**Protocol Title:** Physical Activity and Screen-Time Regulations in Childcare Centers: Influence on Young Children's Health Behaviors (Pause & Play) – Aim 3

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# **Objectives**

# A. Specific Aims

Reducing childhood obesity is identified as a top priority of the Mayor's Health City Initiative (MHCI) of Baton Rouge, Louisiana, which is a non-profit organization that brings together key community stakeholders to promote healthy living and active lifestyles. Louisiana's prevalence of obesity in preschoolers is 60% higher than the national average: 13.8% of preschoolers in the state are obese¹ compared to 8.4% nationally.² Obesity prevalence is particularly high among non-Hispanic black children.² Childhood obesity contributes to a higher risk of adult obesity, premature mortality, and comorbidities including diabetes, hypertension, ischemic heart disease, stroke, asthma, and polycystic ovary syndrome.³ Physical activity is a protective factor against childhood obesity,⁴ whereas sedentary behavior has emerged as a risk factor for obesity.⁵ Yet the majority of preschoolers do not meet nationally recommended guidelines for physical activity or sedentary behavior. Less than 10% of preschoolers obtain the recommended 1 hour/day of moderate-to-vigorous physical activity.⁶,७ Despite recommendations of no more than 2 hours/day of screen-time,⁶ which is the most common sedentary activity among preschoolers,⁶ children view on average 4.1 hours of screen-time each day.¹¹0

Childcare centers represent an opportunity to increase physical activity and reduce sedentary behavior in preschool-aged children, since over 80% of children spend some time in childcare settings by the age of 3 years. <sup>10</sup> Indeed, almost 50% of the variation in preschool children's physical activity occurs in childcare centers. <sup>11</sup> Yet the majority of childcare centers are conducive to low levels of physical activity and high levels of screen-time: many centers schedule little time and do not create designated space for physical activity, <sup>12</sup> and children spend on average 1.3 hours/day watching a screen in these centers. <sup>9</sup> Non-Hispanic black children and children with obesity are most likely to have both low levels of physical activity and high levels of screen time, <sup>13</sup> indicating that this population is particularly important to target to improve health behaviors.

Most states do not have strong regulations for physical activity or screen-time in childcare settings. 14 Louisiana's Department of Education (DOE) is implementing new regulations for children in childcare settings in 2015 to comply with national recommendations: 1) physical activity of at least 1 hour/day and 2) screen-time limited to 2 hours/day. The DOE is also providing extensive training and programmatic support to the centers. For the proposed project, the MHCI joins academic researchers at Pennington Biomedical to evaluate the implementation of these regulations and to

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examine effects on children's health behaviors. During this project, we will answer three major questions: 1) are the regulations being implemented as intended; 2) do the policies benefit the intended audience; and 3) what do stakeholders identify as the most important strategies to improve children's health behaviors. The demographics of Baton Rouge provide an opportunity to examine these questions in a high risk population: 46% of city residents are non-Hispanic black and 28% of children under the age of 5 years live in households below the federal poverty level.<sup>15</sup>

The aims of the project are:

**Specific Aim 3:** To establish community priorities for strategies to improve young children's health behaviors based on focus groups of stakeholders in the greater Baton Rouge area.

**Specific Aim 3** will be achieved through a series of taskforce and focus group meetings administered by the MHCI. Meetings will include monthly meetings of the MHCI advisory boards composed of community stakeholders and focus groups of childcare center directors and parents. Stakeholders will create dissemination and implementation plans to leverage the findings of the project.

Through this academic-community partnership, we are taking advantage of a natural policy experiment to examine the childcare environment and children's behaviors before and after implementation of a policy change. We will also facilitate conversations among stakeholders to create additional strategies to increase young children's physical activity and decrease screen-time both in childcare centers and in other settings. The overall goal is to increase physical activity and reduce screen-time among preschoolers enrolled in childcare centers. If successful, we will disseminate findings throughout the Gulf States region as a model of how changing policies in childcare settings can improve children's health behaviors and reduce childhood obesity.

