**C**omparing Treatment **A**pproaches to Promote Inpatient **R**ehabilitation **E**ffectiveness **for** **TBI**


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# CARE-4-TBI Collaborators
















# CARE4TBI Leadership

**Principal Investigators**

Jennifer Bogner, PhD

Cynthia Beaulieu, PhD

Erinn Hade, PhD

**Consumer Stakeholder Lead:** John Corrigan, PhD

**Research Information Technology Lead:** Timothy Huerta, PhD

**Therapy Leads:** Chad Swank, PhD (PT), Mary Ferraro, PhD (OT), Kimberly Frey, PhD (SLP), Alyssa Kociba (RT)

**National Data and Statistical Center:** Dave Mellick, PhD

**NIH Scientific Officer:** Nsini Umoh, PhD

| TBIMS Site | Site Leads | Therapists | Rehab Team Leaders | Informaticists/Information Technologists |
|---|---|---|---|---|
| North Texas | Simon Driver, PhD | Chad Swank, PT | Megan Eubank Ladue, SLP | Scott Gardner |
| Rocky Mountatin | Candy Tefertiller, PhD | Kaitlyn Hays, PT | Kimberly Frey, SLP | Robyn Depan, Emily O'Shea, Doug Hinchey |
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| Moss | Amanda Rabinowitz, PhD | Andrew Packel, PT | Mary Ferraro, OT | Lisa Peck |
| Kessler | Anthony Lequerica, PhD, Nancy Chiaravalloti, PhD | Erin Donnelly, PT | Irene Ward, PT | Scott Gardner |
| Mayo | Dmitry Esterov, DO | Kayla Johnson | Jon Potter, OT | Kathy Davis |
| Southeaster Michigan | Robin Hanks, PhD | Nicole Williams, PT | Ali Zein, OT | Andrea Hargreaves-Thomas |
| JFK | Monique Tremaine, PhD | Deanna Dutcher, SLP | Kate Bernard, LSW/CCM | Michael Weidenhamer, Patrick Hayes |
| Mt. Sinai | Kristen Dams-O'Connor, PhD, Eric Watson, PhD | Jacqueline D'Alessio, PT | Debra Zeitlin, SLP | Stacey Cohen |
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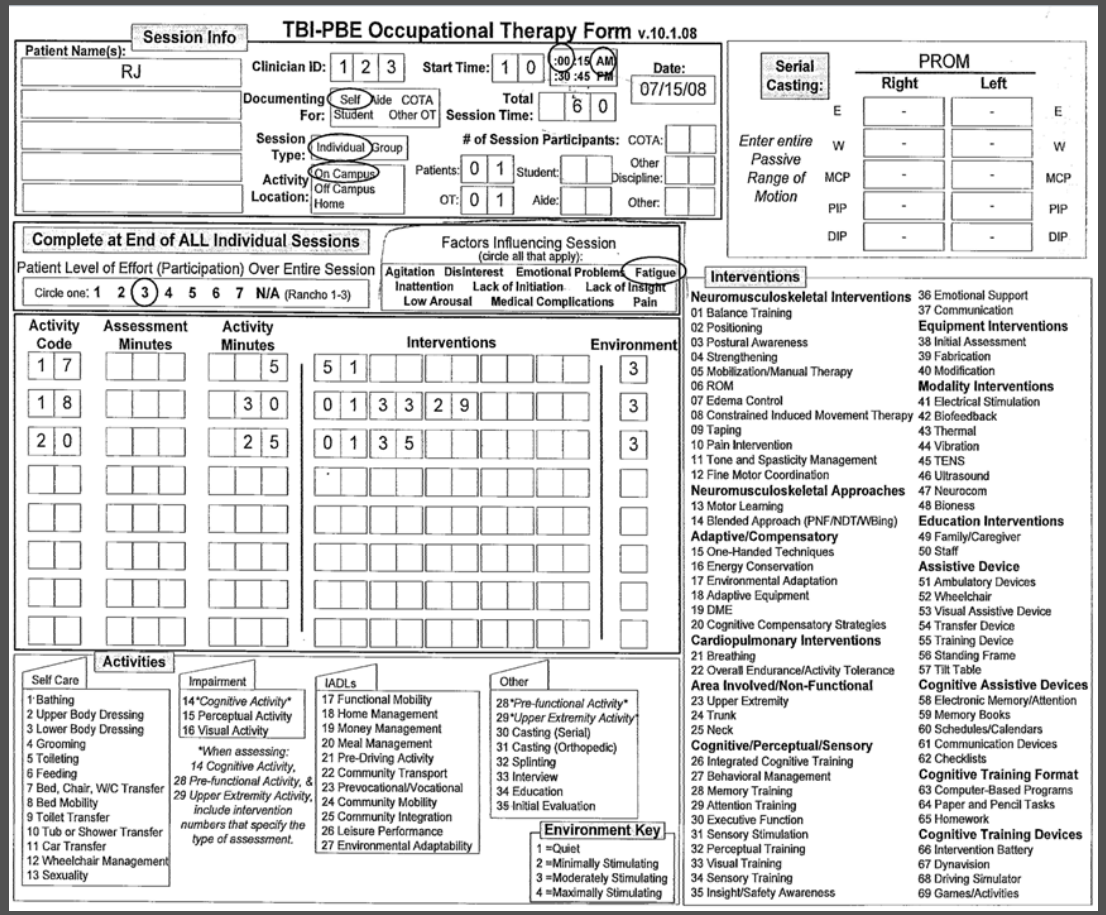
| TIRR Memorial Hermann | Angelle Sander, PhD, Shannon Juengst, PhD | Richhpal, PT | Julie Laymon, PT | Susann Evatt |
| UAB | Jennifer Marwitz, MA, Robert Brunner, MD | Mary Bowman, OT | Valley McCurry, OT | Camille Asbury |
| VCU | Richard Kunz, PhD, Amol Karmarkar, PhD | Kaitlin Sullivan, OT | David Rothman, Psy | Michael Mellerman |
| OSU | Jennifer Bogner, PhD, John Corrigan, PHD | Jodi Jones, OT | Melanie Swan, OT | Nicole Rutledge<br>Stephanie Rios |
| Tampa VA | Marc Silva, PhD | Barbara Darkangelo, PT | Kathryn Kieffer, SLP, Imelda Llanos, OT | |

