

## HHRF Research Grant Application Cover Page

Title of Project: Effects of Hippotherapy on Balance and Gait in Ambulatory Children with Spastic Cerebral Palsy      Submission Date: May 4, 2010

Principal Investigator Name and Title: Debbie Silkwood-Sherer DHS, PT, HPCS  
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(NOTE: The contact person is the only person with whom HHRF will have direct contact. The contact person receives all letters and notification from the HHRF office.)

Institute: Central Michigan University

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Primary focus area of the investigation (i.e. mental health, physical therapy, speech therapy, occupational therapy, education, recreation, the horse-human relationship): Physical Therapy and balance, quality of life

Years and Titles of past HHRF Funding Applications:

2008 Do Children with Mild to Moderate Balance Disorders Improve More when Hippotherapy is Included in their Rehabilitation Program?

### Safety and quality standards for EAA/T:

Name(s) of personnel directly involved with any associated EAA/T:

Nancy H. McGibbon MS, PT, HPCS

Ellen Erdman DPT, HPCS

Tricia Coates OTR/L HPCS

Nancy O'Meara Krennek PT, HPCS

Joann Benjamin PT, HPCS

Trudy Epstein OT, HPCS

Are all listed personnel certified to provide the activities? Yes  No  (If yes, please provide member numbers with each name)

Certifying organization's name, website and contact information, or evidence of equivalent standards adhered to (please attach explanation if necessary):

**Professional Testing Corporation** certifies Hippotherapy Clinical Specialists: [www.ptcny.com](http://www.ptcny.com) ; 1350

Broadway, 17th Floor New York, New York 10018 Phone: 212-356-0660 in conjunction with the **American Hippotherapy Certification Board**; 3038 SW 91<sup>st</sup> Terrace, Gainesville, FL 32608

**Site standards for EAA/T:**

Is the site providing EAA/T programming accredited to do so? Yes  No  Member Number: See APPENDIX E

Therapeutic Riding of Tucson (TROT)

Quest Therapeutic Services, Inc.

Turning Point Therapy

Ride on Center for Kids (ROCK)

Ride on Therapy Services

Accrediting organization's name, website address and contact information, or evidence of equivalent standards adhered to (please attach explanation if necessary):

NARHA member centers: [www.narha.org](http://www.narha.org) 1-800-369-RIDE

Will others collaborate or consult with you on this project? Yes  No  If yes, attach letters to you that state their agreement to do so. APPENDIX E

Brief description of project (60 words or less): The purpose of this randomized controlled clinical trial is to determine if 12 weeks of weekly hippotherapy, when added to the usual therapy for young children with CP, will improve their balance and gait more than their usual therapy alone. We will also evaluate the children's visual motor integration, activities, participation and quality of life before and after hippotherapy.

Pilot Study Completed? Yes  No  Completion Date: 2007

Is project Institutional Review Board approved? Yes  No  Pending

Please attach a copy of the IRB application.

Start Date of Project: September 2010

End Date of Project: March 2012

Total Project Budget: \$ 54,974

Amount Requested from HHRF: \$49,954

**II. Scientific Abstract** - 200 words or less, double spaced, describing the proposed project.

The purpose of this study is to determine if the addition of 12 weekly hippotherapy sessions to a child's usual therapy program will improve balance and gait. Thirty children with spastic cerebral palsy, ages 3 – 6 years, will be recruited for this multi-site, randomized controlled clinical trial. An intervention group will receive 12 weeks of once weekly hippotherapy in addition to their usual therapy (Th+H), and a control group will continue with their usual therapy (Th) without hippotherapy. All children will be tested at baseline, 12, 24, and 36 weeks.

Outcome measures: Balance and gait measures will be the pediatric balance scale, the standardized walking obstacle course, and the 1-minute walk test. The Activities Scale for Kids (5-6 yr) and the Children's Assessment of Participation and Enjoyment-preschool version (3-4 yr) will measure activities and participation. The Beery Test of Motor Integration will measure visual-motor integration, and the PedsQL-CP will be used to measure health-related quality of life.

Statistical analysis of the data will determine if the children who received hippotherapy made greater gains on the tests than those who did not receive hippotherapy and if there are correlations between the specific measures.

### III NEED/JUSTIFICATION

Balance problems are common in children with spastic cerebral palsy (CP) and the resultant challenges can have profound effects on their quality of life: poor standing balance, awkward gait, difficulties walking on uneven terrain or in new environments, tendencies to trip and fall, difficulties with motor coordination during games and active play (hopping, jumping, ball handling, etc) and general clumsiness in many motor activities. As a result, these children often hesitate to engage with other children for fear of losing balance and falling, being unable to ‘keep up’, or being ‘made fun of’.

Poor balance is usually a result of poor postural control, and postural control is an integral part of a human’s ability to interact in their environment and provide coordinated movement.<sup>1</sup> It is defined as the ‘ability to control the body position in space for the purpose of stability and orientation’.<sup>2</sup> Adequate postural control requires maintaining the center of mass (COM) over the base of support (BOS) in a given sensory environment.<sup>3</sup> When the COM goes beyond the BOS, the child will lose balance and fall unless he quickly steps or grabs hold of a support. Essential to effective balance are the development of neuromuscular balance strategies (ankle, hip, and stepping) and the development and integration of information from the visual, somatosensory, and vestibular systems so that changes in the environment can be either reacted to or anticipated. For children with CP this lack of postural control is often the rate-limiting factor in their ability to participate in activities at home, school and play.<sup>4</sup>

#### *Treatment of postural control deficits and balance disorders*

The most commonly used interventions to train postural control and balance in children with CP consist of either providing perturbations to a child, or passively assisting the child to weightshift in different directions.<sup>5</sup> Harris and Roxborough<sup>6</sup> noted the scant amount, as well as

low level, of empirical evidence on the effectiveness of physical therapy intervention for treatment of postural control in children with CP. Their review showed that treatment of postural control fell into 5 categories; seating devices (n=5), balance training protocols or devices (n=3), ankle-foot orthoses (n=2), motor therapy (n=1), and the use of Lycra garment (n=1). The three research projects specific to balance training protocols assessed the effects of externally generated movement on improving postural control. Two of these studies had less than 6 participants and found only small improvements in balance following intervention and no carry-over to function.<sup>7,8</sup> The 3<sup>rd</sup> study by Kuczyski and Słonka<sup>9</sup> used a microprocessor-driven artificial saddle to provide perturbations to 25 children with CP (ages 3-10 years). This artificial saddle mimicked the 3D movement of the horse. All 25 children demonstrated improved postural sway measurements in quiet standing following 3 months of biweekly sessions of 20 minute duration but carry-over to function was not assessed.

No hippotherapy studies have directly focused on balance in children with CP; however, a number of studies have shown evidence of improvement in factors *related* to balance and provide groundwork for this study. Results of hippotherapy research have shown improvements in standing posture;<sup>10</sup> muscle symmetry of the trunk and upper leg muscles during standing and walking;<sup>11,12</sup> dynamic head and trunk stability;<sup>13</sup> reaching skills;<sup>13</sup> and function as measured by the Gross Motor Function Measure and Pediatric Evaluation of Disability Inventory;<sup>14,15</sup> and decreased energy expenditure during walking.<sup>15</sup> Unfortunately, the small number of participants in most of the studies, lack of control groups, and experimental designs make the quality of most of the evidence low level.<sup>16</sup> The lack of large randomized controlled trials remains a barrier to the widespread inclusion of hippotherapy in the treatment of balance problems in children with CP.

Debusse<sup>17</sup> in her qualitative study of the effects of hippotherapy from the user's perspective reported that children and adults with CP who received hippotherapy reported improved trunk control and walking ability with carryover to daily living skills and psychological improvements such as increased confidence and self-esteem. More importantly, they all reported that they did not get any of these benefits from the more traditional therapies they had been receiving for years.

Westcott and Burtner<sup>18</sup> have proposed that habilitation of postural control in children with CP include activities that address the musculoskeletal, motor and sensory processing factors. They further suggest the intervention focus on static as well as dynamic equilibrium tasks with mass and random practice in order for improvements in postural control/balance to have effects on children's participation in normal childhood activities. We propose that hippotherapy meets Westcott and Burtner's treatment requirements and that it is ultimately a better treatment for improving balance and gait in children with cerebral palsy than the more traditional methods currently used in rehabilitation.

A 2007 pilot study<sup>19</sup> completed on 16 children 5-16 years of age, with the various diagnoses of Cerebral Palsy, Down Syndrome, Developmental Coordination Disorder, and Autism Spectrum Disorder, demonstrated statistically significant improvement in balance after 6 weeks of twice-weekly hippotherapy, as measured by the Pediatric Balance Scale<sup>20</sup> (PBS) ( $p < .0001$ ) and function as measured by the Activities Scale for Kids<sup>21</sup> (ASK) ( $p < .0001$ ) when compared to their pre-intervention assessments. (Appendix B) Additionally a Spearman rho correlation of .700 ( $p = .003$ ) was found demonstrating a relationship between the PBS and ASK, suggesting improved balance does correlate to function.<sup>19</sup> Gait and visual motor integration were not assessed, although subjective and clinical observation of the children suggested that these

improvements occurred. Finally, the pilot study did not determine if the improvement after hippotherapy was better than what the children would have had with only their traditional therapy, so this question needs to be answered.

#### **IV. RESEARCH NARRATIVE**

##### **RESEARCH QUESTIONS AND HYPOTHESES**

Due to large effect sizes found for the PBS ( $d=1.59$ ) and ASK ( $d=1.51$ ) in the pilot study,<sup>19</sup> we propose to replicate the study on younger children (3-6 year-olds) with more pliable nervous systems and to expand the study in size and scope. We have chosen to limit the subjects to one diagnosis and add a control group for greater scientific rigor.

**Specific Aim #1** – To determine if the addition of 12 weekly hippotherapy sessions to a child’s therapy program will improve balance, gait, and endurance in children with spastic CP, ages 3-6 years.

**H<sub>01</sub>**: For children with spastic CP, twelve weeks of therapy including hippotherapy (Th+H) will improve balance, gait, and endurance to a greater degree than twelve weeks of therapy without hippotherapy (Th), as determined by the Pediatric Balance Scale (PBS), Standardized Walking Obstacle Course (SWOC), and the 1 minute walk test (1MWT).

**Specific Aim #2** – To determine if the addition of 12 weekly hippotherapy sessions to a child’s therapy program will improve visual-motor integration, participation and quality of life.

**H<sub>02</sub>**: For children with spastic CP, 12 weeks of therapy including hippotherapy (Th+H) will improve visual motor integration, participation in daily activities, and quality of life as measured by the Beery-Buktenica Development Test of Visual-Motor Integration (VMI); the Activities Scale for Kids (ASK 5-6 year olds)/PreSchool Child’s Activities

Participation and Enjoyment (CAPE 3-4 year olds); and Peds Quality of Life- CP (PedsQL-CP) respectively.

**Specific Aim #3** - To determine if there is a relationship between balance and gait and visual-motor integration.

**H<sub>02</sub>:** There will be a correlation between balance and gait scores measured by the PBS, SWOC, and 1 MWT and visual motor integration scores as measured by the VMI, in children with spastic CP.

