INFORMED CONSENT DOCUMENT

Project Title: **A Pharmacist Intervention to Improve Mother and Child Health**

Principal Investigator: Hao Tran
Research Team Contact: Shelby Francis, 319-678-8037

This consent form describes the research study to help you decide if you want you and your child to participate. This form provides important information about what you and your child will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your and your child's participation with anyone you choose such as family or friends.
- Do not agree for you and your child to participate in this study unless the research team has answered your questions and you decide that you want you and your child to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you and your child to participate in this research study because you are a new mother who had at least 2 elevated blood pressure readings during your pregnancy.

The purpose of this research study is to determine if contact with a research pharmacist improves the health of new mothers and their babies.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 25 mother/child pairs will take part in this study conducted by investigators at the University of Iowa.

HOW LONG WILL MY CHILD AND I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for approximately 1 month. There will be 1 enrollment visit that will last for approximately 20-30 minutes. You will have 2 phone calls (1 a week after enrollment and 1 a month later) with a research pharmacist that will last 5 – 20 minutes. Finally, you will be asked to complete an exit survey that will take less than 10 minutes to complete.

WHAT WILL HAPPEN DURING THIS STUDY?

At the enrollment visit, you will be asked to complete a baseline demographic survey interview-style with a research team member. This survey will ask for information about your race, ethnicity, marital status, employment status, student status, and highest level of education. You will be provided with a blood pressure cuff and taught how to use it. You will be enrolled in our bi-directional text messaging system that will send you a text message 2 times per day for 7 days after enrollment asking you to text back your blood pressure values. After the visit, any other conditions that you have (i.e., co-morbidities)

will be obtained from your medical record. After the 7 days have passed, you will receive a phone call from the research pharmacist. They will review your blood pressure values with you and help you address any health concerns about yourself or your baby. The research pharmacist will document each of the well-child visits that your family has attended as well as all vaccinations that your child has received. They will also assist you with finding a primary care physician and/or health insurance, if necessary. 1 month later, you will be asked to text in 1 blood pressure value per day for 3 additional days. After those 3 days, you will have a second call with the research pharmacist. After reviewing your blood pressures, medications, and lifestyle, the research pharmacist may recommend changes to your blood pressure medications as part of your clinical care. When the second phone call is complete, you will be sent a text message with a link to an exit survey asking about any difficulties you had with the study and any suggestions for future studies.

Data Storage for Future Use

A**s** part of this study, we are obtaining data from you and your child. We would like to study your data in the future, after this study is over without further consent. Your data may be placed in a central repository or other national repositories sponsored by the National Institutes of Health or other Federal agencies. If this happens, it may be stripped of identifiers (such as name, date of birth, address, etc). Other qualified researchers who obtain proper permission may gain access to your sample and/or data for use in approved research studies that may or may not be related to in the purpose of this study.

The tests we might want to use to study your data may not even exist at this time. Therefore, we are asking for your permission to store your and your child's data so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding the health of postpartum women, but it is unlikely that what we learn from these studies will have a direct benefit to you or your child. It is possible that your data might be used to develop products tests, or discoveries that could be patented and licensed. In some instances, these may have potential commercial value and may be developed by the Investigators, University of Iowa, commercial companies, organizations funding this research, or others that may not be working directly with this research team. However, donors of data do not retain any property rights to the materials. Therefore, there are no plans to provide financial compensation to you or your child should this occur.

Your data will be stored *with a code which may be linked to your name*. If you agree now to future use of your data but decide in the future that you would like to have it removed from future research, you should contact Hao Tran at 319-356-7825. However, if some research with your data has already been completed, the information from that research may still be used.

WILL I BE NOTIFIED IF MY/MY CHILD'S [DATA\BIOSPECIMENS\IMAGES] RESULT(S) IN AN UNEXPECTED FINDING?

The results from the data we collect in this research study are not the same quality as what you would receive as part of your routine health care. The data results will not be reviewed by a physician who normally reads such results. Due to this, you will not be informed of any unexpected findings. The results of your data will not be placed in your medical record with your primary care physician or otherwise. If you believe you are having symptoms that may require care, you should contact your

primary care physician.

