Supplementary file 5: Research protocol

March 15th, 2016

To: The IWK Health Centre – Research Ethics Board
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Subject: Research Protocol

Project Title: A Maternal Device for the Prevention of Stillbirth and Low Birthweight

Foreword

This project, entitled A Maternal Device for the Prevention of Stillbirth and Low Birthweight, was originally submitted on March 10th, 2014 to Grand Challenges Canada in response to their Request for Proposals: Stars in Global Health – Round 7 Phase I. Grand Challenges Canada's peer review of this proposal was led by the Canadian Institutes of Health Research. This proposal was recommended to proceed to the next stage of the *Stars in Global Health* grant process, which involved due diligence and grant agreement negotiations between the primary organization for this project, Innovative Canadians for Change Foundation (ICChange – Edmonton, AB), and Grand Challenges Canada, which were completed on December 19th, 2014. Funding for this project was approved on December 19th, 2014.

Note that this proposal includes two feasibility studies – one in Halifax, Canada, and one in Accra, Ghana. Both studies include human participants; therefore, both studies will require ethics approval. For the study in Halifax, ethics approval was received on June 16th, 2015 (Project #1018753) from The IWK Health Centre Review Ethics Board (REB). For the study in Accra, ethics approval was received from The IWK-REB on June 16th, 2015 (Project #1019318) and from the Noguchi Memorial Institute for Medical Research Institutional Review Board (local ethics board) on March 4th, 2015 (CPN 069/14-15).

The purpose of this document is to set forth the research protocol for the study related to The IWK Health Centre in Halifax, Canada as per the guidelines given in the document Protocol Components provided under the New Submissions – Guidelines and Templates section of the IWK Health Centre Research website:

http://www.iwk.nshealth.ca/research/application-materials-forms

This research protocol is submitted for review by The IWK Health Centre's Review Ethics Board as part of the requirements in the document Researcher's Checklist for Submissions: Delegated Review.

This document is divided into two main sections. The first section – “Scientific” – describes the scientific aspect of the study. The second section – “Ethical” – describes the ethical aspect of the study.

Sincerely,

Allan Kember

1 Scientific

1.1 Introduction

According to the WHO, stillbirth (SB) is defined as fetal death at gestation ≥28 weeks or weight ≥1000g [1]. In Canada, the definition of SB is wider, including fetal death at gestation ≥20 weeks or weight ≥500g [2]. In addition to the loss of life for the stillborn baby, SB assails parents with psychological grief of losing their baby and results in markedly increased mortality when compared with non-bereaved parents [3]. Current risk factors for SB in high-income countries are well established and documented. In a recent systematic review with meta-analysis [4], the three most important modifiable risk factors for SB were found to be obesity (population attributable risk (PAR) 8-18%), advanced maternal age (PAR 6-8%), and smoking (PAR 4-7%). Of these, smoking is the only modifiable risk factor that can be realistically addressed during the course of a pregnancy.

Low birthweight (LBW) is defined as a weight less than 2500g at birth [5]. LBW is a significant contributor to SB [4], and infants with LBW are 20 times more likely to die in the first year than heavier babies [5]. Although LBW babies constitute only about 15% of live births, they account for 60-80% of neonatal deaths [6] [7] [8] [9]. Neonatal deaths (death within the first year of life) account for 40% of all deaths under the age of five years [10]. LBW also accounts for significant morbidity such as cognitive impairment [11], and chronic diseases later in life [5] [12]. LBW arises through short gestation (preterm birth) or in-utero growth restriction, or both [13].

Maternal sleep position during pregnancy has recently emerged as a risk factor for LBW and SB [14] [15] [16]. A device to modify maternal sleep position and mitigate this risk factor has been developed (see section 1.1.3). The purpose of this *Stars in Global Health* project is to test the effectiveness of this device and assess the feasibility of incorporating this device into an antenatal care clinic in Ghana. Data will be used in effect size calculations for large-scale trials targeted at reducing poor pregnancy outcomes in Canada and worldwide.

1.1.1 Research Problem

In 2009, the World Health Organization reported the global prevalence of stillbirth (SB) to be 2.6 million (uncertainty range: 2.1-3.8 million), of which 98% occur in countries of low and middle income [1] – see Figure 1. Sub-Saharan Africa has the highest rate of SB worldwide and has made the least progress in SB reduction [1]. Little is known about effective interventions for SB, especially those that can be implemented in resource-limited settings.

In addition to the global burden of SB, the global incidence of LBW infants remains a significant public health challenge. Each year, there are over 20 million infants born with LBW, of which 96% occur in developing countries with the highest concentrations in Asia and Africa [5] – see Figure 1. Efforts to reduce the incidence of LBW have not been successful in these regions, and thus the incidence has remained largely unchanged [5].

Low- and middle-income countries urgently require simple, inexpensive, and effective interventions to reduce the rates of SB and LBW.

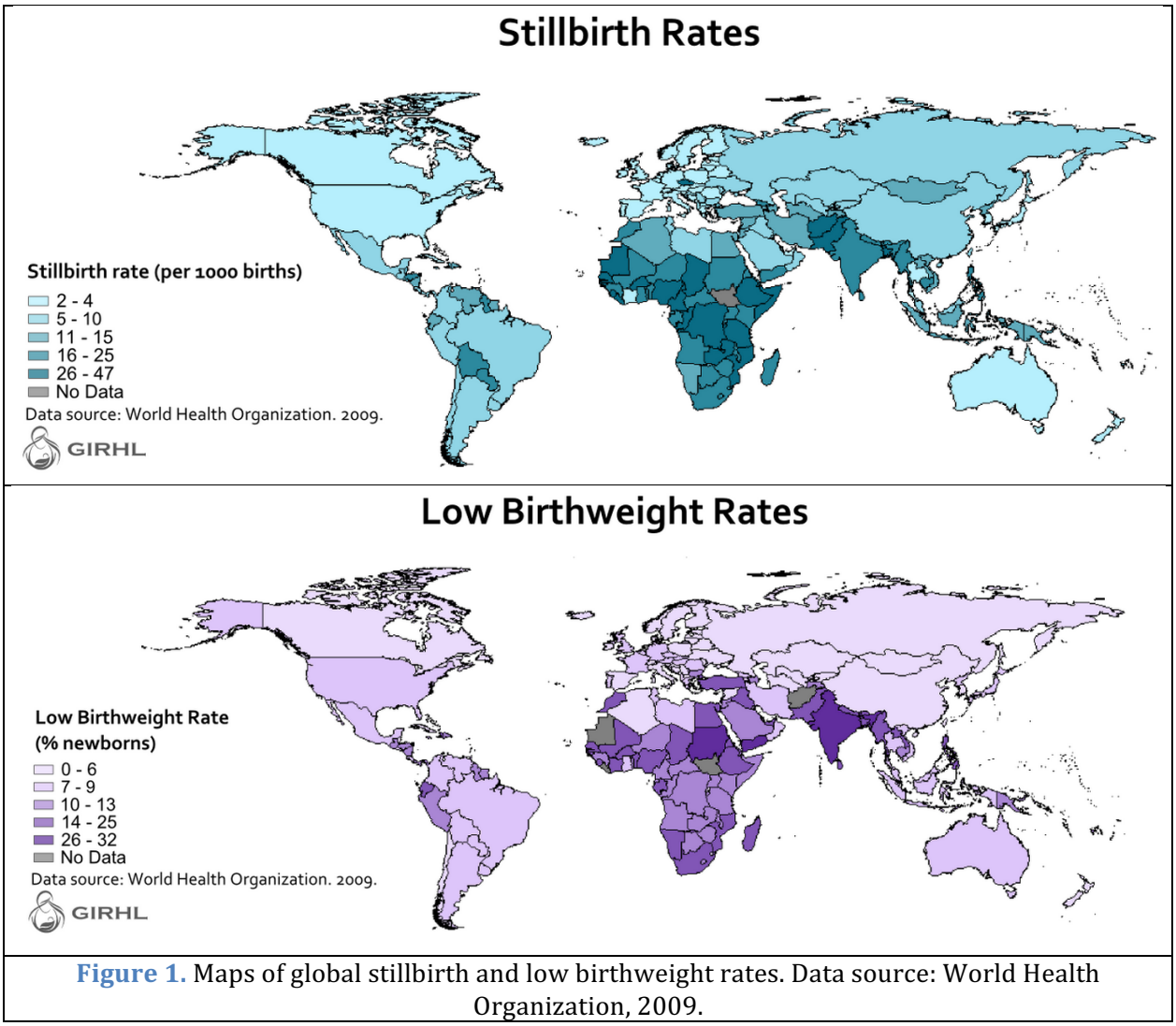

Figure 1. Maps of global stillbirth and low birthweight rates. Data source: World Health Organization, 2009.

