PRETERM BIRTH:
A CAUSE OF CONCERN FOR HIGH INFANT MORTALITY RATES

INTERNSHIP PRACTICUM REPORT

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CHAPTER 1

INTRODUCTION

In partial fulfillment of curriculum requirements for Masters in Clinical Research Management, I did a six months internship through June 2nd, 2009 to November 6th, 2009 in the Baylor Research Institute (BRI) located at Baylor All Saints Medical Center, Fort Worth, TX. I was under the supervision of my onsite mentor, Jennifer M. Thomas, RN, BLN, CCRC and research nurse, Theresa Cheyne, RN. During my internship I performed the day to day activities expected from a clinical research coordinator. During this period, there were four ongoing clinical trials of which three were device studies and one was an oncology study. I helped Mrs. Tracy Messing (Clinical Research Manager of Baylor Research Institute, Fort Worth) the research coordinator for this study, by filling out the IRB forms that are a prerequisite for any study. I attended the Institutional Review Board (IRB) meeting which reviewed this project. It was truly a learning experience to witness such meetings. The clinical trial involved subjects with recurrent head and neck cancer. The IRB had concerns regarding subject compliance for the proposed medication and standard of care. This clinical trial is being conducted at different sites across the United States.

The other study I was actively involved with was a device study that examined whether a gel can prevent postoperative adhesion formation in subjects undergoing gynecological laparoscopic adhesiolysis. In this study, the adhesions are removed and a polyethylene glycol (PEG) based absorbable gel that forms a hydrogel and acts as a barrier is poured through the

device during the endoscopic surgery. It is a randomized single blinded multi-site study conducted at several locations throughout the United States. I had an opportunity to see the endoscopic surgery for one of the subjects who was randomized into the device study. Also I observed the recruitment procedures and the informed consent process for the above device study.

BRI conducts mostly sponsor based studies that are multi-site. Many of the issues must be dealt with before a study gets approval. These include financial matters, Baylor Institutional policies, sponsors and other sites involved. Occasionally, a principal investigator also wants to examine the data apart from that mentioned by the sponsor. Thus, for the study to begin it actually takes 2-3 months apart from the time required for the IRB approval.

The success of any clinical trial depends on the active participation of the subject and their cooperation throughout the study. It is especially needed in trials related to cancer therapy. Since there is a high chance that the subject may withdraw from the study, recruiting subjects for such studies is another obstacle. This results in an increase in the cost and time involved in obtaining the results. The study can get delayed because of the technical issues such as non-availability of the personnel to conduct the study, or insufficient supply of the device, drugs, or paper work required for the study.

During a meeting with the monitor of a device study, I met with one of the mid-wives who is the Principal Investigator in this study. In this study, a device that measures the cervical length will be compared with ultra-sonogram results. This will involve a short questionnaire seeking subject satisfaction levels for either of the two procedures. During that meeting, the Principal Investigator described the use of the device for detecting preterm labor. This meeting led to the development of my research question. My literature search for studies related to

preterm birth and labor showed two results. There are studies that have been conducted that suggest various risk factors for preterm births, and preventive measures that can be implemented. However, there is not much awareness among pregnant women regarding preterm birth/labor which can lead to serious complication. Thus, it becomes imperative to find a solution to this serious health issue facing the world. In order to address this problem, discussion with the pregnant women population regarding their concerns, preferences and ideas about preterm birth is necessary.

LITERATURE REVIEW

Definitions

1. Pregnancy is defined as the state of carrying a developing embryo or fetus within the female body.[1] The birth of a baby is a process that starts when women experience labor pain caused by uterine contractions and ends with a delivery.
2. Full term births are defined as babies born between 37 weeks and 42 completed weeks.
3. Preterm births are babies born before 37 weeks of gestational period or 259 days from the first day of the last menstrual cycle as per the World Health Organization.

Preterm births are most commonly classified as:[2]

- Late term-premature: Babies that are born between 34 to 36 weeks of gestation.
- Moderately premature: Babies that are born between 32 to 36 weeks of gestation.
- Very premature: Babies that are born before 32 weeks of gestation.

Stages in Fetal Development and Labor

The World Health Organization defines normal pregnancies as between 37 to 42 weeks. These weeks are divided into three trimesters, and each trimester characterizes a unique stage of fetal development.[3] The duration of each trimester is three months.

The first trimester (1 week, 0 day to 13 weeks, 0 day), is the time of rapid growth and development of the embryo into its major organs like brain, spinal cord, liver and digestive system. The heart starts beating, and formation of the placenta takes place. By the end of second month, the fetus has a complete cartilage skeleton replaced by bone cells and the arms and legs

begin to appear. By the end of first trimester, the kidneys become functional, the toes and fingers appear, and the face looks more human like.

The second trimester (14 weeks, 0 day to 26 weeks, 0 day), marks the ability of the embryonic baby to make facial expressions. They can perceive sound. The skin, eyebrows and scalp begin to develop and an accumulation of fat takes place. They can flex and kick because of limb development. And lastly, development of the reproductive system begins. Even though the lungs are not well developed, a fetus born at the end of six months can survive if provided with intensive care.

The third trimester (27 weeks, 0 day to 40 weeks, 0 day), the baby starts to open and close the eyes and respond to light. The color of the eyes is established, bones become fully developed, and movements become more forceful. The skeleton begins to store calcium, iron, and phosphorus. Weight gain occurs and a slight movement of the diaphragm is seen as the fetus attempts to breath. Reproductive development continues, and the skin begins to thicken.

These developmental stages of a fetus described above can be visualized by using an ultrasonographical technique which has been approved by the FDA. As the birth gets closer, frequent and prolonged vigorous contractions are experienced. This stage is accompanied by back pain, vaginal discharge and membrane rupture. These vital signs are an indication of labor which is the concluding step of pregnancy. Labor is divided into three stages: the first stage is a change in the cervical length caused by dilation due to continuous contraction. This is further divided into two parts: latent and active labor. In latent labor, the cervix starts thinning out and opens slowly, while in active labor the cervix begins to dilate rapidly. The contractions get longer, stronger and closer together. This is also referred to as the transition phase. In the second

stage, the cervix is fully dilated and this stage ends after the baby is born. The third stage starts immediately after the baby is born and ends with the separation and delivery of the placenta. These stages are observed irrespective whether it is a normal or preterm birth.

Preterm Birth Statistics

There has been a significant increase in the number of preterm births in the United States from 11.6% in 2000 to 12.7% in 2007, which has been shown to be associated with increased risk of infant mortality. In 2005 68.6% of infant deaths were related to preterm birth. According to the statistics reported for 2007, nearly 549,000 babies were born preterm, i.e., a percentage increase of approximately 34.0% since the 1980s[4], during which the preterm birth rate was estimated to be 9.5% of all births.[2, 4] There has been a significant increase of about 11% in the number of late-preterm births from 8.2% of all births in 2000 to 9.1% of all births in 2005.[2] Recent studies indicate an increase in Cesarean births irrespective of age, race, ethnicity or socioeconomic status. This increase in singleton preterm birth was seen mainly in deliveries that were by Cesarean section, the largest increase seen in late-preterm deliveries.[5, 6] The very premature birth rate rose from 1.9% of all births in 2000 to 2.0% of all births in 2005, representing a percentage increase of 5.0%. Death resulting from preterm birth related causes was 34.6% of all births in 2000 to 36.5% in 2005, also representing a percentage increase of 5.0%. The rates of infant death due to preterm related causes are found to be higher among African Americans and Puerto Ricans as compared to Caucasians and Hispanic mothers.[6] With an increase in preterm birth rates, the babies require additional hospitalization, extra care, and pediatric surveillance that add to the overall health expenditure. According to the 2007 statistics, the average annual cost for premature births is approximately 10 times that of a full term birth. Thus, the cost involving prenatal care for a preterm baby right from its birth to their first birthday

roughly amounts to $449,033. This serious health problem costs the United States $26.0 billion annually.[7]

Causes and Risk Factors

Although, physicians have been unsuccessful in determining the cause of preterm labor, some factors have been identified. One important factor is spontaneous premature rupture of the amnionic membrane (PROM).[8] The opening up of amniotic sac too soon, i.e., before the labor begins results in PROM; this is also referred to as water breaking. According to one study, smoking or excessive caffeine drinking can result in PROM.[9]

Secondly, premature birth can be due to spontaneous labor caused by either genitourinary infection that triggers the body's natural response to induce early labor or premature dilation of cervix with no contractions (referred to as cervical shortening.)

Thirdly, premature birth may be due to a medical condition such as bleeding caused by placental abruptions. This result in tearing of the placenta from the uterine wall, stretching or over distension of the uterus that is seen in multiple pregnancies, during the gestation of twins or triplets, or early induction due to health problems like diabetes or pre-eclampsia or C-section carried out in complicated cases. All of these conditions increase the risk of preterm labor.

Furthermore, women who have had a history of prolonged PROM may also be at increased risk in subsequent pregnancies. Preterm births have a tendency to recur in subsequent pregnancies and the risk of delivering preterm is often around the same gestation time as the previous preterm birth.[10] Preterm labor cannot be predicted because any woman can deliver a premature baby, but it has been observed that some women are at more increased risk than

others. This is mainly due to difference in lifestyle, genetic make-up, occupation, education or some other parameter.

Researchers have identified these risks and grouped them as:[11]

- Risk due to socio-demographics
- Risks due to lifestyle
- Risks due to medical conditions
- Risks due to certain uterine, cervical abnormalities or stretching or distension seen when pregnant with twins, triplets, or a singleton fetus after in-vitro fertilization
- Risks due to complications such as fetal birth defects, bleeding from the vagina, women with a history of premature birth, and those who do not allow adequate spacing between children.[12]

Studies have shown that socio-demographic factors have an effect on preterm births. Low economic status, poor education or an unfavorable neighborhood increases the likelihood for gender discrimination, with increased level of stress, low self esteem, poor sanitation and nutrition.[13, 14] These parameters showed higher impact in African Americans rather than in Caucasian women in terms of the preterm birth rates. One study implicated age as one of the criteria for increased risk irrespective of the socio-demographic status, the reason being some inherent biological factors that causes premature labor.[15] It has been reported that African American women have higher premature birth rates compared to Caucasian and Hispanics. This may be due to difference in genetic or psycho-social factors. [16]

Smoking increases the risk for premature membrane rupture, one of the causes for premature birth and also increases the risk due to intrauterine growth restrictions.[17] Alcohol

consumption and especially heavy and binge drinking patterns augment the risk for preterm labor even if the consumption of alcohol is stopped during pregnancy.[18] Drugs of abuse such as cocaine and methamphetamines are associated with increased incidence and high risk of premature membrane rupture, as well as placental abruptions and maternal hypertension[19, 20]. Recent research has shown that women exposed to diethylstilbestrol (DES) before birth produced offspring called "DES Daughters." Mothers who took DES or their daughters had a higher percentage of preterm babies than the unexposed women population.[21] Thus, DES is banned for use. Stress (physical, emotional, or both) is an important risk factor involved in preterm births. Long term strenuous activities, shift duties and domestic violence have all been associated with preterm labor.[21] Studies have linked air pollution to preterm birth due to the release of organic compounds, such as polycyclic aromatic hydrocarbons in air.[22, 23] This may be because of combustion of fossil fuels, industrial waste products, wood, cigarettes, or some food items. These compounds have shown to produce toxic effects on the fetus if exposed early or late in pregnancy. One theory suggests that an immature immune system increases the susceptibility of developing life threatening conditions.

Infections, such as chorioamnionitis, bacterial vaginosis, asymptomatic bacteriuria, acute pyelonephritis, and cervical/vaginal colonization, can result in premature rupture of the amniotic membrane and preterm labor indications.[11, 24] Studies have shown that treatment of these infections reduces preterm delivery up to 50%. Studies have also demonstrated that systemic inflammation caused by various conditions such as diabetes, hypertension, pre-eclampsia and obesity increase the risk for preterm births that may be PROM dependent or independent.

Additional studies have revealed a higher incidence of preterm births in women who are underweight and those who gain little weight during pregnancy.[25] A recent study has correlated

periodontal disease to be one of the risk factors for preterm birth. According to American Dental Hygienists Associations women with periodontal disease are 3 to 5 times at greater risk of preterm birth compared with healthy women with no periodontal disease. This may be due to the inflammation of the gums caused by gram- negative bacterial infection which release endotoxins and cytokines into the cervicular fluids resulting in loss of teeth and bone destruction. However, it is yet to be established that periodontitis and preterm are correlated; it is argued that periodontitis can serve as a marker for preterm births. Since poor dental hygiene reflects unhealthy habits increasing the risk for preterm birth/labor.[25, 26]

Another risk of premature birth is due to complications like bleeding, distress due to multiple pregnancies, and any past history of preterm birth.[13] One study suggests that women born preterm are predisposed, to having a preterm baby. Thus, the maternal intrauterine environment may play a role in predisposing women for preterm birth.[27] In all these cases, the labor is induced by the physician.

Medical complications in the premature babies

A number of complications are more likely to be seen in premature babies than in full-term healthy babies. The main reason for these complications is less well developed organs that carry out the function of breathing by the lungs and the pumping of blood by the heart.[28] The babies that are born very preterm have less chances of survival and may develop serious lasting disabilities as compared to babies born at late preterm. The most common conditions resulting from preterm birth include infant respiratory distress syndrome, apnea, patent ductus arteriosis, anemia and chronic lung disease, intra-ventricular hemorrhage, necrotizing enterocolitis, retinopathy and jaundice. Preterm babies are also at increased risk of auditory impairment.[29]

Recent population based studies link preterm births to a higher risk of developing autism like symptoms as well as other related social, behavioral and speech problems.[30]

Medical complications are seen in babies born less than 28 weeks that have low birth weight. These babies are at high risk for developing the above mentioned complications. However, most babies born around week 28 have an 80% chance of survival if provided an extended stay in the intensive care unit.[8]

Babies that are born between 28 to 31 weeks of gestation have a 96% chance of survival. Many of them require oxygen, surfactant and assistance to help them breathe. They are also at risk for developing the above mentioned conditions but they may not be as severe.[8]

Babies that are born between 32 to 33 weeks of gestation have a 98% chance of survival. These babies may or may not require oxygen to help assist in breathing. They have less chances of developing serious disabilities, but they are at risk for developing learning and behavioral problems.[8]

Babies that are born between 34 to 36 weeks of gestation (late preterm) have a greater than 99% chance of survival. However, surviving babies remain at higher risk for developing newborn health problems than full term babies. [8]

Methods to detect preterm birth

If detected early for prematurity, one can prolong the birth of the baby by administering appropriate treatments and medications on time. Proper prenatal care can be followed by the physician or mid-wives since they can diagnose and treat preterm labor. The steps involved in diagnosing preterm labor include diagnosis of the symptoms recognized by the women followed

by clinical evaluation testing for any infection, maternal assessment, blood test or physical exam. There are many ways one can detect prematurity, including:

Cervical Length: Cervical length is an important indicator for premature labor.[31] There is an inverse relationship between the cervical length and preterm delivery. Cervical length of an unaffected cervix measures around 3.5 to 4.8 cm in length. Measure of cervical length can be accomplished by using a transvaginal ultrasound technique; however, this requires a skilled sonographer. The high costs involved and limited amounts of data to support its efficacy have delayed application. Recently, a new device is under study that measures cervical length and would be cheaper compared to the ultrasound technique.[32]

Fetal Fibronectin: A biochemical marker that assesses the true risk of preterm birth.[8] It is an extracellular fluid that is found in the fetal membrane, amniotic fluid and deciduas, and functions as an adhesive between the developing embryo and the interior surface of the uterus. Measurement of fetal fibronectin is a test that has been approved by the FDA for use between the 24^{th} and 34^{th} completed weeks of pregnancy. A positive test indicates that there is an increased risk for premature labor.

Home Monitoring of Uterine Activity: Though it is still not approved because of efficacy issues, home monitoring of uterine activity is licensed for use in women with a previous preterm birth. This can help reduce number of incidences through early recognition of preterm contractions.[33, 34] It is a device placed on the abdomen for at least one hour that helps to record any faint contractions that women may not be able to detect.

Salivary Estriol: Estriol is a biochemical marker that can assist in assessing the risk factors for preterm birth.[35] Estriol is a form of estrogen that is released by the fetus and the placenta and can

be detected in the saliva and blood of the mother. An increase in plasma estriol concentration stimulates oxytocin receptors in the uterus, myometrial gap junction proteins and prostaglandin synthesis, all which act as precursors to labor. Salivary estriol levels greater than 2.1 ng/ml of saliva are considered positive. Salivary estriol can be collected by the woman at home. The sample should be collected one hour after eating, drinking, smoking, chewing gum, brushing or flossing. However, this test has a high chance of showing a false positive value and bleeding gums affect the accuracy of the test.

Management of Preterm Labor

If detected early on during pregnancy, preterm labor can be prolonged by administering medication on time, providing good care and informing the patients of their likelihood in experiencing preterm labor. There are different ways in which one can manage preterm labor, this includes[10, 24]:

Physician Monitoring: One can reduce the preterm incidence by consulting a physician before and during pregnancy since the physician will be able to provide early and regular prenatal care. Early consultation with health care providers can help women with diabetes and hypertension to receive preconceptional medication, and the care necessary to reduce the risk to these preterm labor patients.[11] Specific strategies for management of preterm labor are available; their use should be considered before 37 completed weeks to produce an effect.

Tocolytic agents: Tocolytic agents such as magnesium sulfate, nifedipine and indomethacin[36] offer short-term benefit to preterm labor, and usually are administered before steroid therapy However, they result in many maternal complications, so it should be established that the

benefits outweigh the risks involved in their use. No studies have effectively proven that the use of tocolytic agents reduce mortality and perinatal morbidity.

Steroids: Use of corticosteroids at least 48 hours prior to delivery can reduce mortality, respiratory distress syndrome and intra-ventricular hemorrhage in infants born between the 24th and 34th weeks of gestation.[37]

Antibiotic therapy[8, 24]: Use of antibiotics for prenatal benefits is still not clear, however, they tend to sustain pregnancies in women with PROM and those treated for urinary tract infection. Nevertheless, their use in women with an intact amniotic membrane remains to be established.

17-Hydroxy progesterone: In one double blind study,[38] results showed a decrease in uterine activity due to progesterone application every night from 24-34 weeks compared to a placebo. Uterine contractions are the indicators of preterm labor, since women who are experiencing strong contractions have a higher chance of delivering a preterm baby. Also, use of vaginal progesterone suppositories reduces the risk of premature birth in women with a short cervix and those who had no previous history of premature birth.

Folic Acid: Some studies[39] have shown that continuous use of folate medication one year prior to conception helps in reducing preterm risk and also helps to reduce birth defects.

Other standard recommendations prescribed for women at high risk for preterm labor and delivery includes bed rest, hydration, and pelvic rest. However, the beneficial outcome from these is still to be established.

Preliminary studies/data

To reduce the incidence of preterm labor one needs to understand women's views on preterm labor. If they are better aware of the facts of prematurity and early diagnosis then treatment can be made available. Two studies[40, 41] have shown a lack of knowledge among the population, especially, mothers about preterm labor. Health care was seen at the top of the list followed by birth defects and smoking, while less than 1% of the population stated prematurity as a problem. The study also pointed out the fact that white (Caucasians) women were better able to define preterm birth when compared to African American and Hispanic women. African Americans more likely believed preterm labor is more common among them than among white women. This study was carried out on White, African American and Hispanic women who were not pregnant, pregnant or had a previous preterm or healthy baby. No comparison was made with respect to their knowledge gained through earlier delivery.

