Cover Page

Research Protocol

Official Title: Korle Bu Teaching Hospital - Global Innovations for Reproductive Health & Life Healthy Birth Weight Study: A Cross-Section

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Title: KBTH-GIRHL Healthy Birth Weight Study: A Cross-Section

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Abstract

Recently, three studies have suggested that maternal back sleep may be a risk factor for stillbirth (SB) and low birth weight (LBW). This is significant given that the majority of third-trimester pregnant women spend up to 25% of their sleep time on their back. The Ghana PrenaBelt Trial (GPT), currently underway at the Korle Bu Teaching Hospital (KBTH) and led by a member of our team (Dr. Jerry Coleman), is the first interventional trial investigating this possible relationship between maternal back sleep and LBW. However, a limitation of the GPT is that due to its sham-control design, all participants in the trial (treatment group and sham-control group) have been educated during the consent process about back-sleep in late pregnancy as a possible risk factor for SB and LBW. At interim analysis of the GPT, no difference in birth weight was found between the two groups. The GPT team has had anecdotal reports from sham-group participants who indicate that they have trained themselves to sleep exclusively on their left side. Further, there is evidence in the literature that when instructed to sleep on their left, third-trimester pregnant women can increase the percentage of left-sided sleep to approximately 60% of the night on average and maintain this across multiple nights.

Given this, it is questioned if the back-sleep education during the consent process could be having an effect on the sleep behaviour of the GPT participants independently of their treatment allocation; therefore, the aim of this study is to establish a reference birth weight of babies born to a cohort of women comparable to the cohort in the GPT but who have not received back-sleep education, did not participate in the GPT, and whose babies were born in a similar time period and weighed on the same newborn scales – in essence, a control group for the GPT.

This cross-sectional study will be accomplished via recruiting a control group from a pool of women having recently delivered at KBTH, reviewing their hospital records, and having them complete a short questionnaire.

The results of this study, together with the results of the GPT, will enable us to determine whether or not education about back-sleep in pregnancy affects pregnancy outcomes, specifically birth weight.

1 Background

According to the WHO, stillbirth (SB) is defined as fetal death at gestation ≥28 weeks or weight ≥1000g (1). Low birth-weight (LBW) is defined as a weight less than 2500g at birth (2). LBW is a significant contributor to SB (3), and infants with LBW are 20 times more likely to die in the first year than heavier babies (2). Although LBW babies constitute only about 15% of live births, they account for 60-80% of neonatal deaths (4) (5) (6) (7). Neonatal deaths (death within the first 28 days of life) account for 40% of all deaths under the age of five years (8). LBW also accounts for significant morbidity such as cognitive impairment (9), and chronic diseases later in life (2) (10).

In obstetrics, it is well-known that when a pregnant woman lies on her back during the day, maternal cardiovascular parameters (11) (12) (13) and/or fetal oxygenation (14) are altered, occasionally causing significant fetal heart rate changes, particularly during labor (15). However, until recently, there has been little evidence on the effect of the back position during sleep in pregnancy. Recently, three studies, including a 2012 study based in Ghana by members of our team (Dr. Jerry Coleman, Dr. Louise O'Brien), have suggested that maternal back sleep may be a risk factor for SB (16) (17) (18) and LBW (18). This is significant given that the majority of third-trimester pregnant women spend up to 25% of their sleep time on their back (19).

1.1 Relevance & Innovation

Women in Ghana suffer from one of the highest perinatal mortality rates in the world. Every day in Ghana, 47 babies are stillborn (1) and 232 babies are born with LBW (20) – many of whom will die in infancy or suffer lifelong consequences. As such, Ghana urgently requires inexpensive interventions to reduce perinatal morbidity and mortality – assisting pregnant Ghanaian women to avoid sleeping on their back might be one such intervention.