1.1.2 Background – Maternal Position

In obstetrics, it is well-known that when a pregnant woman assumes the supine position during the day, maternal cardiovascular parameters [17] [18] [19] and/or fetal oxygenation [20] are altered, often causing fetal distress, particularly during labour [21]. However, until recently, there has been little evidence on the effect of supine position during sleep in pregnancy. Recently, three studies have suggested that maternal sleep position may be a risk factor for SB [14] [15] [16] and LBW [16]. This is significant given that the majority of third trimester pregnant women spend up to 25% of their sleep time supine [22]. In the Auckland Stillbirth Study [15], the population attributable risk (PAR) for non-left sleep position was found to be 37%, which is greater than the PARs of the three most important modifiable risk factors for stillbirth (obesity, advanced maternal age, and smoking) combined [4]. In an African population [16], the newborns of women who reported supine sleep during pregnancy were at increased risk of low birth weight (OR, 5.0; 95% CI, 1.2–20.2; P=0.025) and stillbirth (OR, 8.0; 95% CI, 1.5–43.2; P=0.016) with a logistic regression that controlled for the covariates maternal age, gestational age, parity, and the presence of pre-eclampsia. Notably, low birth weight was found to mediate the relationship between supine sleep and stillbirth [16]. Currently, there is much interest [23] and follow up

research occurring worldwide, with a growing body of evidence regarding the detrimental effects of supine sleep position on pregnancy outcomes [24].

One proposed hypothesis is that the maternal supine position during sleep plays a causative role in LBW and SB via compression of the abdominal aorta and inferior vena cava ('aortocaval compression'), resulting in negative sequelae. In 2014, drawing on the triple risk model that has been useful in understanding the pathogenesis of sudden infant death syndrome, Warland and Mitchell [25] proposed a similar triple risk model (see Figure 2) to explain the inter-relationship between risk factors and stressors that may result in SB. Although any one risk factor may be insufficient to cause death, together they may produce a lethal combination (as represented by the intersection of the circles), particularly if the fetus is vulnerable [25]. Examples of factors and stressors for each circle are:

- Placental and Fetal vulnerability – e.g., intrauterine growth restriction, placental insufficiency.
- Maternal factors – e.g., obesity, advanced maternal age, smoking
- Fetal stressors – e.g., maternal aortocaval compression, umbilical cord compression

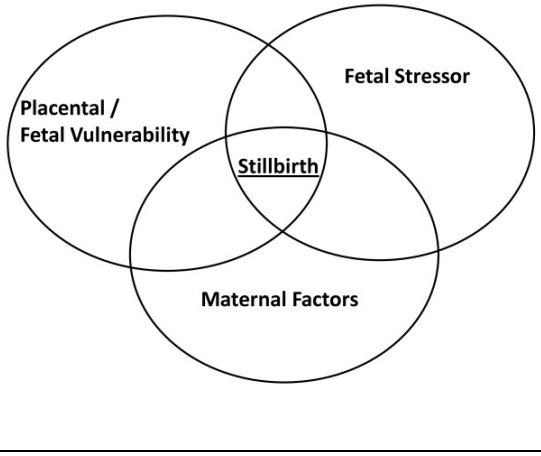

Figure 2. Triple risk model for unexplained late stillbirth **[25]**.

We consider that by addressing these factors and preventing their intersection, we may protect the vulnerable fetus from LBW or SB and thereby effect a significant reduction in the global rates of LBW and SB. In this *Stars in Global Health* project, we focus on how we may intervene to reduce the likelihood of a fetal stressor occurring, in particular maternal aortocaval compression caused via the maternal supine sleeping position.

1.1.3 Background – Maternal Device

Some pregnant women sleep with many pillows supporting their body, including a pillow behind their back to avoid the supine position. Asking women to sleep on their left increases the percentage of left sided sleep to approximately 60% of the night; however, this may come at a cost of a slightly reduced sleep duration, perhaps due to the women feeling they need to make a conscious effort to maintain sleep position [26].

Maternal sleep position has recently been implicated as a potential modifiable risk factor for LBW and SB [14] [15] [16]. Hence, a simple, low-cost, and easily-implemented device has been developed for use by pregnant women to mitigate this risk factor. We anticipate that using this device will remove the need for the woman to make a conscious effort to avoid the supine sleeping position. The device name is 'PrenaBelt'. The PrenaBelt is currently at the prototype stage of development, and as such, this proposal is a proof-of-concept/feasibility project.

The PrenaBelt is a belt-like, positional therapy device designed specifically for pregnant women. While the PrenaBelt does not prevent the user from lying on her back or right side during sleep, it is expected to significantly decrease the amount of time she spends in these two positions via the mechanism of positional therapy. Positional therapy is a simple, non-invasive, inexpensive, long-established, safe, and effective intervention for preventing people with positional-dependent snoring or mild to moderate obstructive sleep apnea from sleeping on their back [27] [28] – a position that exacerbates their condition [29] [30] [31] [32].

The PrenaBelt is worn at the level of the waist. By virtue of its design and position on the user's body, the PrenaBelt affects subtle pressure points around the midriff (back and right side) of the user when she lies on her back or right side, respectively. These subtle pressure points activate her body's natural mechanism to spontaneously reposition itself to relieve discomfort [33] [34] [35], thereby reducing the amount of time she remains on her back or right side. Alternatively, the PrenaBelt can be worn at the level of the thorax with the back of the device centered at the mid-back, in which case the front of the device would sit just below the breasts at the level of the fundus (upper abdomen).

The PrenaBelt is also designed for adjustability and comfort. As such, its configuration can be easily adapted by the user to only help her avoid sleeping on her back if she requires the option of sleeping on her right side as well as her left for comfort reasons.

Members of our team at Global Innovations for Reproductive Health and Life (GIRHL, Cleveland) have developed a Body Position Sensor (BPS) to be integrated into the PrenaBelt. The BPS is a small, electronic data acquisition device developed for research purposes only and in accordance with the original proposal to our funder, Grand Challenges Canada. The BPS fits into a pocket on the PrenaBelt and uses a three axes accelerometer to detect orientation of the PrenaBelt, and thus the user, in three-dimensional space. The accelerometer data is collected and stored on the BPS hard drive and can be accessed via connecting it to a computer.

The PrenaBelt only comes into contact with intact skin and, as such, is a non-invasive medical device. As per Rule 7, subrule (1) in the Government of Canada's Medical Devices Regulation – Classification Rules For Medical Devices, the PrenaBelt is classified as a Class I medical device [36]. The BPS is a research-use only device and, as such, does not fall under medical device regulation.

