Magee-Womens Hospital
Of University of Pittsburgh Medical Center
Department of Obstetrics, Gynecology, and Reproductive Sciences

CONSENT TO ACT AS A SUBJECT IN A RESEARCH STUDY

TITLE: Heart Health Doula Program

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Key Points	
You are being asked to take part in a research study. Research Studies include only people who choose to take part. The study team members will explain the study to you and will answer any questions you might have. You should take your time to make your decision.	
Summary of the research	• **Purpose of the research:** To learn if providing a doula and other types of support after a hypertensive disorder of pregnancy can improve blood pressure and weight after a year. • **Study Visits:** All women in the study will be asked to attend 2 in person visits (at baseline and when your baby is about 1 year old), 2 phone call check in's (when your baby is 3 and 9 months old), and 1 video visit (when your baby is 6 months old). The first visit happens right after you give birth and are still in the hospital. The 2nd visit will happen when your baby is about a year old. Both visits will involve physical measures, blood draw and answering questionnaires. We will also monitor your blood pressure throughout the study (see more below). At the 2nd visit you will be given a Fitbit for physical activity monitoring. We will also schedule a phone call with you to check in when you are 3 and 9 months postpartum and review yours and your child's medical record as it relates to pregnancy. • **Randomization**: If you decide to participate you will be randomly selected to take part in one of 2 groups: o **Usual care:** which involves home blood pressure monitoring and no Doula visits. o **Intervention - Doula support + blood pressure monitoring:** which involves 8-12 weeks of weekly Doula support visits, an invitation to join a social support group led by a doula (for 6 months), and remote weight + home blood pressure monitoring (for 8-12 months).

Foreseeable Risks and Discomfort	**Risks and side effects related to study procedures** include those which are: • **Likely:** From the blood draw you may also experience bruising, bleeding, swelling, and pain at the puncture site. You may experience discomfort from answering questionnaires. • **Less Likely:** Rarely, people having a blood draw may experience infection at puncture site; fainting; lightheadedness. There is a risk of weight loss from the intervention.
Expected Benefits	You may or may not have benefits from the study depending on which group you are randomized into. If randomized for the intervention, you will receive the direct benefit of a postpartum doula providing you support weekly. You may receive the indirect benefit of information regarding your cardiovascular risk profile. There is also considerable potential benefit to women, including participants in this study, and to society.

Please note: your physician may be involved as an investigator in this research study. Before agreeing to participate, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your physician.

Why is this research being done?
The purpose of this research program is to conduct an intervention study for 8–12-weeks with a heart health focused Doula intervention program, compared to women who receive usual care. In other words, this study looks at how easy and convenient an 8–12-week heart health focused doula program would be for moms, and how effective the program is at reducing weight and high blood pressure after 1 year.

Who is being asked to take part in this research study?
Women who have recently delivered will be invited to participate in the study. Women must be age 18 or older and have been diagnosed with high blood pressure during pregnancy.

What procedures will be performed for research purposes?
This study involves being randomly assigned to a usual care or Doula intervention group, participating in check-ins with study staff every 3 months until your baby is one year old, and 2 in person study visits. We will also follow up with you in the future to see if you are interested in new research studies. Below is a description of these activities:

Randomization
If you decide to participate you will be randomly selected to take part in one of 2 groups (randomization is like flipping a coin). One group will receive care as usual, and the other group will receive the Doula intervention.

Study visits
All women in the study will be asked to attend 2 in-person visits, 1 video visit, and have 2 check-in phone calls. The first in person visit happens right after you give birth and are still in the hospital, at our research clinic, or in your home. The 2nd in person visit (or follow up visit) will happen when your baby is about a year old at Magee Women's Hospital or at your home. Women will be randomized to a study intervention group at their first visit. Below is an outline of the study visits and check-ins:



Usual Care Group
If you are randomized to the usual care group, you will participate in the clinical home blood pressure monitoring program through Magee for 6 weeks. You will be given a blood pressure cuff by clinical staff. You will also receive a blue tooth enabled blood pressure cuff from the research study. When your baby is about 6 months old, we will reach out to you to have you take blood pressure measurements over the phone or via text for one week (this will be in preparation for your 6-month video call).

