

Craig Hospital Research Summary – 2020

Mission Statement:

“To conduct high-quality research to promote optimal health, independence, and life quality for people affected by spinal cord injury and traumatic brain injury.”

Core Values:

- Advance the state of the science of disability and rehabilitation research.
- Adhere to ethical and legal principles governing research activities.
- Conduct research and dissemination that is meaningful to our constituents.
- Involve individuals with disabilities and their families, the interdisciplinary treatment team, other professionals and community members, in the research and dissemination process.
- Integrate research in clinical practice, education and evaluation.
- Foster a research culture throughout Craig Hospital.
- Promote scientific enquiry that will contribute to evidence-based practice.
- Lead and participate in spinal cord injury and traumatic brain injury collaborative research.
- Participate in setting the national disability research agenda.

Introduction:

The Craig Hospital Research Department currently has a staff of 27 with an annual budget of \$6.9 million in federal, state, and foundation-sponsored grants, devoted to conducting a wide variety of applied spinal cord injury (SCI) and traumatic brain injury (TBI) rehabilitation research. In addition, funds raised from the annual PUSH Dinner support clinical research.

The Research Department was established in 1974 when Craig Hospital was first awarded a Spinal Cord Injury Model System grant from the US Department of Health and Human Services, National Institute on Disability, Independent Living and Rehabilitation Research (NIDILRR). In 1998, Craig’s brain injury program received a similar designation when it was first named a TBI Model System. Each Model System project consists of a three-pronged research effort: contributing to a national longitudinal database, conducting local research projects that are of interest and importance to Craig, and collaborating with other Model Systems in research of common interest.

In 2006, Craig was named the TBI Model Systems National Data and Statistical Center, managing the TBI National Database and coordinating research among all TBI Model Systems. Perhaps the greatest benefit of the Model Systems programs is the research climate they have spawned here at Craig Hospital, giving us the expertise to successfully compete for and obtain funding from other sources as well.

Craig currently receives research funding not only from NIDILRR, but also from MindSource (formerly the Colorado TBI Trust Fund), the Congressionally Directed Medical Research Program (CDMRP) which is part of the Department of Defense, the Craig H Neilsen Foundation and other research organizations via subcontracts, and foundations. As research has become more important to the mission and reputation of Craig, the Research Department has increased collaboration with other institutions by leading and participating in multi-center research and becoming a national data coordinating center. Below is a list of Craig Hospital’s currently funded research projects.

GENERAL CLINICAL RESEARCH FUNDS		
PUSH dinner proceeds		2013 - ongoing
The purpose of Craig Hospital's Clinical Research Fund is to provide funding for clinical research projects. This includes startup funding to cover the clinician's time to design research projects, equipment if necessary, consultations, and costs to conduct the actual studies.		
Contact:	<i>Susie Charlifue</i>	<i>303-789-8306</i>

Spinal Cord Injury (SCI) Research

ROCKY MOUNTAIN REGIONAL SPINAL INJURY SYSTEM (SCI MODEL SYSTEM)		
National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR)		2016 - 2021
Grant #90SI5015-01-00	PI(s): Charlifue, Monden, Coker	\$2,418,222

Simvastatin to Improve Bone Health in SCI: A Double-Blind, Randomized, Placebo-Controlled Clinical Trial		
This clinical trial led by Craig Hospital will determine whether a 12-month course of daily simvastatin 1) prevents bone loss in the paralyzed lower extremity, 2) promotes neurological recovery after SCI, and 3) reduces neuropathic pain after SCI.		
Contact:	<i>Susie Charlifue</i>	<i>303-789-8306</i>

LEAD Module Project: Utilization of Complementary and Integrative Healthcare to Treat Pain in Persons with Spinal Cord Injury		
The goal of this module project is to provide comprehensive information regarding utilization of complementary and integrative healthcare (CIH) to treat pain in people with SCI, and barriers and facilitators to utilization for people with SCI.		
Contact:	<i>Jennifer Coker</i>	<i>303-789-8229</i>