Per the Government of Canada's Medical Devices Regulation – Part 3: Medical Devices For Investigational Testing Involving Human Subjects, Section 80, Subsection (3), "A manufacturer or importer of a Class I medical device may sell the device to a qualified investigator for the purpose of conducting investigational testing if the manufacturer or importer possesses records that contain all the

information and documents required by Section 81" [36]. Note that the information and documents required by Section 81 can be found in the Product Information document.

To date, no studies have investigated positional therapy in the pregnant population, and no positional therapy devices have been designed specifically for pregnant women (see Attachment 1). This is likely because the association between maternal sleeping position and adverse pregnancy outcomes has only recently been discovered and published in the literature [14] [15] [16]. The only FDA-approved product for treatment of positional dependent snoring and mild obstructive sleep apnea is the Zzoma Positional Sleeper by Sleep Specialists, LLC (Abington, PA) [37]. However, the Zzoma device was designed specifically for patients with positional-dependent snoring and mild obstructive sleep apnea and not for pregnant women, who are notably different in many aspects including anatomy (e.g., the gravid uterus) and nocturnal behaviour (e.g., rising up more often during the night).

1.1.4 Hypotheses

The following are hypotheses for the study proposed for Halifax:

1. When compared to one night of sleep with no positional therapy (PT) treatment, treatment with a PT intervention (PrenaBelt) during one night of sleep in the third trimester of pregnancy will significantly reduce the percentage of time spent in the supine and right-lateral positions and, thereby, have a favourable effect on maternal respiratory and cardiovascular parameters.
2. Maternal satisfaction, comfort, and desire to continue use of the PrenaBelt during third trimester sleep will be acceptable[1] after one night of use.

1.2 Relevant Literature

Below, is a list of additional relevant literature that has not been discussed in this research protocol.

1.2.1 Maternal Sleep Practices as Risk Factors for Adverse Pregnancy Outcomes

Romero R and Badr MS. *A role for sleep disorders in pregnancy complications: challenges and opportunities.* American Journal of Obstetrics & Gynecology, 2014; DOI: http://dx.doi.org/10.1016/j.ajog.2013.11.020

O'Brien LM, Bullough AS, Owusu JT, Tremblay KA, Brincat CA, Chames MC, Kalbfleisch JD, and Chervin RD. *Snoring during Pregnancy and Delivery Outcomes: A Cohort Study.* Sleep, 2013; 36(11):1625-1632.

1.2.2 Sleep Position and Polysomnography During Pregnancy

O'Brien LM, Bullough AS, Shelgikar AV, Chames MC, Armitage R, and Chervin RD. *Validation of Watch-PAT-200 Against Polysomnography During Pregnancy.* Journal of Clinical Sleep Medicine, 2012; 8(3):287-294

[1] "Acceptable" for each of these measures (satisfaction, comfort, intention to use) is defined independently for each measure as being rated 5 out of 10 or higher on a scale from 1 to 10 on the PrenaBelt User Feedback Questionnaire. Each measure has a note indicating the user's subjective evaluation correlated with various numbers on the scale.

1.2.3 Stillbirth and Low Birthweight

Bukowski R, et al. *Fetal Growth and Risk of Stillbirth: A Population-Based Case-Control Study.* PLOS Medicine, 2014; 11(4)e1001633

1.2.4 Positional Therapy (as a Treatment Option for Sleep Disordered Breathing)

Jokic R, Klimaszewski A, Crossley M, Sridhar G, and Fitzpatrick MF. *Positional treatment vs continuous positive airway pressure in patients with positional obstructive sleep apnea syndrome.* Chest, 1999; 115(3):771-781

Skinner MA, Kingshott RN, Filsell S, and Taylor DR. *Efficacy of the 'tennis ball technique' versus nCPAP in the management of position-dependent obstructive sleep apnoea syndrome.* Respirology, 2008; 13(5)708-715

Permut I, et al. *Comparison of positional therapy to CPAP in patients with positional obstructive sleep apnea.* Journal of Clinical Sleep Medicine, 2010; 6(3):238-243

1.3 Feasibility Study Objectives

The following are objectives for the study proposed for Halifax:

1. Compare maternal sleep position in third trimester pregnant women between a night with and a night without a positional therapy (PT) intervention (PrenaBelt).
2. Obtain PrenaBelt user experience feedback to evaluate PrenaBelt feasibility and acceptability and optimize PrenaBelt design for future research.

1.4 Research Design and Methodology

In Halifax, the utility of the PrenaBelt in modifying maternal sleeping position and the effect of the PrenaBelt on maternal respiratory and cardiovascular parameters during sleep and sleep staging in the third trimester of pregnancy will be evaluated via a two-night, randomized, cross-over, sham-controlled, triple-blind, sleep study in third trimester pregnant women.

- **Two Nights:** one night with positional therapy (PT) and one night with sham-PT to determine treatment effect on outcomes[2].
- **Randomized**: participants will be randomized to treatment order: sham-PT on first night, then true PT on second night, or vice versa. This will avoid the potential impact of changes to sleep across the two nights resulting from familiarization with the equipment, which could bias the results.
- **Cross-over:** on the second night, each participant will be crossed over from PT to sham-PT (or vice versa, depending on randomization order) to allow each participant to act as her own control for comparison of treatment effect on outcomes.
- **Sham-controlled:** a sham-PT device that has the same feel, fit, and form of the true PT device but without the ability of function (pressure points) will be used as a control. The purpose of a

[2] These nights need not be consecutive as this may be onerous on some participants who may have children at home; therefore, we will accommodate the schedule and wishes of the participants in the sleep test booking.

sham-PT device is to identify any specific benefit of one element of a PT device (e.g., fit or form) above and beyond all benefits that might be attributed to everything else about a that device (e.g., function). Note that there is no established effective therapy for the population for the indication under study.

- **Triple-blind**: participants, research assistants monitoring and sleep technologists scoring the sleep tests, and the specialized sleep physician reviewing and reporting the sleep test results will be blinded to the intervention – PrenaBelt or sham-PrenaBelt – received each night.
- **Laboratory**: conducting this study in a controlled lab setting will allow for continual, real time monitoring of various cardiovascular, respiratory, uterine, and sleep parameters of each participant by the research assistant. This contributes to a more controlled and safer study overall.
- **Sleep Test**: body position, various cardiovascular and respiratory parameters, uterine contractions, and sleep staging will be continuously recorded while the participants are sleeping. Sleep lab procedures will be followed by the personnel conducting, scoring, reviewing, and reporting the sleep tests from participant preparation through discharge.

1.4.1.1 Methods

After the recruitment, consent, and enrolment processes (see Section 2.5), each participant will be contacted by a researcher and booked for two overnight sleep tests at the Capital Health Sleep Disorders Clinic (4th floor, Abbie J Lane Building, QEII Hospital, 5909 Veterans Memorial Lane, Halifax, NS). These sleep tests will be booked to take place late in her pregnancy (28-37 weeks) but not beyond 37 weeks unless she is comfortable doing so. These two tests need not be consecutive nights as this may be onerous on the participants, who may have children at home; we will accommodate the schedules and wishes of the participants. The sleep clinic has two beds that can be dedicated to research; therefore, two participants should be booked into the clinic per night for budgetary reasons: two participants can be monitored by one research assistant in a twelve hour shift (see section 1.7).