CARE4TBI

A comprehensive investigation of ‘real-life” rehabilitation approaches to generate findings that can directly impact clinical practice.  We are accomplishing this with:

- Lessons learned from >10 years of preliminary studies
- The infrastructure of the NIDILRR-funded TBI Model Systems
- Stakeholder engagement
- Development of standardized data capture within EMRs to allow for collection of data on inpatient rehabilitation as it naturally occurs
- Use of advanced causal inference methods to test hypotheses comparing rehab approaches

# TBI Practice-Based Evidence Study



**TBI-PBE Occupational Therapy Form** v.10.1.08

**Session Info**

Patient Name(s): RJ

Clinician ID: 1 2 3 — Start Time: 1 0 :00 :15 :30 :45 AM PM — Date: 07/15/08

Documenting For: Self Aide COTA Student Other OT — Total Session Time: 6 0

Session Type: Individual Group — # of Session Participants: Patients: 0 1 — Student: — OT: 0 1 — Aide: — COTA: — Other Discipline: — Other:

Activity Location: On Campus Off Campus Home

**Serial Casting:** — Enter entire Passive Range of Motion

| | PROM Right | PROM Left | |
|---|---|---|---|
| E | - | - | E |
| W | - | - | W |
| MCP | - | - | MCP |
| PIP | - | - | PIP |
| DIP | - | - | DIP |

**Complete at End of ALL Individual Sessions**

Patient Level of Effort (Participation) Over Entire Session

Circle one: 1 2 (3) 4 5 6 7 N/A (Rancho 1-3)

