

Active Research Projects – November 2022
(Version 11/10/2022)

TECHNOLOGY & DATA SCIENCE RESEARCH

Project# 678
IRBNet# 856262
LiveWell RERC: Tech Factory (John Morris, PHD)
Sponsor: NIDILRR

Project# 731 – NR
IRBNet# 1097300
Usability Lab: Accessibility User Research Collective (John Morris, PHD)
Sponsor: Microsoft Corporation

Project# 791 – NR
IRBNet# 1483433
Usability Testing (John Morris, PHD)
Sponsor: Samsung

Project# 803 – Exempt Research
IRBNet# 1533647
Disability and Rehabilitation Research Project (DRRP): App Factory (Michael Jones, PHD)
Sponsor: NIDILRR

Project# 808 – Exempt Research
IRBNet# 1562714
RERC on Mobile Rehabilitation: Clinician Perceptions on Use of Information and Communication Technologies to Support Home-Based Therapy and Exercise (Mike Jones, PHD)
Sponsor: NIDILRR

Project# 828 – Exempt Research
IRBNet# 1678841
Usability Lab: Technology Access Feedback for Intel (John Morris, PHD)
Sponsor: Intel

Project# 836
IRBNet# 1702528
The Learning Health System: Applying Advanced Analytics to Rehabilitation Care - An Exploratory Study (George Collier, PHD)

Project# 845 - NR
IRBNet# 1752930
LinkedIn Usability Feedback (John Morris, PHD)
Sponsor: LinkedIn

Project# 884
IRBNet# 1884046
User Testing of MagTrack Motion Tracking Inertial Measurement Electronics Controller
(John Morris, PHD)
Sponsor: Georgia Research Alliance

Project# 886 - NR
IRBNet# 1898687
UX Lab 3rd Party Market Research Vendors - Umbrella Protocol (John Morris, PHD)
Sponsor: Multiple Commercial Sponsors

Project# 890 - NR
IRBNet# 1917081
UX Lab: McDonald's User-Centered Research- Umbrella Protocol (John Morris, PhD)
Sponsor: McDonald's Corporation

Project# 891 - NR
IRBNet# 1955600
UXLAB: Microsoft-126-Microsoft Store Accessibility (John Morris, PhD)
Sponsor: Microsoft

Project# 894 - NR
IRBNet# 1942683
UX Lab: Roku Screen Reader Survey (John Morris, PhD)
Sponsor: Roku

Project# 895 - NR
IRBNet# 1944853
UXLAB: Roku-002-Vision Ethnography Study (John Morris, PhD)
Sponsor: Roku

Project# 899 - NR
IRBNet# 1953645
UXLAB: Microsoft -9022-Accommodations Benchmarking Study (John Morris, PhD)
Sponsor: Microsoft

Project# 910-NR
IRBNet# 1974831
UXLAB: Roku-003-Research Modalities (John Morris, PhD)
Sponsor: Roku

Project# 916-NR
IRBNet# 1981783
UXLAB: Microsoft-128A- Accommodations Documentation Survey (John Morris, PhD)
Sponsor: Microsoft

Number of Studies in Section: 17

MULTIPLE SCLEROSIS RESEARCH

Project# 552

IRBNet# 261795

A Randomized, Double-Blind, Double-Dummy, Parallel-Group Study to Evaluate the Efficacy and Safety of Ocrelizumab in Comparison to Interferon Beta-1a (Rebif®) in Patients with Relapsing Multiple Sclerosis - Genentech current protocol WA21092 (OPERA) (Ben Thrower, MD)

Sponsor: Genentec

Project# 706

IRBNet# 1008745

An Open-Label, Single-Arm Study to Evaluate the Effectiveness and Safety of Ocrelizumab in Patients with Early-Stage Relapsing Remitting Multiple Sclerosis (Protocol # MA30143) (Ben Thrower, MD)

Sponsor: F. Hoffman-La Roche LTD

Project# 713

IRBNet# 1038441

Shepherd Center MS Outcomes Data Registry (Deborah Backus, PT, PHD)

Project# 738

IRBNet# 1130891

Comparative Effectiveness of an Exercise Intervention Delivered via Telerehabilitation and Conventional Mode of Delivery (Deborah Backus, PT, PHD)

Sponsor: PCORI

Project# 776

IRBNet# 1371420

Pilot Study Evaluating Functional and Wellness Outcomes of the Shepherd Can Do MS Program (Deborah Backus, PT, PHD)

Sponsor: Genzyme Corporation

Project# 781

IRBNet# 1435240

Feasibility of the Multiple Sclerosis Performance Test for Assessment of Functional Performance Measures in Patients with Multiple Sclerosis (Deborah Backus, PT, PHD)

