

## Study Record: PHS Human Subjects and Clinical Trials Information

Please complete the human subjects section of the Research & Related Other Project Information form prior to completing this form.

The following items are taken from the Research & Related Other Project Information form and displayed here for your reference. Any changes to these fields must be made on the Research & Related Other Project Information form and may impact the data items you are required to complete on this form.

Are Human Subjects Involved	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Is this Study Exempt from Federal Regulations?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Exemption Number:	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8

### If No to Human Subjects

Does the proposed research involve human specimens and/or data? ☐ Yes ☐ No

If Yes, provide an explanation of why the application does not involve human subjects research.

Skip the rest of the PHS Human Subjects and Clinical Trials Information Form.

### If Yes to Human Subjects

Add a record for each proposed Human Subject Study by selecting 'Add New Study' or 'Add New Delayed Onset Study' as appropriate. Delayed onset studies are those for which there is no well-defined plan for human subject involvement at the time of submission, per agency policies on Delayed Onset Studies. For delayed onset studies, you will provide the study name and a justification for omission of human subjects study information.

### Other Requested Information

### Study Record(s)

InPACT

### Delayed Onset Study(ies)

## Study Record: PHS Human Subjects and Clinical Trials Information

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### Section 1 - Basic Information

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**1.1. \* Study Title (each study title must be unique)**

InPACT

**1.2. \* Is this Study Exempt from Federal Regulations?** [ ] Yes [X] No

**1.3. Exemption Number** [ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5 [ ] 6 [ ] 7 [ ] 8

**1.4. \* Clinical Trial Questionnaire**

If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial.

**1.4.a. Does the study involve human participants?** [X] Yes [ ] No

**1.4.b. Are the participants prospectively assigned to an intervention?** [X] Yes [ ] No

**1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?** [X] Yes [ ] No

**1.4.d. Is the effect that will be evaluated a health-related, biomedical, or behavioral outcome?** [X] Yes [ ] No

**1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable**

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### Section 2 - Study Population Characteristics

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**2.1. Conditions or Focus of Study**

Twenty high-and 20 low-socioeconomic schools will be randomized into one of two treatment arms: 1) InPACT, a classroom-based physical activity intervention with family educational nights and community-based physical activity programming; or 2) control.

**2.2. Eligibility Criteria**

Schools will be eligible to participate in this study based on their willingness to accept assignment to a treatment or control, and if they match our high/low socioeconomic definitions. High-socioeconomic schools will be defined as less than or equal to

**2.3. Age Limits**      **Minimum Age**      8      Years      **Maximum Age**      10      Years

**2.4. Inclusion of Women, Minorities, and Children**      Women, Minorities, and Children

**2.5. Recruitment and Retention Plan**      Recruitment and Retention Plan

**2.6. Recruitment Status**      Not yet recruiting

**2.7. Study Timeline**      Study Timeline

**2.8. Enrollment of First Subject**      08/01/2019      Anticipated

**Inclusion Enrollment Report(s)**

ID000000049

## **INCLUSION OF WOMEN AND MINORITIES**

Equal numbers of boys and girls will be recruited for this study. This study exclusively focuses on children hence; adult women will not be included in this study. Because physical inactivity is particularly prevalent among ethnic minority groups, with low-income African Americans constituting the largest “at-risk” minority population in the Ann Arbor, Ypsilanti, and Wayne Westland area we have ensured that these populations are appropriately represented in our study.

## **INCLUSION OF CHILDREN**

This study will be conducted exclusively in children ages approximately 8-10 years. Younger children will be excluded because some of the proposed measures (i.e., questionnaires) may not be appropriate in younger children. This study will be conducted exclusively in children because evidence suggests the prepubescent period represents an age when preferences and motivations for physical activity are established as well as a period when peak weight velocity occurs. Also, some evidence suggests that early physical activity interventions may be more successful in the long-term prevention of obesity-related diseases including some cancers. Members of the investigation team (Principal Investigator: Hasson; Co-I's: Colabianchi, Vance, Reischl, and Eagle, and other study personnel: Stockdill, Malinoff, Bartholomew) have several years of experience working with children and adolescents.