**Specific Aim #4** – To determine if there is a relationship between balance and gait and the child’s participation and quality of life.

**H<sub>03</sub>:** There will be correlation between the balance and gait measures (PBS, SWOC, 1MWT) and the activity and participation measures of the ASK, PreSchool CAPE, and PedsQL-CP in children with spastic CP.

**Specific Aim #5** – To determine if effects of hippotherapy in the domains measured are maintained after hippotherapy treatment is discontinued.

**H<sub>04</sub>:** Benefits of hippotherapy for children with spastic CP will be maintained following cessation of hippotherapy services.

## **DESIGN**

This study is a multi-site, randomized repeated-measures controlled clinical trial. It will consist of 2 groups, an intervention group who will receive 12 weeks of once weekly hippotherapy in addition to their usual therapy (Th+H), and a control group who will continue with their usual therapy (Th) without hippotherapy. All children will be tested before and after the 12 week treatment period as well as at week 24. The group receiving hippotherapy will also be tested at week 36. (Appendix C)



## MEASURES

The children will be assessed for balance ability utilizing the Pediatric Balance Scale (PBS)<sup>20</sup> (test-retest reliability ICC=0.998; interrater reliability ICC = 0.977). In addition to the tool's scoring method of 0-4, the items of single leg stance, tandem stance, alternating stool touch, and eyes closed will be timed. The reach forward item will be measured using a tape measure and recorded in centimeters. Adding timing of these specific items as well as measuring reach was found to be beneficial for data analysis in the 2007 pilot study for children with the milder balance deficits. The PBS takes approximately 15 minutes to complete, thus fits into the attention span of 3-6 year old children, and with its high interrater reliability will be suitable for a multi-center study. We also found in the pilot study that it had a high interrater reliability when scored via videotape as well (ICC (2,1) range 0.88 for baseline to 0.94 for post-test scores).<sup>19</sup> This is important as the PBS assessments will be videotaped.

Measurement of gait will be assessed utilizing the Standardized Walking Obstacle Course (SWOC),<sup>22</sup> which has a test-retest reliability of  $p=0.97$ , interrater reliability of  $r=0.96-1.0$ , and concurrent validity with the Fifty Foot Walk Test of  $r=.072-0.88$ .<sup>23</sup> The SWOC was developed as a clinical assessment tool to assess ambulation in environments similar to what children would find in the home, community and at school. (Appendix D) It also requires children to carry objects while ambulating, which is not found in most other assessments of children's gait. Additionally the SWOC requires minimal equipment and with its high interrater reliability is ideal for a multi-center study. The SWOC also only takes approximately 15 minutes to complete.

Gait speed is often used as a measure of function and energy efficiency, therefore we will measure gait speed with the 1 minute walk test (1MWT). Due to the number of assessments being performed on the children, the 1 minute walk test was chosen since it takes less time to complete than the more traditional 6 minute walk and thus will be less tiring for the children. The

1 MWT has been validated on ambulatory children with spastic cerebral palsy GMFCS levels I, II, and III as a measure for assessing functional ability due to its significant correlation with the Gross Motor Function Measure (GMFM) ( $r=0.92$ ;  $p<0.001$ ).<sup>24</sup> It has also been shown to be a moderate predictor of energy efficiency<sup>25</sup> as well as having good test-retest reliability<sup>26</sup> making it an excellent choice for repeated assessments. The test provides an inexpensive and easy measure of function and energy efficiency.

Visual motor integration will be measured by the Beery-Buktenica Developmental Test of Visual-Motor Integration (VMI) -5<sup>th</sup> edition.<sup>27</sup> This test is used to assess a child's ability to integrate and coordinate their visual perceptual and motor abilities. The test consists of 3 sections that measure visual-motor integration, visual perception, and motor coordination. This test is primarily a paper and pencil test in which the child traces and copies shapes. The interrater reliability of the test is 0.94 – 0.98 for the different portions of the test. Test-retest reliability ranges are 0.83-0.87 for the different sections.<sup>27</sup> This test takes 10-15 minutes for the child to complete. It requires no special equipment to administer and is able to differentiate between aspects of visual-motor integration difficulties, visual perceptual difficulties and/or motor coordination difficulties.

The Activities Scale for Kids (ASK)<sup>21</sup> and the PreSchool version of the Children's Assessment of Participation and Enjoyment (CAPE)<sup>28</sup> will be used to measure activities and participation. Test-retest reliability of the ASK is  $ICC=0.97$ , with a validity of parent-reported ASK scores to clinician ratings of function of  $ICC=0.94$ .<sup>21</sup> This tool was also used in the 2007 pilot and found to be very accurate in providing information regarding the children's ability to function in a variety of settings. The ASK is a self administered 30-item questionnaire that measures the domains of general tasks and demands; mobility; self-care; domestic life; major life

areas such as education, work and community life, thus taking into account the child's natural environment. The ASK has minimal ceiling effects, no floor effects and changes in score by 1.73 standard deviations have been shown to be clinically important change.<sup>29</sup> The ASK has only been validated for children as young as 5 years of age and thus will only be used for the 5 and 6 year old children. The newly developed Pre-School CAPE<sup>28</sup> will be used as the measure of participation for the 3-4 year old children. It is based on the CAPE designed for children 6-15 years of age with activities more appropriate to preschool children, such as skill development, physical recreation, and play/social activities. Early research shows it has good construct validity and reliability (r ranges from 0.62-0.71 for activity type), while the test- retest reliability is similar for children with (ICC=0.85) and without disability (ICC=0.83).<sup>28</sup>

The PedsQL is an instrument that measures health-related quality of life.<sup>30</sup> We will use the module specifically designed for children with CP. The test consists of 23 items incorporating physical, emotional, social, and school function, and can be used for children 2-18 years. Total scale score reliability is reported as 0.88 for the Child Self-Report and 0.90 for the Parent Proxy-Report.<sup>31</sup> We will use the parent proxy reporting for the 3-4 year children and self-report for the 5 and 6 year children. It has been shown to be responsive to clinical change over time.<sup>30</sup>

## **METHODS**

### *Therapist and Sites: Selection and Training*

To assure highest quality hippotherapy practice and strong safety guidelines, a site coordinator with the following qualifications will be contracted to supervise each participating research site: 1) Licensed pediatric physical or occupational therapist who is also a Board Certified Hippotherapy Clinical Specialists® (HPCS). The HPCS designation represents the

highest level of knowledge and experience in hippotherapy. 2) Ability to provide or supervise provision of all hippotherapy treatments at the site. 3) Willingness to sign a written commitment to comply with all study procedures, safety precautions, and timelines, and 4) attend training in all protocols by the co-investigators.

The attached list of sites has indicated a desire to participate in the study (Appendix E). Since not all the sites provide year round services, two sites will be selected based on their ability to recruit and treat participants in a timely manner relative to the grant funding cycle. The specific sites on the list were identified based on the following criteria: 1) must be a NARHA member, 2) must be compliant with safety standards as outlined by NARHA, 3) Program has at least one experienced pediatric physical therapist who has completed at a minimum the Level II American Hippotherapy Association (AHA) equine skills and therapy educational programs, 4) Has the ability to recruit enough subjects within their geographic area; 5) Is able to recruit other pediatric therapists for subject testing who are not involved in the provision of the hippotherapy services; 6) Is committed to comply with all study procedures, safety precautions, and timelines.

The primary investigators will train the site coordinators who will be responsible for subsequent training of site therapists. Training will include a strong emphasis on all safety precautions, as well as correct testing and data management procedures.

### *Interventions*

The therapists providing hippotherapy (Th+H group) will follow a general hippotherapy treatment protocol, which will be reviewed by each therapist prior to initiating hippotherapy. (Appendix E) However, since therapeutic interventions for children must be individualized, the therapist will be allowed some discretion in advancing the treatment protocol. All subjects will wear ASTM approved helmets while on and around the horses. The therapist, in consultation

with the site horse professional, will match each participant to a horse whose width, general movement, and temperament best matches the needs of the child.

Therapy excluding hippotherapy (Th) will include any type of recognized treatment in clinic, school, or in the home for the child's specific needs. Therapists treating these children will be asked to continue with the child's customary therapy program throughout the duration of the study with no changes in protocols or types of intervention. Information on the type of therapy the child is receiving will be collected upon intake for later use in data analysis.

### *Subject selection*

A total of 30 children with spastic cerebral palsy, Gross Motor Function Classification System Level II or II, will be recruited by the site coordinators. There will be no cost to the parents to participate in the hippotherapy sessions. For those children whose hippotherapy treatment cost is not covered by insurance, \$75 per treatment will be paid by grant monies. Parents of control group children will receive \$50 for each testing session to cover time and travel. Subject recruitment will be conducted through fliers and phone contacts with pediatric physical therapy clinics and therapists, pre-schools, and pediatricians.

Inclusion criteria for participation in the study are: 1) between and including the chronological ages of 36 months to 78 months [3-6 ½ years]; 2) a diagnosis of spastic cerebral palsy made by a pediatric neurologist; 3) ability to stand 4 seconds without an assistive device; 4) ability to walk with or without an assistive device for 40 feet; 5) a PBS score of  $\leq 51$ ; 6) able and willing to follow instructions for testing procedures; 7) commitment to attend the 12 intervention sessions and required testing sessions; 8) parents/guardians willing to either complete or help the child complete the ASK/ PreSchool CAPE and PedsQL forms; 9) physician referral for physical therapy services if required by state practice act.

Exclusion criteria will be 1) any orthopedic or medical condition not related to spastic cerebral palsy but that could affect motor ability (eg. sprained ankle); 2) any previous hippotherapy experience or horseback riding experience, 3) uncontrolled seizures, 4) allergies or aversion to horses; 5) refusal to sign the hippotherapy/riding facility's liability release forms; 6) expected implementation of new treatments within one month of the start of the study; or within the study period; 8) insufficient hip mobility to sit astride a therapy horse; 9) inability to understand or carryout instructions.

All parents/ guardians will be required to sign informed consent forms as required by IRB protocol and treatment center's liability forms. Additionally the children will be asked to give verbal assent to participate. IRB approval has been received by CMU's Human Subjects Institutional Review Board. (Appendix G)

#### *Randomization and Group Assignment*

For this study the age of the child, the severity of balance disorder, and the GMFCS level could affect the responsiveness to treatment. Therefore, once a child is determined to be eligible for the study and has been given a preliminary PBS test score and GMFCS level, this information will be forwarded, along with the child's age and gender to the PI. The children will then be assigned to a group through a masked randomization process performed by a graduate research assistant. To ensure even distribution between groups relative to age, GMFCS level, and severity of balance disorder, we will use a blocked randomization technique. Blocking will also ensure a close balance of numbers between the groups at any time during the trial. Once a child has been assigned to a group the information will be forwarded to the site coordinator. The facility will also be given a code for each child in order to maintain confidentiality of assessment information that is to be used on all documents.

