RESEARCH PROTOCOL

Date	May 25, 2017
Title	**The Use of Weighted Blankets in the Care of Infants with Neonatal Abstinence Syndrome (NAS)**
Principal Investigator	Virginia R. Summe, RN
Sub-Investigators	Peggy (Margaret) Eichel MSN, RN, RNC-NIC
Research Specialist	Rachel Baker, PhD, RN
Department	Good Samaritan Hospital, Neonatal Intensive Care Unit
Hatton #	17-008

Purpose of Study

At the Good Samaritan Hospital Neonatal Intensive Care Unit (NICU), care is provided to approximately 2-5 infants with neonatal abstinence syndrome (NAS) each month. These infants often display symptoms including hyperactivity, irritability, jitteriness, poor feeding, and poor sleep patterns. The recommended first line of treatment to relieve these symptoms involves nonpharmacological interventions; however, there is little evidence supporting the effectiveness of specific nonpharmacological interventions. The purpose of the current pilot study is to provide preliminary data to assist in the design of a larger scale study to examine one potentially effective nonpharmacological intervention, the use of weighted blankets, to reduce symptoms of NAS among infants.

Research Questions & Hypotheses

Aim 1. To determine the feasibility of recruiting patients for a study evaluating the use of weighted blankets in the care of infants with NAS

Research Question 1: How many potential subjects will be identified each month?

Research Question 2: What percent of potential subjects will enroll in the study each month?

Aim 2. To determine the feasibility and safety of the study procedures.

Research Question 3: Will the study staff be able to complete the study procedures in addition to the clinical care for the patients?

Research Question 4: Will study staff complete the assessment tools?

Research Question 5: Will infants tolerate the weighted blankets?

Aim 3. Examine whether there is a clinical benefit to using weighted blankets for the treatment of symptoms in infants with NAS.

Research Question 6: What is the mean Finnegan score for infants without use of a weighted blanket?

Research Question 7: What is the mean Finnegan score for infants after application of a weighted blanket?

Research Hypothesis 1: Among infants with neonatal abstinence syndrome, the application of a weighted blanket will result in decreased severity of NAS symptoms compared to not using a weighted blanket.

Background

In the Good Samaritan NICU, we provide care to approximately 2-5 infants each month with NAS. These infants can have a wide range of central nervous system symptoms (including hyperactivity, irritability, tremors, excessive high pitched crying, restlessness, jitteriness, poor sleep patterns), metabolic/vasomotor/respiratory symptoms (including sweating, sneezing, increased respiratory rate), and gastrointestinal symptoms (including excessive sucking, poor feeding, vomiting, watery stools) (Finnegan, 1990; Hudak et al., 2012). The recommended initial line of treatment to decrease these symptoms includes nonpharmacological interventions, such as keeping the infant in a quiet and dark room, swaddling, swaying and rocking, providing frequent and small volumes of formula or human milk. If these nonpharmacological interventions do not relieve symptoms, drug therapy is recommended. Drug therapy has been shown to provide short-term alleviation of symptoms. However, use of pharmacologic intervention is associated with a longer duration of hospitalization and can present a potential barrier to maternal-infant bonding (Hudak et al., 2012). Because of the limited benefit and potential adverse effects of pharmacologic intervention, it is important that the best nonpharmacological interventions are used in the first line of treatment to potentially reduce the need to advance to drug therapy. However, there is little rigorous evidence surrounding the effectiveness of nonpharmacological interventions in this patient population. **This study seeks to fill this gap in the literature by studying one novel nonpharmacological intervention to decrease symptoms among infants with NAS, weighted blankets.**

Weighted blankets are a non-invasive and low cost intervention. Theoretically, weighted blankets are a way to provide deep tissue pressure which provides tactile sensory intervention. It is theorized that tactile sensory intervention helps patients organize their sensory input and adjust better to environmental stimuli, thereby decreasing anxiety and promoting calmness (AETMIS, 2010).

Weighted blankets, or weighted vests, have been studied in several patient populations, including children with autism (Gringas et al., 2014; Hodgetts et al., 2011; Leew et al., 2010), children with attention deficit hyperactivity disorder (ADHD) (Hvolby & Bilenbery, 2011), children with pervasive developmental disorders (Fertel-Daly, Bedell, and Hinojosa, 2001), adult psychiatric patients (Novak et al., 2012), and healthy adults undergoing an anxiety-producing procedure (Chen et al., 2013).

