DOCUMENT: INVESTIGATOR STUDY PLAN

STUDY TITLE: A Pilot and Feasibility Study to Promote Physical and Food Literacy among Children with Intellectual Disabilities (Study Nickname: New Skills – No Scores)

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1. TITLE
A Pilot and Feasibility Study to Promote Physical and Food Literacy among Children with Intellectual Disabilities (Study Nickname: New Skills – No Scores

2. EXTERNAL IRB REVIEW HISTORY*
UMass Chan will be the lead institution and reliance agreements have been put in place with Tufts University and UMass Boston.

3. PRIOR APPROVALS: N/A

4. OBJECTIVES*
The specific aims of the study are as follows:

(1) To test the feasibility of a remote physical literacy and food literacy intervention for adolescents with ID ages 12-16 years.

(2) To assess preliminary efficacy of the intervention for increasing:

a) physical literacy including movement skills, physical self-concept, and desire to participate in physical activity.

b) food literacy including knowledge around making healthy food choices, basic food preparation skills, and engaging in healthy eating behavior.

We hypothesize that demand for the intervention will be similar to our previous studies (high level of interest), and attendance and retention will be high (≤10% dropout). We also hypothesize that participants will enjoy the intervention, and that parents and participants will be satisfied with the intervention and perceive it as appropriate. We expect that implementation fidelity will be high (>80% of checklist items on average) and that participants will show significant improvements in physical literacy and food literacy outcomes. This pilot and feasibility study represents an important first step toward promoting health and reducing inequities that exist for adolescents with ID. If successful, the next step is a larger controlled study to test whether changes in physical literacy and food literacy skills can promote increased physical activity and healthier food choices in adolescents with ID.

5. BACKGROUND*
This information described extensively in the grant narrative that has been uploaded into the eIRB system. Below is a brief description of the background/context for the study:

Regular participation in physical activity (PA) maintains health and reduces the risk of disease. In children and youth, benefits include improved blood pressure, bone health,4health-relatedfitness, psychological health, and preventing/treating obesity. The US guidelines for children recommend at least 60 min/day of moderate-to-vigorous activity but less than 25% children meet this goal. PA levels are lower in girls than boys, and decline from childhood to adolescence. 53 Children with intellectual disabilities (ID) are no exception; most do not meet

the guidelines and are less active than their typically developing (TD) peers. A healthy diet is also necessary for overall health and well-being. The Dietary Guidelines for Americans are promulgated to help people make healthy food and beverage choices. Data from the 2015 Youth Risk Behavior Surveillance Survey suggest that a substantial number of youth do not meet these guidelines; only 61% of high school youth consumed ≥1 vegetables and only 63% consumed ≥1 servings of fruit or 100% fruit juice daily. Although data on dietary intake of children and youth with ID are lacking, our work in youth with ID suggests that many do not meet the dietary guidelines for fruits/vegetable intake and that their diets are high in added sugars. Barriers to healthy eating include lack of knowledge about food in today's complex food environment which makes decision-making around food choices difficult. Other barriers include difficulty estimating portions sizes, food selectivity, and limited of access to healthy foods.57

The concept of physical literacy has gained considerable momentum internationally in health promotion research, practice, and policy. The International Physical Literacy Association describes physical literacy as "the motivation, confidence, physical competence, knowledge and understanding to value and take responsibility for engagement in physical activities for life." It imparts the knowledge and tools to pursue and enjoy a variety of sports and PA. Physical literacy is considered the gateway to an active lifestyle. In the US, the physical literacy movement is embraced by organizations like the American College of Sports Medicine and President's Council on Fitness, Sports & Nutrition. In 2014, "physically literate" replaced "physically educated" as the goal for all students in the US National Standards for Physical Education.

The essential components of physical literacy, in the US definition, are:

1) Ability: competency in basic movement skills and overall fitness:
2) Confidence: self-efficacy for the ability to play sports or enjoy physical activities: and
3) Desire: the intrinsic enthusiasm for PA.

These components build on one another and provide the foundation to be active for life. Specifically, as children develop proficiency in movement skills, their increased confidence in their ability leads to greater enjoyment and motivation to participate. Mastering fundamental movement skills such as jumping, running, catching, and throwing is considered to be the most important step toward developing physical literacy. Children and adolescents with more developed motor skills are more active/fit, which enhances movement proficiency and increases overall activity levels.

Food literacy has also gained recent attention and has been defined as "the capacity to obtain, process and understand basic information about food and nutrition as well as the competence to use that information in order to make appropriate health decisions," although a standard definition of this concept is not yet established. A food literacy intervention for adolescents with ID must consider the adaptations needed to make information accessible and understandable, teach skills that are reasonable and manageable, and meet the needs of a heterogeneous population. The range of knowledge in adolescents with ID is likely to be quite variable. Although adolescents with ID may live in supervised settings or at home with their parents, they nevertheless make food choices throughout their day. Thus, they need to be able to identify healthy food choices and be able to identify unhealthy foods which are often the targets of marketing and advertising. Moreover, adolescents with ID have higher rates of food selectivity

than their TD peers, which may be a result of sensory sensitivities, behavioral rigidity, and/or preferences for familiar foods. These adolescents need to be exposed to healthy foods in a positive and supportive manner. Food literacy is critical to the health of adolescents with ID who require requisite knowledge and skills for making healthy choices, especially as they move toward more independent living.

