VMRF REQUEST FOR VASDHS RESEARCH EMPLOYEE EFFORT

This page to be completed by VASDHS Office of Research Agreements

EMPLOYEE INFORMATION

Employee Name **Employee's VA Position/Job title**

Date this request was received

REQUEST INFORMATION

*(If employee is to be paid from **more than one VMRF project** or VA time is being requested **from more than one service**, please complete separate form for each request/account)*

Requestor: **Requestor email:**

IRB Protocol #

Name of Study/ Project:

Principal Investigator: **Funding Source:**

VMRF project/MOU# **PO #**

If employee is mapped to more than one service, time is requested from ☒N/A

Bi-Weekly Hours (per pay period) requested for VMRF project: __ hours/__% effort *(round to whole hours)*

Effective Start Date: Estimated End Date:

**Please check applicable box (please see pg.3 of agreement for important information):

- ☐ Employee to work during normal tour of duty (billed at normal rate)
- ☐ Employee will work overtime on VMRF project (Billed at overtime rate)
- ☐ Other:

Please describe duties to be performed for research/study (be as specific as possible):

Standing up a Clinical Research Center: Effort Involved, Program Impact, and Lessons Learned

Amrita Kamat, PhD

Associate Chief of Staff R&D
South Texas Veterans Health Care System
Audie L Murphy Memorial Veterans Hospital
and
Professor/Dept of Medicine
University of Texas Health San Antonio

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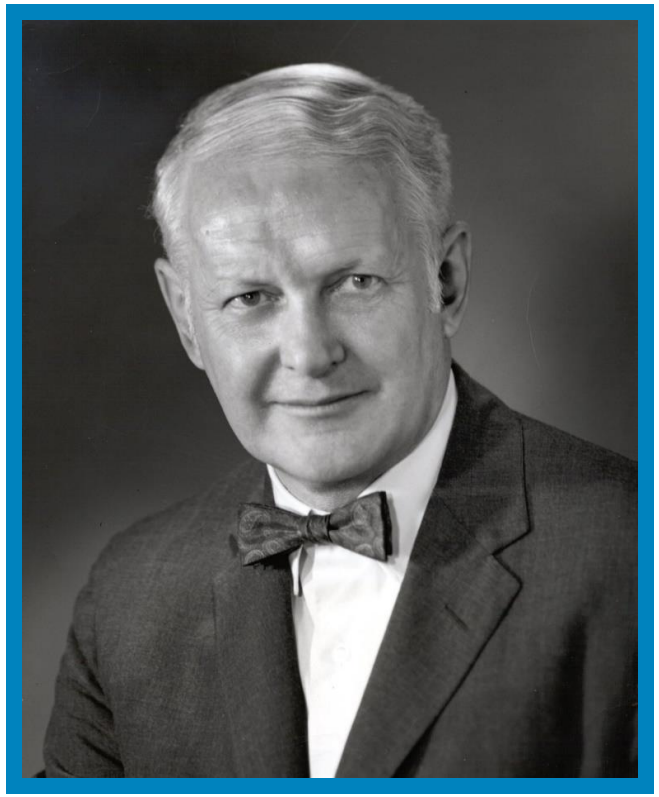
UT Health San Antonio

South Texas Veterans Health Care System (STVHCS)

- STVHCS is one of the fastest growing healthcare systems in the VA
- Serves more than 120,000 Veterans, tallying ~1.4M outpatients annually and has 4800 employees
- Comprises of 3 campuses – the Audie L. Murphy Memorial Veterans Hospital (ALMMVH) in San Antonio, the Northwest Health Care Center in San Antonio, and the Kerrville VA Hospital in Kerrville – as well as 15 Satellite Clinics
- ALMMVH is a quaternary care facility and includes the Bartter Clinical Research Unit, Spinal Cord Injury Center, Polytrauma Center, Hematopoietic Stem Cell Transplantation Program, a Community Living Center, Substance Abuse Residential Rehabilitation Treatment Program and the Geriatric Research, Education and Clinical Center (GRECC)
- ALMMVH houses the Foundation for Advancing Veterans' Health Research (FAVHR)-nonprofit corporation which supports research and education activities at STVHCS
- ALMMVH is connected to the affiliate University of Texas Health San Antonio by a skybridge

