PARENTAL PERMISSION FORM
CONSENT FORM: Ages 18 and up

Study Title: PLAY 2 (Preschoolers Learning and Active in PLAY)

Principal Researcher: Pooja S. Tandon

The Research Team:

<table>
<thead>
<tr>
<th>Name/Degree</th>
<th>Title</th>
<th>Department</th>
<th>Phone Number</th>
<th>E-mail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pooja S. Tandon</td>
<td>MD, MPH</td>
<td>Pediatrics</td>
<td>206-884-1130</td>
<td><a href="mailto:Pooja@uw.edu">Pooja@uw.edu</a></td>
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<tr>
<td>Albert Hsu</td>
<td>Research Associate</td>
<td>Pediatrics</td>
<td>206-884-7563</td>
<td><a href="mailto:Albert.hsu@seattlechildrens.org">Albert.hsu@seattlechildrens.org</a></td>
</tr>
<tr>
<td>Amanda Marchese</td>
<td>Research Associate</td>
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</tr>
</tbody>
</table>

If you have questions about your rights as a research study participant, you can call the Institutional Review Board at (206) 987-7804.

1. Researchers’ Statement:

You have the option to take part in a research study. The goals of this form are to give you information about what would happen in the study if you choose to take part and to help you decide if you want to be in the study.

Feel free to take notes, write questions or highlight any part of this form.

Potential Participants 18 years and older: This is a consent form. It provides a summary of the information the research team will discuss with you. If you decide that you would like to take part in this research study, you would sign this form to confirm your decision. If you sign this form, you will receive a signed copy of this form for your records.

Parents/Guardians: You have the option of having your child or teen join a research study. This is a parental permission form. It provides a summary of the information the research team will discuss with you. If you decide that your child can take part in this study, you would sign this form to confirm your decision. If you sign this form, you will receive a signed copy for your records.

The word “you” in this form may refer to you and/or your child.
2. What you should know about this study:

- This form explains what would happen if you join this research study.
- Please read it carefully. Take as much time as you need.
- Please ask the research team questions about anything that is not clear.
- You can ask questions about the study any time.
- If you choose not to be in the study, it will not affect your care at Seattle Children's.
- If you say ‘Yes’ now, you can still change your mind later.
- You can quit the study at anytime.
- You would not lose benefits or be penalized if you decide not to take part in the study or to quit the study later.

3. What is the goal of this study?

The goal of any research study is to answer questions. We (the research team listed on the front of this form and our staff) are doing this research study to answer 3 questions:

- How well does a physical activity program that includes a wrist-worn activity tracker work with preschool children?
- Does participating in the program increase students’ physical activity?
- How well does the wrist-worn activity tracker work compared to a hip-worn activity meter?

4. Why do I have the option of joining the study?

You have the option to take part in this research study because you have a child that attends a child care center where we are doing this study.

5. How many people will take part in the study?

We think that about 180 students, 120 parents, and 48 teachers will take part in this research study over 2 years.
6. If I agree to join this study, what would I need to do?

Your child’s center will be randomly selected to one of three groups – group 1, group 2, group 3. Some centers will be in Phase 1 and participate right away; other centers will be in Phase 2 and participate during the 2nd years of the program.

For groups 1, 2, and 3:
Your child would be asked to:
- Wear a wrist-worn activity tracker for the duration of the program (6 months).
- At 3 time points (beginning, month 1, and month 6) during the study, wear a hip-worn activity meter for 1 week in addition to the wrist band.

You would be asked to:
- Fill out a survey in the beginning and at the end of the study. You have the option of completing the surveys on paper or electronically.
- Receive weekly text messages which give you tips and ideas (you can always opt out at any time)
- Some parents will also be asked to wear a wrist activity tracker (Groups 2 & 3 only).
- Have the option of using the Garmin Connect smartphone application to sync your child’s wrist band and/or view your or your child’s physical activity.
- During weeks wear your child is wearing the hip-worn activity meter, record the times your child takes off and puts on the meter.

