

## CONCISE SUMMARY EXAMPLE 2

**Research Study Title:** A Randomized Trial of Continuous Positive Airway Pressure (CPAP) for Sleep Apnea in Pregnancy (SLEEP)

**Sponsor:** This research is being funded by <<Sponsor Name>>.

### STUDY SUMMARY

We have summarized the key information about this research study at the beginning of this consent document. More complete details are included following this summary.

We invite you to take part in a research study because you have mild or moderate sleep apnea. Sleep apnea is a common sleep disorder in which you have one or more pauses in breathing or shallow breaths while you sleep. It is your choice whether to be in the study.

The purpose of the study is to find out if treating sleep apnea will affect certain disorders that happen during pregnancy and other complications during pregnancy. The study will last throughout your pregnancy and will finish after delivery of your baby. Everyone in the study will answer questionnaires and have blood taken at study visits. You will either be assigned to a treatment group that uses a CPAP machine or another group that gets advice about getting good sleep. What group you will be in is decided by chance, like flipping a coin. We will be following-up with you by phone, text messages or e-mail in between study visits. After you deliver your baby, we'll ask to take a tissue sample from the placenta. The procedures will be described in more detail later in this document.

There are some risks and discomforts from the blood draw and if you use the CPAP machine. There is a risk of loss of confidentiality. All the risks will be described in more detail later in this document. You may benefit from being in the study, but there is no guarantee of benefits. You might help others in the future by being in this research study.

You can get standard care for your pregnancy or sleep apnea even if you decide not to be in this study.

You may take this document home to read or to discuss with your family members or doctor before deciding to take part in this research study. Please take your time and read this information carefully. You should ask the research staff if you have any questions about this study, or if there is anything you do not understand. If you decide to take part in the study, you will be asked to sign this form.