The majority of the research on weighted blankets and vests has examined their use with children with autism. Studies in this patient population have reported no significant clinical benefits to weighted blanket use, but have reported child and parent preference for using weighted blankets. Hodgetts, Magill-Evans, and Misiaszek (2011) studied the use of weighted vests in 6 children with autism. They found that weighted vests did not decrease stereotyped behaviors, arousal, motoric stereotyped behaviors, or heart rate. They found that one child had a decrease in verbal stereotyped behaviors with the use of the weighted vest. Leew, Stein, and Gibbard (2010) studied the use of weighted vests in toddlers with autism spectrum disorder and found no effect of the vests on competing behaviors or joint attention. However, they did find that there was an increase in mothers' morale when weighted vests were used. Finally in a

study of 67 children with autism, Gringas and colleagues (2014) concluded that weighted blankets did not increase sleep time, decrease time to fall asleep, or impact the number of times children woke during sleep. However, they reported that parents and children preferred using the weighted blankets for sleep and positively rated using the blankets (Gringas et al., 2014). While no statistically significant results have been reported in children with autism, families and children like using the weighted blankets and no adverse events were reported.

The use of weighted blankets or vests has been studied less frequently in other patient populations, but has demonstrated some potential benefits. Using a weighted blanket or vest was associated with decreased time to fall asleep, improved teacher ratings of symptoms of activity level, and improved attention span in 8-13 year olds with ADHD (Hvolby & Bilenbery, 2011). However, another study examined the use of weighted vests with elementary school students who had difficulty attending and found no significant impact on time on task (Collins & Dworkin, 2011). While these two studies came to conflicting conclusions, they were both conducted on small sample sizes (21 children – Hvolby & Bilenbery, 2011; 10 children – Collins & Dworkin, 2011) which may have impacted the ability for treatment effects to be observed. Fertel-Daly, Bedell, and Hinojosa (2001) studied 5 preschool age children with pervasive developmental disorders (PDD) and found that use of a weighted vest resulted in an increase in attention to task, decrease in self-stimulatory behaviors, and a decrease in number of distractions. In adult patients admitted to an acute inpatient psychiatric unit, the use of weighted blankets resulted in a decrease in distress and anxiety (Novak et al., 2012). Finally, the use of weighted blankets among 15 healthy adults who were undergoing dental procedures resulted in a significant decrease in heart rate and a calming effect was reported (Chen et al., 2013).

This review demonstrates that there is mixed and contradictory evidence supporting the use of weighted blankets with a wide range of patient populations. Many of these studies involved a small sample size and lacked power to detect small effects of the intervention. There is some preliminary evidence that the use of weighted blankets could improve sleep patterns (Hvolby & Bilenberry, 2011), decrease self-stimulatory behaviors (Fertel-Daly et al., 2001), decrease anxiety (Novak et al., 2012; Chen et al., 2013), and decrease heart rate (Chen et al., 2013). Many of these symptoms are symptoms that are problematic for infants with NAS (disturbed sleep patterns, jitteriness, etc). However, to date, the use of weighted blankets has not been studied in infants with NAS.