A maternal positional therapy device, called "PrenaBelt", has been developed by members of our team (Allan Kember, Ali Borazjani) to modify maternal sleep position and mitigate this risk factor. The Ghana PrenaBelt Trial (Principal Investigator: Dr. Jerry Coleman; Ethics: NMIMR-IRB#069/14-15, IWK-REB#1019318; Regulation: FDA/CT/152, NCT02379728) is a sham-controlled, double-blind, randomized trial in N=200 healthy, third-trimester pregnant women at the Korle Bu Teaching Hospital Obstetrics and Gynaecology Department. The purpose of the Ghana PrenaBelt Trial is to determine the effect of

PrenaBelt use during sleep throughout the third trimester on birth weight. Recruitment for the Ghana PrenaBelt Trial was 100% complete on 02MAR2016 and data collection was completed on 25JUN2016.

1.2 Rationale

At the half-way point in the Ghana PrenaBelt Trial ("GPT") (n=41 births in each group), no difference in birth weight was found between the two groups (PrenaBelt versus sham-PrenaBelt) on a two-sample t-test (p=0.51). Conclusions were the same using a non-parametric method (Wilcoxon rank sum test). Note that hypothesis for the GPT is that the birth weights will be higher in the PrenaBelt group than in the sham-PrenaBelt group.

The GPT was originally proposed as a randomized controlled trial with a treatment (PrenaBelt) group and a control (no PrenaBelt) group; however, the Noguchi-IRB strongly recommended that the study be sham-controlled and double blinded. Our team elected to follow the IRB's recommendation.

In the GPT, participants are educated on the rationale for the study as part of the informed consent process, i.e., back sleep in late pregnancy has been recently implicated as a possibly modifiable risk factor for stillbirth and low birth weight. Participants are subsequently randomized to receive treatment with a PrenaBelt or a sham-PrenaBelt and are blinded to their treatment allocation.

Given the results of the interim analysis, it is questioned if the back-sleep education during the consent process could be having an effect on the sleep behaviour of the participants independently of their treatment allocation. The GPT Team reports that the education could be having an effect, for example, some participants in the sham-PrenaBelt group have reported that they stopped using their assigned device because they had since trained themselves to sleep exclusively on their left side using alternative means.

Many campaigns have had unprecedented impact on public health by education alone, for example, the "back-to-sleep" campaign to prevent sudden infant death syndrome. Therefore, since both the PrenaBelt (treatment) and sham-PrenaBelt (sham-control) groups have received back-sleep education, our team contends that an investigation of a third group without back-sleep education, a true control group, is warranted for comparison.

2 Research Question

What is the mean birth weight and standard deviation of babies born to a cohort of women who:

- Meet the same inclusion/exclusion criteria as the cohort in the Ghana PrenaBelt Trial,
- Have not received education that back sleep during late pregnancy is a possible modifiable risk factor for low birth weight and stillbirth,
- Did not participate in the Ghana PrenaBelt Trial, and
- Gave birth to their babies in a similar time period (year 2016) as the Ghana PrenaBelt Trial?

3 Aims

To establish a reference birth weight (mean and standard deviation) of babies born to a cohort of women comparable to the cohort in the Ghana PrenaBelt Trial but who have not received back-sleep education, did not participate in the Ghana PrenaBelt Trial, and whose babies were born in a similar time period and weighed on the same newborn scales. This reference birth weight will serve as a control for the Ghana PrenaBelt Trial.

3.1 Specific Objectives

1. Conduct a review of hospital records to confirm the control group participants meet the inclusion/exclusion criteria of the Ghana PrenaBelt Trial and record the:
    a. Birth weight
    b. Date of delivery
    c. Mode of delivery
    d. Gestational age at delivery
2. Administer a questionnaire to collect demographic, obstetric, and sleep habit data for characterization of the control group and comparison of the control group to the groups (treatment, sham-control) in the Ghana PrenaBelt Trial.

4 Literature Review

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 low- and middle-income countries (1) – see Figure 1.

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 low- and middle-income countries with the highest concentrations in Asia and Africa (2) – 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 (2).

