CONSENT TO PARTICIPATE IN A RESEARCH STUDY
-COVER SHEET-

Study title: MIRACLE of LIFE Study- Longitudinal Observational Study of Pregnant Women to Identify Biomarkers of Gestational Age and Delivery Date

Study Sponsor: Mirvie, Inc.

KEY INFORMATION

This form has information to help you make a decision about taking part in this research study.
All of this information is important, but here are some key points to help you make a decision:

Why am I being asked to review this form?

- You are being asked to join a research study. This is research. Doctors and scientists do research to learn about diseases and how to treat them. Research can be different than medical care.
- This form is for you to read and understand why you might or might not want to join.
- Joining is completely up to you. Even if you sign up, you are free to quit if you change your mind.

What is the purpose, length of time, and procedures of this study?

- The *purpose* of the study is to develop a blood test that can predict pregnancy complications, like having your baby too early, preeclampsia, and gestational diabetes.
- *Your time* in this study depends on how far along in your pregnancy you are:
  - If you are in your *first trimester*, you can have up to 3 study visits, 15 minutes each.
  - If you are in your *second trimester*, you can have up to 2 study visits, 15 minutes each.
- The *procedures* involved in this study include:
  - Collecting information about you (your delivery plans, health, and pregnancy)
  - Donating a blood sample (less than 2 tablespoons of blood)
  - Collecting information from your and your baby's medical record after you deliver your baby
- This study is being done with researchers at Woman's Hospital and Mirvie, Inc. Your study data and medical record will be shared with them.

What are the possible risks and discomforts?

- **Blood sample**: There is the possibility of infection and/or pain and bruising at the vein on your arm where the needle is put in. Aseptic (sterile) technique and trained personnel limit these risks.
- **Collection of your personal information:** There is a low chance of a security breach – this means that it is unlikely for someone not a part of the research staff to see your data.

The main risk for taking part in this study is loss of confidentiality.

If you do not join the study, are there other choices?

- You have the choice at any time not to participate in this research study.
- If you decide not to take part, there is not another option for this study.

Please take the time to read this entire form. Please ask any questions you have about the study.
You may also wish to discuss this study with your family, friends, and doctor to help you make a decision about taking part. If you decide to take part in the study, you will be asked to sign this form.

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Longitudinal Observational Study of Pregnant Women to Identify Biomarkers of Gestational Age and Delivery Date

The "MIRACLE of LIFE" Study

Who is doing the study?

Principal Investigators: Elizabeth Sutton, PhD
Woman's Hospital | 225-924-8446

Eugeni Namsaraev, PhD
Mirvie, Inc. | (510) 717-1357

Dr. Sutton (from Woman's) and Dr. Namsaraev (from Mirvie, Inc.) direct this study. We expect about 3,700 pregnant women from Woman's Hospital will be enrolled in this study. Your time in this study will be up to 3 visits, about 15 minutes each.

Mirvie, Inc. is a company based in San Francisco that is focused on developing simple tests during pregnancy to help find women at risk for preterm birth, preeclampsia, or gestational diabetes. Their goal is to identify women early in pregnancy before problems develop so that both mom and baby have a safe and healthy delivery.

Where is this study taking place?

This study takes place at Woman's Hospital in Baton Rouge, Louisiana and at Mirvie, Inc. in San Francisco, California. Patients are being enrolled at Woman's Hospital. Blood samples and information collected for the study will be sent to Mirvie, Inc. for storage, testing, and analysis.

What is the purpose of this study?

The **Miracle of Life study** is a research study to try to find signals (called "biomarkers") in pregnant women's blood that can predict their true delivery date, or predict pregnancy complications, like having your baby too early, preeclampsia, and gestational diabetes.

Who can join this study?

Pregnant women (at least 6 weeks pregnant and less than 28 weeks pregnant) who are pregnant with one baby and are not planning to deliver by c-section or plan to have induced labor can join this study. To join the study, you must also agree to let your study information and left-over blood samples be kept by Mirvie for future pregnancy and fetal health research.