CHAPTER 2

SPECIFIC AIMS AND SIGNIFICANCE

Specific Aim 1

To determine if there exist any knowledge base difference between the first time mothers and those who have had healthy full term or a previous preterm birth baby.

SIGINIFINANCE

According to the National Vital Statistics of 2007, about 12.7 percent of babies are born prematurely. The state of Texas reported 13.6% preterm birth rate for the year 2007 which represents a decrease of approximately 1.0% in the preterm birth rates when compared to 2006 statistics. The state of Vermont reported a preterm birth rate of 9.2%, and the territory of Puerto Rico reported 19.4% preterm birth rate these represent the lowest and highest number of preterm infants born in United States for the year 2007. The rate of preterm birth was 18.3% among the African American while the Caucasians and Hispanic population reported 11.7% and 12.2% preterm birth rates respectively for the year 2007.[4, 4] This suggests that racial disparity among the population is one of the factors that results in preterm birth/labor, with Black population having an approximately two-fold higher risk for delivering preterm babies than Whites. Nearly more than half million babies i.e. one in every eight babies, are born preterm, thus increasing the in health care cost for babies that are born prematurely. Premature babies can be born to any woman irrespective

of race, economic status or educational qualification. No studies to date suggest that it is prominent in any particular race or people belonging to a particular socio-economic status. Rather, data suggests that race, or socio-economic status might be one of the factors that cause preterm birth/labor, but there are some factors that place women at higher risk for preterm labor/ birth than the others.[11] These factors are responsible for causing early contractions due to either premature rupture of the membrane or spontaneous preterm birth as a result of the bodies' defense mechanism against infection or other emergent problems. It has been observed by physicians that babies born prematurely due to a serious medical indication have a better chance of survival when compared to the preterm births resulting from other factors such as premature membrane rupture or spontaneous birth. However, many programs aimed at reducing preterm birth focus on spontaneous birth rather than medically indicated birth.

It is important here to note the fact that although there is a decline in prenatal mortality, because of the availability of better medical care for births resulting from medical indications, there is no change in the preterm related morbidity. Babies born prematurely are at an increase risk for life-threatening problems such as respiratory conditions, lung problems, infections and developmental disabilities. These would include: mental retardation, learning and behavioral disabilities, cerebral palsy, vision and hearing loss. Some of these conditions have a long lasting effect on the child such as affecting its overall development or developing some other neurological problems. The first objective of this practicum project is to understand whether pregnant women consider preterm birth to be a serious health issue. To achieve this objective, a comparative study was carried out by conducting a survey via questionnaire to the women who are first time pregnant and to those who are pregnant with second or third child with a previous term or preterm baby.

Subjects were asked questions which tested their knowledge about preterm birth/labor. These questions covered their perception about preterm birth. Do they feel preterm birth is one of the main problems for perinatal morbidity and mortality? What about the lifestyle they follow, and what in their view, is the risk to mothers? Questions were also designed to determine whether stress, age, race, and diabetes, high blood pressure were significant risk factors for preterm birth/labor. Additional questions queried what the subject's believe are the signs and symptoms of preterm labor.

Specific Aim 2

To design an effective program that educates women about preterm birth/labor based on responses obtained from study population.

SIGINIFINANCE

There has been a significant increase in number of preterm births across United States and other developed countries in the last two decades despite many clinical and community based preterm prevention programs. These programs provide guidance for prenatal care, nutrition to be followed, supplements to be taken and usage of tocolytic drugs to prolong or stop early contractions. The main reason for these programs to be unsuccessful is the lack of interest, seriousness, and the myths among the pregnant women that babies born prematurely can be saved and protected by the health care professionals. These babies are often addressed as "MIRACLE BABIES." But not all the babies born prematurely are lucky enough to survive even if provided with the best medical treatment or care. This just proves the fact that new findings and modern techniques cannot save a premature infant from life threatening diseases or death very often. Furthermore, the perception among the general public and pregnant women in particular, has led to the belief that preterm babies are not a serious cause of mortality and morbidity, and it is normal to

have preterm birth. This study can help in planning a multifaceted prematurity awareness program such as planning workshops, doing a documentary, organizing lectures/talks since the program would be designed based on the feedback we receive after distributing the questionnaire to the women population.

CHAPTER 3

METHODOLOGY

Study Design

This study will examine how pregnant women define preterm birth, whether they consider preterm birth to be a serious health issue, whether they consider preterm birth to a serious threat to infant health, and whether they understand the signs and symptoms of preterm labor. The study population was divided in two groups: The first group consisted of first time mother and the second group consisted of mothers who had a preterm baby or full term baby before. The study sample included Caucasians, African American, Hispanic and Asian women who are covered or uncovered under insurance. The questions were given to the two groups and assessed for their gain of knowledge. The questions were administered before they were counseled by the mid-wives about the general health care they are to follow and preterm labor prevention/education in particular, which usually occurs around the 24^{th} week. The questions related to their nutrition, medication, symptoms, stress, where they obtain new information, their views about signs and any significant symptoms experienced in the early gestation period. The questions can be found in appendix B.

Data Collection:

The study was conducted at Andrews Mid-wife Clinic a part of Texas Health Care located at Baylor All Saints Medical Center. The data was collected by distributing the questionnaire to the

women populations who met the inclusion criteria for the study. That is, those who were 13 years and above. First time mothers or have had a previous full term or preterm baby before and in their 1-24 weeks of gestation. Subjects with more than 24 weeks of gestation were excluded as well as subjects whose English was not the first language.

Based on the literature review the sample size for the study was calculated using to be 300-350 subjects with 95% of confidence level.[42]

Study procedures used for the analysis of the study were approved by the Baylor Institutional Review Board Dallas, TX and by the University of North Texas Health Science Center Institutional Review Board, Fort Worth, TX. The IRB protocol can be found in Appendix C

Variables:

Dependent variable:

Response given by the first time mother was considered, No, and those who have had babies before preterm or full term was considered, Yes.

Independent Variable

Age: Age was characterized into three groups: less than 18 years, 18-34 years, and more than 35years.

Race: Race was characterized into five groups: Asian, African American, Caucasians, Hispanic, and Others.

Education: Education was categorized into three categories: High school or less, Undergraduate School, and College degree or more.

Gestation week: Women were characterized according to the gestation week into three groups: less than 12 weeks, 13-24 weeks, and more than 24 weeks.

Insurance: The site in which study was carried out accepts patients with Medicaid, Cook's insurance (Insured) insurance.

Questions 1-14 are all considered to be independent variables.

For question 6: Response was considered, No, if checked for poor education, poverty, walking, spicy food, and it was considered to be, Yes, if checked for smoking, alcohol consumption, previous preterm, heavy physical activities, accidents, drinking coffee-based on the literature review.

For question 9: Response was considered, No, if checked for nausea, diarrhea, none of the above options, and was considered, Yes, if checked for uterine contractions, vaginal discharge, back pain, or bleeding based on the literature review.

Due to the small sample size, only the main indicators that will predict any change in the knowledge or attitude between the two groups were considered.

Questions 15 and 16 will be used for the analysis of Specific Aim 2.

Analysis:

The data set was created and variables were recoded using SPSS Version 17.0.

There are two steps in the analysis:

1) Descriptive analysis:

   Descriptive statistics were calculated for categorical variable such as frequency and percentage.

2) Multivariate logistic regression analysis.

   All statistical results were analyzed at 5% level of significance.

CHAPTER 4

RESULTS AND DISCUSSION

Results

There were 73 subjects who completed the survey for this research. One hundred percent (100%) response was obtained from the survey questions. Among all 1.4% Asians, 24.7% African American, 26.0% of Caucasians, and 48.0% of Hispanic population participated in the survey. Data are presented as per the demographics such as age, race, education and gestation week and the response to the study questions. The study population was categorized into two groups: first time mothers and those with previous full term or preterm. Among the population, 43.8% of the pregnant women were first time mothers and 56.2% have had a previous full term or preterm baby before.

Distribution of demographics among the study population

According to the age group it was found that the number of first time mothers under less than 18 years to be 18.6%, 78.1% were under 18-34 years group, and 3.1% under more than 35 years age group. There were 2.4% of women under less than 18 years of age group, 95.1% women between the age group 18-34 years, and 2.4% who were more than 35 years was observed for women who had full term or preterm babies. These data are shown in figure 1

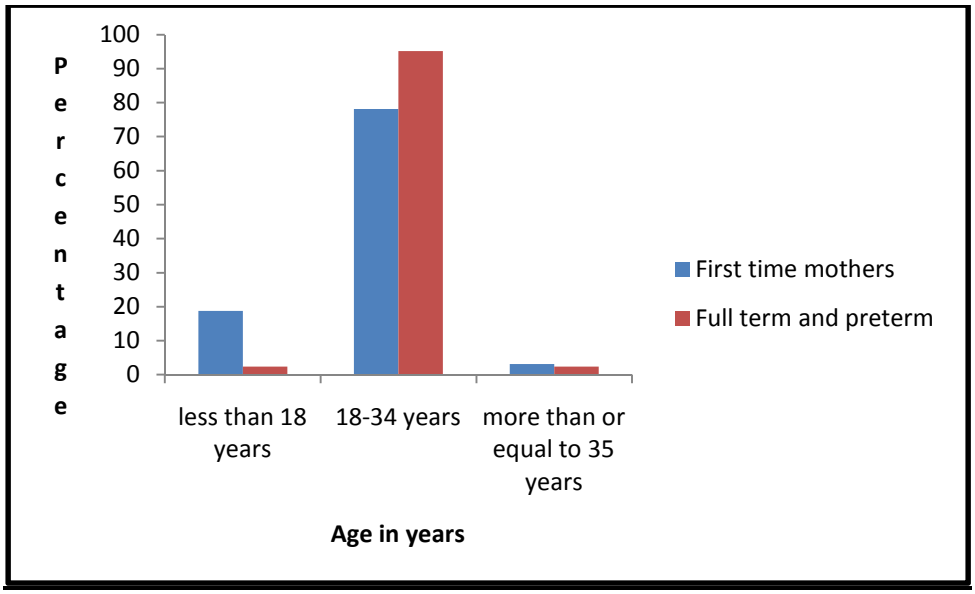

Figure 1: Distribution of age among the study population

Gestation week: In the first time mother it was observed that 12.5% women were less than 12 weeks pregnant, while 87.5% women were in their 12-24th week of pregnancy. The following results were observed for subjects in the second category 24.4% women were less than 12 weeks pregnant, 75.6% women were in their 12-24th week of gestation.

Race: First time mother who participated in the survey belonged to following categories: 3.13% Asians, 21.9% African Americans, 25.0% Caucasians, and 50.0% Hispanics. Respondents in the second category were mostly in the above mentioned categories namely 26.8% African American, 26.8% Caucasians, and 46.3% Hispanic. These data are shown in figure 2 .

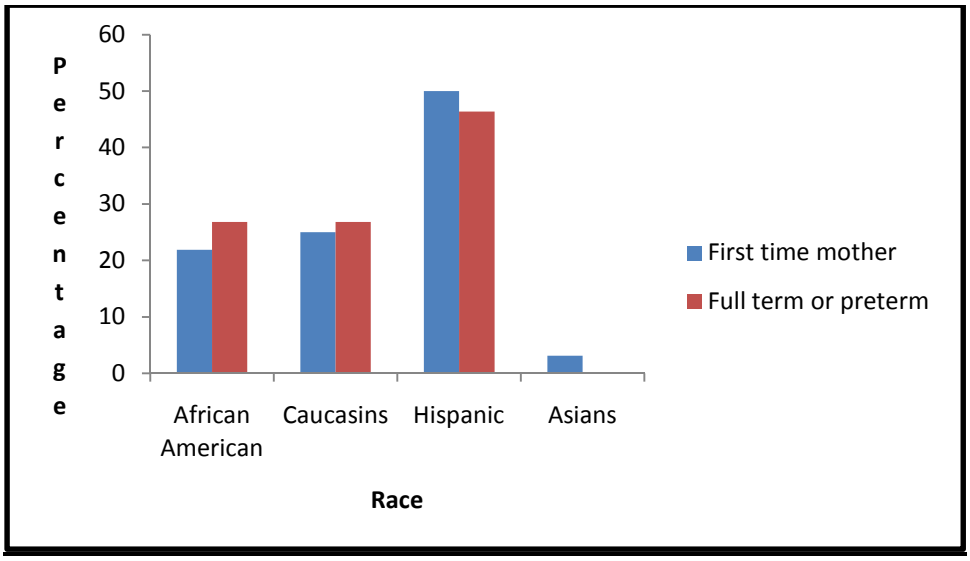

Figure 2: Distribution as per the race among study population

Education: It was observed for the first time mother that 71.9% women received a high school education or were less educated, 15.6% had an undergraduate degree, 12.5% women had a college degree or more. There were 73.1% women with a high school education or less, 22.0% had an undergraduate degree and 4.9% had a college degree or more. The above data was observed for women who had a full term or preterm baby before.

The first aim of the study is to observe for any difference in the knowledge about preterm birth among the first time mothers and those who have had babies before. The following results were obtained:

Of the total first time mothers, only 50.0% of them have heard about preterm birth/ labor, 37.5% women never heard about preterm birth/labor and 12.5% women responded that they did not know about it. While 78.1% mothers with previous full term or preterm have heard about preterm birth and labor and 12.2% responded to “No” and another 9.8% responded to “don’t know.” There were 59.4% of first time mothers defined correctly as preterm to be birth of a

infant born before 37 weeks, however, in the second category 65.9% of mothers responded correctly. The rest either answered incorrectly or did not answer the question. These data are shown in figure 3

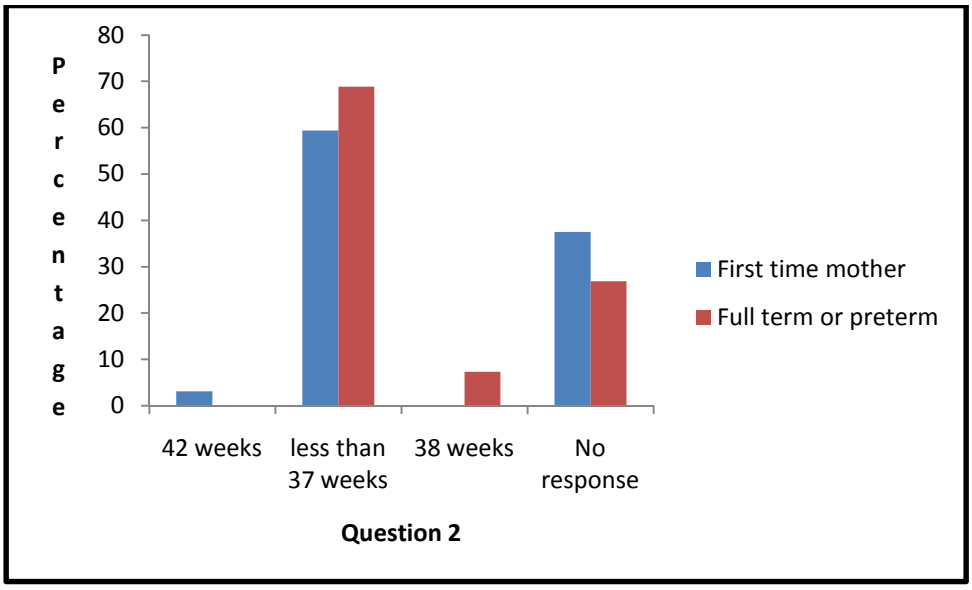

Figure 3: Response among the group when asked to define prematurity

Perceived seriousness of preterm as a health problem: 46.9% women in the first category think that preterm birth/labor is a serious health issue as opposed to 18.9% women who did not consider it to be a serious health issue and 28.1% women don't know about it or are unsure. 53.7% of women with previous preterm or full term consider it to be a serious health issue as opposed to 14.6% who did not consider it while 26.8% women don't know about it or are unsure. These data are shown in figure 4

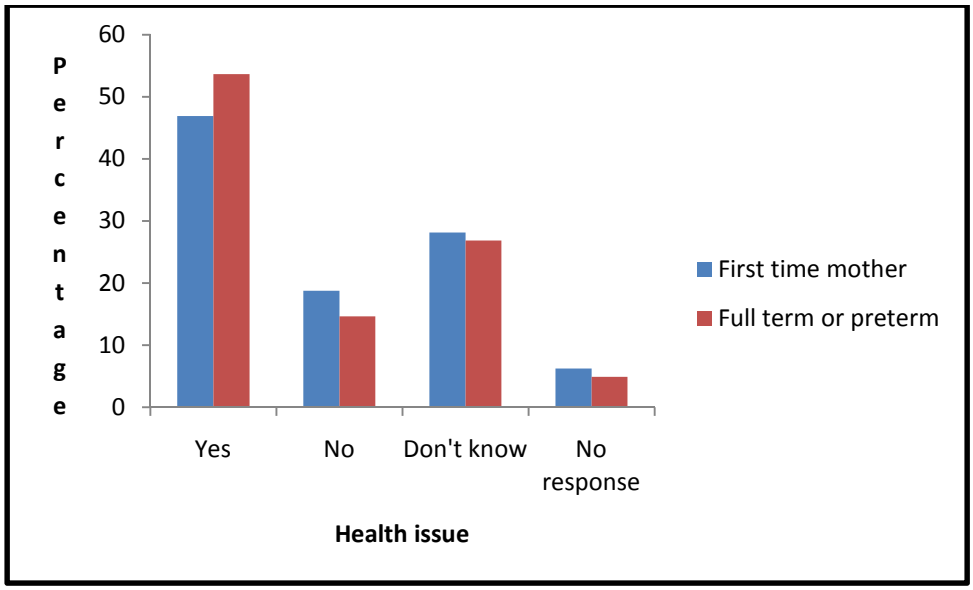

Figure 4: Response among the two groups on the preterm as a health issue

Viewpoint among the study population about effects on preterm on the Infant's health: There were 65.6% women in the first category who considered babies born prematurely increases the threat to the infant's health and 6.3% did not consider it to be a threat to the infant's health. Data indicated that 28.1% of first time mothers said they were unsure or have no idea. In the second category the response was 70.7% responded "Yes", 7.3% "No" and 19.5% were "not sure." These data are shown in figure 5

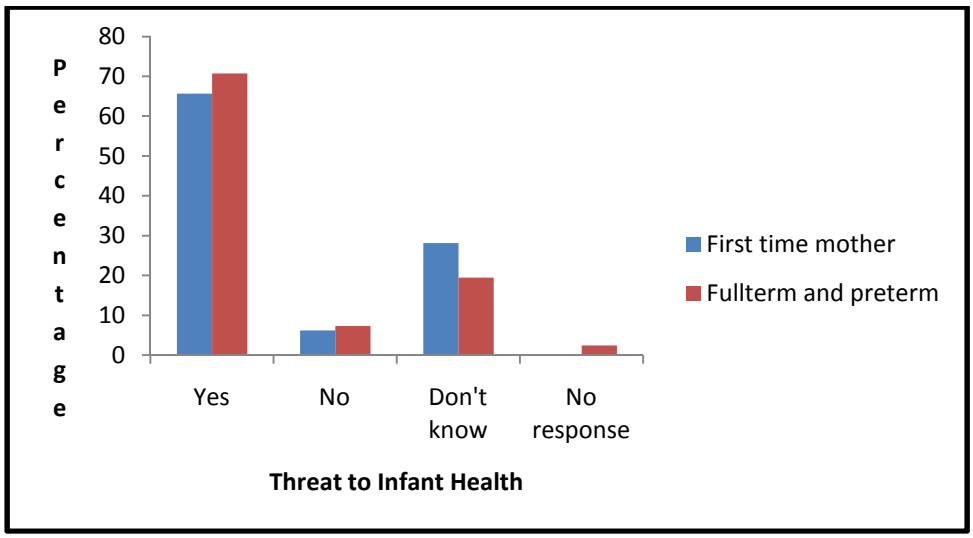

Figure 5: Distribution of response among the two study group

There were 40.6% of women in the first category who think that a baby born early will have a risk of developing long term health problems as opposed to 34.4% women who did not consider it to be a serious health issue; 21.9% women didn't know about it or were unsure. There were 63.4% of women with previous preterm or full term consider it to be a serious health issue as opposed to 17.1% who did not consider it was serious, and 17.1% women did not know about it or were unsure.