# **Background**

The Problem to Address: Obesity and Physical Inactivity in Preschool Children

The Gulf States of Louisiana, Mississippi, and Alabama each rank in the top ten for highest prevalence of childhood obesity, adult obesity, physical inactivity, type 2 diabetes, and hypertension. In Louisiana, obesity affects 13.8% of children aged 3 to 5 years and 29% of all children aged 2 to 17 years, which is substantially higher than the national prevalence. Obesity during childhood contributes to several serious comorbidities including diabetes, hypertension, ischemic heart disease, stroke, asthma, and polycystic ovary syndrome. Moreover, children with obesity are at higher risk for premature mortality.

Increased physical activity and decreased sedentary behavior are key recommendations to reduce the risk for obesity and related comorbidities. <sup>18</sup> Low levels of physical activity and high levels of sedentary activity contribute to a variety of mental and physical health consequences during the preschool and early childhood years, including obesity, high blood pressure, behavioral problems, academic problems, irregular sleep, and feelings of sadness and boredom. <sup>9</sup> Indeed, physical activity and screen-time together explain 65% of the variance in children's body mass index (BMI) from age 3 to 7 years. <sup>19</sup> However, children are not obtaining sufficient levels of physical activity and are spending too much time in sedentary pursuits. Nearly half of preschool-

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aged children do not meet the recommended 1 hour of moderate-to-vigorous physical activity (MVPA) each day.<sup>7</sup> Screens are highly prevalent in children's lives due to increased device availability and marketing efforts,<sup>20</sup> and preschool children are estimated to spend between 1.5 and 7.0 hours each day in screen-time<sup>21,22</sup> despite recommendations for 2 or fewer hours of daily screen-time.

Reducing childhood obesity is identified as a top priority of the Mayor's Health City Initiative (MHCI) of Baton Rouge, which is a non-profit organization that brings together key stakeholders in the community to promote healthy living and active lifestyles. *Pennington Biomedical has joined with the MHCI to lead a number of projects to establish the prevalence of obesity and health risk factors in the community, to evaluate simulated effects of policy changes on childhood obesity prevalence, and to coordinate medical, academic, and non-profit organizations to strategize ways to promote healthy behaviors among children and families. This proposal represents a step forward in the partnership between the MHCI and Pennington Biomedical to empirically test the effects of a health policy aimed at improving children's health behaviors in childcare settings. Given the vast majority of preschool children attend childcare centers, <sup>10</sup> implementing policies that promote physical activity in these centers may have direct, impactful health benefits for young children.* 

#### A Carrot and Stick Approach to Improve Community Policies

Over the past year, the Louisiana Department of Education (DOE) has been given authority of childcare center licensing in the state of Louisiana. A 2012 state legislative mandate seeks to create a unified early childhood system under the DOE. With this transition, all licensing requirements are being revised; early care and education programs are being organized under local childcare center networks; new standards are being implemented for all childcare center providers that accept public funds; and a quality rating system is being redeveloped. Specific to the proposed project, new licensing standards will affect children attending over 1,300 licensed childcare centers state-wide and include: 1) physical activity of at least 1 hour/day and 2) screen-time prohibited for children younger than 2 years and limited to 2 hours/day for children over 2 years. Childcare centers in East Baton Rouge Parish must begin implementing changes by 2016 to renew their annual license.

In addition to the mandated regulations, the DOE is also offering new training and programmatic opportunities to help childcare centers achieve the regulations. The DOE has engaged directly with childcare centers around the state by supporting the implementation of the Nutrition and Physical Activity Self-Assessment for Child Care (NAP SACC) intervention, which is funded by the state's Maternal and Child Health Title V Block Grant and 1305 funding. NAP SACC is a national evidence-based intervention to prevent and reduce childhood obesity.<sup>23</sup> It is implemented in childcare centers and is designed to promote healthy weight development in preschool children by improving the nutritional quality of food served, amount and quality of physical activity, staff-child interactions, nutrition and physical activity policies and practices, and related environmental characteristics. Over 200 centers have participated in the program and have integrated practices that support healthy weight behaviors since NAP SACC began in Louisiana in 2010. The Louisiana DOE will train childcare center personnel in East Baton Rouge Parish on these new regulations in 2015-16, offering a natural opportunity to examine childcare centers before and after implementation of the new policy.