What will happen to you if you join the study?

The study and this document will be reviewed with you before any study tests are done. The study will collect blood samples from pregnant women at 3 times in pregnancy: 6-12 weeks of pregnancy, 18-22

weeks of pregnancy, and 24-28 weeks of pregnancy. If possible, your blood will be collected when you are already having your blood drawn for other tests. How many blood samples you can give will depend on when in your pregnancy you join the study:

1. In the 1st trimester of your pregnancy (6-12 weeks of pregnancy): up to 3 blood samples
2. In the 2nd trimester of your pregnancy (18-22 weeks of pregnancy): up to 2 blood samples
3. In the 2nd trimester of your pregnancy (24-28 weeks of pregnancy): 1 blood sample

Note, your study visits (and blood sample donations) must be at least 8 weeks apart. This may exclude you from being able to give a research blood sample if you had another one collected less than 8 weeks ago.

The study procedures will include:

- *Consent*: Reviewing of the informed consent form (this document)
- *Collecting Your information:* The study team will ask you questions about your delivery plans, pregnancy history, and health.
- *Blood sample*: A small needle will be placed in your arm vein to draw blood. 2 tablespoons of blood will be collected at each study visit. This would be in addition to the other blood drawn if you are already having your blood drawn for other tests. Once collected, your blood sample will be transported to Mirvie (San Francisco, California) where the genetic, protein and metabolic material in your blood will be studied. Samples will be stored at Mirvie until all tests needed to develop our new blood test(s) are done, which may take many years.
- *Your Medical Record*: The study team will collect your and your baby's medical records for the study after you deliver your baby. We will collect data about your pregnancy, delivery, and your baby's health.
- **IF YOU ARE LESS THAN 13 WEEKS PREGNANT AT THE TIME YOU JOIN THE STUDY:** You have the option to have 2 more visits where your blood is collected and information updated during your 2nd trimester - between 18-22 weeks and 24-28 weeks.
- **IF YOU ARE LESS THAN 23 WEEKS PREGNANT AT THE TIME YOU JOIN THE STUDY:** You have the option to have 1 more visit where your blood is collected and information updated during your 2nd trimester - between 24-28 weeks.

What are the possible risks and discomforts?

- **Blood sample**: There is the possibility of infection and/or pain and bruising at the vein on your arm where the needle is put in. Aseptic (sterile) technique and trained personnel limit these risks. If possible, your blood will be collected when you are already having your blood drawn for other tests.
- **Collection of your personal information:** There is a low chance of a security breach – this means that it is unlikely for someone not a part of the research staff to see your data. Although we have extremely tight security measures, we will let you know if we discover this happens.
- In addition to the risks listed above, you may experience a previously unknown risk or side effect.

What are the possible benefits?

We cannot promise any benefits from your being in the study. If you join, you may be helping future moms to better prepare for their pregnancy and keep their babies healthy.

If you have any questions or problems, whom can you call?

If you have any questions about your rights as a research volunteer, or have any concerns or suggestions about the study, you should call Ericka Seidemann, the Human Protections Administrator, at 225-231-5296 or our Vice President over Research at 225-924-8739. If you have any questions about the research study or think you have a research-related injury or medical illness, contact Dr. Sutton 225-924-8446.

If you do not want to join the study, are there other choices?

You have the choice at any time not to join this research study. The care you get from your doctors will not change if you decide not to be in the study. You can join now and change your mind later on.

Can you stop being in the study?

Joining this study is your choice. You may decide not to join the study or quit the study at any time. The care you get from your doctors will not change if you decide to quit the study. If not yet sent to the study sponsor (Mirvie), any information or blood samples not yet used in the study at the time you quit will be deleted and destroyed. Once your samples have been sent to Mirvie, they will be kept forever. *To stop being in the study or discuss stopping*, you should contact the study coordinator by phone at 225-231-5275 or email research@womans.org.

Can your taking part in the study end early?

