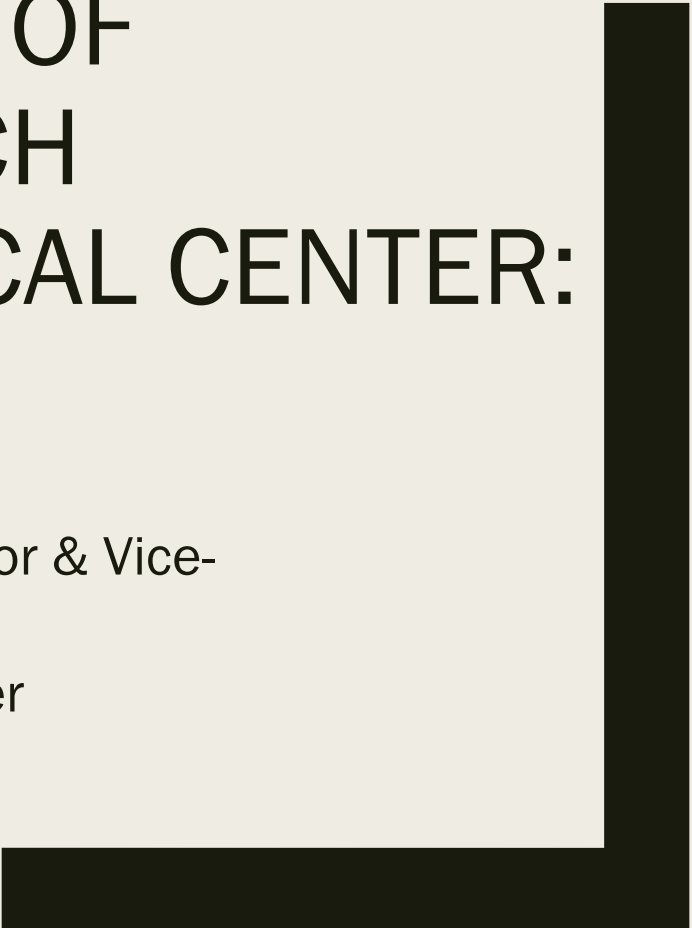




# NATIONAL INSTITUTE OF NURSING RESEARCH PATIENT SAFETY AT THE CLINICAL CENTER: RIGHT PATH?

Sue Wingate PhD, RN, ANP-BC, Clinical Director & Vice-  
Chair Medical Executive Committee  
Brian Walitt, MD, MPH, Medical Officer



# Outline

- Overview of NINR
- NINR Intramural Science
- Program Development & Patient Safety: The NINR Journey
- Impact of PDS Closure

