

Thursday, April 7, 2016

9 to 11am

**RESEARCH COMMUNITY
COFFEE AND DONUTS**

Albertsons Library - 1st Floor – Maker Lab

Clinical Translational Research

What is Clinical/Translational Research?

And why should I participate in it?

9am to 10am Social

10am to 11am Opening Remarks

Cheryl Jorcyk, Director, Clinical/Translational Research, Boise State University
cjorcyk@boisestate.edu

Community CTR Opportunities

Hilary Flint-Wagner, Applied Research Manager, St. Luke's Research
flintwah@slhs.org

Nichole Whitener, Director, Neuroscience Services and Research Administrator, St. Alphonsus
nichwhit@sarmc.org

Calvin Allan, Manager of Advanced Technology Development, Acutus Medical
Calvin.allan@acutus.com

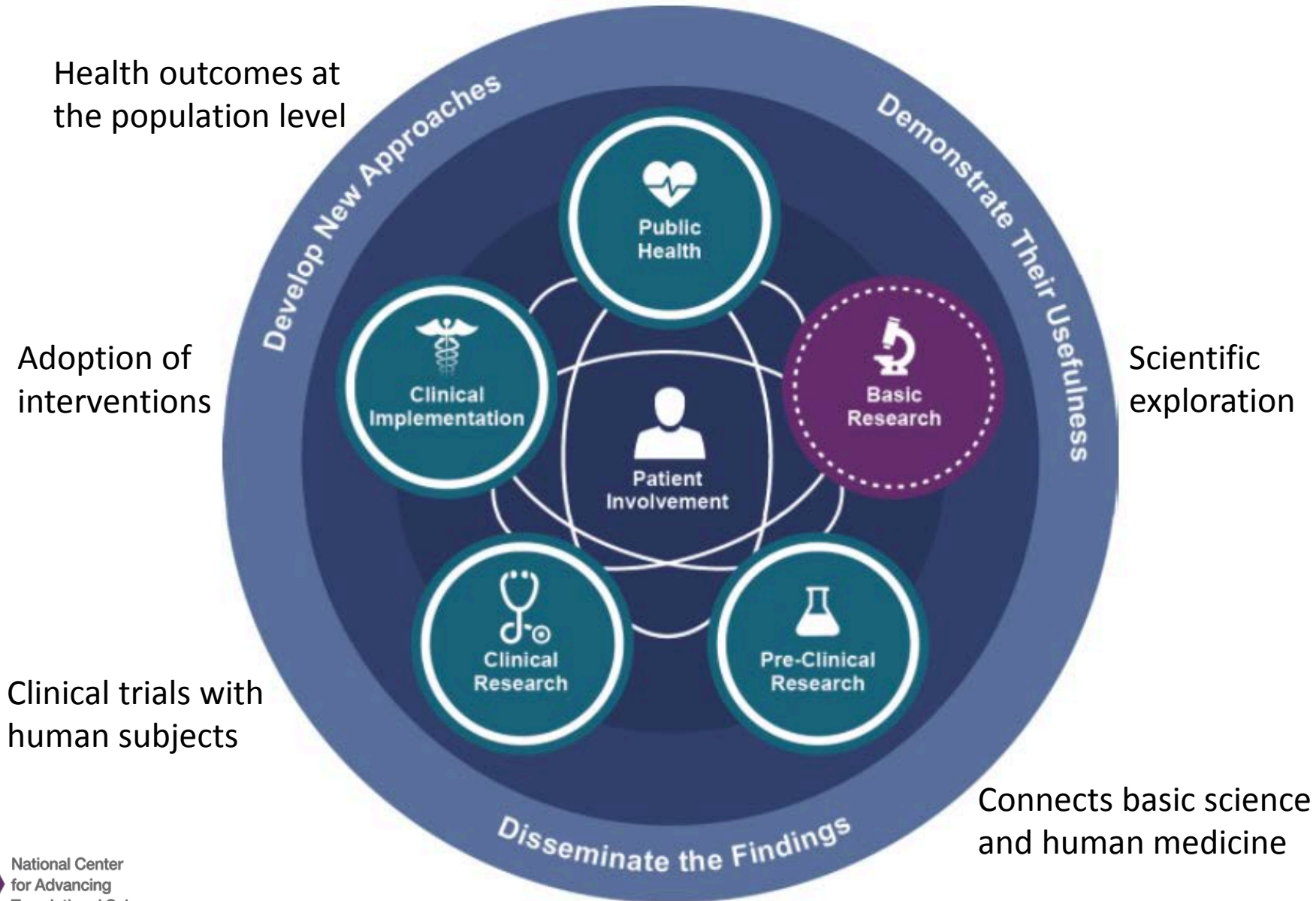
Projects involving Boise State Faculty

Julie Oxford, Director, Biomolecular Research Center (BRC)
joxford@boisestate.edu

Shelley Lucas, Associate Professor of Kinesiology
smlucas@boisestate.edu

Discussion

Translational Science Spectrum



Clinical Research is...

