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Consent to Participate in a Research Study

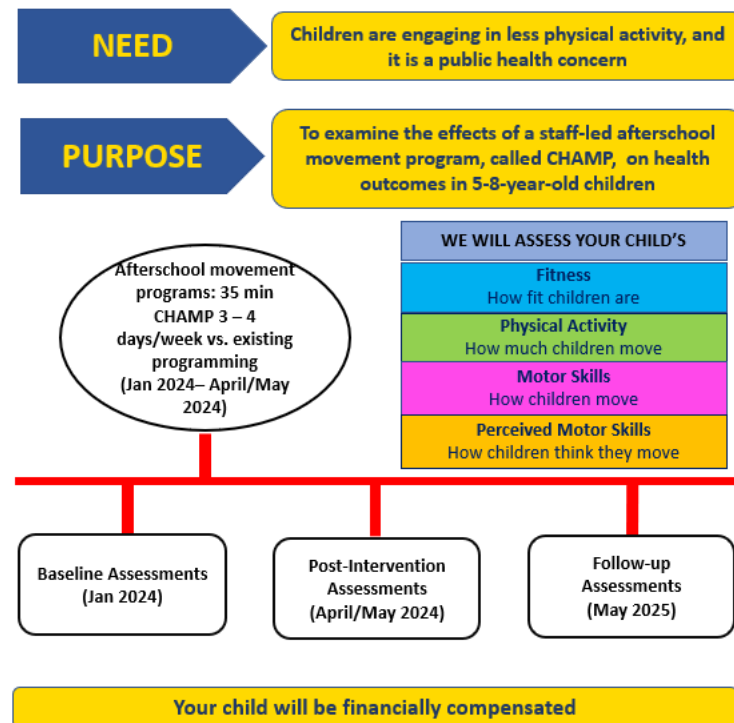
Title of the Project: The CHAMP Afterschool Program: Promoting Physical Activity & Health in Children
Principal Investigators: Leah E. Robinson, Ph.D., University of Michigan, School of Kinesiology
 Karin Pfeiffer, Ph.D., Department of Kinesiology, Michigan State University
Co-investigators: Lu Wang, Ph.D., University of Michigan, School of Public Health
 Nicholas Meyers, Ph.D., Department of Kinesiology, Michigan State University

Invitation to Participate in a Research Study

We invite your child to participate in a research study funded by the National Institutes of Health that examines the effects of a staff-led afterschool movement program on health outcomes in children. Researchers from Michigan State University are part of this federally funded project and will be participating in all aspects of this study, including data collection of the measures listed below (items 1 – 9). They will also oversee and analyze the physical activity data that are collected in the project (item 2).

Study Overview

Afterschool programs will be assigned to 1 of 2 movement programs, the **Children's Health Activity Motor Program – Afterschool Program (CHAMP-ASP)** or **control (regularly scheduled/standard of practice within their existing ASP)**. The ASP movement programs will last for 10 -12 weeks (35 - 40 minutes/2 -3 days per week). If you agree to have your child



Your child will be financially compensated

participate in the study, we will assess their: **motor skills, physical activity, perceived motor skills, and fitness levels** prior to the start of the program, during, immediately following the program, and 1-year after the study. All tests, except for physical activity, will be collected in small groups during the afterschool program over 4 days and will last less than 30 minutes.

These measures will be assessed for the study:

1. **Motor skills** will be measured with the Test of Gross Motor Development to assess your child's performance in the following skills - run, skip, jump, hop, leap, gallop, slide, roll, throw, catch, strike, bounce/dribble, and kick. We will also measure his/her throwing speed, kicking speed, jump distance, running speed, and hopping speed. Motor skills assessments require us to video record your child's performance that will be viewed and scored at a later time by researchers in a secured lab. Motor skills will be measured at baseline, post-intervention, and at the follow-up assessment.
2. **Physical activity** will be measured with an accelerometer, called an Actigraph. An Actigraph is a small, lightweight water-resistant device that will be attached to your child's wrist (non-writing hand) for 7 days. The monitor records the amount of time your child spends in physical activity. Parents are not financially responsible for devices that are not returned (lost) or broken, but attempts will be made to find the lost device. If a device is not returned children will not participate in the future round of physical activity monitoring. Physical activity will be measured at baseline, post-intervention, and

follow-up assessments. It will also be assessed at various time points during the CHAMP program if your child's site participates in the program.