Supposed causes of prematurity: In this study, for the first category 96.9% respondents selected the correct factor that causes preterm birth or labor which increases the risk of preterm labor as opposed to previous full term or preterm mother with 97.6% that selected the correct factor. These data are shown in figure 6

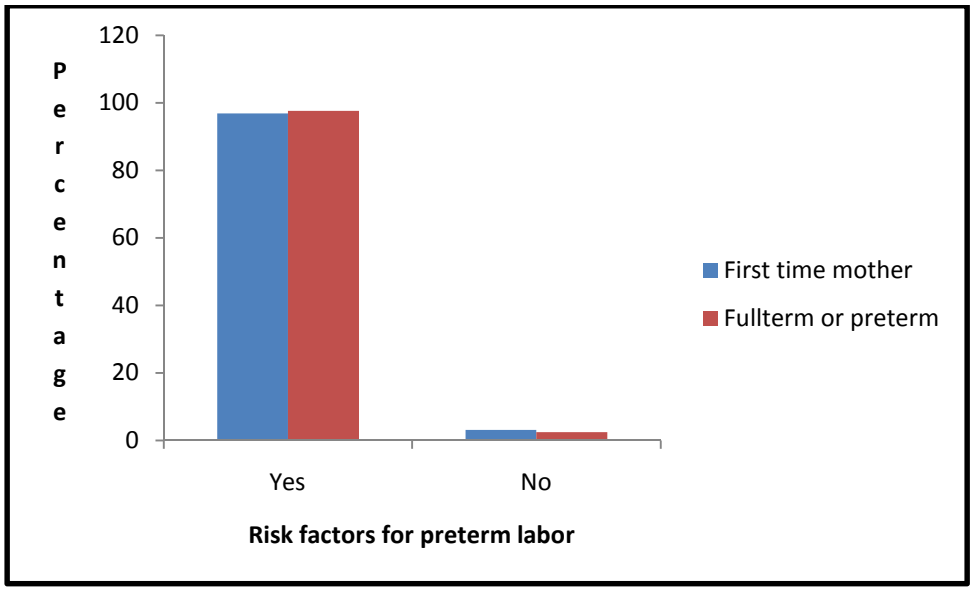

Figure 6: Percent response obtained from two groups

Furthermore, the subjects were asked if stress increase the risk for preterm labor and what do they consider the risk to be. The response among the first time mother was 71.9% women said

"yes" while 25.0% said they are "not sure", while the percentage among the with previous full term or preterm was 80.5% "yes", 17.1% were "not sure." Among the factors that cause stress, both the groups agreed that work requiring long hours of standing, arguments or fights, worrying about money are the likely factors.

Perceived signs and symptoms about preterm labor: When asked about the signs and symptoms of preterm labor: 84.4% first time mothers were able to correctly identify the signs and symptoms as the women with prior pregnancy at 92.7%. These data are shown in figure 7. Most women responded that they will call the midwives in case they experience any symptoms, the next choice being Physician/obstetrician followed by mothers and friends.

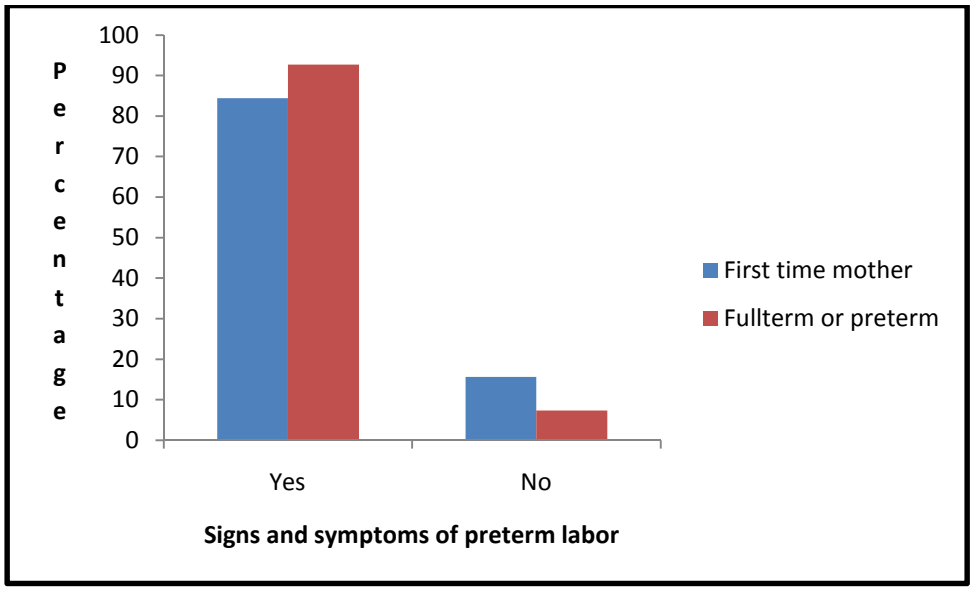

Figure 7: Distribution of response among the two groups

Among the first time mother 56.3% of women have heard or know about preterm labor and 68.3% women among the previous full term or preterm have heard it. Among the first time mother the source to get this information were friends and or relatives, or heard it from physician or midwives, or magazines but fewer mothers choose computer or television as the source of

their information, while among the women with previous pregnancy responded equally to all the options.

Perception on prevention and knowledge: 56.3% first time mothers do not know of any medication or nutrition as compared to 58.5% women with previous pregnancy full term or preterm. Only 15.6% women in the first category said folic acid can be used as compared to 14.6% and 4.9% women in the second category who choose folic acid and progesterone. Women in both the groups considered bed rest as a solution to prevent preterm labor followed by Iron supplement.

There were 48.0% women who agreed that an awareness program is required to prevent number of preterm birth outcomes as opposed to 49.3% who said that they have “no idea”, and 2.7% said “no.” These data are shown in figure 8

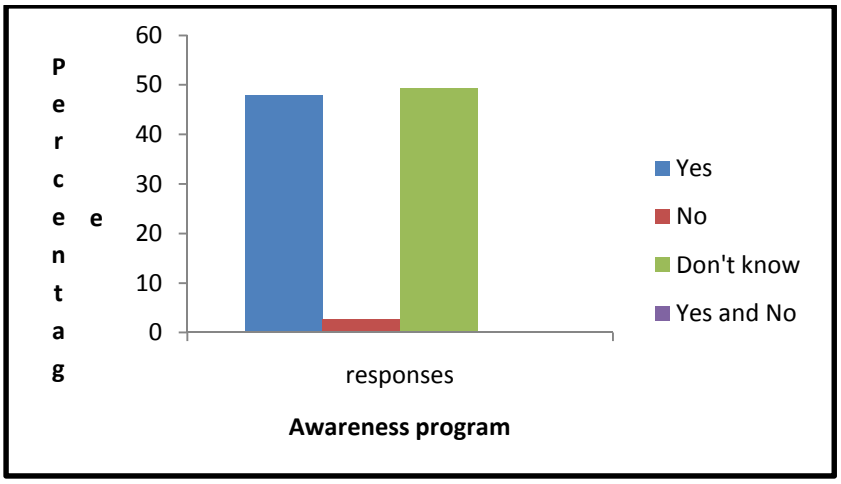

Figure 8: Response among study groups towards the need for awareness program

When asked about the most effective communication tool to learn about preterm birth DVDs, followed by one on one learning, documentary, lectures were the preferred modes of audio-visual aid that can help mothers to learn about preterm labor. Less than 11.9% women thought brochures can be used as a learning tool. These data are shown in figure 9

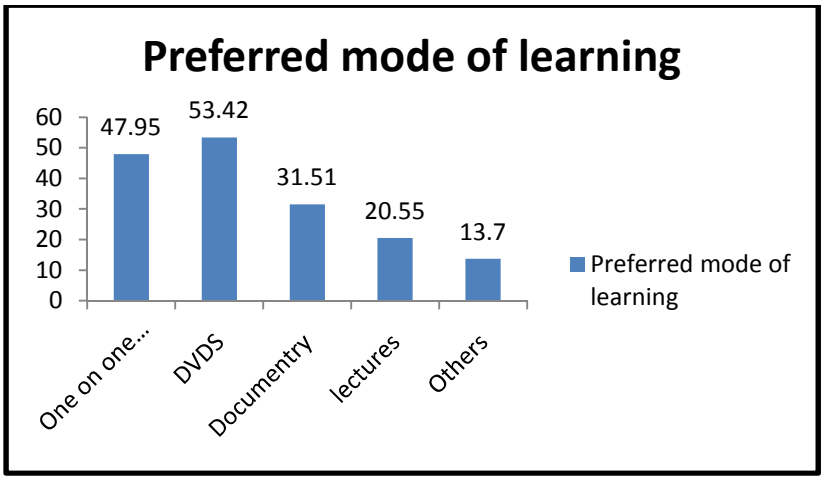

Figure 9: Preferred tool used for communication program

Table 1: Below summarizes the results obtained from the study.

Independent variable	First time mother		Full term or preterm	
	n	%	n	%
Age				
less than 18 years	6	18.75	1	2.44
18-34 years	25	78.13	39	95.12
more than 35 years	1	3.13	1	2.44
Gestation period				
less than 12 weeks	4	12.50	10	24.39
13-24 weeks	28	87.50	31	75.61
more than 24 weeks	-	-	-	-
Race				
Asian	1	3.13	-	-
African American	7	21.88	11	26.83
Caucasians	8	25.00	11	26.83
Hispanic	16	50.00	19	46.34
Other	-	-	-	-
Education				
high school or less	23	71.88	30	73.17
Undergraduate school	5	15.63	9	21.95
College degree or more	4	12.5	2	4.88
Insurance				
Insured	-	-	1	2.44
Uninsured	1	3.13	-	-

Medicaid	31	96.88	40	97.56
Don't know	-	-	-	-
Question 1				
Yes	16	50.00	32	78.05
No	12	37.5	5	12.20
Don't know	4	12.5	4	9.76
Question 2				
42 weeks	1	3.13	-	-
Less than 37 weeks	19	59.38	27	65.85
38 weeks	-	-	3	7.32
Nil	12	37.50	11	26.83
Question 3				
Yes	15	46.88	22	53.66
No	6	18.75	6	14.63
Don't know	9	28.13	11	26.83
Not sure	2	6.25	2	4.88
Question 4				
Yes	21	65.63	29	70.73
No	2	6.25	3	7.32
Don't know	9	28.13	8	19.51
Not sure	-	-	1	2.44
Question 5				
Yes	13	40.63	26	63.41
No	11	34.38	7	17.07
Don't know	7	21.88	7	17.07
yes or no	1	3.13	-	-
Nil	-	-	1	2.44
Question 6				
No	1	3.13	1	2.44
Yes	31	96.88	40	97.56
Question 7				
Yes	23	71.88	33	80.49
No	1	3.13	1	2.44
Don't know	8	25.00	7	17.07
Question 8.1 Work requiring long hours of standing				
Yes	16	50.00	26	63.41
No	16	50.00	15	36.59
Question 8.2 Shift/ night duties				
Yes	5	15.63	10	13.70
No	27	84.38	31	75.61

Question 8.3 Vacuuming				
Yes	-	-	-	-
No	32	100.00	41	100.00
Question 8.4 Sitting in front of computer				
Yes	1	3.13	-	-
No	31	96.88	41	100.00
Question 8.5 Cooking				
Yes	-	-	-	-
No	32	100.00	41	100.00
Question 8.6 Seeing physician or midwives				
Yes	2	6.25	-	-
No	30	93.75	41	100.00
Question 8.7 Arguments/ Fights				
Yes	24	75.00	34	82.93
No	8	25.00	7	17.07
Question 8.8 Worry about money				
Yes	22	68.75	33	80.49
No	10	31.25	8	19.51
Question 9				
No	5	15.63	3	7.32
Yes	27	84.38	38	92.68
Question 10.1 obstetricians				
Yes	14	43.75	17	41.46
No	18	56.25	24	58.54
Question 10.2 midwives				
Yes	31	96.88	41	100.00
No	1	3.13	-	-
Question 10.3 mothers/relative				
Yes	9	28.13	13	31.71
No	23	71.88	28	68.29
Question 10.4 friends/Neighbors				
Yes	2	6.25	1	2.44
No	30	93.75	40	97.56
Question 10.5 none				
Yes	-	-	-	-
No	32	100.00	41	100.00
Question 11				
Yes	18	56.25	28	68.29
No	9	28.13	8	19.51

Don't know	5	15.63	5	12.20
Question 12.1 Computer				
Yes	2	6.25	7	17.07
No	30	93.75	34	82.93
Question 12.2 Television				
Yes	3	9.38	11	26.83
No	29	90.63	30	73.17
Question 12.3heard from frds/ relatives				
Yes	17	53.13	14	34.15
No	15	46.88	27	65.85
Question 12.4 heard from Ob/ midwives				
Yes	7	21.88	13	31.71
No	25	78.13	28	68.29
Question 12.5 Know it before				
Yes	-	-	10	24.39
No	32	100.00	31	75.61
Question 12.6 Magazines				
Yes	6	18.75	10	24.39
No	26	81.25	31	75.61
Question 13				
Yes	6	18.75	8	19.51
No	18	56.25	24	58.54
Don't know	8	25.0	8	19.51
No response	-	-	1	2.44
Question 14.1 Folic Acid				
Yes	5	15.63	6	14.63
No	27	84.38	35	85.37
Question 14.2 Progesterone				
Yes	-	-	2	4.88
No	32	100.00	39	95.12
Question 14.3 Iron supplement				
Yes	8	25.00	7	17.07
No	24	75.00	34	82.93
Question 14.4 Bed rest				
Yes	10	31.25	13	31.71
No	22	68.75	28	68.2
Question 14.5 Vitamin D				
Yes	7	21.88	2	4.88
No	25	78.13	39	95.12

Table 2: Summarizes the response for a need for awareness program

Questions pertaining to awareness	**Responses**	
	N	**%**
Question 15		
Yes	35	47.95
No	2	2.74
Don't know	36	49.32
Yes and or No	-	-
Question 16.1 One on one basis	N	%
Yes	35	47.95
No	38	46.58
Question 16.2 DVDS	n	%
Yes	39	53.42
No	34	46.58
Question 16.3 Documentry	n	%
Yes	23	31.51
No	50	68.49
Question 16.4 Lectures	N	%
Yes	15	20.55
No	58	79.45
Question 16.5 others	n	%
Yes	10	13.70
No	63	86.30

Discussion

Preterm birth is one of the leading causes of infant mortality and morbidity, amounting to billions of dollars each year, thus, increasing the cost for health care. Proper awareness programs about preterm births may help the women population to know and understand better the signs and symptoms of preterm. It will enable pregnant women to avoid certain habits that are responsible for increasing the risk of preterm labor, leading to a decrease in the preterm infant birth rate.

Previous studies on preterm birth indicate that pregnant women, in particular, and the public, in general, do not consider preterm birth as a serious infant health hazard because of a lack of awareness about the implications of preterm. This study primarily tries to compare and correlate the knowledge and awareness about preterm between first time mothers and those who have had a previous preterm and/or full term baby. This study also aims to develop an effective mode of communication to create the awareness regarding preterm birth among the women population. The knowledge obtained from this study will further help to develop method(s) and steps needed to bridge in the gap between the knowledge and seriousness about preterm birth or labor.

A practicum study used a survey to examine responses among the pregnant women regarding preterm birth and what tool to be effective to create awareness among them. Seventy three subjects participated in the study. They were divided into groups: first time mothers and those who previously had a baby

The participants were primarily Hispanics, followed by Caucasians, African American and Asian populations. A majority of the subjects (87.7%) were between the ages 18-34 years, while

9.6% population were less than 18 years and 2.7% of population were greater than 35 years. With regards to education, 72.6% of women participants had a high school degree or less, approximately 19.2% had their undergrad degree and 8.2% had a college degree or more. Results from this study showed that only about 37.5% and 26.8% of the women in the two groups (pregnant for the first time or have had a full term or preterm previously) did not know what preterm meant while the majority in both the study groups, knew the meaning. However, regardless of their understanding of the term, they fail to consider preterm as a serious health issue and threat to the infant health. The data also suggests that approximately 97.3 % of the participants know that smoking, alcohol, previous preterm, heavy physical activities, accidents and drinking coffee are the risk factors of preterm labor/birth.

Approximately 89.0% of the subject population aptly identified some of the most critical signs and symptoms of preterm labor as uterine contractions, vaginal discharge, back pain and bleeding. Most of the subjects in the study population also agreed that the health care professionals (obstetrician midwives) are/will be their primary contact if they experience any preterm labor signs and symptoms. However, only a small number of the study population knew about the preventive measures to be followed to delay the early contractions and medications to be taken so as to prevent preterm labor.

Data collected from this study suggest the need to educate pregnant women about the facts of preterm birth/ labor and how it escalates the health care cost. Thus, to achieve this goal a suitable tool is required. In this study, 48.0% of women thought that an awareness program will help educate them about preterm birth. DVDs and individual teaching will serve as good tools in this process. The study site at Andrews Mid-wives Center provides handouts to women who are past their 24^{th} week of gestation. These handouts contain information about preterm birth, signs

and symptoms, what should be avoided and how to take care during pregnancy. However, there is a high chance that patient lose handouts or throw it away. In today's world of technology, the use of DVDs might serve as an excellent tool that can be used for communicating and educating pregnant women about preterm.

The main limitation of the study is that the number of subjects participating in the survey is small. Due to the small sample size, no significant difference (p-value was greater than 0.05) was observed between the two groups. Thus, the validity of results cannot be applied to the overall women population. Also the survey did not separate the answers based on the demographics mainly race, age, education among the groups.

More subject involvement will be required to decide whether a difference can be found between the two groups and where that difference lies. This study suggests that there is a difference regarding knowing the facts of preterm among the first time mother further research needs to be carried out. With the prior knowledge of this the first time mothers can be educated early on during the pregnancy. Also these awareness programs can be done through DVDs as found out in the study.

Conclusion

Birth of the baby in less than 37 weeks of gestation is known as preterm birth. Preterm affects all the population irrespective of age, race, and economic status due to lack of serious and awareness among the pregnant women as found in the earlier studies as well as this study. This study suggests the use of DVDs as a teaching audio-visual tool about preterm birth to pregnant women. This will help in motivating pregnant women to consider preterm as a serious health issue. Since as the study pointed out most women do know what preterm is, are aware of the risk factors, signs and symptoms it's the attitude among them that needs to be changed.