- (1) **Patient-oriented research** Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena)—involves direct interactions with human subjects
 - (a) mechanisms of human disease
 - (b) therapeutic interventions
 - (c) clinical trials
 - (d) development of new technologies
- (2) **Epidemiologic and behavioral studies**
- (3) **Outcomes research and health services research**

Translational Research occurs...

1. The process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans.
2. Enhancing the adoption of best practices in the community; cost-effectiveness of prevention and treatment strategies is also an important part of translational science

How do I get pilot funding?

ITHS (Institute of Translational Health Sciences)

WWAMI

<https://www.iths.org/investigators/funding-opportunities/>

- Community Partners in Research (Pilot funding); \$10,000
- Collaboration Innovation Awards; \$50,000
- Primate Center Ignition Awards; \$75,000

CTR-IN (Clinical Translational Research—Infrastructure Network)

<http://ctrin.unlv.edu>

AK, HI, ID, MT, NV, NM, WY

- Pilot Grants; \$75,000
- Visiting Scholars; \$40,000
- Mini-Sabbaticals; \$20,000
- Mini-grants; \$10,000

Community CTR Pilot Grants—*Coming soon*

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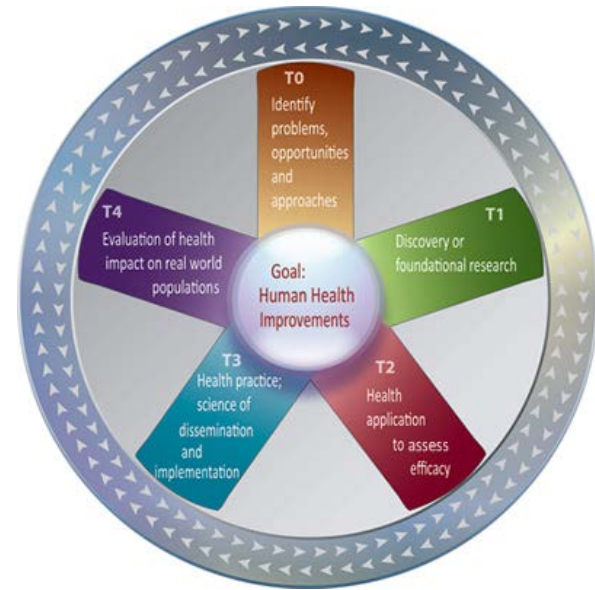
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Discussion

T-PHASES OF TRANSLATIONAL RESEARCH



- T0 is characterized by the identification opportunities and approaches to health problems
- T1 seeks to move basic discovery into a candidate health application.
- T2 assesses the value of application for health practice leading to the development of evidence-based guidelines.
- T3 attempts to move evidence-based guidelines into health practice, through delivery, dissemination, and diffusion research.
- T4 seeks to evaluate the “real world” health outcomes of population health practice.