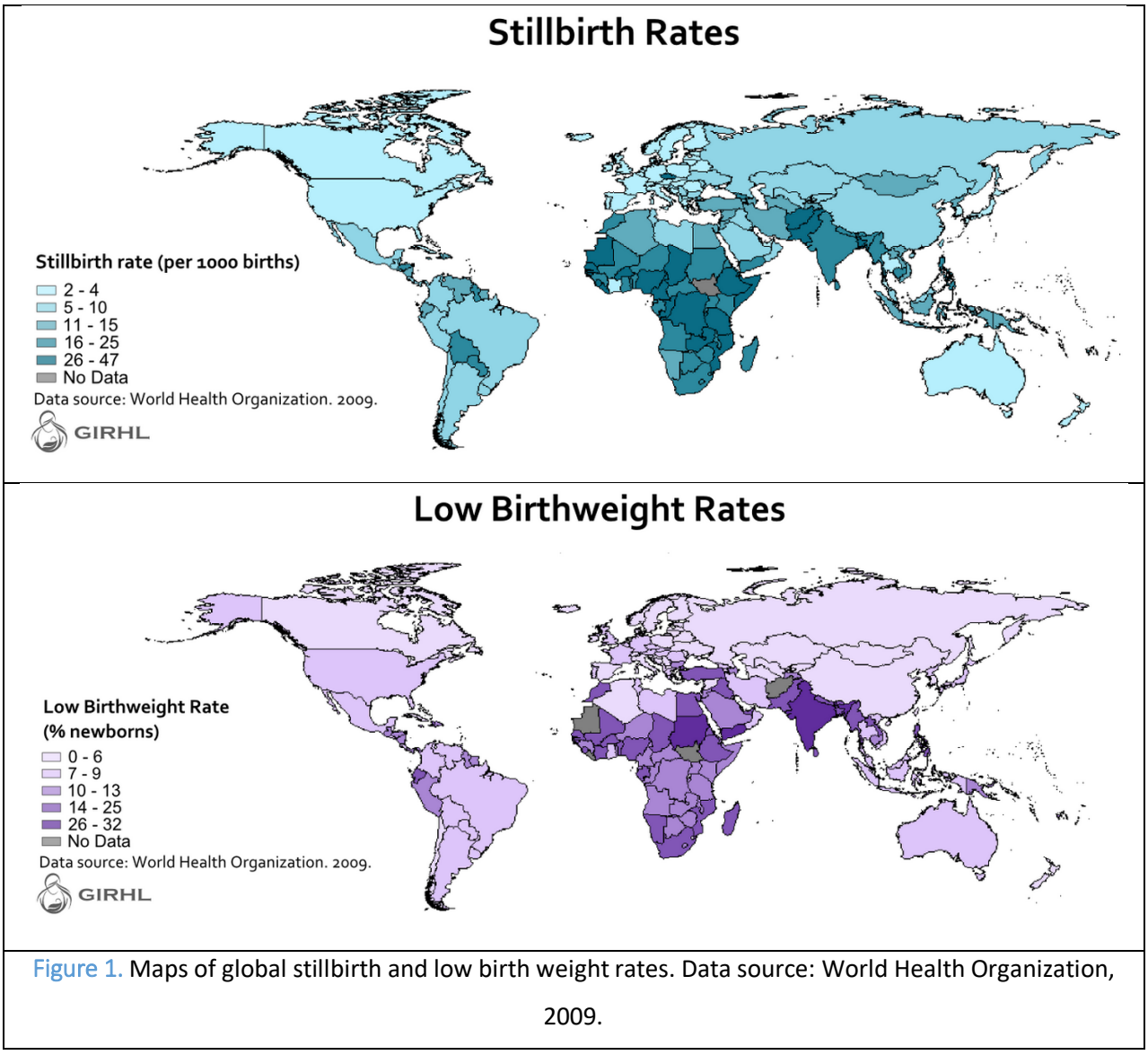

Figure 1. Maps of global stillbirth and low birth weight rates. Data source: World Health Organization, 2009.