Bartter Research Unit (BRU)

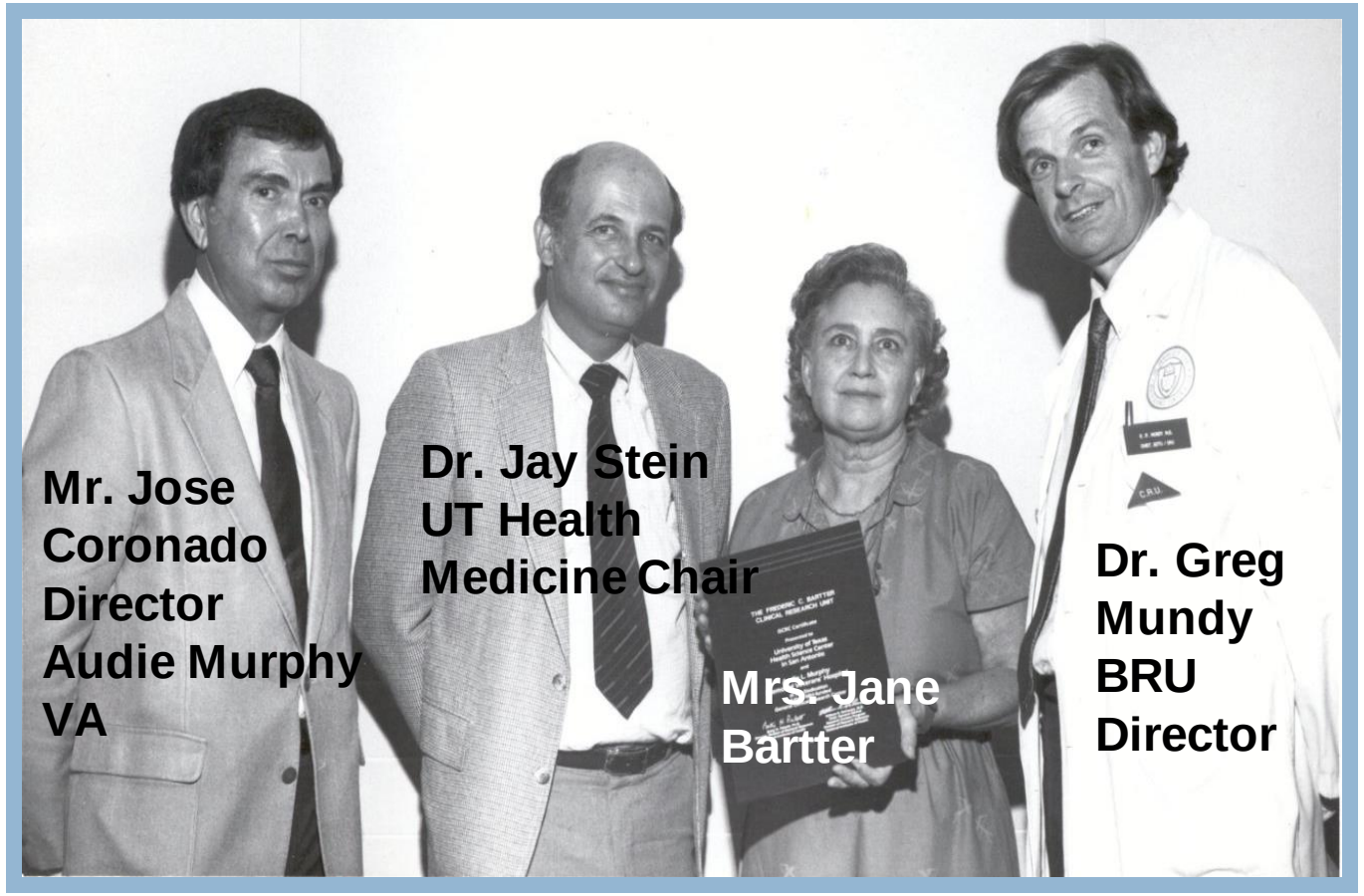
- National Institutes of Health
  - Chief of Endocrinology
- Audie Murphy VA
  - Associate Chief of Staff/Research
- Discovered two important diseases
  - Syndrome of Inappropriate Antidiuretic Hormone (SIADH) Secretion
  - Bartter's Syndrome – a complex disorder of metabolism and potassium balance



