Cover Letter

Study Title: Nighttime Postural Care: Caregiver Training Program and Outcome Measure Feasibility

Principal Investigator: Jennifer Hutson

Date of Document: October 31, 2017; Updated April 15, 2018

Date Document Uploaded to ClinicalTrials.gov: March 2, 2021

St. Catherine University IRB
Amendment request Form

Submit your Amendment Request Form for your protocol through Mentor IRB at the bottom of the protocol page.

Investigators may request approval to make amendments in various aspects of a project. All changes must be approved by the IRB prior to implementation. Amendments include: changes in experimental design, insertion of new information, correction of errors in text, change in primary investigator, change in study duration, change in numbers of subjects, or number of locations (site). Upon completion of review, an approval notification will be sent to the primary investigator.

Primary Investigator:
Jennifer Hutson
Date: 4/15/18

Title of Research Proposal:

Protocol ID:

1. **What are the proposed changes**?
Design change: Instead of one group of participants with pre/post questionnaires and demonstration of positioning a mock client (mock client is one of the research investigators), the participants will be randomized into treatment group (receives the sleep care positioning 2-hour online education program) and control group/lesser intervention (handout with series of web links) groups.

Participants will be blinded to the two group design, however the control group will be informed they were in the control group after completing the "lesser" intervention, the post-questionnaire and the demonstration of sleep positioning with mock client. On the same day the control group will be given the option to complete the same educational package as the treatment group (2-hour online sleep care positioning program).

Participants will complete a 12-20 item quiz after educational intervention. Since the online sleep care positioning training program is being delivered via Brightspace D2L. Statistics from the quizzes will be collected. The quiz is a new addition. This information will be compared along with the results from the questionnaires and demonstration of positioning a person in the sleep system to better understand if the training program leads to learning and competence thus revealing more about the feasibility of the training program for use in future clinical intervention study.

Another change is that participants will only demonstrate the sleep positioning on a mock, rather than real client (i.e. person with CP, family member of research participant).

2**. What is the rationale for proposed changes**? The change results in a better research design. This randomized design will allow for a comparison group, allowing investigators to learn more about the merits of the educational (sleep care positioning training program) than would occur with only one pre/post group.

3. **Do these changes either increase or decrease the benefits of this study**?
If Yes, please explain: It'll increase the benefits of the study in that randomization into groups allows investigators to say that the educational intervention caused the learning (if learning occurs in the treatment group).

4. Do these changes either increase or decrease the risks or the risks of this study?
If Yes, please explain and justify the increase in risk relative to the benefits:
No, it does not increase risk to participants.

If the proposed changes require additional or changes to documents (such as the consent form), list these document titles.
One statement on the invitation to participate will change. I've also made formatting changes on the questionnaire and simulation observation instrument based on advice from a measurement consultant and based on new learning that occurred from a pilot test run that was recently completed. The script may also change slightly to adjust for changes. I spoke with Amy McKenna about the overall change in plans and I wasn't sure if IRB be needs to approve any and all changes (formatting and otherwise) to each document if the risks are not increasing or if minor changes to forms can be made without additional advance approval?

ST. CATHERINE UNIVERSITY

ST. CATHERINE UNIVERSITY REQUEST FOR APPROVAL FOR THE USE OF HUMAN SUBJECTS IN RESEARCH APPLICATION

IRB APPLICATION DOCUMENT CHECKLIST

The items listed below are the application, forms and supporting documents to be uploaded to Mentor IRB for your protocol/application submission. Consent forms and additional supporting documents may be uploaded to separately; see Mentor IRB Directions. For questions, contact the IRB Assistant at 651-690-6204 or irb@stkate.edu.

☐	IRB Application
☐	PI Documentation/CITI Training for Investigator(s)*
N/A	PI Documentation/CITI Training for Faculty Adviser (if applicable)*
☐	Informed consent form
N/A	Child assent form (if applicable)
☐	Recruiting materials (phone script, fliers, ads, etc)
☐	Survey/questionnaire(s), focus group or interview questions (if applicable)
N/A	Conflict of interest/financial interest disclosure (if applicable)
N/A	Letter(s) of support (if you are conducting research at another agency, school, etc).

*PI Documentation/CITI Training is the completion report received for fulfilling the required Human Subjects Research education requirements in CITI Program. Each person will need to upload their PI Documentation to their individual Mentor IRB account. Directions are located in Mentor IRB.