## **RECRUITMENT AND RETENTION**

We will enroll 40 schools (6 classrooms per site, 20 children per classroom) with a total of approximately 4,800 students in the third and fourth grade, all of whom will be distributed across the three school districts. The superintendents from all three school districts support this project (see attached letters): Ann Arbor School District, Wayne-Westland School District, Ypsilanti Community School District. Study enrollment will begin after receiving human subjects approval from the Institutional Review Board for Research Involving Human Subjects. After schools have confirmed their interest in participation and schools are randomized to either control or InPACT conditions, a team of research staff will visit each school on multiple days and present the study to the children in a way that is easy for them to understand. Children will be encouraged to ask questions. A letter and parent/guardian informed consent will be sent home to obtain permission for children to participate in this study. Child assent will also be obtained. Additionally, research staff will stay after school to talk to parents when they pick up their children. Members of the research team will answer any questions that parents have. Only members of the research team, not teachers will handle the informed consent process.

All children in InPACT schools who meet the inclusion/exclusion criteria will have the opportunity to participate in this study. Co-I Eagle's previous school-based research demonstrate high participation rate among students in participating schools (75%) with an attrition rate (25% attrition rate per year over a 1 year period). Therefore, we are confident in our ability to obtain and maintain our targeted N with a 25% oversample. Our team has extensive experience working with schools and we do not foresee difficulties in enrolling this number of schools and/or student participants (see investigators' previous work and letters of support).

## Study Timeline

	Year 1				Year 2				Year 3				Year 4				Year 5			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Formative work (Submit IRB, train teachers, InPACT and reserch staff)	X	X	X	X																
Recruitment Wave & Consenting Process (Cohort 1)		X	X																	
Recruitment Wave & Consenting Process (Cohort 2)						X	X													
Recruitment Wave & Consenting Process (Cohort 3)										X	X									
Baseline assessment (Cohort 1)				X	X															
Baseline assessment (Cohort 2)								X	X											
Baseline assessment (Cohort 3)												X	X							
Treatment/Control (Cohort 1)				X	X	X	X	X												
Treatment/Control (Cohort 2)								X	X	X	X	X								
Treatment/Control (Cohort 3)												X	X	X	X	X				
Post-Intervention assessment (Cohort 1)							X													
Post-Intervention assessment (Cohort 2)											X									
Post-Intervention assessment (Cohort 3)															X					
3-Month Follow-up (Cohort 1)								X												
3-Month Follow-up (Cohort 2)												X								
3-Month Follow-up (Cohort 3)																X				
Data processing					X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Data analysis								X	X	X	X	X	X	X	X	X	X	X	X	X
Manuscript development													X	X	X	X	X	X	X	X

(Note: Q1 = Oct - Dec, Q2 = Jan - Mar, Q3 = Apr - Jun, Q4 = Jul - Sept)

# PHS Inclusion Enrollment Report

## (ID00000049)

1. \* Using an Existing Dataset or Resource      ☐ Yes      ☒ No
2. \* Enrollment Location      University of Michigan will enroll students from 3 school districts in SE Michigan
3. Enrollment Country(ies)  
USA: UNITED STATES
4. Enrollment Location(s)  
University of Michigan will enroll students from 3 school districts in SE Michigan
5. Comments:

### Planned

Racial Categories	Ethnic Categories				
	Not Hispanic or Latino		Hispanic or Latino		Total
	Female	Male	Female	Male	
American Indian/ Alaska Native	24	24	0	0	48
Asian	270	270	0	0	540
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	864	864	0	0	1728
White	990	990	84	84	2148
More than One Race	168	168	0	0	336
<b>Total</b>	2316	2316	84	84	4800

**Cumulative (Actual)**

[illegible]

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### Section 3 - Protection and Monitoring Plans

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#### 3.1. Protection of Human Subjects      Protection of Human Subjects

**3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?**

☐ Yes   ☒ No   ☐ N/A

**If yes, describe the single IRB plan**

#### 3.3. Data and Safety Monitoring Plan      Data Safety Monitoring Plan

**3.4. Will a Data and Safety Monitoring Board be appointed for this study?**

☒ Yes   ☐ No

#### 3.5. Overall Structure of the Study Team      Overall Structure of Study Team

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### Section 4 - Protocol Synopsis