Each participant will be told that she will be randomized by the researchers to which intervention – PrenaBelt device or sham-PrenaBelt – she will receive on the first night and not informed of the treatment order. On the second night, each participant will be switched over to the alternate intervention. Since the PrenaBelt and sham-PrenaBelt will be virtually identical (except for functional PT capability), each participant will be essentially blinded to the intervention received on each night. The PrenaBelt and sham-PrenaBelt will be randomly labeled as either "Device A" or "Device B" by one of the researchers not directly involved in sleep test monitoring, scoring, interpretation, or reporting. The research assistant monitoring and sleep technologist scoring the sleep tests and the sleep specialist physician interpreting and reporting the results will be blind to the intervention used on each night because they will not be told the true identification of "Device A" and "Device B". As such, this triple-blind, cross-over, sham-controlled design enables each participant to serve as her own control and measurements/results can be compared between her sleep tests.

In preparing for the sleep tests, each participant will be directed to follow the instructions within the Information and Consent Form, which are standard instructions that the sleep clinic has published on its website:

- Participants will be asked to not drink alcohol on the days of their sleep tests.
- Participants will be asked to not drink or eat caffeine after 5:00pm on the days of their sleep tests.
- Participants will be informed that there will be healthy snacks and beverages available at the sleep clinic at no cost to them.
- If a participant becomes sick with a cold, flu, chest infection or any other physical/medical disorder that could interfere with her sleep, she will be asked to contact a member of the study team as soon as possible as her sleep tests may need to be rebooked.
- Participants will be asked to try to maintain their regular daytime schedule and, if at all possible, avoid napping on the days of their sleep tests.
- Participants will be asked to bring all of their regular medication to the sleep clinic. Unless otherwise instructed beforehand, participants should continue to take their medication as usual.
- Participants will be required to wear sleep attire and will be asked to try to avoid silky material. Pajamas, or walking shorts and a t-shirt are ideal. Participants can bring their own pillow and/or favorite blanket if they wish.
- To ensure the paste and tape for the various monitors adhere to the participant's skin, participants will be discouraged from using body and facial moisturizers. Participants will be asked to remove artificial fingernails and nail polish from at least one finger before the test as they prevent the function of the pulse oximeter.
- Presently, the sleep clinic does not have shower facilities but is able to provide participants with face cloths and towels. If participants wish to have access to shampoo, soap and combs/brushes, they will be asked to bring their own.
- Participants will be encouraged to bring reading material, puzzles, a movie (on DVD) or some other interest to help them relax before Lights Out. The sleep clinic has portable DVD players that participants can borrow.
- Onsite underground parking is available and presently costs $4.00 for an overnight stay (in after 4:30pm, out before 8:00am). Participants will be reimbursed for this if they choose overnight parking.

The following are the specific details about how the sleep test will proceed:

- Sleep tests will be done in a private clinical/research room with continuous monitoring by a research assistant (in a separate room) through audio-visual and Sandman sleep software.
- Participants (1-4 per night) will be asked to arrive at the sleep clinic waiting room between 7:00pm and 8:00pm on the evenings of their sleep tests. The research assistant and/or study personnel will meet the participants in the waiting room, provide them with two forms to complete (below, first sleep test night only), and bring them to their respective rooms.
    - Participants will be asked to complete the Unexpected Events Contact Form and give it to the research assistant. This will only takes a few minutes to complete.
    - Participants will be asked to complete the Data Collection Form. This form will take about 5-10 minutes to complete. This form will be placed in a sealed envelope for the researchers.

    - The forms can be completed before or after hook up.
- The research assistant will hook up one participant at a time. Several monitors (explained below) will be attached to each participant. Hook up will be according to the American Academy of Sleep Medicine 2014 guidelines. Monitors and software will be used to measure, record, and process the following information during the sleep tests:
    - Body position will be measured by direct observation by the research assistant through audio/video recording and by an electronic Body Position Sensor incorporated into the PrenaBelt.
    - Apnea-hypopnea index, which is a standardized measurement of how many times the breathing pauses or slows during sleep, will be calculated by measuring:
        - Chest and abdominal movement (respiratory effort) by having the participant wear two soft, stretchy belts with sensors (respiratory inductance plethysmography). One belt will be positioned around the rib cage just below the breasts, and one belt will be positioned near the umbilicus.
        - The airflow through the participant's mouth and nose by a soft, rubber tube placed just under the nares at its opening, which measures inspiration and expiration. This tube will also detect if snoring is present and how much.
    - The arterial oxygen saturation will be measured by a pulse oximeter placed on one of the participant's fingers.
    - Heart rate and regularity will be measured by electrocardiography (EKG), which involves attaching two electrodes to the skin on the chest and using wires and tape to connect the electrodes to the central box for signal processing.
    - Sleep staging (wake, stage 1, 2, 3, and REM) will be measured by a combination of EEG, EOG, and EMG, which involves attaching electrodes, tape, and wires (similar to above) to the skin on the head, face, chin, neck, arms, and legs.
- The research assistant and/or study personnel will use a demonstration PrenaBelt to show the participant how to don and doff the PrenaBelt. The participants will be informed that they can remove the PrenaBelt and/or sleep test equipment at any point of the sleep test if they become too uncomfortable.
- Bathroom visits during sleep tests are always possible. The research assistant and/or study personnel will discuss the bathroom visit process with participants before their sleep test. Bathroom breaks during sleep tests are part of routine practice at the sleep clinic. The research assistant will assist the participants when bathroom breaks are required and ensure privacy.
- The research assistant will not be apprised of whether the participant has been assigned the PrenaBelt or sham-PrenaBelt. The study personnel will place the appropriate device in a box in the participant's room. The participant will open the box and put on the PrenaBelt before lights out.
- The PrenaBelt will be preconfigured for the participant by the study personnel based on whether the participant indicated to the IWK Research Assistant that she would like the option of sleeping on her right side. If the right side sleeping position is requested, the balls will be removed from the pockets on the right side of the PrenaBelt. When the balls are removed from

the right side pockets, the configuration of the PrenaBelt as such will then only help the user avoid sleeping on her back.

- Lights Out is usually between 10:30pm to 11:00pm. Just before lights out, the research assistant will run calibration testing, which requires participation from the participants (e.g., "close your eyes, open your eyes, roll your eyes, look left, look right, clench your teeth, breath through your mouth, breath through your nose, hold your breath and move your belly in and out,…"). The research assistant will monitor the incoming sleep data in real time throughout the night for quality assurance.
- If a channel faults, the research assistant may fix it if the participant is still awake or wakes up for a bathroom break. If the research assistant cannot solve the fault, he/she may consult with the sleep technician (if present) or call the on-call sleep technician (Friday and Saturday evenings). Throughout the night, the research assistant may also add notes to the data that may assist with subsequent scoring of the data.
- If the device (PrenaBelt or Sham-PrenaBelt) cannot be tolerated by the participant and is removed during the sleep test (note that the Information and Consent Form clearly informs the participants that they are free to remove the device at any time at no penalty if it becomes too uncomfortable), this will be noted by the research assistant via the Sandman software. The sleep test data recording will continue until morning. Study personnel will follow up with the participant to determine whether or not she wishes to withdraw from participating in the study.
- The sleep tests will be finished between 6:00am and 6:30am. When the participant awakes, the research assistant will enter the room and unhook the participant from the sleep test equipment. It is expected that participants will be out of the sleep clinic bedrooms by 7:00am whenever possible.
- After participants are unhooked and before they leave the sleep clinic, they will be asked to complete the PrenaBelt User Feedback Questionnaire, which will take 5-10 minutes and will be sealed in an envelope for the researchers.