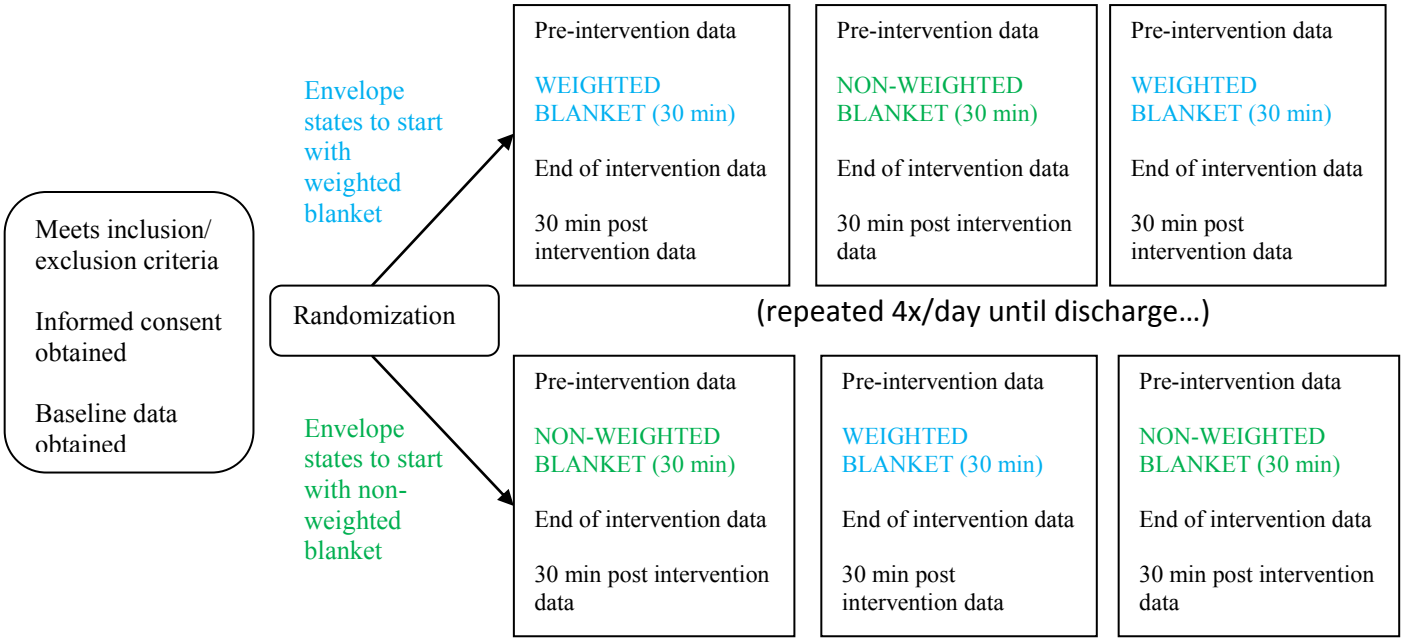
Therefore, the current study seeks to fill this gap in the literature by taking the first step in rigorously studying the use of weighted blankets in infants with NAS. Because weighted blankets have not been studied in this patient population and have not been used to impact Finnegan scores (the proposed outcome measure), a small effect size was used to conduct a power analysis. To detect a small effect size (d=0.2), with a level of significance of 0.05 and power of 0.80, 156 subjects would need to be enrolled. Since only approximately 2-5 patients each month would be eligible for this study, it would take many years to complete data collection if only Good Samaritan NICU patients are enrolled. Therefore, the current pilot study is proposed to examine the proposed study procedures (Aims 1 and 2) and to obtain a more

accurate estimate of the effect size (Aim 3). This will allow us to work through any obstacles with the study procedures. If this pilot study shows that the procedures are feasible, we will conduct a power analysis with an evidence-based effect size determined through this pilot study and then develop a multi-site study to determine intervention effectiveness.

Research Plan

- **Study Design**

This pilot study will assess the feasibility of a cross-over randomized controlled design to study the impact of a weighted blanket on infants' symptoms of NAS. Because there are no published data on the use of this intervention with this population, the effect size is unknown and a power analysis could not be conducted. Therefore, a pilot study will be used to determine effect size that can then be used to calculate sample size for a larger powered study. Additionally, the pilot study will be used to assess the feasibility of the recruitment plans and study design (cross-over randomized controlled trial).



- **Setting for the study**

This study will take place at Good Samaritan Hospital in the NICU. The NICU is a 60 bed Level III neonatal intensive care unit that provides care for premature infants and infants with critically ill conditions. In this setting, approximately 2-5 infants with NAS are provided care each month.

Before the study begins, the study staff will provide education to all of the nurses working on the unit. This education will include information about the study design, the intervention, and the inclusion/exclusion criteria.

- **Participants**

This study will enroll all patients who meet the inclusion/exclusion criteria and whose parents/guardians consent to the study.

Inclusion criteria:

- Admitted to the NICU
- Gestational age ≥ 37 weeks
- Positive maternal drug screen at delivery

Exclusion criteria:

- Clinical staff does not give permission to enroll the patient
- Had intrauterine growth restriction (IUGR)
- Has any medical diagnosis in addition to NAS diagnosis