**Factors Influencing Session** (circle all that apply):

Agitation, Disinterest, Emotional Problems, Fatigue, Inattention, Lack of Initiation, Lack of Insight, Low Arousal, Medical Complications, Pain

| Activity Code | Assessment Minutes | Activity Minutes | Interventions | Environment |
|---|---|---|---|---|
| 1 7 | | 5 | 5 1 | 3 |
| 1 8 | | 3 0 | 0 1 3 3 2 9 | 3 |
| 2 0 | | 2 5 | 0 1 3 5 | 3 |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

**Activities**

Self Care
1 Bathing
2 Upper Body Dressing
3 Lower Body Dressing
4 Grooming
5 Toileting
6 Feeding
7 Bed, Chair, W/C Transfer
8 Bed Mobility
9 Toilet Transfer
10 Tub or Shower Transfer
11 Car Transfer
12 Wheelchair Management
13 Sexuality

Impairment
14 *Cognitive Activity*
15 Perceptual Activity
16 Visual Activity

*When assessing: 14 Cognitive Activity, 28 Pre-functional Activity, & 29 Upper Extremity Activity, include intervention numbers that specify the type of assessment.*

IADLs
17 Functional Mobility
18 Home Management
19 Money Management
20 Meal Management
21 Pre-Driving Activity
22 Community Transport
23 Prevocational/Vocational
24 Community Mobility
25 Community Integration
26 Leisure Performance
27 Environmental Adaptability

Other
28 *Pre-functional Activity*
29 *Upper Extremity Activity*
30 Casting (Serial)
31 Casting (Orthopedic)
32 Splinting
33 Interview
34 Education
35 Initial Evaluation

**Environment Key**
1 =Quiet
2 =Minimally Stimulating
3 =Moderately Stimulating
4 =Maximally Stimulating

**Interventions**

**Neuromusculoskeletal Interventions**
01 Balance Training
02 Positioning
03 Postural Awareness
04 Strengthening
05 Mobilization/Manual Therapy
06 ROM
07 Edema Control
08 Constrained Induced Movement Therapy
09 Taping
10 Pain Intervention
11 Tone and Spasticity Management
12 Fine Motor Coordination

**Neuromusculoskeletal Approaches**
13 Motor Learning
14 Blended Approach (PNF/NDT/WBing)

**Adaptive/Compensatory**
15 One-Handed Techniques
16 Energy Conservation
17 Environmental Adaptation
18 Adaptive Equipment
19 DME
20 Cognitive Compensatory Strategies

**Cardiopulmonary Interventions**
21 Breathing
22 Overall Endurance/Activity Tolerance

**Area Involved/Non-Functional**
23 Upper Extremity
24 Trunk
25 Neck

**Cognitive/Perceptual/Sensory**
26 Integrated Cognitive Training
27 Behavioral Management
28 Memory Training
29 Attention Training
30 Executive Function
31 Sensory Stimulation
32 Perceptual Training
33 Visual Training
34 Sensory Training
35 Insight/Safety Awareness
36 Emotional Support
37 Communication

**Equipment Interventions**
38 Initial Assessment
39 Fabrication
40 Modification

**Modality Interventions**
41 Electrical Stimulation
42 Biofeedback
43 Thermal
44 Vibration
45 TENS
46 Ultrasound
47 Neurocom
48 Bioness

**Education Interventions**
49 Family/Caregiver
50 Staff

**Assistive Device**
51 Ambulatory Devices
52 Wheelchair
53 Visual Assistive Device
54 Transfer Device
55 Training Device
56 Standing Frame
57 Tilt Table

**Cognitive Assistive Devices**
58 Electronic Memory/Attention
59 Memory Books
60 Schedules/Calendars
61 Communication Devices
62 Checklists