6. INCLUSION AND EXCLUSION CRITERIA*

The participants in this study will be 30 male (n=15) and female (n=15) adolescents with intellectual disabilities (ID) ages 12-16 years. Because the etiology of ID is variable with many known and unknown causes, we expect the sample will include adolescents with various syndromes such as Down syndrome, Fragile X, Williams syndrome, as well as adolescents with ID of unknown etiology.

Inclusion criteria:

- measured IQ and adaptive functioning scores of ≤75 as measured by the Kaufman Brief Intelligence Test-2 (KBIT-2) and Vineland Adaptive Behavior Scales-III (VABS-III). A score > 75 for participants that do not have a syndrome that is associated with ID will be exclusionary. However, participants with such syndromes (e.g., Down syndrome) may have scores above this cut-point but are still classified as having an intellectual disability and thus will qualify for the study.
- participants must be ambulatory and in sufficiently good health to engage in moderate-to-vigorous physical activity
- able to communicate verbally in English, follow simple instructions, and provide assent.
- approval from the participants' primary care physician and specialists (as necessary) will be required for participation.
- in-home space that is a minimum of 7 feet by 10 feet to allow the participant enough room to complete the TGMD-3 and the physical activity component of the intervention

Exclusion criteria:

- uncontrolled medical or significant psychiatric condition
- insulin-dependent diabetes
- physical/orthopedic impairment that would preclude participation in physical activity
- legally blind or deaf
  habitual problem behaviors such as aggression or noncompliance

We will seek approval from participants' physicians and specialists to ensure they can participate safely.

7. STUDY-WIDE NUMBER OF SUBJECTS* N/A

8. STUDY-WIDE RECRUITMENT METHODS* N/A

9. STUDY TIMELINES*

The table on the next page depicts study activities over the two years of the project. The 12-week intervention will run remotely in three concurrent waves/cohorts of 10 participants (winter/spring 2022 through summer 2022). Conducting the intervention remotely will allow us to recruit

throughout the state of Massachusetts, which will assist in enrolling the planned number of participants (n=30).

The study was put on-hold in March 2020 due to COVID shortly after enrolling participants and commencing with the intervention. The timeline listed below illustrates our new plan.

	Year 2 **Sept 1 2020 to Aug 31 2021**												**Year 3 – Current Year (no-cost extension)** **Sept 1 2021 to Aug 31 2022**											
Tasks ⇩ Months ⇨	**S**	**O**	**N**	**D**	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**
Participant-related activities suspended due to COVID-19	X	X	X	X	XX	X	X	X	X	X	X	X												
Start-up activities – hire staff, training and preparation													X	X	X	X								
Recruit, screen, & enroll participants																X	X	X						
Data collection – baseline measures																X	X	X						
Intervention																			X	X	X	X		
Data collection – post intervention measures																							X	
Data coding, entry & analysis																							X	X
Dissemination - presentation and manuscript preparation.																								X

10. STUDY ENDPOINTS*

The measures used in this project are designed test the feasibility of the intervention and assess its preliminary efficacy for increasing physical literacy and food literacy in adolescents with ID. Measures of physical literacy and food literacy will be obtained **at baseline and after the 12-week intervention**.

Below are brief descriptions of the measures – these are also described in the grant application, which includes bibliographic references for validated measures.

(1) General sample characterization

We will collect the following information at baseline to characterize the sample:

- **Demographic Questionnaire**. Parents will be asked to complete a demographic questionnaire that contains basic demographic questions about the adolescent's date of birth, sex, adolescent/family race/ethnicity, and parent education. This questionnaire also contains questions about individual, social, community, and family barriers to physical activity for the adolescent.

(2) Feasibility Measures

Process measures of demand, acceptability, and implementation will be obtained as follows:

- *Demand* will be assessed by documenting number of inquiries into the program and number of participants screened and enrolled. Attendance will be recorded for each session and we will document reasons for any absences. Withdrawal, date of withdrawal, and reasons will also be documented.
- *Acceptability* will be assessed via participant and parent surveys of enjoyment, satisfaction, and perceived appropriateness at weeks 6 and 12. Surveys will be adapted from those used in our previous work, and will include close-ended questions with Likert scale response options and opportunities for open-ended feedback. The participant survey will be simple and will include visual cues (e.g., happy face for "like it") to assist in understanding questions and response choices. The survey will be administered orally and will take about 15 minutes. Participants will be queried about program elements such as: appropriateness and enjoyment of the sport/healthy eating activities; sports equipment; support/instructional methods used by staff; using Zoom to conduct the intervention remotely; barriers/facilitators of participation in physical activity and healthy eating; enjoyment of interactions with other adolescents; preferred sports and taste test foods; perceived improvements in physical/food literacy; and enjoyment/perceptions of "*Bring it Home and Give it a Try"* activities. Parent satisfaction via a survey will query perceptions such as: program quality; benefits to adolescent; staff effectiveness; appropriateness of activities; adolescent enjoyment; quality of the facility; and barriers to/facilitators of participation.
- *Implementation* will be assessed via documenting the factors affecting program implementation and sufficiency of resources (e.g., space, staff), and fidelity checks. Through observation and discussions with staff, participants, and parents, we will document: adaptations made to increase success; effective/ineffective strategies used to promote participation; most appropriate sports; quality of activity sessions; and barriers and facilitators encountered. Fidelity checks will be conducted in 25% of the program