INTERNSHIP ACTIVITY SUMMARY

My daily activities varied from filling out forms to arranging binders. I assisted the Baylor Research Institute (BRI) staff with the consenting process, filling out IRB forms like amendment form, and deviation form for the ongoing studies. I realized a lot of paper work is involved in the process. As mentioned in the clinical research class, if it is not written than it did not happen thus documentation is key to clinical trials since these documents serve as a proof in the process.

Conducting the study: I was actively involved with Covidien Hydrogel study which is a device study that helps to prevent adhesions after the endoscopic surgery. The task involved was to recruit and screen the subjects. Of the five patients screened, two could be in the study. I observed the surgery for the same. The study involved in all four visits and two surgeries. Before the main surgery there is a pre-surgery visit in which the blood is withdrawn and checked for indices of pregnancy. After four days, laparoscopic surgery is performed in which the adhesions are removed and PEG- absorbable gel is sprayed over the entire surface where the surgery is carried out. After the surgery, the subject comes back after one week for the follow-up visit. During the follow-up visit, enquiries about reactions of the drugs and side effects of the surgery are made. Within the next three-eight weeks the subject undergoes a second surgery to ensure that the gel sprayed is no longer there and no adhesions are seen. After two weeks the subject comes in for the final visit. The subject response is filled into the patient log with notes attached. These are then entered electronically and sent to the study monitor. It served as a good experience to understand the intricacies of clinical trials ranging from subject interaction to the paper work involved.

I also learned to arrange the regulatory binder. This varies from sponsor to sponsor; I looked over three binders which were all different from each other.

Filling out IRB forms for new study: I got a chance to fill out forms and write a protocol that involved informed consent for the new cancer study. I attended the IRB meeting for the same. It was a full board review. Various questions were asked during the discussion session. It was a great learning experience as to how the IRB conducts its procedures.

Filling out the deviation form and the amendment form: Many times during the trials there are deviations from what has been approved. I got a chance to fill in the deviation forms. It is important to fill in the deviation form and send it to IRB within the seven working days after being reported. Also, during the trial which is usually many years long, lots of changes take place with the advent of new findings, and change of personnel. Thus, it is necessary to implement new changes in a timely manner. Once approved, the new document is used in practice.

Paper work for continuing review: One needs to keep a track of deadlines when they are due for the continuing review. Depending on the study, mostly all studies are approved for a period of one year whether expedited or full board. One needs to have photocopies of the documents approved by the IRB, status of the project, reports of any side effects or adverse events, and its validity. This involves lots of paper work

Maintaining study files and patient log: I also assisted in maintaining study files and patient logs. This is essential and becomes handy when the monitor visits the site for auditing.

This helped me when I was doing my thesis project as to how to approach the subject for participation in the study, telling them about the study. This experience also helped me in writing my protocol, cover letter, and filling out forms.

In all this internship was an excellent platform for me to gain an insight into clinical trials. Furthermore, it imparted training for the duties performed by the Clinical Research Coordinator.

APPENDIX A

DAILY LOG

INTERNSHIP DAILY ACTIVITY JOURNAL

Internship Starting Date: June 2nd 2009

June 2nd Tuesday

Jennifer showed me my office and introduced me to the other BRI staff

Read Study Binders assigned to me, and policies at the Baylor All Saints Medical Center.

Read HIPAA regulation, Belmont Report, Standard Operating Procedures, Budget templates.

Read the handbook for new clinical research coordinator

June 3rd Wednesday

Had a committee meeting to discuss the time-lines and requirements for thesis submission

Read two protocols of the start- up study

June 4th Thursday

Completed Study Manager training

Read protocol of a study due for continued review

June 5th Friday

Did hands on Study manger

Completed BLN modules

June 8th Monday

Filled out amendment form for study 009-009

Read through the investigational Brochure for protocol number 008-247

Filled out Form 7 for the study number 008-247

June 9th Tuesday

Gave the completed form 7 to Theresa for checking

Filled out Form 7 for protocol number 007-054

Made changes to the informed consent as per the sponsor's protocol

June 10th Wednesday

Filled out deviation form for studies 08-044 and 08-045

June 11th Thursday

Gave the forms to Tracy for checking

Helped Theresa in stacking up the binders

June 12th Friday

Browsed the internet to look up articles on Cord Blood

Participated in the discussions concerning the issues and solutions for the Cord Blood study

June 15th Monday

Meeting with Jennifer regarding the thesis project

Read protocol informed consent for the study number 2-04-09

June 16th Tuesday

Met Nancy, principal investigator for Cervilenz study

Helped Theresa in putting up the charts

June 17th Wednesday

Searched articles and browsed the net for my internship practicum

June 18th Thursday

Meeting with Jennifer to discuss about the study and issues related to it

Learnt how arrange a regulatory binder

Helped Theresa in arranging Regulatory Binders

June 19th Friday

Read articles

Read books related to Clinical Research Management, and How to recruit subjects

Helped Shawnta in setting up the table for BRI ad

June 22nd Monday

Read articles related to preterm labor, cervical length

June 23rd Tuesday

Attended workshop on how to fill IRB forms

Helped Theresa in filling subject charts

June 24th Wednesday

Worked on my proposal

June 25th Thursday

Attended lecture on How to write grants to NIH

Read protocol for the study number 007-054

June 26th Friday

Read Investigator Brochure for study number CA 22531

June 29th Monday

Read sponsor's protocol and informed consent for study CA 22531

June 30th Tuesday

Assigned task of filling out IRB forms for study CA 22531 requisite for starting any new study.

Filled out Review of Scientific and Scholarly Validity IRB form 18

July 1st Wednesday

Filled out form 1 for application and Summary for new study

Filled out form for Financial Disclosure,

Went with Theresa to see a follow-up study subject for project number P0071

Helped in filling out the follow-up template provided by the sponsor

July 2nd Thursday

Wrote an informed consent for study CA-22531

July 3rd Friday

Holiday

July 6th Monday

Submitted forms and informed consent to Tracy for checking

Edited the forms for minor changes

July 7th Tuesday

Read protocol and investigator brochure for new device study

July 8th Wednesday

Went with Theresa to see a new subject and observed the informed consent process for study Gyn-06-001

Searched articles and information for my thesis

July 9th Thursday

Met Jennifer to discuss about thesis project

July 10th Friday

Met with the monitor of Cervilenz study

Met Nancy to discuss about the thesis

July 13th Monday

Observed an endometriosis surgery for protocol Gyn-06-001

Went with Theresa to see a subject in the device study for its follow-up visit

July 14th Tuesday

Read articles on preterm

Worked on my proposal

July 15th Wednesday

Helped Theresa in arranging binders

Worked on my thesis

July 16th Thursday

Attended Full Board IRB meeting at Dallas

July 17th Friday

Worked on my proposal

Helped Theresa in trashing of the supplies and device used for the study

July 20th Monday

Worked on my proposal

Helped Theresa in filling out patient charts

July 21st Tuesday

Saw a subject who came for the follow-up visit for a drug study

Read articles for my thesis

July 22nd Wednesday

Helped Theresa in clearing off tubes and other materials provided by the sponsor for the study

July 23rd Thursday

Helped Theresa in pulling up patient charts and arranging it

Made photocopies of Investigators brochure

July 24th Friday

Helped Tracy in arranging subject binders as per the sponsor log

July 27th Monday

Helped Theresa in arranging subject file

Worked on my proposal

July 28th Tuesday

Helped Theresa with paper work

July 29th Wednesday

Browsed internet for articles

July 30th Thursday

Read protocol and informed consent for device study

July 31st Friday

Submitted thesis proposal

Helped Tracy in arranging subject file

August 3rd Monday

Met Nancy to discuss about what questions should be asked

Pulled out the forms to be filled for the expedited study

August 4th Tuesday

Filled out Form 1 for my study

Filled out form 23

August 5th Wednesday

Filled out form 24

Wrote a letter for requesting Parental Waiver

Filled out form 18

August 6th Thursday

Wrote a Cover letter for my study

Helped Theresa in arranging patient logs

Filled out form 14

Took Theresa's signature on them

August 7th Friday

Gave the IRB filled documents to Jennifer for checking

Read articles for the study

August 10th Monday

Read the investigators Brochure for project 009-145

Filled out Form 7 for project number 009-145

August 11th Tuesday

Went with Theresa to consent subject for the device study

Observed Theresa while collecting the blood

Centrifuged the blood sample and labeled it with the identification number

August 12th Wednesday

Helped Theresa in arranging subject file prior to the monitor's visit

Worked on my thesis

August 13th Thursday

Made corrections to the IRB forms

Helped Theresa in putting up the charts

August 14th Friday

Browsed the internet for the articles

Made copies of the IRB documents

August 17th Monday

Designed questionnaire for my study

Gave to Nancy for reviewing

Made changes to the questionnaire

August 18th Tuesday

Went with Theresa to Dr. Johns office for getting his signatures on IRB documents

Saw a patient and told her about the study

Wrote protocol

Browsed the internet for finding out the sample size calculator

August 19th Wednesday

Went with Theresa to see two subjects who had come for their follow-up visit

Observed blood -draw

Centrifuge the tubes and labeled the tubes

August 21st Friday

Made a copy of protocol

Listed the items required for IRB submission

August 24th Monday

Did not go to the internship site

August 25th Tuesday

Attended monthly staff meeting

Had a meeting with Jennifer regarding the IRB submission

August 26th Wednesday

Helped Theresa in paper work required for the continued review for one of the drug study

August 27th Thursday

Went over at Dr. Johns office to get his signature on Form 18

Assigned a Nursing Project

August 28th Friday

Pulled out articles related to Nursing

Browsed the internet for information regarding Nursing Research

August 31st Monday

Meeting with Jennifer regarding nursing project

Mail sent from the IRB office regarding the submission

Made changes in the IRB document

September 1st Tuesday

Went with Theresa to see subject for the study INS 009-145

September 2nd Wednesday

Went at Dr. Johns office to collect the forms and papers

Attended meeting on Billing Compliance

Submitted the corrected IRB documents

September 3rd Thursday

Worked on nursing project

Prepared power point of nursing project

September 4th Friday

Did not go to the internship site

September 8th Tuesday

Did not go to the internship site

September 9th Wednesday

Went with Theresa to see a subject that had queries regarding the sterilization study

Consented the subject for the device study that prevents the adhesions around the uterine wall

September 10th Thursday

Got the IRB documents back

Made changes to the document, since student cannot be the PI for the study

September 11th Friday

Read articles

Filled out form 14

Took Jennifer's signature on it and on the forms since she is the PI for the study

Explored Andrews Women Hospital

September 14th Monday

Went over to Dr. Johns office for his signature on Form 18

Submitted IRB documents

September 15th Tuesday

Spoke with Juliana at the IRB office

Made changes to the informed consent (cover letter)

September 16th Wednesday

Attended BRI –Investigator's Breakfast

Explored Baylor All Saints Hospital

September 17th Thursday

Prepared Excel sheet for my study

Spoke to ITS people regarding SPSS installation on my computer

September 18th Friday

Helped Tracy in putting up the subject files

Read brochures on diabetes and studies carried out at Baylor All Saints

Made photocopies of the changed Investigator Brochure

September 21st Monday

Went with Theresa to consent the subject

Observed the Blood draw

Centrifuge the tube and labeled it

September 22nd Tuesday

Met Jennifer regarding IRB submission

Called Juliana to ask the status of the project

Told to contact Deborah that looks over the financial support

September 23rd Wednesday

Contacted Deborah

Got the approval letter from the IRB office

Called up Nancy to inform her about the approval

September 24th Thursday

Went to Texas Health Care to carry out the survey

Handed out questionnaire to the subjects

Went to school to drop off the IRB documents at OHHRP office

September 25th Friday

Stopped the study since require school IRB approval

Wrote a mail to Nancy

Started writing protocol synopsis

September 28th Monday

Took signature of Jennifer on conflict of interest form and on her resume

Wrote a parental permission letter

Made photocopy of all documents submitted to UNTHSC IRB

Went to school for submitting IRB documents

September 29th Tuesday

Worked on my thesis

September 30th Wednesday

Helped Theresa in filling out patient log for device study

Went to school to submit Jennifer's BLN lessons

October 1st Thursday

Worked on my thesis

Pulled out articles

Read March of Dimes bulletin

October 2nd Friday

Attended seminar on hypertension

Worked on my thesis

October 5th Monday

Worked on my thesis

Helped Theresa in putting in subject charts

October 6th Tuesday

Did not go at the internship site

October 7th Wednesday

Called up at OHHRP office to know the status of the project

Called up Juliana to find out if I can make changes in the approved documents

Went with Theresa to see a subject that withdrew from the cancer study

October 8th Thursday

Got the UNTHSC IRB approval for my study

Wrote mail to Nancy

Went to school to collect IRB approval letter

Submitted a draft of thesis

October 9th Friday

Made copies of questionnaire sets, instruction sheet

Went to Texas Health Clinic

Pulled out patients charts

October 12th Monday

Conducted survey

Attended seminar on Breast Cancer

Made the data entry in the Excel sheet

Pulled out patient chart for tomorrow

October 13th Tuesday

Made copies of questionnaire

Conducted survey

Made data entry into the Excel sheet

Pulled out patient chart for tomorrow

October 14th Wednesday

Conducted survey

Made data entry into the Excel sheet

Pulled out patient chart for tomorrow

October 15th Thursday

Made copies of questionnaire set and instruction sheet

Conducted survey

Attended meeting for IUD

Made the data entry into Excel sheet

Pulled out the chart list for tomorrow

October 16th Friday

Conducted survey

Made the data entry into Excel sheet

Pulled out the chart list for Monday

October 19th Monday

Conducted survey

Made data entry into Excel sheet

Helped Theresa in arranging patients files

October 20th Tuesday

Conducted survey

Made data entry into Excel sheet

October 21st Wednesday

Conducted survey

Made data entry into Excel sheet

Worked on SPSS

October 22nd Thursday

Meeting with Nancy to tell about the survey

Conducted survey

Made data entry in Excel sheet

October 23rd Friday

Feed the data in SPSS

Run the results

Created tables in Excel sheet

Made copies of questionnaire set and instruction sheet

October 26th Monday

Conducted the survey

Feed the data in SPSS

Made bar graphs

Worked on my thesis

October 27th Tuesday

Conducted survey

Feed the data

Worked on my thesis

Made copies of questionnaire, instruction sheet

October 28th Wednesday

Submitted thesis draft to Dr. Gwirtz

Meeting with Jennifer

Conducted survey

Worked on thesis

October 29th Thursday

Worked on my thesis

Appendix B

Questionnaire

QUESTIONNAIRE

To be filled in by midwives or research assistant

SUBJECT: Identification Number: PB00

Age: □ < 18yrs □18-34yrs □>35 yrs

Gestation week: □ < 12weeks □13-24weeks □>24weeks

Race: □ Caucasian □ African American □ Hispanic □ Asian □ Other

Education: □ High School or less □ Undergraduate School □ College degree/ more

Health Insurance: □ Insured □ Uninsured □ Medicaid □ Don't know

For question below check all the boxes that are applicable

- □ **First time mother**
- □ **Previous full term delivery (≥37 weeks)**
- □ **Previous preterm delivery (≤37 weeks)**

Q1. Have you heard about preterm labor?

- □ Yes
- □ No
- □ Don't know

If you answer yes proceed to next question, otherwise, go to question number 3

Q2. A baby is considered preterm if born before how many weeks?

- □ 42 weeks
- □ less than 37 weeks
- □ 38 weeks

Q3. Do you consider preterm labor to be a serious health problem?

- □ Yes
- □ No
- □ Don't know

Q4. Do you consider preterm birth a serious threat to the infant's health?

- □ Yes
- □ No
- □ Don't know

Q5. Do you think babies born early are at an increased risk of developing long term health problems?

- Yes
- No
- Not sure

Q6. What do you think might be the cause of preterm birth? (Mark all that is applicable)

- Smoking
- Alcohol consumption
- Previous preterm
- Poor education
- Poverty
- Heavy physical activities
- Walking
- Spicy food
- Daily chores
- Accident
- Drinking coffee

Q7. Do you think stress might be one of the factor for preterm birth?

- Yes
- No
- Don't know

If you answered yes proceed to question number 8, otherwise, go to question number 9

Q8. What in your opinion is stress?

- Work requiring long hours of standing
- Shift/ night duties
- Vacuuming
- Sitting in front of computer
- Cooking
- Seeing physician/midwives/older family members
- Arguments/fights with family members
- Worry about money

Q9. What in your opinion are the signs and symptoms of preterm labor?

- Nausea
- Uterine contractions
- Vaginal discharge
- Diarrhea
- Back pain
- Bleeding
- None of the above

Q10. Who would you contact in case you experience any of the above symptoms?

- Obstetrician or clinic staff
- Midwives
- Mothers/relatives
- Friends/neighbors
- None of the above

Q11. Have you ever come across or heard about preterm labor?

- Yes
- No
- Not sure

If yes answer the next question, otherwise, proceed to question number 13.

Q12. Where have you come across this information?

- Computer (Google)
- Television
- Heard from a friend/relative
- Heard from physician or midwives
- Know it because of previous pregnancy
- Magazine

Q13. Do you know about any medication or particular nutrition that can prevent preterm?

- Yes
- No
- Don't know

If you answered yes proceed to next question, otherwise, go to question number 15

Q14. Do you think one of these medication/practices prevent preterm labor?

- Folic acid
- Progesterone

- Iron supplement
- Bed rest
- Vitamin D

Q15. Do awareness programs help in reducing the number of premature birth outcomes?

- Yes
- No
- Don’t know

Q16. Which of the following would be the best way for you to learn about preterm labor?

- One on one learning
- DVDS
- Documentary
- Lectures
- Others (please specify)

_____
_____
_____
_____

Appendix C

IRB Documents

BAYLOR
Research Institute
Affiliated with Baylor Health Care System

3310 Live Oak
Suite 501
Dallas, Texas 75204
(214) 820-2687
(214) 820-4952 Fax
BaylorHealth.com

APPROVAL

September 15, 2009

Jennifer Hayes Thomas, RN
1400 Eighth Ave.
Forth Worth, Tx 76104

Re: Preterm Birth: A Cause of Concern for High Infart Mortality Rates
Project#: 009-205 Protocol#: N/A Protocol Dt:

The following items received expedited review:

- Education Report (08/24/2009)
- Application and Project Summary - IRB001 (08/24/2009)
- Review Scientific/Scholarly Validity - IRB018 (08/24/2009)
- Authorization to Enroll Children in Research - IRB (08/24/2009)
- Authorization to Enroll Pregnant Women in Research (08/24/2009)
- Questionnaire / Survey
- Projected Number of Subjects/Charts/Specimens - 300-350
- Letter to request waiver of patental permission (08/17/2009)
- Instructions to complete survey
- Key Personnel Contact Information
- Research Protocol

Expedited Approval was granted 09/15/2009 for a period not to exceed 12 months and will expire on 09/14/2010. Your Continuing Review is scheduled for 08/10/2010. This Expedited review will be reported to the fully convened Institutional Review Board ~ Red on 10/13/2009.

On behalf of the Institutional Review Board, I have reviewed the above referenced research project in accordance with 45 CFR 45 & 164 and 21 CFR 50 & 56. This review was conducted in accordance with the expedited review process as outlined in 45 CFR 46.110(b). Based on the information presented, I have determined that the study meets the criteria specified below. NOTE: The list of categories is from the November 9, 1998 Federal Register.

