CONSENT FOR RESEARCH

The Pennsylvania State University

Title of Project: **Healthy Mom Zone**
Principal Investigator: Danielle Symons Downs, Ph.D.
Address: 266 Recreation Building, Department of Kinesiology, University Park, PA 16802
Telephone Number: 814-863-0456

Subject's Printed Name: _____

We are asking you to be in a research study. This form gives you information about the research. Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you. Please ask questions about anything that is unclear to you and take your time to make your choice. Some of the people who are eligible to take part in this research study may not be able to give consent because they are less than 18 years of age (a minor). Instead we will ask their parent(s)/guardian(s) to give permission for their participation in the study.

1. **Why is this research study being done?**
   This research is being done to better understand how to design and deliver a behavioral program that promotes eating healthy, physical activity, goal-setting, and self-monitoring of weight gain to pregnant women in an effort to improve health for moms and their babies. We are asking you to be in this research because there is little available research on what strategies really help women to eat healthy, stay active, and manage weight throughout pregnancy.

2. **What will happen in this research study?**
   - You will be randomly placed into one of two groups. We do not select your group and you will not be able to change your group assignment.
   - **All participants will complete the following study procedures:**
     - **Baseline Assessment (6-16 weeks gestation):**
       1. The **on-site visit** is expected to take 90 minutes and will take place at the Clinical Research Center. The information obtained will help us detect if there are any health conditions that would keep you from participating in this study or that should be reported to your healthcare provider for follow-up. The following procedures will occur:
          - Complete study paperwork and listen to instructions on the procedures.
          - A nurse will conduct a brief physical exam to assess your health, height, weight, and blood pressure.
          - A nurse will conduct a standard blood draw (you do NOT have to be fasting) to measure levels of micronutrients like folate and Vitamin D. If the initial blood draw is unsuccessful it may need to be repeated, with your permission. The amount of blood drawn will be less than 5 teaspoons (25 milliliters).
          - A study staff member will assess your body composition with the BodPod and measure waist circumference and skin fold. The BodPod is a capsule that you will sit inside to measure your body composition. You will sit as still as possible for two to three 45-second measurements over a 5-minute period. You will hear two popping noises; they are part of the test and are normal.
       2. The **at-home visit** is expected to take 90 minutes. The following procedures will occur:
          - Explain and demonstrate study procedures and trainings on the technology devices (i.e., activity monitor, wi-fi weight scale, dietary tracking, mobile metabolism device) that you will use during the study.

Procedures on how to collect your urine will also be explained. All of the technology devices are safe and pose no risk to you or your baby.
- Answer any remaining questions about your study participation.

- **Follow-up Assessment (35-37 weeks gestation):**
  1. The on-site visit will be the exact same as the pre-intervention onsite visit except there will not be a physical exam. It is expected to take 60 minutes.
  2. There will be an exit interview with a study team member. This interview will be audiotaped using an Olympus DM-420 voice recorder. You will be asked questions about your preferences for the intervention materials and procedures. Your feedback is extremely valuable and will help us to improve the program for future moms like yourself. You will not be individually identified by your responses. This interview is expected to take 30 minutes.