Sponsor: Biogen

Project# 794

IRBNet# 1486979

An Observational Study of Ocrelizumab -Treated Patients with Multiple Sclerosis to Determine the Incidence and Mortality Rates of Breast Cancer and All Malignancies (Ben Thrower, MD)

Sponsor: F. Hoffman-La Roche LTD

Project# 801

IRBNet# 1523467

Qualitative Evaluation of the STEP for MS Trial (Deborah Backus, PT, PHD)

Project# 811

IRBNet# 1583172

Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Trial of the Efficacy and Safety of Nabiximols Oromucosal Spray as Add-on Therapy in Patients with Spasticity Due to Multiple Sclerosis (Ben Thrower, MD)

Sponsor: GW Pharma

Project# 812

IRBNet# 1595132

An Open-Label, Multicenter Study to Assess Disease Activity and Biomarkers of Neuronal Damage in Minority Patients with Relapsing Multiple Sclerosis Receiving Treatment with Ocrelizumab (CHIMES) (Ben Thrower, MD)

Sponsor: Genentech, Inc

Project# 852

IRBNet# 1779895

A Phase 1, Dose-Escalating, Open-label Study to Evaluate the Safety, Tolerability, and Exploratory Efficacy of Single Dose of IV IMS001 in Subjects with Multiple Sclerosis and Treatment Failure to Prior Disease Modifying Treatments (DMTs) - Protocol IMS001-01 (Ben Thrower, MD)

Sponsor: ImStem Biotechnology

Project# 853

IRBNet# 1782910

Safety, Feasibility, and Usability of Tele-exercise with BurnAlong in Persons with Multiple Sclerosis: a Pilot Study (Deborah Backus, PT, PHD)

Project# 863

IRBNet# 1829230

Multiple Sclerosis (MS) Self-management Program (Louise Palmer, MS)

Project# 872

IRBNet# 1851081

CorEvitas SPHERES (Synergy of Prospective Health & Experimental Research for Emerging Solutions) Registry for Neuromyelitis Optica Spectrum Disorder (NMOSD) (Jacqueline Rosenthal, MD)

Sponsor: CorEvitas

Project# 874

IRBNet# 1855870

Pilot Study to Validate Assessment of Fatigue using Wearable Inertial Measurement Unit Sensors (Brad Willingham, PHD)

Project# 875

IRBNet# 1855872

Developing an Integrated Remote Monitoring System to Inform the Calibration of Rehabilitation and Exercise Interventions for People with Multiple Sclerosis (Brad Willingham, PHD)

Project# 852

IRBNet# 1779895

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Project# 887

IRBNet# 1875650

A Phase IIa, Open-label, Multicentre Dose-Finding Trial in Patients with Relapsing Forms of Multiple Sclerosis (RMS) to Evaluate the Safety, Tolerability and Preliminary Efficacy of EHP-101 (Jacqueline Rosenthal, MD)

Sponsor: Emerald Health Pharmaceuticals, Inc.

Project# 888

IRBNet# 1897818

A Therapeutic Experience Program (TEP) Study Assessing Adherence to On Label PoNS® Therapy for Improvement of Gait in People with Multiple Sclerosis (MS) in a Real-World Clinical Setting

(Deborah Backus, PT, PHD)

Sponsor: Helius Medical Technologies

Project# 895

IRBNet# 1957953

Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate Efficacy, Safety, and Tolerability of IMU-838 in Patients with Progressive Multiple Sclerosis- CALLIPER Study

(Jacqueline Rosenthal, MD)

Sponsor: Immunic AG

Number of Studies in Section: 25

SPINAL CORD INJURY RESEARCH

Project# 446

IRBNet# 120672

A Phase 1 Safety Study of GRNOPCI in Patients with Neurologically Complete, Subacute, Spinal Cord Injury (David Apple, MD)

Sponsor: Lineage Cell Therapeutics

Project# 640

IRBNet# 680039

A Long-Term Follow-up Study of Subjects with Cervical Spinal Cord Injuries Who Received AST- OPC1 in Protocol AST-OPC1-01 Asterias AST-OPC1-02 (Donald Peck Leslie, MD)

Sponsor: Lineage Cell Therapeutics

Project# 729

IRBNet# 1096982

Improving Quality of Personal Care Assistance Services for People with SCI through Online Education

(John Morris, PHD)

Sponsor: NIDILRR

Project# 762

IRBNet# 1285044

Random Noise Stimulation to Enhance Corticomotor Drive for Improved Hand Function

(Anastasia Zarkou, PT, PHD)

Sponsor: Craig H. Nielsen Foundation

Project# 779

IRBNet# 1405806

A Multicenter, Two Part (Open-Label Single-Ascending Dose Followed by Double-Blind, Placebo-Controlled Repeat Dose) Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of AXER- 204 in Subjects with Chronic Spinal Cord Injury (the RESET* Study)

(Donald Peck Leslie, MD)

Sponsor: ReNetX Bio, Inc.