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#### **Preliminary Data**

Baton Rouge, which is part of the Lower Mississippi Delta (LMD), represents one of the most medically underserved, at-risk populations living in the U.S. The Louisiana LMD is characterized by high levels of poverty, food insecurity, obesity, and related diseases. Approximately 40% of the Louisiana LMD population is African American, and 28% of residents live in poverty, compared to 12% at the national level. 15 This grant proposal arose from an ongoing collaboration between MHCI Director Mr. Allen and academic researcher Dr. Staiano, based on a shared interest to improve the health behaviors of young children in the Baton Rouge area. As part of a national effort organized by the U.S. Conference of Mayors, the MHCI was launched in Baton Rouge in response to the growing obesity epidemic and its relationship to chronic diseases which may be prevented or lessened through regular exercise and healthy eating. Community PI Mr. Allen directs the efforts of MHCI, which is a 501(c)(3) non-profit organization and includes three Advisory Boards that bring together community stakeholders on a monthly basis. As an Assistant Professor at Pennington Biomedical. a world-renowned nutrition and obesity academic research center, Dr. Staiano serves on the academic advisory board of the MHCI. Additionally, a medical advisory board and a community advisory board bring together stakeholders from area hospitals, nonprofit organizations, and government agencies.

This partnership arose from several years of collaboration between Pennington Biomedical and local health organizations. From 2008-2012, Louisiana researchers and child health advocates, through the leadership of Pennington Biomedical, released an annual report card (Louisiana's Report Card on Physical Activity & Health for Children and Youth<sup>25</sup>) that provided grades on indicators related to children's physical activity and health. The Report Card is an advocacy tool targeting adult decision makers and is intended to increase awareness of the health concerns associated with physical inactivity, to highlight the growing problem of physical inactivity and obesity among children and youth in Louisiana, and to generate political will for policy and environmental reform. In the 2011 Report Card, <sup>26</sup> rather than assign grades, the Report Card research advisory committee followed the model set by the Healthy People initiative<sup>27</sup> and established specific targets to reach by the year 2020 for each of the report's indicators. These targets were also released for public comment. The target set for childhood obesity was a 20% reduction from baseline levels to year 2020. In 2012, a committee composed of Pennington Biomedical researchers including Dr. Staiano. as well as the lead policy analyst for chronic disease outcomes within the Louisiana Department of Health and Hospitals, and the Louisiana Director for Advocacy and Government Relations for the American Heart Association, convened to determine whether the 2020 childhood obesity target was achievable and to make evidence-based recommendations about policy approaches that would make the biggest improvements for this indicator. Our team used the Prevention Impact Simulation Model (PRISM), a systems model capable of projecting changes in obesity prevalence overall and among children.<sup>28,29</sup> Eight of the policy and environmental interventions considered within PRISM are interventions advocated for childhood obesity, and one of these eight focuses on physical activity in childcare centers. The PRISM model estimated that a childcare center policy to increase children's physical activity and reduce screen-time to meet recommendations would reduce overall childhood obesity prevalence by 2% by the year 2020. Given the new 2015 DOE state regulations to require physical activity

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and reduce screen-time in childcare centers, the MHCI's prioritization of childhood obesity prevention, and the prior work by Pennington Biomedical and the MHCI, this academic-community partnership is primed to evaluate progress towards creating healthier childcare centers in the city of Baton Rouge. The proposed project allocates resources to both the MHCI and Pennington Biomedical, using a community-based participatory research approach to ensure findings will directly impact the local community.

# Significance

We created a unique partnership between a community-based non-profit organization (the MHCI) and a world-renowned academic research institute (Pennington Biomedical) to examine the effects of a health policy change in childcare centers on children's health behaviors. The **timing is ideal** to establish baseline values of the physical activity environment and behaviors of children, then to evaluate these environments and behaviors one year after the childcare centers receive training, programmatic support, and mandated regulations to achieve the new physical activity and screen-time regulations. Community stakeholders in the MHCI have identified childhood obesity prevention as a top priority, but the majority of parents fail to recognize obesity in preschool children,<sup>24</sup> and many mistakenly think that obesity is not a health problem at this age. We seek a shift in the climate of the community to recognize that preschool is a critical opportunity to improve health behaviors in order to put children on a trajectory towards life-long healthy living.