**Cognitive Training Format**
63 Computer-Based Programs
64 Paper and Pencil Tasks
65 Homework

**Cognitive Training Devices**
66 Intervention Battery
67 Dynavision
68 Driving Simulator
69 Games/Activities

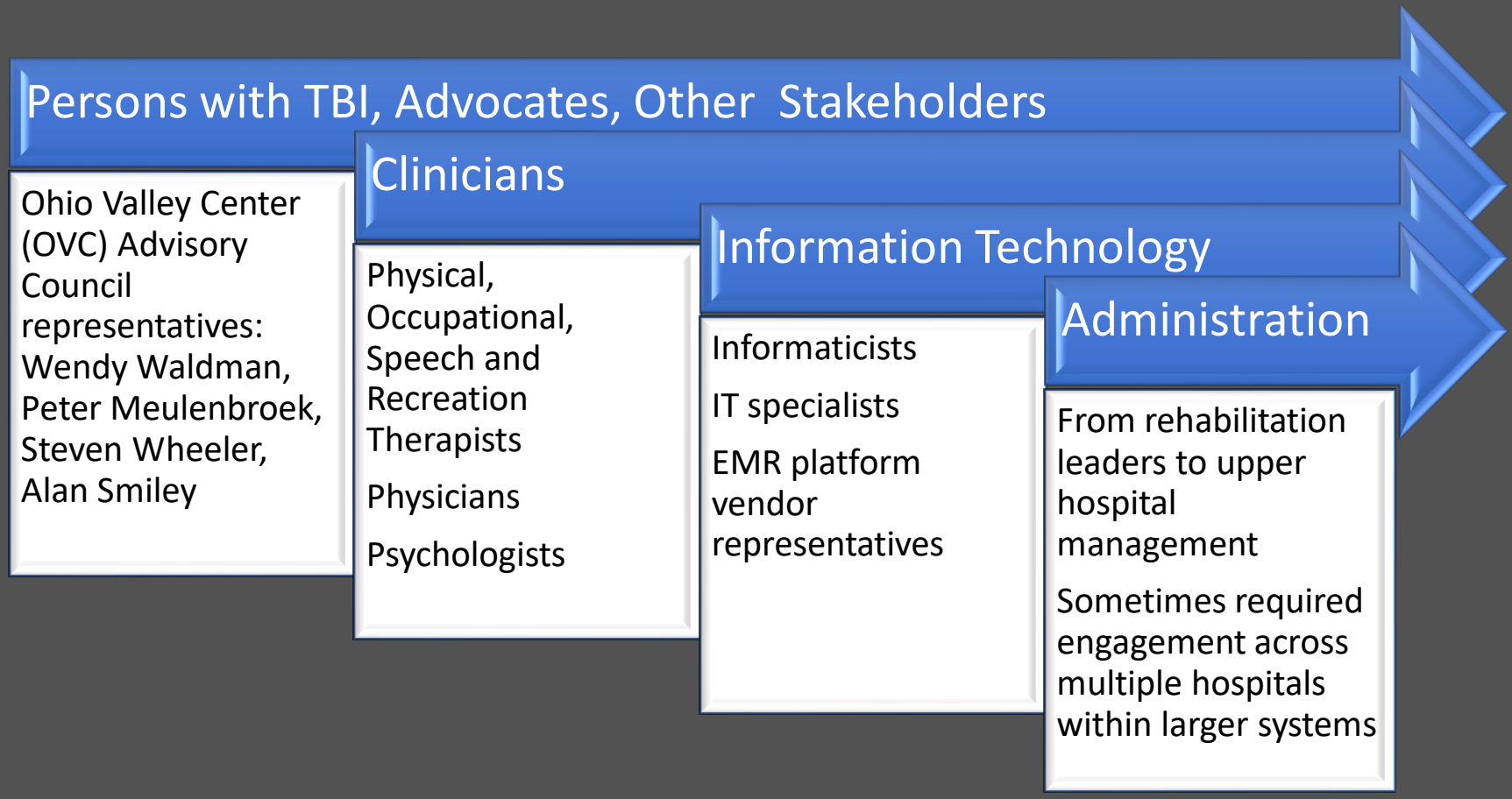
- Led by John Corrigan, PhD and Susan Horn, PhD
- Funded by NIDILRR and NIH
- Included 9 US sites and 1 Canada site
- Provided insight into the “black box” of rehabilitation therapies, their natural variation, and association with outcomes
- Therapists designed data collection forms that they completed IN ADDITION to their standard clinical documentation