sessions starting in week 3 to assess the degree to which the intervention is implemented as planned. We will develop a checklist with critical elements of the program and will discretely observe and record if the elements are executed. Protocol "violations" will be recorded and brought to the investigative team for discussion and trouble-shooting. In addition, we will have all active staff complete a Field Notes form at the end of each session to note any challenges with the session and/or participants. While these forms will have participant names on them they will be stored in a locked box after the session and brought de-identified as soon as possible by redacting the name and adding the subject ID instead.

- *Session Observation Form:* The Session Observation Form will be completed by nutrition students who will be involved in the intervention. During and immediately following the session they will take notes and fill out the form in order to capture aspects of program implementation. This form will assist us to evaluate the feasibility of and participant engagement with the program.

(3) Measures of Physical Literacy

- *Movement Skills.* **Test of Gross Motor Development-Third Edition (TGMD-3)** will be used to measure movement skills. The TGMD-3 assesses 13 fundamental motor skills that are divided into two sub-scales: 1) locomotor skills and 2) ball skills. The TGMD-3 is a direct observation skill assessment with 3-5 performance criteria for each skill. The following skills from the TGMD-3 will be assessed: skipping, two-foot jumping, one-foot hopping, sideways sliding, overhand throw, underhand throw, catch, hand dribble, and kick. The TGMD-3 will be administered via Zoom (i.e., remotely) at baseline and post-12 weeks. Specifically, a trained tester will provide verbal instructions and demonstrations for each skill on the TGMD during a recorded Zoom meeting. A parent/guardian will assist by ensuring that the participant's performance is clearly visible in the frame of the camera and may provide prompting and/or clarification to their child. Additionally, instructional videos for each TGMD skill will be provided to the participants and parents in advance for them to review and practice before the testing session. It should take approximately 30-40 minutes to administer. A trained professional will review and code the video-recorded TGMD-3 performance on each skill and provide a score at baseline and post-test.
- *Motivation and Confidence in Physical Activity.* As an indicator of confidence, Physical Self-Concept will be measured using **the Very Short Form of the Physical Self-Inventory-Intellectual Disability (PSI-VSF-ID)**. The PSI-VSF-ID is simple, accommodates short attention span, and assesses the multidimensionality of physical self-concept. The PSI-VSF-ID has 12 items that measure six dimensions of self-concept: 1) Global Self-Concept; 2) Physical Self-Worth; 3) Sport Competence; 4) Physical Attractiveness; 5) Physical Condition; and 6) Physical Strength. We have modified the language of the items of the PSI-VSF-ID for clarity and understanding by children with ID based on our extensive experience with this population. The 3-item confidence subscale, and 3-item motivation subscale of the **Canadian Assessment of Physical Literacy – Second Edition (CAPL-2) Questionnaire** will also be used to assess participant confidence in their ability to be physically active and motivation to participate in physical activity. This combined 18-item questionnaire including the PSI-VSF-ID and CAPL-2 subscales will be verbally administered virtually over Zoom. We reduced the

number of response options to four to accommodate children with ID who may find 5 or 6 choices difficult, and modified the language so that there was consistency across all of the 18 items in the combined motivation and confidence questionnaire. The response options are simply-worded for children with ID, and range from "yes, definitely" to "no, definitely not"**.**

- *Desire to Participate in Physical Activity.* The adequacy and predilection for physical activity subscale of the **Canadian Assessment of Physical Literacy – Second Edition (CAPL-2) Questionnaire** will estimate the participant's desire to participate in physical activity. The 6-item questionnaire subscale includes 3 items that assess perceived adequacy (i.e., self-perception that one has the capability to achieve an acceptable standard of success conceptualized by the self and others) and 3 items that assess perceived predilection for physical activity (i.e., likelihood of selecting physical activity over sedentary behavior when given the choice). This shortened and refined version of the original CAPL Questionnaire is underpinned by self-determination theory which is often used to understand motivation and perceived competence (Gunnell et al., 2018). The adequacy and predilection subscale, called "What's Most Like Me?", uses an alternative response choice format to present statements about preferences and feelings about physical activities and an adolescent chooses the option that is most like them. For example, "some kids don't have much fun playing sports" and "other kids have a good time playing sports." We have modified the response items to ask participants to select which option is most like them. The CAPL-2 Questionnaire subscale will be verbally administered virtually over Zoom. Total scores will range from 0-6 with an item response assigned 0 or 1.

