Clinical Translational Research
What is Clinical/Translational Research?

And why should I participate in it?
9am to 10am  Social

10am to 11am  Opening Remarks

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Community CTR Opportunities

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Projects involving Boise State Faculty

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Discussion
Translational Science Spectrum

Connects basic science and human medicine

Clinical trials with human subjects

Adoption of interventions

Health outcomes at the population level

Scientific exploration

Disseminate the Findings

Develop New Approaches

Demonstrate Their Usefulness

Public Health

Basic Research

Pre-Clinical Research

Clinical Research

Clinical Implementation

Patient Involvement

NIH National Center for Advancing Translational Sciences
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**

Source: Based on Institutional Clinical and Translational Science Award (U54) RFA-RM-07-007 CTSA RFA
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
  • Pilot Grants; $75,000
  • Visiting Scholars; $40,000
  • Mini-Sabbaticals; $20,000
  • Mini-grants; $10,000

Community CTR Pilot Grants—Coming soon
9am to 10am  Social

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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.

Khoury MJ et al; Genet Med 2007
ACUTUS MEDICAL
The Company

Carlsbad, CA

Boise, ID
Problem

![Comparison of normal heart and atrial fibrillation](image-url)
Atrial Fibrillation (AF) - Incidence

Breakdown of AF types

- **Persistent** 33%
- **Paroxysmal** 35%
- **Permanent** 32%

**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.
The Challenge:
Identifying and treating *only* the necessary regions of the heart wall.
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
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)
MedTech Furnace - VISION

To create an environment that attracts and supports medical technology engineering, commercialization and manufacturing in Idaho
THANK YOU
Questions?
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
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.
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.

Professor Pennie Seibert is giving two presentations at the International Conference on Neurology and Epidemiology on Nov. 18, 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 Nassans. The presentation was also 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.
Sleep disturbances dramatically influence cognition, emotion, and health. Poor sleep is associated with increased risk of chronic diseases, such as diabetes and cardiovascular disease. Sleep disorders can cause daytime sleepiness and impaired cognitive function, affecting work and daily activities.

One effective method to improve sleep is through the use of sleep apnea therapy. Sleep apnea therapy involves the use of continuous positive airway pressure (CPAP) devices, which help to keep the airways open during sleep, thereby avoiding Upper Airway Obstruction Syndrome (UAS). This intervention can significantly improve sleep quality and reduce the risk of long-term health complications.

In conclusion, improving sleep quality is essential for overall health and well-being. By addressing sleep disturbances and implementing effective therapies, we can significantly enhance the quality of life for individuals affected by sleep disorders.
http://www.saintalphonsus.org/research-integrity

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