RESEARCH SUBJECT CONSENT & AUTHORIZATION FORM

Title:	The SPROUT (pilot) project: Starting pregnancy with robustness for optimal upward trajectories
Investigator:	Erin Wentz, PT, PhD and Carol Sames, PhD 750 E Adams St. NAB 3318 Syracuse, NY 13210
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RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

What should you know about this research?

- Someone will explain this research to you and this form provides a written explanation in addition.
- Taking part in this research is voluntary. Whether you take part is completely up to you.
- If you decide to take part and then later change your mind, you can drop out at any time for any reason, no questions asked.
- If you don't understand anything about this study or the consent form, please ask questions.
- Ask all the questions you want before you decide on whether or not to participate.

How long will you be in this research?

You will be in the study for about 15 months (+/- 4 to 8 weeks), depending on when you start the study.

Why is this research being done?

The purpose of this research is to study two different approaches to exercise that we believe will result in improved health for moms and babies. We are trying to determine if the two types of exercise programs (supervised & home exercise) result in health improvements for moms and babies. We also want to see if the tests and questionnaires we are using in the study can find the changes we anticipate will happen throughout pregnancy and for 6-months after birth.

What happens to you if you agree to take part in this research?

If you decide to take part in this research study, the general procedures include being assigned to one of three study groups, participating in an exercise program (during and after pregnancy), attending in person study visits and allowing the researchers to measure your baby's motor skills and cognitive development monthly (in your home) until your baby is six months old.

At various visits, you will be asked to provide information about you and/or your baby, perform a walking test, and complete questionnaires.

Could being in this research hurt you?

The most important risks or discomforts that you may expect from taking part in this research include muscle soreness, tiredness, increase in blood pressure, dizziness, and heart rhythm disorders from the exercise, especially if you have been inactive.

Will being in this research benefit you?

The most important benefit that you may expect from taking part in this research includes helping with weight control. Possible benefits to others include learning whether an exercise program results in improved health for moms and babies.

What else should you know about this research?

In person study visits will take place at the Institute for Human Performance (IHP) on the Upstate Campus located at 505 Irving Ave. You will need permission from your obstetrician to participate in the study.

Subjects in two of the study groups will have 3 in person visits to the IHP while subjects in the third study group will have up to 150 in person visits to the IHP (3 visits per week for 50 weeks).

DETAILED RESEARCH CONSENT

You are being invited to take part in a research study. A person who takes part in a research study is called a research participant.

Why is this research being done?

The purpose of this research is to learn whether two different approaches to exercise training will improve exercise adherence and mom and infant health outcomes. This is a *pilot study* where we are trying to determine if it is possible for two types of exercise interventions (supervised & home exercise) to be similar in terms of design, implementation and adherence. Additionally, we are trying to determine if the tests and questionnaires for the exercise intervention are able to detect changes in a mom's aerobic fitness, quality of life (QOL), fatigue, sleep quality, depression, and weight change throughout pregnancy and 6-months after birth.

About 18 participants will take part in this research.

What happens to you if you agree to take part in this research?

You will be randomly assigned to one of three study groups: **UC** (usual care group), **EX** (supervised exercise group) or **HOMEX** (home exercise group). You will be put into a study group by chance (like drawing straws). You have a one out of three chance of being placed in each group. You cannot choose your study group.

Participants in all three study groups will perform exercises that follow the ACSM (American College of Sports Medicine) and ACOG (American College of Obstetricians and Gynecologists) guidelines for "moderate-intensity."

You will be asked to complete an exercise/physical activity diary on each day that you perform cardiovascular or resistance exercise to record: date, type of activity, duration, heart rate (HR), and rating of perceived exertion (RPE). This should take about 5 minutes to complete for each day of exercise/physical activity.

You will be given a Polar Ignite watch to wear. The watch will alarm you if your heartrate goes above a moderate intensity level. You will wear the Polar Ignite watch during the course of the study as it tracks information about activity during the day and about sleep at night. The watch will alarm you if your heartrate goes above a moderate intensity level. If this happens you should slow your exercise down until the monitor alarm stops.