Each day, the study staff will review the patients admitted to the NICU to determine potential subjects. In addition, the study staff expects that the staff education provided before implementation of the research study may result in clinical nurses notifying study staff when an eligible infant is admitted. By reviewing daily census and involving the clinical staff in identifying potential subjects, the study staff hopes to approach all families of potentially eligible infants. All potentially eligible infants will be entered in a Recruitment Log. When an infant appears to be eligible, study staff will complete the Inclusion/Exclusion Criteria Checklist. If the infant is eligible, study staff will talk with the infant's clinical team to obtain permission to approach the family about the study. Next a study staff member will meet with the parents/guardians and describe the study and answer any questions. If the parents/guardians are interested in enrolling their infant in the study, the study staff will review the Informed Consent Form and HIPAA form with the parents/guardians and obtain written informed consent. Parents/ guardians will receive a copy of their signed Informed Consent form and HIPAA form. The Recruitment Log entry will be completed for all infants with information about whether the infant was enrolled in the study. If the infant was not enrolled in the study, the reasons for not enrolling will be included on the Recruitment Log. The Recruitment Log will be stored in a password protected folder on the U drive that only study staff will have access to.

Sample Size Determination: Since there are no published data on the use of this intervention with this population, the effect size is unknown and a power analysis could not be conducted. Therefore, this is a pilot study will be used to determine effect size that can then be used to calculate sample size for a larger powered study. Additionally, the pilot study will be used to assess the feasibility of the recruitment plans and study design. Since we could not estimate sample size, we determined sample size based on feasibility of the team conducting a pilot study in the clinical setting. We decided to collect data for approximately7 months (recruitment and enrollment will end on December 1, 2017 and then we'll complete data collection on any enrolled infants) and all eligible infants during this time will be approached. Based on the unit leadership's estimation that approximately 2-5 infants meeting criteria are cared for each month, we expect a maximum of 30 infants will be enrolled in the pilot study. Seven months of

data will allow us to determine the feasibility of recruitment and study procedures and enrolling approximately 30 patients will allow us to calculate effect size and determine sample size for a larger subsequent study.

- **Data Collection**

The following variables will be collected:

- Independent variable: Use of the weighted blanket
- Dependent variable: Severity of NAS symptoms
- Potentially confounding variables: age, gender, weight, medications, stage of methadone weaning, and other nonpharmacological interventions being used

To obtain data on these variables, the following procedure will be followed. After obtaining informed consent, the *Demographic Form* will be completed by the study staff which includes information about the infant's age, gender, weight, medications currently taking, step of methadone weaning protocol (if applicable), nonpharmacological interventions being used, and whether the infant's symptoms center around feeding, sleeping, or both feeding and sleeping. The *Demographic Form* was developed by the study staff.

Next, the study staff will perform a baseline assessment of symptoms using relevant items from the *Modified Finnegan Neonatal Abstinence Scoring Tool.* This tool is the predominant tool used clinically in the United States to quantify the severity of symptoms of NAS (Hudak et al., 2012). It provides a summative score obtained from the assessment of 21 items related to neonatal withdrawal. The total score ranges from 0 to 43 with a higher score indicating more severe symptoms. Values above 8 have been described as being indicative of neonatal abstinence syndrome (Finnegan et al., 1975; Zimmermann-Baer et al., 2010). The total score of this tool has been found to have excellent inter-rater reliability (r=0.82 Finnegan et al., 1975; *ICC* = 0.996 Retskin & Wright, 2014).

Randomization:

After collecting baseline information, the subject will be randomized into one of two groups:

1. Weighted blanket first
2. Non-weighted blanket first

All infants will receive care with both the weighted blanket and the non-weighted blanket, allowing them to serve as their own controls. Randomization will determine which blanket is to be used first and then the blanket type will be alternated with each episode.

To randomize the subject after baseline information is collected, the study staff will select the next randomization envelope out of a box of pre-labeled study envelopes. The envelope will have the subject ID number on the outside. This number will be added to the top of the completed baseline *Demographic Form* and *Modified Finnegan Neonatal Abstinence Scoring Tool.* Envelopes will be created before study enrollment begins and will be filled with which intervention to use first (weighted blanket first or non-weighted blanket first). The order of interventions inside the envelope will be created from a computerized simple random number generator (1:1 randomization). Study staff will add the patient's name to the Recruitment Log

that connects the subject ID number to the patient's name. This is the only list that will connect patient identifiers to study ID numbers. Beginning with selection of the envelope, all documents will be labeled with only subject ID number and no patient identifiers.