1.4.1.2 Measures

The information collected from her on the Data Collection Form is collectively referred to as "demographic and sleep habits information" in Section 1.4.1.6:

- Gestational age at time of sleep test
- Parity
- Maternal age
- Ethnicity/race
- BMI (weight, height) at time of sleep test and BMI at conception or early pregnancy
- Typical bed and rise times, usual sleep duration, habitual snoring (3 or more nights per week; if present, for how long this has been the case), typical position she goes to sleep in and wakes up in currently and when she is not pregnant, what part of the bed she sleeps on, if she has a bed partner, and if she uses pillows when she sleeps (if so, how)
- Presence of new pregnancy-related conditions since signing the consent form for this study

For each participant, identical measurements (below, collectively referred to as "sleep variables" in Section 1.4.1.6) will be recorded on both nights using the same methods, equipment, and software. The sleep tests will be set up and monitored by a research assistant trained in polysomnography and under the supervision of a sleep technologist except on Friday and Saturday evenings. On Friday and Saturday evenings, either two research assistants will be present or one research assistant and one authorized study personnel will be present and a sleep technician will be on call. The sleep tests will be scored by a sleep technologist holding board certification in sleep technology (RPSGT). Scoring will be according to the current American Academy of Sleep Medicine Manual for the Scoring of Sleep and Associated Events. The sleep tests and scores will be interpreted and reported by a sleep specialist physician. Note that the measurements, methods, equipment, and software employed will be non-invasive:

a. Maternal position: direct observation by the sleep technologist through real-time or recorded audio/video and by an electronic Body Position Sensor incorporated into the PrenaBelt
b. Chest and abdominal respiratory movement: respiratory inductance plethysmography (RIP) via Pro-Tech zRIP DuraBelt with Sandman PSG software
c. Nasal and oral airflow and presence of snoring: Braebon nasal pressure transducer. If the participant is a total mouth breather, Braebon thermistor will be available as a back-up.
d. Arterial blood oxygenation: pulse oximetry (SpO_2) via Embla Sandman
e. Heartbeat rate and regularity: via electrocardiography (EKG)
f. Sleep staging: via electroencephalography (EEG), electromyography (EMG), and electrooculography (EOG). Note that if a participant is uncomfortable or cannot tolerate some of the EEG, EMG, or EOG electrodes/leads, e.g., EMG electrodes/leads on arms and legs, these electrodes/leads may be removed.

In the morning following each sleep test, before each participant is discharged home, she will be asked to complete the approved PrenaBelt User Feedback Questionnaire and seal it in a provided envelope for the researchers. Participants will be asked:

a. What position she adopted upon settling down last night
b. What position she fell asleep in last night
c. What position she woke up in this morning
d. If she changed position during night
e. If she remembers changing positions
f. Her level of satisfaction with the PrenaBelt as it relates to the quantity and quality of her sleep last night
g. Her level of comfort while wearing and sleeping with the PrenaBelt
h. Her intention to use the PrenaBelt for the remainder of her pregnancy if it was available to her
i. Any suggestions of changes/ modifications/ improvements she may have for the PrenaBelt

1.4.1.3 Outcomes

Primary Outcomes: For both sleep tests, the following are the primary outcomes for each participant:

- % of time spent in the supine and right-lateral positions with each intervention
- PrenaBelt User Feedback Questionnaires

The following data will be collected from each participant across each intervention and serve as pilot data to inform effect size calculations for future research.

- Apnea Hypopnea Index (AHI)
- Arterial blood oxygenation (SpO_2)
- Maternal heart rate (ECG)
- Sleep parameters (total sleep time, presence of snoring, RDI, sleep onset latency, sleep efficiency, sleep quality, number of arousals, number of position changes, mean AHI while supine, mean SpO_2 while supine)

When the two sleep tests are complete (interpreted and reported by the sleep specialist physician), the results will be provided to the participant's maternity care physician who will discuss her results with her at her next antenatal care visit. If warranted by the results of the sleep tests for a given participant (e.g., severe obstructive sleep apnea is discovered), contact will be made with the participant and her maternity care physician by a researcher to allow for proper management and care at the earliest opportunity. If her maternity care physician has any concerns about the sleep test results and plan for further investigation/management, he/she may consult with Dr. Debra Morrison (Site-Investigator, Respirologist, Sleep Specialist Physician) who will be available to address these concerns.

1.4.1.4 Inclusion/Exclusion Criteria

Inclusion criteria: ≥18 years old, low-risk singleton pregnancy, in the last trimester of pregnancy (≥28 weeks of gestation), and residing in the Halifax Regional Municipality.

Exclusion criteria: BMI ≥ 35 at booking (first antenatal appointment for current pregnancy), pregnancy complicated by obstetric complications (hypertension [pre-eclampsia, gestational hypertension, chronic hypertension], diabetes [gestational or not], or intra-uterine growth restriction [<10^{th} %ile for growth]), sleep complicated by medical conditions (known obstructive sleep apnea, known to get <4 hours of sleep per night due to insomnia, or musculoskeletal disorder that prevents sleeping on a certain side [e.g., arthritic shoulder]), multiple pregnancy, known fetal abnormality, non-English speaking and reading.

1.4.1.5 Sample size

To date, there has never been a positional therapy study performed on pregnant women [38]; therefore, there is little-to-no relevant data on which to base a proper sample size analysis. As a feasibility study, this study will be used to generate preliminary data to be used in effect size calculations for future clinical trials targeted at reducing poor pregnancy outcomes in Canada and globally.

A sample size of twenty-five[3] (n=25) pregnant volunteers is selected for this feasibility study.

Rationale:

- For a one-sided paired t-test with power (β) of 0.80, significance level (α) of 0.05, n=25 pairs enable a detectable effect (*d*) of -0.5, which is a medium effect size per the literature regarding Cohen.
- Based on expert opinion (Dr. Louise O'Brien, Scientific Mentor on *Stars In Global Health* project, University of Michigan), n=25 was originally budgeted and proposed to Grand Challenges Canada, which was subsequently approved by Grand Challenges Canada and the Canadian Institute for Health Research.

1.4.1.6 Justification of Statistical Methods

Cross-over study design: each participant is her own control for comparison.

Descriptive statistics (mean, median, standard deviation, maximum, minimum) for demographic and sleep habits information and sleep variables (Section **Error! Reference source not found.**) will be reported.

For continuous variables, the assumption of normality will be assessed using Q-Q plots and the Anderson-Darling test. If normal, paired t-test will be used for evaluating differences. If non-normal, Wilcoxon signed rank test will be used for evaluating differences. For dichotomous data, we will evaluate for differences using McNemar's test for repeated measurements.

1.5 Timeline

November 2014 to May 2015: Halifax study preparation, PrenaBelt development and production of test samples, obtain ethical and research protocol approval from the IWK Health Centre REB.
November 2015 to July 2016: Training, recruitment, consent, enrolment, and data collection in Halifax.
July 2016 to August 2016: Data analysis, report writing, dissemination of findings from Halifax.

November 2014 to May 2015: Ghana study preparation, obtain ethical and research protocol approval from Noguchi Memorial Institute for Medical Research IRB, IWK Health Centre REB, and the Ghana FDA.
April 2015 to July 2015: Production of PrenaBelt test samples for Ghana study.
July 2015 to January 2016: Training, recruitment, consent, enrolment, and data collection in Ghana.
January 2016 to May 2016: Data analysis, report writing, dissemination of findings from Ghana.

1.6 Definition of Adverse Events

Labour is a natural process, so it will be classified as an unexpected event (not an adverse event) in this study should it begin to occur during a sleep test.

[3] Note: the EAS Form submitted to the IWK states that a maximum number of thirty (n=30) participants will be recruited. The discrepancy of five (n=5) participants is a buffer to account for an approximate drop-out rate of 20%.

Participants may experience minor irritation of skin in areas in contact with the stickers that hold the sleep electrodes on their body.