#### **Inclusion and Exclusion Criteria**

Two to three focus groups of 8-10 parents and childcare directors will be conducted to elicit community priorities for strategies to improve young children's health behaviors.

#### Inclusion Criteria:

- Either a director of a licensed childcare center in East Baton Rouge Parish <u>OR</u> a legal guardian and/or primary caretaker of a child aged 3 to 5 years who is enrolled in a licensed childcare center
- Able to understand and speak English
- Willing to be audio-taped during the focus group (for transcription purposes) Exclusion Criteria:
- Being affiliated with 1 of the 10 childcare centers being assessed for Specific Aims 1 or 2, either as a director/teacher or as a parent of a student
- Cognitive impairments that interfere with participation in a group discussion

#### **Number of Subjects and Subject Timeline**

We plan to conduct 2-3 focus groups of 8-10 parents and childcare directors, for a total of 16-30 participants. Participation in the focus group part of the study will last approximately 1 day. We plan to conduct all focus groups between January 2016 and June 2017.

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## **Study Timeline**

This study will last from July 1, 2016 until June 30, 2017. A proposed timeline of all study procedures is listed below:

	Jul 2016	Aug 2016	Sep-Oct 2016	Oct-Dec 2016	Jan-Mar 2017	Apr-Jun 2017
Recruitment						
for focus						
groups						
Focus group						
meetings						
Focus group						
transcription						
and analysis						
Focus group						
manuscript						
preparation						

#### **Recruitment Methods**

Parents and childcare directors at EBR Parish childcare centers will receive information about the focus groups via email, mail, fax, phone, or in-person. Individuals who express interest in the focus groups will be further contacted by study staff for scheduling. Out of the pool of 192 DOE licensed childcare centers in EBR parish, we should not have a problem recruiting 16-30 parents/childcare directors. We aim to recruit all focus group participants between July 2016 and December 2016.

#### **Procedures**

Focus Groups. A group informed consent will be obtained when participants arrive at the focus group location prior to the start of the focus group discussion. Participants will complete a brief demographic questionnaire. Focus groups will be moderated by 1-2 study staff members and will be audio and video-taped to aid in later transcription. The moderator will lead the focus group discussion with a series of scripted, open-ended questions designed to facilitate focused discussion and optimize consistency across focus groups. Each focus group should last approximately 1.5 hours. Participants will receive a \$20 as compensation for their time.

#### **Consent Process**

A script explaining all aspects of the focus group that are normally detailed in a consent document will be read to the group prior to the focus group discussion. The researcher reading the consent script will stress that focus group participation is voluntary and will be available to answer questions during this time. Subjects who do not wish to participate in the focus group will be asked to leave the room prior to the start of the focus group discussion. By staying in the room during the focus group, this will be the participants' way of telling the researchers that he/she agrees to participate.

#### **Primary Endpoints and Data Analysis Plan**

Transcripts of the focus group discussions will be imported into NVivo software (Version 10, QSR, Victoria, Australia) to allow for thematic evaluation. The evaluation process will include the following: 1) generation of key words, phrases, and quotes coded as variable themes agreed upon by at least one other participant in the group and repeated independently in another focus group; 2) grouping of variables based on Page 6 of 11

unifying concepts and themes; and 3) review of the variable groupings to ensure consistency and relevance of proposed unifying concepts. Primary endpoints of the focus groups will be qualitative concepts, themes, and quotes of the childcare center directors and parent perspectives that may aid in developing new strategies to increase physical activity and reduce sedentary behavior in preschool children.

## **Power Analysis**

Power is achieved in qualitative focus groups when data saturation occurs, i.e. when themes are agreed upon by at least two participants in the group and repeated independently in another focus group. The completion of 2-3 focus groups with 8-10 individuals each should allow for the perception of themes.