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#### 4.1. Brief Summary

Physical inactivity in pediatric populations is a top public health concern with less than one in five children amassing the recommended 60 minutes of daily activity. Socioeconomically disadvantaged children have the highest rates of inactivity, a dispari

#### 4.2. Study Design

##### 4.2.a. Narrative Study Description

Study Design. We propose a cluster randomized trial, in which 20 high-socioeconomic and 20 low-socioeconomic (SES) schools in southeast Michigan will be randomized into one of two treatment arms: 1) InPACT; or 2) control. We will define High-SES schools a

##### 4.2.b. Primary Purpose      Prevention

##### 4.2.c. Interventions

Intervention Type: Behavioral (e.g., Psychotherapy, Lifestyle Counseling)  
Intervention Name: InPACT  
Intervention Description: Classroom based physical activity intervention where teachers will implement 5, 4-minute moderate-to-vigorous physical activity breaks throughout the school day during the academic year. Students and their families will also participate in InPACT family education nights and community physical activity events throughout the calendar year.

##### 4.2.d. Study Phase      Other

**Is this an NIH-defined Phase III clinical trial?**   ☐ Yes   ☒ No

##### 4.2.e. Intervention Model      Parallel

##### 4.2.f. Masking      ☐ Yes   ☒ No

☐ Participant   ☐ Care Provider   ☐ Investigator   ☐ Outcomes Assessor

##### 4.2.g. Allocation      Randomized

#### 4.3. Outcome Measures

Prevention

#### 4.4. Statistical Design and Power      Statistical Design and Power

#### 4.5. Subject Participation Duration      12 months

**4.6. Will the study use an FDA-regulated intervention?**   ☐ Yes   ☒ No



**4.6.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status**

**4.7. Dissemination Plan**      Dissemination Plan

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**Section 5 - Other Clinical Trial-related Attachments**

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**5.1. Other Clinical Trial-related Attachments**

## **HUMAN SUBJECTS RESEARCH**

Human Subjects Involvement Characteristics and Design – Children (approximately 8-10 years;  $N=4800$ ) from Ann Arbor, Wayne-Westland, and Ypsilanti, MI will serve as participants in this study. Children will be recruited from three school districts: Ann Arbor School District, Wayne-Westland School District, and Ypsilanti Community School District. This sample size reflects the minimum number to show effect as described in the methods section to account for attrition rate. Every effort will be made to retain children for the duration of this study, but children have the right to withdraw from the study. Children are the targeted population for this study due to the current rates of physical inactivity among children in the United States. Additionally, this population is being targeted because health behaviors established at an early age could track into adulthood, and physical inactivity is a risk factor for long-term disease risk including some cancers.

Children enrolled in public schools in Ann Arbor, Wayne-Westland, and Ypsilanti, MI that provide assent, as well as, parental or legal guardian consent will be eligible to participate in the study. Any children with a specified developmental and/or physical disability will be allowed to participate in the InPACT intervention but will not be a subject in the project (i.e., no data will be collected on these individuals).

The projects proposed in this application meet the definition of Behavioral and Biomedical Research. Human Subjects Approval will be obtained by the Institutional Review Board for Human Subjects Research of the University of Michigan prior to data collection and are discussed in detail below. The University of Michigan will conduct all data collection and all individuals have or will have undergone Program for Education & Evaluation in Responsible Research and Scholarship PEERS (or equivalent) human subjects training for the Protection of Human Subjects, in addition to criminal background checks.

### **Sources of Research Material**

Several sources of research material/data will be collected for this study. Student variables include questionnaire data, demographic data (date of birth, sex, race/ethnicity), anthropometric measures (height, weight), physical activity (via accelerometry and direct observation), health-related physical fitness, and weight status. Parent variables include questionnaire data. Teacher variables include questionnaire data, focus groups and direct observation. On all records, the participants' names will be removed and replaced with a number in order to preserve the participant's confidentiality. Only the PI and project coordinator will have knowledge of participants' identities. Data will be coded, analyzed, and entered into a database that will be stored on a computer and backed-up to a secondary device and the University secured server. Only the PI and project coordinator will have access to the database. All materials pertaining to this study will be stored in a locked cabinet in Childhood Disparities Research Laboratory (University of Michigan) that has keycode access. Data from this study will be used solely for research purposes.