Module Project: Using a Health Technology Assessment Framework for Evaluating the Utilization and Efficiency of Wearable Exoskeletons for SCI Rehabilitation		
This collaborative SCI module led by the Rehabilitation Institute of Chicago will obtain evidence that informs consumers, clinicians, insurers, and manufacturers about the utilization and cost-effectiveness of RT-exo in inpatient, outpatient, and community settings.		
Contact:	<i>Susie Charlifue</i>	<i>303-789-8306</i>

Module Project: Residential Instability in Chronic SCI: An Investigation of Patterns and Consequences		
This collaborative SCI module led by Northern New Jersey Spinal Cord Injury Model System (Kessler). The main objective of this exploratory project is to better understand residential instability among people with SCI and generate new knowledge on this potentially important and unexplored challenge to health, healthcare utilization, and independent living.		
Contact:	<i>Susie Charlifue</i>	<i>303-789-8306</i>

Module Project: Impact of pain at follow-up in individuals with SCI		
This collaborative module, led by University of Miami will characterize the type of pain in individuals with SCI, its location in the body, its intensity, and its interference with mood, sleep, work and daily function using the International SCI Pain Basic Data Set 2, as well as assess the pain treatment(s) used by individuals with pain and SCI.		
Contact:	<i>Susie Charlifue</i>	303-789-8306

MULTI-SITE COLLABORATIVE RESEARCH PROJECT		
National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR)		2017 – 2022
90DPHF0002-01-00	PI(s): Charlifue, Monden, Coker	\$2,500,000
Reinventing Yourself after SCI: A multi-site randomized controlled trial of an intervention to improve outcomes after spinal cord injury. Craig Hospital is the lead site in collaboration with Kessler and the University of Michigan aimed at increasing SCI-specific and general self-efficacy beliefs, enhancing emotional well-being, improving participation in society for people with SCI living in the community, and increasing resilience.		
Contact:	<i>Susie Charlifue</i>	303-789-8306

LIFESTYLE INTERVENTION TARGETING ENHANCED HEALTH AND FUNCTION FOR PERSONS WITH CHRONIC SCI IN CAREGIVER/CARE-RECEIVER RELATIONSHIPS: EFFECTS OF CAREGIVER CO-TREATMENT		
National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR)		2015 - 2020
90DP0074-01-00	PI(s): Charlifue	\$763,695
Lead Center: University of Miami – Randomized Clinical Trial to determine the efficacy of a lifestyle intervention to improve health and function of individuals with SCI.		
Contact:	<i>Susie Charlifue</i>	303-789-8306

NEURORECOVERY NETWORK LOCOMOTOR TRAINING		
Christopher and Dana Reeve Foundation		2012 – ongoing
	PI(s): Tefertiller	
Activity based therapy involves using intense practice and repetition of task specific mobility activities with the goal of improving walking ability and functional independence in individuals with paralysis. The purpose of the national database is to identify demographic variables and quantify mobility outcomes as well as quality of life outcomes associated with participation in this activity based therapy program. The database is also analyzed to track individual treatment program performance compared to network-wide aggregate data.		
Contact:	<i>Candy Tefertiller</i>	303-789-8251

SCI QOL VALIDATION		
Craig H. Neilsen Foundation		2017 - 2020
	PI(s): Charlifue	\$49,048
This study will assess the reliability and validity of the International SCI QoL Basic Data Set (SCI-QoLBDS), evaluating if there are differences in scores and understanding of items across languages and cultures.		
Contact:	<i>Susan Charlifue</i>	303-789-8306

EFFECTS OF EKSO-ASSISTED GAIT TRAINING ON BONE HEALTH AND QUALITY OF LIFE: A RANDOMIZED CLINICAL TRIAL		
Department of Defense		2017 - 2020
Grant #: W81XWH-15-2-0078	PI(s):	\$2,364,955
The purpose of this study is to determine whether exoskeleton-assisted gait training increases bone strength in the paralyzed lower extremity and improves quality of life after SCI. Secondly, to determine whether gait training improves the following related outcomes and mediators of quality of life: mood, pain, and cortical activity of related emotional networks in the brain.		
Contact:	<i>Susie Charlifue</i>	303-789-8306