In the Auckland Stillbirth Study (17), the population attributable risk (PAR) for non-left sleep position to SB was found to be 37%, which is greater than the PARs of the three most important modifiable risk factors for SB (obesity, advanced maternal age, and smoking) combined (3). In an African population (18), members of our team (Dr. O'Brien, Dr. Coleman)

found that back sleep during pregnancy was an independent predictor of LBW (OR, 5.0; 95% CI, 1.2–20.2; P=0.025) and SB (OR, 8.0; 95% CI, 1.5–43.2; P=0.016), when controlling for covariates maternal age, gestational age, parity, and the presence of pre-eclampsia. Notably, LBW was found to mediate the relationship between back sleep and SB (18). In the Sydney Stillbirth Study (16), the back sleep position was associated with SB (adjusted OR, 6.26; 95% CI, 1.2–34) and the PAR for reported back sleep was 9.88% (95% CI, 5.67-14.1%). Currently, there is much interest (21) and follow up research occurring worldwide (22).

One proposed model for maternal back sleep playing a causative role in low birth weight and stillbirth is that back sleep is a "fetal stressor" via compression of the abdominal aorta and inferior vena cava ('aortocaval compression') when lying on the back, and, when combined with "maternal factors" and "placental or fetal vulnerability", may result in negative sequelae. This model is known as the triple-risk model for late unexplained stillbirth (23) – see Figure 2. Our team proposes that by mitigating the "fetal stressor", we may protect the fetus from LBW or SB.

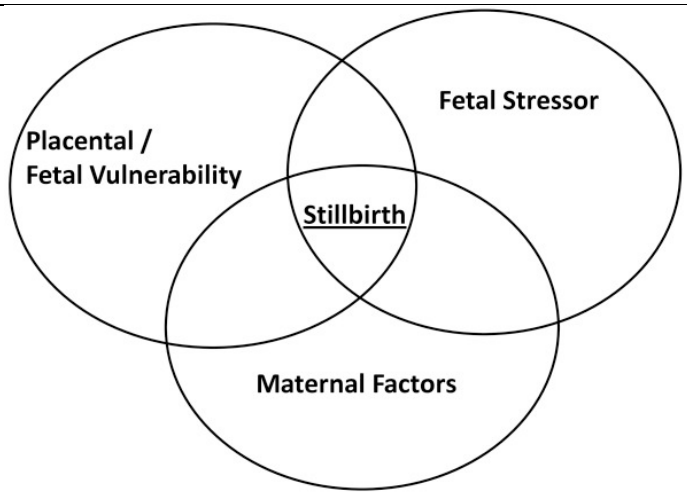

Figure 2. Triple Risk Model for Late Unexplained Stillbirth **(23)**.

Some pregnant women sleep with many pillows supporting their body, including a pillow behind their back to avoid the supine position. Indeed, we expect that some pregnant women in Ghana may increase the amount of time that they spend sleeping on their left side as their pregnancy progresses perhaps due to hearing or reading a "sleep on the left in pregnancy" or "SOS" (Sleep-On-Side) message, for example, hearing about the Ghana PrenaBelt Trial or browsing other resources (24).

Our colleague and team member from Australia (Dr. Jane Warland), has recently published data (25) relevant to the issue under consideration in this research protocol:

- Moderate correlation between diary-reported and video-determined indicators of sleep position indicates that third-trimester pregnant women are reliable when self-reporting their sleep position.
    - Comment: This lends credence to anecdotal reports of participants in the sham-control group in the GPT who report that they have trained themselves to sleep on their left side.
- Instructing third-trimester women to sleep on their left side can increase the percentage of left-sided sleep to approximately 60% of the night; however, this can be highly variable (ranging from 11% to 98%) and may come at a cost of a slightly reduced sleep duration for women who do not normally adopt the left position, perhaps due to women feeling they need to make a conscious effort to maintain the left sleep position.
    - Comment: This lends credence to our hypothesis that back-sleep education may be having an independent effect on sleep behavior in the GPT regardless of treatment assignment.
- When third-trimester pregnant women are instructed to sleep on their left, the percentage of time spent sleeping on the left side is relatively consistent within individuals across multiple nights, with an average difference of only 15% between nights (maximum 40%).
    - Comment: If participants in the sham-control group in the GPT have truly trained themselves to sleep on their left side, this indicates that many will be able to consistently maintain the left side position throughout the remainder of their pregnancy without the assistance of a device.