45 CFR 46.110(b)(1)(7):
(1) some or all of the research appearing on the category list and found by the reviewer(s) to involve no more

than minimal risk:
(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior), or research employing survey, interview, oral history, focus groups, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.

Based on this review, the above referenced items are approved for implementation.

The Board reminds you that Baylor Policy requires that that unless waived, fully documented informed consent must be obtained in accordance with 45 CFR 46.116 and 21 CFR50.20 from all human subjects involved in this research study. Informed consent must be obtained by the principal investigator or other key personnel as listed in this submission. Documentation of informed consent must be kept on file for a period of three years past completion or discontinuation of the study and will no doubt be subject to inspection in the future.

In addition, 45 CFR 164 requires that, unless waived by the IRB, authorization must be obtained for use and disclosure of Protected Health Information. If this project is currently open to new enrollment, the approved version of the consent form(s) is listed above. The document(s) reviewed in this submission has been determined to satisfy the requirements as outlined in 45 CFR 164.508.

DHHS and FDA regulations require you to submit periodic and terminal progress reports to Baylor's Institutional Review Board and to receive at least annual approval of your activity from this Committee.

You are also required to report to this Committee immediately any death, unanticipated problems invoving risks to subjects or others, or serious adverse incidents resulting from your study. These events must be reported in accordance with current BRI Policies 830 and 838.

Federal regulations and institutional policies require that the IRB review any and all changes in your research activity. This includes amendments, revisions, administrative changes, advertisements, or ANY other change in the information as presented at initial review. In other words, should your project change, another review by the Board is required. Failure to comply with any of the above requirements, federal regulations, or institutional policy may result in severe sanctions being placed on the Medical Center and on you as the Principal Investigator. These sanctions could result in your research being permanently terminated for non-compliance.

Receipt of approval does not convey institutional authority to gain additional patient information. It is your responsibility as Principal Investigator to abide by institutional and/or departmental policies regarding confidentiality, access, and release of patient data.

Please be advised: there may be additional administrative requirements from Baylor Research Institute that must be met before the study may begin enrolling subjects.

Sincerely,

Lawrence R. Schiller, MD, Chair
Institutional Review Board ~ Red

Project# 009-205

UNIVERSITY of NORTH TEXAS HEALTH SCIENCE CENTER at Fort Worth
TEXAS COLLEGE OF OSTEOPATHIC MEDICINE
INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS

BOARD ACTION

IRB PROJECT #: 2009-105 DATE SUBMITTED: September 28, 2009

PRINCIPAL INVESTIGATOR: Patricia Gwirtz, PhD (with Amruta Oak, CRM Student)

PROJECT TITLE: Preterm Birth: A Cause of Concern for High Infant Mortality Rates

PROTOCOL #: n/a

DEPARTMENT: Clinical Research Management (CRM) TELEPHONE EXTENSION: x 2079

In accordance with UNT Health Science Center policy on the protection of human subjects, the following action has been taken on the above referenced project:

Approval, when given, is **only** for the project as submitted. **No changes** may be implemented without first receiving IRB review and approval.

✓ Project has received approval through October 8, 2010.

✓ Informed Consent approved as submitted on October 8, 2009. You **MUST** use this version (attached) rather than previously approved versions. In addition, only consent documents which bear the official UNTHSC IRB approval stamp can be used with subjects.

✓ Study Protocol dated October 8, 2009 approved as submitted.

____ Protocol Synopsis approved as submitted on _____.

____ Amendment _____ to the protocol approved as submitted.

____ Based upon the recently completed Continuing Review (IRB Form 4), project has received continued approval through _____.

____ Project has been reviewed. In order to receive approval, you must incorporate the attached modifications. You must submit one "highlighted" copy and one "clean" copy of the revised protocol synopsis, informed consent and advertisements to the IRB for review. YOU MAY NOT BEGIN YOUR PROJECT UNTIL NOTIFIED BY THE IRB.

____ Consideration of the project has been tabled pending resolution of the issue(s) outlined below.

____ Project is disapproved for the reason(s) outlined below.

____ Completion of project is acknowledged and all required paperwork has been received.

✓ Special Findings:

See attached page for findings related to protocol approval

Chairman, Institutional Review Board

October 8, 2009
Date

IRB Form 2 revised 12-03 MA 04-1487

IRB Board Action **October 8, 2009**

2009-105 **Patricia Gwirtz, PhD** **CRM Program**
(with Amruta Oak, CRM Student)

Preterm Birth: A Cause of Concern for High Infant Mortality Rates

Study to be conducted at Texas Health Care (Baylor, Dallas) also requiring approval by Baylor Research Institute (BRI) IRB.

As reviewed by UNTHSC IRB, and in concurrence with the findings of BRI-IRB, this study meets the criteria for Expedited Review, under the provisions of 45 CFR 46.110 (b) (1) category # 7, research employing survey, interview methodologies; and under the provisions of 45 CFR 46.404 (research not involving greater than minimal risk in minors).

Given that the study will be conducted only at Baylor health care facilities (Texas Health Care) as described in the protocol submitted, protocol synopsis and consent form approved by BRI-IRB accepted as submitted for use in Texas Health Care facilities only as approved by BRI-IRB, and for use in Texas Health Care facilities only. NO UNTHSC IRB-Approved stamp is required or provided.

It is also noted that only data collected after the protocol was approved by UNTHSC-IRB can be used for this UNTHSC graduate student project. Thus, only those data collected on or after October 8, 2009 may be used in any research report, presentation, thesis, dissertation or publication by any UNTHSC faculty, staff, or student.

Please note that Dr. Gwirtz, on behalf of the student, must file a Final Report at project completion, but not later than one year from this approval date.

Research Protocol

Preterm Birth: A Cause of Concern for High Infant Mortality Rates

BACKGROUND:

According to National Vital Statistics there has been a significant increase of about 30% in preterm birth rates from the 1980s thus increasing the cost for prenatal care. This serious health problem costs the United States $26.0 billion annually. Babies born prematurely (that is less than 37 weeks) are at an increased risk of developing genetic defects and or complications that may lead to death. The number of preterm births is high among non-Hispanic black population as compared to non-Hispanic white or Hispanic population as per the National Statistics. Despite such a high rate and cost involved its exact etiology is not known.

Several studies have identified factors such as smoking, excessive alcohol, caffeine consumption, heavy physical activities, stress, education, age, genetic make-up, lifestyle, diabetes, high blood pressure, previous history of preterm, multiple pregnancy , pregnant with twins, triplets requiring C-sections or such other medical complication that increases the risk for preterm labor. Apart from this lack of awareness, seriousness, false misconception can also increase risk for preterm labor. Two studies have pointed out this fact when questionaire pertaining to preterm birth and its cause were asked to general public and pregnant women in particular. When asked what can be a problem for society prenatal health care tops the list while prematurity is at the bottom half of the list. This approach in the public towards preterm birth points the preconceived notion they have that the best medical care would be given and modern technology will be utilized to protect the preterm infants from any harmful effects. This stresses the need to educate women about preterm labor, its signs and symptoms, person to be contacted if experiencing uterine contractions and medications available in the market that help to prolong preterm labor. Studies have shown that early intervention and detection can help prevent preterm labor and thus preterm birth thus helping to reduce the cost involving prenatal care

The proposed study will help us understand whether prior pregnancy better prepares mothers in terms of understanding the signs and symptoms, and facts about preterm birth than first time mother. Also the study aims at proposing an effective educational program based on the feedback that is received from the study population.

STUDY AIMS:

1. To observe for any difference in the knowledge and approach towards preterm birth when compared between first time mother and those who had a previous full term or preterm baby.
2. To design an educational program that will help in educating women about preterm birth.

METHODS OF STUDY:

Inclusion Criteria: Women who are pregnant and at 1-24 weeks of gestation will be approached.

- Age 13 years or older
- First time mother or mothers who have had previous full term or preterm baby before
- Has not been counseled about preterm birth.

Exclusion Criteria: Women who cannot read English

Those consenting to the study will have to fill out the questionnaire.

1. Each questionnaire sheets will be assigned a specific number such as PB001, PB002, etc and handed out to the study subject at Texas Health Care.
2. It will take around 10 minutes to fill out the questionnaire.
3. Subjects will fill out the questionaire and hand over to the staff or the researcher.

SAMPLE SIZE AND STATISTICS:

To achieve accuracy of the test with a p value of 0.05 approximately 300-350 patients will be enrolled in the study. Multivariate regression analysis will be use to report the outcomes of the study.

REFERNCES:

1. Brady E. Hamilton. Preliminary data for 2007. National Statistics Report. March 18, 2009; 57
2. Marian F. Mac Dorman PD, T.J. Mathews. MS. Recent trends in infant mortality in the United States. National Center for Health Statistics Data Brief. October 2008; Number 9
3. March of Dimes: Facts about Prematurity
4. Reedy NJ. Born Too Soon: The Continuing challenge of Preterm Labor and Birth in the United States. Journal Midwifery Women Health. 2007;52:281-290
5. Nancy S Green MD, Colleen E. Ryan MA, Lisa Shusterman MA, Ellen L. Fiore, Karla Damus RN, PhD. Understanding pregnant women's perspectives on Preterm Birth. Contemporary OB-Gyn. Jan 2003:70-87
6. Holly A. Masset PhD, Marion Greenup MEd, MPH, Colleen E. Ryan MA, Douglas A Staples BA, Nancy S. Green MD, Edward W Maibach PhD. Public Perception about Prematurity a National Survey. American Journal of Preventive Medicine. 2003; 24:120-127

PROTOCOL SYNPOSIS

PROTOCOL TITLE	Preterm Birth: A Cause of Concern for High Infant Mortality Rates.
PRINCIPAL INVESTIGATOR	**PATRICIA GWIRTZ, Ph.D.,** DEPARTMENT OF INTEGRATIVE PHYSIOLOGY, UNTHSC, Fort Worth, TX
PRINCIPAL INVESTIGATOR CONTACT INFORMATION	817-735-2079
CO-INVESTIGATOR	Jennifer M. Thomas, RN, BSN, CCRC, BRI
STUDENT INVESTIGATOR	Amruta Oak , Graduate student in Biomedical Department, UNTHSC Fort Worth, Texas
SPECIFIC AIM	1. To observe for any difference in the knowledge and approach towards preterm birth when compared between first time mother and those who had a previous full term or preterm baby. 2. To design an educational program that will help in educating women about preterm birth.
BRIEF SUMMARY AND SIGNIFICANCE	Preterm birth is found to be a leading cause of mortality and morbidity globally, in recent years. According to National Vital Statistics of 2007, 12.7% babies were born prematurely across the United States, accounting for an annual cost of $26.0 billion. Preterm birth rates were found to be high among the Non- Hispanic Blacks as compared to the Non-Hispanic Whites and Hispanic populations. Despite these high rates and the costs involved, the exact cause is still unknown. Several studies have identified factors that increase the risk for preterm labor/birth. “Two studies showed that general public and women, in particular, are unaware of preterm and its related signs and symptoms.” Also, these studies highlighted the fact that the study population not only lacked seriousness and awareness but also had misconceptions about preterm birth/labor. Our study aims to find out whether previous pregnancy, full term or preterm, helps to better prepare the mother to

	follow any signs or symptoms of preterm labor and to see if they are better aware about preterm birth than the first time mother.
PRELIMINARY STUDIES	Two telephonic survey studies related to preterm birth were conducted. The study populations were tested on their understanding about preterm birth/labor through the designed questionnaire. But no comparisons were made between the study populations.
INVESTIGATOR EXPERIENCE	Dr. Patricia Gwirtz is a faculty at University of North Texas Health Science Center, Fort Worth, Texas. She has been honored by various awards for her contribution towards research. Jennifer Thomas, the co-investigator of the study, heads Baylor Research Institute at Fort Worth and Dallas and has expertise in research involving human subjects. Ms. Amruta Oak is a graduate student in the department of biomedical sciences, at University of North Texas Health Science Center, Fort Worth, Texas. All investigators involved in this study have completed CITI training for conducting human research.
METHODS AND PROCEDURES	Questionnaire would be distributed to the study population during their OB-Gyn visits. Instruction sheet would be attached to this questionnaire. The sheet will educate the subject about the study and also emphasize that the participation in it is entirely the subject's choice.
DATA ANALYSIS AND DATA MONITORING	All the data collected from the questionnaire will be converted to SPSS format. Multivariate Regression Analysis would be used to calculate the difference in the knowledge gained based on the age, race, education, insurance or any previous pregnancy.
DATA STORAGE AND CONFIDENTIALITY	The data collected will be used for research purposes only. Only the key personnel approved by both the UNTHSC and the Baylor Institutional Review Board (IRB) will participate in collection and analysis of data.

	All records and medical information will be kept confidential as required by the current local, state, and federal laws. The research data collected will be kept in the Department of BRI in the office of the Research Coordinator in a locked filing cabinet. All electronic data will be kept in a password-protected, secure computer database in the investigator's office. These files will only be accessible to the Key Personnel of this study, the UNTHSC and Baylor IRB, and regulatory agencies. The databases will contain no personal identifiers.
STUDY SETTING	Questionnaire would be given to the study subjects at Texas Health Care during their OB-GYN visit. Each study subject would be assigned a unique ID.
DURATION OF STUDY	The study will last for a period of three months; however the time spent by each subject will be approximately about 10 minutes.
INCLUSION CRITERIA	➢ Women who are pregnant ➢ 1-24 weeks of gestation ➢ Age 13 years or older ➢ First time mother or mothers who have had a full term or preterm baby before. ➢ Has not been counseled about preterm birth in the last 6 months.
EXCLUSION CRITERIA	➢ Women who cannot read English.
SAMPLE SIZE	Approximately 300- 350 subjects will participate in the study.
RISK/BENEFIT	The proposed study involves a questionnaire that needs to be answered by the subject. No personal information or health history would be collected from the subject. This study carries minimal risk to the subjects regarding loss of confidentiality. There are no direct benefits for subjects from this study. However, this study will help us understand the differences in the approach towards preterm birth between the first time mothers and those who have had full term and/or preterm babies previously and what in their view might be an effective way to

	create awareness about preterm birth.
PAYMENTS/ COMPENSATION	No costs involved for the subjects participating in this research study. Subjects will not be compensated for participating in this study
LIST OF KEY PERSONNEL	Dr. Gwirtz, Ph.D. will help in looking over the research study. Jennifer Thomas co-investigator will help in carrying out the research work at the site Amruta Oak will give out the questionnaire , collect the data and will help in analyzing the data set
REFERENCES	1. Brady E. Hamilton. Preliminary data for 2007. National Statistics Report, March 18,2009 ;57 2. Marian F. Mac Dorman Pd, T.J. Mathews. MS. Recent trends in infant mortality in the United States. National Center for Health Statistics Data Brief . October 2008; Number 9 3. March Of Dimes : Facts about Prematurity 4. Nancy S Green MD, Colleen E. Ryan MA, Lisa Shustermann MA, Ellen L. Fiore, Karla Damus, RN, Ph.D. Understanding pregnant women"s perspectives on Preterm Birth. Contemporary OB-Gyn. Jan 2003:70-87 5. Holly A Masset, Ph.D., Marion Greenup Med, MPH, Colleen E. Ryan MA, Douglas Staples BA, Nancy S. Green MD, Edward W Maibach, Ph.D. , Public Perception about Prematurity a National Survey. American journal of Preventive Medicine. 2003; 24: 120-127

Version Date: 09/11/2009 IRB Project # 009-205

Preterm Birth: A Cause of Concern for High Infant Mortality Rates

I am a Student intern at Baylor Research Institute and I am conducting a research project on **Preterm Birth: A Cause of Concern for High Infant Mortality Rates** and I would appreciate you taking part in this project. This research project is intended to give us an idea if there is a difference in the knowledge about preterm birth between the first time mother and those who had a baby before. You have been selected to be in this study because you are 1-24 weeks pregnant and have not yet been counseled about preterm birth since this is your first/second Ob-Gyn visit.

To take part in this study, you will need to complete a short survey that asks several questions regarding preterm birth such as:

- Do you think preterm is a serious health problem or cause of infant mortality
- What do you think are risk factors associated with preterm birth?
- What are the signs and symptoms that indicate preterm labor?
- Who would you contact if you experience these symptoms?
- What would be an effective way to learn more about preterm birth/labor?
- This should take only about 10 minutes. Do not write your name on the survey. Once you have completed the survey return it to me or the mid-wife. I will use the results of this project to write a research paper. The results may be published in the mid-wife journal.

There are no risks or benefits to you for been in this study. You have the option to not complete the survey and therefore not to be in the study. By filling out the attached survey and returning it to me or the mid-wife, you are saying that you are willing to take part in this study.

If you have any questions about this project, please contact me at 817-922-7159. If you have any questions about your rights as a research subject, please contact Lawrence Schiller, MD at 214-820-2687.

Thank you for the time. I hope you will take a few minutes to complete the survey and to return it to me or the mid-wife. Without the help of people like you, this important research would not be conducted.

Sincerely,

A. G. Oak

Amruta Oak

Key Personnel Contact Information

Title	Name	Business Address	Telephone number	Email address
Principal Investigator	Jennifer Thomas	1400 Eighth Avenue Fort Worth Texas 76104	817-922-2560	jenniha@baylorhealth.edu
Co-Investigator	Amruta Oak,	1400 Eighth Avenue Fort Worth Texas 76104	817-922-7159	amruta.oak@baylorhealth.edu

BAYLOR RESEARCH INSTITUTE
BHCS Departmental Research Support Form
Estimate of Associated Cost for Research Study

Principal Investigator: Jennifer Thomas, RN Department: BRI West

Telephone #: 817-922-2560 Fax #: 817-922-7360 E-mail: jenniha@baylorhealth.edu

Name of Study: Preterm Birth: A Cause of Concern For High Infant Mortality Rates

Is there an outside sponsor being sought? Yes X No

IRB/IACUC#009-205 Date Approved 09/15/09

Brief Description of the Study: There has been a significant increase in the number of infant related deaths due to preterm or preterm related cause. Survey results from earlier studies on pregnant women and on the general public suggested a lack of seriousness, awareness, and some false misconception the study population had about preterm birth/ labor. This might be one of the reasons for an increase in number of preterm birth. The purpose of this study is to find whether women who had earlier pregnancy have heard or know about preterm birth/ labor and are better prepared than the first time mother. To achieve the objectives of research general questionnaire have been designed which the subject needs to fill out and hand over to the mid-wife or to the researcher. The questionnaire test the views and general understanding about preterm birth/labor among the study population. Also the study aims at proposing an effective educational program based on the feedback that is received from the study population.