### **Potential Risks**

There is low to minor risk associated with this study. The only foreseen risks or adverse events (AEs) that may occur are typical injuries (e.g., falls, scrapes) that children experience from engaging in movement and physical activity programs (InPACT). We do not foresee any serious adverse events (SAEs, e.g., orthopedic injury and loss of confidentiality) as a result of participation in InPACT. During data collection, we foresee there might be some discomfort associated with the collection of anthropometric measures or wearing the accelerometers. Measures will be taken to eliminate this embarrassment or discomfort by conducting weight measurements in a separate room or using a screen. All measurements in this study have been tested and validated for use in pediatric populations. Please see the Data and Safety Monitoring Plan as it relates to the handling of potential risks.

### **Recruitment and Informed Consent**

At the time of recruitment, all procedures, risks and benefits, and the option to withdraw will be explained to each participant and parent(s)/guardian(s). The voluntary nature of participation will be emphasized. Written, informed consent will be obtained from each parent along with participant assent prior to his or her enrollment in the study. The consent form will provide a description of the overall purpose of the research, the specific details of the protocol, risks and benefits, costs and payments, confidentiality, the risk to withdraw from participation and contact information for the PI, should they have any questions. A copy of the signed consent form will be kept in the study research files at each site in locked file cabinets. Participants will also be given a copy of their signed consent form.

### **Training of Research Staff**

All members of the study team will be required to complete the web-based University of Michigan Responsible Conduct of Research Training Program and to sign a confidentiality document stating that s/he understands the procedures to be followed to ensure the integrity and confidentiality of the data and the consequences of disregarding them. Careful training and ongoing monitoring of data collectors will be provided by the PI and will follow a set of procedures used successfully in our previous studies.

### **Data and Safety Monitoring Plan**

This is a low risk research study. Any adverse events (AEs) that may occur are typical injuries (e.g., falls, scrapes) that children experience from engaging in movement and physical activity programs. We do not foresee any serious adverse events (SAEs, e.g., orthopedic injury and loss of confidentiality) from participation in InPACT.

All participants will be monitored by the project coordinator from each site, and research staff with whom participants will interact multiple times per week during the active phase of the study. All AEs will be reported by the PI within 24 hours and reported quarterly and during routine annual continuation reports to the Institutional Review Board (IRB) at the University of Michigan. SAEs will be reported to the PI immediately and reported to IRB within 24 hours.

Minimization of these risks is described below.

1. A core group from the research team consisting of the PI, Co-Investigators and Statistician will be responsible for ongoing monitoring of the trial and reporting to the Institutional Review Board (IRB) any issues regarding the safety of study participants or threats to data integrity.
2. The IRB at the University of Michigan is a fully authorized Institutional Review Board that provides oversight to research conducted at the university. It functions in compliance with the congressional statutes governing Assurance of Compliance with Health and Human Services (HHS) Regulations for Protection of Human Research Subjects. This board will be providing oversight to the current study.

### **Data collection and security issues**

Names will be removed from all of the data and replaced with a participant ID number. All data will remain in a secured and locked location where only the PI and project coordinator have access.

### **Protection against Risk**

Every effort will be made to ensure confidentiality. Confidentiality of recorded and all other information obtained in the study will be maintained by labeling the information with a numerical code/ID number. A computer file and a paper document linking the code to the subject's identity will be located separately and will be accessible only to authorized personnel.

### **Potential Benefits of the Proposed Research to the Subjects and Others**

Participation in the study will contribute to the community of science and provide information as it relates to health behaviors (i.e., physical activity) in young children. Children who participate in the treatment condition will receive an evidence-based movement and physical activity program (i.e., InPACT). If our hypotheses are supported, findings will support the use and development of classroom-based physical activity interventions in education settings that promote positive and sustainable physical activity behaviors that contribute to healthy growth and development.

### **Importance of the Knowledge Gained**

The study will provide a unique opportunity to identify the immediate and long-term effect of movement and physical activity programs on physical activity behaviors in children. The target population will contribute to new knowledge relating to pediatric physical activity disparities in low socioeconomic communities. These potential benefits far outweigh the minimal risk associated with participation in the study.