(4) Measures of Food Literacy

- *Healthy Food Knowledge.* This pictorial-based knowledge assessment will be based on the content of the food literacy curriculum. We will provide participants with pictures of 25 different foods and ask them to classify them by the correct food group (e.g., an apple belongs to the fruit group) (5 foods for each of the 5 food groups). The participants will be shown three pictures of whole grain foods in their packaging and three pictures of non-whole grain foods in their packaging and asked to indicate whether or not each food is a whole grain. We will do qualitative probes to understand why/how the participant selected their response. Likewise, participants will be presented with a bottle of water and a bottle of soda and asked which has less sugar. This will be repeated with water and a sports drink. Qualitative probes will query the reason for the answer. Participants will be shown 2 plates of food: (1) chicken, rice, and broccoli; and (2) chicken, rice, and bread, and asked which is the healthier meal. Again, we will query why they made the choice they did. This question will be repeated with 2 other plates of food: (1) salmon, quinoa, and asparagus; and (2) salmon, quinoa, and bread. This assessment will be administered remotely via Zoom.
- *Healthy Eating Behavior.*
    - Changes in adolescent dietary behavior will be obtained by parent proxy from modificiations of the dietary assessment questions as part of the Youth Risk Behavioral Surveillance Survey (YRBSS). There are 9 questions related to dietary intake that align with our lessons around fruit/vegetables and added sugars. Parents will be asked to answer questions on the YRBSS about their adolescents'

intake of fruits and vegetables and sugar-sweetened beverages over the past week. A proxy measure of food intake is most appropriate given the wide range of cognitive abilities we expect among participants and difficulty with accurate recall. Parents will complete the 9 questions for their adolescent at baseline and post-intervention virtually over Zoom, to yield a summary dietary behavior score.

- We will also administer a modified food frequency questionnaire (FFQ) that we have developed for other studies that contains lists of foods organized by food group. This will be administered virtually over Zoom. Parents will be asked to indicate which foods their teen eats, which foods their teen will not eat, and whether any of the foods are never served to the teen. There is also a single question that asks parents to indicate how willing their teen is to try new foods. The FFQ will allow us to assess whether the teen's willingness to try new foods changes as a result of the intervention and whether there is an increase in the proportion of foods of the total that they consume post-intervention.

11. PROCEDURES INVOLVED*

Overview

The intervention will be conducted remotely using Zoom.

We will recruit 15 male and 15 female adolescents with ID ages 12-16. To establish the presence of ID (IQ ≤ 75), the Kaufman Brief Intelligence Test, 2nd ed. (KBIT-2) will be used to determine IQ score and the Vineland Adaptive Behavior Scales-III (VABS-III) will be used to assess adaptive functioning. Because the etiology of ID is variable, we expect the sample will include adolescents with various syndromes (e.g., Down syndrome, Fragile X, Williams syndrome) as well as those with autism and ID of unknown etiology. The KBIT-2 will be administered remotely via Zoom by a trained research assistant per the protocol developed by the test developer Pearson Assessments. The VABS-III will be completed online via the online administration program developed by Pearson.

Participant Screening & Enrollment

Parents will be phone-screened for their adolescent child's eligibility via a or Zoom phone interview. The procedures for adolescents who meet the inclusion criteria on the phone screen will be as follows:

- In order to determine they key inclusion criteria of the adolescent having an intellectual disability, parents will first be asked to complete an online version of the Vineland Adaptive Behavioral Scales-III which enables us to ascertain the adolescent's adaptive behavior. They must receive a score of 75 or less to be eligible. The VABS-III can be done at the time of the screening call with the RA or at another time of the parent's choosing. The RA can offer to be present during the time that the parent is completing this questionnaire in the event they have questions, but this is not necessary or a requirement. Will give parents the option of how/when they wish to complete the VABS-III. Pearson Assessments provides an online platform for parents to complete the VABS-III. The platform will then automatically score the questionnaire. Pearson will not be provided with or have access to any identifying information about the parent or child.

- If the VABS-III yields a score of 75 or less, we will then schedule a Zoom meeting for the adolescent and their parent. The RA will meet briefly with the adolescent to introduce himself to the adolescent and briefly describe the program. If the adolescent indicates an interest and willingness to proceed, the RA will administer the Kaufman Brief Intelligence Test – 2 (KBIT-2) to confirm an IQ of 75 or less, which is required for classifying the adolescent as having an intellectual disability (ID). If the KBIT-2 yields a score of 75 or lower, the rest of the enrollment meeting will proceed as described below. If the score is 76 or higher, the adolescent and parent will be told that the adolescent does not meet our screening criteria for ID. The KBIT-2 will be administered to the adolescent over Zoom, according to remote administration guidelines published by Pearson.
- If the adolescent meets criteria for ID, we will then review the online Assent Form which has been constructed as a "social story" which provides visual supports/information as the RA describes the program to the adolescent. We have chosen to acquire assent after the IQ test so that the participant does not potentially become interested/excited about the program only to be informed of the inability to participate, should they not meet inclusion criteria.
- Upon completing the assent we will administer the baseline questionnaires described above to both the adolescent and parent, including the Food Knowledge Test. We will provide the option to have these take place at a separate, second enrollment session that will be virtual. We will also provide the parent with the option to complete the parent questionnaires independently, offline, and offer additional Zoom calls in the event they have any questions or are unable to complete the forms on their own.

At the last enrollment session that will again take place over Zoom, the Test of Gross Motor Development-Third Edition (TGMD-3) measures will be administered by a trained professional with the help of the participant's parent.

One week prior to the start of the intervention, we will hold parent orientation Zoom calls to orient parents to the session structure, at-home components, and what their week-to-week responsibilities will be.