ACUTUS MEDICAL



The Company

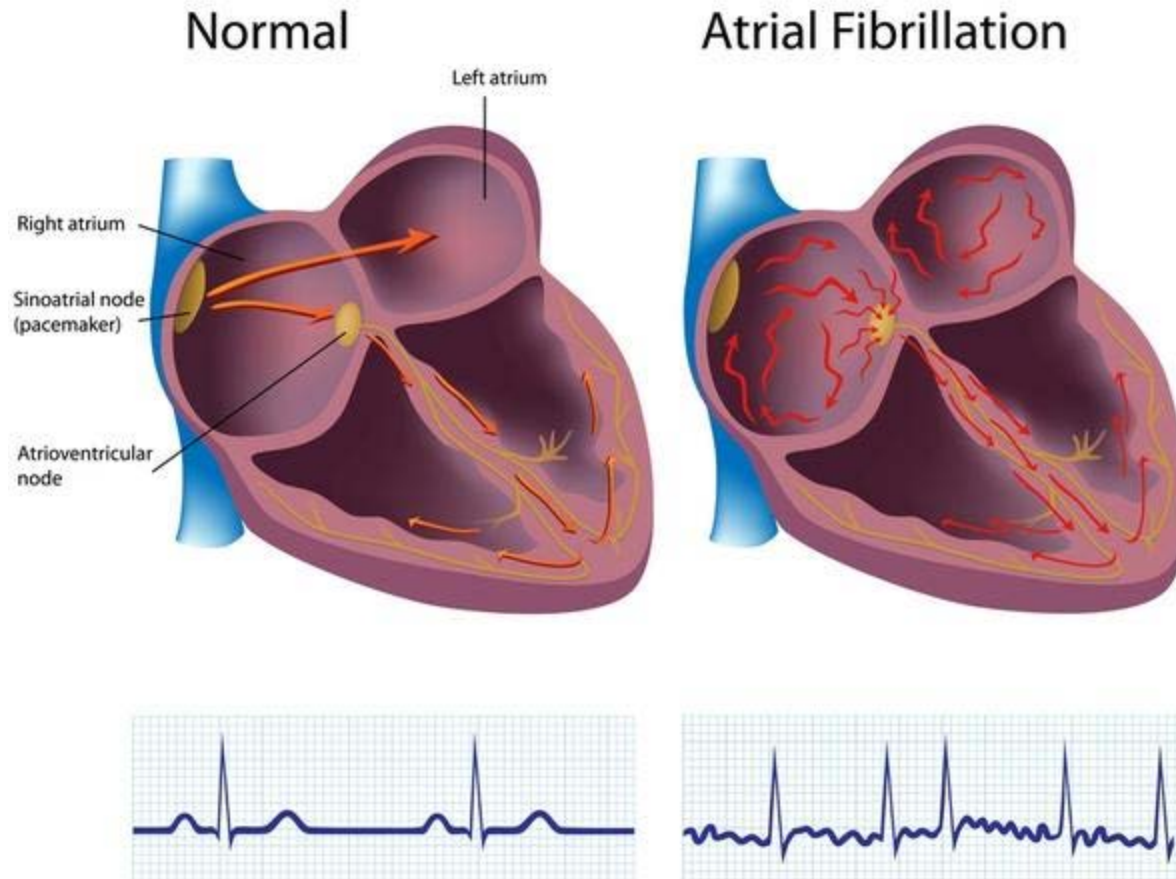


Carlsbad, CA



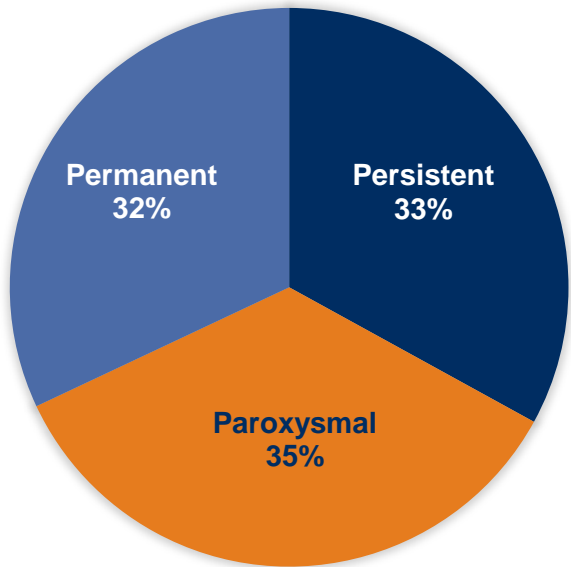
Boise, ID

Problem

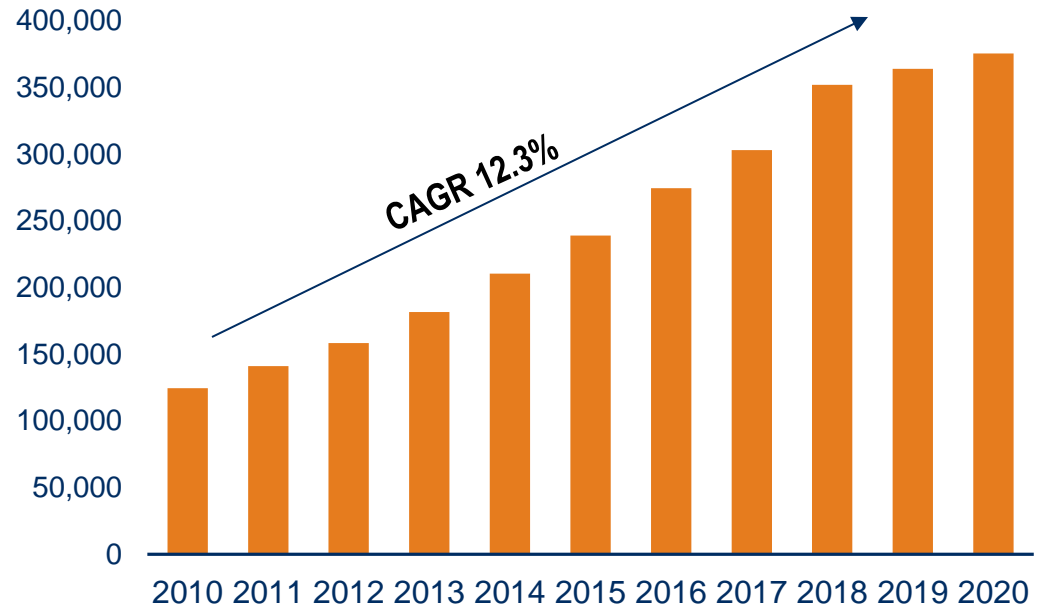


Atrial Fibrillation (AF) - Incidence

Breakdown of AF types



USA Cardiac Ablation Procedures



- **Most common arrhythmia.**
- **2nd leading cause of stroke**
- **~600,000 US hospitalizations/year.**