The study team or sponsor (Mirvie, Inc.) can take you out of the study at any time without your permission. They may take you out of the study in the unlikely event the study may be harmful to you, you don't follow study directions, we find out you don't qualify, study is canceled, or for other reasons.

What if information becomes available that might affect your decision to stay in the study?

During this study, there may be new findings from this or other research which may affect your desire to continue. Information about any such new findings will be given to you.

What information will be kept private?

Every effort will be made to keep the confidentiality of your study records. However, someone from Woman's Hospital Foundation Institutional Review Board, Woman's Hospital Research Center and collaborators, like the study sponsor Mirvie, Inc., Woman's Hospital Research and Development Committee, and federal agencies as required by law may inspect and/or copy the medical records related to the study.

- Privacy and Confidentiality: We will give you a special study number (or "ID") that links your study information to your blood samples. This study ID lets us not need to use your identity in study records. All study information and blood samples collected at Woman's and sent to the study sponsor (Mirvie, Inc.) will use this study ID. You will given the option to have an electronic copy of the consent form sent to you, which could pose a risk of loss of privacy and confidentiality if it is seen or kept on a personal electronic device (like your phone or computer), especially if that device is shared with other users. Only the study team will be able to access your study information. We work hard to limit risks of breach of confidentiality and privacy by taking off your personal information from the data and samples. We also limit these risks by collecting data through

encrypted and secure web-based databases. We will keep your study records forever. The records will be stored in a password protected database. Again, although steps will be taken to keep privacy, total confidentiality cannot be certain.

- Results of the study: Test results performed on your blood sample will not be shared with you or your baby, but results may be published. We will keep your name and other identifying information private. Other than as set forth above, your identity will remain confidential unless disclosure is required by law.
- Identifiable Private Information or Identifiable Biospecimens: Any information that could identify you (called an "identifier") will be removed from your identifiable information or identifiable blood samples. After this removal, the information or biospecimens could be used for future research studies or given to another investigator for future research without additional informed consent from you.

What charges will you have to pay?

None.

What payment will you receive?

If you agree to take part, we will compensate you $50 after each blood sample is collected. Payment will be offered in the form of a gift card.

What you need to know about future research with your blood samples

Research with your blood samples can help to find out more about pregnancy and the causes and development of pregnancy complications. Your blood samples will be sent to Mirvie, Inc. Any personal information that could identify you will be removed before the blood samples are shared.

What you should know about your blood samples:

- The samples will be stored forever.
- If you agree to have your samples stored, you can change your mind until they have been sent to the study sponsor, Mirvie. After the samples are at Mirvie, they will be kept forever.
- Your blood samples will not be used for whole genome sequencing.
- We will give your samples a special study number (or "ID"). Mirvie, Inc. will store your samples with this ID. A key connecting your ID with you will be kept at Woman's.
    - The future research may or may not take place at Woman's Hospital or Mirvie, Inc. and may or may not involve Woman's Hospital or Mirvie, Inc. Researchers.
- You will not be compensated for any research studies that might be conducted in the future.
- You will not be informed of the details of any specific research studies that might be conducted in the future.
- The collection of samples may give scientists valuable research material that can help them to develop new diagnostic tests, new treatments, and new ways to prevent diseases.
- The research done with your specimens may also help to develop new products in the future, or may be used to establish a test that could be patented or licensed. You will not receive any financial compensation for any patents, inventions, or licenses developed from this research.

Signatures

By signing this consent form, I agree to take part in this study as it is described. This study has been explained to me and all of my questions have been answered. I can call the study investigators, listed on page 1, with any further questions I may have. This study has been reviewed and approved by an Institutional Review Board. I agree to the terms above and acknowledge that I will be been given a copy of this consent form. I have not waived any of my legal rights by signing this form.

_____	_____	_____
Printed Name of **Subject**	Signature of **Subject**	**Date**

_____	_____
Signature of Person Obtaining Consent	Date

The study subject has indicated to me that the subject is unable to read. I certify that I have read this consent form to the subject and explained that by completing the signature line above the subject has agreed to take part.

_____	_____
Signature of Reader	Signature of Witness