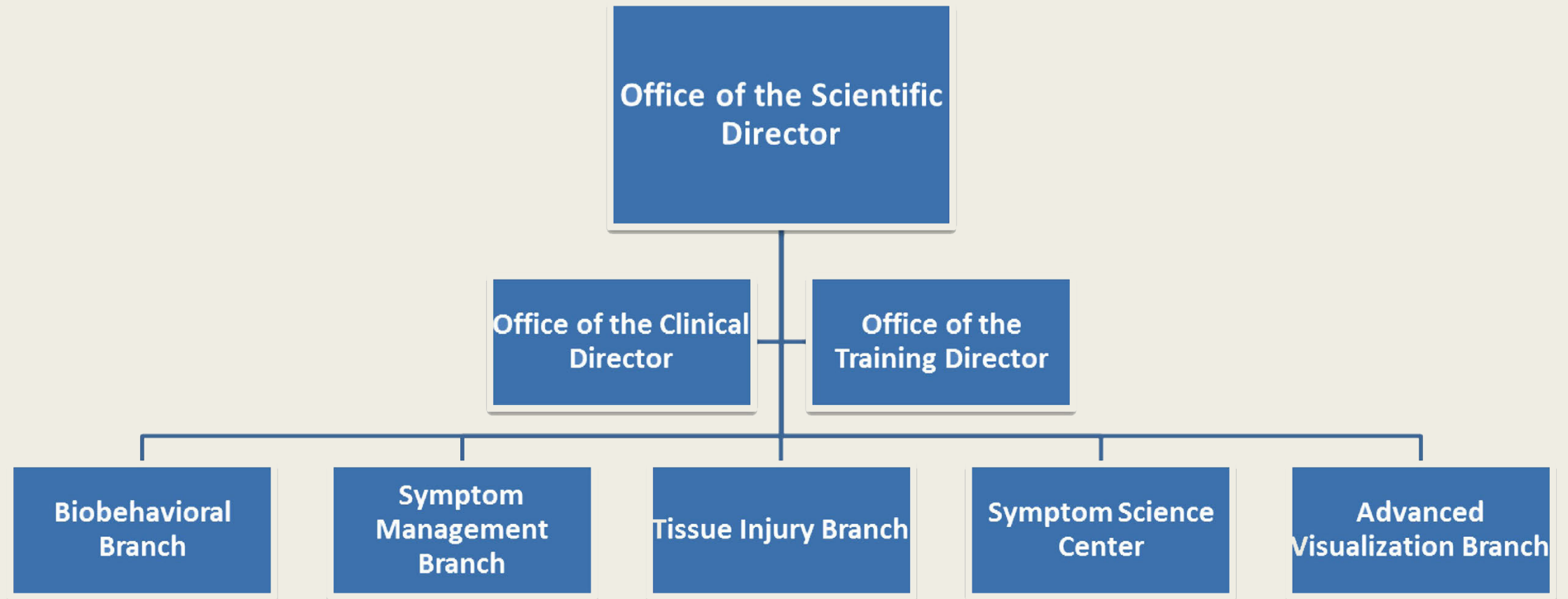
# Outline

- Overview of NINR
- NINR Intramural Science
- Program Development & Patient Safety: The NINR Journey
- Impact of PDS Closure

# Overview of NINR

- Investigators:
  - Principal Investigators
    - 1 Tenured Investigator (Lasker Scholar)
    - 3 Tenure-track Investigators
    - 1 Assistant Clinical Investigator
  - 1 Staff Clinician/Medical Officer
  - 1 Staff Scientist, Research Fellows
- Trainees (Post-doctoral, Post-baccalaureate)
- 12 clinical protocols
  - 2 additional pending in IRB
- 2 IND studies
- 2 Bench-to-Bedside awards
- Currently all protocols are out-patient based

# Overview of NINR



# Overview of Clinical Director's office

## Clinical Director

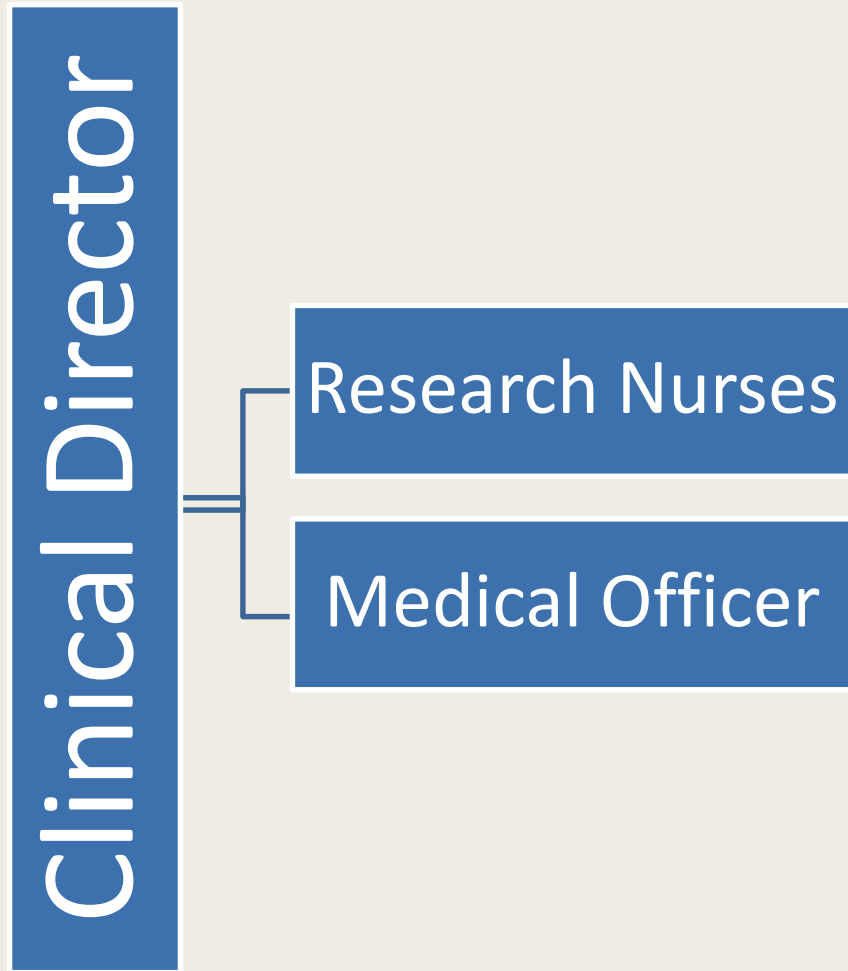
- Nurse Practitioner
- Vice-Chair of Medical Executive Committee