# TBI Model Systems

- Funded by the National Institute on Disability, Independent Living, and Rehabilitation Research, Administration for Community Living
- World's largest TBI longitudinal database with over 19,000 participants
- Follows individuals with moderate-severe TBI from inpatient rehabilitation through their lifetime
- Currently 16 sites
- The TBI Model System National Data and Statistical Center provides the infrastructure to manage not only the National Database, but to also host affiliate studies as well as the VA TBI Model Systems

NDSC
National Data and Statistical Center
Traumatic Brain Injury Model System

# CARE4TBI Stakeholder Engagement



# Standardize Data Capture in the EMR
# …across 15 sites with two EMR vendors (AIM 1, 9/2021-8/2023)

Therapist-driven development with guidance and support for design from Informatics and Information Technology (IIT) experts:

- Identify, design, standardize data elements to be captured in the daily session notes and extracted for both research and clinical operations.
- Reduce/eliminate redundancy with existing data fields.
- Ensure retention of data for regulatory/payment purposes.
- Strive for “Click Reduction”-format with efficiency in mind!
- Ingest, implement, adopt new data fields into each site’s workflow to maximize documentation efficiency.

Cynthia Beaulieu, PhD
Ohio State University

## Ohio Valley Advisory Council

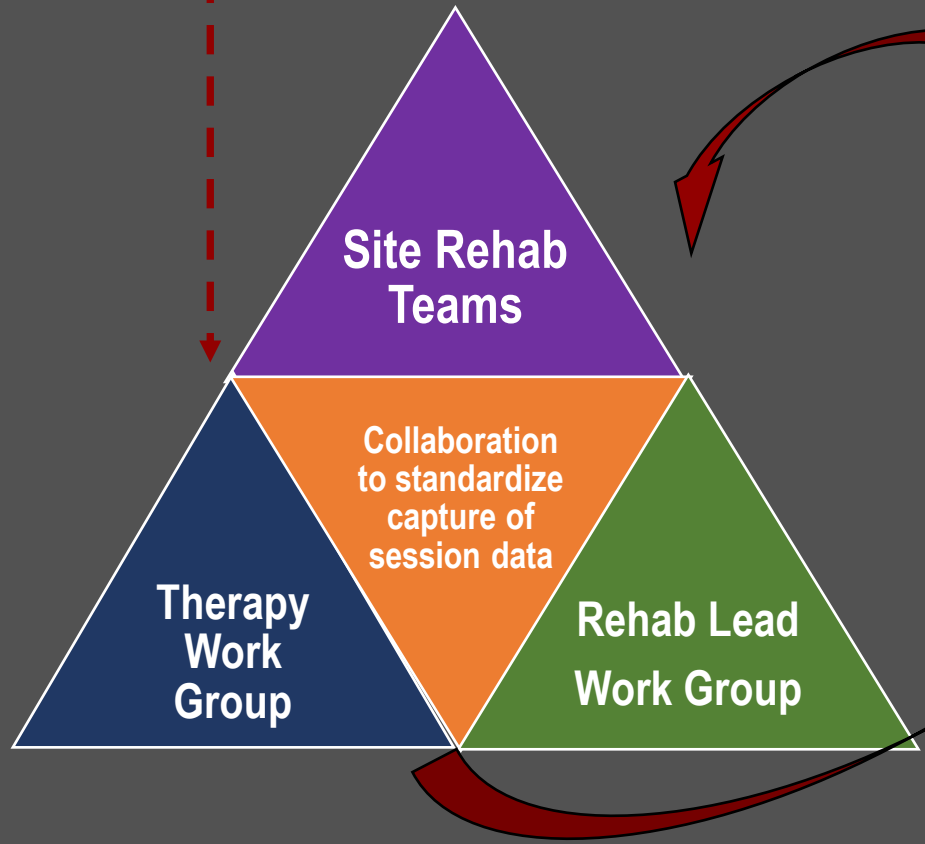
- Facilitated by John Corrigan
- Nominate 2-3 members to provide input on:
  - Variable selection
  - Implementation
  - Interpretation
  - Dissemination
- Monitor progress