Data collection:
On the *Demographic Form* it will be noted whether the infant's specific symptoms center around feeding, sleeping, or both feeding and sleeping. If just feeding was marked, the study staff will wait until the next feeding. If just sleeping was noted, the study staff will wait until the next time the infant will be going to sleep. And, finally, if both feeding and sleeping are noted, the study staff will wait until the next feeding or sleeping episode. Approximately 30 minutes before the episode (scheduled feeding or trying to get to sleep) begins, the study staff will complete a *Pre-Intervention Data Collection Sheet.* This sheet consists of the relevant components of the *Modified Finnegan Neonatal Abstinence Scoring Tool* and a place to document the infant's heart rate, respiratory rate, temperature, time that the blanket (weighted or not-weighted) was placed on the infant, and the exact time that assessment occurred.

For the intervention, the study staff will place the weighted or non-weighted blanket on the infant (depending on which was specified to start with in the randomization envelope). The blanket will stay in place for approximately 30 minutes (+/- 5 minutes), at approximately 30 minutes after placement of blanket and before removing the blanket, the study staff will complete an *End of Intervention Data Collection Sheet*. This form contains the *Modified Finnegan Neonatal Abstinence Scoring Tool,* documentation of the infant's heart rate, respiratory rate, temperature, and any comments about the infant's behavior or response to the blanket. Next, the study staff will remove the blanket and the clinical staff can begin to feed the infant or begin the sleep routine. Then, approximately 30 minutes after the blanket was removed, the study staff will complete the *30 Minutes Post-Intervention Data Collection Sheet.* This sheet contains the relevant components of the *Modified Finnegan Neonatal Abstinence Scoring Tool,* documentation of the infant's heart rate, respiratory rate, documentation of the time the blanket was taken off, and any comments about the infant's behavior and response to the event (feeding or sleeping). This same procedure (alternating between a weighted and a non-weighted blanket) will be repeated each time a scheduled episode (feeding and/or sleeping) is planned, for a maximum of 4 times over each 24-hour period.

Infants in both groups will continue to receive standard of care procedures throughout the study. The use of a blanket (weighted or non-weighted) will be in addition to standard care.

- **Intervention or experimental aspect of the study**

The therapeutic weighted blankets are made from a cotton and poly-blend and are machine washable. Additionally they can be covered with a pillow case. The blanket manufacturer has created 6 prototypes of an infant sized blanket and donated them to the study team. The manufacturer will receive summary findings from the study, the same findings that will be publically available through presentations and publications, and will not have access to raw

data. Additionally, the blanket manufacturer will have no access to study design or input in the study procedures.

The weighted blanket meets the FDA's requirements to be considered a nonsignificant risk device because it is not intended as an implant, is not used in supporting or sustaining human life, is not of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health, and does not present a potential for serious risk to the health, safety, or welfare of a subject. Therefore, we plan to follow the abbreviated IDE requirements (812.2b) including: labeling the blanket with the statement "CAUTION – Investigational Device. Limited by Federal (or United States) law to investigational use," obtaining IRB approval, obtaining informed consent from parent/legal guardian, monitoring (infants will be on heart rate/respiratory rate monitors and directly observed during blanket use), maintaining records of all use of the blanket and records of all investigators involved in the study.

Each infant will have their own weighted blanket that will not be shared. The weighted blanket will remain in the infant's room until the infant is discharged from the unit or until the study is completed. At that time, the blanket will be cleaned following the same procedure that linens are cleaned on the unit and will be available for use with the next infant enrolled.

Benefits of the weighted blanket include possible calming effects including decreased jitteriness, decreased anxiety, and improved ability to cope with environmental stimuli. Additionally, benefits may exist that are unknown.

In a review of all evidence on weighted blankets, there were no reports of adverse events resulting from use of a weighted blanket. One article contained reference to a death of a child with autism related to the improper use of a weighted blanket (AETMIS, 2010). In the current study, the blankets will be laid directly on top of infants and will cover them from their shoulders to their feet. Blankets will not be wrapped around infants and will allow for movement under the blankets. Additionally, all infants will be on heart rate and respiratory rate monitors during the blanket application. If any distress is noted, blankets will be removed immediately. Study team members will review data collection sheets every 3-4 days to determine any adverse events associated with the intervention. If a similar adverse reaction occurs in more than 1 infant or if an adverse reaction that does not resolve with removal of blanket occurs in 1 infant, study procedures will be suspended and clinical unit leadership will be consulted about safety of continuing study.