## Scope of Office

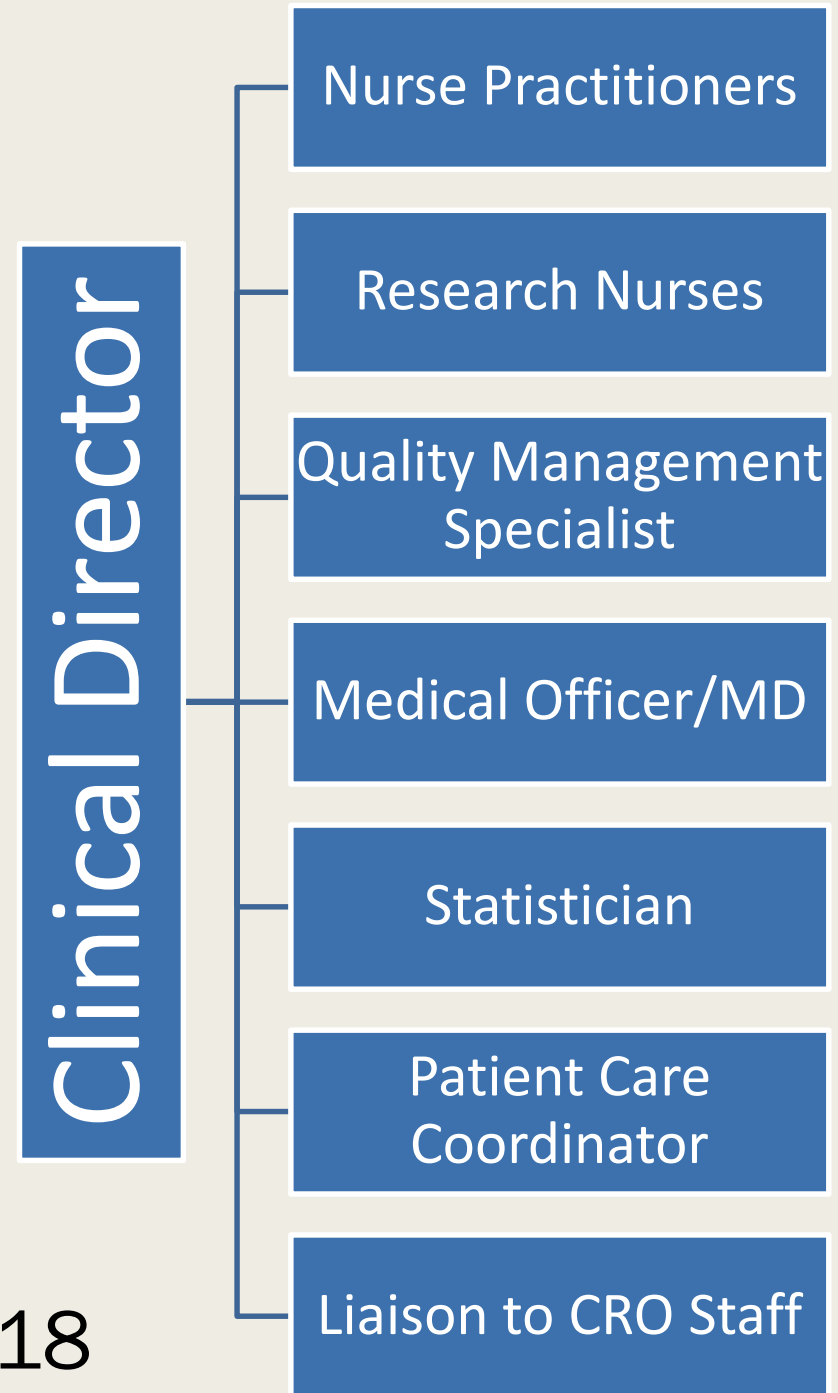
- Oversee all clinical and regulatory aspects of the on-campus research activities of NINR scientists