## Steering Committee Governance

- Facilitated by Jennifer Bogner
- Executive Committee closely monitors progress and assists with immediate troubleshooting
- Full committee:
  - Consists of MPIs, NDSC, Site Leads, Therapy Leads, VA Reps, Consultants, NIH Project Scientist
  - Monitors progress on milestones
  - Reviews and approves deliverables
  - Assists with problem-solving and troubleshooting
  - Ensures successful study implementation

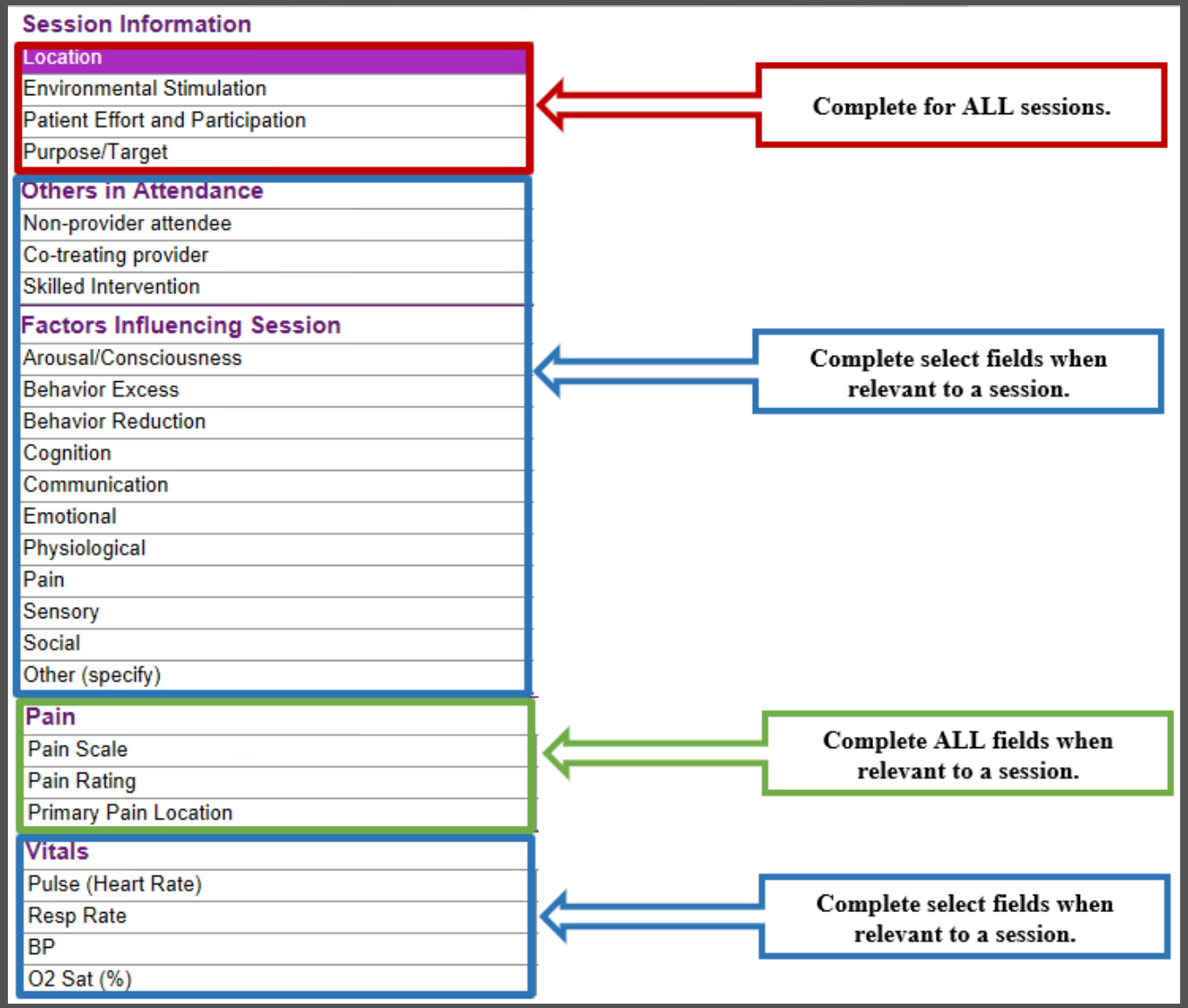
## Informatics & Information Technology Advisory Board