The sleep tests for a given participant may reveal that an adverse event has been occurring in her pregnancy without prior knowledge. The sleep test may reveal the presence of maternal obstructive sleep apnea (OSA). We do anticipate that OSA will be discovered in some participants – especially since OSA is common yet often undiagnosed in pregnant women [39] [40] [41] [38] [42] [43] [44]. This adverse event is not related to this study, rather it is related to other obstetric and medical factors and only discovered by this study. It should also be noted that any events (e.g., OSA) that we do observe would be already occurring without anyone's knowledge. If severe OSA is discovered during any of the sleep tests, we will notify the participant and her maternity care physician, give them the test results, and ask them to speak with one another at earliest opportunity to ensure proper management and care. Her maternity care physician will also be informed that if he/she has any concerns about the sleep test results and plan for further investigation/management, he/she may consult with Dr. Debra Morrison (Site-Investigator, Respirologist, Sleep Specialist Physician) who will be available to address these concerns.

Should a medical emergency occur, the sleep technologists at the Capital Health Sleep Disorders Clinic have been trained according to internal policies and procedures for handling emergencies and unexpected events during sleep tests. The sleep technologists will call EMS and provide basic life support (if needed) until EMS arrives. The sleep technologists are trained in CPR.

Although the risk is low, a participant may go into labour during the sleep study; therefore, our exclusion criteria excludes women at risk of pre-term labour, and we will not book any participants for a sleep test beyond 37 weeks gestation unless the participant is comfortable in doing so. The research assistant will follow a basic plan of action should the participant go into labour during a sleep test:

1. If a participant begins labour during a sleep test, stop the test immediately.
2. Urgent: if onset of labour is sudden and participant is in distress, call EHS to transport the participant to the IWK. Otherwise proceed to 3.
3. Non-urgent: if onset of labour is slow and participant is stable, use the information from the Unexpected Events Contact Form and assist the participant in reaching her contact to transport her to the IWK.

Pregnancy is associated with many risks for the mother and fetus, yet sleep tests are non-invasive and safe for pregnant women and their developing baby to undergo. Although the risks that this study poses to the pregnancy are minimal, all adverse events will be reported to the CDHA Patient Safety Reporting System as per hospital standard operating procedures.

1.7 Budget

For the budget related to research activities in the study in Halifax, see lines 77, 113, and 225 in the Project Budget (submitted as a component of the Researcher's Checklist for Submissions: Delegated Review).

1.8 Resources

Letters of support will be obtained from the applicable institutions (denoted by †) listed in Table 1 and submitted as a component of the Researcher's Checklist for Submissions: Delegated Review.

Table 1. Resources for Halifax Study

Study Component	Institution (Department)	Key Personnel (Position)	Lab/Facility	Equipment
Grant fund administration, Project Monitoring, and Advisory Board	Innovative Canadians for Change Foundation	Dr. Andre Isaac (Project Manager)	n/a	n/a
Ethics Process	IWK Health Centre (Review Ethics Board)	Bev White (REB Manager/ Information Officer)	n/a	n/a
Participant recruitment, consent, enrolment	IWK Health Centre† (Women's and Newborn Health)	Dr. Heather Scott (Obstetrical Co-Director) Ms. Darlene Baxendale (RN, Research Assistant)	Perinatal Centre	n/a
Sleep tests	Capital Health† (Sleep Disorders Clinic)	Dr. Debra Morrison (Clinical Director, Staff Respirologist) TBD (Certified Sleep Technologist) TBD (Polysomnography Research Assistant)	Two sleep rooms in the sleep laboratory	A/V equipment, Braebon nasal pressure transducer, Braebon thermistor, Pro-Tech zRIP DuraBelt, Embla Sandman, Sandman PSG software, EKG, EEG, EMG, EOG, consumables
PrenaBelt engineering, liaison with Kaishin Design	Global Innovations for Reproductive Health and Life	Ali Borazjani (President, Co-Founder, Biomedical Engineer)	n/a	n/a
PrenaBelt samples: design, production	Kaishin Design	Kaishin Chu (Apparel Design and Development Strategist/Consultant)	n/a	n/a
Scientific Innovation	University of Michigan	Dr. Louise O'Brien	n/a	n/a
Business Innovation	Harvard Business School	Dr. John McArthur	n/a	n/a

n/a – 'not applicable'

2 Ethical

2.1 Potential Benefits to Participants and Others

2.1.1 Participants in Halifax

Undergoing a sleep test may benefit a participant and her developing baby. Due to physiological and anatomical changes in pregnancy, pregnant women have been found to be more susceptible to sleep-disordered breathing – e.g., snoring, obstructive sleep apnea (OSA) – than non-pregnant women [38]. Possible association between OSA and complications in pregnancy (gestational diabetes, gestational hypertension, pre-eclampsia, intra-uterine growth restriction) have been shown [45] [39] [40] [46] [47], and OSA is common yet often undiagnosed in pregnant women [39] [40] [41] [38] [42] [43] [44]. After the sleep tests are scored for a given participant, a researcher will follow up with her maternity care physician if she requests this in the Information and Consent Form. Her maternity care physician will

discuss her results with her at her next antenatal care appointment. We have found in previous studies that most women appreciate this.

If severe OSA is identified for a given participant, she and her maternity care physician will be notified immediately, given the sleep test results, and advised to discuss this issue together at earliest opportunity to ensure proper management and care. Proper management of her OSA may result in instant and long-term benefits for her and her baby.

In addition, the opportunity to assist in the advancement of sleep-in-pregnancy knowledge and the possibility of benefiting other pregnant women globally in the future may be a source of immediate satisfaction to participants.

2.1.2 Others

Note: the following section refers to the WHO definition of stillbirth and not the definition used by Statistics Canada (see Section 1.1).

In Canada, three babies are stillborn every day (≥1000g birthweight or ≥28 weeks completed gestation) [1]. This is a largely unrecognized national tragedy yet pales in comparison to Ghana, where 47 babies are stillborn every day [1] (Note: in Ghana, the birth rate is 2 times greater than that in Canada, but the stillbirth rate is more than 15 times greater). In addition, every day, 61 Canadian babies are born with low birthweight (≤2500g) [48], and 232 Ghanaian babies are born with low birthweight [49] – many of whom will die in infancy or suffer lifelong consequences. These statistics and disparities are unconscionable, yet even they pale when compared to regions of further impoverishment where the state of affairs has been aptly described by one author as 'obstetric carnage' [50].

Maternal supine sleep has recently emerged as a potential risk factor for SB and LBW [14] [15] [16]. If supine sleep has a causative role in LBW and subsequently SB, the population attributable risk (PAR%) suggests that up to 17% of LBW, and consequently 26% of SB, might be averted by changing maternal sleep position [16] – this translates to the aversion of 3.7 million LBW and 676,000 SB annually [1] [5]. Since LBW is a major contributor to stillbirth [4], morbidity [5] [11] [12], and neonatal mortality (60-80%) [6] [7] [8] [9], further benefit may be realized.

This study will test a novel approach to reducing the global incidence of SB and LBW by determining whether this potential risk factor can be mitigated via treatment with a simple, positional therapy device. Demonstrating that maternal sleep position is, in fact, amenable to positional therapy will be a valuable contribution to existing knowledge and may be a key component to reducing the rates of SB and LBW in Canada and worldwide.

Currently, research is underway to determine whether a causal relationship between maternal sleep position and SB and LBW exists and collect a robust evidence base from which to advise whether a public health intervention should be considered (dissemination of research findings expected by August 2016) [24]. If a public health intervention is advised, our study will be at the forefront of scientific investigation into one possible intervention, i.e., positional therapy.