## **DATA SAFETY AND MONITORING PLAN**

### **Study Team Oversight**

There will be a core group that will serve as the oversight for this project to monitor the study and ensure the safety of the participants (subjects). Data safety and monitoring will be the responsibility of the Principal Investigator (PI, Hasson), Co-Investigators, and Project Coordinator.

This is a low-to-minor risk research study.

### **Potential Risks**

There is low-to-minor risk associated with this study. The only foreseen risks or adverse events (AEs) that may occur are typical injuries (e.g., falls, scrapes) that children experience from engaging in movement and physical activity programs (InPACT). We do not foresee any serious adverse events (SAEs, e.g., orthopedic injury and loss of confidentiality) from the children's participation in InPACT. However, our team will document and report any AEs or SAEs that occur in intervention or control schools and report to the IRB accordingly. During data collection, we foresee there might be some distress associated with questionnaires or wearing the accelerometers. All measurements in this study have been tested and validated for use in pediatric populations.

#### Adverse Events (AEs) and Serious Adverse Events (SAEs)

Any adverse events (AEs) that may occur are typical injuries (e.g., falls, scrapes) that children experience from engaging in movement and physical activity programs. We do not foresee any serious adverse events (SAEs, e.g., orthopedic injury and loss of confidentiality) from the children's participation in InPACT. All participants will be monitored by the Project Coordinator and graduate research assistant from each site, and research staff with whom participants will interact multiple times per week during the active phase of the study. AEs, in both intervention and control schools, will be reported by the Principal Investigator within 24 hours and reported quarterly and during routine annual continuation reports to the Institutional Review Board (IRB) at the University of Michigan. SAEs will be reported to the PI immediately and reported to IRB within 24 hours.

Minimization of these risks is described below.

1. A core group from the research team consisting of the Principal Investigator, Co-Investigators and Statistician will be responsible for ongoing monitoring of the trial and report to our IRB any issues regarding the safety of study subjects or threats to data integrity.
2. The IRB at the University of Michigan have fully authorized Institutional Review Boards that provide oversight to research conducted at the university. It functions in compliance with the congressional statutes governing Assurance of Compliance with Health and Human Services (HHS) Regulations for Protection of Human Research Subjects. This board will be providing oversight to the current study.
3. Data collection staff will be trained to deal with any issues during data collection (e.g., asthma symptoms). If students experience asthma-related symptoms, students will follow their individualized asthma plan of care established with their primary care physician. If school nurses are present in the building, they will be contacted. Parents will be notified by Co-I Eagle, a medical physician.
4. All InPACT staff will be IRB trained since they will be involved in intervention delivery and process evaluation.

### **Data collection and security issues**

Names will be removed from all of the data and replaced with a participant ID number. All data will remain in a secured and locked location where only the PI and Project Coordinator will have access.

### **Protection against Risk**

Every effort will be made to ensure confidentiality. Confidentiality of recorded and all other information obtained in the study will be maintained by labeling the information with a numerical code/ID number. A computer file and a paper document linking the code to the subject's identity will be located separately and will be accessible only to authorized personnel.

## **OVERALL STRUCTURE OF THE STUDY TEAM**

The administrative and data coordinating site for the proposed study is the University of Michigan. The University of Michigan will be enrolling students from three school districts in Southeast Michigan (Ann Arbor Public Schools, Wayne-Westland Community Schools, Ypsilanti Community Schools). There is no separate laboratory or testing center included on the proposed study.

## STATISTICAL DESIGN AND POWER

All statistical analyses will use two-tail alpha to reject null hypotheses at 0.05, using version 15 of Stata, IC software (StataCorp, 2017. *Stata Statistical Software: Release 15*. College Station, TX: StataCorp LLC). Statistical reports will emphasize our desire to characterize the evidence, in addition to reporting significance levels. Prior to final analyses, we will screen the data, consulting with the PI as needed. Statistical assumptions will be tested, & appropriate data transformations or model adjustments will be used as needed. If the proposed statistical plan cannot be conducted after reasonable data/model adjustments, we will revert to alternative, possibly non-parametric techniques that address our aims. Given our extensive experience with these methods, we anticipate nominal missing data, however Co-I Ploutz-Snyder our biostatistician is equipped to consider multiple imputation methods for handling missing data if needed.