## Activities of Office

- Clinical care & safety of research participants
- Competency assessment of staff and trainees
- Credentialing of clinicians
- Pre-IRB and on-going protocol review
- Regulatory and quality management of protocols
- Protocol resource use



2013→2018



# Medical Officer

- Expertise in chronic symptoms
- Physician collaborator with nursing investigators
- Medical Advisory Investigator (MAI) for 8 NINR protocols
- Shared resource with other Institutes (NIDCR, NINDS, NIAMS)
- IRB member
- Scientific Review Committee member



# Outline

- Overview of NINR
- NINR Intramural Science
- Program Development & Patient Safety: The NINR Journey
- Impact of PDS Closure

# NINR Intramural Science

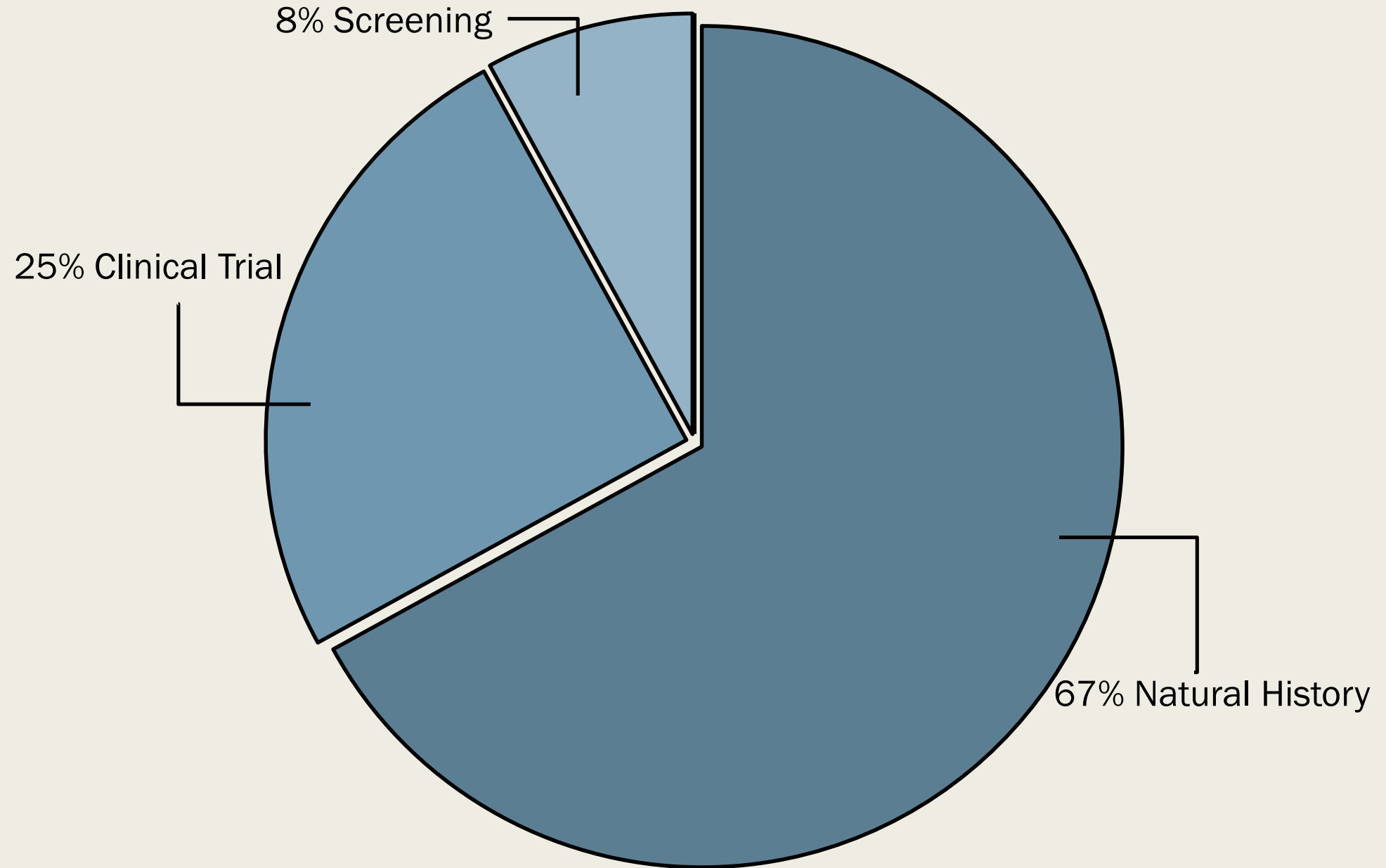
## ■ Symptom Science

- **Describe symptom experiences and the biology underlying those experiences**
  - Fatigue: cancer, post-infectious chronic fatigue syndrome (ME/CFS)
  - PTSD, Depression with Traumatic Brain Injury (TBI)
  - Symptoms with congenital muscle disorders, digestive disorders, post-solid organ transplant
- **Explore the biologic mechanisms that play a role in the establishment of chronic symptoms that exist in the absence of gross pathologic change**
  - TBI, post-cancer treatment fatigue, ME/CFS

## ■ Translational Science

- **Develop novel clinical interventions**
  - Symptoms: Ketamine for fatigue, Neurotrophin for fibromyalgia