5 Methodology

5.1 Study Design

This study will be of a cross-sectional design.

5.2 Study Site

This study will be conducted at the Korle Bu Teaching Hospital within the Obstetrics and Gynaecology Department (labor wards, Biostatistics Department, Dr. Jerry Coleman's office). The existing KBTH infrastructure (Detecto digital newborn scales installed by GIRHL in partnership with KBTH) and existing Ghana PrenaBelt Trial instrumentation (laptop, tablet, Surfline, printer, scanner/copier, filing cabinet, stationary – all property of GIRHL) will be used for this study.

5.3 Subjects/Study Population

The participants (subjects) will be healthy, Ghanaian women who have recently delivered a live birth at KBTH.

The inclusion/exclusion criteria criteria will be similar to the Ghana PrenaBelt Trial with one difference and one additional inclusion criterion – see Table 1:

Table 1: Inclusion/Exclusion Criteria

Ghana PrenaBelt Trial	KBTH-GIRHL Healthy Birth Weight Study
Inclusion Criteria	
≥18 years old	Same
Low-risk singleton pregnancy	Same
Entering the last trimester of pregnancy (in range 26-30 weeks of gestation)	Different: Delivered a live birth >28 weeks gestation at KBTH within the past 48 hours.
Residing in the Greater Accra Metropolitan Area or area served by the KBTH	Same
Fluent in either English, Twi, or Ga	Same
N/A	Additional: Has not received education/ information about back sleep position in pregnancy as a potential risk factor for stillbirth and low birth weight.
Exclusion Criteria	
BMI ≥ 35 at booking (first antenatal appointment for current pregnancy)	Same
Pregnancy complicated by obstetric complications (hypertension [pre-eclampsia, gestational hypertension, chronic hypertension], diabetes [gestational or not], or intra-uterine growth restriction [<10th %ile for growth])	Same
Sleep complicated by medical conditions (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])	Same
Multiple pregnancy	Same
Known fetal abnormality	Same

Maternal age >35	Same

5.4 Sample Size Determination

A sample size of one-hundred sixty-two (N=162) participants is selected for the KBTH-GIRHL Healthy Birth Weight Study. N=162 is the minimum combined group size for the Ghana PrenaBelt Trial: n=81 treatments plus n=81 sham-controls. The Ghana PrenaBelt Trial sample size was statistically justified (using power of 0.8 and type I error probability of 0.05 and accounting for 20% lost to follow up) based on a previous study in a Ghanaian population by members of our team (Dr. O'Brien, Dr. Coleman) (18) and using the PS Power and Sample Size Program (Version 3.0).

In order to avoid variance bias in comparison of the non-educated (KBTH-GIRHL Healthy Birth Weight Study) group to the back-sleep educated group (Ghana PrenaBelt Trial), the group sizes should be the same; therefore, one-hundred sixty-two (N=162) participants will be included in this study to match the 162 (minimum) participants in the Ghana PrenaBelt Trial. Since this is a cross-sectional study to recruit a control group only, no participants in this study will be lost to follow up; therefore, 162 participants are required in this study.

5.5 Procedures

1. Each participant will be screened, consented, and enrolled per Section 9.4 – Process for Seeking Consent.
2. Each enrolled participant will be assigned a six-digit alpha-numeric code by the study personnel. As each new participant is enrolled, the study personnel will construct the key to this code, which links the code to the participant's KBTH hospital record. This key will be kept strictly confidential by the study personnel - see Section 9.3 Minimization of Potential Harms for data security and privacy/confidentiality protection measures. All study data will be collected only in association with this code, thus automatically de-identifying the data.
3. The study personnel will complete the Data Collection Questionnaire with each participant. Since the questionnaire will be administered on the wards, it is possible that the participant's responses may be overheard by others other than the study personnel conducting the questionnaire; therefore, the participant will be informed

that she may refuse any question that she feels uncomfortable answering. It is expected that the questionnaire will take ten to fifteen minutes to complete.