IRB RELATED POLICIES:

Listed below as well as throughout the application are St. Catherine policies related to human Subjects research

- IRB Policy: www.stkate.edu/pdfs/irb-human-subject-research-policy.pdf
- Intellectual Property Policy: www.stkate.edu/pdfs/orsp-policy-intellectual-property.pdf
- Research Misconduct Policy: www.stkate.edu/pdfs/orsp-policy-research-misconduct.pdf

ST. CATHERINE UNIVERSITY

ST. CATHERINE UNIVERSITY REQUEST FOR APPROVAL FOR THE USE OF HUMAN SUBJECTS IN RESEARCH APPLICATION

Complete the following application in its entirety. You may excerpt material from your thesis or grant proposal, but your application should be relatively concise. Consent forms and additional supporting documents may be uploaded to separately; see Mentor IRB Directions. For questions, contact the IRB Assistant at 651-690-6204 or irb@stkate.edu.

Date of application: October 31, 2017

Investigator name(s) and credentials (e.g., PhD, RN, etc.): (*List all co-investigators*)

Jennifer Hutson MS, OTR/L, ATP

Project Title: Nighttime postural care: Caregiver training and outcome measure feasibility

Department: Occupational Therapy

Level of Review:

In the Mentor IRB system, you must select the Review Type; selecting Exempt and Expedited will prompt additional questions for you to fill out. The default level of review is Full if not selected. For more information on the levels of review, go to the Mentor IRB Info page: Determine the Level of Review.

[ ] **Exempt** [X] **Expedited** [ ] **Full**

Has this research been reviewed by another IRB?

[ ] **Yes** [X] **No**

If YES, you may not need to complete a St Kates IRB application and may be able to use your external IRB application instead. Please include a copy of the letter of approval and approved IRB application from the external IRB with your Mentor IRB submission, or indicate the status of your application here. Contact the IRB coordinator at IRB@stkate.edu with any questions. Examples: "See attached" or "Pending approval"

Will this research be reviewed by another IRB?

[x] **Yes** [ ] **No**

If YES, please indicate your plans for review

This research will take place at St. Catherine University. Select students in the St. Kate MAOT program will be contributing to this study helping to finalize the draft of training program and carry out the intervention. Two will be hired as research assistants (names to be identified by February 9, 2018).
Study participants will be recruited from Gillette Children's Specialty Healthcare. Gillette uses the University of Minnesota (UMN) IRB. Therefore, an application to UMN IRB will also be submitted. I (Jennifer Hutson) will be submitting a request for scientific review to Gillette by the end of November, 2017 and once approved I will receive a letter (indicating Gillette's willingness to agree to subject recruitment). Then I will submit application to UMN IRB.

Note: *Cooperative Research is when a research protocol requires approval from outside institutions (e.g., a hospital IRB or other college/university) as well as St. Catherine University. Sometimes it is possible for an IRB to accept an external IRB's review to reduce duplication of review effort. Contact the IRB coordinator at IRB@stkate.edu if you have questions about cooperative research and how to determine when only one IRB will need to review your IRB application. You can also reference the Cooperative Research Policy Addendum:*

1. **RESEARCH SUMMARY:** *Complete each section in clear, easy to read language that can be understood by a person unfamiliar with your research and your field.*

   a. **Purpose of the research:** *Provide a clear, concise statement of your purpose.*

The purpose of this study is to examine the feasibility of a caregiver training protocol and sleep-based outcome measure (intended for future use in a larger nighttime postural care intervention study).

   b. **Background:** *Provide a concise summary in 1 - 2 brief paragraphs to explain the importance of the research and how it fits with previous research.*

Postural care is an intervention aimed at protecting body shape and ultimately enhancing health, primarily for people who have impaired ability to move or change positions. When applied during sleep (at nighttime), the intervention involves use of equipment to support symmetrical lying. Limited research examining the effectiveness of nighttime postural care has been conducted and no studies, to date, have been published in the United States. Research is needed to determine the potential impact of this intervention for persons with mobility issues especially as it relates to outcomes such as sleep, pain, body shape, quality of life and perceived caregiver burden (all issues common to those with movement disorder).