### *Data Collection Procedure*

If the child qualifies based on the initial PBS testing, then the SWOC, 1MWT, and the Beery VMI will be administered. Finally, the parent/child will be requested to complete the ASK or PreSchool CAPE, dependent on the child's age, and PedsQL. Only after the initial testing will the parent/child be informed of their group assignment. Additional information to be collected about the child includes time in therapy, types and frequency of traditional therapies (physical, occupational or speech therapy), complementary therapies, past surgeries, botox injections, and other adapted recreational activities in which the child might be participating as these could be covariances to the effects of hippotherapy.

It is planned that testing will occur in a neutral site (such as an elementary school gymnasium) for both the hippotherapy and control groups in an effort to make testing conditions equal for both groups and neutral from the therapy settings. Site coordinators will be responsible for testing implementation and protocol compliance.

All PBS and SWOC tests will be videotaped using a DV camcorder on a tripod, with pre-determined angles to insure that all aspects of the child's performance can be viewed. To distinguish subjects within a videotape, the therapist performing the test will place a placard in front of the lens prior to testing a specific participant. The placard will provide the patient's code number and which test is being performed (i.e. baseline or post-test). Full videotapes will be sent via certified mail to insure delivery to the PI. However if the videotapes should be lost no identifying information will be contained on them. Additional pediatric therapists will be recruited to score the videotapes, thus increasing the objectivity of testing. The placard with identifying test information will be edited from the randomized DVDs prior to being sent to

therapists for scoring. Scoring therapists will be trained to assure acceptable intra- and inter-rater reliability.

In an effort to further remove bias and mask the “paper/pencil” tests, the Beery VMI, ASK, Preschool CAPE, and PedsQL-CP completed forms will be scored by a graduate physical therapy student trained in scoring these scales. This same student will then enter the information into the data base using the patient’s identifying code prior to the PIs seeing the results.

#### **DATA ANALYSIS**

The most current version of SPSS will be used for data analysis. First, the Shapiro-Wilk test will be used to determine if each group’s data is normally distributed.<sup>32</sup> With normal distribution, the independent *t*-test will be used to determine differences between the control and intervention groups’ baseline and post-intervention scores on all tests. The paired-sample (dependent) *t*-test will be used to measure differences between baseline and post-test scores within each group. Since we will be using a repeat measures design, i.e. we have 2-3 posttests depending on group, the two-way repeated measures analysis of variance (ANOVA) will also be run to assess changes within groups across the length of the study period. If the data is not normally distributed, then the appropriate nonparametric tests will be conducted, which are the Mann-Whitney test for between group comparisons and the Wilcoxon signed-rank test for within group comparisons.<sup>32</sup> Friedman’s ANOVA will be used for the repeated measure assessment. Finally, analysis of co-variance tests will be performed to assess for the effects of co-variants such as age, GMFCS levels, gender, other therapies etc. For determining correlation between balance, gait, visual motor integration, participation and quality of life correlation analysis will be performed utilizing Pearson’s correlation for parametric analysis, or Spearman rho if the data does not meet normal distribution.



## V. PROPOSED TIMELINE

It is expected this study will require 15-18 months to complete according to the following timeline:

Months 1-3	Months 4-6	Months 5-10	Months 10-15	Months 15-18
Site visit; training of site coordinator(s) & outcome measures	Recruit children Treatment and testing 30 children & ongoing submission of data			Statistical analysis
Finalize consenting forms and data forms	Recruit and train scoring therapists	Begin masked scoring	Complete masked scoring and data entry	Manuscript preparation

## VI. INTENT TO PUBLISH

We have every intention of publishing in a peer-reviewed journal and believe that this study would be accepted, since both investigators have published hippotherapy research studies in scientific journals. Both researchers have also presented on hippotherapy research at national and international conferences. It would be our intention to present the findings of this study at the NARHA Conference, the AHA Conference, and other national and international venues.

## VII. Budget

Effects of hippotherapy on balance and gait in ambulatory children with spastic cerebral palsy.

					TOTAL 30
					R+H
					15
Comments	Each rx	# rx	Cost Per Child		
<b>TREATMENT</b>					
Hippotherapy treatment	Group R+H	\$75	12	\$900	\$13,500
Treatment without hippotherapy	Group R - pay \$50/test	\$50	3	\$150	\$2,250
<b>Total Treatment</b>					<b>\$15,750</b>
<b>PERSONNEL</b>					
Investigator (1)					\$8,930
Investigator (2)					\$5,000
Site Coordinators	\$500 per coordinator -(2)				\$1,000
Data entry and randomization	Research assistant				\$4,500
Testing therapists (TH+h)	1 hour per child @ \$50 per hour X 4 tests			\$200	\$3,000
Testing therapists (TH)	1 hour per child @ \$50 per hour X 3 tests			\$150	\$2,250
Testing therapists (additional tests)	1/2 hour per child @ \$50 per hour X10			\$25	\$250
Independent video scoring therapists (TH+H)	1 hour per child @ \$50 per hour			\$200	\$3,000
Independent video scoring therapists (Th)	1 hour per child @ \$50 per hour			\$150	\$2,250
Training time for scoring therapists	2 hours each per therapist @ \$50 = \$100 per therapist				\$300
Data transfer and randomization for scoring therapists				\$1,500	\$1,500
<b>Total</b>					<b>\$29,980</b>
<b>PERMANENT EQUIPMENT</b>					
Testing Manuals-					
PBS	no-charge				\$0
SWOC	no-charge				\$0
VMI	1 manual + 100 sf@ \$100 + .25@72.50				\$335
ASK					\$525
CAPE	no-charge				\$0
PEDS-QL-CP Version					\$750
<b>Total</b>					<b>\$1,610</b>
<b>CONSUMABLES-</b>					
Data recording sheets	40 total per child			\$4.00	\$120
DVD's / mini-cassettes	DVD's - 1 to keep and 1 to mail (2 per child)			\$2	\$56
	Scoring DVD's			\$1	\$28
Disposable dark glasses					\$180
Postage	mailing DVD's to scoring office; out to scoring therapists				\$750
Conference calls - 4					\$400
Incidentals	including phone calls to sites				\$400
<b>Total</b>					<b>\$1,934</b>
<b>CONSULTANTS</b>					
Statistician	data analysis				\$700
<b>Total</b>					<b>\$700</b>
<b>HORSE EXPENSE</b>					
	included in rx cost				\$0
<b>TRAVEL</b>					
Two investigator meetings					\$1,000
Final site assessments					\$1,500
Site coordinator training					\$2,000
Ongoing consultation and problem-solving					\$500
<b>Total</b>					<b>\$5,000</b>
<b>TOTAL GRANT</b>					<b>\$54,974</b>
<b>Expected In kind Donations</b>					
CMU - Postage					\$400
Copying of data sheets	PBS, SWOC				\$120
Graduate Assistant					\$4,500
testing materials					
<b>Total</b>					<b>\$49,954</b>
<b>TOTAL REQUEST</b>					<b>\$49,954</b>

All budget items must be related directly to the research question and methodology and will be prorated. Larger grants may be paid in progressive payments, checks written only after progress reports are sufficiently completed. All budget referrals should be related in U.S. dollars. **Please provide itemized budget and narrative justification. No indirect costs are allowed.** There are no word limits to this section, however, please be concise in explanation.

**TOTAL GRANT REQUEST (US Funds): \$ 54,974.00**

- 1) **PERSONNEL:** (*Principal investigator, co-investigator, statistician, research assistant*) Please describe scope of work, salary, fringe benefits, FTE.

Funding in the amount of \$6,930 is requested to cover release time for the primary PI-DSS equal to 1 credit release each in the fall of 2010 and 2011. This is based on the PI's anticipated salary for 2010-2012 academic year (9 month). Fringe benefits are not being charged to the grant and will be covered by the institution in an effort to decrease expenses for the PI and use this money for other portions of the grant. This amounts to \$1,437 and this amount is not accounted for anywhere else in the budget. Release time is not be requested for spring 2011 as Dr. Silkwood-Sherer is on sabbatical and this research project is included in her sabbatical plan. Funding in the amount of \$5,000 is requested to cover the salary of the second PI-NM. Funding for both investigators totals \$11,930. Duties of the PI and co-PI include the training and supervision of all other personnel involved in the study, development of data base, monitoring of data entry, data analysis, writing manuscripts and presentation of research findings.

Funding in the amount of \$4,500 is requested for graduate research assistant stipend. This money will include some salary and tuition reimbursement, but not at the students full rate of pay. This amount is prorated based on the amount of time it is anticipated that the graduate assistant will spend on this project. The graduate assistant will score all paper/pencil tests and input data into the data base.

Funding in the amount of \$1,500 is requested for media services support to download, edit and burn video clips of the pediatric balance scale and standardized obstacle walking course (SWOC) for dissemination to the therapists scoring them. This is based on an estimated 60 hours of work, calculated at 2 hours/ research participant, which accounts for 30 research participants. This is at a rate of \$25/hour.

One thousand dollars has been budgeted for 2 site coordinators (\$500/coordinator) to assist with recruitment and scheduling of children for the study. Funds in the amount of \$5,500 are requested to pay physical therapists to perform baseline and follow-up testing. This amount is based on 105 one-hour assessments at a rate of \$50/assessment. This rate is based on an hourly salary of \$50 per hour, which is the current pay for experienced pediatric physical therapists. We have added an additional \$250 to this amount in case some children pass the initial screen for baseline testing, but do not pass the PBS score requirement once tested. We have budgeted the at the rate of pay for ½ hour of testing times 10 children. An amount of \$5,250 is requested for the therapists scoring the balance and gait assessments via videotape. This cost is based on the same pay and anticipated amount of time as the therapists performing the assessments. We have not budgeted for additional testing time as these therapists will only score tests for children who have completed the testing. An additional \$300 is budgeted to pay the therapists performing the video scoring for training time. This amount is based on a pay of

\$50 for 2 hours of training for 3 therapists. Total budget for personnel to perform assessments is \$12,050.

**Personnel Total: \$29,980**

**Personnel % of total budget: 54.5%**

- 2) **PERMANENT EQUIPMENT:** Itemize and describe purpose, justification of needs, how it will be acquired, etc.

Funding in the amount of \$1,610 is requested to cover the following costs: \$525 for a license to use the Activities Scale for Kids; \$750 for a license for the Pediatric Quality of Life – Cerebral Palsy Version; \$335 for Beery-Buktenica Developmental Test of Visual-Motor Integration (VMI) -5<sup>th</sup> edition manual and 125 scoring sheets. There is no cost for the PreSchool Children’s Assessment of Participation and Enjoyment, Pediatric Balance Scale or the Standardized Walking Obstacle Course

**Permanent Equipment Total: \$ 1,610.00**

**Permanent Equipment % of total budget: 2.9%**

- 3) **CONSUMABLE SUPPLIES:** Itemize and describe justification of needs, how it will be acquired, etc.