4. After the study personnel completes the questionnaire with the participant, the study personnel will review the participant's KBTH hospital record and complete the participant's Delivery Outcomes Form.
5. For each participant, the study personnel will upload the Data Collection Questionnaire and Delivery Outcomes Form data (both documents include de-identified data only) to the research team's secure Microsoft OneDrive cloud for data extraction in preparation for the data analysis by the research team.

6 Data Handling

All study personnel involved in the conduct of this study at the study site (Maxfield Okere, Dr. Jerry Coleman) and data handling have received Good Documentation Practice (GDP) training as part of the Ghana PrenaBelt Trial within the past two years. Reference Section 10 and Section 34 in the Ghana PrenaBelt Trial Site Study Master Record (FDA regulatory file) in Dr. Jerry Coleman's office. Also reference GIRHL-SOP.005 – Guidelines for Completing Forms in the Ghana PrenaBelt Trial SOP/SSP Binder in Dr. Jerry Coleman's office. In addition, Dr. Jerry Coleman has completed Good Clinical Practice training with the Ghana Food and Drugs Authority in the past two years.

All study personnel involved in off-site data handling and data quality monitoring (Allan Kember, Jonathan Gale) have completed Tri-Council Policy Statement (TCPS-2) training within the past two years. In addition, Allan Kember has completed Good Clinical Practice (GCP) training for investigators from the Collaborative Institutional Training Initiative (CITI) Program within the past two years.

See Section 9.3 Minimization of Potential Harms for measures in place to ensure data security and protect participant privacy and confidentiality.

7 Statistical Analysis

Descriptive statistics (mean, median, standard deviation, maximum, minimum) will be employed for collected demographic, obstetric, and sleep habits information from the Data

Collection Questionnaire and key measurements (e.g., birth weight, gestational age at delivery) from the Delivery Outcome Form.

Interpretation of the results from this study will be conducted in conjunction with results from the Ghana PrenaBelt Trial (GPT) as follows:

- Comparison of groups (back-sleep education, no back-sleep education):
    - 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 and categorical data, we will evaluate for differences using Chi-squared, Fisher's exact test, or McNemar's test for repeated measurements.
- Note that all analyses will be conducted via the intention-to-treat approach in order to provide unbiased comparisons among treatment groups.

Central quantitative data will be sorted and stored in Microsoft Excel files. Quantitative data analysis will be performed in the R statistical software. We will report the number of participants with missing data.

Any deviations from the original statistical plan will be done under the supervision of our consultant statistician on the GPT (Mr. Michael Butler, M.Sc. Statistics, MD Candidate 2018) and described in full and justified in the final report, as appropriate.

8 Dissemination of Results

Since the results of this study will be interpreted and presented in conjunction with the results of the Ghana PrenaBelt Trial (GPT), we will follow the dissemination plan of the GPT:

Per Section 3.5.3. Final Report in the Ghana FDA's Guidelines for Conducting Clinical Trials in Ghana, publication of the GPT results in a scientific journal or other medium for the purpose of disseminating the information obtained to stakeholders may be encouraged only after 30 days of acknowledgement of receipt of the Final Report (1 soft copy, 1 hard copy) by the Ghana FDA. After these 30 days, the following shall take effect:

1. According to **Grand Challenges Canada's** (GPT funder) Open Access Policy, we must "*make available to the public through open access channels the results of the research emerging from the Project, or any reports or other publications regarding the Project funded by this grant (collectively, the "Materials"), and anticipates that the Materials will be published in a treatise, thesis, trade publication or in any other format that is available for the interested public as soon as practical, consistent with the need to first secure intellectual property rights in a manner that maximizes the benefits to developing world interests. Specifically, the Grantee is expected to use good faith efforts and work in a collaborative fashion with its subcontractors and funders associated with the Project to facilitate broad dissemination and accessibility of the Materials in the developing world*." Therefore, we intend to make our results freely available on the Canadian **International Development Research Centre's** Open Access Digital Library and on our websites (www.girhl.org, www.icchange.ca).
2. For any papers accepted and published in peer-reviewed journals, we shall post a Word version of our peer-reviewed, accepted article on our organizational websites (www.girhl.org, www.icchange.ca) immediately after publication in print or online. The Word document will indicate the article's citation and a link to the published article on journal website.