Project# 813

IRBNet# 1610332

Antecedents, Consequences, and Interventions for Travel Participation after SCI (Edelle Field-Fote, PHD)

Sponsor: University of Indiana

(Craig H. Nielsen Foundation)

Project# 843

IRBNet# 1743215

A Randomized, Double-Blind, Placebo-Controlled Proof of Concept Study to Assess the Safety and Efficacy of Elezanumab in Acute Traumatic Cervical Spinal Cord Injury (Michael Yochelson, MD)

Sponsor: Abbvie

Project# 848

IRBNet# 1756739

A Phase 2a, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of MT- 3921 in Subjects with Acute Traumatic Cervical Spinal Cord Injury. Protocol #MT-3921- A01

(Donald Peck Leslie, MD)

Sponsor: Mitsubishi Tanabe Pharma Development America Inc.

Project# 849

IRBNet# 1760876

Single-group Pretest-Posttest Study of "Shepherd's Get Your Verve Back" Virtual Wellness and Leisure Program (Jenny DiLaura)

Project# 851

IRBNet# 1778550

Neuromodulation of spinal circuits: effects on spasticity, nociception, and motor activation

(Edelle Field-Fote, PHD)

Project# 856

IRBNet# 1804592

SCI Model Systems of Care Data Collection and Transmission (Edelle Field-Fote, PHD)

Sponsor: NIDILRR

Project# 864

IRBNet# 1819580

Scale Up Trial of Project WOWii to Increase Exercise among People with Spinal Cord Injury (SCI)

(Michael Jones, PHD)

Sponsor: NIDILRR

Project# 867

IRBNet ID# 1833741

Discovery of Biomarker Signatures Prognostic for Neuropathic Pain after Acute Spinal Cord Injury (BSCIP) Protocol Number: HSC-MS-19-0258 (Faiz Ahmad, MD)

Project# 868

IRBNet# 1833729

Systemic Hypothermia in Acute Cervical Spinal Cord Injury A Prospective, Multi-center Case Controlled Study (David Gimbel, MD)

Sponsor: DOD

Project# 877
IRBNet# 1842303
SCIMS Site Specific Project: Activating Spinal Circuits to Improve Walking, Balance, Strength, and Reduce Spasticity (Edelle Field-Fote, PHD)
Sponsor: NIDILRR

Project# 883
IRBNet# 1885502
Evaluating the Effectiveness of Brain Health Training for Individuals with SCI/TBI and Their Family Members (Brick Johnstone, PHD)

Project# 894
IRBNet# 1951305
Evaluating Technologies for Monitoring Skin Changes across Skin Tones (Sharon Sonenblum, PHD)

Project# 908
IRBNet# 1946158
Unintentional Injuries (James Krause, PHD)

Number of Studies in Section: 20

CONCUSSION, TRAUMATIC/ACQUIRED BRAIN INJURY RESEARCH

Project# 695
IRBNet# 953445
Characterization of Post-Concussive Vestibular Impairment Brain Structural and Functional Connectivity Dysfunction and the Impact of Vestibular Rehabilitation (Russell Gore, MD)

Project# 773
IRBNet# 1344883
Magnetic Resonance Spectroscopy Applications in Disorders of Consciousness (MRS for DoC) (Shepherd PI; Andrew Dennison, MD, Emory PI: Candace Fleischer, PHD)

Project# 782
IRBNet# 1434952
Rehabilitation Pathways after Concussion: Understanding Management of Cognitive Communication Complaints (Tracey Wallace CCC-SLP)

Project# 785
IRBNet# 1457709
tDCS Paired with Exercise and Attention Training Compared with Exercise Alone with Attention Training for TBI (April Hodge, PT)

Project# 786
IRBNet# 1454512
SUCCESS: Success in College after Concussion with Effective Student Supports (Tracey Wallace, CCC-SLP)

Project# 790 – Exempt Research
IRBNet# 1479195
Veteran Goal Directed Comprehensive Care Outcomes in Chronic Mild Traumatic Brain Injury (Tracey Wallace, CCC-SLP)

Project# 810

IRBNet# 1603621

Rehabilitation Pathways after Concussion: A Retrospective Chart Review of Referral for Cognitive-Communication Services (Tracey Wallace, CCC-SLP)

Project# 826

IRBNet# 1680496

Documenting the General Effectiveness of Recreational Therapy Services for Individuals with Acquired Brain Injury (Brick Johnstone, PHD)

Project# 827

IRBNet# 1680644

Shepherd Center Foundation to Advance Brain Rehabilitation Post-Acute Rehabilitation Outcome Study (Brick Johnstone, PHD)

Project# 833

IRBNet# 1702962

Improving Access to Comprehensive TBI Treatment for Military Veterans and Service Members with Co-occurring Substance Use (Russell Gore, MD)