**Experimental Design:** The proposed is a 3-factor cluster-randomized experiment designed to evaluate the effects of the proposed InPACT intervention (vs. control) and school socioeconomic status (high, low) on physical activity outcomes of students nested within classrooms and schools, evaluated at baseline, immediately post intervention, and 3 months later. Thus, it is a 2 (socioeconomic status: High, Low) x 2 (Group: InPACT, Control) x 3 (Time: Pre, Post, Follow-up) completely factorial experimental design, using data from n= 40 schools randomized to condition within socioeconomic stratum, each containing 10 participating schools, each with 6 classrooms enrolling approximately 20 students per class, resulting in approximately 4,800 student subjects.

**Randomization to condition:** We have established collaborations with high and low socioeconomic school districts as described above. Schools within each socioeconomic stratum will be randomized to receive InPACT or Control conditions by simple randomization. All classrooms within school will receive the school-level randomized treatment to reduce possible treatment contamination within school.

**Sample Size, Power and Attrition:** We consulted the literature on physical activity interventions targeting school-age children and found no studies that specifically addressed all of our aims. Unfortunately, very little is currently known about the effects of socioeconomic on school-age physical activity interventions, a research gap that the current study is designed to address. Nevertheless, we were able to extract reasonable effect size information from one study that used an exercise promotion intervention on school-age children, and reported the effects on total moderate-to-vigorous physical activity, our primary outcome, in a classroom setting. While this study did not report effects of socioeconomic status, it is helpful to inform our ability to detect overall intervention effects. That study compared physical activity outcomes from 16 intervention classrooms in 15 elementary schools with n=19 students per class versus 12 control classrooms each with n=19 students per classroom. Their reported effect size for total moderate-to-vigorous physical activity (in-school + out of school) is most directly relevant for our Aim 1 was 0.44, with a reported ICC of 0.08. We used these data to inform a cluster-randomized power and sample size analysis using Optimal Design software (Raudenbush, S. W., et al. (2011). Optimal Design Software for Multi-level and Longitudinal Research (Version 3.01) [Software]. Available from [www.wtgrantfoundation.org](http://www.wtgrantfoundation.org)). Our calculations assume a similar effect magnitude and 80% power to detect a significant difference at two-tailed alpha = 0.05, and a conservative estimate of n=20 students per classroom, even though we anticipate 20-30 student participants per classroom in the proposed study. Per Table 4 below, our calculations suggest that n=23 classrooms would be necessary to achieve at least 80% power to detect exercise intervention effects of similar magnitude.

While encouraging as our primary outcome, outcomes of total physical activity, and total physical activity outside of the school require greater numbers of classrooms in order to detect effects at 80% power. Furthermore, as mentioned previously, this study was not designed to evaluate potential socioeconomic effects. Therefore, we are proposing a stratified sample of high and low socioeconomic schools, randomizing 10 high- and 10 low-socioeconomic schools to our InPACT intervention, and the same number randomized to control. We anticipate n=20 students per

Outcome	Reported Effect Size <sup>1</sup>	Reported ICC	Minimum N-Classrooms <sup>2</sup>
Total MVPA (Aim 1 Primary Outcome)	0.44	0.08	23
Total Physical Activity (TPA)	0.21	0.15	140
TPA in school	0.92	0.24	13
TPA out of school	0.14	0.09	220

<sup>1</sup> Kriemler et al 2010.

<sup>2</sup>Parameters: 2-tailed  $\alpha=0.05$ ,  $1-\beta=0.80$ , n=20 students per classroom

classroom, resulting in a total of 4,800 students nested within 240 classrooms and 40 schools. This large sample size will meet 80% power within socioeconomic stratum to detect intervention effects on moderate-to-vigorous physical activity, and if the intervention is not as effective in low socioeconomic versus high socioeconomic schools, should be sufficient for determining possible interaction effects and characterizing the magnitude of the differences attributable to socioeconomic status.