Funding in the amount of \$834 is requested to cover costs of videotapes and DVDs plus postage for the sites to mail videotapes to the PI and then mail DVDs between PI and therapists scoring them. Additional costs include consumable supplies such as copy costs of data recording sheets (\$120), disposable dark sunglasses for the children to use during the SWOC tests (\$180) and other items needed to set up the course (\$400), conference calls between the PIs, site coordinators, and assessing therapists, as well as phone calls to sites (\$400).

**Consumable Supplies Total: \$ 1,934.00**

**Consumable Supplies % of total budget: 3.5%**

- 4) **CONSULTANT COSTS:** Describe rate of pay, scope of work, justification of need, etc.

The statistician is budgeted for 10 hours of consultation at \$70/hour for a total of \$700. We are not budgeting extensive time with the statistician as Dr. Silkwood-Sherer has experience doing statistical analysis.

**Consultant Costs Total: \$ 700**

**Consultant Costs % of total budget: 1.3%**

- 5) **TRAVEL:** *(Will only cover subject travel reimbursement or for meeting of work groups.)*

Travel costs are budgeted at \$5,000. This includes 2 investigator meetings (\$1,000) for planning of training sessions at a cost of \$400 in airfare and \$100 for 1 hotel night for each meeting for travel of one investigator. Funds of \$1,500 are budgeted for visits to at least 3 sites that have agreed to participate in the event that there are unforeseen problems with our first 2 choices of sites. This funding amount is based on a budget of \$400 in airfare and \$100 for 1 night in a hotel. We budgeted for Transportation for the site coordinators for training is budgeted at \$1,500, which is \$700/coordinator and includes the cost of 1

overnight stay and food. An additional \$1,000 has been budgeted in case travel is necessary to the sites for on-going consultation and/or problem-solving.

**Travel Costs Total: \$ 5,000**

**Travel % of total Budget: 9.1%**

- 6) **CLIENT-RELATED EXPENSES:** Itemize and describe all related costs.

The amount of \$13,500 for hippotherapy services is based on a rate of \$75/session times 12 sessions per/child times 15 children. Hippotherapy services are not commonly covered by 3<sup>rd</sup> party insurance carriers or Medicare/Medicaid therefore we have budgeted for the entire cost of the hippotherapy treatment sessions. Individuals in the control and treatment groups will continue to pay for their traditional therapy as they had prior to inclusion into the study (insurance coverage), so no monies are budgeted. All centers will be asked to assess funding of hippotherapy services by 3<sup>rd</sup> party payers for each subject. If 3<sup>rd</sup> party reimbursement is available, it will be the primary payor of hippotherapy treatment with grant money used to make sure all centers are paid at the \$75/session rate and for subjects without insurance coverage. An additional \$2,250 has been budgeted for the control group costs. This cost is based on payment to parents for bringing their children to the testing at \$50/assessment times 4 assessment sessions (total of \$200/child).

**Client-Related Expenses Total: \$ 15,750**

**Client-Related Expenses % of total budget: 28.7%**

- 7) **HORSE EXPENSE:** (*Must be directly related to research question and methodology.*) Explain cost basis related to percentage of time used in project.

**Horse Expense Total: \$0**

**Horse Expenses % of total budget: 0**

- 8) **BUDGET JUSTIFICATION:** Please provide any further budget justification or explanation here.

**OTHER INCOME SOURCES and ANTICIPATED FUNDING SUPPORT:**

**a. Active/Committed:** Is this project being funded by other sources (federal, institutional and/or private grants or other sources)? Please provide source/institution name, project titles, specified designations and restrictions, starting and ending dates and amounts. Do not include general or overall program support.

**No**

**Total Active/Committed: \$0**

**b. Pending:** Is support for this project being sought elsewhere? Please provide source/institution name, project titles, specified designations and restrictions, starting and ending dates and amounts.

Yes. Should this project be funded by HHRF, the primary PI – DSS plans to apply for internal funding from the Office of Research and Sponsored Programs at Central Michigan University to increase the number of participants in each group by 3 so that there is a total of 36 children in the study. This additional funding will cover the cost of treatment, assessment for control group children and hippotherapy. Maximum amounts allowed for these internal grants is \$5,000.

**Total Pending: \$5,000**

**c. Related Support:** List all other sources of support, pending or current, including federal (NIH, VA, NSF, etc.), foundation, industrial, or other. Give complete titles of all grants as well as total funding, yearly funding, funding for your salary, funding for your research, and inclusive funding dates.

Central Michigan University will cover the cost of a PT graduate assistant to assist with data entry, randomization, scoring of tests etc at a cost of \$4,500. They will also cover the cost of postage at \$400, cost of copying data recording sheets (\$120).

**Total Related Support: \$ 5,020.00**

## **VIII. Lay Language Article**

Date: April 28, 2010

Title of Project: Effects of Hippotherapy on Balance and Gait in Ambulatory Children with Spastic Cerebral Palsy

Name of Principal Investigator: Debbie Silkwood-Sherer DHS, PT, HPCS & Nancy H. McGibbon MS, PT, HPCS

Cerebral palsy is a condition that affects a child's ability to move and play like other children. Even those who are able to walk independently may trip and fall frequently, particularly on uneven ground. This awkwardness affects their quality of life because they have difficulty with games and play activities such as hopping, jumping, running, and ball handling. These problems with balance and walking are the focus of this study.

The purpose of this study is to determine if children with cerebral palsy will be able to balance and walk better if hippotherapy is added to their normal therapy program. Thirty children who have a diagnosis of spastic cerebral palsy and who are between the ages of 3 years and 6 years will be recruited to participate.

*Method:* This study will use two different hippotherapy sites in order to find and treat the required number of children. Once the children are recruited, based on specific criteria, they will be matched by age, severity of their cerebral palsy, and a balance score based on a standardized test called the Pediatric Balance Scale. They will then be randomly assigned to one of two groups. Group 1 will continue with their regular therapy during the 12-week study period. Group 2 will receive 12 weeks of 45-minute weekly hippotherapy sessions in addition to their regular therapy program.

All children will be tested before and after the 12 weeks using standardized tests. The pediatric balance scale (PBS) will be used to measure balance. The standardized walking obstacle course (SWOC) will measure walking ability. The Activities Scale for Kids (ASK)

will be used for the 5-6 yr children to measure how well the child is able to perform daily tasks such as getting out of bed, getting dressed, and playing sports. A similar test called the Children's Assessment of Participation and Enjoyment-preschool version will be used for the 3-4 yr olds. The Beery Test of Visual-Motor Integration (VMI) will measure the child's ability to recognize and copy shapes such as triangles and squares. This tests the ability to use visual information for guiding movement, an important requirement for balance in different environments. A questionnaire called the PedsQL will be used to measure health-related quality of life. These tests have been specially chosen because they are suitable for 3-6 year old children and provide information on many different but important aspects of a child's life.

At the end of the 12-week study period, Groups 1 and 2 will be compared to see if the children who received hippotherapy made greater gains on the tests than those who did not receive hippotherapy. We will also assess whether there is a relationship between any of the measurements. For example if the child has better balance are they able to participate in more age appropriate activities?



## IX. Biographical Sketch of Principal Investigator

### BIOGRAPHICAL SKETCH -PI

NAME Silkwood-Sherer, Deborah Jo		POSITION TITLE Associate Professor Graduate Program in Physical Therapy	
eRA COMMONS USER NAME (credential, e.g., agency login) silkw1d			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
University of Kentucky, Lexington KY	BHS	12/78	Physical Therapy
DePaul University, Chicago, IL	MS	6/90	Rehabilitation Administration
University of Indianapolis, Indianapolis, IN	DHS	12/07	Physical Therapy - Pediatrics

#### A. Personal Statement

The goal of this research project is to investigate the effects of the addition of hippotherapy to traditional physical, occupational, and speech therapies on improving balance, gait, participation, and quality of life in preschool children with spastic cerebral palsy. I have the expertise in using hippotherapy as a treatment strategy, in addition to the expertise of conducting clinical research on its effects. I have been utilizing hippotherapy for over 15 years and am a board certified hippotherapy clinical specialist<sup>®</sup> (HPCS). I also have a broad background and additional education in the treatment of children with disabilities. The majority of my research has been centered on the effects of hippotherapy primarily on balance and gait in adults and children. Additionally I have completed research on maturational changes of postural control and balance in typically developing children (submitted for publication and in review process). My doctoral project assessed the effects of hippotherapy on balance and participation of children with numerous disabilities. (Manuscript submitted and in review) This project logically expands on that research by adding more assessments to cover all aspects of the International Classification and Function model of wellness and this publication is in review. I have the necessary administrative skills to manage a budget and oversee the completion of the research project. As a faculty member I have supervised student research projects, in addition to completing my own research. As the PI on a university funded project I was able to complete the project within the allocated budget and oversee the students' treatment sessions, data collection and am currently assisting in the analysis of the data. I have selected a co-investigator (McGibbon) who also has research experience in the area of hippotherapy. We have worked together on other projects and therefore have developed a good working relationship that will benefit us in completing this current project.

#### B. Positions and Honors

##### Positions and Employment

12/1978–3/1980 Staff Physical Therapist Mt. Sinai Hospital Medical Center, Chicago, IL  
3/1980–12/1981 Senior Physical Therapist, Clinical Education Coordinator  
Schwab Rehabilitation Hospital, Chicago, IL  
1/1982–7/1984 Education Program Leader, Rehabilitation Services Ingham Medical  
Center, Lansing, MI  
6/1983–6/1987 Supervisor Physical Therapy Department Ingham Medical Center, Lansing,  
MI  
6/1987–6/1992 Director Rehabilitation Services Ingham Medical Center, Lansing, MI  
6/1992–6/1995 Dean, Allied Health Baker College, Flint, MI  
5/1995–9/1995 Self-employed Physical Therapist, contracts with Ingham Intermediate  
School District, Sparrow Home Care, Brighton Physical Therapy.  
9/1995–8/1997 Staff Physical Therapist Early Intervention Services Ingham Intermediate  
School District, Mason, MI  
5/1994-0/1999 Volunteer Therapist providing hippotherapy services, Beekman  
Therapeutic Riding Center, Lansing, MI  
9/1997–8/2000 Staff Physical Therapist (0.6 FTE) Early Intervention Services  
Ingham Intermediate School District, Mason, MI  
8/1997–5/2000 Assistant Professor (Temporary Faculty 0.5 FTE) Graduate Program in  
Physical Therapy Central Michigan University, Mt. Pleasant, MI  
10/1999 – Contract therapist providing hippotherapy services CHUM Therapeutic  
Riding Center, Dansville, MI  
8/2000–8/2008 Assistant Professor Graduate Program in Physical Therapy, Central  
Michigan University, Mt. Pleasant, MI.  
8/2008 - Associate Professor Graduate Program in Physical Therapy, Central  
Michigan University, Mt. Pleasant, MI