Doula Intervention Group
If you are randomized to the Doula group, you will participate in 8-12-weeks of weekly Doula visits. Doula services are provided by Healthy Start Inc, which is a local resource for new Moms in our community. You will get to decide if you prefer virtual or in-person Doula visits. The visits will focus on topics important to you and your heart health. A doula can also support women with breast feeding and adjusting to life with a new infant. You will be offered a support group with other moms that is led by a doula for 6 months. You will also measure your weight and blood pressure at home (remote monitoring) from the time you give birth, until you have your 1 year follow up visit. We will send you reminders to take your blood pressure and we will reach out to you when your baby is about 6 months old to ask you to take your blood pressure again. Finally, the study team will select a small number of women to have 1 hour of 1 support session with their doula audio recorded.

What happens at a check-in call and at the video visit?
We want to check in with you about every 3 months until you complete our research study. The check-ins (which happen when your baby is 3, 6, and 9 months old) will take about 15-25 minutes and involve you answering questions over the phone or a via video call about your medications, and other changes in your health (including any hospital stays or ER visits). We may also ask you to measure your blood pressure for us, and schedule future appointments during these calls. If the in-person visits cannot be scheduled for any reason, we will invite you to complete these appointments remotely.

Regardless of what study group you are randomized in to, we will set up reminders for you to take your blood pressure every day for 1 week prior to your 6-month video visit. At the video visit we will ask you to answer similar questions about medications, changes in your health status, and you will also be asked to measure your weight.

What happens at a study visit?
At both study visits you will complete questionnaires, a blood draw, urine collection, and

physical measurements (like blood pressure and weight). We will also perform a pregnancy test at the 12-month visit to ensure you are not pregnant. As a part of the study, the study team will also review your and your child's medical record.

Blood pressure & other physical measurements: Your blood pressure will be measured at home and in person by yourself and study staff. The study or clinical staff will work with you one-on-one to train you on all aspects of home blood pressure monitoring. A checklist of proper technique will be provided. We will also provide education on safe blood pressure. We will measure your blood pressure using a standard blood pressure cuff or a Bluetooth enabled cuff. We will also measure your waist and hips using a tape measure.

Body Fat Percentage Measurement: You will stand on a special scale that measures body fat percentage by passing a small, harmless electric current through your body. It is approved by the FDA for this purpose and is painless.

Blood Draw and urine collection: We will perform a blood draw at both your visits. You will have no food or drink except for water for 8-12 hours before your second visit. About 70 ml of blood sample will be collected (this is about four and a half tablespoons). We will collect urine to test in the future.

In addition, participants completing visits remotely will have the option to have their sample collection performed at a Quest Diagnostics location.

Questionnaires: You will complete questionnaires about demographics, medical history, obstetric and gynecologic history, physical activity, mood, diet, breastfeeding, sleep, and your overall health and support. At your second visit you will also answer questions about the intervention to give us feedback on your participation in this study overall.

Medical records: We are requesting your permission to gather information from your medical records and your baby's medical record, relating to each of your pregnancies where you delivered or had prenatal care at UPMC facilities from the past, present, and future. We are also requesting access to your Anywhere EPIC record (also called 'Care Everywhere'), which includes information from medical visits outside of UPMC. This helps us keep your contact information up to date. We will collect information on your weight, blood pressure, glucose testing, diabetes or other pregnancy-related diagnoses, prenatal care, medications, delivery information, breastfeeding, contraception, and your baby's health outcomes. We will also collect details on your cardiac-related hospitalizations, health visits and mental health visits up to one year after delivery. This information will be added to the data we collect as part of this research study and will remain a part of the research records indefinitely. A UPMC medical record will be made for your visit to the Magee CTRC as well as the results of your clinical lab work. The authorization is valid for an indefinite period of time; however, you can always withdraw your authorization to allow the research team to abstract your medical records by contacting the principal investigator listed on the first page and making the request in writing. If you do withdraw your authorization any information obtained from you up to that point will continue to be used by the research team.

Return of Results:

Results will be returned to you via e-mail following the completion of your 2nd in-person visit and review of results by study staff. You will receive an e-mail with a document providing you the details of your study visit results and contact information for our study staff should you have any questions regarding the results returned. We will return results from blood specimen testing done at the UPMC clinical lab, which is CLIA certified. We will return weight and blood pressure as measured at the study visit. We may also send you summary results at the end of the study explaining what we learned from this research project overall.

If randomized to the doula intervention:

Support and education: The doula will provide you with support and education on topics such as breastfeeding, blood pressure cuff usage and blood pressure readings, meal preparation, diet, exercise, mental health and wellness, and even occasional contactless support such as medication or grocery pickup and drop-off. This may all be done virtually via e-mail, internet, text, or phone or in-person. The goal of this study is to provide support for you and learn about how we can help women with high blood pressure in pregnancy to get heart healthy and stay healthy.