According to National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre (2017), a feasibility study is research done before a main study to determine criterion needed for study design. Feasibility studies are important because they can help investigators avoid undesirable consequences from occurring when embarking on a larger study (Thaban et al. 2010). In the case of this feasibility study, results will help investigator/s to determine if both a sleep care positioning caregiver training program and the sleep disturbance scale for children assessment (SDSC) are feasible for use in a future nighttime postural care intervention research study.

   c. **Research Methods and Questions:** *Give a general description of the study design and specific methods you will use in your investigation. Specify all of your research questions and/or hypotheses. Reviewers will consider whether the information you are gathering is necessary to answer your research question(s), so this should be clear in your application.*

Research Questions. This project investigates both the feasibility of a sleep care positioning training protocol and the internal consistency reliability of the sleep disturbance scale for children (SDSC), a 26 item Likert-type rating scale developed by Bruni et al. in 1996 to evaluate sleep disturbances via caregiver report. Two Population Intervention Comparison Outcomes (PICO) questions will be addressed: 1. Is the training protocol feasible for use in training caregivers? 2. Does SDSC applied to children with cerebral palsy (CP) in the United States have sufficient internal consistency reliability for use in intervention research? Question one includes the following sub questions: A. Do caregivers have perceived competence and capacity to position children with CP (or similar mobility limitations) for sleep using sleep care positioning systems? B. Does the training protocol prepare caregivers to implement nighttime postural care (NTPC)?

Target Population. A convenience sample of 40 adult participants identified as professional or non-professional care providers (primarily from two community organizations that specialize in serving clients with CP) will be recruited for the study. Care providers of children with severe CP (those with limited ability to move and/or whom require use of a wheelchair) aged 6 to 12 are the primary target population, since this matches the intended sample of the future intervention study. However caregivers of children whom are outside of the 6-12 age range whom are candidates for NTPC and have similar mobility limitations as those with severe CP will not be excluded. Professional care providers might be nurses, occupational and physical therapists, assistive technology providers, etc. Non-professional care providers may be family members, care attendants, etc. Only individuals with knowledge of the child's sleep habits or routines will be included in the study

This is a feasibility study. Feasibility studies are completed in advance of larger studies to better determine study design and are thought to help investigators avoid undesirable consequences from occurring when embarking on the larger studies (NIHR, 2017; Thaban et al., 2010). To understand the training protocol feasibility, data will be gathered from participants via questionnaire pre-training and post-training and via observational notes at the time of intervention simulation. Quantitative methods will be used to analyze numerical data and qualitative type methodology will be used to examine subjective data; however, the primary methodology of this study is quantitative.

Description of training protocol. All participants will receive the sleep care positioning training protocol with content on NTPC intervention implementation strategies. The primary topic areas include state of the evidence, outcome measurement, risk factor monitoring, and sleep care positioning methods and equipment. The content will be delivered using primarily electronic interactive tutorials, however some hands-on training may take place in person. Total training time is anticipated to require between 4 and 8 hours. Participants will simulate aspects of the intervention (with mock client, either researcher or actor) at the end of the training session. Additionally participants will be given the option of demonstrating aspects of the intervention with their own child (or child for whom they provide care) after completion of the training session and simulation.

Data Collection. Data will be collected to assess both the training protocol and the SDSC internal consistency reliability. To assess feasibility of the training protocol, data will be collected at baseline, post-training and post-simulation via questionnaire. The questionnaires (developed by investigators) contain Likert type rating scales and semi-structured questions about both participants' perceived competence to implement aspects of intervention and perceptions of the training protocol efficacy. A simulation observation instrument (developed by investigators) contains a structured format by which investigators can document observational notes of caregiver performance at time of intervention simulation. For this aspect of the study, raters will be trained by investigators to document observations of participant caregiver performance based on a set of criteria of competence.

Internal consistency reliability of SDSC data will be collected during the training session. For this aspect of the study, a protocol will be issued to ensure consistent administration and scoring of the 26 idem assessment.

Data Analysis. Results of the training protocol and SDSC internal consistency reliability data will be analyzed. Data analysis of the feasibility of training protocol will be conducted using statistics for the numerical data and a systematic process of coding and theme identification for non-numerical data. Both within group and between group analyses will be conducted. Paired T-test statistics will be used to analyze changes that occur within groups pre-training vs. post-training, after calculating both total scores and sub scores of competence Likert scale ratings. Between group comparisons (comparing professional vs. non-professional) will be made using 2 sample T-test after calculating mean score change for each participant. Information provided by participants in response to open ended questions will be analyzed via a qualitative type coding process. Investigators will first code the data and analyze for themes independently and then discuss collectively. Any discrepancies will be resolved via discussion and

further examination of the data. Internal consistency reliability or how well test items measure the same construct, will be analyzed using Cronbach's Alpha.

d. Expectations of Participants: *Give a step by step description of all procedures that you will have participants do. Attach any surveys, tests, instruments, interview questions, data collection forms, etc. that you will use with participants*.