- Facilitated by Beaulieu, Hade, Huerta
- Consists of experts nominated by the sites
- Data governance
- Provides oversight of cross-site data standardization
- Provides guidance to resolve and minimize cross-site heterogeneity
- Provides oversight for data integrity across sites



# UG3 AIM ! Results

- Consensus was reached on critical data elements for the session level as well as activity level
- Templates were built with the data elements and incorporated into site workflows
- 13 sites trained clinical staff and went live in accordance with timeline
- One site is changing vendors this year and will go live next year
- One site could not complete the full build due to administrative issues and decided to discontinue


Session Information
Location
Environmental Stimulation
Patient Effort and Participation
Purpose/Target
Others in Attendance
Non-provider attendee
Co-treating provider
Skilled Intervention
Factors Influencing Session
Arousal/Consciousness
Behavior Excess
Behavior Reduction
Cognition
Communication
Emotional
Physiological
Pain
Sensory
Social
Other (specify)
Pain
Pain Scale
Pain Rating
Primary Pain Location
Vitals
Pulse (Heart Rate)
Resp Rate
BP
O2 Sat (%)
Complete for ALL sessions.
Complete select fields when relevant to a session.
Complete ALL fields when relevant to a session.
Complete select fields when relevant to a session.

# Problems and Solutions

Significant differences in the formatting and options between EMR platforms, and sometimes within the same platform as used between different facilities

For one of the platforms, OSU built a template that could be ingested by sites using that platform. They then customized to their workflow

Sites on the other platform shared tips and lessons learned as they built site-specific templates that incorporated the common data elements

# Problems and Solutions

Therapists vary in their preference for the use of discrete fields (e.g. dropdown menus) versus narration

Terms used to describe the same activities varied between therapists.

A comment section was provided for each therapeutic activity, allowing therapists to narrate impressions (if that is their preference) in addition to completing the discrete fields indicating what they did in the session

Reached consensus on terminology when able, allowed for customization at entry level as long as extraction report was consistent with common terminology, developed operational definitions. When the list of potential activities was too long to include in a drop down, a narrative field was provided (discrete fields capture most project required elements).

# UH3 Phase
# Collect Prospective Data and Conduct Analyses to:

**1.** Compare the effectiveness of well-defined rehabilitation approaches to improve community participation and functional independence of patients with TBI.

**2.** Identify patient, provider, setting, and post-discharge factors that modify the effect of therapy on outcomes.

Erinn Hade, PhD
New York University Grossman School of Medicine and Langone Health

# UH3 Phase
# 9/1/23 to 8/31/28

- Participant enrollment began 9/1/23.  Will accrue 1575 participants in about 3.5 years
- Data quality audits have been initiated
- Outcomes on community participation and functional independence will be collected at discharge, 6 months, and 12 months post-injury
- All data is being compiled and stored at the TBIMS National Data and Statistical Center at Craig Hospital

# Stay Tuned!