You will complete six questionnaires at nine different times during the study that ask questions about your quality of life, sleep quality, mood, fatigue, and amount of physical activity that you perform. In addition, you will be weighed at the end of each trimester of pregnancy and each month for six months after giving birth. Lastly, your baby will be measured for height and weight, and assessed for their physical movement and cognitive development each month for the first six months after birth.

Participants assigned to the UC (usual care) group

Participants in this group will continue with their usual (pre-pregnancy) exercise routine, if any. You will be given an activity log to record your activity. A member of the research team will call, text, or email you each week to remind you to complete the weekly activity log. The weekly phone call, text, email will take about 15 minutes to complete. We will download your heartrate data from the watch to ensure that your activity is in the moderate intensity range.

You will have three exercise test visits at the IHP (beginning of the study, 3-months after delivery and at the end of the study which is 6-months after delivery).

You will complete questionnaires at your first exercise test visit to the IHP. You will receive home visits for second trimester (25-26 weeks of pregnancy) and third trimester (37-38 weeks of pregnancy) to complete questionnaires and weight measurement. These home visits will take approximately 1 hour.

Participants assigned to the EX (supervised exercise) group

If assigned to the EX group, you will attend three exercise sessions each week at the Institute for Human Performance (IHP). You may choose exercise times between the hours of 7:30 am- and 6:00 pm, Mon-Fri. These exercise sessions will be supervised by members of the research team. Each exercise session will consist of: 5 minutes each of flexibility warm-up and cool-down; 40 minutes of moderate intensity aerobic activity; and 20 minutes of strength training activity. Each exercise session will take approximately 75-90 minutes.

If you are unable to exercise for 30-40 minutes of continuous aerobic exercise, you will be given a gradual exercise program that breaks activity into smaller 10-minute sessions and/or increases rest between sessions to meet the 150 minutes/week of moderate intensity activity.

Your heartrate data will be downloaded and analyzed from the watch to confirm that you are exercising in a moderate intensity rate**.**

Depending on when you start the exercise program, you will have between 130-150 visits at the IHP.

You will complete questionnaires at the end of the second trimester and third trimester in addition to weight measurement during your exercise training at the IHP, which will add an additional 30 minutes to these two visits.

Participants assigned to the HOMEX (home exercise) group

Participants in this group will participate in a home exercise program consisting of 3-5 days a week of exercise. You will meet in person at your home with Dr. Wentz or Dr. Sames to discuss instructions for your home exercise program including tips for walking indoors and outdoors, exercise handouts for warm-up/cool-down activities, demonstrations for resistance training activities, safe exercise principles, and an exercise log. You will be contacted twice per week to discuss your progress, barriers/challenges faced, ask questions, and strategies to achieve the exercise guidelines. You will be given written information and demonstrations on exercising in a moderate intensity range for both aerobic and strength exercise and a weekly exercise program.

Your heartrate data will be downloaded and analyzed from the watch to confirm that you are exercising in a moderate intensity rate**.** This weekly contact will take approximately a total of 30 minutes.

If you are unable to exercise for 30-40 minutes of continuous aerobic exercise, you will be given a gradual exercise program that breaks activity into smaller 10-minute sessions and/or increases rest between sessions to meet the 150 minutes/week of moderate intensity activity.

You will have three exercise test visits at the IHP (beginning of the study, 3-months after delivery and at the end of the study which is 6-months after delivery).

You will complete questionnaires at your first exercise test visit to the IHP. You will receive home visits for second trimester (25-26 weeks of pregnancy) and third trimester (37-38 weeks of

pregnancy) to complete questionnaires and weight measurement. These home visits will take approximately 1 hour.

All Participants: Exercise Testing - These three visits will take place at the Institute for Human Performance (IHP)

Visit 1 (11-13 weeks of pregnancy, late first trimester): This visit will take about two hours.