Participants will complete a baseline questionnaire to determine their level of knowledge or competence related to a select aspects of the NTPC intervention (i.e. state of the evidence, outcome measurement, sleep care positioning methods and equipment, & risk factor monitoring).

Participants will receive a 4-8 hour sleep care positioning training protocol. Participants will learn about various strategies used to implement NTPC and gain practice in assessments, positioning equipment and methods and development of risk monitoring plan. The content will be delivered primarily using electronic interactive tutorials and some in-person training. As a part of the training, participants will be asked to discuss and apply information relevant to their own child or client (if professional care provider).

Participants will then complete a post-training questionnaire, rating their competence to implement aspects of the NTPC intervention and the quality and/or utility of the received training protocol.

After training, participants will simulate aspects of the intervention (with mock clients, either researcher or actor). The simulation will take place at the end of the in-person training period. Participants will then complete a post-simulation questionnaire, again rating their competence to implement aspects of the NTPC intervention and the quality and/or utility of the received training protocol. Participants will be given an option of demonstrating aspects of the NTPC intervention with their own child/client at the end of the training session after simulation.

The baseline questionnaire will be completed prior to training on the same day as the training session or no more than one week in advance of the in-person training session. The post-training questionnaire will be completed on the same day as the in-person training. The post-simulation questionnaire will be completed on the same day as the in-person training or no later than two days post in-person training/simulation session.

The time requirement for participants is expected to be no more than 8 hours.

e. Estimated Time Commitment for Participants:

1 in-person session	**Number of sessions for each participant**
4-8 hours	**Time commitment per session for each participant**
8	**Total time commitment for each participant**

f. Access to Existing Data: *If you are analyzing existing data, records, or specimens, explain the source and type, means of access, and permission(s) to use them. If not accessing existing data, indicate "NA"*

N/A

2. SUBJECTS: *Provide your best estimates below*.

a. Age Range of Subjects Included: 18 – 65

b. **Number:**
(*Indicate a range, or maximum, if exceeded, you will need to submit an amendment)*

15 Male 25 Female 40 Total

c. **Target Population:** Describe your target population (the group you will be studying; e.g. seniors, children ages 9-12, healthy adults 18 or over, etc.)

Adults aged 18 years and over identified as professional or non-professional care providers. Non-professional care providers may be family members, care attendants, or others whom provide daily care to person with CP or mobility limitation. Professional care providers may include occupational therapists, assistive technology providers or health care providers whom work with persons with disability or have experience in providing assistive technology-related service.

d. **Specific Exclusions:** *If women and/or minorities are to be excluded from the study, a clear rationale should be provided in section "f" below.*

Those whom do not have knowledge of a child's typical sleep habits and routines. In other words, those whom would be unable to apply the information directly to someone they know.

e. **Special Populations Included:** *Select any special population that will be the focus of your research.*
NOTE: *These groups require special consideration by federal regulatory agencies and by the IRB.*

- [ ] **Minors (under age 18)**
- [ ] **St. Catherine Employees**
- [ ] **Students**
- [ ] **Pregnant women**
- [ ] **Elderly/aged persons**
- [ ] **Cognitively impaired persons**
- [ ] **Minority group(s) and/or non-English speakers *(please specify)*** _____
- [ ] **HIV/AIDS patients**
- [ ] **Economically disadvantaged**
- [ ] **Educationally disadvantaged**
- [ ] **Hospital patients or outpatients**
- [ ] **Prisoners**
- [X] **Other Special Characteristics and Special Populations**

(please specify) Overall, it is not expected that those being recruited fall into the category of special populations. It is possible that economically or educationally disadvantaged persons may be interested in participation. Such individuals are not being actively recruited or excluded.

f. **Provide reasons for targeting or excluding any special populations listed above**.

No special populations will be included in the study nor are these populations intentionally excluded from the study.

The study requires participants be care providers (either non-professional or professional). It is anticipated that participants interested in this study will be those individuals whom have some practice and educational experience to advocate for needs of their children/clients with disability and sufficient English speaking skills to answer sleep-based questions from assessment/s written in English. As a result, a majority of the special populations identified above (section e.) would not be represented by the larger population of this study's participant pool.