  - Muscle Function: N-acetylcysteine (anti-oxidant) for RYR1 congenital myopathy
  - Virtual reality for chronic disease self-care
- **Develop biomarkers and bioassays**
  - TBI, cancer-related fatigue, weight gain in solid-organ transplant
  - “Stool tool” for rapid pathogen identification

# NINR Clinical Studies



## Biobehavioral Branch

### Digestive Disorders Unit



Dr. Wendy Henderson: Brain-Gut-Micro-biota mechanisms in symptom distress related to digestive disorders. Biobehavioral interventions to target digestive disorder symptoms

### Sensory Science & Metabolism Unit



Dr. Paule Joseph: Molecular and neural mechanisms associated with sensory symptoms in metabolic conditions

## Symptom Management Branch

### Symptoms Biology Unit



Dr. Leo Saligan: Characterize distinct and shared functional pathways of fatigue. Identify potential therapeutic targets

### Genomic and Clinical Biomarkers Unit



Dr. Ann Cashion: Biomarkers, outcomes, and therapies in solid organ transplant recipients

## Tissue Injury Branch

### Brain Injury Unit



Dr. Jessica Gill: Mechanisms associated with risks for neurological and behavioral symptoms in Traumatic Brain Injuries (TBIs) and concussions, Omic biomarkers associated with risks

### Neuromuscular Symptoms Unit



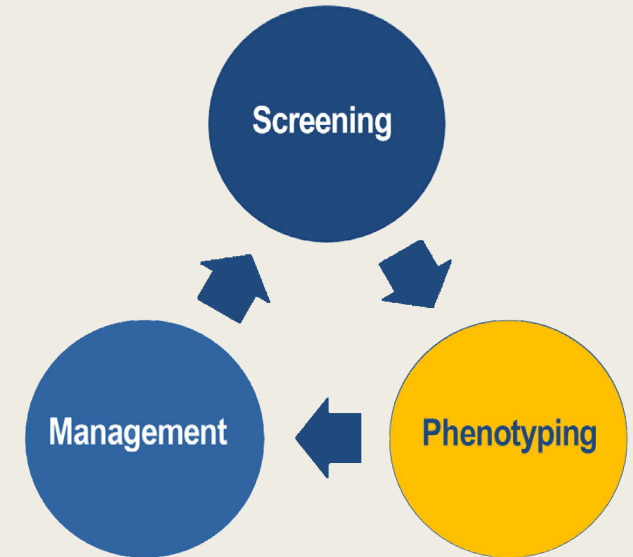
Dr. Katy Meilleur: Novel clinical outcome measures and treatments in congenital myopathies and muscular dystrophies