3. **Perceived motor skills** will be measured with the a) Harter and Pike Pictorial Scale of Perceived Motor Competence and Social Acceptance and the b) Perceived Fundamental Motor Skill Competence Video-based Scale. For both assessments, children will see 2 static pictures and/or video clips of a child engaged in a motor-related task – one image shows a highly competent/skilled child and the other image shows a not a highly competent/skilled child. This child is asked to select the image that most resembles them. Perceived motor skills will be measured at baseline, post-intervention, and follow-up assessments.
4. **Fitness** will be assessed with cardiorespiratory endurance and upper body strength. Specifically, children will complete a 6-min walk test (i.e., measure the overall distance walked) for their cardiorespiratory endurance and will squeeze a handgrip dynamometer in both the right and left hand to measure upper body strength. Fitness will be measured at baseline, post-intervention, and follow-up assessments.
5. **Body composition.** Your child will stand on a standard height and weight scale to measure their height and weight. Percent body fat collected with a Tanita (e.g., bioelectric impedance analysis) scale. Body composition will be measured at baseline, post-intervention, and follow-up assessments.
6. **CHAMP-ASP Acceptability Questionnaire.** Children will complete an acceptability survey to provide information on how they like participating in the CHAMP-ASP program. The CHAMP-ASP Acceptability Questionnaire consists of 6 questions about the program's features such as children's autonomy to determine for how long they want to be doing the selected activity and how the ASP staff provided them feedback. For each question, the child will answer with yes or no. The CHAMP-ASP Acceptability Questionnaire will be completed at post-intervention.
7. **Social-Emotional Well-being.** Parents will be asked to complete the 25-item Strength and Difficulties Questionnaire (SDQ) to provide information on their child's emotional and behavioral health. The SDQ has a three response category from zero to two (not true, somewhat true, and certainly true). The assessment will be completed at baseline, post-intervention, and follow-up assessments.
8. **Family Questionnaire.** During the consenting process, you will be asked to complete a family questionnaire to provide us with some additional information regarding the home environment, family structure, physical activity behaviors, sleeping behaviors, and screen time habits that could help to inform our findings. Fully completed questionnaires will be entered in a drawing to win one of eight \$25.00 cash awards. The family questionnaire will be measured at baseline.
9. **Sleep Reporting.** Parents will receive a morning daily text message during the seven days your child will be wearing the accelerometer. We will ask you to respond to 2 questions: 1) what time did your child go to bed? and 2) what time did your child wake up? Note, you will not incur any charges for these text messages.

Benefits of Participation

Although your child may not directly benefit from being in this study other than the health benefits of engaging in more physical activity, others may benefit because findings will contribute to science and answer novel questions linking motor skills to physical activity. Parents will receive a yearly report regarding their child's assessment findings.

Risks and Discomforts of Participation

We have taken steps to minimize any risks for the study. Risks include common play injuries that young children might experience when playing on a playground or outside. There is a potential risk (i.e., skin irritation) to children while wearing the physical activity monitors on the wrist. To eliminate the risk of this irritation, children should continue to bath/shower as normal while wearing the physical activity monitors. Upon request, a fabric / elastic type band will be provided to children.