Following successful completion of this proof-of-concept (Phase I) study, there is potential for transition-to-scale (Phase II) funding from Grand Challenges Canada (contingent on 50% matching through partnerships) of up to $1,000,000 CAD for up to 2-3 years. In addition to this funding, other grant options in the area of maternal, newborn, and child health (MNCH) are available, e.g., Bill and Melinda Gates Foundation, Saving Lives at Birth. Such grants would enable exploration of the effectiveness of this intervention in populations that have very high perinatal mortality rates.

Finally, this project may bring beneficial opportunities to members of the research team. For example, it may cultivate future research collaboration with other teams worldwide through publication in journals and presentations/networking at global health conventions. Another example is that the inventors of the PrenaBelt (Mr. Borazjani, Mr. Kember) plan to establish or partner with a social enterprise organization to ensure sustainability and maximum benefit to mothers and their babies globally.

2.2 Potential Harms to Participants and Others

This study is minimal risk. Participants in this study are at no greater risk of harms when completing the activities of this study than those risks they encounter in their everyday life.

The PrenaBelt device is a non-invasive medical device of Class I designation (see section 1.1.3). Pregnant women typically sleep with many pillows supporting their body, including a pillow behind their back to avoid the supine position. The PrenaBelt is a positional therapy device that may assist pregnant women to avoid supine sleep. Positional therapy devices have been shown to be safe and approved for use by humans by the US Food and Drug Administration [37]. In addition, maternal body pillows, regular pillows, and pelvic belts (lumbar support) have been used by pregnant women during sleep without reports of serious adverse effects for the mother or neonate [51].

In Halifax, wearing the PrenaBelt and sleep monitoring equipment may be uncomfortable for a participant and disturb her sleep. Each participant will be told that she can remove these devices at any time overnight if she becomes too uncomfortable.

In order to ensure the monitor electrodes remain adhered to participant's skin, the research assistant will need to prepare the area of skin, which involves cleaning and slight abrasion with an abrasive skin preparation gel. In the morning, after the monitors are removed, participants may experience slight discomfort and redness on the regions of their skin that were in contact with the electrodes. Rarely, a person will have a minor skin reaction on the area of his/her skin that was in contact with the electrodes. This reaction is not dangerous and usually goes away on its own within 24 hours to a few days.

Since personal information will be collected from participants, there always exists the potential harm should breach of confidentiality inadvertently occur.

2.3 Alternative Treatments or Procedures

2.3.1 Positional Therapy

There are several techniques used for positional therapy such as positional alarms, verbal instructions, special pillows, tennis balls, vests, and "shark fins". The latter three techniques prevent the wearer from lying supine in a passive manner by applying pressure points to the wearer's back when lying supine, which is similar to the mechanism of the PrenaBelt.

To date, no studies have investigated positional therapy in the pregnant population, and no positional therapy devices have been designed specifically for pregnant women (see Attachment 1). This is likely because the association between maternal sleeping position and pregnancy outcome has only recently been published in the literature [14] [15] [16] [25].

There are several positional therapy products for persons with positional-dependent obstructive sleep apnea (POSA) (see Attachment 1). However, these devices are designed specifically for persons with POSA, not pregnant women, who may also have POSA but are notably different in aspects such as anatomy (e.g., the gravid uterus) and nocturnal behaviour (e.g., rising up more often during the night). Of these products, only the Zzoma Thoracic Anti-Supine Band is FDA-approved for the treatment of OSA. In addition, these devices are characteristically limited in that they are designed to only prevent supine sleep. Some of these devices involve expensive electronic components and, therefore, are not feasible for widespread deployment in low-resource areas.

2.3.2 Sleep Study

Sleep studies can be performed at home or in a sleep lab setting. Sleep studies for diagnosis of sleep disordered breathing in adults can vary in complexity. A Level I sleep study includes full polysomnography, is conducted in a sleep lab setting, and is considered the gold standard in sleep testing. A Level III sleep study is less complex and is generally performed in the home setting. In Halifax, we are proposing a Level I study.

2.4 Minimization of Potential Harms

While the risks of this study to the participants and their developing babies are minimal, all adverse events will be reported to the CDHA Patient safety Reporting System as per hospital standard operating procedures

Wearing the PrenaBelt and sleep monitoring equipment may be uncomfortable for a participant and disturb her sleep. Each participant will be instructed how to, and told that she can, remove these devices and discontinue use at any time if she becomes too uncomfortable. If bothersome skin irritation occurs for a given participant as a result of contact with the electrodes, we will limit the contact of sleep electrodes to one overnight study.

Personal health information (PHI) used to identify potential participants will not be accessed by anyone other than the researchers within their circle of care.

Upon enrolment in the study, each participant will be assigned a random, six-digit, alphanumeric code. All data collected from participants during the studies will be collected only in association with this code, thus automatically de-identifying the data and minimizing the risk of identification. The key to the code, which links the codes to patient names and contact information, will be kept in a secure location away from the de-identified study data, thus minimizing the risk of re-identification. The de-identified data in forms (paper) and files (electronic) will be secured in a locked filing cabinet and in password-protected files on a password-protected computer, respectively, in a locked office with limited access.

For all study activities, all data collected from participants will be protected from unauthorized access to safeguard participant privacy and confidentiality in accordance with TCPS2, PHIPA, and PIPEDA and personal information policies at the IWK Health Centre.

There is a reasonable foreseeable risk that the Unexpected Events Contact Form for a given participant (contains participant's first name, name of contact, phone numbers of contact, and relationship of contact) could be matched with her Data Collection Form, PrenaBelt User Feedback Questionnaires, or sleep recording files (which contain her alphanumeric code) and be used to re-identify her de-identified information. To mitigate this risk of re-identification, the research assistant will be the only person who will have access to the Unexpected Events Contact Form and will be instructed to keep it in a separate secure location and shred it in a cross-cut shredder after the second sleep test is complete. In addition, the research assistant will not have access to the Data Collection Form or PrenaBelt User Feedback Questionnaires, which will be delivered and retrieved from each participant in a sealed envelope.

Study data will only be exchanged in de-identified form and between authorized research team members per the approved EAS Form. Data will be protected in electronic transfers through password protection and encryption if deemed necessary.

After study closure, study data will be stored securely (locked cabinets, password-protected files, password-protected computers, locked offices) in de-identified form for five years, after which it will be destroyed in a secure manner (e.g., incineration and cross-cut shredding).

2.5 Process for Seeking Consent

1. **Ethical Approval and Training:** The study requires approval from the Review Ethics Board at the IWK Health Centre (Halifax, Canada). All study personnel will be trained to the approved Research Protocol by Mr. Allan Kember (Sub-investigator, Project Lead).

2. **Recruitment:**

   - The IWK OB/GYN will review charts of her/his patients scheduled for their routine antenatal visit at the clinic to identify potential participants. These patients will then be screened by the OB/GYN within their circle of care using the Screening Inclusion Form to determine if they meet the inclusion/exclusion criteria for this study.
   - Patients who meet the inclusion/exclusion criteria will be invited to participate in the study by their OB/GYN at the end of their antenatal care visit via the approved Flyer. The Flyer will

also be posted in the clinic rooms and waiting areas. A patient who expresses interest in participating in the study will be asked if she is agreeable to speak to the IWK Research Assistant about the study.

- If she is agreeable, the IWK Research Assistant will then come to the clinic, confirm the inclusion/exclusion criteria by reviewing the patient's chart, and conduct the formal consent process using the approved Information and Consent Form.
- If she does not wish to speak with the IWK Research Assistant immediately but is still interested in participating in the study, she will be given the Information and Consent Form to take home and read and asked whether she would agree to be contacted by the IWK Research Assistant in one week's time.
  - If she agrees, her name and contact information will be given to the IWK Research Assistant who will contact her in one week's time to see if she is still interested in participating in the study.
  - If she does not agree, she will be informed that she is free to contact the IWK Research Assistant whenever she wishes to do so.

