



INFORMED CONSENT DOCUMENT

Project Title: Preeclampsia And Nonsteroidal Drugs for Analgesia (PANDA): a randomized non inferiority trial

Principal Investigator: Jonathan Hirshberg, MD

**Research Team Contact: Shannon Martin, RN
314-362-8523**

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you are currently pregnant and undergoing delivery at Barnes Jewish Hospital and have preeclampsia.

The purpose of this research study is to determine if the use of non-steroidal anti-inflammatories (NSAIDs), such as ibuprofen, worsen hypertensive diseases of pregnancy when given post-delivery.

Ibuprofen is approved by the U.S. Food and Drug Administration to help in pain management.

WHAT WILL HAPPEN DURING THIS STUDY?

You will be screened to determine if you meet initial study criteria upon being admitted to Labor and Delivery at Barnes Jewish Hospital. Once enrolled, you will be randomized (assigned by chance) to either a pain management regimen with or without NSAIDs. This randomization is a 50/50 chance, like flipping a coin. We will be using ibuprofen as the NSAID in this study.

If you are enrolled in the group that will use an NSAID, you will receive 600mg of ibuprofen every 6 hours as needed for pain, 1000mg of acetaminophen every 8 hours as needed for pain, and 5-10mg of oxycodone every 4 hours as needed for pain. These medications will be taken orally during your postpartum stay at the hospital until you are released.

If you are enrolled in the group that will not use an NSAID, you will receive 1000mg of acetaminophen every 8 hours as needed for pain, and 5-10mg of oxycodone every 4 hours as needed for pain. These medications will be taken orally during your postpartum stay at the hospital until you are released.

You will receive standard postpartum care for the duration of your hospital stay. We will collect some data points from your medical record, including vital signs, pain scores, and medication usage.

Once you have been discharged, you will not need to follow the medication procedures you were assigned to while in the hospital. You will be able to take pain medication as needed for continued postpartum care.

At your six week postpartum visit, the study staff will meet with you and administer a brief questionnaire about your satisfaction with pain control during the study. You may skip any questions that make you uncomfortable.

Additional data will be collected from your electronic medical record including demographics, medical history, obstetric history, labor and delivery information, pain scores, vitals, medications, blood pressure, lab values that tell us about your organ function, information on any hypertension-related outpatient visits postpartum, and any hospital readmissions postpartum.

If you do not return to the clinic for your 6 week postpartum visit, we will attempt to contact you via the contact means you provided at the time of your enrollment so that you may complete the survey over the phone. We will attempt to contact you at least three different times.

We may also wish to contact you via phone for up to 12 months after you have completed your 6 week survey. We may contact you to collect additional information from you regarding your medical history. This is optional, and you may still participate if you do not want to be contacted after you have completed the survey.

Do you agree to allow us to contact you up to 12 months after you have completed your survey?

 Yes No
Initials Initials

Will you save my research information to use in future research studies?

We might remove identifiers from your private information and then use the information for future research studies or share them with other researchers for their future research. If this occurs we will not ask you for additional consent for these uses of your information.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 286 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for up to 6 weeks after your delivery. You will return to the clinic for your standard of care postpartum visit, and the study staff will give you a brief questionnaire to complete. We anticipate this survey taking about 5 minutes to complete.

We may also contact you by phone up to 12 months after you have completed this survey to collect more medical information from you. This is optional. If you choose to allow us to contact you, your participation could last an additional 12 months. We anticipate these phone follow ups to last about 5-10 minutes.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Some risks described in this consent document, if severe, may cause death.

Some of the survey questions may make you uncomfortable. You may skip answering any question that makes you uncomfortable.

Likely / Common

Mild

- Stomachache
- Heartburn
- Dizziness
- Abdominal cramps and pain
- Rash
- Drowsiness
- Nausea
- Vomiting
- Gas
- Constipation
- Diarrhea
- Ringing in the ears

Rare

Serious

- Liver problems
- Allergic reaction
- High blood pressure
- Kidney problems
- Bleeding, ulceration, and perforation of the stomach or intestines
- Stroke
- Heart attack
- Heart failure

Breach of Confidentiality

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled “*How will you keep my information confidential?*” for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because we will learn better methods to treat postpartum pain in women with preeclampsia, which may result in reduced opioid use and improved maternal outcomes.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you could use the standard postpartum pain management of acetaminophen and hydrocodone.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any additional costs for being in this research study.

You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

You will receive a \$25 gift card to Target once you have completed your 6 week follow up survey. If you complete the survey over the phone, we will mail this card to the address you provide.

WHO IS FUNDING THIS STUDY?

The University and the research team are not receiving payment from other agencies, organizations, or companies to conduct this research study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator Jonathan Hirshberg, MD, at 314-362-4661 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. We will keep your participation in this research study confidential to the extent permitted by law.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- Your primary care physician if a medical condition that needs urgent attention is discovered
- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, we will assign you a unique study ID to identify you. This ID will be used on all case report forms and database reporting. The database we will use is REDCap, which is a WUSTL approved, HIPAA-compliant database that is encrypted and password protected. Only the study team will have access to the master list that links you to this number and your information. All data entry and analysis will be done on a secure, password-protected WUSTL computer. Any hard copies will be maintained in a locked cabinet in a locked office of the research staff. Surveys will be completed either via paper (with a unique ID) or via a secure WUSTL tablet.

A description of this clinical trial will be available on <http://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.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).

- To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at <https://hrpo.wustl.edu/participants/withdrawing-from-a-study/> or you may request that the investigator send you a copy of the letter.
 - **If you revoke your authorization:**
 - The research team may only use and share information already collected for the study.
 - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant’s withdrawal from the research study or for safety reasons.
 - You will not be allowed to continue to participate in the study.

Can we contact you by email?

We would like to contact you by email for the purposes listed below. Some of these emails may contain health information that identifies you.

- Appointment reminders, attempts to contact you if you miss your 6 week follow up visit, questions about the study

Only the research team will have access to your email communications. We will only communicate by email to send you the information listed above. If you have any questions or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email.

- There is always a risk that the message could be intercepted or sent to the wrong email address. To avoid sending messages to the wrong email address, the first email we send you will be a test message to ensure we have the correct email address.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any email communications sent or received on any electronic devices used for work or through a work server.

Do you agree to allow us to send your health information via email?

 Yes **No**
Initials **Initials**

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at <https://hrpo.wustl.edu/participants/withdrawing-from-a-study/> under Withdrawing from a Research Study.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because you no longer meet study criteria or because the investigator feels it would not be safe for you to continue.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself or experience a research-related injury, please contact: Shannon Martin, 314-362-8523.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, <http://hrpo.wustl.edu>. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 03/11/20.

(Signature of Participant)

(Date)

(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

(Signature of Person who Obtained Consent)

(Date)

(Name of Person who Obtained Consent - printed)