Based on Minnesota (MN) and CP demographics, it is expected that some individuals that are economically or educationally disadvantaged are providing care to persons with CP in MN. As a

result, such individuals may be interested in the NTPC intervention and study participation. Such individuals would not be excluded from the study unless unable to respond to questionnaires.

g. Do you have any conflict of interest (financial, personal, employment, dual-role) that could affect human subject participation or protection? *Dual-role examples: faculty–student (does not apply to action research projects for education students), medical practitioner-patients, supervisor-direct reports, etc.*

[ ] **Yes** [X] **No**

If Yes, please indicate the steps you will take to minimize any undue influence in your research, recruitment and consent process. You can also reference the university Financial Conflict of Interest policy: https://www.stkate.edu/pdfs/orsp-policy-fcoi.pdf

I currently have no conflict of interest, however there may be appearance of a financial conflict of interest. As a part of the research study I as principle investigator will be examining the sleep care positioning caregiver training program developed through my dissertation work as well as in my role as master's project advisor. An aspect of the training program involves information on sleep care positioning systems and methods for how to properly use such positioning devices.
In addition to my employment at St. Catherine University I am also employed as a sleep care positioning consultant by a small for-profit business, Bridgeway Independent Living Designs (BILD) LLC, that sells sleep care positioning systems. In this consultant position, I am paid a flat rate (non-commission) to evaluate and educate clients/potential clients about the risks and benefits of the nighttime postural care / sleep care positioning intervention.
While there is no conflict of interest, based on definitions provided in the St. Catherine University Office of Research and Sponsored Programs' Financial Conflict of Interest Policy, there may be the appearance of a financial conflict of interest. For instance, if participants are interested in purchasing a sleep care positioning system and they are aware of my employment with BILD, BILD may indirectly benefit due to participants new knowledge about the small business. This is not a financial conflict of interest, since my employment / relationship with BILD does not have the potential to "directly and significantly affect the design, conduct or reporting" of the research (p. 3). In my role as primary investigator I'll be representing St. Catherine University, not BILD. BILD is not providing any funding for the research. To reduce potential for conflict of interest, BILD will not be identified in any of the sleep care positioning caregiver training program materials or research participant recruitment / research related documents. It is possible that research participants may already be aware / or become aware of my consultant work during the research period. If persons in their role as participants inquire about BILD I will remind participants that I'm representing St. Catherine University, in my role as PI on the study and that any further questions about BILD can be addressed after the data collection period has ended.

3. RECRUITMENT: LOCATION OF SUBJECTS *(Select all that apply)* :

[ ] **St. Catherine University students**

[ ] **School setting (PreK – 12)**

[ ] **Hospital or clinic**

[ ] **Other Institution *(Specify)*:** _____

[X] **None of the above *(Describe location of subjects)*:**
(Specify):
A convenience sample of care providers from two different organizations have expressed interest in the study. Other care providers known to the PI whom might be interested in this

research study may also be recruited for participation. Care providers working at the following twin cities organizations have identified initial interest: Gillette Children's Specialty Healthcare and LiveLife Therapy Solutions, Inc. Note: If identified recruitment efforts fail to produce the desired number of participants, flyers may also be delivered via email or posted as hard copy in health-based programs at St. Catherine University and University of Minnesota.

NOTE: *If subjects are recruited or research is conducted through an agency or institution other than St. Catherine University, submit either written or electronic documentation of approval and/or cooperation. An electronic version should be sent from the email system of that particular institution. The document should include the name of the PI, Title of the approved study, as well as the name and title of the appropriate administrator sending the approval. You should include an abstract/synopsis of your study when asking for approval from an external institution.*

a. Recruitment Method: *Describe how you will recruit your subjects? Attach a copy of any advertisement, flyer, letter, or statement that you will use for recruitment purposes.*

Care providers (both professional and non-professional) whom have previously identified having interest in nighttime postural care training sessions at St. Catherine University or whom have considered NTPC as an intervention for their children/clients will be recruited for participation in the study. Care providers from two organizations (Gillette Children's Specialty Healthcare and LiveLife Therapy Solutions, Inc.) have already verbalized having interest in participation and will be invited to participate. Additionally, individual care providers (professional) from other organizations known to have interest in the NTPC intervention will also be invited.

A flyer will be sent via email to recruit participants for the study. This flyer will be/is attached to the application. Additionally the following script will be included in the body of the email.