Treatment option #1 Drug therapy



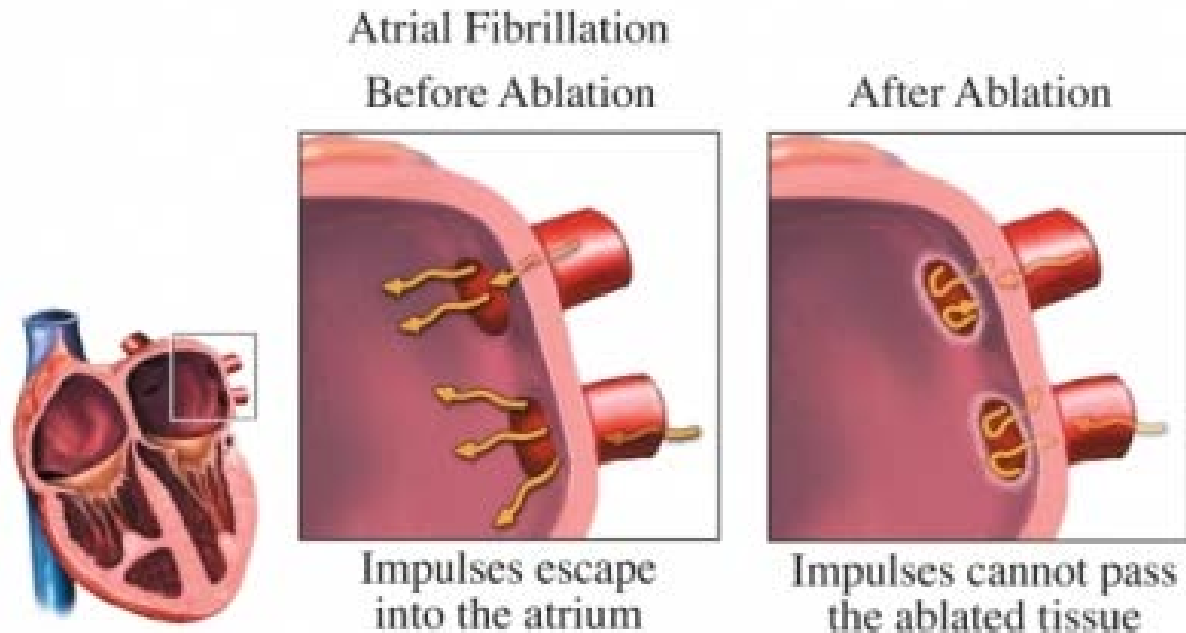
- Expensive.
- Significant side-effects.
- Palliative - does not cure AF.

Treatment option #2 Cardioversion



- Low percentage of conversions.
- Does not fix the problem.
- Serious side-effects possible.

Treatment Option # 3 – Cardiac Ablation



The Challenge:

Identifying and treating *only* the necessary regions of the heart wall.

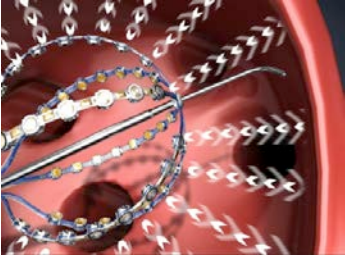
Acutus Medical Solution

Ultrasound & Dipole Density to globally image the anatomy and continuously map cardiac arrhythmias.

Translation:

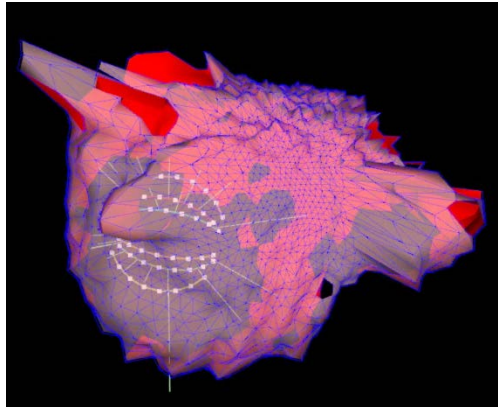
High-Precision Electrical, Anatomical Mapping