DEVELOPMENT AND VALIDATION OF AN ABBREVIATED COGNITIVE SCREENING BATTERY FOR INDIVIDUALS WITH SCI		
New Jersey State Department of Health/Spinal Cord Research		2019 – 2022
Grant #: CSCR19IRG021	PI(s): Monden, Coker	\$150,679
The purpose of this project is to validate the use of a brief, abbreviated cognitive screening battery, developed from established, common, motor-free neuropsychological tests that are sensitive to SCI-related cognitive impairment.		
Contact:	<i>Jenn Coker</i>	303-789-8229

STIGMA FOLLOWING SCI AND ITS IMPACT ON PSYCHOSOCIAL OUTCOMES		
American Psychological Foundation		2017 - 2020
	PI(s): Monden	\$10,000
The goals of the proposed study are to assess the relationship between stigma and psychosocial outcomes (mood disturbance, quality of life, social participation, self-efficacy, perceived disability, and return to work/school) among individuals with spinal cord injury (SCI), and examine the potential mediating and/or moderating effects of sociodemographic (gender, race) and injury factors (level of injury, time since injury, injury etiology, injury completeness) with stigma on psychosocial outcomes.		
Contact:	<i>Kimberley Monden</i>	303-789-8562

ASSISTIVE TECHNOLOGY AND FUNCTIONAL OUTCOMES FOLLOWING SPINAL CORD INJURY		
Department of Defense		2018 - 2021
	PI(s): Monden	\$638,000
The long-term goals of this project are to identify perceived barriers and facilitators to access to and utilization of assistive technology in veteran and civilian populations, and quantify the impact of assistive technology on outcomes following tetraplegia. This study will evaluate the impact of assistive technology (AT) on functional and psychosocial outcomes among people with high-level spinal cord injury (SCI) using both focus group sessions and a survey.		
Contact:	<i>Kimberley Monden</i>	<i>303-789-8562</i>

FUNCTIONAL MRI IN SCI PATIENTS WITH BELOW-LEVEL NEUROPATHIC PAIN		
Craig Hospital Foundation		2018 - 2020
	PI(s): Falci	\$29,000
To Determine whether DREZ procedure changes cortical activity of emotional and pain processing networks in the brain. We will also determine if DREZ procedure improves the following related outcomes: mood, pain, quality of life.		
Contact:	<i>Susie Charlifue</i>	<i>303-789-8306</i>

TRANSCUTANEOUS SPINAL CORD STIMULATION IN COMBINATION WITH MASSED PRACTICE TRAINING IN SPINAL CORD INJURY		
Craig Hospital Foundation		2018 - 2020
	PI(s): Tefertiller	\$44,300
The primary objective of this study is to determine the feasibility and safety of using transcutaneous electrical stimulation in a clinical setting to promote neurological recovery in individuals with SCI. Our secondary objective is to collect pilot data assessing neurological and/or functional recovery due to transcutaneous electrical stimulation in individuals with chronic SCI.		
Contact:	<i>Candy Tefertiller</i>	<i>303-789-8251</i>

VALIDATING THE INJUSTICE EXPERIENCE QUESTIONNAIRE IN A SPINAL CORD INJURY SAMPLE		
Craig Hospital Foundation		2018 - 2020
	PI(s): Monden	\$47,000
This study has two primary aims: (1) to validate the measurement model of the Injustice Experience Questionnaire in a sample of individuals with SCI, and (2) to test the reliability and validity of the IEQ in the same sample.		
Contact:	<i>Kimberley Monden</i>	<i>303-789-8562</i>

BIDETS FOR INDEPENDENCE AND QUALITY OF LIFE		
Craig Hospital Foundation		2019-2020
	PI(s): Severe	\$13,018
The purpose of this study is to determine if utilization of a bidet could reduce the time to complete a bowel program, improve hygiene, decrease caregiver burden, and improve satisfaction/quality of life related to bowel routines. Additionally, bidet use may allow some individuals with spinal cord injury to achieve independence with their bowel program when, without the bidet, they have needed some caregiver assistance.		
Contact:	<i>Ellen Severe</i>	<i>303-789-8243</i>