**-Aims 1a and 1b Analyses:** Our primary outcome for Aims 1a and 1b is the amount of time students spent in moderate-to-vigorous physical activity (MVPA) collected by accelerometers worn for 1-week during each of three time periods (pre, post, follow-up). We will calculate each students' average daily MVPA time per time period for statistical analysis using hierarchical (aka multilevel) modeling. We address both aims in a fully factorialized statistical model that incorporates both the treatment and socioeconomic status parameters. More specifically, our statistical model will include fixed parameters evaluating the effects of school socioeconomic status (high, low), treatment (InPACT, control), time (pre, post, follow-up, with baseline as reference), all 2-way interaction terms, and the 3-way interaction terms. Given our nested experimental design, random Y-intercepts will be used to accommodate the nesting of students within classroom and school. We do not anticipate random slope coefficients in our models, however preliminary model diagnostics and fit statistics may suggest the need to accommodate random slopes on classroom or school level variables, in which case we will alter the model accordingly using unstructured variances/covariance among random intercept and slope terms. We will evaluate our secondary outcome, student's average daily sedentary/light activity time, in a similarly designed multilevel model.

**Aim 2a Analysis:** Aim 2a is focused on identifying possible school, classroom, or teacher factors that may facilitate or become a barrier to the successful implementation of our classroom-based exercise intervention. The report from the Center for Education, Design, Evaluation and Research described above will provide qualitative information that specifically addresses our Aim 2a of identifying school, classroom, and teacher barriers to successful implementation of the InPACT intervention into classrooms.

We will also address this aim using quantitative implementation outcomes derived from teacher survey data and in-class direct observations of the InPACT exercise interventions. Specifically, teacher surveys will provide the number of InPACT activity breaks that were delivered to the classroom, and the length of these breaks, our two primary measures of InPACT implementation. Secondly, direct observations of random samples of interventions will also provide exercise intensity estimates. This analysis focuses only on data collected and summed over the entire intervention time period (i.e. school year).

We will utilize multivariate-mixed-effects regression methods regressing School-level (ex. teacher: student ratios), Classroom-level (room square footage per student), and Teacher-level (ex. teachers' physical activity level) parameters identified in Table 2 on these multivariate outcomes (measured at the classroom level, nested within schools). in order to assesses their possible contributions to InPACT implementation throughout the school year. Because we are interested in determining whether these predictors affect implementation similarly in Low versus High SES schools, we will also include interaction terms in the model for each predictor by SES. Due to the large number of predictors in this model, our reports will emphasize the relative effect magnitude among candidate predictors using squared semi-partial correlation coefficients rather than significance levels of individual predictors. Our statistical reports will emphasize the identification of the possible barriers and facilitators of successful InPACT implementation that interact with SES so that we may better understand the unique barriers and facilitators that a future school-based exercise intervention may face if implemented in low, versus high-SES schools.

**Aim 2b Analysis:** Aim 2b is designed to identify and characterize the potential differences in community and home environments by SES that relate to physical activity outcomes among students in the InPACT and Control groups. Our primary outcome for this aim is MVPA, and we will evaluate the contributions of the variables assessing students' communities, and parent (Table 2) in two steps.

First, we will compare these community and parent variables by SES status to determine which among them differ based on SES status using simple independent t-tests. The purpose of this initial analysis is to reveal SES-specific differences that exist in homes and communities, and that may in a subsequent analysis predict how effective our *classroom*-based InPACT intervention may be at improving students' *total* physical activity, both inside and outside the classroom. We will select all variables from this first analysis that show significant differences at the  $p < .010$  level to be included in our final analysis.

Next, we will regress the selected community and home variables from Step 1 in a mixed-effects regression model predicting the change in students' MVPA following the intervention (Post-Pre). Fixed effects parameters will be included for each parameter, as well as a treatment parameter (InPACT, control), and all 2-way interaction terms involving treatment, with random intercepts to accommodate the nested data structure. This model enables us to determine whether the community and home factors shown to differ on SES status from step 1 relate to differences in students' total MVPA, and also whether or not the InPACT intervention altered their impact.



## **DISSEMINATION PLAN**

As Responsible Party, I will share information about this/these trial(s) via timely registration, updates, and results reporting in ClinicalTrials.gov in accordance with NIH policy. The informed consent documents used for this/these trial(s) will include statements to inform participants that information about the trial will be posted in ClinicalTrials.gov. The University of Michigan's Human Research Protections Program (HRPP) Operations Manual is the primary location where rules, policies, practices, and guidance pertaining to the University's HRPP are provided, including Part 11 (section II.H) which addresses the requirements to register trials and report results. Compliance with these provisions is monitored by designated components of the UM HRPP.