We may wish to contact you in the future about additional research studies. To do this, we will store your name, date of birth, phone number, address, elevated blood pressure values, and dates of those values to determine if you may be eligible for future studies. Agreeing to participate in the current study does not obligate you to participate in any future studies. You will need to sign a separate consent document for any future studies you wish to participate in.

WHAT ARE THE RISKS OF THIS STUDY?

You and your child may experience the risk indicated below from being in this study. In addition to this, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

A potential risk of participating in this study is loss of confidentiality. We will minimize this risk by storing all of your electronic data on password-protected, secure servers. We will store your paper consent document in a locked cabinet in the research team office.

WHAT ARE THE BENEFITS OF THIS STUDY?

You and your child will not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because we may learn ways to monitor health concerns of postpartum mothers from their homes.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You may have costs associated with the text messaging in this research study.

WILL MY CHILD AND I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your address so a check can be mailed to you. You may choose to participate without being paid if you do not wish to provide your address for this purpose.

You will be mailed a check up to $25 upon completion of all study procedures. Compensation will be pro-rated based upon completion of the enrollment visit ($20) and the exit survey ($5). You will also be allowed to keep the blood pressure cuff after you complete the study.

Your baby will also be provided with a small gift.

WHO IS FUNDING THIS STUDY?

The U.S. Department of Health and Human Services, National Institutes of Health (NIH) is funding this research study. This means that the University of Iowa is receiving payments from the NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the NIH for conducting this study.

WHAT ABOUT CONFIDENTIALITY?

We will keep your and your child's participation in this research study confidential to the extent permitted by law. However, it is possible that 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 and your child.

- federal government regulatory agencies,
- auditing departments of the University of Iowa,
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies), and
- Twilio, the company that coordinates the sending/receiving of text messages.
- Boomerang, the server system on which the data is stored.

To help protect your and your child's confidentiality, we will store all of your electronic data on password-protected, secure servers that are only available to the research team. We will store your paper consent form in a locked cabinet in the research team office. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you and your child cannot be directly identified.

WILL MY AND MY CHILD'S HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires University of Iowa Health Care to obtain your permission for the research team to access or create "protected health information" about you and your child for purposes of this research study. Protected health information is information that personally identifies you and your child and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you and your child, as described in this document, for purposes of this research study. Once University of Iowa Health Care has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your and your child's health information related to this study with other parties including federal government regulatory agencies and the University of Iowa Institutional Review Boards and support staff.

You and your child cannot participate in this study unless you permit us to use your and your child's protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your and your child's right to medical care that is not research related. Your signature on this Consent Document authorizes University of Iowa Health Care to give us permission to use or create health information about you and your child.

Although you may not be allowed to see study information until after this study is over, you may be given access to your and your child's health care records by contacting your health care provider. Your

permission for us to access or create protected health information about you and your child for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to Hao Tran, 1300 Boyd Tower, 601 Newton Rd, Iowa City, IA 52242. However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose for you and your child not to take part at all. If you decide to be in this study, you and your child may stop participating at any time. If you decide for you and your child not to be in this study, or if you and your child stop participating at any time, you and your child won't be penalized or lose any benefits for which you otherwise qualify.

What if I Decide to Drop Out of the Study?

If you decide to leave the study early, we will ask you to contact a member of the research team so that we do not continue trying to reach you to collect study data.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Shelby Francis, 319-678-8037. If you or your child experience a research-related injury, please contact: Hao Tran, 319-356-7825.

If you have questions, concerns, or complaints about your and your child's rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your and your child's experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

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APPROVED BY: IRB-01
IRB ID #: 202305322
APPROVAL DATE: 07/23/25

This Informed Consent Document 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 signing this Informed Consent Document. 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 copy of this form.

Child/Subject's Name (printed): _____

Mother/Subject's Name (printed): _____

_____ _____
(Signature of Mother/Subject for own participation) (Date)

Parent/Guardian's Name and Relationship to Child/Subject:

_____ _____
(Name - printed) (Relationship to Subject - printed)

_____ _____
(Signature of Parent/Guardian for child's participation) (Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)