The following procedures will occur at this visit:

- We will ask you questions about your medical history, including any prescription drugs that you are taking, and exercise history.
- Your height will be measured to the nearest 0.25 inch using a stadiometer and converted to meters. Weight will be measured to the nearest 0.2 lb. using a Seca Digital Column Scale (Chico, CA). BMI will be calculated using the self-reported pre-pregnancy weight and the weight recorded by the Seca scale.
- You will be asked to perform a walking test to estimate your aerobic fitness and your target heart rate range for exercise. The fitness test is called a submaximal Balke-Ware treadmill test which estimates your aerobic fitness using a math equation. You will walk on the treadmill at a speed of 3.0 mph (easy walking speed) and an incline of 0%. After three minutes, the incline is increased to 2.5% every three minutes until you decide to stop the test, you have symptoms such as pain or you achieve 85% of your estimated maximal heart rate.
- You will complete the following questionnaires: Quality of Life (SF-12), Sleep Quality (PSQLI), Depression, (CES-D, EPDS) Fatigue (MFIS), and Weekly Activity Volume (PPAQ). A description of these questionnaires is listed below in this document.
- You will be given a Polar Ignite watch and given the opportunity to review the watch operation, charging, and downloading online procedures for physical activity, heart rate, and sleep.

Visit 2 (3 months after delivery): This visit will take about 60 minutes.

The following procedures will occur at this visit:

- You will be weighed and your BMI will be calculated.
- You will be asked to perform the Balke-Ware walking test to estimate your aerobic fitness and your target heart rate range for exercise.
- You will complete the previously mentioned six questionnaires (SF-12, PSQLI, CES-D, EPDS, MFIS, PPAQ).

Visit 3 (6 months after delivery, end of study): This visit will take about 90 minutes.

- You will be weighed and your BMI will be calculated.
- You will be asked to perform the Balke-Ware walking test to estimate your aerobic fitness at the conclusion of the study.
- You will complete the previously listed six questionnaires (SF-12, PSQLI, CES-D, EPDS, MFIS, PPAQ).

All participants: After Delivery Exercise Routine-Study Week #30-52 (starts 4-8 weeks after delivery)

You will continue in your assigned group beginning 4 to 8 weeks after delivery once cleared by your physician.

If you experience any of the warning signs to stop physical activity (information will be given to you and included in your physical activity diary), immediately contact your healthcare provider.

All participants: After Delivery Monthly Home Visits-Study Week #30-52 (Visits occur one time per month through 6-months after delivery)

Regardless of group assignment, all participants will receive six monthly home visits that will occur once per month through 6-months after delivery. During each visit the following procedures will occur:

- Your baby will have their movement control and mental development measured using the Bayley Scales of Motor Development, 4th edition.
- Your baby's height and weight will also be measured.
- You will have your weight measured at monthly visits 1, 2, 4 and 5.
- You will complete the previously mentioned six questionnaires (SF-12, PSQLI, CES-D, EPDS, MFIS, PPAQ) at monthly visits 1, 2, 4, and 5.

Future follow-up:

We may contact you in the future to see if you are continuing with the exercise program.

Study Results:

At the end of the study, you will be given your individual baseline, 3-month, and 6-month post-delivery Balke submaximal test results. In addition, you will be given a summary exercise record of your exercise MET level and average # weekly minutes of moderate intensity activity at the end of the 2nd & 3rd trimester and at 3- and 6-months post-delivery. The investigators can go over these results with you. Lastly, at the time of article submission, you will be mailed a copy of the article abstract.

Description of Questionnaires to be used in this study:

Pregnancy Physical Activity Questionnaire: 36-questions to assess typical physical activity, occupational activity, and home activity completed in the past trimester (approximately 12 weeks) listed by either hours/day or hours/week. This questionnaire will be completed at baseline (end of 1st trimester), end of 2nd & 3rd trimester, and 3- and 6-months post-delivery. Will take about 15 minutes to complete.