Phase 2 group
This year:
- At 3 time points (beginning, month 1, and month 6) your child will be asked to wear a hip-worn activity meter for 1 week
- You will be asked to complete two surveys

Next year: Your child’s center will be randomly assigned to group 1, group 2, or group 3.

Explanation of Research Tests or Procedures:
- Wrist Activity Tracker (Garmin Vivofit3)
  A small, light, battery powered band, similar to a Fitbit or small watch that is worn on your or your child’s wrist. It measures your activity using steps and minutes of activity.

- Hip Activity Meter (Accelerometer)
  A small, light, electronic device that worn by your child on a belt, it is smaller than the size of a pager and measures body movements.
7. How long would I be in the study?

If you choose to take part in all the study visits, you would be in the study for 6 months (or 18 months if your child’s center is selected to Phase 2). We may monitor the Garmin Connect application in the 6 months following the study to see if your child continues to use the activity tracker after your participation concludes.

If you join the study, you can decide to stop at anytime and for any reason. If you decided to stop, please let the researchers know. We may ask about your decision to leave the study and ask some follow up questions about your experiences to improve studies in the future.

8. What are the potential harms or risks if I join this study?

- You may feel uncomfortable having your child’s activity monitored. We have worked with experienced professionals to help make the study an engaging and positive experience for students. Activity goals will be group based and we will not encourage any direct competition between students.
- The wrist activity tracker and hip activity meter are small, lightweight electronic devices that are designed to be worn over long periods of time by children and adults. Some people may feel slightly uncomfortable wearing the devices for long periods of time.
- Some people may feel that wearing an activity meter is an invasion of privacy.
- Some participants may feel embarrassed if their devices are seen or questioned by others.

9. What are the potential benefits if I join this study?

**Potential Benefits for You:**

- You may become more aware of your child’s physical activity levels
- You or your child may engage in more physical activity
- You or your child may learn about how physical activity is good for health and well-being

**Potential Benefits for Others:**

We hope to use information we get from this study to learn about how to best design programs to help increase physical activity and wellness in child care centers.
10. What other options do I have?

The alternative to participating in this study is to not take part. All children will be provided the wrist activity tracker at your center. If you choose not to take part your child can still wear the wrist activity tracker but no research data will be collected on your child. If you prefer that your child not use a tracker, the center will keep the tracker for future use.

11. What about confidentiality and privacy?

If you join the study, we will keep your information confidential as provided by law.

This information may include things like:

- Past or future medical records,
- Research records, such as surveys, questionnaires, interviews, or self-reports about medical history
- Medical or laboratory records related to this study, and
- Information specific to you like your name, address, or birthday

This information may be used by or shared with:

- Researchers (such as doctors and their staff) taking part in this study here and at other centers,
- Research sponsors – this includes any persons or companies working for, with, or owned by the sponsor,
- Review boards (such as Seattle Children's Institutional Review Board), data and safety monitoring boards, and others responsible for watching the conduct of research (such as monitors),
- Governmental agencies like the U.S. Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS), including similar agencies in other countries, and
- Public health authorities to whom we are required by law to report information for the prevention or control of disease, injury, abuse, or disability.
- If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

This information may be used or shared to:

- Complete and publish the results of the study described in this form,
- Study the results of this research,
- Check if this study was done correctly, and
- Comply with non-research obligations (if we think you or someone else could be harmed).
Researchers continue to analyze data for many years, and it is not always possible to know when analysis will be done. If your information is banked as part of this study, it may be used in the future for other research. We would not ask for your permission prior to this future research.

If the results of the study are published, information that identifies you would not be used.

CERTIFICATE OF CONFIDENTIALITY

We have a Certificate of Confidentiality from the federal government. It means we can't be forced to give out information about you if you take part in this study. This is true even if we are asked to by a court of law. It's not likely that someone would ask us to give out your personal information but this Certificate helps protect it. However, there are times when we would still need to share information about you.

Even with the Certificate, your information could still be given out under these situations:

- Federal agencies, like the FDA, may review study records
- Seattle Children's or the funding agency may look at study records to make sure the study is being done well
- You or a family member could share information about you or your part in this research study
- You give written permission to an insurer, employer or other person to receive information about you
- We must report child abuse or if you intend to hurt yourself or others

12. Would it cost me money to be in the study?

If you take part in this study, there would be no cost to you and no cost to your insurance company. If you choose to receive texts from the study, standard messaging rates would apply.