- Snowball sampling may be used as well, i.e., potential participants who are interested may tell their friends about the study (share the Flyer and Information and Consent Form with them) and direct them to contact the IWK Research Assistant.

3. **Consent and Enrolment**:

- Potential participants, having
  - met the study inclusion/exclusion criteria,
  - been invited to participate in the study,
  - shown express interest in participating in the study, and
  - given verbal consent to speak with the IWK Research Assistant,

  will meet with the IWK Research Assistant to complete the consent process.

- In the meeting, the IWK Research Assistant will go through the approved Information and Consent Form with the potential participant, ensuring full and accurate disclosure of the,
  - nature of the study (what is involved, who will be conducting it, how the results will be used, how confidentiality and privacy will be protected),
  - the risks and benefits involved in participating in the study, and
  - the free choice to decline participation in or withdraw from the study at any time without consequence (no adverse or negative effect on her or her family's care in any way)

  to each potential participant.

- The capacity of each potential participant to provide consent will be assessed by the IWK Research Assistant by asking the potential participant questions to verify she understands the information relevant to giving or refusing consent and appreciates the outcomes of both choices:

- What is this study about?
- Why is this study important?
- What will you need to do in this study?
- What are the risks to you from being involved in this study?
- What are the benefits to you from being involved in this study?
- What happens if you choose to not participate today?
- What happens if you choose to participate today and then change your mind at another time either before the study starts or during the study?

- The IWK Research Assistant will give each potential participant an opportunity to ask any questions she may have.
- Voluntary, written, informed consent (form) will be obtained by the IWK Research Assistant from a potential participant who has demonstrated capacity and maintains an interest in enrolling in the study. Authorization or refusal of consent by a potential participant will be accepted by the IWK Research Assistant.

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Attachment 1: Treatment and Device Search

PrenaBelt Patent Search

Positional Therapy for Positional-dependent Obstructive Sleep Apnea (POSA) – Product Search

Pregnancy Sleep Product Search

Table 1. PrenaBelt Patent Search

Publication Number	Application Number	Publication Date	Title	Potential Similarity to PrenaBelt†
US4471767 A	US 06/558,335	09/18/84	Therapeutic device for positional treatment for gastroesophageal reflux	1
US20110132378 A1	US 12/794,498	06/09/11	Systems and methods for controlling position	2
US 20110179573 A1	US 12/975,144	07/28/11	Suspended back pillow for sustaining a side sleeping position	1
US 20130043999 A1	US 13/695,209	02/21/13	Method and device for sleep posture correction	3
US 20120197340 A1	US 13/251,856	08/02/12	Screening devices and methods for obstructive sleep apnea therapy	1
US 20130108995 A1	US 13/286,037	05/02/13	System and method for monitoring and influencing body position	1
US 20100319131 A1	US 12/581,732	12/23/10	Suspended Back Pillow for Sustaining a Side Sleeping Position	1
US4506396 A	US 06/480,943	03/26/85	Comfort pillow for pregnant females	1
US 5359739 A	US 08/113,076	11/01/94	Patient repositioning and position maintenance device	1
US6886201 B1	US 10/698,244	05/03/05	Maternity pillow	1
USD547586 S1	US 29/192,913	07/31/07	Maternity pillow	1
WO 2008120897 A1	PCT/KR2008/001712	10/09/08	A maternity belt with vibration speaker	1
US20130067642 A1	US 13/239,179	03/21/13	Maternity belt structure	2
US20130072087 A1	US 13/239,164	03/21/13	Adjustable protective maternity belt	2
US 8396229 B2	US 11/834,085	03/12/13	Musical maternity belt	1
USD560328 S1	US 29/261,923	01/29/08	Maternity belt	1
US3315670	---	04/25/67	Maternity belt	1
US2765470	---	10/09/56	Maternity belt	2
US 20070037483 A1	US 11/271,892	02/15/07	Maternity belt	1
US2486211	---	10/25/49	Maternity belt	2
US6537132 B1	US 09/696,873	03/25/03	Maternity brace	1
US 20090142988 A1	US 11/998,477	06/04/09	Lower uterine segment maternity support belt	2
USD658350 S1	US 29/370,112	05/01/12	Asymmetric maternity support belt	1
US 3623488	---	11/30/71	Belly-band	2
Notes: †Subjective scoring: 1=minimal to no similarity → 5=highly similar				

Table 2. Positional Therapy for Positional-dependent Obstructive Sleep Apnea (POSA) – Product Search

Company	Device(s)	Description	Cons
NightBalance B.V. (Delft, The Netherlands)	NightBalance Sleep Position Trainer	For light and moderate POSAS. Electronic sensor worn on an ergonomic strap around the chest. Vibrates when in supine position. Comfortable and user friendly. Trains user not to sleep supine. Can monitor sleep data on computer.	Expensive. Requires batteries. High-tech. Only prevents supine sleep. Available by prescription only (requires sleep examination).
Advanced Brain Monitoring(CA, USA)	Sleeptech Night Shift Sleep Positioner	For POSAS and snoring. Electronic sensor worn around the neck. Vibrates when wearer is supine and increases in intensity until wearer shifts. Can monitor sleep data on computer.	Price ($270). Rechargeable battery lasts three nights. High-tech. Only prevents supine sleep.
N/A	Tennis ball technique	For POSAS. Simple. No electric components. A belt or shirt with pockets large enough to put a tennis ball inside. Also in the form of a pouch with straps.	Back discomfort. Low compliance long term. Only prevents supine sleep. Tennis balls can move around or fall out while sleeping.
Zzoma (PA, USA)	Zzoma Thoracic Anti-Supine Band	For POSAS. No electric components. A belt with a large piece of foam mounted on the area that covers the wearer's back. Prevents the wearer from rolling onto back while sleeping. Side elastics for comfortable breathing.	Bulky. Worn around the upper torso. If wearer wants to switch from left to right side, they must do so via the stomach. Only prevents supine sleep. Available by prescription only.

Table 3. Pregnancy Sleep Product Search

Company	Device(s)	Description	Cons
Utterly Yours (VA, USA)	Pregnancy Pillow	For maternal sleep. Simple, full-length, wedge, or U-shaped pillows to support and align the back and hips, and support the belly, knees, and/or body to help reduce pain and provide a good night sleep. Claim to benefit a pregnant mother's comfort, rest, and health.	Expensive. Bulky. Emphasizes comfort, not optimal position. Encourages lateral sleep, but does not prevent supine sleep or lateral-right sleep.
Boppy (CO, USA)	Cuddle Pillow, Custom Fit Total Body Pillow, Pregnancy Wedge		
Leachco (OK, USA)	Snoogle Total Body Pillow		
Today's Mom (CO, USA)	Coolmax, Cozy Cuddler, Cozy comfort		
Oggi (USA)	Elevation		
Yaz Design (USA)	Pillowband		
Peachy Products (South Africa)	Stress Nest		
Motherhood Maternity (USA, Canada)	Tummy Sleeve, Ultimate Maternity Belt, Maternity Support Belt	Wide pieces of stretchy fabric in a tube configuration designed to discreetly offer back support and lower belly support during pregnancy. Some have additional suspender-like straps to provide further fixation and support.	Does not affect sleeping position.
Mama Band (USA)	Belly Band		
Ingrid & Isabel (CA, USA)	Bellaband, BeBand		
Cabea, LLC (CT, USA)	BabyBellyBand		