Starts with Real-time 3D Imaging of the Heart



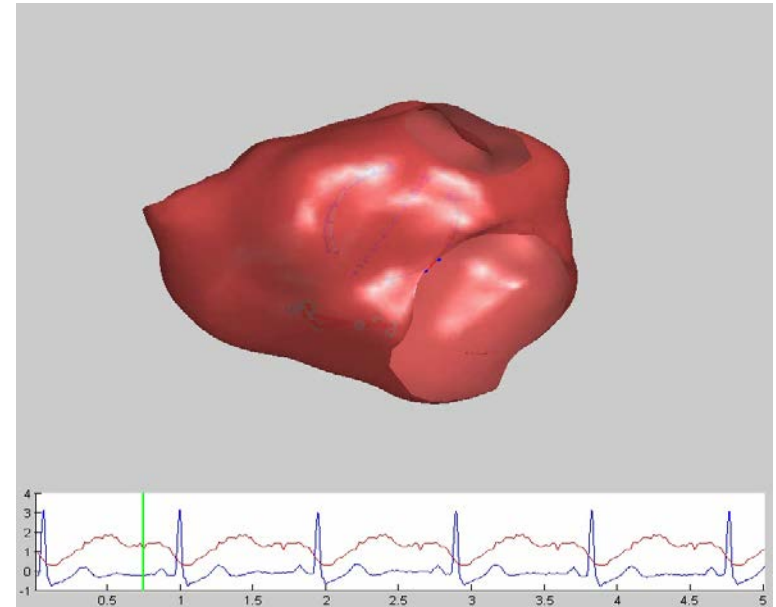
Step 1 – U/S Imaging

Ultrasound continuously “pings” the chamber wall - creating a Point Cloud



Step 2 – CT Quality Image

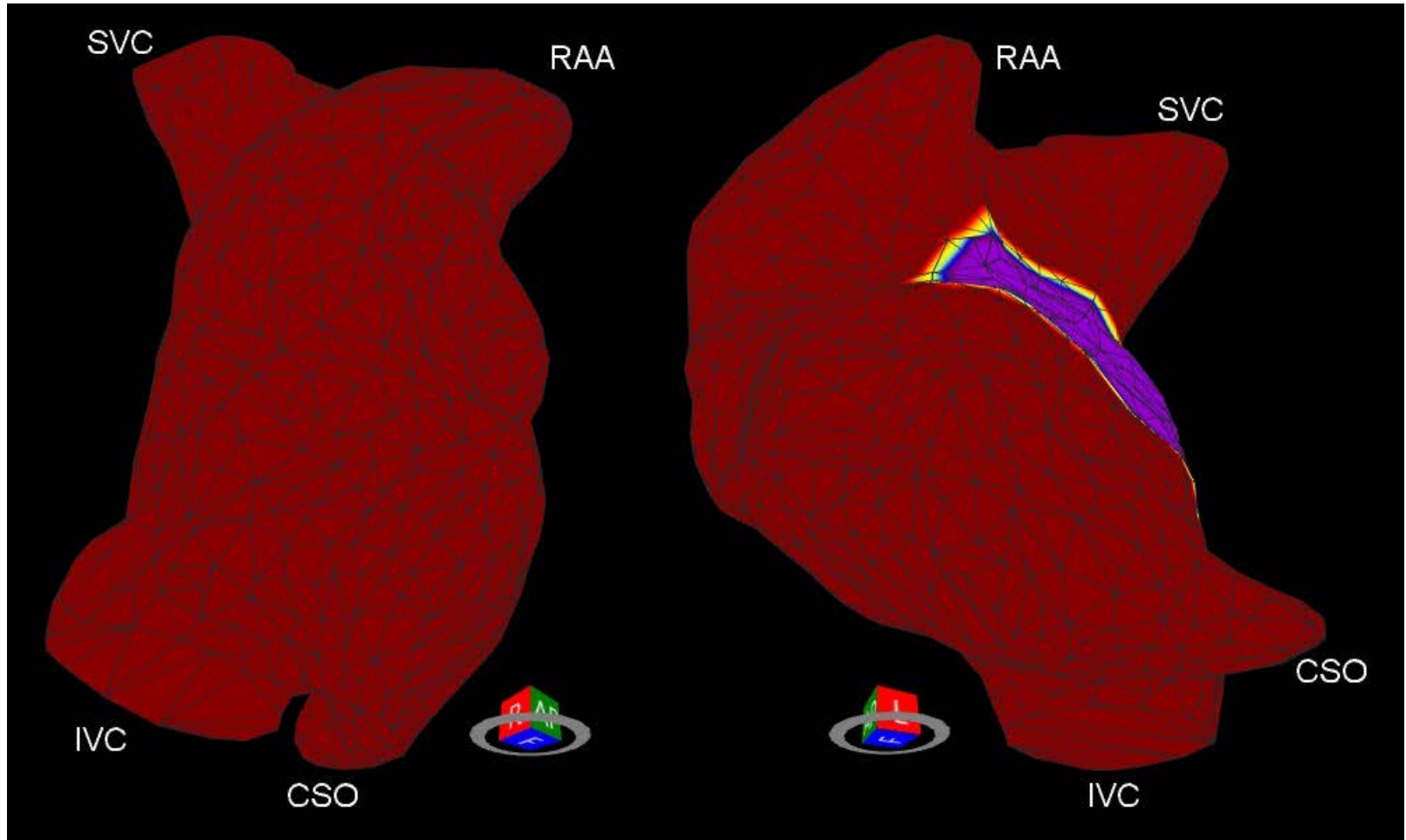
Ultra-dense Point Cloud yields CT quality reconstruction



Step 3 - Functional EP

Real time electrical and mechanical (wall motion) analysis

Dipole Density Map of Typical AFL



Management Team



Randy Werneth
Founder, President, CEO
San Diego & Boise



Dr. Graydon Beatty
CTO



John Dahldorf
CFO



Martin Chambers
CCO



Steve McQuillan
Clinical

Advanced Technology Division - MedTech Furnace

Next-Gen Projects

- Robotic Assisted Catheter
- Force-Sensing Technology
- Catheter Testing
- Catheter Production Scale-up

Team

- Acutus Medical Staff (Boise-Based)
 - Calvin Allan
 - Brandon Lee
- Boise State Resources
 - College of Engineering Support
 - 6 Professors (Faculty Collaboration)
 - 3 Interns / Contractors: ME, EE, and Material Sciences

