*This template is for a* ***Cross-Sectional study design*** *(involves sampling subjects at a point in time). Use this template for survey studies or taking physical or biochemical measures at a single point in time. The IRB will use this protocol to make their exempt determination (unless children will be subjects). Please reference sections in this document to complete the application.*

**Title**

(Descriptive title; keep it tight, no 100 word titles)

**Version Date**

(e.g., the date the protocol was created)

**Significance/Background:** Using the literature, establish any previous work related to your research question. This section should describe the gaping hole in the literature and how your specific aims will attempt to address it. **Make sure to cite your references in this section!**

***Example:***

*One of the challenges facing the field of obstetrics today is the demand to limit physician work hours, for the benefit of both the physician and the patient. One possible solution to this dilemma is transition to a laborist model. The idea of the “laborist”, initially proposed by Weinstein1 in 2002, is that hospital obstetrical care at the time of labor and delivery can be provided by a hospitalist staff of ob/gyn physicians, rather than by a patient’s individual primary ob/gyn care provider. 2*

*Long and unpredictable work hours and increasing liability costs are causing many physicians to abandon their obstetric practice. Also, resident physicians are increasingly dropping out of ob/gyn training programs in favor of fields more conducive to personal and family life.3,4 The laborist movement arose in response to these challenges.*

*Previous studies of patient satisfaction conducted among midwife patients have shown that continuity of care is less important than the attitudes and responsiveness of the caregiver.5 This study will attempt to address similar issues among general ob/gyn patients, and the effect that transition away from the historical model of care towards a laborist model of care is likely to have on patient satisfaction.*

**Objective(s):** Identify the specific aim(s) for your study.

***Example:***

*To compare the satisfaction rate of patients whose primary ob/gyn physician was present at the time of delivery to patients whose ob/gyn physician was not present at the time of delivery.*

***Outcome Variables:***Describe any outcome variables for the study.

***Example:*** *Survey responses.*

***Setting/Resources for the Study:*** Describe where the research will take place. This includes both the setting for the research, as well as the location of any of the patient records to be obtained or surveys to be conducted. You will also need to describe the capability of the investigators to perform the research, as well as the timeframe for the study.

***Example:*** *The Near West Michigan OB/GYN clinic will be the setting for this research. The investigators have all participated in research previously and have successfully completed the CITI program. The timeframe set for this study is one year.*

***Study Design:*** Describe the study design.

***Example:*** *Cross-sectional study*

***Study Subjects:*** Describe where you will obtain your subjects, over what time period and the specific inclusion and exclusion criteria used.

***Example:*** *The subjects will be women 18 years of age and older who are patients at Near West Michigan OB/GYN clinic who will be delivering their first child. Patients will be recruited into the study at one of the office visits three months prior to delivery. Non‐English speaking subjects, women who delivered multiples and those who experienced serious complications at delivery will be excluded.*

***Study Procedures (some of these sections may not apply to your study):*** This section describes methods for creating your survey, selecting your sample and obtaining responses.

***Example:***

*From January 1, 20XX through December 31, 20XX the investigators will perform the following tasks related to the development and administration of the survey.*

**Survey/Data Collection Tool:** When designing a survey, keep in mind the reading level of your target audience. The rule ofthumb is for the survey to be understood by anyone with an 8th grade reading level. Consideryour questions carefully. If surveys have a bad reputation, it is because they are not wellthought out. See below for steps that should be taken when designing a survey

***Example:***

***Item construction:*** *Items will be drafted using careful consideration for question type, wording and layout, matching response options to questions and applicability of the survey questions to the study objective and the participants. Approximately 5-10 patients not selected for the study sample will be asked to verbally go through the questions with one of the investigators for feedback (e.g., readability, applicability, understanding). Feedback will be reviewed by the investigators and necessary changes will be made to the items. If major changes occur, this process will be repeated to ensure the items used in the survey will return good data.*

***Questionnaire design:*** *The platform to be used for this survey study will be SurveyMonkey. Careful consideration will go into the type of font, color and the layout of the online survey. Office ipads will be used for data collection. There are three ipads available to use at the Near West Michigan OB/GYN clinic.*