#### **Data Management and Confidentiality**

The Pediatric Obesity and Health Behavior Laboratory, supervised by Dr. Staiano, will have primary responsibility for data collection, data management, manual data entry, tests for inter-rater reliability, and data analysis. All electronic data will be stored in the secure Pennington database, with access given to only necessary, HIPAA-certified staff. All hard copies of data will be stored in a secure, locked cabinet at Pennington Biomedical Research Center. Data collected at the childcare centers will be securely transported to PBRC by trained staff. Access to data files can be made only with permission of the Academic Principal Investigator. Data will be stored for 5 years following study completion.

# Provisions to Protect the Privacy Interests of Subjects and Monitor the Data to Ensure the Safety of Subjects

This study does not involve more than minimal risk to participants. Focus group questions do not contain sensitive items to ensure participants are comfortable responding. Only first names will be used during the focus group discussion and only focus group participants and the 2 moderators will be present in the room during the focus group discussion. Data will be stored in a secured area and all study staff must be HIPAA certified. Following transcription of the focus group discussions, all transcripts will be de-identified and original audio/video tapes that contain names and images will be destroyed. Only pertinent study staff will have access to study data.

## Withdrawal of Subjects

Participation is voluntary, so participants may withdraw from the study at any time. Data that have already been collected during the course of study participation from a withdrawn participant will be used, unless a specific request is otherwise received. Withdrawn participants will not be able to be removed from group data that have already been collected, such as the focus group discussions. Participants may be withdrawn from the study for the following reasons:

 Unwillingness on behalf of the participant to participate in the study or cooperate with study staff

#### Risks to Subjects

There are no foreseeable risks to participants in this study. The focus group discussions will not include any sensitive topics that could make participants uncomfortable.

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## **Potential Benefits to Subjects**

We cannot promise any direct benefits to the participant from participating in the focus group discussion, although policy changes and directions identified in the focus group discussions may improve physical activity and screen-time behaviors for children/students of focus group participants.

## **Vulnerable Populations**

This study does not involve vulnerable populations.

## **Sharing of Results with Subjects**

Study results will not be shared with participants unless requested. If requested, only group summary data will be available for the focus groups.

## Setting

Focus groups will be held at a convenient community location or a meeting room inside Pennington Biomedical Research Center.

#### **Resources Available**

Amanda E. Staiano, Ph.D., M.P.P., *Academic Principal Investigator*, is Assistant Professor and Director of the Pediatric Obesity and Health Behavior Laboratory at Pennington Biomedical. Dr. Staiano is a developmental psychologist with expertise in epidemiological surveys of children's screen-time and public policy related to children's health.

**Corby Martin, Ph.D.,** *Academic Mentor*, Associate Professor, is a licensed clinical psychologist with extensive experience conducting population-based cluster randomized trials, including an ongoing clinical trial to test a home-based obesity intervention for preschool children. As a senior faculty member, Dr. Martin will provide ongoing mentorship to Dr. Staiano.

**Andrew T. Allen, B.A.,** *Community Investigator*, is the Director of the Mayor's Healthy City Initiative and Community Outreach Coordinator for the Office of the Mayor-President in the City of Baton Rouge.

Additional staff members, including a PBRC project coordinator, a PBRC research specialist, and policy student worker located at the Mayor-President's Office will oversee data collection and conduct the focus groups.

Both principal investigators have extensive networks to childcare centers throughout the city. Staff members will spend at least 2 weeks in each childcare center at baseline and 1 year later to establish rapport for recruitment and data collection. There are currently 192 licensed childcare centers and 13 Head Start centers located in EBR Parish, so we do not envision difficulties recruiting 16-30 parents/childcare directors for focus group participation.

#### **Prior Approvals**

None.

# Compensation for Research-Related Injury

No form of compensation for medical treatment or for other damages (i.e., lost wages, time lost from work, etc.) will be available for this research study. In the event of

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injury or medical illness resulting from the research procedures, participants will be referred to a treatment facility.

# **Economic Burden to Subjects and Compensation**

Focus group participants will be responsible for bearing the cost of transportation to and from the focus group location. Focus groups will be held at a convenient community location to cut down on these costs and focus group participants will receive \$20 in compensation upon focus group completion to offset these costs.

# **Drugs or Devices**

N/A

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