Home Monitoring: If randomized to the intervention group, you will receive a Bluetooth enabled home blood pressure monitor to use for the duration of the study. You will be given and trained on how to use a Bluetooth enabled blood pressure cuff, scale, and an app on your smart phone. Since you will be using this Bluetooth cuff via an iHealth App on your smart phone, your encrypted blood pressure data will be accessible by Apple or Android. Although your readings will be uploaded in real time, doulas and research study staff members will ***not*** be monitoring your readings daily. *This does not replace your ongoing care plan with your physician and healthcare team.* Only research staff members and doulas will have access to your blood pressure readings. You will be contacted for follow up if your readings are not in a safe range. You will monitor both your blood pressure and weight at home. We will be assessing body mass index (BMI, kg/m^2) from measures of height and weight. We will provide you with a scale if needed.

At your 2nd study visit

FitBit Physical Activity measures: All women will be given a FitBit at their 2nd study visit. We will ask you to wear this FitBit for 7 consecutive days so that the study team can learn more about physical activity and how it relates to pregnancy. You will get to keep the FitBit. Optionally: You may choose to submit physical activity data to the study team from another device such as an Apple Watch.

Future Use and Storage of Samples and Data:
We will also indefinitely store some of your blood to be able to test in the future. Your blood samples will be stored in locked freezers at Magee Womens Research Institute, which are under the responsibility of Dr. Catov, for both the current and any future studies. Your specimens are stored without a name, but with a study code number. The information linking these code numbers to names is maintained by the data manager in a locked file at the University of Pittsburgh. Researchers not listed on this consent, including investigators outside of the University of Pittsburgh, may have access to these specimens, but only after a research plan is approved by Dr. Catov.

We may share data and biological samples with other agencies not on this list, under the direction and approval of Dr. Catov. Materials or information collected as part of this study and released to any secondary investigators are stripped of study code numbers and cannot be linked back to you. These specimens may also be used for genetic (genome) sequencing, and to produce genetic material (like DNA and RNA) and this material will be stored for an indefinite period of time for future studies, including those that may be unrelated to your current condition. Your samples, data, and genetic data generated from these samples may be shared with others, including federal repositories, and will be shared without identifiers. Some cells may be treated so that they can be studied for many years. These will be destroyed when they are no longer needed.

A federal law called the Genetic Information Nondiscrimination Act (GINA) helps protect you from being treated unfairly because of your genes. GINA generally makes it illegal for health insurance companies and group health plans to use genetic information in making decisions regarding your eligibility or premiums. GINA also makes it illegal for employers with 15 or more employees to use your genetic information when making decisions regarding hiring, promoting, firing, or setting the terms of employment. This Federal law does not protect you against genetic discrimination by companies that sell life, disability, or long-term care insurance. The risks associated with gene studies include the potential for a breach of confidentiality which could affect future insurability, employability, or reproduction plans, or have a negative impact on family relationships and/or result in paternity suits or stigmatization.

Data Sharing:
Your data and specimens used in this research study may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products. You will not retain any property rights, nor will you share in any money that the investigators, the University of Pittsburgh, or their agents may realize.

Data Sharing with Fitbit and iHealth
Since this research study will involve measuring your physical activity, blood pressure, and/or weight remotely, certain information such as your name and readings will be sent to iHealth and Fitbit. You can read more about their privacy practices on their websites below:

- https://ihealthlabs.com/pages/privacy-policy
- https://www.fitbit.com/global/us/legal/privacy-policy

What are the possible risks, side effects, and discomforts of this research study?

Answering Questionnaires: There is a possibility of emotional discomfort associated with answering the questionnaire as some of the questions may be considered "personal" and answering them might be stressful or embarrassing. You may skip questions for which you feel uncomfortable. The study team will review your questionnaire after completion. We may follow up with you to discuss the questionnaire and connect you to appropriate resources.
Risk of -Body Fat Measurements and Other Body Measurements: According to the U.S. Department of Health and Human Services, there have been no reported adverse events induced

by body fat measurements as they will be done in this study, even in the course of thousands of individuals undergoing the measurement. The small current levels involved (< 1 mA) are less than the threshold of pain. However, individuals who have implanted devices, such as cardiac defibrillators, may experience electrical interference and will not undergo this procedure. Blood pressure measurements, which involve squeezing the upper arm, may be briefly uncomfortable. If you happen to have a high blood pressure reading during one of your study sessions, we will document the reading, ask you a few follow-up questions, and then advise you to take next steps accordingly as per our protocol.