In addition to the above dissemination plan, we will freely share our results and the Word version of our peer-reviewed, accepted article with the Korle Bu Teaching Hospital. If the hospital wishes, they may post the documents on the hospital website. We also intend to present our results at various conferences in the fields of sleep medicine, obstetrics, and global health. The Korle Bu Teaching Hospital will be acknowledged in all publications and presentations.

9 Ethical Issues

9.1 Potential Benefits to Participants and Others

9.1.1 Participants

The opportunity to assist in the advancement of sleep-in-pregnancy knowledge and the possibility of benefiting other pregnant women in their community, country, and region in the future may be a source of immediate satisfaction to participants.

9.1.2 Others

In Canada, three babies are stillborn every day (≥1000g birthweight or ≥28 weeks completed gestation) (1). This is a largely unrecognized national issue yet pales in comparison to Ghana, where 47 babies are stillborn every day (1). In addition, every day, 61 Canadian babies are born with LBW (≤2500g) (26), and 232 Ghanaian babies are born with LBW (20) – many of whom will die in infancy or suffer lifelong consequences.

If maternal back 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 (18) – this translates to the potential global aversion of 3.7 million LBW and 676,000 SB annually (1) (2). Since LBW is a major contributor to SB (3), morbidity (2) (9) (10), and neonatal mortality (60-80%) (4) (5) (6) (7), further benefit may be realized.

The results of this study will be imperative for interpretation of the results of the Ghana PrenaBelt Trial (GPT), which is a study testing a novel approach to reducing the global incidence of SB and LBW. Demonstrating that back-sleep education does (or does not) improve pregnancy outcomes (e.g., birth weight) will be a valuable contribution to existing knowledge and may be a key component to reducing the rates of SB and LBW in Ghana 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) (22). If a public health intervention is advised, our studies (Ghana PrenaBelt Trial and KBTH-GIRHL Healthy Birth Weight Study) taken

together will be at the forefront of scientific investigation into two possible interventions, i.e., back-sleep education and positional therapy.

9.2 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 (Data Collection Questionnaire) than those risks they encounter in their everyday life.

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

9.3 Minimization of Potential Harms

Personal health information (PHI) used to identify potential participants will not be accessed by anyone other than the KBTH study personnel 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 the patients' KBTH hospital record number, will be kept in a secure location away from the de-identified study data and destroyed at the earliest possible time after it is no longer needed for study purposes, 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 in a locked office with limited access and on the secure, password-protected, Microsoft OneDrive cloud, respectively.

For all study activities, all data collected from participants will be protected from unauthorized access to safeguard participant privacy and confidentiality in accordance with Tri-Council Policy Statement (TCPS 2) and personal information policies at the Korle Bu Teaching Hospital.

Study data will only be exchanged in de-identified form and between study team members authorized by the Principal Investigator. 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).