- **Statistical Analysis**

Data will be recorded on paper data collection forms with only subject ID and no identifiers. Data from these forms will be entered into a password protected database. Only study team members will have access to the database. No personal information will be entered into the electronic database. Data will undergo range checks when entered into the database, and quality control procedures will be performed to ensure accuracy of the data in the electronic database.

Statistical analyses will be performed using SPSS statistical software. Descriptive statistics (frequencies for categorical data; means and standard deviations and ranges for continuous data) will be used to describe the sample.

Aim 1. To determine the feasibility of recruiting patients for a study evaluating the use of weighted blankets in the care of infants with NAS

- Research Question 1: How many potential subjects will be identified each month?
  Raw numbers of potential subjects will be obtained from the Recruitment Log. These will be summarized and reported as raw numbers and summary data.
- Research Question 2: What percent of potential subjects will enroll in the study each month?
  Percent will be calculated by dividing the number of enrolled subjects (collected on the Enrollment Log) by the number of potential subjects each month (collected on the Recruitment Log).

Aim 2. To determine the feasibility and safety of the study procedures.

- Research Question 3: Will the study staff be able to complete the study procedures in addition to the clinical care for the patients?
  Qualitative information about obstacles encountered during the pilot study will be logged and reviewed to determine any trends or patterns that will need to be addressed in a larger study.
- Research Question 4: Will study staff complete the assessment tools?
  Missing data will be examined and percent of subjects with complete data will be calculated by dividing the number of subjects who complete the study without any missing data by the total number of enrolled subjects.
- Research Question 5: Will infants tolerate the weighted blankets?
  Adverse events experienced during weighted blanket application will be listed and frequency data will be reported.

Aim 3. Examine whether there is a clinical benefit to using weighted blankets for the treatment of symptoms in infants with NAS.

- Research Question 6: What is the mean Finnegan score for infants without use of a weighted blanket?
  Mean Finnegan score and standard deviation for infants after use of the non-weighted blanket will be calculated.
- Research Question 7: What is the mean Finnegan score for infants after application of a weighted blanket?
  Mean Finnegan score and standard deviation for infants after use of the weighted blanket will be calculated.
- Research Hypothesis 1: Among infants with neonatal abstinence syndrome, the application of a weighted blanket will result in decreased severity of NAS symptoms compared to not using a weighted blanket.

To compare the effects of the intervention, a Mann-Whitney U t-test will be used to compare mean total Finnegan scores for infants who had the weighted blanket applied compared to the mean total Finnegan scores of infants who had the non-weighted blanket applied. A level of significance of α=0.05 will be used. With a small sampled pilot study, statistically significant results are not expected. However, effectiveness will be examined and trends will be noted. Additionally, changes in total Finnegan scores will be examined to estimate an effect size that can be used in a power analysis to determine sample size for a larger effectiveness study. Secondary analyses will be planned using multiple regression modelling to adjust for the potential confounding variables.

Ethical Considerations

- **Informed consent**

A study staff member will meet with the parents/guardians of potentially eligible infants and describe the study and answer any questions. If the parents/guardians are interested and the infant meets all the inclusion/exclusion criteria, the study staff will review the Informed Consent Form and HIPAA form with the parents/guardians and obtain written informed consent. Parents/guardians will receive a copy of their signed Informed Consent form and HIPAA form.

Informed Consent forms and HIPAA forms will be stored in a locked cabinet that only study staff will have access to. After the study closes, the signed Informed Consent forms and HIPAA forms will be boxed and sent to off-site storage and securely stored until the infant turns 21 years of age. At that time, the hard copy forms will be shredded.

- **Privacy information**

Personal identifiers will be recorded: on the Informed Consent, on the HIPAA forms, on the Recruitment Log, and on the electronic Enrollment Log. All other data collection forms and electronic database of final data will include study ID number only.

Hard copy forms (including Informed Consent forms, HIPAA forms, and data collection sheets) will be stored in locked cabinets that only study staff will have access to. Electronic data (including Recruitment Log, Enrollment Log, and data entered into an electronic database) will be stored on a password-protected folder on the U drive. Only study staff will have access to the electronic study documents. After data analysis and dissemination is completed, hard copy forms will be boxed and sent to secure storage until the infants are 21 years old at which time they will be shredded. After data analysis and dissemination, electronic data and forms will be de-identified and transferred to a password-protected flash drive which will be sent to secure storage until infants are 21 years old at which time it will be destroyed.