Short-Form 12 (SF-12) Health Survey: 12-questions to assess generic quality of life. This questionnaire will be completed at baseline (end of 1st trimester), end of 2nd & 3rd trimester, and 3- and 6-months post-delivery. Will take about 8 minutes to complete.

Pittsburgh Sleep Quality Index: 9-questions to assess usual sleep habits in the past month. This questionnaire will be completed at baseline (end of 1st trimester), end of 2nd & 3rd trimester, and 3- and 6-months post-delivery. Will take about 6 minutes to complete.

Multidimensional Fatigue Inventory (MFI): 20-questions to evaluate five dimensions of fatigue: general fatigue, physical fatigue, reduced motivation, reduced activity, and mental fatigue. This questionnaire will be completed at baseline (end of 1st trimester), end of 2nd & 3rd trimester, and 3- and 6-months post-delivery. Will take about 10 minutes to complete.

Edinburgh Post-Natal Depression Scale (EPDS): 10-questions that indicate whether a women has symptoms of depression and anxiety during pregnancy and in the year following the birth of a child. This questionnaire will be completed at baseline (end of 1st trimester), end of 2nd & 3rd trimester, and 3- and 6-months post-delivery. Will take about 5 minutes to complete.

Center for Epidemiologic Studies Depression Scale (CES-D): 20-questions comprising six scales reflecting major facets of depression: depressed mood, feelings of guilt and worthlessness, feelings of helplessness and hopelessness, psychomotor retardation, loss of appetite, and sleep disturbance. This questionnaire will be completed at baseline (end of 1st trimester), end of 2nd & 3rd trimester, and 3- and 6-months post-delivery. Will take about 10 minutes to complete.

The Bayley Scales of Infant Development, 4th edition (Bayley-4): will be utilized to monitor the infants' gross motor, fine motor and cognitive development. The Bayley-4 is a standardized, norm-referenced tool with subtest level scaled scores, domain level composite scores, percentile ranks, and developmental age equivalents.

Warning Signs to Stop Physical Activity (From American College of Obstetricians & Gynecologists)

1. Vaginal Bleeding or amniotic fluid leakage
2. Shortness of breath prior to exercise
3. Dizziness, feeling faint, of headache that does not resolve with rest
4. Chest pain
5. Muscle weakness
6. Calf pain or swelling
7. Decreased fetal movement
8. Preterm labor

Safety Precautions for prenatal Physical Activity (From American College of Obstetricians && Gynecologists)

1. Avoid physical activity in excessive heat, especially in high humidity
2. Avoid activities which involve physical contact or danger of falling

3. Avoid scuba diving
4. Avoid exercise at high altitude (>2500m)
5. Maintain adequate nutrition and hydration—drink water before, during and after physical activity
6. Do not hold your breath during strength training activities
7. Know the reasons to stop physical activity (listed above) and consult with your healthcare provider immediately.

Contact the investigator at the number on the 1st page if you experience any of the following:

1. Joint/muscle pain that persists after 4 days or increases in intensity.
2. Chronic fatigue that persists for 3 days.

What are your responsibilities if you take part in this research?

If you take part in this research, you will be responsible to:

- Follow your group assignment to the best of your ability
- Be honest when recording study activities
- Communicate with the investigators about any concerns or questions and about any changes to the exercise program or testing schedule
- Know the warning signs and precautions of when it is not safe for you to exercise

Could being in this research hurt you?

The most important risks or discomforts that you may expect from taking part in this research is muscle soreness or initial tiredness, especially if you have been inactive, that will go away after 7-10 days of regular exercise.

You could experience undesirable responses to exercise including: abnormal blood pressure; dizziness; and disorders of heart rhythm that can be minimized by stopping exercise and immediately informing your doctor of any unusual symptoms. You will be told to maintain a moderate exercise intensity which means you are able to have a conversation while exercising, in addition to monitoring exercise intensity with the Polar Ignite watch, to monitor your heartrate.