MedTech Furnace @ Boise State University

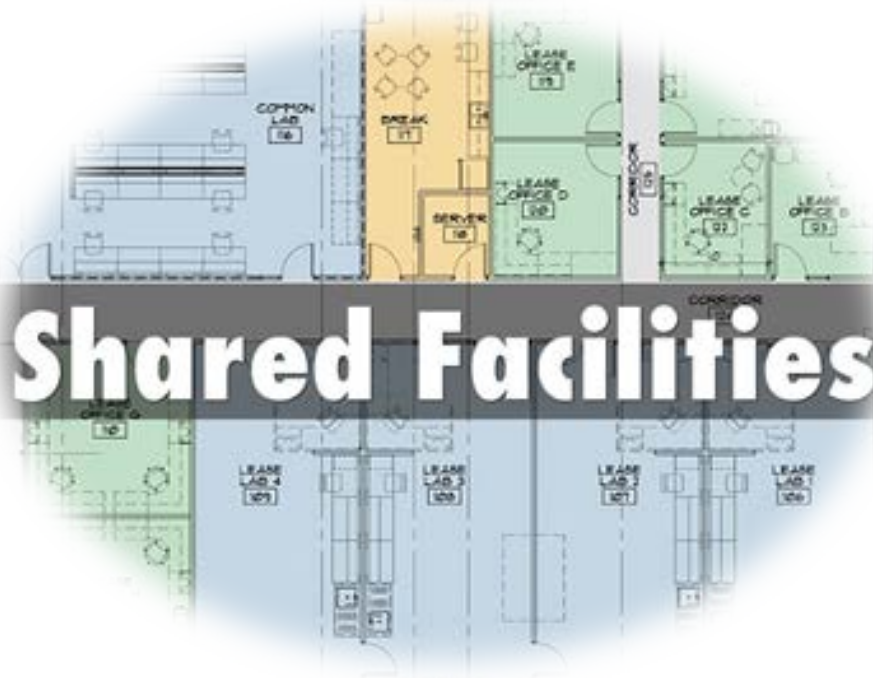
- Acutus Medical, Inc.
- Healthfundr (co-locating)
- Shaw Mountain Technologies
- Behavior Imaging (advising / support)



Behavior Imaging®

MedTech Furnace - VISION

To create an environment that attracts and supports medical technology engineering, commercialization and manufacturing in Idaho



THANK YOU
Questions?



Saint Alphonsus Research Institute

Nichole Whitener, MSN, RN, NE-BC

April 7, 2016



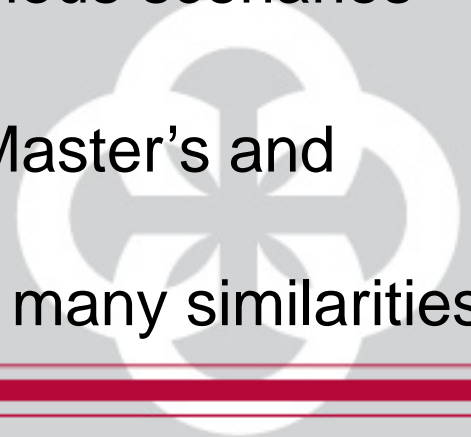
Community Hospital Research Objectives

- Contribute to general pool of healthcare and scientific knowledge
- Define best-practice
- Give patients options for care
- **Develop and strengthen ties with local and national universities**
- Support continuous improvement efforts for patient care, outcomes, and support systems
- Funded projects bring dollars
- Identify optimal training processes
- Physician recruitment and retention
- Name brand recognition
- Projects align with and support strategic directions



Types of Research

- Pharmaceutical trials-phase 2 and 3 randomized, blinded drug trials
- Investigational device trials
- Comparative treatment trials-subjects randomized into different treatments
- Post-market approval outcomes trials-ongoing data collection to demonstrate continued efficacy
- Simulations-observe human response to various scenarios
- Case studies
- Various projects for colleagues completing Master's and Doctorate programs
- Humanitarian Use Devices-not research but many similarities



Areas of Research

- Cardiology-7 studies, n=225
- Orthopedics-11 studies, n=275
- Neuroscience-program of research for CNS related outcomes, n=1400
- Oncology-NCI trials >100 available for enrollment, n=147 & 7 non-NCI trials
- Patient safety-5 studies, n=359
- Radiology-2 study, n=25
- Laboratory/pathology-1 study just initiated
- Misc-4 studies, n=unknown
- HDE-7 open protocols



Funding Sources

- Industry (pharma, device manufacturers, laboratories)-18 studies
- Grants (federal sources, industry, private foundations)-15 studies
- Saint Alphonsus operational dollars-5 studies
- Donations (funds and in-kind work)



Research Staff

- Ph.D. in human factors engineering-patient safety research, simulation research, systems design
- Post grant award management, financial tracker
- IRB administrative specialist
- Research coordinators
 - Cardiology, Neuroscience, Orthopedics
- Research assistant
 - Sepsis, remote monitoring (patient safety)
- Oncology researchers-1 RN, 3 coordinators



University Partners in Research

- Boise State University
 - Dr. Pennie Seibert-partner in research since 1995
 - This month, 7 students will give presentations at Rocky Mountain Psychological Association and Western Psychological Association
 - Dr. Cheryl Jorcyk-new project-role of inflammatory proteins in ovarian cancer
- Idaho State University
 - Pharmacy residents complete a research project
- Duke University & Loyola University
 - System and process design
- University of Utah
 - Electronic health record improvements