"Hello (name), [As you know], I'm conducting a research study entitled "Nighttime postural care: Caregiver training and outcome measure feasibility" at St. Catherine University. I/We am/are trying to determine whether a training program I/we developed will be useful in preparing care providers (both non-professional and professional) to position and monitor children with cerebral palsy or movement limitations for sleep using sleep care positioning systems. I hope that you can participate by attending my/our sleep care positioning training session and completing a questionnaire rating the training. By participating in this research study you will attend a 4-8 hour training session and gain learning in a new sleep-based positioning intervention. You will also receive $50/75 gift card and continuing education contact hours (if preferred by professional care providers). The gift card is being funded by St. Catherine University APDC grant # 00-1471-1.

"Also, if you are a professional care provider and know of any non-professional care providers (i.e. family member, care attendant, etc. of child with cerebral palsy whom might be a candidate for sleep-based positioning interventions) whom might be interested in participating in this study, please send their contact information (via encrypted email if verbal permission is given) to Jenny Hutson"

Please review the attached flyer (with details) and contact Jenny Hutson by [enter date here].
I look forward to hearing from you. Best, Jenny Hutson"

b. Incentives: *Will the subjects be offered inducements for participation? If yes, explain. Note: Please contact the ORSP office about the use of incentives within your research, as there are important university policies that fall outside of the protection of human subject, orsp@stkate.edu or x6156*
Incentive policy link: https://www.stkate.edu/pdfs/participant-incentives-policy-and-procedures.pdf

Care providers will be offered a $50/75 gift card for completing the in-person training session and participating in the research. Additionally, care providers can also receive a certificate of contact hours.

4. RISKS AND BENEFITS OF PARTICIPATION

a. Select all that apply. Does the research involve:

- ☐ **Use of private records (medical or educational records)**
- ☐ **Possible invasion of privacy of the subjects and/or their family**
- ☐ **Manipulation of psychological or social variables**
- ☐ **Probing for personal or sensitive information in surveys or interviews**
- ☐ **Use of deception**
- ☐ **Presentation of materials which subjects might consider offensive, threatening or degrading**
- ☐ **Risk of physical injury to subjects**
- ☒ **Other risks:** No foreseeable physical risk is expected outside of what is typical for participants whom assist or position children for sleep. No foreseeable psychological risk is expected outside of what is typical for caregivers communicating with other caregivers about a child's sleep habits or routines and sleep-based health. Additionally the feedback requested from the study participants in the questionnaire/s is not expected to present psychological risk.

b. Risks: ***Briefly describe the risks of participation in your study, if any. Describe the precautions taken to minimize these risks. Please use "no foreseeable risk" rather than no risks.***

While there are no foreseeable risks beyond minimal risk, participants could feel uncomfortable when asked to provide information on questionnaires about their competence in administering aspects of the NTPC intervention. However such information is aimed more at evaluating the sleep care positioning training protocol rather than the individual, so any psychological stress is very unlikely.

It is also possible that musculoskeletal discomfort could occur as participants demonstrate the positioning of a child during the simulation portion of the in-person training session. While discomfort could occur, this is very unlikely. Participants will only be asked to physically move in ways that are typical to their everyday care of a child/client.

To minimize any risks, participants will be informed of these potential risks during the consent process. During the consent process participants will be asked to communicate any concerns related to their ability to engage in the above identified tasks. If concerns are voiced participants will be given/reminded of the option to decline study participation and/or if appropriate a plan to address the concerns will be activated. Confidentiality will also be maintained to limit potential risks

c. Benefits: *List any anticipated direct benefits to your subjects. If none, state that here and in the consent form.*

1. Direct Benefits: *List any anticipated direct benefits to your subjects. If none, state that here and in the consent form.*

Participants will gain knowledge in the nighttime postural care intervention. Participants will receive a $50/75 gift card. Participants can also receive continuing education (contact hours) credit.

2. **Other Benefits:** *List any potential benefits of this research to society, including your field of Study.*

Information obtained from this feasibility study will allow investigators to develop a more rigorous research design and prevent potential problems from occurring in a future intervention research study. Due to the activities involved in the research study, both investigators and participants will become better informed about effectiveness of training tools designed for NTPC intervention and reliability of outcome measures used to assess sleep. Investigators and participants will also be better prepared to educate other care providers / recipients about the NTPC intervention and serve those with disability. Since this feasibility study is meant to inform an intervention study, it could ultimately impact the use of an intervention aimed at enhancing health for persons with movement impairment and musculoskeletal disorder.

d. Risk/Benefit Ratio: *Justify the statement that the potential benefits (including direct and other benefits) of this research study outweigh any probable risks*.