### **Other Experience and Professional Memberships**

1987–1995 MPTA Licensing Board Liaison  
1987–1997 MPTA Legislative Committee  
1976–1980 Member, American Physical Therapy Association (APTA)  
1983- Member, American Physical Therapy Association  
1983– Member, Michigan Physical Therapy Association (MPTA)  
1995– Member, APTA Pediatric section  
2000– Member, APTA Neurology & Education Section  
1999– NAHRA Registered Therapist  
1999– Member, National American Riding for the Handicapped Association  
(NARHA)  
1999-2004 Member, Hippotherapy section of NARHA  
2004– Member, American Hippotherapy Association (AHA)  
2005– Member, AHA Research Committee  
2007- Board of Directors - AHA  
2007 – AHA Research Committee Chair  
2007 – Horses and Humans Research Foundation - Scientific Review Committee  
2008 – Vice-President AHA Board of Directors  
2007- Reviewer – Physiotherapy Theory and Practice  
2008- Reviewer – Journal of Alternative and Complementary Medicine  
2008- Board Certified Hippotherapy Clinical Specialist®

### **Honors**

2005 Barbara Glasow Therapist of the Year – American Hippotherapy Association  
2007 Volunteer Hall of Fame: Programs - National Multiple Sclerosis Society

### **C. Selected Peer-Reviewed Publications**

1. Silkwood-Sherer D, Warmbier H. Effects of hippotherapy on balance of persons with multiple sclerosis: a pilot study. *Journal of Neurological Physical Therapy*. 2007;31(2):77-84 ( PMID: 17558361)
2. McGibbon NH, Benda W, Duncan BR, Silkwood-Sherer D. Immediate and long-term effects of hippotherapy on symmetry of adductor muscle activity and functional ability in children with spastic cerebral palsy. *Arch Phys Med Rehabil*. 2009;90(6):966-974. (PMID: 19480872)

### **D. Research Support**

#### **Ongoing Research Support**

2009-2010 Central Michigan University Faculty Research Creative Endeavour Grant  
Effects of Hippotherapy on Sensory Organization for Postural Control in Children with Neuromuscular Disorders

The goal of this study is to assess the effects of hippotherapy on a child's ability to organize environmental sensory information for postural control in addition to assessing hippotherapy's effects on reaction times and other measures of balance and participation and the correlation between these measures.

## BIOGRAPHICAL SKETCH – Co-PI

NAME <b>Nancy H. McGibbon, MS, PT, HPCS</b>	POSITION TITLE Director of Therapy Services; Research Consultant		
eRA COMMONS USER NAME			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
University of Pennsylvania, Philadelphia, PA	BS	1966	Physical Therapy
Rommel Klinik – Wildbad, Germany		1987	Hippotherapy
Samuel Merritt College, Oakland, CA	MS	1996	Neurologic PT

### A. Personal Statement

The goal of our proposed research is to investigate the effects of hippotherapy on balance in children with cerebral palsy. I feel that my credentials and experience lend considerable expertise to this study. I have played a major role in four studies of children with spastic cerebral palsy. Three of these studies involved hippotherapy. I have been a principal investigator, research consultant, and evaluator coordinator. In these capacities I have had responsibility for all aspects of research including study design, testing protocols and procedures, and training of research staff. I have worked closely with Burris Duncan, MD of the University of Arizona, Department of Pediatrics, who has extensive research experience. On a major study of international scope, I was responsible for training foreign therapists in the use of all physical therapy outcome measures and developing a precise and successful method for blinded video scoring. I have 30 years experience in pediatric physical therapy and am considered an expert in the field of hippotherapy. I have a strong commitment to excellence in all my endeavors and am known for my attention to detail. In summary, I believe that my experience in research, pediatrics, and hippotherapy make me uniquely qualified to play a major role in this study and to assure its success.

### B. Positions and Honors

#### Positions and Employment

1966-1970	Memorial Hospital Colorado Springs, CO
1970-1985	Tucson Medical Center, Tucson, AZ
1974 – present	Director of Therapy Services , Therapeutic Riding of Tucson, Inc
1995- present	Research consultant for therapeutic riding/hippotherapy programs
2002 – present	Research consultant - University of Arizona, Dept of Pediatrics

#### Other Experience and Memberships

1985 – present	Member - American Physical Therapy Association
1992	Founder and 1 <sup>st</sup> president of American Hippotherapy Association
1994- present	International Lecturer on Hippotherapy and Hippotherapy Research
1998- present	American Hippotherapy Certification Board - Chair
2003- present	Manuscript Reviewer for the Scientific Journals: Physiotherapy Theory and Practice, An International Journal of Physical Therapy

	Journal of Alternative and Complementary Medicine
	Archives of Physical Medicine and Rehabilitation
2003-2005	Advisory Council for the American Hippotherapy Association–
2006-2007	Horses and Humans Research Foundation – Scientific Review Committee
2007-2008	Horses and Humans Research Foundation – Scientific Advisory Committee

### Honors and Awards

- 1999 – present AHCB Board Certified Hippotherapy Clinical Specialist®
- 2004 Woman of Distinction Award Soroptomists  
International of Desert Tucson
- 2004 “Therapist of the Year” Award  
American Hippotherapy Association, Inc
- 2007 James Brady Professional Achievement Award  
North American Riding for the Handicapped, Association

### C. Selected peer-reviewed publications (in chronological order)

1. McGibbon, NH, Andrade, CK, Widener, G, Cintas, HL. The Effect of Equine Movement Therapy on Gait, Energy Expenditure, and Motor Function in Children with Cerebral Palsy, *Developmental Medicine and Child Neurology*, 1998, 40: 754-762.
2. Benda W, McGibbon NH, Grant K, Davis M (2003) Improvement in Muscle Symmetry in Children with Cerebral Palsy after Equine-Assisted Therapy (Hippotherapy). *Journal of Alternative and Complementary Medicine*, Vol 9 , #6, 2003, pp. 817-825.
3. McGibbon NH, Benda W, Duncan BR, Silkwood-Sherer D. Immediate and long-term effects of hippotherapy on symmetry of adductor muscle activity and functional ability in children with spastic cerebral palsy. *Arch Phys Med Rehabil* 2009;90:966-74

### D. Research Support

Project Number: AT00008-05. Benda (PI) (2003-2004)  
NIH / DHHS Effects of hippotherapy on muscle activity in cerebral palsy.  
Role: Paid Research Consultant

Project Number: HSC #04-126 Duncan (PI) (2004 -2007)  
Arizona Disease Control Research Commission  
Acupuncture as a complementary therapy for cerebral palsy  
Role: Evaluator Coordinator

## **HUMAN SUBJECTS**

### **COMPLIANCE WITH U.S. GOVERNMENT REQUIREMENTS**

The following statements are signed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by the following:

The Central Michigan University (Principal Investigator or Institution) agrees that if a research grant is awarded by the Horses and Humans Research Foundation (HHRF) to Debbie Silkywood-Sherer (Applicant/Principal Investigator) for the project Effects of Hippotherapy on Balance and Gait in Ambulatory Children with Spastic Cerebral Palsy (Project Title) and if human subjects are used in any of the activities supported by such award, that it will comply with all applicable U.S. Department of Health and Human Services regulations with respect to the rights and welfare of such subjects. To the extent allowable by the State of Michigan, the Central Michigan University (Institution) agrees to indemnify and hold HHRF harmless from any claims arising from such activities, and acknowledges that HHRF does not and will not assume responsibility for the subjects involved.

#### **SIGNATURE OF APPROVAL BY THE DEAN OR HEAD OF INSTITUTION ON BEHALF OF INSTITUTION**



Signature  
Dr. Ian R. Davison  
Interim Vice Provost for Research

Type/Print Name and Title of Dean or Head of Institution

April 30, 2010

**ANIMAL SUBJECTS**  
**COMPLIANCE WITH GOVERNMENT REQUIREMENTS**

The following statements are signed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by the following:

The \_\_\_\_\_ (Principal Investigator or Institution) agrees that if a research grant is awarded by the Horses & Humans Research Foundation (HHF) to

\_\_\_\_\_ (Applicant or Principal Investigator) for the project

\_\_\_\_\_ (Project Title) and if animal subjects are used in any of the activities supported by such award, that it will comply with all applicable U.S. Department of Health and Human Services regulations with respect to the rights and welfare of such subjects.

To the extent allowable by the State of \_\_\_\_\_, the

\_\_\_\_\_ (Institution) agrees to indemnify and hold HHRF harmless from any claims arising from such activities, and acknowledges that HHRF does not and will not assume responsibility for the subjects involved.

**SIGNATURE OF APPROVAL BY THE DEAN OR HEAD OF  
INSTITUTION ON BEHALF OF INSTITUTION**

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Type/Print Name and Title of Dean or Head of Institution

Date

## **XI. Research Grant Conditions of Award**

1. At least one member of the research team must be fluent in English and published in peer-reviewed English language journals.
2. No institutional overhead or other indirect costs will be paid and should not be included as part of any grant request. A letter to your institution explaining this condition can be requested if needed. Beware that substantive equipment costs could work against the success of the grant request.
3. All funds awarded shall be used in accordance with the submitted and approved proposal and accompanying budget. Any unused portion thereof shall be returned to the Horses and Humans Research Foundation (HHRF). If an unforeseen problem occurs with the study design, notify HHRF immediately. Potential changes to the study design with additional financial assistance from HHRF may be considered to salvage the study and still lead to a favorable outcome.
4. At the midpoint of the grant period a progress report and financial report must be submitted. A final report must be submitted within 60 days of the completion of the project. The final report shall include a scientific abstract, summary data tables, a financial report, and a less-technical lay language article (400 words) to potentially be used in HHRF and related publications as determined by HHRF. Confidential data that could jeopardize formal publication in a peer-reviewed journal should not be disclosed in the lay articles. If a delay in project completion of more than 3 months duration is anticipated, HHRF must be notified promptly with a brief explanation and a request for extension. All investigators are encouraged to communicate and work with HHRF for the best possible outcome of their study. Failure to comply with the above conditions may result in revoking of all award funding.
5. The Principal Investigator must assure HHRF of his or her intended work location. HHRF must be advised at the time of application of all moves, contemplated or real. Changes of address, phone number, fax number and email *within the same institution* must be promptly conveyed to HHRF. Changes in site location during a funded period must be approved by HHRF.
6. All publications (including poster abstracts at medical conferences) resulting from HHRF-funded research must include HHRF in a footnote/credit line/disclosure, and copies of such publications must be provided to HHRF. All publicity and information disseminated about such research must acknowledge HHRF support. This is an essential part of HHRF's conditions of award. Publicity or information about the project is used to keep supporters to HHRF informed about how their donations are being spent. This condition of award does NOT involve disclosure of any information that might jeopardize the applicant's ability to formally publish their findings.
7. The recipient of any research grant awarded must certify that any research, including work involving human and/or animal subjects, will be conducted according to the rules and regulations of the United States Department of Health and Human Services. The recipient must agree to hold HHRF harmless from any and all claims which may arise from any associations/issues related to such research.