Physical Literacy & Food Literacy Intervention.
The 12-week intervention is designed to expose adolescents with ID to a variety of sports skills and healthy eating concepts to equip them with skills and confidence to participate in physical activities and make healthy food choices. The proposed sport sampling and healthy eating program will follow a protocol that can be adapted to meet the needs of a diverse group of adolescents with ID. Sessions will be held weekly for an hour and fifteen minutes. One cohort will meet Thursday evenings, the second cohort will meet Saturday mornings, and the third cohort will meet at a day/time that is to be determined based on the input of participating families on other days/times that would have worked for their schedules. 35 minutes will be dedicated to sport activities followed by 35 minutes dedicated to the curriculum on healthy eating with a 5 minute break in between. All sessions will be recorded to be coded as data at a later time by graduate students.

Sport Skills Sampling. The sport skills program will be delivered remotely with modifications that promote engagement in activities at home. The program will be organized by general sport

types/categories that are familiar to youth with ID and share key underlying motor skills. Four (4) weeks will be dedicated to each sport type including: striking sports, running and jumping sports, and ball sports. This classification of sport types (which are not mutually exclusive) will allow us to focus on fundamental locomotor and object control skills that are building blocks for a variety of sports, games, and physical activities, and that youth with ID can enjoy and practice on their own or with others. The selection of sport types is based on those that are popular for the age group, readily available to youth with ID in schools/communities (e.g., YMCAs), and part of Special Olympics. These include: baseball (striking sport); tennis (striking sport),;basketball (ball sport); soccer (ball sport); track and field (running and jumping sport); floor hockey (striking sport); volleyball (running and jumping sport); and gymnastics (running and jumping sport). Available physical literacy resources, materials, and curricula have guided the development of the sport skills curriculum and lessons. A "sports kit" will be delivered to each participant containing all the equipment that they will need to engage in the sports activities during each session (e.g., soft foam balls, cones, targets, paddles, jump rope, agility ladder). The items in the kit will all be usable in an indoor home setting and suitable for small spaces.

Sport sessions will be delivered by a Physical Activity Instructor with experience running physical activity/sport programs for youth with ID and familiar with instructional, motivational, and behavior modification strategies appropriate for this population. The Instructor will also have some experience delivering physical activity programs remotely. The Instructor will lead and demonstrate all activities in the session and provide verbal instruction, prompting, corrective feedback, and encouragement to engage participants in the activities using proper form. The Research Assistant (RA) will assist the Instructor during the remote sessions to help keep participants on task.

The first 5 minutes of each session will be an interactive greeting to introduce participants to the sport skills of the day, to highlight having fun and trying one's best, and to gather the equipment needed for the activities. A 10-minute dynamic warm-up will prepare and engage participants for the skill circuit. These 10 minutes will focus on "footwork for sports and games" and include fundamental movement skills (e.g., running, skipping, hopping, jumping, sideways sliding) designed to engage participants and build excitement. The footwork activities will use equipment to add interest for participants. For 20 minutes, participants will engage in age- and developmentally-appropriate activities designed to foster movement proficiency through a series of 5-7 sport skill activities for 2-3 minutes each with a short rest/transition between each one. Activities will include catching, throwing, kicking, striking with a paddle, juggling, foot dribbling, and jumping, jogging, and hopping in place using equipment. To increase enthusiasm and engagement, we will include individual, partner, and group challenges with many of the activities.

As originally proposed, the sport skills program will include an additional opportunity for skill development via an at-home play/practice component. Participants will be encouraged to use the equipment from their kit to practice skills outside of the session. We will create activity cards and videos with simple and fun ideas for playing with the equipment both indoors and outdoors. The cards and videos will contain instructions, pictures, and motivational cues to encourage participants to practice kicking, dribbling, throwing, catching, jumping, etc. The goal of the practice is to have participants enjoy sports/physical activities in an unstructured way and to

provide greater exposure. Each session, the Instructor will ask participants if they practiced and to share their experiences. This will be a positive interaction with reinforcement, encouragement, and strategies for practicing skills at home if youth report challenges. As before, we will ask participants to record their participation and submit it to us, but instead of paper-based recording, we will use an online reporting tool through REDCap. Participants will be reminded to input their at-home practice into REDCap using an automated text messaging and emailing application called Remind.

Healthy Eating. After a brief break, youth and parents will meet with the Nutrition Educator after the sport sampling portion of the program. In general, nutrition sessions will focus on a simple nutrition messages, and will include demonstrations, brief interactive activities, some food preparation, and a taste test. In our experience, these sessions are best done in 30-minute blocks.

We previously developed modules around healthy eating for adolescents with ID, *Health U: A Nutrition Curriculum for Teenagers with Intellectual & Developmental Disabilities* (www.tinyurl.com/HealthUCurriculum) that uses hands-on activities to teach about healthy eating. We have implemented these sessions in our weight management interventions and nutrition education programs for youth with ID. We are adapting and building on this curriculum for remote delivery. The program will begin with an introduction, followed by sessions focusing on how to incorporate foods from each food group into meals/snacks using "MyPlate" (www.choosemyplate.gov). The 12 modules include the following topics: 1) Introduction to the nutrition education component of the program; 2) Learn about MyPlate and food groups; 3) Fruits; 4) Vegetables; 5) Dairy; 6) Whole grains; 7) Proteins; 8) Putting a healthy meal together; 9) Added sugars; 10) Healthy snacks; 11) Promoting healthy snacks with fruits and vegetables; and 12) Planning a meal. Healthy eating principles will be reflected in the activities and we will regularly review previously covered material, as youth with ID need repetition and review to promote knowledge retention and skill development. Parents and youth will participate together in the sessions.