Project# 835

IRBNet# 1701690

A Randomized Trial to Compare Effectiveness of Two Interventions for Caregivers of Patients with Acquired Brain Injury (Mike Jones, PHD)

Sponsor: NIDILRR

Project# 841

IRBNet# 1729516

Documenting the General Effectiveness of Chaplaincy Services for Individuals with Chronic Disabilities (Brick Johnstone, PHD)

Project# 842

IRBNet# 1729688

Evaluating the Effectiveness of a Least Restrictive Restraint Training Program for Individuals with ABI (Brick Johnstone, PHD)

Project# 846

IRBNet# 1756486

Drive Safe: Driving Safety in Adolescents and Young Adults after Concussion (Russell Gore, MD)
Sponsor: Andee's Army Brain and Spinal Cord Foundation

Project# 857
IRBNet# 1804339
Documenting Relationships Between Satisfaction with Telehealth Services and Rural/Urban Status for Individuals with Chronic Disabilities (Brick Johnstone, PHD)

Project# 862
IRBNet# 1828705
Altered Central Multisensory Processing in Post-concussion Vestibular Dysfunction (Russell Gore, MD)
Sponsor: NIH

Project# 866
IRBNet# 1825225
Reading Self-Efficacy in College Students with Concussion (Katie O'Brien)

Project# 873
IRBNet# 1833854
The Application of BCVI Screening Criteria to Post-Acute Patients with Traumatic Brain Injury
(Yevgeniya Sergeyenko, MD, MPH)

Project# 892
IRBNet# 1923102
BCVI Screening Practices of Acute Care Hospitals in Shepherd Center's Catchment
(Yevgeniya Sergeyenko, MD, MPH)

Number of Studies in Section: 19

PAIN MANAGEMENT RESEARCH

Project# 855
IRBNet# 1802660
Radiofrequency (RF) Ablation Prospective Outcomes Study (RAPID)
(Erik Shaw, DO)
Sponsor: Boston Scientific

Project# 861
IRBNet# 1826705
Patient Retrospective Outcomes (PRO) Clinical Investigation Plan (Erik Shaw, DO)

Number of Studies in Section: 2

CROSS & INTERDISCIPLINARY RESEARCH

Project# 701
IRBNet# 982013
Shepherd Center Neuropsychology Data Registry Research Protocol
(Kristian Nitsch, PHD)

Project# 834
IRBNet# 1702817
Day-to-Day Experiences of People Using Indwelling Catheters and How They Manage Their Bladder Health
(Shepherd PI: Pete Anziano, External PI: (Jared Meyers)

Project# 870
IRBNet# 1836481
Validation of a Neuropsychological Model of "Disorders of the Self"
(Brick Johnstone, PHD)

Project# 871
IRBNet# 1848326
Evaluation of Oscillation and Lung Expansion (OLE) Using the Volara® System for the Treatment of Respiratory Complications in Patients with Neuromuscular Disease in the Home Setting
(Phillip Wexler, MD)
Sponsor: Hill-Rom (Science37)

Project# 878 Exempt
IRBNet# 1871712
Experience and Perceptions of the Talent Development Environment Questionnaire for Athletes with Physical Disabilities (Andrew Corbett)

Project# 879
IRBNet# 1800118
Internal Consistency of the Functional Impact Tool for Mobility Devices (Mandy McDonald, OTL)

Project# 892
IRBNet# 1967724
A Longitudinal fMRI study of Theistic Relational Processing in Individuals with Neurologic Dysfunction
(Brick Johnstone, PHD)
Sponsor: Shirley Ryan Ability Lab (through the John Templeton Foundation)

Project# 893
IRBNet# 1955662
Sociocultural Determinants of Recovery, Health, and Community Participation in Asian Americans with Disabilities (Jessica Conklin, PHD)
Sponsor: NIDILRR Switzer Fellowship Program

Project# 911
IRBNet# 982013
Days of Intravenous Vancomycin Therapy in Patients with Pneumonia after Negative MRSA Nasal Screen
(Lauren Wilcox, PharmD)

Project# 912
IRBNet# 1967715
Evaluation of Vitamin D Goal Level Achievement in Brain Injury Patients at an Inpatient Rehabilitation Center?
(Elisabeth Webb, PharmD)

Project# 913-NR
IRBNet# 1978156
mRehab RERC: Implementation of SEAM Platform for Home Exercise Program (Mike Jones. PHD)
Sponsor: NIDILRR

Project# 914
IRBNet# 1978976
Green Spaces and Park Survey (Raeda Anderson, PHD)

Project# 915
IRBNet# 1957410
Autocoach Evaluation (Emma Harrington)

Number of Studies in Section: 13

Total Number of Studies: 96