Compensation for Participation

The following compensation will be provided: a) Parent/guardian upon returning the IRB consent letter, will be compensated for your time and will receive a one-time \$5.00 cash incentive, regardless of consent to participate in the study. b) Children (treatment and control) in this research project, will receive a cash incentive of \$10.00 upon the return of the physical activity device **AND** completing the assessments at baseline, \$20.00 upon the return of the physical activity device **AND** completing the assessments at post-intervention, and \$30.00 upon the return of the physical activity device **AND** completing the assessments at the 1-yr follow-up. If a participant only completes one (1) of the noted activities (i.e., return physical activity device **OR** complete the assessments) at baseline, post-intervention, and/or follow-up, they will only receive 50% of the compensation (i.e., \$5.00 at baseline, \$10.00 at post-intervention, \$15.00 at 1 yr-follow-up), and d) Completed Family Questionnaires will be entered into a drawing to win 1 of 8, \$25.00 cash drawings. Early withdrawal from this study will forfeit future compensation.

Confidentiality

Findings will be published from this study and will not include any information that would identify your child. Data from this study will be used for educational and research purposes, and children's performance/responses will be reported as group results. Your child's privacy will be protected and all records will be confidential. To preserve confidentiality, all children will receive an identification number for data collection purposes. However, video data (i.e., digital recordings) could result in a potential breach of confidentiality. Video data will only be reviewed by the research team and stored on a university-secured password-protected computer. Only the study team and individuals with oversight of research responsibilities may have access to the research records.

This research holds a Certificate of Confidentiality from the National Institutes of Health. This means that we cannot release or use information, documents, or samples that may identify you or your child in any action or suit except as described below. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings. An example of a situation in which the Certificate would apply would be a court subpoena for research records.

There are some important things that you need to know:

- The Certificate does not stop reporting of suspected abuse or neglect of a child or vulnerable adult, some communicable diseases, and/or suspected risk of substantial harm to self or others.
- The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.
- We may, but are not required to, also release information about you to others when you say it is okay. For example, you may give us permission to release information to insurers, medical providers, or anyone else.
- The Certificate of Confidentiality does not stop you from personally releasing information about your involvement in this research if you wish.

More information about Certificates of Confidentiality and the protections they provide is available at <https://grants.nih.gov/policy/humansubjects/coc/what-is.htm>

Storage and Future Use of Data

Data will be stored on university-secured password-protected computers and kept in a locked file cabinet located in a key code access laboratory (Child Movement, Activity, and Developmental Health Lab) in School of Kinesiology Building Suite 1000, Room 1084. Physical activity de-identified data will be stored on a university-secured password-protected computers located in a key code access laboratory in the Department of Kinesiology at Michigan State University (Kids At Play Lab, IM Sports Circle 308 W Circle Dr, East Lansing, MI 48824). **All data will be retained for future research use and we will re-contact you to complete follow-up assessments on your child.** No identifiable data will be shared with any outside entity. Any hard copy of data (i.e., paper) will be shredded 8 years after the completion of the study.

Voluntary Nature of the Study

Participating in this study is completely voluntary. Even if you/your child decide to participate now, you/your child may change your mind and stop at any time. Your decision whether or not to allow your child to participate will not jeopardize his/her future relationship with the University of Michigan, Michigan State University, or his/her current educational institution. If you decide to withdraw before this study is completed, your child's data will still be used.

Contact Information for the Study Team

If you have questions about this study (e.g., assessments, compensation, etc), please contact the Child Movement, Activity, and Developmental Health Laboratory at 734-647-8983/tannazs@umich.edu (Tannaz Sabet, Research Coordinator), 734-647-0284/palmerka@umich.edu (Dr. Kara Palmer, Lead Research Scientist), 734-647-7645/lerobin@umich.edu (Dr. Leah Robinson, Principal Investigator).

Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the University of Michigan Health Sciences and Behavioral Sciences Institutional Review Board, 2800 Plymouth Rd., Bldg. 520, Room 1169, Ann Arbor, MI 48109-2800, (734) 936-0933, irbhsbs@umich.edu.

Clinical Trial

This study is registered as a Clinical Trial and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials. However, no individually identifiable data is included in the registration or results reporting. A description of this clinical trial will be available on <http://www.clinicaltrials.gov/>. This Website will not include information that can identify you *or your child*. At most, the Web site will include a summary of the results.

PLEASE PROCEED TO THE NEXT PAGE FOR CONSENTING PROCESS ITEMS.