- **Over the course of the study, the following measures will also be obtained:**
  1. **Daily:** You will weigh yourself everyday using a WiFi scale that we provide for you that connects to the internet and automatically uploads your weight. You will also wear a wrist-worn activity bracelet that we provide. You will wear this device all day and night throughout the study except when you are showering or swimming.
  2. **Weekly:** You will use a phone app or website to track your diet on three days/week. You will also collect an overnight urine sample one time per week (e.g., Sunday to Monday). We will be measuring the level of cortisol in your urine to determine your stress level. You will either drop-off your sample to us on campus or a study team member will come to your house to pick it up.
  3. **Monthly:**
     - Twice a month you will complete online surveys regarding your health and daily habits that may take 30-40 minutes to complete. We will send you a reminder by email to complete the surveys.
     - Every three weeks you will wear a waist-mounted activity monitor for a 14-day period. This is a small monitor the size of a half dollar that will assess your movement. There are no risks for you or your baby associated with wearing activity monitors.
     - Every 4-6 weeks you will use a small, easy to use breathing device that you blow into to assess your metabolism. You will use this device after you wake but before you get out of bed. It takes approximately 2-3 minutes to use this device.
     - Every 4-6 weeks you will have a fetal ultrasound scan that will take about 30 minutes. The scan will require you to lie down and a trained sonographer will place an odorless, colorless gel on your stomach before using a small device called a transducer to view images of your baby. Sonographers will have extensive, direct contact with you and your abdomen being imaged (every effort will be made to maintain privacy). This scan is NOT diagnostic and is not designed to detect abnormalities. However, a clinician certified and trained in reading the ultrasound scans will be reviewing all scans within 72 hours. The clinician will complete a review form, which will include any concerns specific to fetal growth. We will then send this ultrasound scan review form to your OB/GYN practice. It is still important to note that fetal birth defects which are present may not be seen or may be falsely reported during an ultrasound examination. In other words, potential problems develop at different times in pregnancy. A normal ultrasound scan does not rule out potential birth defects, and does not mean or guarantee that a genetic or chromosomal defect is absent. Neither a normal ultrasound scan, nor the results of any other prenatal test, guarantees a normal, healthy baby.
     - During your 3rd trimester (somewhere between 28-36 weeks gestation) you will be asked to download the “SmartIntake” app to take the pictures of the foods that you have consumed as well as the food that is leftover.

You will photograph all meals and snacks for 2 weekday days and 1 weekend day. The process of photographing and uploading your foods will take less than 1-minute per time to complete. Our research staff will show you how to take the photos and help you download the app to your phone.

4. **Delivery:** With your HIPAA authorization, we will obtain your prenatal, labor and delivery, and postpartum record from your physician's office. These data will help us to understand the relationship of the study to your and your baby's health.
5. **6-Weeks Post-Delivery:** you will be asked to complete an online survey regarding your recent delivery and your and your baby's health. This is expected to take 30-40 minutes to complete. You will also be asked to complete the following familiar measures:
    - Weigh yourself using the Aria Wi-Fi scale for a 7-day period.
    - Wear the Jawbone wrist-worn activity monitor for a 7-day period.
    - Complete one Breezing device measurement.
    - Provide one urine sample.
    - One BodPod assessment.
    - Take pictures of all your meals and snacks for 2 weekday days and 1 weekend day.

    You are also being asked to complete the following measures for your baby; these will be done during the same time of your measurements (around 6-8 weeks postpartum):
    - Complete a PeaPod measurement. Your baby's test takes place in a similar small space with a window where you can see you baby the entire time. The baby's test is two minutes long, and typically only one test is needed. We can stop the test at any point. Your baby will be placed in the warm measurement space free of any clothing or blankets. The PeaPod measurement is similar to your BodPod measurement.

- **If you are placed in the intervention group, you will receive different combinations of the following intervention components at different points in your pregnancy. You will be asked to:**
    - Participate in 30-60-min/week of dietary counseling and healthy eating activities (e.g., preparing food, reading food labels) led by a program instructor. You may have the opportunity to receive some of this counseling remotely (e.g., by phone). You may be asked to choose a lunch or dinner meal replacement (one meal per day).Participate in regular moderate-intensity exercise (e.g., ACOG pregnancy recommendations are 150 minutes/week of exercise such as brisk walking, working out at your gym, your normal activities) on your own at home and do some of this activity on-site with a program instructor (e.g., walking or light jogging on a treadmill, stationary bike, low-impact aerobics, resistance bands/balls/light hand weights) for 30 min/session up to three times per week.
    - Receive guided feedback via phone/email/text from instructor up to three days/week to help with overcoming barriers with goal-setting and self-monitoring activities.

3. What are the risks and possible discomforts from being in this research study?

There are no known economic, legal, or social risks associated with participation in this study. There are minimal risks in participating in this research beyond those experienced in everyday life.