8. All studies involving therapeutic riding horses must comply with accepted industry standards for care, treatment, and humane work load. All mounted work must comply with accepted industry standards for safety -- including a certified instructor/therapist or evidence of equivalent standards. Therapeutic riding program sites must be accredited by or provide evidence of equivalent standards for facility safety.
9. A one-year grant period is assumed. HHRF may approve the funding of a multi-year project, with funding of subsequent years pending the successful completion of the initial year. Applicants must consult HHRF prior to submitting a multi-year application.
10. Recipients of HHRF grants will be committed to a serious effort to publish resulting research findings in a peer-reviewed journal. HHRF will be kept informed of publication efforts.
11. All grant applicants must include one signed copy of this "Research Grant Conditions of Award" as a necessary part of their grant application to HHRF.
12. The Foundation reserves the right to terminate an award if the grant holder or staff funded by the grant is in breach of any of the conditions of award or becomes unfit or unable to pursue the work funded by the grant.

*I have read and understood HHRF's "Research Grant Conditions of Award" and my signature below signifies that I agree to abide by all conditions specified.*

Principal Investigator's signature: Debbie Silkwood-Sherer Date: 4/30/10

Principal Investigator's name and title (please print) Debbie Silkwood-Sherer DHS, PT, HPCS

## I. Attachments

### APPENDIX A REFERENCES

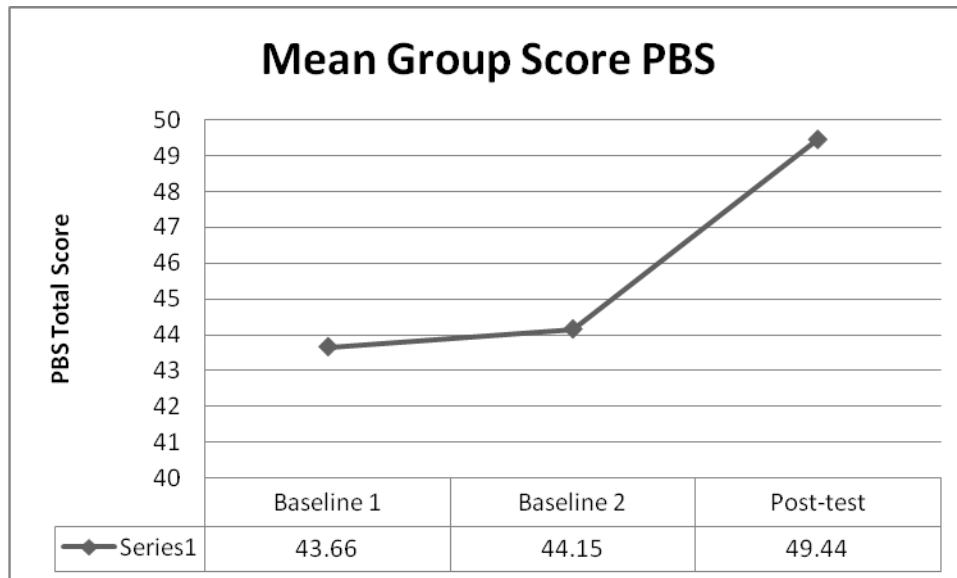
1. Olney SJ, Wright MJ. Cerebral Palsy. In: Campbell SK, VanderLinden Dw, Palisano RJ, eds. *Physical Therapy for Children*. 3<sup>rd</sup> ed. St. Louis, MO. Saunders/Elsevier; 2006: 625-664.
2. Brogren E, Hadders-Algra M, Forssberg H. Postural control in sitting children with cerebral palsy. *Neurosci Biobehav Rev* 1998;22:591-596.
3. Shumway-Cook A, Woollacott MH. *Motor Control: Translating Research into Clinical Practice*. 3<sup>rd</sup> ed. Philadelphia, PA; Lippincott, Williams & Wilkins;2007.
4. Gramsbergen A, Hadders-Algra M. Posture in the picture: on the relevance of postural control in children with developmental motor disorders. *Neural Plast*. 2005;12:73-75
5. Westcott SL, Hartzler-Murray K, Pence K. Survey of preferences of pediatric physical therapists for assessment and treatment of balance dysfunction in children. *Pediatr Phys Ther*. 1998;10:48-61.
6. Harris SR, Roxborough L. Efficacy and effectiveness of physical therapy in enhancing postural control in children with cerebral palsy. *Neural Plast*. 2005;12:229-243.
7. Butler PB. A preliminary report on the effectiveness of trunk targeting in achieving independent sitting balance in children with cerebral palsy. *Clin Rehabil*. 1998;12:281-293.
8. Shumway-Cook A, Hutchinson S, Kartin D, Prince R, Woollacott M. Effect of balance training on recovery of stability in children with cerebral palsy. *Dev Med Child Neurol*. 2003;45:591-602.
9. Kuczyński M, Słonka K. Influence of artificial saddle riding on postural stability in children with cerebral palsy. *Gait Posture*. 1999;10:154-160.
10. Bertoti D. Effect of therapeutic horseback riding on posture in children with cerebral palsy. *Phys Ther*. 1988;68:1505-1512.
11. Benda W, McGibbon NH, Grant KL. Improvements in muscle symmetry in children with cerebral palsy after equine-assisted therapy (hippotherapy). *J Altern Complement Med*. 2003;9:817-825.
12. McGibbon NH, Benda W, Duncan BR, Silkwood-Sherer D. Immediate and long-term effects of hippotherapy on symmetry of adductor muscle activity and functional ability in children with spastic cerebral palsy. *Arch Phys Med Rehabil*. 2009;90:966-974. PMID: 19480872

13. Shurtleff TL, Standeven JW, Engsberg JR. Changes in dynamic trunk/head stability and functional reach after hippotherapy. *Arch Phys Med Rehabil.* 2009;90:1185-1195.
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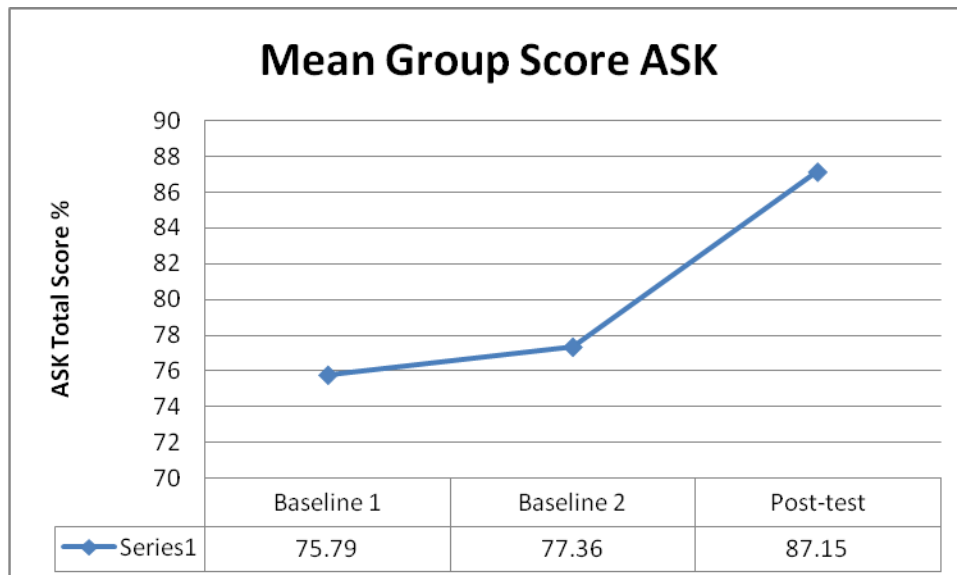
## APPENDIX B RESULTS OF 2007 PILOT STUDY

Figure 1. Changes in Mean Pediatric Balance Scale Scores



*Changes in total PBS score (range 0-56) following 6 weeks of bi-weekly hippotherapy sessions*

Figure 2. Changes in Mean Activity Scale for Kids Score



*Changes in total ASK score following 6 weeks of bi-weekly hippotherapy sessions. Reported as a percentage score where 100% represents full participation.*

## APPENDIX C RESEARCH DESIGN

<b>Experimental Design</b>	T 1	12 weeks usual therapy	T 2	12 weeks usual therapy	T 3	12 weeks usual therapy	T 4
<b>Experimental Group</b>	X	<b>Usual therapy plus hippotherapy</b>	X	Usual therapy only- No hippotherapy	X	Usual therapy only- No hippotherapy	X
<b>Control Group</b>	X	Usual therapy only- No hippotherapy	X	Usual therapy only- No hippotherapy	X		

## APPENDIX D PHOTO OF STANDARDIZED WALKING OBSTACLE COURSE

### Standardized Walking Obstacle Course Course SWOC<sup>1</sup>

The course is a 12.2 m long and .92 m wide path with 3 directional changes; one 30° to the right, another 90° back toward the left, and finally a 70° turn to the right. The child begins the course by standing up from the chair with the arms. He/She walks several feet and turns 30° right before stepping over an axillary crutch. Next, the child turns 90° to the left and walks across a visually stimulating mat in the path. A 70° right turn is then required as the child moves toward a large kitchen trash can which he or she must step around. Finally, the child walks across a rug and returns to a seated position in the chair without arms.

The child is asked to negotiate this course under 3 different conditions.

**Condition 1: Hand free ambulation.** The child negotiates the obstacle course as described above while walking at a comfortable pace. This condition consists of ambulating in the direction described above and then returning to the original chair, which results in walking the course "backward".

**Condition 2: Walking and carry basket.** The child negotiates the obstacle course forward and backward, while carrying a weighted laundry basket. The amount of weight is dependent upon the child's ability to lift the basket.

**Condition 3: Hands free ambulation in simulated dark environment.** The child dons dark sunglasses (simulating a dimly lit environment) and walks through the course in both directions.

**Data Collection.** All trials are timed and the number of stumbles and steps off path are counted for each trial.

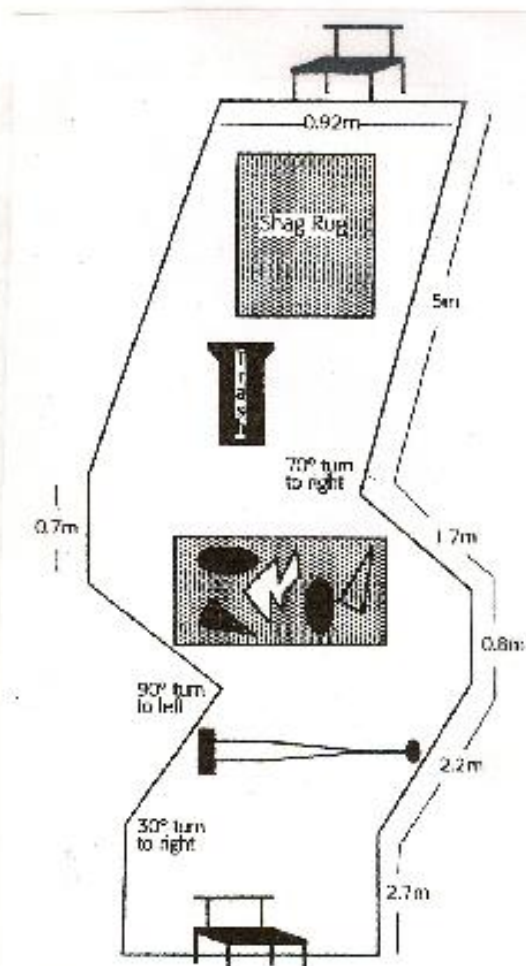


Figure 1. Diagram of SWOC illustrating dimensions and direction of course as well as placement of obstacles. Two chairs are required, one with arms and another without. Obstacles include axillary crutch, shower curtain or vinyl tablecloth with busy print (36" x 30"), kitchen size trash can, and heavy pile shag rug (black preferred, 30" x 50"). Course can be fabricated from 13' x 15' carpet remnant.