Cost/Budget

Weighted blankets have been provided at no cost to the study team. Other costs including costs associated with copying data forms will be covered by the department. There will be no other costs associated with this study.

Estimated Period of Time to Complete Study	
When will study begin?	2/15/2017
Protocol Development Completed	2 weeks
Admin Review Time	2 weeks
IRB Approval	6 weeks
Data collection	8 months
Data analysis	2 months
Presentation development (if applicable)	2 weeks
Manuscript Development (if applicable)	1 month
Journal submission process (if applicable)	6 months
Study closure	1 month

- **When and how will results be disseminated?**

Results will be disseminated internally to the Good Samaritan NICU leadership and system-wide through the TriHealth Research Council. Results will be disseminated nationally through presentation at a professional organization conference. Finally, results will be disseminated nationally and internationally by publication in a relevant peer-reviewed journal, such as *Critical Care Nursing.*

References

AETMIS. (2010). Summary. Weighted blankets and vests: Safety, efficacy and issues related to their use in different intervention settings. https://www.inesss.qc.ca/fileadmin/doc/AETMIS/Rapports/ServicesSociaux/2010_04_res_en.pdf

Chen, H-Y., Yang, H., Chi, H-J., & Chen, H-M. (2012). Physiological effects of deep touch pressure on anxiety alleviation: The weighted blanket approach. *Journal of Medical and Biological Engineering, 33*, 463-470.

Collins, A. & Dworkin, R.J. (2011). Pilot study of the effectiveness of weighted vests. *American Journal of Occupational Therapy, 65*, 688-694.

Fertel-Daly, D., Bedell, G., & Hinojosa, J. (2001). Effects of a weighted vest on attention to task and self-stimulatory behaviors in preschoolers with pervasive developmental disorders. *The American Journal of Occupational Therapy, 55,* 629-640.

Finnegan LP. (1990). Neonatal abstinence syndrome: assessment and pharmacotherapy. In: Nelson N, editor. *Current Therapy in Neonatal-Perinatal Medicine*. 2 ed. Ontario: BC Decker.

Finnegan, LP., Kron, RE., Connaughton, JF., & Emich, JP. (1975). Assessment and treatment of abstinence in the infant of the drug-dependent mother. *International Journal of Clinical Pharmacology and Biopharmacy, 12*, 19-32.

Gringras, P., Green, D., Wright, B., Rush, C., Sparrowhawk, M., Pratt, K., Allgar, V., Hooke, N., Moore, D., Zaiwalla, Z., & Wiggs, L. (2014). Weighted blankets and sleep in autistic children – A randomized controlled trial. *Pediatrics, 134*, 298-306.

Hodgetts, S., Magill-Evans, J., & Misiaszek, J.E. (2011). Weighted vests, stereotyped behaviors and arousal in children with autism. *Journal of Autism and Developmental Disorders, 41*, 805-814.

Hudak, M.L., Tan, R.C., The Committee on Drugs, & The Committee on Fetus and Newborn. (2012). Neonatal drug withdrawal. *Pediatrics, 129*, e540-e560.

Hvolby, A. & Bilenberg, N. (2011). Use of ball blanket in attention-deficit/hyperactivity disorder sleeping problems. *Nord J Psychiatry, 65*, 89-94.

Leew, S.V., Stein, N.G., & Gibbard, W.B. (2010). Weighted vests' effect on social attention for toddlers with autism spectrum disorders. *Canadian Journal of Occupational Therapy, 77*, 113-124.

Olson, L.J. & Moulton, H.J. (2004). Occupational therapists' reported experiences using weighted vests with children with specific developmental disorders. *Occupational Therapy International, 11*, 52-66.

Novak, T., Scanlan, J., McCaul, D., MacDonald, N., & Clarke, T. (2012). Pilot study of a sensory room in an acute inpatient psychiatric unit. *Australas Psychiatry, 20*, 401-406.

Retskin, C.M. & Wright, M.E. (2014). Interobserver reliability of the Finnegan Neonatal Abstincence Scoring Tool in an acute care setting. *Journal of Obstetric, Gynecologic, & Neonatal Nursing, 43*, S61.

Zimmermann-Baer, U., Notzli, U., Rentsch, K., & Bucher, H.U. (2010). Finnegan neonatal abstinence scoring system: Normal values for first 3 days and weeks 5-6 in non-addicted infants. *Addiction, 105*, 524-528.