Risks of the Doula Intervention Program: For the small number of women who have a doula session audio recorded, there is a risk of breach of confidentiality. There is also a risk of being uncomfortable due to being asked questions about your health.

Weight Loss Risk: In rare instances, risks associated with rapid weight loss can include gall stones and difficulty producing milk or breastfeeding.

Risks from Blood Draw and Fasting: Likely (occurs in more than 25% of subjects, or more than 25 out of 100 subjects): bruising, bleeding, swelling, and pain at the venipuncture site. Rare (occurs in less than 1% of subjects, or less than 1 out of 100 subjects): infection at venipuncture site; fainting; lightheadedness. Since we are asking you to fast for the 2nd in-person visit, you may feel some discomfort due to being hungry.

Risks of urine collection: Providing a urine sample may be briefly uncomfortable.

Risks of Genetic Research: Genetic studies include the potential for a breach of confidentiality, which means someone could see your genetic testing results who is not authorized. The information could be used to affect what insurance or jobs you may be able to get. Or it could affect your decision to have children. It could also cause stress and conflict in your family relationships, as it can confirm who is a child's father, identify a risk for a certain disease, or cause you or other people to have negative feelings if the results show you may be more likely to get certain diseases.

Risks from Breach of Confidentiality: In rare instances, information about your participation in this research study, including information collected from the tests listed and any information you provide may be breached or leaked. This is very rare, and we will do everything in our power to ensure your confidentiality. This includes the use of medical records and the audio recording of the final study questionnaire. Confidentiality during Internet communication activities cannot be guaranteed, and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.

Electronic Communication and Information: The study team and doulas use text-messaging, e-mail, and other electronic services to contact you and schedule your study visits. We will ask you about your preferred contact method to ensure we can reach you. With any electronic or outside services, there is a risk for breach of confidentiality due to information these services need to provide successful support and/or transportation.

What are possible benefits from taking part in this study?
You may receive the direct benefit of a postpartum doula providing you support weekly. You may receive the indirect benefit of information regarding your cardiovascular risk profile. Women with hypertensive disorders during pregnancy often experience a gap in health care after giving birth, and this research study will determine if a heart health focused Doula intervention can help improve heart health after pregnancy. Therefore, there is also considerable potential benefit to women, including participants in this study, and to society as a whole.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?
You will be promptly notified if, during the conduct of this research study, any new information develops that may cause you to change your mind about continuing to participate.

Will the insurance provider be charged for the costs of any procedures as part of this research study?
Neither you nor your insurance company will be charged for any procedures performed in this research study, as all costs related to this study will be covered by the study budget. You and/or your insurer will be billed for any usual standard care services not connected to the study and will be responsible for any co-payments, coinsurances, or deductibles.

Will I be paid if I take part in this research study?
You will be compensated a total of $240 plus a FitBit valued at $80 for completing the full research study. You will receive $75 after completing the baseline visit, $25 after completing the 3, 6 and 9-month check-ins, $50 + a Fitbit for the 12 month follow up visit, and $40 for collecting the Fitbit data for us and returning your log. For each visit if you are on time and do not reschedule, we will provide you with a $10 bonus payment. You will also be reimbursed for parking or bus fare, travel, and childcare.

You will be provided with a blood pressure cuff for the study. You may also receive a scale for measuring weight depending on what group you are randomized into.

Our goal is to collect 1 weeks' worth of physical activity data from you after or at the 12 month follow up visit. If at the time of the follow up visit you already have an activity tracker (such as an Apple Watch or FitBit) and you are willing to give us 1 week of data, we may compensate you $100 (total) at the time of the 12-month visit, in place of the FitBit. Study staff can assist you with how to send this information to the study team.

Optional Childcare reimbursement: If childcare is a barrier for you being able to attend a study visit, you may be eligible to receive an additional $25 payment.

Optional travel incentive: If travel is a barrier for you being able to attend a study visit, you may be eligible to receive an additional $20 payment. In some circumstances the study team may be able to arrange transportation for you instead of providing this payment.
Remuneration to participants is considered taxable income regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a "Form 1099 – Miscellaneous" with the IRS and provide a copy to the

taxpayer. We are required to give your name and social security number to the Accounting Office. Participants who do not provide a social security number may still participate in the research, but the IRS requires that 24% of the payment be sent by the institution to the IRS for 'backup withholding;' thus you would only receive 76% of the expected payment.