Start Date: 09/24/09 End Date: 12/31/09 Total Years: 3 months

Number of Patients in Study Approximately 300-350

Estimated Annual Costs Per Patient:

Salaries/Fringes	$ 25.40	
Supplies	$ 0.10	
Lab or Other Diagnostic Services	$ 0.0	
Miscellaneous	$10.00	(Please explain)
Total Annual Cost Per Patient	$ 35.50	
Total Estimated Annual Cost	$ 10,650.00	(# of patients X cost per patient)

Does Project involve any of the following (Indicate date of committee approval, if applicable):

[ ] Biological Safety/Recombinant DNA..... Date Approved: _____
[ ] Radioisotope/Radiation Safety.....Date Approved: _____
Questions on completion of this form should be directed to Sponsored Research at (214) 820-0990

APPROVALS:

Jennifer Thomas 9/24/09 9/23/09

Principal Investigator Date Department Administrator Date

Chief of Service/] Medical Director/ Department Director Date Department Vice President Date

Office of Sponsored Research Date BHCS Entity Financial Officer Date

IRB Number: 009-205 Version Date: 08/24/09

Baylor Research Institute
Institutional Review Board
Application and Project Summary

This form must by TYPED – Handwritten copies not accepted

Project Title: Preterm Birth: A cause of Concern for High Infant Mortality Rates
Principal Investigator: Jennifer Thomas, RN Clinical Department: BRI West
Telephone Extension: 817-922-2560 FAX: 817-922-7360
Mailing Address: 1400 Eighth Avenue Forth Worth Texas 76104
Email Address: jenniha@baylorhealth.edu

Contact Person (if different from PI): Theresa Cheyne, RN Department: BRI West
Telephone Extension: 817-922-2579 FAX: 817-922-7360
Mailing Address: 1400 Eighth Avenue Fort Worth Texas 76104
Email Address: theresa.cheyne@baylorhealth.edu

THIS BOX FOR IRB USE ONLY	
DATE RECEIVED:	**IRB MEETING ASSIGNMENT:**
PRIMARY REVIEWER:	
PRIMARY REVIEWER:	

Instructions: All sections must be completed. All questions must be answered. It is NOT acceptable to answer *see attached* or *see protocol* – the one exception is that you may attach a copy of the schedule of events to the form to supplement the information provided in that section. This portion of the document is to summarize the protocol and provide supplemental information to the IRB to assist in conducting a thorough review. DO NOT DELETE ANY QUESTIONS ON THIS FORM OR ALTER ANY OF THE TEXT WITHIN THE QUESTIONS. If a question does not apply to your study – answer N/A.

	Sponsor of Study - Resources
1	**Funding Source: N/A**
	☐ Industry: Name of Sponsor: _____
	☐ NIH: Specific Institute: _____
	☐ National Science Foundation
	☐ Public (Federal, State or Local): _____
	☐ Baylor Department: _____
	☐ Baylor Foundation
	☐ Private Foundation: _____
2	**Are resources for conducting this research being provided from other sources?** ☐ Yes ☒ No **If yes, please specify what resources are being provided:** No funding **If yes, please specify the source:** _____
	Contracts for industry sponsored studies must be negotiated through the BRI Office of Sponsored Research. Grants must be submitted through BRI Office of Sponsored Research. Funding from the BHCS

	Foundation or from within the Baylor department also require the completion of specific forms. These must be submitted to the BRI Office of Sponsored Research.
	Purpose and Background
3	**OBJECTIVES OF THE STUDY:** Preterm births are growing cause of concern for high infant death. There are number of factors that increase the risk for preterm labor. Primary objective: To see if there is a difference in the knowledge between the first time mother and those who have had a baby before. Secondary objective: Is to design an educational program based on feedback obtained from the survey results.
4	**SUMMARIZE THE STUDY DESIGN:** This is a survey study. Subjects would be handed out a questionnaire sets which they will fill out and return to the researcher or the mid-wife.
5	**PROVIDE THE SCIENTIFIC RATIONALE:** National Vital Statistics for 2007 showed infant death due to preterm birth or related cause to be 12.7% that means an increase of about 30% as compared to 1980s statistics. Even than the etiology of why women experience preterm labor is not known. Many factors have been identified that may increase the risk of preterm birth/labor. These factors can be grouped into five major categories: 1. Due to lifestyle followed like Excessive alcohol, caffeine consumption, drug addiction, smoking 2. Due to socio-demographic issues such as Low education, status, poor sanitation, nutrition, gender discrimination, physical mental stress, genetic factors 3. Due to certain medical condition like diabetes, hypertension, urinary vaginal infection, heavy bleeding requiring C-sections 4. Due to medical complications like birth defects in baby, bleeding from vagina, women with a prior preterm baby, not enough spacing between the two pregnancy(multiple pregnancy) 5. Due to other factors like uterine, cervical abnormalities or Stretching or distension seen when pregnant with twins, triplets, singleton fetus after in-vitro fertilization. Studies have shown that the babies born prematurely are at an increase risk for developing long lasting birth defects and those born very prematurely have a lower chances of survival. Due to the development in technology and medicine early intervention and treatment can help in delaying the birth of the child. But lack of awareness, seriousness, misconception among general public and pregnant women in particular is the root cause of the problem. Study aims at finding out the difference in the approach among the women who have had a baby before than the first time mother.
6	**HISTORICAL INFORMATION – ANIMAL STUDIES:** N/A
7	**HISTORICAL INFORMATION – HUMAN STUDIES:** Earlier survey studies carried out on pregnant women and general public showed lack of awareness, misconception and belief towards the preterm birth/labor. This might be one of the reasons for increasing infant death due to preterm or preterm realteed cause.
	This section applies only to studies involving drugs: ☒ Section N/A
8	**Phase of the trial:** ☐ I ☐ II ☐ III ☐ IV ☐ Other: _____
9	**Provide the following information for each drug used in this study (If additional drugs are used, please attach separate list and check here ☐ :**
A	**Drug name:** _____ **Is this drug approved by the FDA?** ☐ Yes ☐ No **If yes, is it being used in accordance with current approval?** ☐ Yes ☐ No **If the answer to either question is no, provide IND#:** _____ **IND number is indicated on which sponsor document (protocol, IB, Letter, etc.):** _____

	Where will drug be stored?*:_____
B	**Drug name: _____** **Is this drug approved by the FDA?** ☐Yes ☐ No **If yes, is it being used in accordance with current approval?** ☐Yes ☐ No **If the answer to either question is no, provide IND#: _____** **IND number is indicated on which sponsor document (protocol, IB, Letter, etc.): _____** **Where will drug be stored?*:_____**
C	**Drug name: _____** **Is this drug approved by the FDA?** ☐Yes ☐ No **If yes, is it being used in accordance with current approval?** ☐Yes ☐ No **If the answer to either question is no, provide IND#: _____** **IND number is indicated on which sponsor document (protocol, IB, Letter, etc.): _____** **Where will drug be stored?*:_____**
D	**Drug name: _____** **Is this drug approved by the FDA?** ☐Yes ☐ No **If yes, is it being used in accordance with current approval?** ☐Yes ☐ No **If the answer to either question is no, provide IND#: _____** **IND number is indicated on which sponsor document (protocol, IB, Letter, etc.): _____** **Where will drug be stored?*:_____**
	***For all drugs stored in your facility, you are responsible for following guidelines set forth in BRI Policy 118 regarding storage and control of investigational drugs in outpatient settings.**
	This section applies only to studies involving devices. ☒ Section N/A
10	**Provide the following information for each device being used in this study (If additional devices are used, please attach separate list and check here ☐ :**
A	**Device name: _____** **Is the device used in this study approved by the FDA?** ☐Yes ☐ No **If yes, is the device being used in accordance with current approval?** ☐Yes ☐ No **If the answer to either question is no, provide IDE #: _____ HCFA Category:** ☐ A ☐ B **FDA Letter indicating IDE # and HCFA Category must be provided.** **Where will device be stored?*: _____**
B	**Device name: _____** **Is the device used in this study approved by the FDA?** ☐Yes ☐ No **If yes, is the device being used in accordance with current approval?** ☐Yes ☐ No **If the answer to either question is no, provide IDE #: _____ HCFA Category:** ☐ A ☐ B **FDA Letter indicating IDE # and HCFA Category must be provided.** **Where will device be stored?*: _____**
C	**Device name: _____** **Is the device used in this study approved by the FDA?** ☐Yes ☐ No **If yes, is the device being used in accordance with current approval?:** ☐Yes ☐ No **If the answer to either question is no, provide IDE #: _____ HCFA Category:** ☐ A ☐ B **FDA Letter indicating IDE # and HCFA Category must be provided.** **Where will device be stored?*: _____**
D	**Device name: _____** **Is the device used in this study approved by the FDA?** ☐Yes ☐ No **If yes, is the device being used in accordance with current approval?** ☐Yes ☐ No **If the answer to either question is no, provide IDE #: _____ HCFA Category:** ☐ A ☐ B **FDA Letter indicating IDE # and HCFA Category must be provided.** **Where will device be stored?*: _____**

	***You are responsible for control of investigational devices in accordance with BRI Policy 113 Investigational Device and Radiologic Accountability.**
	Study Subjects
11	**Age Range: 13 years and older**
12	**Number of subjects: Locally:** 300-350 **Nationally/Internationally (multi-center trials):** N/A
13	**Gender:** ☐ Male ☒ Female ☐ Both
	Special Populations
14	☒ **Children (age<18)** – Complete IRB Form 23 Authorization to Enroll Children. Are any (or all) of the potential subjects in this study considered to be Wards of the State? ☐Yes ☐ No. If you answer yes to this question, special provisions must be made to comply with 45 CFR 46.409. Please contact the IRB Office Directly for further guidance.
15	☐ **Neonates** – please check all that apply (See BRI Policy 856 for definitions) ☐ **Viable Neonates** – Complete IRB Form 23 Authorization to Enroll Children ☐ **Non-Viable Neonates** – Contact the IRB Office for Special Instructions ☐ **Neonates of Uncertain Viability** – Contact the IRB Office for Special Instructions
16	☒ **Pregnant women** - Complete IRB Form 24 Authorization to Enroll Pregnant Women Are any (or all) of these pregnant woman under the age of 18? ☒Yes ☐ No. If so, complete IRB Form 23 Authorization to Enroll Children.
17	☐ **Prisoners or parolees – NOT ALLOWED - If you have a research subject who becomes a prisoner while on the research study, they must be removed from the study, except for follow up activities to assure safety. Please contact the IRB Office immediately if this occurs during the study for guidance.**
18	☐ **Spanish speaking subjects – please specify which document you will use** ☐ Spanish translation of the entire consent document ☐ Spanish version of the short form document –bilingual witness required With either of these documents you must also have a translator available who will facilitate the translation process. This translator can NOT be a family member/friend of the research subject. It can be a member of the research team, physician practice group, certified translator from the hospital guest services department or other comparable individual. Translator: _____ ☐ **Other non-English speaking subjects – please specify which document you will use** ☐ Translation of the entire consent document ☐ Translated version of the short form document –bilingual witness required Specify language(s): _____ With either of these documents you must also have a translator available who will facilitate the translation process. This translator can NOT be a family member/friend of the research subject. It can be a member of the research team, physician practice group, certified translator from the hospital guest services department or other comparable individual. Translator: _____
19	☐ **Terminally Ill** **Protocol specific rationale for enrolling these subjects:** _____ **Special provisions to protect these subjects:** _____
20	☐ **Elderly (>64)** **Protocol specific rationale for enrolling these subjects:** _____ **Special provisions to protect these subjects:** _____
21	☐ **Cognitively Impaired (mentally challenged, alzheimers, etc)** (See BRI Policy 857 for guidance) **Protocol specific rationale for enrolling these subjects:** _____ **Special provisions to protect these subjects:** _____

	How will you assess the capacity of these individuals to provide informed consent: _____ **Special Consent Requirements:** ☐ Informed consent will be obtained from legally authorized representative (See BRI Policy 857 for individuals who qualify under Texas Law) ☐ Assent of the subject will be obtained. Provide specific information on method and timing: _____
22	☐ **Medically Unable to Consent (comatose, head trauma, etc)** (See BRI Policy 857 for guidance) **Protocol specific rationale for enrolling these subjects:** _____ **Special provisions to protect these subjects:** _____ **Special Consent Requirements:** ☐ Informed consent will be obtained from legally authorized representative (See BRI Policy 857 for individuals who qualify under Texas Law) ☐ Informed consent will be obtained from the subject as soon as they are physically able to provide such and they will be informed that they can withdraw from the study if they so choose. Provide specific information on method and timing: _____
23	☐ **Employees (BHCS)** **Protocol specific rationale for enrolling these subjects:** _____ **Special provisions to protect these subjects:** _____
24	☐ **Students (this only applies to students from institutions working with BHCS)** **Protocol specific rationale for enrolling these subjects:** _____ **Special provisions to protect these subjects:** _____
25	☒ **Educationally/Economically Disadvantaged** **Protocol specific rationale for enrolling these subjects:** Studies suggest that subjects are not aware about preterm birth/labor this may be due to lack of awareness, education. These subjects will be included in the study since they will help us to know if better education prepare women for pregnancy. **Special provisions to protect these subjects:** _____
26	☐ **Other (be specific):** _____ **Protocol specific rationale for enrolling these subjects:** _____ **Special provisions to protect these subjects:** _____
	Inclusion/Exclusion Criteria
27	**Inclusion Criteria:** who are pregnant and at1-24 weeks of gestation will be approached ➢ Age 13 years or older ➢ First time mother or mothers who have had a full term or preterm baby before ➢ Has not been counseled about preterm birth
28	**Exclusion Criteria:** ➢ Women who cannot read English
29	**Protocol specific rationale for the exclusion of any group of individuals for whom this treatment could potentially benefit (i.e., women, children, non-English speaking):** N/A
	Recruitment of Subjects
30	**Subjects will be recruited from the following sources (check all that apply):** ☐ my private practice ☐ physician referral sources ☐ posters/flyers within the local community ☐ copies of these items are available and are included with this submission ☐ copies of these items are NOT available and will be submitted prior to use ☐ advertise with the local media (newspaper, radio, television) ☐ copies of these items are available & are included with this submission ☐ copies of these items are NOT available & will be submitted prior to use ☐ listing on Baylor internet site

	☐ listing on www.clinicaltrials.gov ☒ other (be specific): patients from Andrews Mid-wife clinic will be recruited for the study.
31	**Describe methods that will be used to identify potential subjects, obtain and record subject PHI (i.e. BCON search, medical records query, database query, etc). This section should specifically state what records will be searched, who will conduct the search, what (if any) data will be recorded for future contact with subjects, what relationship the individuals who review the data have with the potential subject: N/A**
32	**Recruitment incentive offered: N/A** ☐ Cash or Visa/American Express Gift Card How much?$ _____(total for entire study) How frequently will payments be made? _____(Payments must be made to the subject at least every six months and bonus payments cannot be given for completion of the study.) ☐ Store or Other type of Gift Card: _____(location) How much?$ _____(total for entire study) How frequently will payments be made? _____(Payments must be made to the subject at least every six months and bonus payments cannot be given for completion of the study.) ☐ Other (be specific): _____
	Study Procedures
33	**Procedures involved in the study – Be sure to include at least the following information: study schedule; study procedures; number of visits; duration of participation. Procedures, tests or activities that are not considered standard of care and are being done for research purposes only should be differentiated from any procedures, tests or activities that are already being performed for diagnostic or treatment purposes.** Those consenting to the study will have to fill out the questionnaire. 1. Each questionnaire sheets will be assigned a specific number such as PB001, PB002, etc and handed out to the study subjects at Texas Health Care 2. It will take approximately 10 minutes to fill out the questionnaire 3. Subjects will fill out the questionnaire and return to the staff or to the researcher
	Potential Risks to Research Subjects
34	**Physical Risks:** There are no known physical risks to the subject
35	**Psychological Risks:** Study hold no known psychological risk
36	**Social Risks:** None identified
37	**Legal Risks:** Patients do not waive any legal rights by taking part in the study.
38	**Economic Risks:** None identified
39	**RADIATION SAFETY ISSUES: If this study involves the use of any the following procedures for either diagnostic or therapeutic purposes, provide the following information:** ☒ Section N/A
A	**Simple Diagnostic x-ray:** ☐Yes ☐ No **Specify type** (i.e. chest, abdominal, extremity)**:** _____
	If yes, is it for Standard of Care* ☐ **or Research **** ☐ (see definitions below)
	How many procedures will be done:_____ **What is the estimated dose per procedure:** _____
	Where (facility) will the above procedures be performed? _____
B	**CT Scanning:** ☐Yes ☐ No **If yes, what part of body:** _____
	If yes, is it for Standard of Care* ☐ **or Research **** ☐ (see definitions below)
	How many procedures will be done:_____ **What is the estimated dose per procedure:** _____
	Where (facility) will the above procedures be performed? _____

	☐ listing on www.clinicaltrials.gov ☒ other (be specific): patients from Andrews Mid-wife clinic will be recruited for the study.
31	**Describe methods that will be used to identify potential subjects, obtain and record subject PHI (i.e. BCON search, medical records query, database query, etc). This section should specifically state what records will be searched, who will conduct the search, what (if any) data will be recorded for future contact with subjects, what relationship the individuals who review the data have with the potential subject: N/A**
32	**Recruitment incentive offered: N/A** ☐ Cash or Visa/American Express Gift Card How much?$ _____(total for entire study) How frequently will payments be made? _____(Payments must be made to the subject at least every six months and bonus payments cannot be given for completion of the study.) ☐ Store or Other type of Gift Card: _____(location) How much?$ _____(total for entire study) How frequently will payments be made? _____(Payments must be made to the subject at least every six months and bonus payments cannot be given for completion of the study.) ☐ Other (be specific): _____
	Study Procedures
33	**Procedures involved in the study – Be sure to include at least the following information: study schedule; study procedures; number of visits; duration of participation. Procedures, tests or activities that are not considered standard of care and are being done for research purposes only should be differentiated from any procedures, tests or activities that are already being performed for diagnostic or treatment purposes.** Those consenting to the study will have to fill out the questionnaire. 1. Each questionnaire sheets will be assigned a specific number such as PB001, PB002, etc and handed out to the study subjects at Texas Health Care 2. It will take approximately 10 minutes to fill out the questionnaire 3. Subjects will fill out the questionnaire and return to the staff or to the researcher
	Potential Risks to Research Subjects
34	**Physical Risks:** There are no known physical risks to the subject
35	**Psychological Risks:** Study hold no known psychological risk
36	**Social Risks:** None identified
37	**Legal Risks:** Patients do not waive any legal rights by taking part in the study.
38	**Economic Risks:** None identified
39	**RADIATION SAFETY ISSUES: If this study involves the use of any the following procedures for either diagnostic or therapeutic purposes, provide the following information:** ☒ Section N/A
A	**Simple Diagnostic x-ray:** ☐Yes ☐ No **Specify type** (i.e. chest, abdominal, extremity)**:** _____
	If yes, is it for Standard of Care* ☐ **or Research **** ☐ (see definitions below)
	How many procedures will be done:_____ **What is the estimated dose per procedure:** _____
	Where (facility) will the above procedures be performed? _____
B	**CT Scanning:** ☐Yes ☐ No **If yes, what part of body:** _____
	If yes, is it for Standard of Care* ☐ **or Research **** ☐ (see definitions below)
	How many procedures will be done:_____ **What is the estimated dose per procedure:** _____
	Where (facility) will the above procedures be performed? _____