BIOFEEDBACK FOR TREATMENT OF ANXIETY ASSOCIATED WITH CHRONIC SPINAL CORD INJURY		
Neilsen Foundation		2019 - 2021
	PI(s): Monden	\$200,000
<p>The proposed pilot study is designed to find a signal of a treatment effect that would support a larger study and to examine the feasibility of conducting a larger study biofeedback intervention to treat anxiety in individuals with SCI. Biofeedback training monitors a person's breathing and heart rates and teaches them to slow their breathing to better match their heart rate. This type of training has been shown to strengthen a person's psychological resilience.</p>		
Contact:	<i>Kimberley Monden</i>	<i>303-789-8562</i>

CRAIG CAREGIVER ASSESSMENT OF REWARDS AND EFFORT (C²ARE) – VALIDATION OF A NEW TOOL TO ASSESS CAREGIVER DISTRESS AND BENEFIT		
Neilsen Foundation		2019 - 2021
	PI(s): Charlifue	\$400,000
<p>The aim of the project is to validate C²ARE for assessing SCI caregiver distress and benefit. Validation will include extensive psychometric analysis of C²ARE data collected in a new large sample of SCI caregivers to fully evaluate its validity and test-retest reliability. Having a valid and reliable measurement tool specifically designed for use in SCI has the potential to be useful both in the clinical and research settings. Such an assessment can help clinicians and service providers better target their interventions to family caregivers, and will add to the resources that can be used by researchers to determine if caregiver intervention studies are effective.</p>		
Contact:	<i>Susie Charlifue</i>	<i>303-789-8306</i>

Traumatic Brain Injury (TBI) Research

THE ROCKY MOUNTAIN REGIONAL BRAIN INJURY SYSTEM (TBI MODEL SYSTEM)		
National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR)		2017 - 2022
Grant # 90DPTB0007-01-00	PI(s): Harrison-Felix, Monden, Mellick	\$2,295,000

Self-Advocacy for Independent Life (SAIL) after TBI		
PI(s): Hawley, Harrison-Felix		
This study will evaluate the efficacy of an intervention to empower people with TBI to improve their lives by gaining the skills to advocate for needed services and resources.		
Contact:	<i>Lenny Hawley</i>	<i>303-789-8570</i>

LEAD Module Project: Development and Assessment of Crosswalks in the TBIMS Database		
Using data from the National TBI Model System Database we intend to evaluate various procedures for creating crosswalks between the FIM™ and the Continuity Assessment Record and Evaluation (CARE) Item Set, as well as evaluate the existing crosswalk between the Patient Health Questionnaire (PHQ-9) and the Traumatic Brain Injury Quality-of-Life (TBI-QOL) Depression Short Form and between the Generalized Anxiety Disorder 7-item (GAD-7) scale and the TBI-QOL Anxiety Short Form.		
Contact:	<i>Dave Mellick</i>	<i>303-789-8563</i>

Module Project: Caregiver Resilience: A Longitudinal Investigation		
This collaborative TBI module led by Virginia Commonwealth University TBIMS focusing on resilience offers a promising opportunity to better understand and conceptualize caregivers' experiences after TBI and will allow us to gain a new and better understanding of how caregiver attributes, namely resilience, relate to survivor outcomes and caregiver burden and needs.		
Contact:	<i>Kimberley Monden</i>	<i>303-789-8562</i>

Module Project: Return to Driving after Moderate-Severe TBI: Who, When, Where and How Safe?		
This collaborative TBI module led by the University of Alabama-Birmingham TBIMS intends to expand knowledge concerning driving behaviors for persons with a TBI and establish predictors of return to driving and safe driving.		
Contact:	<i>Kimberley Monden</i>	<i>303-789-8562</i>