1. Taylor MJ, Gunther J. *Standardized Walking Obstacle Course: Preliminary Reliability and Validity of a Functional Measurement Tool. J Rehabil Outcomes Meas.* 1998;2:15-25.

**APPENDIX E: SITES AND HPCS COORDINATORS  
LETTERS OF INTENT**

<b>NAME OF CENTER</b>	<b>LOCATION</b>	<b>NARHA #</b>	<b>HPCS THERAPIST COORDINATOR</b>
THERAPEUTIC RIDING OF TUSCON	TUSCON, AZ	1146	NANCY H. MCGIBBON MS, PT, HPCS
QUEST THERAPEUTIC SERVICES, INC	WEST CHESTER, PA	58825	ELLEN ERDMAN DPT, HPCS
TURNING POINT THERAPY	WELLINGTON, FL	60803	TRICIA COATES OTR/L, HPCS
RIDE ON CENTER FOR KIDS	GEORGETOWN, TX	40603	NANCY O'MEARA KRENEK PT, HPCS
RIDE ON THERAPY SERVICES	CHATSWORTH, CA	12875	JOANN BENJAMIN PT, HPCS TRUDY EPSTEIN OTR, HPCS



# QUEST

Therapeutic Services, Inc.



November 14, 2009

Seen by fax to 986-774-2780

To: Debbie Silkwood-Sharer DSS, PT, HPCS  
Nancy H. McGibbon MS, PT, HPCS

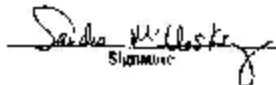
Re: Research Project: *"Effect of Hippotherapy on Balance and Gait in Ambulatory Children with Cerebral Palsy"*

I am pleased to support your research proposal, entitled, *"Effect of Hippotherapy on Balance and Gait in Ambulatory Children with Cerebral Palsy"*. Quality research in the field of pediatric therapy, and specifically hippotherapy, is greatly needed. Quest is enthusiastic and willing to contribute to this important work by helping recruit, treat with hippotherapy, and test children for this study. Given that Quest is a NARHA Premier Accredited Center that treats more than 100 children per week, we are uniquely positioned to help with a multi-center research project. We are committed to contributing to the therapy professions by performing quality research, and have been successful in carrying out small research studies that are now being submitted for publication. We would be pleased to be part of a larger study that would have even greater impact.

We believe that Debbie and Nancy are uniquely qualified to carry out this study, based on their research expertise and track record of publishing quality research studies. We look forward to collaborating with you on this important work.

Sincerely,

Sandra McCloskey, PT, HPCS  
Site Administrator

  
Signature

Ellen Erdman, PT, DPT, HPCS  
HPCS Therapist

  
Signature

*Building Potential. Empowering Lives*

**QUEST THERAPEUTIC SERVICES, INC.**

451 East Row, Wika Center, PA 16382 • Phone: 810-682-8562 • Fax: 810-682-0307 • [www.questhippo.org](http://www.questhippo.org)



November 11, 2009

To: Debbie Silkwood-Sheer DHS, PT, HPCS and Nancy H. McGibbon MS, PT, HPCS  
(researchers)

Re: Title of Research: *"Effect of Hippotherapy on Balance and Gait in Ambulatory Children with Cerebral Palsy"*.

I wish to express my enthusiastic support for your proposed research project, *"Effect of Hippotherapy on Balance and Gait in Ambulatory Children with Cerebral Palsy."*

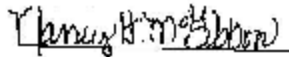
Therapeutic Riding of Tucson is willing to participate in the study by helping recruit, treat with hippotherapy, and test children for the study at our facility. TROT has previously worked with Nancy H. McGibbon on several research projects which were conducted in a highly professional and collaborative manner. Her experience in previous studies and her extensive background and leadership in the field of hippotherapy make her uniquely qualified to successfully conduct the proposed study.

TROT would be honored to collaborate in the proposed study and I wish you success in your grant application.

Leslie Engelhorn, Executive Director  
Site Administrator Name (printed)

  
Signature

Nancy H. McGibbon, MS, PT, HPCS  
HPCS Therapist (printed)

  
Signature

Turning Point Therapy

948 Cindy Drive, Wellington H. 33414 phone 561 758-5860 fax 561 793-1907

11/13/09

To: Debbie Silvevant-Sherer DHS, PT, HPCS and Nancy H. McGibbon MS, PT, HPCS

Re: "Effect of Hippotherapy on Balance and Gait In Ambulatory Children with Cerebral Palsy"

Your research proposal to study the "Effect of Hippotherapy on Balance and Gait in Ambulatory Children with Cerebral Palsy" has my enthusiastic support. I am honored to assist you in this study by helping to recruit and test children for the study as well as treating children utilizing hippotherapy.

The two of you will make a great research team. Your prior research studies involving cerebral palsy and your presentations to the international community will be an asset to this endeavor.

I look forward to collaborating with you on this project and wish you the best of luck with your grant application.

Sincerely,

*Tina Coroneo* *11/13/09* HPCS

Tina Coroneo, DTR/L HPCS



R.O.C.K., Ride on Center for Kids, is partnering with the horse to improve independence and life skills.

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Mark F. Overland

November 12, 2009

Debbie Silkwood-Silvior DHS, PT, HPCS and Nancy H. McGillbain MS, PT, HPCS

RE: Effect of Hippotherapy on Balance and Gait in Ambulatory children with Cerebral Palsy

Dear Debbie and Nancy,

The R.O.C.K. Research committee is willing to support your research proposal titled *Effect of Hippotherapy on Balance and Gait in Ambulatory children with Cerebral Palsy*. The past articles published by you have encouraged our research committee as we continue to develop research protocols. We are excited about the possibilities of this study. The R.O.C.K. Research Committee and therapists look forward to collaborating with you both on this project.

Sincerely,

Karion Wilson  
Executive Director

Nancy H. McGillbain Krenel, PT, HPCS  
Director of Therapy

A Community Service of



P.O. Box 2425 • Georgetown, TX 78627 • Website: [www.rockride.org](http://www.rockride.org)  
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**therapy services- RO**

|| **chatsworth**  
21129 shuford street  
chatsworth, california 91311  
818.790.2878 ph  
818.704.7823 fx

|| **newbury park/thousand oaks**  
401 royal court  
newbury park, california 91328  
805.375.9078  
805.375.9640 fx

Date: 12 November 2009

To: Debbie Silkwood-Sherer DTS, PI, HPCS

Nancy H. McGibbon MS, PT, HPCS

Re: Title of Research: "*Effect of Hippotherapy on Balance and Gait in Ambulatory Children with Cerebral Palsy*".

Your proposal to investigate the use of the horse's movement/Hippotherapy in the treatment of Balance and Gait dysfunction in children with Cerebral Palsy has my enthusiastic support. As a PT who sees many children with CP, and who uses Hippotherapy as a tool to address their impairments, I think that this is an important and useful project. Representing Therapy Services at Ride On, we would be happy to help this endeavor by recruiting, treating and/or testing subjects participating in this study. We have made great use of your past research studies and we are quite confident that you will be able to spearhead this project in an expert direction.

We wish you all the best in your pursuit of the project, and please know that you have our full support and will help in whatever way that we can to bring it to completion.

\_\_\_\_\_  
Joann Benjamin, PT, HPCS  
HPCS Therapist

*Joann Benjamin*  
12 Nov 2009

\_\_\_\_\_  
Trudy Epstein, OTR, HPCS  
HPCS Therapist

*Trudy Epstein*  
12 Nov 2009

## APPENDIX F HIPPO THERAPY TREATMENT PROTOCOL

Muscle relaxation	5	Relax and elongate muscles	<u>No progression</u> - horse is maintained at a steady, relaxed, walk on straight lines and gentle curves
Sustain optimal postural alignment of head, trunk, lower extremities and independent sitting	10	Optimal alignment, mobility, centered posture, balance, symmetry	<p><u>Progression of Horse Movement:</u></p> <p>A. Figures- circles, figures of 8, serpentine (Increases challenge to lateral weight shift and postural control across midline beginning with larger figures and progressing to smaller figures)</p> <p>B. Lengthening of horse's stride. Greater stride length produces a greater amplitude of movement transmitted to the child. (Increases pelvic mobility in the child and increases the challenge to postural control in 3 planes )</p> <p>C. Slow to rapid acceleration/deceleration (Increases challenge to anticipatory or feedback postural control, primarily in the sagittal plane)</p> <p>D. Level terrain to hills (Increases challenge to postural control and incorporates predictive visual environmental cues)</p>
Active exercises (Introduced when the child becomes comfortable with the horse's movement)	10	Stretching, strengthening, dynamic balance, and postural control	<p><u>Progression of Exercises:</u> performed at a halt and then at a walk. Challenge may be increased with the addition of figures (A) or by increasing the energy of the walk (B)</p> <p>Level 1 - Promote postural alignment Backward sit; supine to sit; reaching for knees and ankles, walking hands up horse's mane</p> <p>Level 2 - Increase challenge to sitting postural control Arm abduction and elevation; reaching for objects and to parts of the horse; riding on uneven terrain; guiding the horse with the reins</p> <p>Level 3 - Lower extremity strengthening, graded midrange control and coordination using a saddle and stirrups Sit-stand-sit: child rises slowly from sit to squat to partial stand and slowly returns to sitting. Two-point : child maintains standing in the stirrups with slight hip and knee flexion, initially with hands on horse for balance and later with no hands</p>
Muscle relaxation	5	Relax and feel body position	<u>No progression</u> - horse is maintained at a steady, relaxed, walk on straight lines and gentle curves; child encouraged to feel new body position and alignment

Ref: McGibbon, NH, Andrade, CK, Widener, G, and Cintas, HL (1998) *Effect of an equine movement therapy program on gait, energy expenditure, and motor function in children with spastic cerebral palsy: a pilot study*. *Developmental Medicine and Child Neurology* 40: 754-762.

## APPENDIX G IRB APPROVAL LETTER AND CONSENT FORMS

**CMU**  
Central Michigan University

DATE: April 28, 2010

TO: Debbie Silkwood-Sherer, DHS, PT  
FROM: Central Michigan University IRB 1 (HP/HSBS)

STUDY TITLE: [165383-1] Effect of Hippotherapy on Balance and Gait in Ambulatory Children with Spastic Cerebral Palsy

IRB REFERENCE #:  
SUBMISSION TYPE: New Project

ACTION: APPROVED  
APPROVAL DATE: April 23, 2010  
EXPIRATION DATE: April 22, 2011  
REVIEW TYPE: Full Committee Review

Thank you for your submission of New Project materials for this research study. Central Michigan University IRB 1 (HP/HSBS) has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This study has received Full Committee Review based on the applicable federal regulation.