- The surveys may ask personal questions and you may feel uncomfortable, but they are not expected to cause feelings different from what is experienced in everyday life. There are minimal risks for healthy, pregnant women with no obstetric or medical complications and no anticipated risks to your fetus, when exercising during pregnancy. Moderate-intensity exercises like walking or light jogging on a treadmill, riding the stationary bike, low impact aerobics are safe in pregnancy and recommended by the U.S. Department of Health and Human Services, American College of Sports Medicine, and the American Congress of Obstetricians and Gynecologists. If you are asked to participate in exercise, there will be hand guides on the sides of the treadmill, and a study nurse and instructor will monitor the sessions. You will be asked to report any symptoms such as muscle soreness or nausea

frequently. Some anticipated problems that are not adverse events may include sore muscles, minor aches/pains/headache, mild Braxton Hicks contractions, minor nausea (normal for pregnancy), minor bruise/sprain (e.g., ankle, wrist, bump on leg). The staff member will assess the symptom and provide a recommendation to the participant to either modify the activity or stop altogether. These will be recorded and participants will be encouraged to speak with their healthcare provider if the issue is not resolving itself or the symptom appears to get worse.

- No risks are associated with wearing the activity monitors or using the breathing device for measuring metabolism.
- No risk is associated with participating in the interview.
- You may experience some discomfort while in the BodPod if you are fearful of small-enclosed areas. The capsule has a window for you to see out of and to let light in. There is a blue button on the seat that you can press if you feel like you need to get out immediately.
- Your ultrasounds will be made as safe and enjoyable as possible. Some women experience minimal discomfort during the scan. The sonographer may press firmly on your stomach to get a clear image of your baby. After the ultrasound scan, the sonographer will send the images through a secure e-mail to an OB GYN physician at Hershey Medical Center. This doctor will review the scan images and send a review form to your OB GYN provider. If there is an abnormality noted on the review form, you may receive a phone call from your provider about 1-3 weeks after the scan regarding the study ultrasound scan. Your doctor will likely do a follow-up scan with you before any diagnosis is made. No medical diagnosis can be made by any study staff member. The ultrasound machine and sonographer used for this study are different than those used by your OB GYN and there may be slight differences between scans. **Is the ultrasound safe?** ***Official Statement on Safety in Training and Research Work (Approved, 2012)***
    - *Diagnostic ultrasound has been in use since the late 1950s. There are no confirmed adverse biological effects on patients resulting from this usage. Although no hazard has been identified that would preclude the prudent and conservative use of diagnostic ultrasound in education and research, experience from normal diagnostic practice may or may not be relevant to extended exposure times and altered exposure conditions. It is therefore considered appropriate to make the following recommendation: When examinations are carried out for purposes of training or research, ultrasound exposures should be as low as reasonably achievable (ALARA) within the goals of the study/training. In addition, the subject should be informed of the anticipated exposure conditions and how these compare with normal diagnostic practice. Repetitive and prolonged exposures on a single subject should be justified and consistent with prudent and conservative use.*

- Blood draws may cause mild pain, swelling or bleeding. There may be some bruising (blood under the surface of the skin), which is decreased by pressing on the site after the needle is removed. There is also a slight chance of infection, dizziness or fainting. These risks will be minimized and most likely eliminated by having trained staff draw the blood in a clinical setting using sterile supplies. If dizziness or fainting occurs, the symptoms will be reduced by having you lie flat with your feet raised. If these should occur, we may ask that you remain at the clinic until we have checked your blood pressure and we are sure that you feel OK. There is a small risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your electronic data created by you or by the researchers will be maintained to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.
- You may experience some mild nausea or dislike a food item during a healthy eating demonstration.
- There are no known risks of taking pictures of your food and uploading them to the mobile app.
- There are no risks to you or your child having a PeaPod measurement done

4. What are the possible benefits from being in this research study?

4a. What are the possible benefits to you? The possible benefits of your participation include:

(a) You might learn more about yourself and your eating and exercise behaviors, weight, and health.

(b) You might have a better understanding of how your diet, exercise, and health behaviors influence your weight gain as well as your pregnancy, labor, and delivery, and your baby's health after you deliver.
(c) You will get to see your baby during the ultrasound scans. You may receive a printed ultrasound image of your baby when feasible. Ultrasound images are NOT guaranteed at each visit; taking your own photos or videotaping is NOT allowed. This is NOT an anatomical scan, and we will NOT be determining the sex of your baby. Please keep in mind that the ultrasound images you may receive can vary in quality due to position of the baby (i.e. sonographer may not be able to get an image of baby's face or profile).

4b. What are the possible benefits to others? The anticipated benefits of your participation to others may include, that the significant others in your life become more aware of their own eating and exercise behaviors, weight, and health. There may also be health benefits for your baby.