13. What if I were injured because I joined the study?

We do not anticipate that any study procedures will cause you or your child to be injured.

If you think you have been harmed from this study, please contact Pooja Tandon (phone 206-884-1130 or pooja.tandon@seattlechildrens.org).

14. Would I be paid if I join this study?

Your family will receive a $10 gift card for wearing the accelerometer for 1 week at the start of the study, $20 for wearing the accelerometer for 1 week during month 1 of the study, and $30...
for wearing the accelerometer for 1 week during month 6. If your center is in Phase 2, you will get the gift cards in the first and second years. Your child can also keep the activity tracker after the study is over. If you are one of the parents asked to wear an activity tracker for the study, you get to keep your band also after the study is over.

15. Who do I contact if I have problems, questions or want more information?

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<th>If I have questions or would like to know about …</th>
<th>You can call …</th>
<th>At …</th>
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<tbody>
<tr>
<td>Emergencies</td>
<td>Pooja Tandon</td>
<td>Phone: 206-884-1130</td>
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<td>General study questions</td>
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<td>Any research concerns or complaints</td>
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<tr>
<td>Emergencies</td>
<td>Albert Hsu</td>
<td>Phone: 206-884-7563</td>
</tr>
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<td>Your rights as a research participant</td>
<td>Institutional Review Board</td>
<td>Phone: (206) 987-7804</td>
</tr>
<tr>
<td>Study questions, concerns or complaints.</td>
<td>This is a group of scientists and community members who make sure research meet legal and ethical standards.</td>
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<tr>
<td>Contacting someone outside of study team</td>
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16. If I join the study, can I stop?

Yes. Taking part in research is always voluntary. If you decide to be in the study, you can change your mind at any time. We ask that you tell Albert Hsu if you decide to leave the study. You can contact this person by phone at 206-884-7563 or e-mail at Albert.hsu@seattlechildrens.org.

If you choose to leave the study, it will not affect your care at Seattle Children’s Hospital. You will not lose any benefits or be penalized if you choose to leave the study.

17. What would my signature on this form mean?
Your signature on this form would mean:

- The research study was explained to you.
- You had a chance to ask all the questions you have at this time. All your questions have been answered in a way that is clear.
- You understand that the persons listed on this form will answer any other questions you may have about the study or your rights as a research study participant.
- You have rights as a research participant. We will tell you about new information or changes to the study that may affect your health or your willingness to stay in the study.
- By signing this consent form, you do not give up any of your legal rights. The researcher(s) or sponsor(s) are not relieved of any liability they may have.
  - You agree to take part in the research study.
  - If the person reading this form is a parent/guardian, you agree to have your child take part in this research study.

Please Note: If the person taking part in this research study is a foster child or a ward of the state, then please tell the researcher or their staff.

Signature of Research Participant (required if 13 years or older)

Printed Name of Research Participant

Printed Name of Parent or Legally Authorized Representative

Signature of Parent or Legally Authorized Representative

Date ______________ Time ______________

18. Researcher’s Signature
I have fully explained the research study described by this form. I have answered the participant and/or parent/guardians questions and will answer any future questions to the best of my ability. I will tell the family and/or the person taking part in this research of any changes in the procedures or in the possible harms/possible benefits of the study that may affect their health or their willingness to stay in the study.

__________________________
Printed Name of Researcher Obtaining Parental Permission or Consent

__________________________
Signature of Researcher Obtaining Parental Permission or Consent

Date _____________________
Time ______________________

Contact Information

Part of the program includes weekly texts from the PLAY team, check this box if you decline getting text messages. Standard rates may apply for the texts.

☐ Cell Phone: __________________________

☐ E-mail: __________________________

You may opt out of this anytime by e-mailing albert.hsu@seattlechildrens.org or calling (206)884-7563.

Original form to: Research Team File

Copies to: Participant