Program Structure

Research Ideas Proposed
by Physicians and/or
Chief Research Scientist

The Chief Research Scientist designs and conducts all aspects of research including statistical analysis, and is assisted by her research team in literature searches, data collection and entry, quality checks, writing abstracts and manuscripts, preparing and presenting research for regional, national, and international professional meetings

Chief Research Scientist

Research Coordinators

Research Assistants

Research Assistant Responsibility

LEVEL 1

Data Collection
Scoring
Literature Searches
Follow-up Calls

LEVEL 2

Quality Checking Data
Data Entry
Medical Record Checks
Write Abstracts

LEVEL 3

Chart Set-up
Write Papers
Prepare Presentations
Develop Special Interest
Area

- This program of research engenders novel views of treatment and recovery providing a more comprehensive perspective than may otherwise be observed and documented. Recovery from trauma, illness, or injury is multifaceted: one-dimensional or inconsistently recorded measures can inadequately represent the treatment and recovery process.
- Over 270 Boise State University students have taken research courses at SARMC, many of whom have become medical professionals, clinicians, and neuroscientists. This approach has yielded numerous international, national, and regional awards for research excellence. Research students normally present at a minimum of one professional conference per year and coordinators present at a minimum of two. Students' names are included on all manuscripts, reports, and presentations.



UPDATE

 YOUR SOURCE FOR CAMPUS NEWS

Pennie Seibert

BY: CIENNA MADRID | PUBLISHED 11:23 AM / SEPTEMBER 22, 2015 | SHARE | EMAIL | PRINT



Pennie Seibert

Professor
Department of Psychology
College of Arts and Sciences

This week, Pennie Seibert will be presenting research at the annual meeting of the Congress of Neurological Surgeons, held Sept. 26-30 in New Orleans. Seibert and Dr. Christian Zimmerman, a neurosurgeon at Saint Alphonsus Health System, co-authored "Sex Differences in the Toxic Relationship Shared by Spinal Injury and Sleep Disorders" and "The Potential for Recovery from Traumatic Brain Injury is Compromised by Sleep Disturbance," both of which they will be presenting at the conference. Boise State students Katherine Nassans, Jaime Martin, Michael Mooney and Emily Carroll contributed to the papers as well.



UPDATE

 YOUR SOURCE FOR CAMPUS NEWS

Pennie Seibert

BY: CIENNA MADRID | PUBLISHED 4:13 PM / NOVEMBER 17, 2015 | SHARE | EMAIL | PRINT



Pennie Seibert

Professor
Department of Psychology
College of Arts and Sciences

Professor Pennie Seibert is giving two presentations at the International Conference on Neurology and Epidemiology on Nov. 19, held in Gold Coast, Queensland, Australia. The first presentation, "Diabetes and Sleep Disorders: A Synergism That Complicates Neurological Treatment," is co-authored with Boise State students Michael Mooney, Rachel Aguilar, Elora Williams and Katherine Nissans. The presentation also was co-authored with Dr. Christian Zimmerman, a neurosurgeon at Saint Alphonsus Regional Medical Center.

Professor Seibert's second presentation is "Parkinson's Disease: Comparing Impacts On General Health And Well-Being Experienced By Individuals With PD And Their Caregivers." It was co-authored with Boise State students Colleen Poulton and Jory Peredes.

Christian G. Zimmerman, MD FACS, MBA,
Michelle Whitener, RN, CNRN,

DEMOGRAPHICS
 Study includes 256 female participants (age range: 1.17 – 83.25; 49.66).
 26 are in menopause, 136 in post-menopause, and 94 are non-menopausal

Menopause Status	Percent of Participants
No menopause	36.70%
Menopause	16.22%
Postmenopause	47.08%

OBSTRUCTIVE SLEEP APNEA
 Disturbances can influence cognitive functioning, emotional well-being, and general health. Menopausal women are at an increased risk for developing obstructive sleep apnea. Additionally, research has shown a significant increase in OSA incidence following menopause. Our data reveals significant differences across the age groups, with women in the post-menopause experiencing a higher frequency of severe OSA. These findings could be due to alterations in upper airway physiology associated with hormonal changes. A myriad of complex reciprocal interactions exist between sleep and hormones. For example, progesterone may reduce upper airway collapsibility, epinephrine has stimulatory effects, and histamine has bronchoconstrictive effects. Sleep patterns are also influenced by these interactions by influencing serum hormone levels.^{1,2}

Legend: No menopause Menopause Postmenopause

TOTAL TIME ASLEEP**

Menopause Status	Time asleep (minutes)
No menopause	~365
Menopause	~335
Postmenopause	~315

SLEEP ARCHITECTURE

	Normal	No menopause	Menopause	Postmenopause
% Stage 1 ***	5.0%	9.6%	14.1%	18.2%
% Stage 2	50.0%	65.6%	68.7%	73.9%
% Stage 3 **	10.0%	4.6%	1.5%	1.1%
% Stage 4 ***	10.0%	6.0%	2.6%	1.0%
REM	25.0%	12.8%	14.6%	19.8%

DISCUSSION
 Sleep disturbances dramatically influence cognition, emotional well-being, and general health. Despite their prevalence, SDBs remain inadequately reported and understood. Additionally, psychotropic medications are prescribed to patients with sleep disturbances in this population. Further knowledge about the pathophysiology of SDBs, psychological well-being, and the use of psychotropic medications is needed to enhance overall health and quality of life of women.