Who will know about my participation in this research study?
All paper records and electronic records pertaining to your involvement in this research study will be stored in a locked file cabinet and a secure server in the office of the research staff and Healthy Start, Inc. A case number will also be used to indicate your identity on these records. This information will be accessible to the investigators their research staff, and Healthy Start, Inc. Individuals from the agencies funding this research may review the records as part of their ongoing audit of this project, which will not include any identifiable information. Any information about you or your hospital treatment, including the information we collect from your medical records, will be handled in a confidential (private) manner consistent with other hospital medical records and will be labeled with the case number when added to your research records. You will not be specifically identified in any publication of research results.

The study team will collect emergency contact information from you. If we are unable to get in touch with you, we may reach out to your emergency contact and therefore they will be informed of your participation in this study. We may work with your emergency contact to facilitate getting resources for you, such as access to a smart device. You may choose to not provide an emergency contact.

Who will have access to identifiable information related to my participation in this research study?
In addition to the investigators listed on the first page of this consent form and their research staff, including Healthy Start Inc., the following individuals will or may have access to identifiable information (which may include your identifiable medical information) related to your participation in the research study:

Authorized representatives of the University of Pittsburgh Office of Research Protections (ORP) may review your identifiable information (which may include identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study.

If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of (1) fulfilling orders made by the investigators for hospital and health care services (e.g., laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal hospital operations (i.e. quality assurance).

Authorized representatives from the sponsor of this research study, such as federal agencies or federal data repositories, may review and/or obtain de-identified information (which may include de-identified medical information) related your participation in this research study for the purpose of monitoring the accurate and the completeness of the research data and for performing required scientific analyses of the research data. The investigators involved in the conduct of this research study may receive funding from the sponsor to perform the research procedures and to provide the sponsor with de-identified research and medical information related to your participation in the study.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?
The investigators may continue to use and disclose information related to your participation in this research study for a minimum of seven years after the final reporting or publication of a project.

Is my participation in this research study voluntary?
Your participation in this research study, including the use and disclosure of identifiable information for the purposes described above, is completely voluntary. Note, however, that if you do not provide consent for the use and disclosure of identifiable information for the purposes described above, you will not be allowed to participate in this research study. Whether or not you provide consent for participation in this research study or withdrawal at a later date, will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

Your doctor may be involved as an investigator in this research study, and as both your doctor and a research investigator; he/she is interested both in your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, he/she may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your doctor.

If you chose to withdraw from the study, previous data and specimens obtained from you up to that point will continue to be used by the research team. If you would like for none of the data or specimens obtained to be used by the research team, you must express this to the Principal Investigator listed on the first page in writing.

If I agree to take part in this research study, can I be removed from the study without consent?
You may be removed from the research study by investigators, if, for example, the study is terminated. You may also be removed from the study if we never hear back from you to start the intervention or to complete your research appointments. If you become pregnant again during the 12 months of active study participation you will be withdrawn because this program is designed for postpartum women, and not pregnant women. If you have received any services or support during this time to help you complete the intervention, such as Wi-Fi service, the study team will need to shut it off.
What happens if I believe I was injured by participating in this study?

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. Currently, there is no plan for any additional financial compensation. You do not waive any rights by signing this form.

Certificate of Confidentiality

A federal Certificate of Confidentiality has been issued for this research to add special protection for information and specimens that may identify you. With this certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena. Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about your participation in this study. Even with these measures to protect your privacy, once your identifiable information is shared outside UPMC, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private. Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire. The results of this research may be published in a medical book or journal or used to teach others. However, your name or other identifiable information will not be used for these purposes without your specific permission.

VOLUNTARY CONSENT

I certify that I have read the above information, or it has been read to me. All of the above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form. Any questions that I have about my rights as a research participant will be answered by the Office of Research Protection, University of Pittsburgh (1-866-212-2668).

By signing this form, I consent to participate in this research study and provide my authorization to share my medical records and my child's medical records with the research team. A copy of this consent form will be available to me.

_____

Printed Name of Participant

_____ _____

Participant's Signature Date

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits and possible risks of study participation. Any questions the individual had about this study have been answered, and we will always be available to address further questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date