Will it cost you money to take part in this research?

There is no cost to take part in this research.

Will being in this research benefit you?

We cannot promise any benefits to you or others from your taking part in this research especially since this is a pilot study trying to determine if the study methods are appropriate for what we ultimately hope to test in a larger study. However, there are major benefits for exercising during

pregnancy that future work will hopefully demonstrate. One benefit of exercise during pregnancy is helping with weight control since excessive weight gain and inactivity are a risk factor for pregnancy complications including gestational diabetes, gestational hypertension, and macrosomia (large baby). Furthermore, exercise during pregnancy has been associated with a reduction in pre- and post-natal depression with mixed results for improvement in sleep quality, fatigue, and quality of life.

Besides being associated with higher Apgar scores (test to check a newborn's health), exercise during pregnancy has also been linked to decreased risk for childhood obesity and has been demonstrated to increase blood growth factors in the developing fetus which may have beneficial outcomes for brain health and cognitive performance. Infants of mothers who exercised during pregnancy demonstrated higher movement abilities at 1-month of age than infants of mothers who did not exercise.

What other choices do you have besides taking part in this research?

This research is not designed to diagnose, treat or prevent any disease. Your alternative is to not take part in the research.

What happens to the information collected for this research?

All information collected during this study will be stored in a locked file cabinet in a locked office at the IHP.

Data collected in this research might be de-identified and used for future research or distributed to another investigator for future research without your consent.

Who can answer your questions about this research?

Contact the investigators at the phone number listed above on the first page if you have questions or concerns of any type, including but not limited to:

- Any questions regarding the strength training or aerobic activity program
- Any questions on the warm-up and cool-down exercises
- Any questions about the Polar Ignite watch operation during physical activity, sleep monitoring, or charging
- If you experience any unusual symptoms that do not require immediate medical attention

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (315) 464-4317 if:

- You have questions, concerns, or complaints that are not being answered by the research team.

- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

What if you are injured because of taking part in this research?

In the event of a research related injury, treatment is available at University Hospital but is not free of charge. The costs will be billed to you or your insurance company in the usual fashion. SUNY Upstate Medical University has no funds set aside to compensate you for injuries. You have not waived any of your legal rights by signing this form.

Can you be removed from this research without your approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- You have a side effect that requires stopping the research
- Your health care provider decides you should be withdrawn
- You are unable to keep your scheduled appointments

We will tell you about any new information that may affect your health, welfare or choice to stay in this research.

What happens if you agree to be in this research, but you change your mind later?

If you decide to leave this research, contact the research team so that the investigator can cancel all remaining appointments and notify your obstetrician.

Will you be paid for taking part in this research?

You will be compensated for your parking and in appreciation of your time as follows:
If you complete the whole study:

- Usual care group (UC): $24 for parking and $90 in appreciation for time
- Home exercise group (HOMEEX): $24 for parking and $90 in appreciation for time
- Supervised exercise group (EX): $880 for parking and $1100 in appreciation for time

Payments will be made as follows: The UC and HOMEEX groups will be paid at each home or IHP visit. The EX group will be paid monthly.

If you do not complete the entire study for whatever reason, you will be paid for the visits that were completed as follows: $4-8 for parking for each visit (depending on time at the IHP); $10 for time for each visit (IHP and Home visits).

By accepting payment for participating in this study, identifying information about you (such as your full name and social security number) needs to be collected and may be shared with auditors and the finance office to ensure compliance with Internal Revenue Service (IRS) requirements. If you do not want to provide this information for payment reasons, you have the option to decline the payment and still participate in the study. Please note that if you earn $600 or over in a calendar year as a research subject, you may have to pay taxes on these earnings. Information provided for payment purposes will be kept confidential.

Confidentiality of records and authorization to use/share protected health information for research:

If you agree to participate in this research, identifiable health information about you will be used and shared with others involved in this research. For you to be in this research we need your permission to collect and share this information. Federal law protects your right to privacy concerning this information.