C	**Fluoroscopy:** ☐Yes ☐ No **If yes, what part of body:** _____ **minutes of fluoroscopy per procedure** _____ **minutes of digital cine pre procedure** _____
	If yes, is it for Standard of Care* ☐ **or Research **** ☐ (see definitions below)
	How many procedures will be done:_____ **What is the estimated dose per procedure:** _____
	Where (facility) will the above procedures be performed? _____
D	**Radionuclide Studies:** ☐Yes ☐ No **Specify type** (liver scan, bone scan, HIDA scan, PET, etc): _____
	If yes, is it for Standard of Care* ☐ **or Research **** ☐ (see definitions below)
	How many procedures will be done:_____ **What is the estimated dose per procedure:** _____
	Where (facility) will the above procedures be performed? _____
F	**Therapeutic Radiation (external beam or other):** ☐Yes ☐ No **If yes, what part of body:** _____
	If yes, is it for Standard of Care* ☐ **or Research **** ☐ (see definitions below)
	How many procedures will be done:_____ **What is the estimated dose per procedure:** _____
	Where (facility) will the above procedures be performed? _____
G	**Other administration or use of Radioactive Substances:** ☐Yes ☐ No
	If yes, is it for Standard of Care* ☐ **or Research **** ☐ (see definitions below)
	How many procedures will be done:_____ **What is the estimated dose per procedure:** _____
	Where (facility) will the above procedures be performed? _____
H	**Will women of child-bearing potential be exposed to radiation (including any diagnostic or therapeutic radiology or nuclear medicine procedure) as part of this study?** **Yes** ☐ **No** ☐
	If YES, then pregnancy status might need to be evaluated prior to each radiation procedure. Please indicate what provisions for pregnancy status are proposed for your study. This should include (but is not limited to) such information as when study required pregnancy tests are done and what type of birth control is required per protocol. _____
	*Standard of Care: Use of radiation or radioactive substances that would be part of the routine care or follow-up of patients with disease as part of current standard of care (examples: radiation therapy for certain tumors, follow-up CT scans after chemotherapy, spiral CT scan of chest in patients with suspected pulmonary embolism). If the number or frequency of such procedures is greater than, or the manner in which such procedures are performed is different from, the same procedures that would be performed in these patients if they were not part of this research, then this does not qualify as Standard of Care.
	**Research: Use of radiation or radioactive substances in normal individuals or in patients that would not routinely be indicated or done as part of current standard of care (examples: fluoroscopy to place tube in small bowel in normal subjects for research study, additional heart catheterization to assess patency of coronary artery stent in asymptomatic patients, MUGA scans to evaluate cardiac function after novel chemotherapy, novel use of implanted radioactive seeds to treat tumor). This also includes standard of care procedures that would not be performed on these patients unless they were in this research or standard procedures that are done more often for research purposes.
	Provisions to Minimize Risks
40	**Based on your knowledge of the subject matter, do you believe that this study involves the alternative of least risk for the potential subjects to be enrolled in the study?** ☒Yes ☐ No **If no, provide justification for conducting the study:** _____
41	**Have evaluations of less risky alternatives been done?** ☐Yes ☒ No **If yes, summarize:** _____
42	**What provisions are in place for monitoring study related data to assure the protection of the rights, welfare and safety of the research subjects. This would include (but is not limited to) such**

	information as protocol compliance, adverse events, serious adverse events, complaints by subjects, and other risks to subjects? If your study involves greater than minimal risk, at least one of these options must be chosen. Check all that apply: N/A ☐ Data Safety Monitoring Board (DSMB), Data Monitoring Committee or other committee _____ provided by sponsor. Process to provide reports to the PI and IRB: _____ ☐ Medical Monitor, Data Monitor or other monitor _____ provided by sponsor. Process to provide reports to the PI and IRB: _____ ☐ Review of AE's, problems and other data by investigator on a regular basis. Frequency of review: _____ ☐ Review of AE's, problems and other data by another researcher or physician on a regular basis. Identify who will review the information: _____ and frequency of review:_____ ☐ Other (provide details):
43	**If the study has the potential for research related injuries or problems (physical or psychological) – please describe any procedures that are in place to provide medical/psychological care to the subjects if these problems occur. This explanation should not simply address who will pay for the care, but should address how the care will be provided:** N/A
	Potential Benefits
44	**Potential direct benefits to research subjects:** No direct benefit to the study subject
	Potential future benefits to individuals with the condition being studied: By the end of this study we will be able to design a educational program based on the survey results. This will help in creating an awareness among the women about preterm and thus help in reducing preterm births.
	Potential benefits to society in general: It will help in designing a new study program that will help educate the women about preterm birth/ labor.
	Potential benefits to others involved in the research: None identified
	Risk to Benefit Analysis
45	**Protocol specific information justifying the risks of the study in relation to the anticipated benefits and importance of the knowledge that may reasonably be expected to result from the study:** It is a survey study with no risk identified to the subject
	Privacy and Confidentiality
46	**Provisions in place to protect confidentiality of research related information:** Neither name nor personal history will be collected from the study subject
47	**Provisions in place to protect the privacy of the research subjects:** Standard Good Clinical Practice and Baylor confidentiality policies, all computers password protected and records stored in locked file cabinets in low traffic areas.
48	**Provisions in place to protect the PHI collected during the study:** Neither name nor personal information will be collected from the study subject.
	Key Personnel
	The Principal Investigator must be current on the IRB education modules on the Baylor Learning Network before this project will be put on the IRB agenda. All other members of the research team must be current on the lessons before the final approval will be granted. Provide name and credentials/qualifications (MD, PhD, CCRC, RN, etc.) of all members of the study team. If a CV/Resume is not on file with the IRB Office for an individual, one must be provided.
49	**Principal Investigator:** Jennifer Thomas
50	**Other Investigators*:** Amruta Oak
51	**Research Coordinators*:**
52	**Other Research Staff*:**

53	**Support Staff (no interaction with research subjects) *:** N/A
54	**Collaborators with outside institution(s):** N/A **Will any of these individuals interact with BHCS subjects or have access to their BHCS PHI?** ☐ Yes ☐ No
	***Please attach contact information for all individuals listed in 49 -52. This should include business address, phone number and email.**
	Location of Research Activities
55	☐ **Baylor Facility** a. Location: _____Bldg: _____ Room: _____ Specific research activities to take place at this location: _____ b. Location: _____Bldg: _____ Room: _____ Specific research activities to take place at this location: _____ c. Location: _____Bldg: _____ Room: _____ Specific research activities to take place at this location: _____ d. Location: _____Bldg: _____ Room: _____ Specific research activities to take place at this location: _____ e. Location: _____Bldg: _____ Room: _____ Specific research activities to take place at this location: _____ ☒ **Non-Baylor Facility** a. Address: 1650 W Magnolia Suites 204 and 212 Fort Worth, TX 76104 Specific research activities to take place at this facility: subject will complete survey b. Address: _____ Specific research activities to take place at this facility: _____ c. Address: _____ Specific research activities to take place at this facility: _____
	If additional locations, please attach separate list and check here ☐
	Informed Consent Process
56	**Location of obtaining informed consent.** *Provide a specific location, such as clinic office, surgical suite, and/or patient's hospital room. If more than one location is possible, please list a summary of the types of places that you would expect to obtain the informed consent*: Subjects will be handed out the informed consent letter prior to providing questionnaire.
57	**Timing of obtaining informed consent.** *Include specifics and such details as when in relation to the beginning of the study procedures you will obtain informed consent, and the amount of time the subject has to make the decision. It is important that you allow the subject sufficient time to make an informed decision prior to beginning the study and that they have the opportunity to discuss this with family or other significant individuals in their lives. If the nature of the study requires that consent be obtained immediately prior to the beginning of the research, give the rationale*: Subjects will be given sufficient time to read and decide whether to participate in the study or not. Any questions regarding the study will be addressed by the researcher or by the research staff before handing out questionaire to them.
58	**Individuals designated to obtain informed consent (all must be listed as key personnel):** Amruta Oak, Theresa Cheyne, RN
59	**Consent as an ongoing process:** N/A
60	**Describe steps taken to minimize the possibility of coercion or undue influence. :** Subjects have an option not to fill in the survey and return to the researcher or the mid-wife and will not be a part of the study.
61	**If additional tools, handouts, other written materials are used (other than the IRB approved consent forms) these must be listed here and provided to the IRB for review and approval prior to their use. If you will use these materials, please list here:** None Identified

62	**Where will the medications be administered? (Check all that apply)** ☐ BUMC ☐BIR ☐Baylor Irving ☐Baylor All Saints Fort Worth ☐BSH ☐Baylor All Saints City view ☐Baylor Garland ☐OCH ☐Baylor Waxahachie ☐Baylor-Plano ☐ BHVH ☐Baylor Grapevine ☐Baylor Irving Coppell ☐Clinic ☐Outpatient ☐Physician's Office ☐Other: _____
63	**The sponsor will supply all medications for this study.** ☐Yes ☐No
64	**Some or all medications for this study will need to be purchased by the hospital pharmacy.** ☐Yes ☐No **If yes, which medications will need to be purchased: ____**
65	**If inpatient, all medications will be dispensed from hospital stock. The patient or the insurance company will be billed for the product.** ☐Yes ☐No
	Supplemental Review – Other Committees
66	**Radiation Safety Committee: Radiation Safety Committee:** If you answered yes to any of the questions outlined in #38, you must obtain approval from the Committee on Radiation Safety and Radioisotopes (CRSR). Please contact CRSR at 214-820-7133 for specifics on submission process. All protocols involving the following types of radiation exposure must be approved by the CRSR at a full Committee meeting: 1. use of novel (non-FDA approved) radioactive materials, devices, or therapies; 2. novel uses of approved radioactive materials; any type of radiation that exceeds 50 rem to any organ or body part and is delivered in a manner, dose, or frequency that is beyond that which would be employed in standard clinical practice if the patient were not on the protocol. The CRSR committee meets quarterly. Protocols involving radiation exposure that meets "Standard of Care" criteria and/or involves lower radiation doses MAY be approved at more frequent intervals by appropriate subcommittees of the CRSR.
67	**Institutional BioSafety Committee:** Does this study involve the use of recombinant DNA? ☐YES ☒NO Does this study involve the use of Select Agents*? ☐YES ☒NO Does this study involve the use of Select Agent Toxins*? ☐YES ☒NO
	If you answered "YES" to any of the questions above, your study must be submitted to the Institutional Biosafety Committee (IBC) for review. Send a copy of the protocol and IRB Application to: Steven J. Phillips, Ph.D., BRI Biosafety Officer, Baylor Research Institute 214-820-9993 (Phone) 214-820-4952 (Fax) steveph@baylorhealth.edu
	**A list of Select Agents and Select Agent Toxins can be viewed at the website of the Centers for Disease Control: www.cdc.gov/od/ohs/biosfty/bsat.pdf*
68	**Tissue Bank Committee:** Does this study involve the use and/or collection of human tissue, either in the form of glass slides or fresh/fresh-frozen tissue? ☐YES ☒NO If yes, further review may be required by the BRI Tissue Bank Utilization Committee. To facilitate this process, please complete the BHCS Tissue Bank/Fresh Tissue Procurement Application (ADM012) and submit to: BHCS Tissue Bank, Hoblitzelle Bldg., Suite 326
69	**Nursing Research Committee:** Does this project study nursing in the area of practice, professional issues, education, or management? ☐Yes ☒No If yes, this must be submitted to the Nursing Research Committee at: John Dixon, MSN, RN, The Center for Nursing Education & Research, Baylor University Medical Center

70	**Credentials Committee** Do all members of the research team hold appropriate medical staff and/or allied health professional credentials required to perform any standard procedures that are being done as a part of this study? ☒Yes ☐No If no, please explain: ____

INVESTIGATOR COMMITMENT:

I understand that as Principal Investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to the IRB approved protocol and any additional stipulations imposed by the IRB. I assure the IRB that I have sufficient time to conduct and complete the research in accordance with IRB guidelines. I agree to comply with all Baylor Research Institute IRB policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human subjects in research. I certify that no similar proposal has been disapproved by another IRB. I agree to maintain strict confidence of information that may be disclosed including subject/patient, data, employee, institution proprietary, industry trade secrets, and any other form of confidential information.

I agree to report immediately to the IRB any non-compliance, unanticipated problems involving risks to subjects or others, complications or adverse incidents with respect to human subjects.

I agree to perform the project with qualified personnel according to the approved protocol. I agree that I am to implement no changes in the approved protocol or consent form without prior IRB approval (except in an emergency, if necessary to safeguard the well-being of human subjects). I agree to obtain the legally effective informed consent from human subjects or their legally responsible representative, and use only the currently approved, date-stamped consent form. I agree to evaluate on an individual subject basis, whether or not an individual subject understands the information presented during the informed consent process. I agree that informed consent is an ongoing process and it is my responsibility to determine over a period of time that all research subjects continue to be willing to participate.

I understand that I have the responsibility to make the Department Administrator aware of all protocols that are submitted to the IRB.

The Institutional Review Board of the Baylor Research Institute will suspend approval of all research projects of investigators who are non-compliant with the above requirements. The Chief-of-Service will be notified of the suspension as will the Chairman of the Medical Board and other Institutional Officials. Non-compliance of IRB requirements could result in Institutional Officials reporting these actions to the Office of Human Research Protections, the US Food and Drug Administration, the Study Sponsor or other agencies.

Investigator Signature _____ Date _____

STATEMENT OF BAYLOR ADMINISTRATOR:

I have reviewed the proposal to be submitted to Baylor Research Institute and understand that by signing below I have committed the resources needed by my department to conduct this study. It is my responsibility to assure that budget issues related to this study are resolved. If this study involves the resources of another Baylor department, I have contacted that department administrator for input regarding their department. If applicable, I will ask the investigator to obtain a second signature for said department administrator.

Jennifer Thomas _____ 8/24/09

Baylor Administrator Date

(If the study is funded solely by a Baylor department, must be signed by VP)

Name and Title of Baylor Administrator: _____

Baylor Research Institute
Office of Research Subject Protection

Research Personnel Financial Disclosure Statement – Form 14

IRB/IACUC #: 009-205 Date: 08/24/09

Project Title: Preterm Birth: A Cause of Concern for High Infant Mortality Rates

Name: Jennifer Thomas Department: BRI West

Address: 1400 Eighth Avenue Fort Worth Texas 76104 Phone: 817-922-2560
E-Mail: jenniha@baylorhealth.edu
Sponsor: N/A

Significant Financial Interest includes the following:

- anything of monetary value of $10,000 or more, including but not limited to, salary or other payment for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights)
- ownership interest less than $10,000 whose value could not be referenced to publicly available prices or other measures of fair market value
- ownership interests of any value that could be affected by the outcome of the research
- ownership interests greater than 5% interest in any single entity
- compensation related to the research in any amount that would be affected by the outcome of the research
- board or executive relationship related to the research, regardless of compensation

Family member means a spouse or dependent child or stepchild.

List below any relationships in which you or your family members are involved that constitute a significant financial interest as defined above, with any institution sponsoring this research project.

Institution/Company	Relationship/Role (explain)	Amount of Financial Interest
		☐ $10,000 - $25,000 ☐ $25,001 - $50,000 ☐ $50,001 - $100,000 ☐ >$100,000 _____ (record amount)
		☐ $10,000 - $25,000 ☐ $25,001 - $50,000 ☐ $50,001 - $100,000 ☐ >$100,000 _____ (record amount)
		☐ $10,000 - $25,000 ☐ $25,001 - $50,000 ☐ $50,001 - $100,000 ☐ >$100,000-_____ (record amount)

If you have nothing to disclose, please confirm such by checking the below statement and sign at the bottom of the form.

☒ I hereby certify that none of the financial interest or arrangements listed above exists for myself, my spouse, or my dependent children.

Signature Acknowledgement

I have read the Financial Conflict of Interest requirements as outlined in 42 CFR 50, Subpart F. I hereby agree to report immediately in writing to the BRI Vice-President any new situation with the potential for a conflict of interest that may develop before the completion of my next Statement of Disclosure.

The answers above are true and accurate to the best of my knowledge as of the date of this disclosure.

Signature: Jennifer Thomas Date: 8/24/09

Baylor Research Institute
Office of Research Subject Protection

Research Personnel Financial Disclosure Statement – Form 14

IRB/IACUC #: 009- 205 Date: 08/24/09

Project Title: Preterm Birth: A Cause of Concern For High Infant Mortality Rates

Name: Amruta Oak Department: BRI West

Address: 1400 Eighth Avenue Fort Worth Texas 76104 Phone: 817-922-7159
E-Mail: amruta.oak@baylorhealth.edu

Sponsor: N/A

Significant Financial Interest includes the following:

- anything of monetary value of $10,000 or more, including but not limited to, salary or other payment for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights)
- ownership interest less than $10,000 whose value could not be referenced to publicly available prices or other measures of fair market value
- ownership interests of any value that could be affected by the outcome of the research
- ownership interests greater than 5% interest in any single entity
- compensation related to the research in any amount that would be affected by the outcome of the research
- board or executive relationship related to the research, regardless of compensation

Family member means a spouse or dependent child or stepchild.

List below any relationships in which you or your family members are involved that constitute a significant financial interest as defined above, with any institution sponsoring this research project.

Institution/Company	Relationship/Role (explain)	Amount of Financial Interest
		☐ $10,000 - $25,000 ☐ $25,001 - $50,000 ☐ $50,001 - $100,000 ☐ >$100,000 ____ (record amount)
		☐ $10,000 - $25,000 ☐ $25,001 - $50,000 ☐ $50,001 - $100,000 ☐ >$100,000 ____ (record amount)
		☐ $10,000 - $25,000 ☐ $25,001 - $50,000 ☐ $50,001 - $100,000 ☐ >$100,000-____ (record amount)

If you have nothing to disclose, please confirm such by checking the below statement and sign at the bottom of the form.

☒ I hereby certify that none of the financial interest or arrangements listed above exists for myself, my spouse, or my dependent children.

Signature Acknowledgement

I have read the Financial Conflict of Interest requirements as outlined in 42 CFR 50, Subpart F. I hereby agree to report immediately in writing to the BRI Vice-President any new situation with the potential for a conflict of interest that may develop before the completion of my next Statement of Disclosure.

The answers above are true and accurate to the best of my knowledge as of the date of this disclosure.

Signature: A. Gr. Oak Date: 08/17/09

BAYLOR RESEARCH INSTITUTE
INSTITUTIONAL REVIEW BOARD
Review of Scientific and Scholarly Validity – IRB Form 18
This form must by TYPED – Handwritten copies not accepted

IRB Project # 009-205 (for BRI use) Date Submitted: 08/24/09

Project Title: Preterm Birth: A Cause of Concern For High Infant Mortality Rates

Principal Investigator: Jennifer Thomas, RN Department: BRI West
Telephone Extension: 817-922-2560 FAX: 817-922-7360
Mailing Address: 1400 Eighth Avenue Fort Worth Texas 76104
E-Mail Address: jenniha@baylorhealth.edu

Contact Person (if different from PI): Amruta Oak Department: BRI West
Telephone Extension: 817-922-7159
E-Mail Address: amruta.oak@baylorhealth.edu

Funding Source: Industry ☐ BHCS Foundation ☐ Private Foundation ☐
NIH ☐ Public (Federal, State, Local) ☐ Baylor Department/None ☒

- Contracts for Industry Sponsored trials must be negotiated through the BRI Office of Sponsored Research.
- BHCS Foundation funding requires completion of BRI Foundation Form and Baylor Department funded or sponsored non-funded studies require completion of BHCS Departmental Research Support Form. Both of these forms must be submitted to the BRI Office of Sponsored Research.

Name of Sponsor: N/A

Please check ALL of the following that apply:

☒ Project has received scientific evaluation from an independent source:
- ☐ FDA
- ☐ NIH
- ☐ Sponsor/Manufacturer ____
- ☒ Other Patricia Gwirtz PhD(Dept. Physiology) at University of North Texas Health Science Center.