THE TRAUMATIC BRAIN INJURY MODEL SYSTEMS (TBIMS) NATIONAL DATA AND STATISTICAL CENTER (NDSC)		
National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR)		2016 – 2021
Grant #90DP0084-01-00	PI(s): Harrison-Felix	\$3,412,500
<p>The TBIMS NDSC manages the TBI Model Systems National Database and provides technical assistance, training, and methodological consultation to 16 centers and 3 follow-up sites as they collect and analyze longitudinal data from people with TBI in their communities, and as they conduct research toward evidence-based TBI rehabilitation interventions. A grant supplement was awarded in FY18-19 for \$100,000 to develop a plan to determine the prevalence of TBI by state and, within each state, the use of home and community based services by individuals with TBI.</p>		
Contact:	<i>Dave Mellick</i>	<i>303-789-8563</i>

TRAUMATIC BRAIN INJURY MODEL SYSTEMS (TBIMS) MULTI-SITE COLLABORATIVE RESEARCH PROJECT		
National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR)		2018 – 2023
90DPTB-01-00	PI(s): Harrison-Felix, Monden, Hoffman	\$3,127,000
<p>Characterization and Treatment of Chronic Pain after Moderate to Severe TBI. Craig Hospital is the Lead site collaborating with 12 TBI Model Systems Centers and one VA TBI Model Systems Center to examine chronic pain and pain treatment after TBI to improve the health and function through improved patient stratification and treatment guidelines. Outcomes from this study will include educational materials on chronic pain and pain treatment to benefit patients, family members, clinicians, and policymakers. A grant supplement was awarded in FY18-19 for \$127,000 to improve the understanding of opioid use and pain management after moderate to severe TBI.</p>		
Contact:	<i>Kimberley Monden</i>	<i>303-789-8562</i>

TRACK-TBI		
NIH, National Institutes of Neurological Disorders and Stroke, and Department of Defense subcontracts from the University of California, San Francisco to Craig Hospital		2017 - 2020
	PI(s): Harrison-Felix	~ \$20,000
<p>This is a collaboration with Denver Health in a longitudinal study of TBI that enrolls participants through Level 1 Trauma Centers across the US. Participants represent the entire spectrum of age, demographics, and injury severity. The overall goal of TRACK-TBI is to improve TBI classification/taxonomy for targeted clinical treatment trials, in order to improve TBI outcome assessments, such that the size and costs of clinical trials can be reduced, identify the health and economic impact of Mild TBI patient disposition, and create a legacy database with analytic tools and resources to support TBI research.</p>		
Contact:	<i>Cindy Harrison-Felix</i>	<i>303-789-8565</i>

ROLE AND NEUROANATOMIC BASIS OF CONCURRENT MEDICAL CONDITIONS IN OUTCOME FOLLOWING MODERATE TO SEVERE TRAUMATIC BRAIN INJURY: DEVELOPMENT OF A TBI-SPECIFIC INDEX

Mindsources Brain Injury Network (formerly Colorado Brain Injury Research Program)	2017 - 2020
PI(s): Whiteneck	\$348,498
The goal of this project is to utilize data on co-occurring medical conditions to assess the impact of these conditions on outcome in traumatic brain injury. The study will incorporate a novel system for assessing the acuity of concurrent medical conditions to develop a TBI-specific index for use in brain injury research.	
Contact: <i>Gale Whiteneck</i>	<i>303-789-8204</i>

DISCHARGE PLANNING AFTER TBI

A grant to the University of Washington from the Patient-Centered Outcomes Research Institute (PCORI) with a subcontract to Craig Hospital as the Data Coordinating Center	2017 - 2020
PI(s): Mellick	\$382,823
This is a multi-center randomized control trial that aims to compare the effectiveness of Standardized Discharge Care (SDC) vs. Optimized Transition Care (OTC) on improving patient-reported outcomes of (1) participation, and health-related quality of life, for individuals with moderate-to-severe TBI who are discharged from inpatient rehabilitation	
Contact: <i>Dave Mellick</i>	<i>303-789-8563</i>