9.4 Process for Seeking Consent

1. **Ethical Approval and Training:** This study requires approval from the Korle Bu Teaching Hospital Institutional Review Board (Accra, Ghana). All study personnel will be trained to the approved Research Protocol by Mr. Maxfield Okere (Principal Investigator).
2. **Recruitment**:
   - Study personnel (KBTH staff person) within the circle of care of patients who delivered a live baby at the KBTH Obstetrics and Gynaecology Department within the past 48 hours will visit the wards to invite patients to join the study. In an effort to avoid selection bias, the study personnel will visit the wards daily in the morning (before patients are discharged) and 100% of patients will be approached and invited to participate in the study – this will occur until the target sample size for the study is reached. Patients who are interested in joining the study will then be screened by the study personnel using the approved Screening Inclusion Form to determine if they meet the inclusion/exclusion criteria for this study. Note that only study personnel that are within these patients' circle of care will access their patients' health records. Researchers on the study team who are not within the circle of care will not access the patients' health records.
   - Patients who meet the inclusion/exclusion criteria will be invited to participate in the study by the study personnel within the circle of care. If a patient is interested in participating, the study personnel will conduct the consent process using the approved Information and Consent Form.
3. **Consent:**
   - Potential participants, having
     - met the study inclusion/exclusion criteria,
     - been invited to participate in the study, and
     - shown express interest in participating in the study

     will meet with study personnel to complete the consent process.

- In the meeting, the study personnel 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),
    - risks and benefits involved in participating in the study, and
    - 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; her de-identified data up to the point of withdrawal will be retained by the study team)
- The capacity of each potential participant to provide consent will be assessed by the study personnel 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:
    a. What is this study about?
    b. Why is this study important?
    c. What will you need to do in this study?
    d. What are the risks to you from being involved in this study?
    e. What are the benefits to you from being involved in this study?
    f. What happens if you choose to not participate today?
    g. What happens if you choose to participate today and then change your mind at another time and choose to not participate?
- The study personnel will give each potential participant an opportunity to ask any questions she may have.
- Voluntary, written (or participant's thumb print along with the signature of an impartial witness if the potential participant is not English literate), informed consent will be obtained with the participant's contact information by the study personnel from a potential participant who has demonstrated capacity and maintains an interest in enrolling in the study. When the Information and Consent Form is signed, the participant will be enrolled in the study and assigned a six-

digit, alphanumeric code for the purposes of de-identifying all data collected from her while enrolled in the study.

- Authorization or refusal of consent by a potential participant will be accepted by the study personnel.
- The Informed Consent Form is the source documentation of the informed consent process. The original, signed, and dated consent will be placed in the secure files of the Principal Investigator.

10 Timeline/Work Schedule

March-July 2016: Obtain ethics approval from KBTH-IRB for the KBTH-GIRHL Healthy Birth Weight Study

July-November 2016: Conduct the KBTH-GIRHL Healthy Birth Weight Study (chart reviews, questionnaires)

December 2016: Analyze data from the KBTH-GIRHL Healthy Birth Weight Study in conjunction with data from the Ghana PrenaBelt Trial.

Table 2 – Study Personnel

Name	Role
Maxfield Okere	As Principal Investigator, he will conduct screening of potential participants and consent for questionnaire and hospital chart review. He will also conduct data capture (via Data Collection Questionnaire and Delivery Outcome Form) and storage (via OneDrive cloud).
Dr. Jerry Coleman	He will serve as a co-investigator and on-site obstetrician for any questions that may arise in relation to the conduct of the study. He will serve as the KBTH representative to liaise with the Head of Department and KBTH staff in relation to any issues pertaining to the study.
Allan Kember	He will serve as a co-investigator and will sponsor the study. He will administer the study funds and lead the statistical analysis. He will be the GIRHL representative to liaise with collaborating organizations.
Jonathan Gale	He will serve as a co-investigator and direct data processing from OneDrive storage to analysis in the R statistical package.

11 Budget

Salary of study personnel: 5000 GHS

Total: 5000 GHS

Note that these funds will be managed by GIRHL, not by the KBTH Administration. Note that this budget does not include the KBTH-IRB review fee, which is to be determined and will be paid by GIRHL. Note that all instrumentation (including stationary supplies, printing, and internet charges) required for the KBTH-GIRHL Healthy Birth Weight Study will be supplied by the Ghana PrenaBelt Trial.

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13 Appendices

13.1 Screening Inclusion Form

Attached.

13.2 Information and Consent Form

Attached.

13.3 Data Collection Questionnaire

Attached.

13.4 Delivery Outcome Form

Attached.

13.5 Principal Investigator CV

Attached.