# Two New Branches

## Symptom Science Center



Dr. Leo Saligan: To promote the understanding of the biologic and bio-behavioral mechanisms of symptoms to improve patient outcomes.



Dr. Patricia Brennan, Director of the National Library of Medicine: Develops augmented reality (AR) and virtual reality (VR) tools to improve the patient experience in the home environment, creating scenarios designed for patient self-management in a variety of venues to support best patient self-care practices.

# Outline

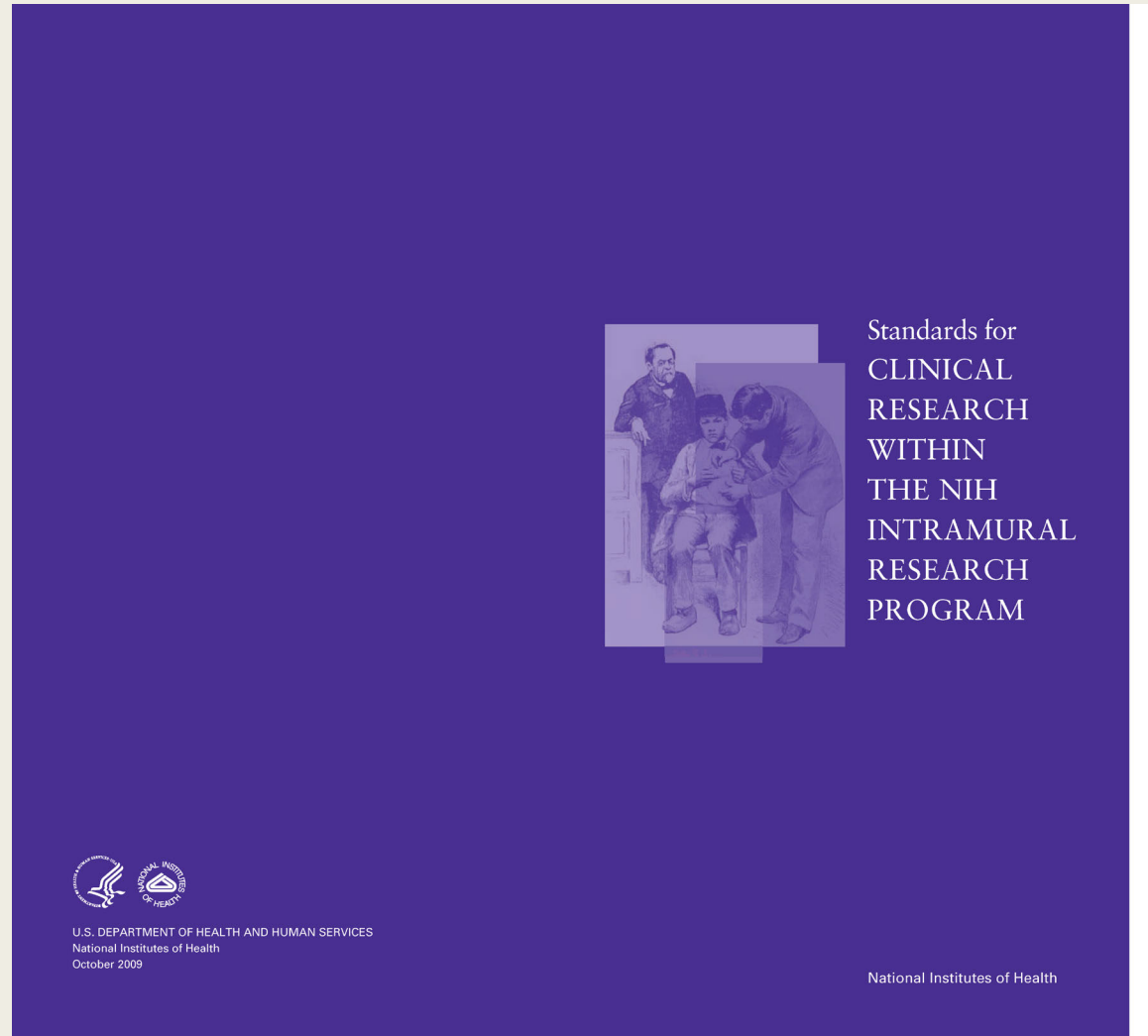
- Overview of NINR
- NINR Intramural Science
- Program Development & Patient Safety: The NINR Journey
- Impact of PDS Closure