DEVELOPMENT AND IMPLEMENTATION OF A TBI REGISTRY AND OUTREACH PROGRAM

Administration for Community Living grant to Mindsources Brain Injury Network (formerly Colorado Brain Injury Research Program) with subcontract to Craig Hospital	2018 - 2021
PI(s): Eagye	\$60,000
The goal of this study is to analyze data from the TBI Surveillance System (in partnership with the Colorado Department of Public Health and Environment (CDPHE)) and the Craig prevalence study to develop a data-driven, targeted outreach and linkage program to be operationalized by Brain Injury Alliance of Colorado (BIAC).	
Contact: <i>CB Eagye</i>	<i>303-789-8557</i>

COMPLEMENTARY AND INTEGRATIVE HEALTHCARE (CIH) UTILIZATION AND BARRIERS TO UTILIZATION IN PEOPLE WITH TBI

Craig Hospital Foundation	2018 - 2020
PI(s): Coker	\$45,000
The goal of this study is to characterize the utilization of complementary and integrative healthcare (CIH) by people with traumatic brain injury (TBI), to identify barriers to utilization of CIH by people with TBI, and to determine the relationship between utilization of CIH and functional and psychosocial outcomes.	
Contact: <i>Jennifer Coker</i>	<i>303-789-8229</i>

LANGUAGE DISORDERS IN TRAUMATIC BRAIN INJURY

Craig Hospital Foundation	2019 - 2020
PI(s): Frey	\$16,315
The purpose of this study is to retrospectively investigate the incidence of aphasia in traumatic brain injury as well as the relationship between impaired language and orientation testing scores.	
Contact: <i>Kim Frey</i>	<i>303-789-8278</i>

VALIDATING THE RUFF NEUROBEHAVIORAL INVENTORY (RUFF) AS AN AWARENESS MEASURE.		
Craig Hospital Foundation		2019 - 2020
	PI(s): Chao, Schraa	\$1,000
The purpose of this study is to validate the RNBI as an awareness measure by using the discrepancy between caregiver and patient self-report to determine level of awareness, and therefore predicted prognosis, at time of discharge from inpatient rehabilitation. Impaired self-awareness following a traumatic brain injury (TBI) can reduce the effectiveness of rehabilitation, resulting in poorer outcomes e.g. employability, community reintegration.		
Contact:	<i>Dominique Chao</i>	<i>720-569-0597</i>

MANUAL WHEELCHAIR CONFIGURATION FOR INDIVIDUALS WITH HEMIPLEGIA: EFFECTS OF FRAME TYPE ON EFFICIENCY OF PROPULSION		
Permobil		2019 - 2020
	PI(s): Tefertiller	
The purpose of this industry-funded study is to address the importance of axle position and frame type on upper extremity propulsion. Understanding the effects of axle position and frame type on this propulsion technique is critical in assuring frame recommendations that maximize independence and life participation.		
Contact:	<i>Candy Tefertiller</i>	<i>303-789-8251</i>

VIRTUAL REALITY AND TREADMILL TRAINING AFTER TRAUMATIC BRAIN INJURY		
Craig Hospital Foundation		2019 - 2020
	PI(s): Tefertiller	\$68,613
The primary goal of this study is to evaluate the safety and feasibility of using treadmill training augmented with virtual reality in a sample of individuals with chronic TBI and to provide data to support a fully powered randomized controlled trial in the future that would evaluate the efficacy of this intervention in TBI		
Contact:	<i>Candy Tefertiller</i>	<i>303-789-8251</i>

AN INTERDISCIPLINARY APPROACH TO ASSESSMENT OF READINESS FOR A BEHIND THE WHEEL DRIVING EVALUATION FOLLOWING BRAIN INJURY		
Craig Hospital Foundation		2019-2020
		\$15,472
The purpose of this retrospective study is to determine if using a multi-disciplinary approach to assess and improve upon the skills required to pass the Behind-The-Wheel (BTW) evaluation through therapy and practice prior to the evaluation will increase the success in attaining clearance to return to driving.		
Contact:	<i>Michael Bruno</i> <i>Charlene Hamrick</i>	<i>303-789-8186</i> <i>303-789-8296</i>

Spinal Cord Injury (SCI) and Traumatic Brain Injury (TBI) Research