Each session will begin with an introduction of the topic, followed by an activity and a taste test. Taste tests will be thematically related to the lesson and participants will help with basic food preparation, learning the skills of assembling and spreading to prepare snacks, such as yogurt and fruit smoothies. We will ask participants to rate the food as: *"I like it"; "I don't like it"; "I didn't try it";* and "*Maybe I will try it next time*" using a rating sheet that includes words and pictures (emoticons).

Each week the Nutrition Educator will start the session by asking the youth whether they tried a new food the previous week and what they thought about it. They will then engage the group in a brief review of the previous week's topic. Next the Nutrition Educator will provide a brief review of the current week's topic, after which youth and parents will be assigned to Zoom breakout rooms with 2-3 other parent/youth dyads. In each break-out room a nutrition student will lead an activity related to the topic. In some lessons, the group will remain together.

Health Eating activity materials will be sent to the participants' homes three times throughout the intervention. We will provide the food to families for the weekly sessions by way of a direct grocery delivery, if feasible, or by providing them with the financial resources to make the

purchases themselves. The taste test foods will not require any cooking or heating to help minimize the time away from the group, as well as parental burden.

We will apply the at-home practice concept of "*Give it a try*" to the healthy food component of the intervention as with the sport sampling. Youth will record any new foods they tried over the week using a simple online form through REDCap. At the beginning of each session the instructor will ask the youth to report any new foods they tried during the week as a way to engage them in discussion and help motivate them to try new foods.

12. DATA AND SPECIMEN BANKING* N/A

13. Data Analysis and Management*

All data will be double entered and linked by a common identification number across data sources. We will minimize missing data through careful checking of all surveys and data forms at the time of completion. Baseline characteristics of participants who drop out will be compared to those who complete the study.

Analyses for Specific Aim #1. The process measures of feasibility will assess attendance, degree of participant enjoyment, and participant and parental satisfaction based the aforementioned surveys. These measures will be summarized as means and proportions, with corresponding 95% confidence intervals, and compared across the two waves. If there are no important differences, we will pool across waves. We will use the 6-week and 12-week measures to assess if engagement builds, sustains or declines over the intervention period. We will also examine study completion and attendance by wave.

Analyses for Specific Aim #2a. To assess if the intervention increases aspects of physical literacy including movement competence (ability), confidence, and desire to participate in physical activity, we will conduct 1-sample paired t-tests for change (against the null hypothesis of a change of zero) in separate tests for TGMD-3 scores, PSI-VSF-ID physical self-concept, and CSAPPA score. We will construct 95% confidence intervals around the measure of change separately for boys and girls, and pool them if we discern no important differences by sex. If, based on Aim #1, we believe there were important implementation differences between the two waves, we will analyze them separately, acknowledging our power will be more limited.

Analyses for Specific Aim #2b. Analyses to assess if the intervention increases elements of food literacy (i.e., knowledge and skills) for promoting intake of fruits and vegetables and for decreasing intake of high energy low nutrient dense snack foods will proceed as for Aim #2a. We will use a 1-sample (paired) t-test to test Food Knowledge, Food Skill Master, and Dietary Behavior scores. We will construct 95% confidence intervals around the change separately for boys and girls, pooling them if we discern no important difference by sex. If, based on Aim #1, we believe that there were important implementation differences across the two waves, we will analyze them separately, acknowledging our power will be more limited.

Sample Size Considerations. We established the sample size for this pilot study based on the aforementioned total and skill score on the CAMSA (Specific Aim #2a). Using available estimates from TD adolescents, we calculated the sample sizes needed to capture a 15% change

in score for boys and girls separately (score improvements of 6.63 total; 3.66 skill). Estimates on the CAMSA from adolescents with ID are unavailable in the literature; however, we have no reason to believe that the proposed intervention would have a different impact on adolescents with ID than TD adolescents. We estimated the standard deviation of the change in the measure (5.19 total; 3.10 skill) and the interclass correlation coefficient (0.91 total; 0.80 skill), as recommended. A sample size of 12 boys and 12 girls has, at an alpha level of 0.05, 80% power to assess a difference of 15% in total score and 15% in skill score, analyzing boys and girls separately. We have proposed to enroll 15 boys and 15 girls in our pilot study to allow for attrition and or missing data. If we do not identify important differences in the change in score by sex we will combine them, with the result that we would have adequate power to detect changes of the magnitude ~5% total and skill scores.

14. PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF SUBJECTS*

The physical and food literacy intervention and measurement protocols pose minimal risks to participants. As a supervised sport sampling and healthy eating program that requires approval from each participant's primary care physician and medical specialists (as needed), the proposed study represents a low-risk intervention. The intensity of the sports/physical activities will be guided and monitored by a physical activity instructor with experience instructing adolescents with ID and an academic background in exercise science and/or physical education. The healthy eating activities will be delivered by an experienced nutritionist/registered dietitian with at least an undergraduate degree in nutrition. Because of the minimal risk, the data safety monitoring plan for this study focuses on close monitoring by the PI and a data safety officer, along with prompt reporting of excessive and/or unexpected serious adverse events to the NIH and to the IRB at UMass Chan.

We have identified a data safety officer for this study who has experience conducting physical activity/health promotion intervention studies for adolescents and youth with neurodevelopmental and behavioral health disorders, and thus has a thorough understanding of the issues that arise in a combined program of this type. The data safety officer will review reports of any adverse events or unanticipated problems recorded by the study team. Although highly unexpected, participants could be injured during their physical activity participation or choke on food during the taste tests. We have not experienced these types of events in our previous studies and programs, but they are within the realm of possibility. We will mitigate these risks by providing close supervision of the participants so they do not engage in risky physical behaviors (e.g., over-exertion) or engage in problematic eating behaviors (e.g., over-stuffing their mouths or rapid eating).

The data safety officer will use a checklist to indicate whether there is any corrective action, trigger of an ad hoc review, or stopping rule that should be communicated to the study investigators, the UMass Chan IRB, or the NIH institute to which the project has been assigned. In addition, the data safety officer will comment on whether the PI needs to report any specific concerns to the participant, their parent(s), and/or their primary care physician.

Personal identifying information (PII). The names of the participants will be obtained to ensure that the data are organized during data collection and for the intervention. Names will be transferred to a participant number when the data are entered into the computer and no names

will ever be published. Age and birthdate will also be required as will sex. The addresses and telephone numbers of the parent(s) of each participant will be required in order to maintain contact during the intervention. There will be no attempt to link the PII to the study data.

15. WITHDRAWAL OF SUBJECTS WITHOUT THEIR CONSENT*

Although we do not anticipate the need to withdraw participants without their consent, if we find that an individual adolescent is unable to participate in the program safely (i.e., to keep him/herself or others safe), we will first seek to address the behavior (i.e., address anxiety or other issues that might be leading to the problematic behavior), and engage the adolescents' parents in problem-solving. If those efforts are not successful, we will proceed to withdraw the adolescent from the study.

16. RISKS TO SUBJECTS*

There is the risk of a breach in confidentiality. Measures, described above, will be put in place to lessen this risk.

The physical literacy and food literacy intervention and measurement protocols pose minimal risks to participants. As a supervised sport sampling and healthy eating educational program that requires approval from each participant's primary care physician and any medical specialists (as needed), the proposed study represents a low-risk intervention.

Physical Literacy component. The sport/physical activity stations and small group games will be classified as moderate intensity physical activity, and the Physical Activity Instructor will adjust the intensity, duration, and nature of the activities to accommodate those with lower stamina and to ensure safe participation. Participants will be encouraged to slow down and/or take breaks as necessary. The sport sampling lesson plans and activities will be guided by the Co-I, an expert in adapted physical activity. We do not anticipate that the participants would experience anything different from what they might encounter in a physical education class in school or in a community-based PA program. However, there is some potential that participants could experience bruises, cuts, scrapes, and/or muscle strains as a result of falling. It is likely that any injury will be temporary and easily addressed within their home setting with applying ice or a bandage. Participants who have particularly low levels of cardiorespiratory fitness may also find physical exertion during sports to be uncomfortable, though this will be monitored carefully by the Physical Activity Instructor to ensure that they are not overexerting themselves.

We have put several safeguards into place to protect participants. The sport sampling sessions and activities will be delivered by a qualified Physical Activity Instructor who has prior experience delivering physical activity/sport programming to youth with disabilities, with support from the RA and student assistants. The physical activities/sports/games will be developmentally- and age-appropriate to maximize safety and minimize risk of injury. Participants will be repeatedly reminded of safety rules and encouraged to adhere to the rules.

Healthy Eating (food literacy) component. This component of the intervention poses no discernable risk to participants. The session will involve games and activities to increase healthy food knowledge directed by a Nutritionist or nutrition graduate student with guidance from the Co-Investigator, an expert in the field of obesity and nutrition. The food preparation activities

will not require participants to use knives or other sharp kitchen tools. The Nutritionist will review safe food preparation and handling with participants and parents for the taste tests, and will have knowledge of any participant food allergies so that safe foods will be provided.

The healthy eating activities, educational lessons, and taste tests will be delivered by a nutritionist with support from the RA and students, and pose no risk to participants. Parents will be asked to provide information about their adolescent's food allergies prior to the first session. Substitutions for the foods used in preparation and in the taste tests will be made if a adolescent in the group has allergies so that all adolescents can participate and ensure that adolescents are not exposed to allergens.

Potential risks associated with outcome measures. There are very few risks associated with completing the outcome measures. The Test of Gross Motor Development-Third Edition (TGMD-3) poses no greater risk than the risks associated with the intervention itself, as described above.

There are no discernable, unexpected risks in completing the survey/questionnaire-based measures. There are no risks associated with the measures of food preparation skills, healthy food knowledge, or healthy eating behavior.