It is unlikely for psychological or physical injury to occur, since participants will not be asked to do any activity beyond that which is typical for their daily work or child care related functions. For example, participants will only be asked to demonstrate intervention strategies that are considered safe to use in their typical work/home environment. The direct learning, monetary stipend, as well as receipt of continuing education credit outweighs foreseeable risks.

e. Deception: *The use of deception in research poses particular risks and should only be used if necessary to accomplish the research, and when risks are minimized as much as possible. The researcher should not use deception when it would affect the subject's willingness to participate in the study (e.g, physical risks, unpleasant emotional or physical experiences, etc)*.

Will you be using deception in your research?

[ ] **Yes** [X] **No**

If yes, justify why the deceptive techniques are necessary in terms of study's scientific, educational or applied value. Explain what other alternatives were considered that do not use deception and why they would not meet the researcher's objective. Attach a copy of a debriefing statement explaining the deception to participants.

5. CONFIDENTIALITY OF DATA

a. Will your data be anonymous?

[ ] **Yes** [X] **No**

(*Anonymous data means that the researcher cannot identify subjects from their data, while confidential data means that the researcher can identify a subject's response, but promises not to do so publicly*.)

b. *How will you maintain anonymity/confidentiality of the information obtained from your subjects*?
Interview Example: I will assign pseudonyms to each interview participant. I will de-identify the data, and store the key separate from the recordings and transcripts. I will have the transcriptionist sign a confidentiality statement

Pseudonyms / code #s will be assigned to each participant. Data will be de-identified and a key that contains the name of the participant and their pseudonym/code along with any identifiable information / documents will be stored separately from the de-identified information / documents.

c. Data Storage: *Where will the data be kept, and who will have access to it during that time*? *Examples: I will store audio files and electronic files on a password protected computer or cloud (indicate which; please avoid using flash drives as they are the one of the hardest 'tools' to protect and one of the easiest to exploit or lose, it is suggested to encrypt data on the cloud such as use a file password). I will store all paper files in a secure location (a locked filing cabinet) that is accessible only to myself and my advisor.*

The pseudonym key and all paper files will be stored in a locked filing cabinet in the office of the primary investigator. Electronic files will be stored on the password protected computer of the primary investigator. Only the primary investigator will have key access to the paper files. Research assistants and co-investigators will have access to the files at the point of data collection and data analysis via primary investigator, then files will be returned by the primary investigator to the locked storage cabinet.

d. Data Destruction: *How long will it be kept? What is the date when original data will be destroyed? (All studies must specify a date when original data that could be linked back to a subject's identity will be destroyed. Data that is stripped of all identifiers may be kept indefinitely). Example: I will destroy all records from the study within six months of the conclusion of the study but no later than June 2017.*

All records with identifiers will be destroyed one year after data collection and analysis is completed, by December 2019.

e. Availability of Data: *Will data identifying subjects be made available to anyone other than you or your advisor? If yes, please explain who will receive the data, and justify the need. Example: The data will only be available to me and my advisor.*

The data will only be available to the primary investigator, research assistants and MAOT student investigators.

f. Official Records: *Will the data become a part of the medical or school record? If yes, explain.*

NO

6. INFORMED CONSENT

a. How will you gain consent? *State what you will say to the subjects to explain your research.*

We will say the following to the potential participant: "You have expressed interest in participating in this research study. Before agreeing to participate we want to be sure you fully understand what you are being asked to do as a research participant. You have received the document entitled "ST CATHERINE UNIVERSITY Informed Consent for a Research Study". I will read the contents of the document aloud, then we'd like to hear your questions and/or concerns".
Then read document [ST CATHERINE UNIVERSITY Informed Consent for a Research Study].
"By signing this document you are officially agreeing to participate. Please do not sign until you feel you understand what to expect as a research participant and we've answered your questions and addressed your concerns. Also remember that at any time you can withdraw participation."