**Friendly note: Future submissions must use current IRB application forms.** These can be found on the ORSP website and in the Forms and Templates library in IRBNet.

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All SERIOUS and UNEXPECTED adverse events must be reported to this office. Please use the appropriate adverse event forms for this procedure. All FDA and sponsor reporting requirements should also be followed.

Please report all NON-COMPLIANCE issues or COMPLAINTS regarding this study to this office.

Please note that all research records must be retained for a minimum of three years.

Based on the risks, this project requires Continuing Review by this office on an annual basis. Please use the appropriate renewal forms for this procedure.

If you have any questions, please contact Roop Jayaraman at (989) 774-6401 or r.jayaraman@cmich.edu. Please include your study title and reference number in all correspondence with this office.

**CMU**  
**Central Michigan University**

Principle Investigator: Debbie Silkwood-Sherer PT, DHS, HPCS  
School: Central Michigan University  
Department: Graduate Program in Physical Therapy  
Telephone: 989-774-1337  
Email: silkw1d@cmich.edu

Co-Investigator: Nancy H. McGibbon PT, MS, HPCS  
Telephone: 520-625-8678  
Email: nhmcgibbon@gmail.com

**INFORMED CONSENT FOR PARTICIPATION IN RESEARCH ACTIVITIES**

**TITLE:** Effects of Hippotherapy on Balance and Gait in Ambulatory Children with Spastic Cerebral Palsy.

**1. Purpose of this Research Study:** Your child is being asked to be in this research study because he/she meets the following conditions. Your child:

- is between 3 years (36 months) and 6½ years (78 months) old
- has a problems with balance or falls often
- has spastic cerebral palsy
- can stand 4 seconds without the help of a walker, crutches, or cane
- can follow directions during the testing
- has no other problems that would get in the way of being in this study
- has not been in a hippotherapy or therapeutic riding program within the last year
- has no allergies to, dislike, or fear of horses
- can come to at least 10 of the 12 riding sessions and all testing sessions

Additionally as their parent or guardian you will agree to:

- sign the liability release form used by the therapeutic riding center
- not begin any new treatments for your child during the research study
- get permission from your child’s physician for physical therapy treatment using horses if required by state law

The purpose of this study is to find out if therapists using horses in treatment can help children with balance problems move better so they can play and do other age

Please initial and indicate that you have read and understood the first page \_\_\_\_\_  
Initials

Page 1 of 4

appropriate activities. Your child will be one of 30 children in this study.



- 2. Procedures and Timetable:** If you agree your child can be in this study, you will be asked to bring your child to a local clinic, school, or therapeutic riding center for testing. If your child meets the balance requirements of the study you will be asked to participate. All testing will take place at either a local pediatric therapy clinic, school or the riding center. For the balance test we will ask your child to do things like stand with eyes closed, stand on one leg, sit and stand from a chair. For our walking test we will ask your child to walk in an obstacle course that has him/her step over objects, walk on different surfaces, such as busy printed material and carpet and walk for one minute. We will have your child draw different shapes on paper to test his/her handwriting and ability to mimic shapes. We will also ask you and your child questions about how well you think he/she is able to do every day activities. Although a therapist will do the testing with your child, the balance and walking tests will also be videotaped. The videotapes will be sent to different therapists to watch to score the test. The balance test should take about 15-20 minutes. The walking and handwriting tests take 10-15 minutes each to complete. The questions about how well your child does things will also take about 20 minutes.
- 3. Assignment to group:** Following testing your child will be randomly assigned to either a treatment group or a control group. If your child is placed in the control group we ask that your child continue his/her regular therapy routines for 24 weeks, without the addition of any new treatments or activities. You will then be asked to return with your child to repeat the testing done at the initial testing session at 12, 24 and 36 weeks. If your child is assigned to the treatment group you will be asked to bring your child for hippotherapy sessions at a local therapeutic riding center for the first 12 weeks. The hippotherapy may replace one of your child's regular physical therapy sessions or may be in addition to his/her regular therapy if he/she is not receiving physical therapy. The hippotherapy sessions will be once per week for 12 weeks. Each treatment will take about 45 to 60 minutes (riding time will be 30-40 minutes). Following the 12 weeks of hippotherapy you and your child will be asked to come for post-testing immediately after the hippotherapy has stopped and again 12 and 24 weeks later. This means that you are agreeing to be in this study for a total of 9 months, regardless of the group to which your child is assigned. If your child is assigned to the treatment group we suggest your child wear older play clothes for riding.
- 4. Possible Benefits:** Other studies have said that riding horses may make balance better in people who have trouble moving. In the studies not everyone got better, but as a group riding horses helped improve their conditions. So, even though your child may be in the treatment group in this study he/she may or may not get better. By allowing your child to be in the study information learned by the researchers may help others.
- 5. Possible Risks and Discomforts:** Some children may have some soreness when they begin riding. Horses sometimes do things we don't expect. It is possible that a horse

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may nip or kick out toward your child. The therapist treating your child will reduce this risk by carefully choosing calm horses that have been trained for this type of work. Your child will be closely watched by the research team whenever he/she is around the horses. It is also possible to fall off the horse. The therapists will decrease this risk by having 2 people, one on each side of your child whenever he/she is on a horse. Your child must wear a helmet at all times when on and around the horses.

- 6. Confidentiality of Records:** Any information learned from this study in which your child might be identified will remain confidential. Your child's medical records will be kept at each facility (riding center if in hippotherapy group and clinic if in control group) according to the privacy standards of the federal government (HIPAA) and state law. These records may only be released to other medical professionals or individuals for referral or informational purposes upon receipt of a signed release form from you as the child's parent or guardian. If your child's medical records are requested for any other purpose, such as litigation, they will only be released upon receipt of a subpoena or as required by state law.

All records and videotapes will be stored in a locked file cabinet in a locked room and/or on password protected computers. Only the investigators of the research team will be able to see these records. Videotapes sent to other physical therapists for scoring will not have your child's name on it. Only the investigators will know which videotape belongs to which child. All research materials will be kept for 5 years and then destroyed. Medical records will be kept the length of time required by law. If information learned from this study is published, your child will not be named. By signing this form, however, you allow the research study investigators to make your child's research records available to the Central Michigan University Institutional Review Board (IRB) Office and regulatory agencies as required by law.

- 7. Offer to answer questions and research injury notification:** The therapist from the riding center should answer any questions you have about your child being in this study. If you have more questions, you can call Dr. Silkwood-Sherer at (989) 774-1337 or email her at [silkw1d@cmich.edu](mailto:silkw1d@cmich.edu). There is a small chance your child might get hurt if he/she is in this study. If you think your child has been hurt you may talk with Dr. Silkwood-Sherer. You will get a copy of this informed consent document and your child's assent form for your records.
- 8. Cost to subject/ payment to subject for participation:** If your child is in the treatment group, you will not be asked to pay for any tests done on your child by the investigators or to pay for the hippotherapy sessions. If your child is in the control group the tests done on your child are free of charge and the researchers will reimburse you for your time at the rate of \$50.00 per testing session. No other money is available for your child to be in this research study. You are responsible for transportation to and from the riding center, testing center and the costs of that transportation.

Please initial and indicate that you have read and understood the second page \_\_\_\_\_  
Initials

- 9. Explanation of treatment and compensation for injury:** The possibility that your child might get hurt during horseback riding is about the same as it would be if he/she was playing in general sports activities. Even with the safety precautions in place, there is a small chance of injury to your child if he/she is in this study. If your child gets hurt because of his/her being in this study, you should get medical care for him/her as you would had the injury occurred at any other time. No money has been set aside to pay for any costs (such as lost wages, medical cost reimbursement, lost time or discomfort) you might have should your child get hurt. You are not waiving any legal rights by signing this consent form.
- 10. Voluntary participation with right of refusal:** Your child’s participation in this research study is voluntary. You may withdraw your consent for his/her involvement in this study at any time without penalty. If your child is in the treatment group and you choose to withdraw your child from the study, but want to continue horseback riding you will be responsible for the cost of any more treatments. If your child is in the control group and you withdraw, monies for testing time will stop. If you withdraw from this study it will have no affect on the therapy your child is currently receiving through his/her regular therapist.
- 11. IRB Review and Impartial Third Party:** This study has been reviewed and approved by the Institutional Review Board (IRB) of Central Michigan University (CMU). A representative from the CMU IRB Office is available to discuss the review process and/or your child’s rights as a research subject. The telephone number of the Central Michigan IRB Office is (989) 774-6401 and email address is [staneldm@cmich.edu](mailto:staneldm@cmich.edu).
- 12. Signature for Consent:** By signing this consent form you are stating you have read and understood all the benefits and potential risks to your child as a study participant. You are also stating that all of your questions have been answered. You may still contact the primary investigators if you have other questions regarding this study.

\_\_\_\_\_  
Parent/Guardian’s Name

\_\_\_\_\_  
Parent/Guardian Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Therapist Name

\_\_\_\_\_  
Therapist Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Investigator Name

\_\_\_\_\_  
Investigator Signature

\_\_\_\_\_  
Date

**CMU**  
**Central Michigan University**

**ASSENT SCRIPT AND WITNESS FORM:  
TESTING**

Script:

*Your mom/dad said you can help me learn about how kids keep from falling down. Today I'm going to ask you to stand up, sit down, close your eyes, stand on one foot, get an eraser off the floor, and tap a stool with your foot. I also want you to you walk and step over things and walk around things I put on the floor. Then I want you to draw on some paper for me. Will you tell me or your mom/dad how easy it is for you to do things at home, school and when you play? Would you like to do these things with me? Please tell me at any time if you want to stop.*

Assent  Yes  No

I, the undersigned, have defined and explained the study to the above child participant.

\_\_\_\_\_  
Therapist Printed Name

\_\_\_\_\_  
Therapist Signature

\_\_\_\_\_  
Date

This is to certify that I, \_\_\_\_\_ was present for the oral delivery of  
Print Name

the above information to \_\_\_\_\_  
Print Child's Name

The child appeared to understand all the information delivered and gave clear assent to participate in the study.

\_\_\_\_\_  
Witness Name

\_\_\_\_\_  
Date

**CMU**  
**Central Michigan University**

**ASSENT SCRIPT AND WITNESS FORM:  
FOR TREATMENT GROUP**

Script:

*Your mom/dad said it would be OK for you to come and ride a horse if I help you. I might ask you to do tricks like sitting backward or sideways on the horse. Would you like to do that? You can stop coming any time you want and no one will be mad at you.*

Assent  Yes  No

I, the undersigned, have defined and explained the study to the above child participant.

\_\_\_\_\_  
Therapist Printed Name

\_\_\_\_\_  
Therapist Signature

\_\_\_\_\_  
Date

This is to certify that I, \_\_\_\_\_ was present for the oral delivery of  
Print Name

the above information to \_\_\_\_\_  
Print Child's Name

The child appeared to understand all the information delivered and gave clear assent to participate in the study.

\_\_\_\_\_  
Witness Name

\_\_\_\_\_  
Date