Frederic C. Bartter, MD
1914-1983

BRU Dedication-1983

A productive and sustained partnership: VA, UT Health SA, NIH



Initially operated as a General Clinical Research Center (GCRC) until May 2008 when UTHSA received the Clinical and Translational Science Award

BRU-Partnership Roles

- **VA**-Facilities, Nursing services, Nursing administration, dietary and food services, access to other clinical services required to support clinical research (e.g. pharmacy, radiology, path & lab, surgery, urology, cardiology)

- **UT Health San Antonio,** Institute for Integration of Medicine & Science (IIMS)- Collection of research visit-related expenses and VA reimbursements, management of lab-related responsibilities, advisory clinical research and scientific support as well as administrative support of BRU operations

- **NIH**- research grant awards to UT Health San Antonio
  - General Clinical Research Center (1983-2008)
  - Clinical Translational Science Award (2008-present)

BRU Team

- **Medical Director** Marzieh Salehi, MD MS
- **Nurse Manager** Samantha Elbel, RN
- **Business Administrator** (UTHSA) Lisa Fleming, MPA
- **Nursing Staff** (9 FTE)
- **Investigational Pharmacist** Michael Biaglow, PharmD
- **Investigational Nutritionist** Tamara Sugarek, RD
- **Lab Processing** (2 FTE; 1FTE provided by UTHSA)
- **DXA Technician** (1 FTE provided by UTHSA)
- **Front desk HAS scheduler** (1FTE)

Marzieh Salehi, MD
BRU Director
VA Staff Physician and Professor/UTHSA

Robert Clark, MD
CTSA PI
VA Staff Physician and Professor/UTHSA

BRU Facility and Services

Facility

- BRU is ~ 8000 sq. ft clinical facility located on the 7th floor of ALMMVH
- Inpatient/Outpatient care areas that provide visual/auditory privacy (14 rooms/17 beds).

Nursing services

- Complex glucose studies in humans (OGT and glucose clamp studies using bedside glucose analyzers)
- Intravenous catheter insertion guided by ultrasound
- 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, etc.)

Study coordination services – recruitment, scheduling, informed consent, data collection, record storage
Dietary services – metabolic kitchen, nutritional counseling
Pharmacy services – all investigational drug management
Specimen processing – collection, storage, shipping
Amenities – reception, private exam rooms, work areas

Impact of BRU on the VA Research Program

- BRU supports clinical research phases I-IV and services adult population in all clinical specialties.
- Over 200 active studies including 7 CSP studies (Human gene therapy, diabetes and obesity, transgender, endocrine, cancer, infectious diseases, SCI, PTSD, pain, neurological/psychiatric conditions, geriatric and frailty) conducted by > 150 investigators
- MVP and All of Us national programs
- Increased Veterans access to research
- 24-hour staffing capabilities for extended studies with nurse-patient ratio to meet research intensity
- Specialized support for protocol specific needs
- Centralized services (one stop shop)
- Removes strain on clinical flow, allowing services to embrace research activities
- Overall support for new investigators

Challenges and Lessons Learned

- **Challenges**
  - Timely notification of a study to be conducted at the BRU
  - Timely renewal of BRU sharing agreement
- **Effective Communication between UTHSA and VA**
  - Quarterly Meetings between ACOS and Office of Sponsored Program at UT Health SA to improve processes (e.g. change in UTHSA COP form to include use of VA resources)
  - Meetings with PI, BRU Director, ACOS, NPC CEO before grant submission, after grant funding, and before study approval
  - Daily BRU huddles and weekly meetings with UTHSA and VA BRU team as well as R&D ACOS and AO
  - Research Office-- new employee orientation
- **Disseminating information about the BRU and research at the BRU**
  - ACOS and NPC CEO meetings with Chiefs of Services at VA and UTHSA
  - BRU staff/PIs presenting safety stories at the Director's daily meetings or the High Reliability Organization (HRO) seminar

Building a Productive and Sustained Partnership