5. **What other options are available instead of being in this research study?** You will receive basic health information as part of your prenatal care, but the full extent of the programs in this study cannot be obtained without enrolling in this study.

6. **How long will you take part in this research study?** If you agree to participate in this research, you will participate over your entire pregnancy from when you are recruited (about 6-16 weeks gestation) throughout your pregnancy (about 35-37 weeks gestation). We will also collect data at birth (e.g., prenatal record and labor/delivery information from your doctor's office), and 4-6-weeks postpartum.

7. **How will your privacy and confidentiality be protected if you decide to take part in this research study?** Efforts will be made to limit the use of sharing your personal research information to those people who have a need to review this information.
   - A list that matches your name with an ID number will be kept in a password protected file in a secure online system and a back-up will be stored in a locked file cabinet in 223 Noll Laboratory.
   - Your records will be labeled with a code number. Only the research team members approved for this study will have access to them. The audiotapes from the interview will be used only to confirm notes taken during this session. In addition, these tapes will be used for education (lectures) and research presentations, but you will not be personally identified. Tapes will be stored in a locked room in the Penn State Exercise Psychology Laboratory and destroyed by the PI 5 years after the end of this study.
   - Collaborators at another institution will have limited access to the data. The data they have access to will not have any personal identifiers in order to maintain confidentiality and in accordance with federal law (HIPAA).

   Limits to confidentiality: if the research team is likely to uncover abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities. Federal law provides additional protections of your medical records and related health information. These are described in an attached document. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared. We will do our best to keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people may find out about your participation in this research study. For example, the following people/groups may check and copy records about this research:
   - The Office for Human Research Protections in the U. S. Department of Health and Human Services
   - The research study sponsor, National Institutes of Health, Heart, Lung, and Blood Institute
   - The Institutional Review Board (a committee that reviews and approves research studies) and
   - The Office for Research Protections

   Some of these records could contain information that personally identifies you. Reasonable efforts will be made to keep the personal information in your research record private. However, absolute confidentiality cannot be guaranteed.

8. **What are the costs of taking part in this research study?**
   8a. What will you have to pay for if you take part in this research study? No cost

8b. What happens if you are injured as a result of taking part in this research study?
In the unlikely event you become injured as a result of your participation in this study, medical care is available. It is the policy of this institution to provide neither financial compensation nor free medical treatment for research-related injury. By signing this document, you are not waiving any rights that you have against The Pennsylvania State University for injury resulting from negligence of the University or its investigators.

9. Will you be paid to take part in this research study? Yes.

All participants will receive:

Time	Participation	Total Amount
Pre-Intervention	On-site (Blood draw $25) On-site (Bod Pod, Exam/Height/Weight; $10) At Home (Weight Scale, Dietary Tracking, Activity Monitors, Breathing Device, Surveys; $15)	$25 check $10 + $15 = $25 check
Post-Intervention	On-site (Blood draw $25) On-site (Bod Pod, Height/Weight; $10) At Home (Weight Scale, Dietary Tracking, Activity Monitors, Breathing Device, Surveys; $15)	$25 check $10 + $15 = $25 check
Weekly	Urine collection ($5 per week x 4-week cycles) Dietary Tracking/Activity Monitors/Surveys ($5 per week x 4-week cycles)	$20 gift card every 4-weeks $20 gift card every 4-weeks (up to 7 cycles; $ 280 total)
Monthly	See baby on Ultrasound; picture of baby if available; one picture frame for a photo ($15 value)	$15 value
Birth	Completing 90% or higher of weekly weight/dietary tracking/activity monitors/surveys over the study	$20 check
Postpartum	Survey completion at 5-7 weeks postpartum	$5 gift card
	Total compensation	**$420**

Those randomized to the intervention will also receive:

Aria Wi-Fi Sale to keep ($125 value)	$125 value
Food Scale to keep ($25 value)	$25 value
Compliance Incentive for Attending 90% or higher of sessions	$20 check
Total compensation	**$170**

You will receive an extra $25 for completing the Remote Food Photography during your 3rd trimester, $50 for your baby's measurements, $50 for your postpartum onsite measurements and $75 for the weekly measurements; the extra will total $200. You will be paid, in total $790. Payments will be given via check and gift card as noted above. Please note that your total payment within one calendar year may exceed $600 and will require the University to report these payments to the IRS annually. This may require you to claim the compensation that you receive for participation in this study as taxable income.

