CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

INVESTIGATOR'S NAME: Mistie Mills, M.D., M.S. PROJECT # 2004638

Study Title: Once Daily versus Twice Daily Iron Supplementation to Treat Anemia in Pregnancy: A Prospective, Randomized, Placebo Controlled, Double Blinded, Clinical Trial

INTRODUCTION

This consent may contain words that you do not understand. Please ask the investigator or the study staff to explain any words or information that you do not clearly understand.

This is a research study. Research studies include only people who choose to participate. As a study participant you have the right to know about the procedures that will be used in this research study so that you can make the decision whether or not to participate. The information presented here is simply an effort to make you better informed so that you may give or withhold your consent to participate in this research study.

Please take your time to make your decision and discuss it with your family and friends.

You are being asked to take part in this study because you are pregnant and being tested for anemia as part of routine clinical care. Anemia means a low number of red blood cells. Anemia in pregnancy is treated with pills containing iron.

In order to participate in this study, it will be necessary to give your written consent.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to determine the best dosage of iron pills to treat anemia in pregnancy.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 250 people will take part in this study at the University of Missouri. There are no other study sites.

WHAT IS INVOLVED IN THE STUDY?

You will be tested for anemia as part of your normal prenatal care. If you are found to be anemic, you will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor the researcher will choose what group you will be in. You will have an equal chance of being placed in either group. If you are not anemic, you will have routine clinical care, be asked to complete a survey 3-5 times during the remainder of your pregnancy, and will not be randomized to a treatment group.

If you take part in this study, you will have the following tests and procedures:

If you have anemia, you will be randomized to take a single iron pill either once daily (before breakfast on an empty stomach) or twice daily (before breakfast on an empty stomach and before your evening meal on an empty stomach).

• The amount of iron given in each group is part of the standard care which may be done even if you do not join the study. Both groups will take two pills; one of those pills will be placebo for the group randomized to a single iron pill once daily.

• Your blood count will be monitored in this study in the same fashion as if you are not in the study.

• Whether you are anemic or not, you will have two additional blood samples drawn for use in the study. One will be drawn at enrollment and one at the time of admission to the hospital when you are going to deliver your baby. If possible, these blood draws will be done when you are having blood drawn for a routine clinical test.

• A sample of blood will be taken from the umbilical cord following delivery for research use as well.

Each of these blood draws will be about 10cc (1 tube). There will be no cost to you for these additional samples.

We will keep the information we collect from you for this study to use in future research and to share with other investigators to use in future studies without asking for your consent again. Information that could identify you will be removed from your research data so no one will know that it belongs to you.

HOW LONG WILL I BE IN THE STUDY?

We think you will be in the study from enrollment until delivery, approximately 14-20 weeks. The investigator and/or your doctor may decide to take you off this study if you are unable to comply with taking the study medication as prescribed.

You can stop participating at any time. Your decision to withdraw from the study will not affect in any way your medical care and/or benefits. If you decide to stop participating in the study, you are encouraged to discuss your decision with your doctor. There are no health consequences from withdrawing from the study. If you do withdraw, you will be advised to continue taking oral iron therapy. Your data will not be used in the calculation of study results.

WHAT ARE THE RISKS OF THE STUDY?

While on the study, you are at risk for the side effects described below. You should discuss these with the investigator and/or your doctor. There may also be other side effects that we cannot predict. You may receive other drugs to make side effects less severe and uncomfortable. Many side effects go away shortly after the iron is stopped. Long lasting or serious side effects have not been reported with iron therapy.

Risks and side effects related oral iron therapy include:

Those seen in >10% of individuals taking iron sulfate:

Gastrointestinal: Constipation, dark stools, epigastric pain, GI irritation, nausea, stomach cramping, vomiting

Those seen in 1-10% of individuals taking iron sulfate:
Gastrointestinal: Diarrhea, heartburn
Genitourinary: Discoloration of urine
Miscellaneous: Liquid preparations may temporarily stain the teeth
Those seen in <1% of individuals taking iron sulfate (Limited to important or life-threatening):

Contact irritation

For the reasons stated above the investigator will observe you closely while giving the treatment described and, if you have any worrisome symptoms or symptoms that the investigators or their associates have described to you, notify the investigator(s) immediately. Dr. Mill's telephone number is 573- 499-6084

In clinical trials where you and the investigator do not know what dose of medication you are given, there will be a way to discover which treatment you are receiving if your condition worsens. The pharmacy will keep a record of which patients are assigned to which dose of iron, and they can be contacted at any time to reveal the patient's dosage.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there is no direct medical benefit to you. You may expect to benefit from taking part in this research to the extent that you are contributing to medical knowledge. We hope the information learned from this study will benefit other patients with anemia in pregnancy in the future.

There is no guarantee that taking part in this research will result in any improvement in your condition.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you have these options:
Oral iron therapy at a dose suggested by your provider would be recommended. You are free to decline treatment for your anemia.
An alternative is to not participate in this research study.

WHAT ABOUT CONFIDENTIALITY?

A copy of this consent will be placed in the medical record. Anyone accessing your record will be able to view the document and see that you have agreed to participate in the study. Medical information produced by this study will become part of your hospital medical record. Information that does not become part of your medical record will be stored in the investigator's file and identified by a code number only. The code key connecting your name to specific information about you will be kept in a separate, secure location. Information contained in your records may not be given to anyone unaffiliated with the University of Missouri in a form that could identify you without your written consent, except as required by law. If the investigator conducting this study is not your primary, or regular doctor, the investigator must obtain your permission before contacting your regular doctor for information

about your past medical history or to inform them that you are in this trial.