# Where to Start? Standards for Clinical Research

Starting point to develop infrastructure

- From: Cliff Lane (NIAID)
- Content
  - Clinical Informatics/Data management/Protocol Tracking
  - Biostatistics Support
  - QA & QI
  - Protocol Review
  - Human Resources & Physical Plant
  - Training & Education
  - Research Participants



# NINR Program Assessment

- In addition to review of “Standards for Clinical Research”, the Clinical Director, Medical Officer and team performed a program assessment in 2014-15
- Great science being done in isolation
- Areas to address:
  - Patient Safety
  - Protocol Navigation
  - Protocol Monitoring
  - Regulatory/FDA compliance resources
  - CRIS Documentation
  - Training
  - Credentials: Nurse Practitioner scope, Peer Review

# Red Team Report (April 2016)

- Coincided with ongoing infrastructure development in NINR
- “Critical linkage and synergism of science and safety” was key (noted in Report recommendations)

## REDUCING RISK AND PROMOTING PATIENT SAFETY FOR NIH INTRAMURAL CLINICAL RESEARCH

DRAFT REPORT

April, 2016

The Clinical  
Center  
Working  
Group  
Report to  
the  
Advisory  
Committee  
to the  
Director,  
NIH

# Patient Safety

- Hiring of Quality Management Specialist who is also our Safety Liaison
- Daily Clinical Center huddle attendance; summary of issues for staff
- NINR Safety & Quality meeting– now combined with biweekly Research Nurse meeting– forum for sharing across teams
- Safety Monitor for selected protocols (Clinical Center Rehab Medicine Department)

# Contract Research Organization (CRO) support

- First contract of this type for NINR
- Provides a protocol navigator for each research team
  - Handles protocol development, revision, documentation and communication with IRB
  - Frees up other research team members to focus on other areas
- Provides external monitoring support for selected protocols

# Scientific Review and Research Support

- Clinical Center Nursing Department:
  - Intramural Scientific Review Committee (combined groups)
  - Dr. Gwen Wallen (CNO): Adjunct Investigator in the NINR Symptom Science Center
- Clinical Center Office of Research Support and Compliance:
  - General regulatory support
  - IND support/collaboration
  - Resource for questions
  - External monitoring

# NINR Internal Quality Monitoring & Auditing

- Monitoring schedule set up for all protocols for at least annual monitoring
- CRIS Documentation
  - Every out-patient visit reviewed monthly (now, quarterly) according to established minimum criteria
  - Results: 60%→100%
- Event reporting
  - Quarterly review of Problem Reports for each research team for problem identification and timely reporting
  - Results: 90%→100%

# Training

- Trainees
- Research Nurses



# Oversight of Trainees

- Orientation session for all new trainees (from NIMH)
  - Clinical Center & NINR policies
  - Trainee Scope
  - Training & Competencies
  - Patient Safety, Confidentiality
- Competencies (from NINDS & Laura Lee)

**NATIONAL INSTITUTE OF NURSING RESEARCH (NINR)**  
**COMPETENCY VALIDATION: IRTA**

Clinical Activity: Computerized Cognitive Tests

Name: \_\_\_\_\_ Branch: \_\_\_\_\_

Supervisor: \_\_\_\_\_

Validation Method: D = Demonstration DR = Documentation Review V = Verbalization  
T = Test/Quiz O = Other (specify)