Gaining Assent from Children of Participants. Because participants are given the option of demonstrating the positioning of their child/client after the training/simulation, the assent of the child is needed. While the child/client is not the subject of the research, they still would need to agree to participate. Therefore, we will use the following script "*We would like to see how your [name/title of care provider] positions you in this sleep system [show sleep system]. Please tell us if you are okay with [name of person] positioning you in the sleep system? Please answer yes if this is okay with you OR no if this is not okay with you. It is totally up to you".* The script will be adjusted based on age level and ability to respond. For example if child is able to nod head yes or no, this might be used instead of a verbal response OR if able to use upper extremity to point to options yes / no, cards will be used for child to make selection. Additionally if child agrees and then during positioning shows facial expressions indicating discomfort or desire to end the activity, the positioning of child by caregiver will be stopped.

b. Consent Document: *Attach the consent or assent form or text of oral statement. A template is available in Mentor IRB. Example: "See attached"*

Consent document attached to the Mentor IRB application site.

c. Timing of Consent Process: *Note: In studies with significant risk or volunteer burden, the IRB may require that subjects be given an interim period of 24 hours or more before agreeing to participate in a study*

Once potential participants have expressed interest in participation, the consent form will be sent to them via email. At that time potential participants will be asked to review the document, consider any questions they may have and bring their questions with them to the session. The consent process will take place on the same day as the training session.

d. Assurance of Participant Understanding: *How you will assess that the subject understands what they have been asked to do* (Note: *It is not sufficient to simply ask a yes/no question, such as "do you understand what you are being asked to do?")*

We will ask potential participants to verbally communicate their understanding of the participant expectations, any concerns they have related to their ability to participate in any of the participant tasks and any concerns they have related to potential risks of participation.

We will use a modified list of questions from the UCSD Brief Assessment of Capacity to Consent (UBACC) during the consenting process.

Script: "We want to be sure we've been clear in explaining your role as a research participant. What is the purpose of the study that was just described to you? What makes you want to consider participating in this study? If you participate in this study, what are some of the things you will be asked to do? Do you have to be in this study if you do not want to participate? Please describe some of the risks or discomforts that people may experience if they participate in the study? Do you feel you may be unable to complete the activities or be at risk of injury? Is it possible that this study will not have any benefit to you? Please describe some of the benefits of this study? Who will pay for medical care if you are injured as a direct result of participating in this study?"

If the responses to the above questions show the potential participant is unclear about their role in the research study, we will provide clarifying information and repeat the questions after the clarifying information has been provided.

7. **CITI TRAINING –** *Work with your faculty advisor or contact IRB@stkates.edu if you have any questions about whether you should complete additional training modules within CITI. You can also reference the HSR Mandatory Education Policy: https://www.stkate.edu/pdfs/irb-human-subject-research-education.pdf*

a. Select all the CITI training courses/modules you completed:

REQUIRED COURSE:

Human Subject Research Training Course – only one course is required

[ ]	**Human Subject Research - Social & Behavioral Research Investigators**
[ ]	**Human Subject Research - Education Action Research Program**
[X]	**Human Subject Research - Biomedical Research Investigators**

OPTIONAL MODULES:

- [ ] **Financial Conflict of Interest Course (suggested if you answered YES to Section 2 part g)**
- [ ] **Avoiding Group Harms - U.S. Research Perspectives (suggested if you checked any special populations in Section 2 part e)**
- [ ] **International Research (suggested for PIs doing research outside of the US that is NOT federally funded)**
- [ ] **International Studies (suggested for PIs doing research outside of the US that IS federally funded)**
- [ ] **Cultural Competence in Research (suggested when conducting research across cultures, i.e. with a population that is culturally different from one's own)**
- [ ] **Internet Based Research (suggested for PIs using internet resources during their research (outside of recruitment) – Skype, survey tools, internet activity monitoring, etc)**
- [ ] **Other (prisoners, pregnant women, children):**

8. ASSURANCES

By submitting this application, the researcher certifies that:

- **The information furnished concerning the procedures to be taken for the protection of human subjects is correct.**
- **The investigator has read the IRB policies and to the best of his/her knowledge, is complying with Federal regulations and St. Catherine University IRB Policy governing human subjects in research.**
- **The investigator will seek and obtain prior written approval from the IRB for any substantive modification in the proposal, including, but not limited to changes in cooperating investigators, procedures and subject population.**
- **The investigator will promptly report in writing to the IRB any unexpected or otherwise significant adverse events that occur in the course of the study.**
- **The investigator will promptly report in writing to the IRB and to the subjects any significant findings which develop during the course of the study which may affect the risks and benefits to the subjects who participate in the study.**

- **The research will not be initiated until the IRB provides written approval.**
- **The term of approval will be for one year. To extend the study beyond that term, a new application must be submitted.**
- **The research, once approved, is subject to continuing review and approval by the IRB.**
- **The researcher will comply with all requests from the IRB to report on the status of the study and will maintain records of the research according to IRB guidelines.**
- **If these conditions are not met, approval of this research may be suspended.**