When you sign this consent form at the end, it means that you have read this section and authorize the use and/or sharing of your protected health information as explained below. Your signature also means you have received a copy of Upstate's Notice of Privacy Practices.

Individually identifiable health information under the federal privacy law is considered to be any information from your medical record, or obtained from this study, that can be associated with you, and relates to your past, present, or future physical or mental health or condition. This is referred to as protected health information.

Your protected health information will be kept confidential. Your identity will not be revealed in any publication or presentation of the results of this research.

Why is it necessary to use/share your protected health information with others?
The main reason to use and share your health information is to conduct the research as described in this consent form. Your information may also be shared with people and organizations that make sure the research is being done correctly, and to report unexpected or bad side-effects you may have.

In addition, we may be required by law to release protected health information about you; for example, if a judge requires such release in a lawsuit, or if you tell us of your intent to harm yourself or others.

What protected health information about you will be used or shared with others as part of this research?
We may use and share the results of tests, questionnaires, and interviews. We may also use and share information from your medical and research records.
We will only collect information that is needed for the research.

Who will be authorized to use and/or share your protected health information?
The researchers, their staff and the staff of Upstate Medical University participating in the research will use your protected health information for this research study. In addition, the

Upstate Institutional Review Board (IRB), a committee responsible for protecting the rights of research subjects, and other Upstate Medical University or University Hospital staff who supervise the way the research is done may have access to your protected health information.

The researchers and their staff will determine if your protected health information will be used or shared with others outside of Upstate Medical University for purposes directly related to the conduct of the research.

With whom would the protected health information be shared?
Your protected health information may be shared with:

- Your Health care provider (for example, your obstetrician);
- Federal agencies that supervise the way the research is conducted, such as the Department of Health and Human Services' Office for Human Research Protections, or other governmental offices in the US or other countries, as required by law.

All reasonable efforts will be used to protect the confidentiality of your protected health information. However, not all individuals or groups have to comply with the Federal privacy law. Therefore, once your protected health information is disclosed (leaves Upstate Medical University), the Federal privacy law may not protect it.

For how long will your protected health information be used or shared with others?
There is no scheduled date at which this information will be destroyed or no longer used. This is because information that is collected for research purposes continues to be used and analyzed for many years and it is not possible to determine when this will be complete.

Can you withdraw your authorization to collect/use/share your protected health information?
You always have the right to withdraw your permission (revoke authorization) for us to use and share your health information, by putting your request in writing to the investigator in charge of the study. This means that no further private health information will be collected. Once authorization is revoked, you may no longer participate in this research activity, but standard medical care and any other benefits to which you are entitled will not be affected. Revoking your authorization only affects uses and sharing of information obtained after your written request has been received, but not information obtained prior to that time.

Even after you withdraw your permission, Upstate Medical University may continue to use and share information needed for the integrity of the study; for example, information about an unexpected or bad side effect you experienced related to the study.

Can you have access to your health information?
At the end of the study, you have the right to see and copy health information about you in accordance with the SUNY Upstate Medical University policies; however, your access may be limited while the study is in progress.

Statement of Consent to Participate in Research & Authorization to use and share personal health information

- Participation in this study is entirely voluntary. You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you agree to take part and later change your mind, there will be no penalty or loss of benefits to which you are otherwise entitled.
- I have read this information and this study has been explained to me.
- The consent is written in a language that I understand.
- All my questions about the study have been answered to my satisfaction.

I hereby give my consent for to participate in this research study and agree that my personal health information can be collected, used and shared by the researchers and staff for the research study described in this form. I will receive a signed copy of this consent form.

I have also agreed to have my child participate in the research study. I also agree that my child's personal health information can be collected, used and shared by the researchers and staff for the research study described in this form.

_____ _____
Signature of subject/parent of child Date

_____ _____
Signature of Person Obtaining Consent/Authorization Date

_____
Name of Person Obtaining Consent/Authorization