☐ Project has received scientific evaluation from BHCS representative:
- ☐ Department Chair ____
- ☐ Department Committee ____

INVESTIGATOR COMMITMENT:
It is my opinion that the science involved in this project is ethically sound and that it meets with the mission of Baylor Health Care System.

Jennifer Thomas RN BSN CCRC — PI Signature
9.2.09 — Date

COMMITMENT OF CHIEF OF SERVICE/DESIGNEE:
I have reviewed this proposed research project and my signature below certifies that this project has scientific and scholarly validity. My signature also certifies that this project has undergone scientific and scholarly review to determine that it has scientific of scholarly validity. I also certify that conduct of this project is in compliance with the mission and goals of Baylor Health Care System and this service.

Chief of Service Signature (or designee) — Date 9/2/09

BAYLOR RESEARCH INSTITUTE
INSTITUTIONAL REVIEW BOARD
Authorization to Enroll Children in Research- Form 23
This form must by TYPED – Handwritten copies not accepted

IRB Project # 009-205 (for BRI use) Date Submitted: 08/24/09
Project Title: Preterm Birth: A Cause of Concern for high Infant Mortality Rates

Principal Investigator: Jennifer Thomas, RN Department: BRI West

Contact Person (if different from PI): Amruta Oak Department: BRI West

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Age Range of Child Subjects: 13 to 17. Be specific.

Protocol Specific Criteria for Including Children Enrollment of children in research requires that the research meet specific criteria. Please choose the category that best fits your proposed research project.

☒ Category 1 Research involving no greater than minimal risk **(i.e. drug or device studies do not fit this criteria).**
☐ Category 2 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. The risk is justified by the anticipated benefits to the subjects and the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.
☐ Category 3 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. The risk represents a minor increase over minimal risk; the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations and the intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for the understanding or amelioration of the subject's disorder or condition.
☐ Category 4 Research not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (requires special approval from the federal government.).

Provide protocol specific documentation that the study meets the criteria for the category chosen:
(i.e. if you chose category 1 above, explain why this protocol involves no greater than minimal risk)
The study subject will be asked to complete a questionnaire for the research project. General questions pertaining to what the subject knows or have heard about preterm birth will be asked. Neither identifying information nor health history will be collected from the subject.

Provisions for obtaining parental permission.. Regardless of the regulatory requirements, it is always preferred to obtain consent from both parents if available. The IRB expects that reasonable attempts will be made to include both parents in the decision making process, even in those cases where it is not required by the regulations or the IRB.

Please check all that apply.

☐ Permission will be obtained from both parents (preferred for all categories and required if research is Category 3 or 4).
☐ Permission will be obtained from one parent only (allowed only for category 1 or 2).

Provisions for obtaining assent of the child subject. In almost all situations, the IRB expects that assent will be obtained from all children over the age of six. There are certain specific situations where the regulations will

allow some children to be included in research without their consent. These are outlined in BRI Policy 855. If you believe that your study meets these criteria, please contact the IRB Office for additional guidance for requesting approval to not obtain consent in these situations.

Please check all that apply

☐ Assent will be obtained from all child subjects over the age of six. This will be done by:
- ☐ Separate Assent Form as attached (required for all children ages 7-11).
- ☐ Signature of Child on Parental Consent form (may be allowed for ages 12-17).

Provide a detailed plan regarding your process for obtaining parental permission and assent of the child. This would include any special circumstances surrounding this process that are in place to protect the child subject.

Inclusion of Pregnant Women under the age of 18. While Texas law does provide emancipation for women under the age of 18 who are pregnant, this emancipation does not extend to their participation in a research project. In addition to assent from the pregnant teen, parental permission is required unless specifically waived by the IRB. If you desire to enroll pregnant teens (under age 18) without obtaining parental permission, you must also submit a request for waiver of consent.

I certify that the information in this application is complete and correct.

I understand that as Principal Investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the IRB.

Jennifer Thomas RN CCRC — Investigator Signature

9.1.09 — Date

BAYLOR RESEARCH INSTITUTE
INSTITUTIONAL REVIEW BOARD
Authorization to Enroll Children in Research- Form 23

DO NOT WRITE BELOW THIS LINE – FOR IRB USE ONLY

This submission has received administrative review.

Elizabeth Cothran, MS, CIP Director, ORSP (or designee) — Date 9/16/09

☑ The proposed project has been reviewed and meets the requirements set forth in the above referenced category of Subpart D of 45 CFR 46.

☐ The provisions for obtaining assent of the child and parental permission as outlined above have been reviewed and determined to be appropriate and comply with requirements of Subpart D of 45 CFR 46. The following determinations have been made:

CHOOSE ONLY ONE:
☐ Permission from both parents is required unless one parent is deceased, unknown, incompentent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. OR
☑ Permission of one parent is sufficient even if the other parent is alive, known, competent, reasonably available, and shared legal responsibility for the care and custody of the child and protocol specific criteria for this determination has been outlined in the IRB minutes.

CHOOSE ONLY ONE:
☐ Parental permission is required for all pregnant girls less than 18 years of age (if applicable). OR
☑ Parental permission is waived for all pregnant girls less than 18 years of age (if applicable) and protocol specific criteria for the waiver is included in the IRB minutes.

CHOOSE ONLY ONE:
☑ Assent is required of all children over the age of six. OR
☐ Assent is not required of all children over the age of six. Protocol specific criteria for not requiring assent is documented in the IRB Minutes and communicated to the PI via the IRB approval letter.

☑ This proposal was reviewed by expedited procedures; or
☐ This proposal was reviewed by the fully convened IRB/Privacy Board.

Lawrence R. Schiller, MD, IRB Chair (or designee) — Date 9/17/09

August, 2009
Lawrence Schiller, MD
Chair, Institutional Review Board
Baylor Research Institute
Office of Research Subject Protection
3310 Live Oak, Suite 501
Dallas, Texas 75204

RE: Waiver of Parental permission when enrolling pregnant minors
Protocol: Preterm Birth: A Cause of Concern for High infant Mortality Rates
Sponsor: N/A
Principal Investigator: Jennifer Thomas, RN

Dear Dr. Schiller:

I am applying for a waiver of parental permission for pregnant minor female age 13 to 17 for a survey study. The study involves a questionnaire that the subject will fill out. This questionnaire tests the subject's knowledge and understanding of preterm birth. The data obtained from this study will be used as a guide for preparing an effective awareness program for preterm birth and also will help us to know whether women who have had a previous pregnancy are more aware of preterm than the women who are pregnant for the first time. I feel that this study offers no more than minimal risk to the study subjects and so I am applying for a waiver of parental permission due to the fact that pregnant minors in the state of Texas are allowed to consent for themselves to any medical treatments regarding their pregnancy.

Sincerely,

Jennifer Thomas

BAYLOR RESEARCH INSTITUTE
INSTITUTIONAL REVIEW BOARD
Authorization to Enroll Pregnant Women in Research – Form 24
This form must by TYPED – Handwritten copies not accepted

IRB Project # 009- 205 (for IRB use only) Date Submitted: 08/24/09

Project Title: Preterm Birth: A Cause of Concern for High Infant Mortality Rates
Principal Investigator: Jennifer Thomas Department: BRI West

Contact Person (if different from PI): Amruta Oak Department: BRI West

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Enrolling pregnant women in research requires that the research meet specific criteria. Please provide protocol specific information explaining how your proposed research project meets ALL of the below listed criteria (from 45 CFR 46.204)

Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non pregnant women, have been conducted and data provided for assessing potential risks to pregnant women and fetus.

Explain: There has been a significant increase in the number of infant related deaths due to preterm or preterm related cause. Survey results from earlier studies on pregnant women and on the general public suggested a lack of seriousness, awareness, and some false misconception the study population had about preterm birth/ labor. This might be one of the reasons for an increase in number of preterm birth. Also these studies reported no significant adverse event on the fetus and the mother. The purpose of this study is to find whether women who had earlier pregnancy have heard or know about preterm birth/ labor and are better prepared than the first time mother.

The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.

Explain: The study involves no risk to the fetus. The main purpose of the study is to see if there is any difference in the knowledge about preterm birth/ labor between first time mother and those who had a baby before whether full term or preterm. Also this study will help in finding out or devising new awareness program based on the feedback that will be obtained at the end of the study.

Any risk is the least possible for achieving the objectives of the research;

Explain: To achieve the objectives of research general questionnaire have been designed which the subject needs to fill out and hand over to the mid-wife or to the researcher. The questionnaire test the views and general understanding about preterm birth/labor among the study population. Health history or any other personal information of the subject will be kept confidential. Since the subject has to fill in the questionnaire without disclosing the identity we believe that this study poses the least possible risk for achieving the objectives of the research.

Will inducements, monetary or otherwise, be offered to terminate a pregnancy? ☐Yes ☒No
If answer is yes, project not eligible for approval.

Will individuals engaged in the research have any part in any decisions as to the timing, method, or procedures used to terminate a pregnancy? ☐Yes ☒No
If answer is yes, project not eligible for approval.

Will individuals engaged in the research have any part in determining the viability of a neonate?

BAYLOR RESEARCH INSTITUTE
INSTITUTIONAL REVIEW BOARD
Authorization to Enroll Pregnant Women in Research – Form 24

If answer is yes, project not eligible for approval. ☐Yes ☒No

Will any of the individuals involved in the research be less than 18 years of age? ☒Yes ☐No
If answer is yes, complete IRB Form 23, Authorization to Enroll Children in Research.

Inclusion of Pregnant Women under the age of 18. While Texas law does provide emancipation for women under the age of 18 who are pregnant, this emancipation does not extend to her participation in a research project. Therefore, she is NOT eligible to consent for her own participation in a study. Inclusion of these subjects also requires completion of the IRB Form 23 Authorization to Enroll Children in Research.

Special Informed Consent Requirements

☒ I will obtain consent only from the pregnant woman because (check all that apply):
- ☐ Research holds out the prospect of direct benefit to the pregnant woman
- ☐ Research holds out the prospect of direct benefit to both the pregnant woman and the fetus
- ☐ Risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical or social/behavioral knowledge that cannot be obtained by any other means
- ☒ There is no anticipated risk to the fetus (survey study, etc.)

Provide Protocol specific information to support these answers: **This is a survey study only.**

☐ I will also obtain consent from the father (see definition of father in BRI policy) because the research holds out the prospect of direct benefit **solely** to the fetus.

☐ Informed Consent will provide information regarding the reasonably foreseeable impact of the research on the fetus.
Provide exact location of this information in the consent form:

I certify that the information in this application is complete and correct.

I understand that as Principal Investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, and the protection of the rights and welfare of human subjects, and strict adherence to federal regulations and any stipulations imposed by the IRB.

Jennifer Thomas RN CCRC — Investigator Signature
9.1.09 — Date

DO NOT WRITE BELOW THIS LINE - FOR IRB USE ONLY

This submission has received administrative review.

Director, ORSP (or designee)
9/16/09 — Date

BAYLOR RESEARCH INSTITUTE
INSTITUTIONAL REVIEW BOARD

Authorization to Enroll Pregnant Women in Research – Form 24

☑	The proposed project has been reviewed and meets the requirements set forth in the 45 CFR 46.204.
☐	The process of obtaining informed consent is compliant with requirements set forth in 45 CFR 46.204. ☑ Informed consent is only required of the pregnant woman. ☐ Informed consent is **also** required of the father (unless he is unable to consent due to unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest).
☑	This proposal was reviewed by expedited procedures
☐	This proposal was reviewed by the fully convened IRB Board

IRB Chair or IRB Vice Chair

Date 9/17/09

University of North Texas Health Science Center

Office for the Protection of Human Subjects (OPHS) / Institutional Review Board (IRB)

Request for Review of Expedited Category Research Project

IRB # _____ **(Staff Use Only)**

Research activities that (1) present **no more than minimal risk** to human subjects and (2) involve **only** procedures listed in one or more of the categories below in Section One may be reviewed by the IRB through the expedited review procedure. *Minimal risk means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

If you believe that your research falls into one of the following categories, please indicate which category or categories you believe is or are appropriate. The IRB Chairperson (or designee) will review your research to determine if expedited review is warranted and if approval can be granted. If you have any questions, you may contact the OPHS Office at 817-735-0409.

Title of Research Activity: Preterm Birth: A Cause of Concern for High Infant Mortality Rates

Name of Principal Investigator (Faculty Member): Dr. Patricia Gwirtz

Department/Program: Physiology

Categories Eligible for Expedited Review: (You can check more than one category, as needed.)

Category 1:	**Check if applicable:**	**Check if applicable:**	**Note:** Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is **NOT** eligible for expedited review.
☐ **Clinical studies of drugs and medical devices ONLY when condition (a) or (b) is met:** →	☐ (a) Research on drugs for which an investigational new drug application is not required.	☐ (b) Research on medical devices for which: (i) an investigational device exemption application is NOT required **OR** (ii) medical device is **cleared/ approved** for marketing and it is being used in accordance with its cleared/approved labeling.	
Category 2:	**Check applicable box:**	☐ (b) Other adults and children*, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. **Contact OPHS Staff for criteria**	**Indicate volume and frequency of blood draws.** _____ _____ _____
☐ **Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from:** →	☐ (a) Healthy, non-pregnant adults who weigh at least 110 pounds. **Contact OPHS Staff for criteria**		
Category 3:	**Check all that apply:**	☐ Amniotic fluid obtained at the time of membrane rupture prior to or during labor ☐ Supra- and subgingival dental plaque and calculus. [Collection is not more invasive than routine prophylactic teeth scaling and it is done according to accepted techniques] ☐ Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings	☐ Hair and nail clippings in a non-disfiguring manner ☐ Sputum collected after saline mist nebulization **If research does not include any of the given specimen collections, give a brief description:** _____ _____
☐ **Prospective collection of biological specimens for research purposes by noninvasive means.** →	☐ Placenta removed at delivery ☐ Deciduous teeth taken during exfoliation or routine patient care ☐ Permanent teeth if routine patient care indicates a need for extraction ☐ Excreta and external secretions (including sweat) ☐ Uncannulated saliva		
Category 4:	**Check all that apply:**	☐ Magnetic resonance imaging (MRI) ☐ Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing (appropriate to age, weight, and health of the individual) **If research procedures do not include any of the given procedures, please enclose a brief description:** _____ _____ _____	**NOTE:** *Studies intended to evaluate the safety and effectiveness of a medical device are **NOT** eligible for expedited review, including studies of cleared medical devices for new indications.* *To qualify for this subcategory, the study **CANNOT** involve general anesthesia, sedation or procedures with X-rays or microwaves (such as CT/CAT Scan, etc).*
☐ **Collection of data through noninvasive procedures routinely done in clinical practice. Where medical devices are employed, they must be cleared/approved for marketing.** →	☐ Physical sensors applied to the body surface or at a distance AND do not involve input of significant amounts of energy into the subject or an invasion of subject's privacy ☐ Weighing or testing sensory acuity ☐ Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography		

Category 5: ☐ **Research involving materials (data, documents, records, or specimens) that:** →	**Check if applicable:** ☐ (a) Have already been collected for some **other purpose**,	**Check if applicable:** ☐ (b) Will be collected for **non-research** purposes (such as medical treatment or diagnosis)	**Does the research protocol fit under this category and is condition (a) or (b) met?** ☐ Yes ☐ No
Category 6: ☐ **Collection of data from voice, video, digital, or image recordings made for research purposes** →	**Check all those applied for research study:** ☐ **Voice** ☐ **Video** ☐ **Digital** ☐ **Image**	**Will subjects be informed about the recordings?** ☐ Yes ☐ No	**Include in the protocol a detailed description of how, when and what extent subjects will be recorded. In addition, describe data storage and confidentiality of the recorded data.**
Category 7: ☑ **Research where condition (a) or (b) is applicable:** →	**Check if applicable:** ☐ (a) Individual or group characteristics or behavior (research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior)	**Check if applicable:** ☑ (b) Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.	**Does the research protocol fit under this category?** ☑ Yes ☐ No

Recall: 'Children' in (b) above is defined in the HHS regulations as "persons who have not attained the legal age for consent for treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted" [45 CFR 46.402(a)].In Texas, this is typically under 18 years old.

Does the study involve storage or banking of human specimens or identifiable private information for use in future studies?

Yes ☐ No ☑

Does the study involve genetic testing or DNA/RNA extraction? Yes ☐ No ☑

If any of the answers to the above questions are yes, please ensure that this information is discussed in the informed consent form (if applicable).

Maximum number of subjects recruited for participation: 300-350 Age range of the subjects recruited: 13years and old

Will this study include any of the following subject pools?

☑ Pregnant Women ☐ Cognitively Impaired ☐ Prisoners ☐ Genetics ☐ Military Personnel

☑ Minors (<18) ☐ UNTHSC employees ☐ Fetuses ☐ UNTHSC students ☐ Patients

☐ Economically Disadvantaged (homeless, evacuees)

How will you recruit and correspond with subjects for this study?

☐ Telephone (please submit telephone script with your submission) ☐ Referrals

☐ Advertising (newspaper, email, Daily News, website, brochure, radio, etc.) ☑ Other

Will subjects be compensated for their participation? Yes ☐ No ☑

Document payment schedule in the protocol synopsis, and if applicable, the informed consent.

Will any of the following instruments or methods be used? ***Check all that apply. Include copies of these materials with your submission:***

☐ Interview (attach script/guide) ☑ Surveys/Questionnaires

☐ Standardized (published) tests or assessments ☐ Focus Group (attach guide)

Does the study involve (**check all that apply**):

☐ Painful or aversive stimuli ☐ False Feedback ☐ Emotional Stress

☐ Withholding of critical information ☐ Deception ☐ False Information

List all OTHER KEY PERSONNEL associated with this project (co-investigators, study coordinator, study physician, etc.)

Is there a **STUDENT INVESTIGATOR** associated with this project? ☑ Yes ☐ No

Name of student investigator: Amruta Oak

Email address of student investigator: aoak@hsc.unt.edu Contact number of student investigator: 817-922-7159

Role/ Responsibilities: Consenting the subjects, handing out the questionnaire

CO-INVESTIGATOR:

Name & Degree: _____ Department: Physiology

Role/ Responsibilities: _____

CO-INVESTIGATOR:

Name & Degree: _____ Department: _____

Role/ Responsibilities: _____

STUDY COORDINATOR:

Name & Degree: _____ Department: _____

Role/ Responsibilities: _____

When submitting your Expedited research to the OPHS Office, please submit 2 complete packets with the following information contained within EACH packet.

If the IRB materials you submit fail to capture the most necessary information for a complete/thorough review, or if the application packet is incomplete, your IRB materials will be sent immediately back to you. Please ensure that the following information is submitted in each packet for a more streamlined "speedy" review of your research project. In addition, please keep in mind that the review process takes time, and research may not be initiated until the application has been approved.

(1) IRB Application Form (with original PI signature on one copy)
(2) Protocol Synopsis
(3) Informed Consent Form (if applicable)
(4) Conflict of Interest Form
(5) CITI Training Certificates

If applicable:

(6) Grant Application
(7) Recruitment Materials (flyers, emails, advertisements, etc.)
(8) Surveys/Questionnaires
(9) Telephone scripts/oral scripts
(10) Assent Forms/Parental Permission Forms
(11) Research Agreements
(12) Letters of permission/cooperation, and/or approvals from other IRBs

Patricia A Grants
Principal Investigator Signature

9/28/09
Date

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