REFERENCES

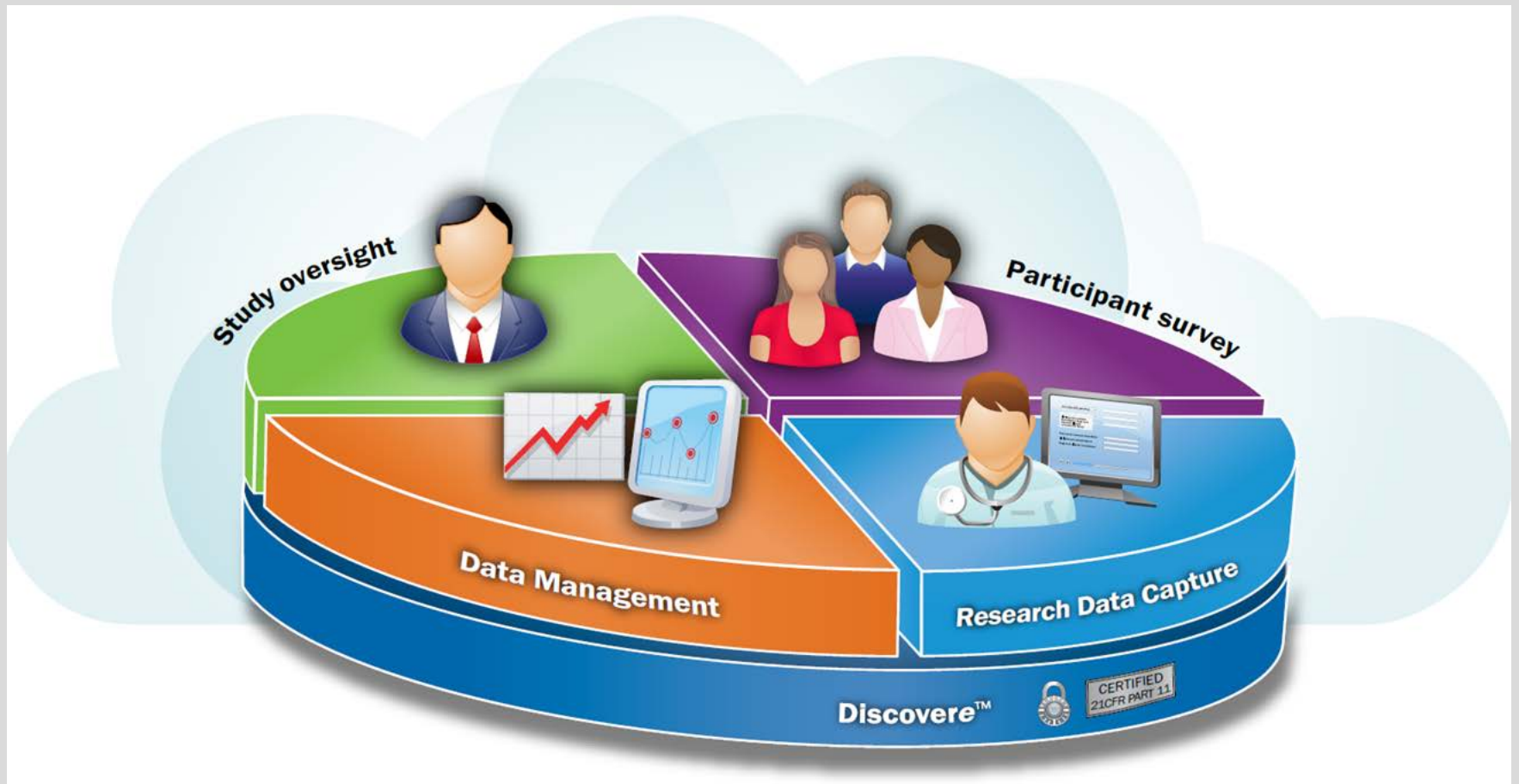
MICroneurography STUDY OF SYMPATHETIC ACTIVITY
 Donadio V, Pennisi M*, Rinaldi R, Avoni P, Di Szali V, Baruzzi A
 *Department of Neurological Sciences, University of Bologna
 **Department of Neurological Sciences, University of Catania

Objective
 Alpha Ectasia (AE) is characterized by sympathetic overactivity and a common feature of acquired, i.e. DeLong-Eriksen (DE) and Morvan's syndrome (MS), and genetic, i.e. Familial Inclusion (FI), conditions with a supposed dysfunction of the thalamo-limbic system. The aim of this study is to investigate the pattern of sympathetic activity acquired and genetic AE.

Methods
 We describe two patients with high levels of serum anticholinergic activity and a 45-year-old confirmed FI.

Results
 All patients underwent microneurography. Sympathetic nerve activity was recorded from the peroneal nerve at rest and during various levels of mental and physical stress. The results were compared with those of healthy controls.







Contact Information

<http://www.saintalphonsus.org/research-integrity>

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