***Pretesting/pilot testing:*** *Once the survey has been created in SurveyMonkey it will be tested for use on the ipad to ensure compatibility with this device. The survey will also be sent to select individuals to test for ease of use, grammar, or other errors relating to design (e.g., spacing, layout). Feedback will be used to make revisions if necessary.*

**Sampling Procedures:**

***Constructing the sampling frame:*** *A list of all patients who meet the inclusion criteria will be generated from the office records of Near West Michigan OB/GYN clinic to create the sampling frame. This information contained in the list will be verified in an effort to eliminate/minimize coverage errors. An initial check will be performed for completeness and duplication (e.g., individual listed twice due to marriage during time as a patient).*

***Selecting the sample:*** *Once the list has been verified to be accurate a simple random sample will be performed.*

**Collecting Responses:**

***Initial notification:*** *The charts of patients included in the sample will be flagged. Patients will be recruited into the study at the first office visit after the selection process has taken place. A script describing the study and its importance will be used at the time of recruitment (see scripts section of the protocol).*

***Survey dissemination:*** *The survey will be given at the first post-partum office visit. ipads will be given to participants at check-in for completion while they wait to be seen. The ipad will be collected after the office visit is over.*

***Response tracking:*** *Responses will be tracked through codes assigned to participants. Codes will be kept by the office assistant and entered into SurveyMonkey prior to giving the device to the participant. This will be done so the participant is not responsible for keeping track of their code or any other information in order to participate.*

***Follow-up reminders:*** *N/A for the example used in this template.**Other sample language:**Reminders will be emailed to those who have not completed the survey. Three reminders will be sent during this timeframe. Pages and/or phone calls will be made to individuals who have not completed the survey toward the end of the timeframe.*

***Thank yous:*** *Personalized thank you post cards will be sent to patients who have completed the survey.*

**Problems/Issues with data collection:**

***Opt-out/lost to follow-up:*** *If a patient chooses to opt-out of participating, their information will be removed from the tracking sheet and moved to an opt-out sheet for tracking purposes. If a patient does not return to the clinic for post-partum follow-up, that person will be called to complete the survey over the phone or emailed the survey/tracking code information for completion at a more convenient time.*

***Participant inquiries:*** *Each communication will include contact information for the investigators, as well as for the IRB in case there are questions and/or complaints about the survey study. Questions will be handled on a case-by-case basis by one of the investigators. If something is brought up that affects the study as a whole, appropriate actions will be taken to address the issue.*

***Reducing/minimizing errors of coverage, sampling, nonresponse, and measurement***

***Coverage Errors:*** *In order to reduce coverage errors, the sampling frame will be verified for accurate information prior to drawing a random sample for the study.*

***Sampling Error:*** *A simple random sample will be drawn from the sampling frame based on sample size calculations described in the statistical plan section. The bound on the error of estimation will be +10%.*

***Non-response Error:***  *In an effort to minimize non-response error a tracking system for survey completion will be used. Codes will be assigned to all potential study participants in order to track completion rates. Follow-up by phone call/email will occur for patients who do not come to the clinic for their first post-partum visit. Previous data would indicate a 20% non-response rate for this population. The investigators feel that by using the techniques described above, this can be reduced to 10%.*

***Measurement Error:*** *In an effort to reduce measurement error, the items and questionnaire will be developed using the steps described above. These include item construction/review, questionnaire design, and pretesting/pilot testing the questionnaire.*

***Statistical Plan* *(please don’t struggle with this section, staff are available to help write this up)***

***Sample Size Determination:*** Describe the statistical methods for determining the sample size for the study (reason for choice of sample size).

***Example:*** *The sampling frame for the study contains 113 patients who meet the study inclusion criteria.*

*The primary outcome variable for this study will be satisfaction with delivery.* *The investigators estimate a satisfaction rate of 80% for the patients whose physician was present at the time of delivery and 40% for patients whose physician was not present at the time of delivery, with 20% of deliveries by the primary physician,* *with =0.05 and =0.20, we will be able to detect a statistically significant difference with 14 patients in the primary physician group and 53 patients in the other physician group, using a 2 test. A simple random sample will be drawn from the sampling frame created for the study. In order to account for non-response errors, these values will be increased by 10%. Therefore, 16 patients in the primary physician group and 59 patients in the other physician group will be recruited.*

***Statistical Methods:*** Use this section to provide a thorough description of the statistical tests that will be used in the analysis of your data.