10. Who is paying for this research study?
Funding for this study has been provided by the National Institutes of Health, Heart, Lung, and Blood Institute, 1R01HL119245-01 and 1R56HL126799-01. Also, the Penn State Clinical and Translational Science Institute.

11. What are your rights if you take part in this research study?
Taking part in this research study is voluntary.
- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.

If you decide to leave this study, contact the investigator to return your activity monitors, Wi-Fi weight scale, and food scale. You will keep any compensation you have received for any participation. The person in charge of the research study or the sponsor can remove you from the study without your approval. Possible reasons for removal include: not attending sessions, not adhering to the study protocol, inappropriate or nonprofessional behavior, and change of health status in meeting inclusion criteria (for example, developing a health condition that will stop you from being able to participate in the study). During the course of the research you will be provided with any new information that may affect your health, welfare or your decision to continue participating in this research.

12. If you have questions or concerns about this research study, whom should you call?
Please call the head of the research study Danielle Symons Downs, Ph.D. at 814-863-0456 if you have questions, complaints or concerns about the research, and/or believe you may have been harmed by being in the research study. You may also contact the Office for Research Protections at (814) 865-1775, ORProtections@psu.edu if you have questions regarding your rights as a person in a research study, have concerns or general questions about the research, and/or cannot reach the research team or wish to talk to someone else about any concerns related to the research.

INFORMED CONSENT AND AUTHORIZATION TO TAKE PART IN RESEARCH
Signature of Person Obtaining Informed Consent

Your signature below means that you have explained the research to the subject and have answered any questions he/she has about the research.

_____	_____	_____	_____
Signature of person who explained this research	Date	Time	Printed Name

(Only approved investigators for this research may explain the research and obtain informed consent.)

Signature of Person Giving Informed Consent and Authorization
Before making the decision about being in this research you should have:

- Discussed this research study with an investigator,
- Read the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.
Signature of Participant

By signing this consent form, you indicate that you voluntarily choose to be in this research and agree to allow your information to be used and shared as described above. Your signature also means that you understand the ultrasound scans are not diagnostic (i.e. does not screen or diagnose chromosomal or structural abnormalities including birth defects.)

_____	_____	_____	_____
Signature of Participant	Date	Time	Printed Name

Signature of Parent(s)/Guardian for Child
By signing this consent form, you indicate that you permit your child to be in this research and agree to allow his/her information to be used and shared as described above.

_____	_____	_____
Signature of Parent/Guardian	Date	Printed Name

OPTIONAL STUDY PARTICIPATION

In addition to the main part of the research study, there is another part of the research. You can be in the main part of the research without agreeing to be in this optional part.

(A) Optional Storage of Biological Materials for Future Research

You will be providing blood and urine samples to us throughout the study.. If you agree, the PIs Dr. Symons Downs and Dr. Savage Williams would like to store leftover sample(s) for future research.

- These future studies may be helpful in understanding fetal growth, metabolic syndrome and cardiovascular disease that may be exacerbated in pregnancy due to high GWG or postpartum weight retention.
- It is unlikely that these studies will have a direct benefit to you.
- Neither your doctor nor you will receive results of these future research tests, nor will the results be put in your health record.
- Sometimes tissue is used for genetic research about diseases that are passed on in families. Even if your sample(s) are used for this kind of research, the results will not be put in your health record.

Your leftover samples will be labeled with a code number.

- These samples will be stored in a freezer (-80^{o} for blood, and -20^{o} for urine) located in the Clinical Research Center where only research staff members will have access.
- The length of time they will be used is unknown.
- You will be free to change your mind at any time.
- You should contact principal investigator if you wish to withdraw your permission for your blood/urine to be used for future research. Any unused blood/urine will be destroyed and not used for future research studies.

You should initial below to indicate what you want regarding the storage of your leftover blood and urine, for future research studies.

a. Your samples may be stored and used for future research studies to learn about**,** fetal growth, metabolic syndrome and cardiovascular disease that may be exacerbated in pregnancy due to high GWG or postpartum weight retention.
_____ Yes _____ No

b. Your samples may be shared with other investigators/groups without any identifying information.
_____ Yes _____ No