It is possible that your medical and/or research record, including sensitive information and/or identifying information, may be inspected and/or copied by the study sponsor (and/or its agent), the Food and Drug Administration (FDA), federal or state government agencies, or hospital accrediting agencies, in the course of carrying out their duties.

If your record is inspected or copied by the study sponsor (and/or its agents), or by any of these agencies, the University of Missouri will use reasonable efforts to protect your privacy and the confidentiality of your medical information.

The results of this study may be published in a medical book or journal or used for teaching purposes. However, your name or other identifying information will not be used in any publication or teaching materials without your specific permission.

State and federal privacy laws (HIPAA) protect the use and release of your health information. If you decide to take part in this study, you also give us your permission to use your private health information, including the health information in your medical records and information that can identify you.

You have the right to refuse to give us your permission for us to use your health information. However, doing so would mean that you could not take part in this study.

The following identifiers will be obtained from your health records:

- ✓ Name
- ✓ Dates related to you
- ✓ Medical Record Number

The following is the type of protected health information that will be used in the study:)

- ✓ Discharge Summaries Medications
- ✓ Progress Notes History and Physical Exams
- ✓ Questionnaires, Surveys, Diaries Laboratory Reports
- ✓ Demographics (age, race, etc.)

Your permission for us to use and release your information will not expire unless you cancel your permission.

You can cancel your permission at any time by writing to:
Investigator's Name: Mistie Mills, MD
Institution: University of Missouri
Department: Obstetrics, Gynecology and Women's Health
Address: 500 N Keene Street, Ste 405 Columbia Mo, 65201

The information we have already collected may still be used for this research study, but we will not collect anymore information after we receive your letter.

You have the right to access your protected health information that is obtained or created during this research project until the end of study ends.
If you have not already received a copy of the University of Missouri Healthcare Privacy Notice, you may request one. If you have any questions or concerns about your privacy rights, you may contact the Privacy Officer at 573-882-9054.

WHAT ARE THE COSTS?

There is no cost to you for enrolling in the study itself. Your study drug will be provided at no cost to you. No procedures or laboratory studies will be performed that are not part of routine prenatal care. In addition, the use of other medications to help control side effects could result in added costs that may or may not be covered by your medical insurance.

Please note that added costs may include insurance co-payments for doctor visits, transportation, parking, and/or other possible expenses during your participation in this study. Please discuss these issues with the study investigator and/or your doctor.

You will not be charged for any tests that are part of this research study beyond what you are being charged for routine prenatal care. You or your insurance company will, however, be charged for any other portion of your care that is considered standard care.

You or your insurance company will be charged for continuing medical care and/or hospitalization.

WILL I BE PAID FOR PARTICIPATING IN THE STUDY?

You will receive no payment for taking part in this study.

WHAT IF I AM INJURED?

It is not the policy of the University of Missouri to compensate human subjects in the event the research results in injury. The University of Missouri, in fulfilling its public responsibility, has provided medical, professional and general liability insurance coverage for any injury in the event such injury is caused by the negligence of the University of Missouri, its faculty and staff. The University of Missouri also will provide, within the limitations of the laws of the State of Missouri, facilities and medical attention to subjects who suffer injuries while participating in the research projects of the University of Missouri. In the event you have suffered injury as the result of participation in this research program, you are to contact the Risk Management Officer, telephone number (573) 882-1181, at the Health Sciences Center, who can review the matter and provide further information. This statement is not to be construed as an admission of liability.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Participation in this study is voluntary. You do not have to participate in this study. Your present or future care will not be affected should you choose not to participate. If you decide to participate, you can change your mind and drop out of the study at any time without affecting your present or future care in the University of Missouri. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. In addition, the investigators of this study may decide to end your participation in this study at any time after he or she have explained the reasons for doing so and has helped arrange for your continued care by your own doctor, if needed.

You will be informed of any significant new findings discovered during the course of this study that might influence your health, welfare, or willingness to continue participation in this study.
A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research related injury, contact Dr. Mistie Mills at 573-499-6084

You may also contact the University of Missouri Institutional Review Board (IRB) if you:

- Have any questions about your rights as a study participant;
- Want to report any problems or complaints; or
- Feel under any pressure to take part or stay in this study.

The IRB is a group of people who review research studies to make sure the rights of participants are protected. Their phone number is 573- 882-3181.
If you want to talk privately about your rights or any issues related to your participation in this study, you can contact University of Missouri Research Participant Advocacy by calling 888-280-5002 (a free call), or emailing MUResearchRPA@missouri.edu.
A copy of this consent form will be given to you to keep.

SIGNATURE

I confirm that the purpose of the research, the study procedures, the possible risks and discomforts as well as potential benefits that I may experience have been explained to me. Alternatives to my participation in the study also have been discussed. I have read this consent form and my questions have been answered. My signature below indicates my willingness to participate in this study.

_____ _____
Signature Date

*The presence and signature of an impartial witness is required during the entire informed consent discussion if the patient or patient's legally authorized representative is unable to read.

_____ _____
Witness (if required) Date

IRB USE ONLY
Approval Date: October 4, 2019

_____ _____

SIGNATURE OF STUDY REPRESENTATIVE **Date**

I have explained the purpose of the research, the study procedures, identifying those that are investigational, the possible risks and discomforts as well as potential benefits and have answered questions regarding the study to the best of my ability.

IRB USE ONLY
Approval Date: October 4, 2019