***Example:*** *Summary statistics will be calculated.  Quantitative data will be expressed as the mean+SEM and nominal data will be expressed as a percentage.*

***References:*** Use this section to provide all of the references used throughout your study. Pick a format from your favorite journal and use it consistently.

***Example:***

*1. Weinstein L. The laborist: a new focus of practice for the obstetrician. Am J Obstet Gynecol 2003;188:310-2.*

*2. Watcher RM, Goldman L. The emerging role of “hospitalists” in the American health care system. N Engl J Med 1996;335:514-7.*

*3. Pearse WH, Haffner WHJ, Primack A. Effect of gender of the obstetric-gynecologic work force. Obstet Gynecol 2001;97:794-7.*

*4. Defoe DM, Power ML, Holzman GB, Carpentieri A, Schulkin J. Long hours and little sleep: work schedules of residents in obsetrics and gynecology. Obstet Gynecol 2001;97:1015-8.*

*5. Waldenstrom U. Continuity of carer and satisfaction. Midwifery 1998,14:207-13.*

**Script(s):** Whether you’re delivering your survey by phone, mail or face‐to‐face, you will need toprepare a script to follow. The script will provide your subject with basic backgroundinformation about your survey.

**Example - Initial Contact:** Hi my name is \_\_\_\_\_\_\_\_\_\_. I am conducting a research study to assess your satisfaction with your childbirth experience. This information is important for us to know in order to deliver quality/satisfactory care to our patients from the first prenatal visit to the delivery of the child and after. You are being asked to participate in this study because you will be giving birth to your first child in the next 3 months. We would like you to participate in a survey at your six-week post-partum office visit. The extent of your involvement will be completing this survey, which should take approximately 5-10 minutes.

You are under no obligation to agree to participate and your decision will have no effect your treatment on this visit or any future visits related to your care at Near West Michigan OB/GYN clinic. If you decide to participate, you may change your mind at anytime prior to completing the survey at the six-week post-partum visit. Be assured, your information will be kept confidential. The results from this study may be used for publication. However, your name will not be used in any reports. Your privacy and confidentiality will be kept to the full extent required by law. We value our patients and appreciate you taking a moment to help us with this important research.

Do you have any questions for me?

Would you be willing to participate in this survey study?

**Example - time of survey administration:** Prior to delivery, you agreed to participate in research study to assess your satisfaction with your childbirth experience. This information is important for us to know in order to deliver quality/satisfactory care to our patients from the first prenatal visit to the delivery of the child and after.

You are under no obligation to complete this questionnaire. Be assured, your information will be kept confidential and will in no way affect your future treatment or office experience at the Near West Michigan OB/GYN clinic. The results from this study may be used for publication. However, your name will not be used in any reports. Your privacy and confidentiality will be kept to the full extent required by law. We value our patients and appreciate you taking a moment to help us with this important research.

Would you still be willing to participate by completing the survey?

Do you have any questions for me?

**Example - lost to follow-up:** Hi my name is \_\_\_\_\_\_\_\_\_\_ from the Near West Michigan OB/GYN clinic. Prior to giving birth to your child, you agreed to participate in research study to assess your satisfaction with your childbirth experience. This information is important for us to know in order to deliver quality/satisfactory care to our patients from the first prenatal visit to the delivery of the child and after. From our records it appears that you did not attend your six-week prenatal visit in which the survey would have been administered. Would you still be willing to participate in the study?

You are under no obligation to complete this questionnaire. Be assured, your information will be kept confidential and will in no way affect your future treatment or office experience at the Near West Michigan OB/GYN clinic. The results from this study may be used for publication. However, your name will not be used in any reports. Your privacy and confidentiality will be kept to the full extent required by law. We value our patients and appreciate you taking a moment to help us with this important research.

Would you still be willing to complete the survey? This could be done over the phone or through email. Which would be more convenient for you?

 Administer survey or collect email address

 email address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Thank you for your time!