Reason for validation: ☐ Orientation ☐ Re-validation Validation Frequency: \_\_\_\_\_

Validator/Role: \_\_\_\_\_

Required Training: \_\_\_\_ Instruction session(s), \_\_\_\_ Observation session(s), \_\_\_\_ Supervised sessions(s)  
State number of sessions completed

Behavioral Indicators	Validation Method	Met	Not Met	Comments
Explains to patient: purpose of testing, patient expectations, expected time for completion	Other (specify in _____)			
Sets up computer system for patient	Other (specify in _____)			
Directs patient how to perform the testing	Other (specify in _____)			
Addresses patient questions during testing	Other (specify in _____)			
Ensures proper data capture and closes program	Other (specify in _____)			

List Cognitive Tests: \_\_\_\_\_

Recommendation: ☐ Can Perform Activity as per Policy

Employee Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Supervisor's Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Version 2 (July 2018)

# Research Nurse Training

- NIH Intramural Research program  
Clinical Trial Orientation Program
- On-line training followed by  
classroom session
- (from NCI)

## NIH IRP Clinical Trial Orientation Series November 2018

**Day 1: November 1, 2018  
FAES Room 7**

8:30 AM – 9:15 AM	Overview of NIH
9:15 AM – 9:45 AM	NIH IRP Human Research Protections Program
9:45 AM – 10:45 AM	NIH IRP Protocol Development, Review and Approval Process
10:45 AM – 11:00 AM	<i>Break</i>
11:00 AM – 11:45 AM	Responsibilities of the Research Team
11:45 AM - 12:30 PM	Informed Consent Vignettes, Discussion, NIH IRP Resources
12:30 PM – 1:30 PM	<i>Lunch</i>
1:30PM – 2:30 PM	Event Reporting Vignettes & Discussion
2:30 PM – 2:45 PM	<i>Break</i>
2:45 PM – 3:45 PM	Data Management, Monitoring & Auditing
3:45 PM – 4:00 PM	Q & A

**Day 2: November 2, 2018  
FAES Room 4  
NCI ONLY**

12:30 PM – 4:00 PM	<u>CENTER FOR CANCER RESEARCH SPECIFIC</u>  Overview of NCI and Center for Cancer Research (CCR) CCR specific operations RECIST
--------------------	---

# Credentials and Peer Review

- Plan for Nurse Practitioners to practice to full extent of scope of practice in state of MD
- Peer Review

# Peer Review

- Ongoing Professional Practice Evaluations
- Self-evaluation and 2 peer reviews
- (from NIMH)

## Ongoing Professional Practice Evaluation National Institute of Nursing Research

Peer-Evaluation for:

Completed by:

Date:

1. Based on your judgment of this provider's performance at the NIH Clinical Center, please rate the following:

1 = poor      2 = fair      3 = good      4 = very good      5 = excellent or N/A (not applicable)

1. Basic Medical Knowledge	1	2	3	4	5	N/A
2. Clinical Competence	1	2	3	4	5	N/A
3. Technical Skill	1	2	3	4	5	N/A
4. Cooperativeness	1	2	3	4	5	N/A
5. Quality/timeliness of documentation	1	2	3	4	5	N/A
6. Practitioner/patient relationship	1	2	3	4	5	N/A

2. Please note any other comments/information that would be important to know about this provider's clinical practice.

---

---

---

---

---

Thank you.

# Outline

- Overview of NINR
- NINR Intramural Science
- Program Development & Patient Safety: The NINR Journey
- Impact of PDS Closure

# Impact of PDS Closure

- Immediate impact: PDS Closure affected 2 protocols in NINR
  - Gill
    - Drug for sleep study quarantined in PDS; unable to be used
    - Unable to obtain medication from outside sources
    - Study closed
  - Henderson
    - Sugar solution to measure gut permeability: outside source vs internal individual order
    - Significant on-site and off-site study delay

# Summary

- Significant improvement in protocol resources and study oversight and safety, via a parallel process of internal review and external Red Team Report items
- Collaborations/sharing with other Institutes & the Clinical Center have been key for us
- Future:
  - In-patient protocol