17. POTENTIAL DIRECT BENEFITS TO SUBJECTS*

Participants may benefit from the intervention by increasing their physical literacy including movement skills, physical self-concept and desire to participate in sports/physical activities, and food literacy including healthy eating knowledge, basic food preparation skills, and improved healthy eating behavior. They may also benefit by participating in an enjoyable group-based intervention with their peers. However, these benefits cannot be guaranteed.

18. VULNERABLE POPULATIONS*

All participants in the project will be adolescents ages 12-16 years with an intellectual disability.

We will obtain consent from a primary caregiver (i.e., father, mother, guardian); in the case of divorce, we will obtain consent from the both parents if they have joint legal custody, or the parent who has sole legal custody. In the case where the adolescent is under the care of an agency such as the Department or Children and Families, we will seek permission/consent from the responsible party at the agency. Adolescents who have guardianship other than their parents will be required to provide written proof of their authority to grant permission for the adolescent to participate in activities such as research (or to receive medical care).

With the assent process, we will develop a simply worded document which we will read/review with the adolescent and invite them to ask questions. If they indicate an interest in participating, we will ask them to sign their name to the form. If they indicate that they do not wish to participate, we will try to ascertain their concerns and allay them, but if their unwillingness persists, we will not proceed with enrolling them in the program, and will make it clear to them that this is a choice that they have the right to make. We have used these procedures in the past with this population and have had good success.

19. MULTI-SITE RESEARCH* N/A

20. COMMUNITY-BASED PARTICIPATORY RESEARCH* N/A

21. SHARING OF RESEARCH RESULTS WITH SUBJECTS*

Upon completing the study, analyzing the results, and publishing the main paper(s) from the intervention, we will write to participants to provide them with a lay description of the findings and to give them references to the published papers.

22. SETTING

The project will be carried out at the E.K. Shriver Center at UMass Chan Medical School, although the intervention itself will be conducted remotely using Zoom.

23. RESOURCES AVAILABLE

The study team consists of researchers and personnel from University of Massachusetts Chan Medical School Eunice Kennedy Shriver Center, University of Massachusetts Boston (UMass Boston), Merrimack College, and Tufts University School of Medicine (TUSM) who will work collaboratively on this clinical trial.

Principal Investigator is a well-established health researcher with a focus on obesity prevention and treatment through tailored interventions for youth with intellectual and developmental disabilities. She will oversee the entire project and ensure that it is carried out according to the approved protocol and established timelines. She will manage the collaborative efforts among the Co-Investigators and will coordinate the weekly meetings of the research team. The PI will also be responsible for supervising the work of the Project Coordinator and Research Assistant. She will oversee the recruitment, interactions with the IRB, and will be responsible for the budgetary aspects of the grant. The PI will direct the development of the satisfaction and enjoyment questionnaires to test the feasibility of the intervention, and will oversee the collection of the psychosocial data (i.e. confidence, perceived competence). She will work with the Co-Investigators, and the Data Analyst on data interpretation, manuscript preparation, and dissemination. The PI will devote 10%FTE in both Years 1 and 2 of the project.

Co-Investigators

The Co-Investigators involved in the project are PhD-level investigators and accomplished researchers in the fields of nutrition and physical activity in children and youth with ASD/IDD. The co-investigators will work with the PI to carry out the project and will each oversee the following aspects of the project according to their areas of expertise: (1) development of the physical activity and food literacy curricula and the preparation of the related materials and resources; (2) supervise and support program interventionists; (3) oversee data collection, analysis, and interpretation; and (4) assist with manuscript preparation and dissemination. Co-investigators may also be involved in participant consenting activities, and other intervention-related interactions with participants and their family members. They will participate between 4% and10%FTE in Years 1 and 2 of the project.

Project Coordinator (PC) will be responsible for working with the PI and the research team to support the implementation and evaluation of the physical and food literacy intervention. The

Project Coordinator will work with the research team to develop the REDCap database for participant tracking and data entry. S/he will oversee data entry and data management activities and record-keeping. S/he will also work closely with the PI, Co-Investigators, Research Assistant, and other research staff to ensure the data are managed according to protocol. The PC will participate in data interpretation and dissemination activities. S/he will also coordinate communications with the IRB. S/he will participate on the project for 30% FTE in Year 1 and 28% FTE in Year 2.

Research Assistant The Research Assistant will assist with recruiting participants, coordinating screening/enrollment and intervention visits, coordinating communications with parents/participants, and coordinating fiscal aspects of the program (e.g., invoicing for study sites, track instructor hours, purchase supplies, etc.). S/he will also assist and support the Physical Activity Instructor and Nutritionist during the intervention sessions to ensure that they are implemented according to the approved protocol. The Research Assistant will coordinate and assist with data collection of physical and food literacy skills under the supervision of the Co-Investigators. The Research Assistant will attend weekly meetings with research team and assist with day to day project-related tasks. S/he will participate 100% FTE in both Years 1 and 2 of the project.

Physical Activity Instructor will be an individual with prior experience delivering physical activity/sport programming to youth with disabilities. S/he will work with the research team, under direct supervision of one of the Co-Is to develop and adapt the overall physical literacy curriculum and design the activity plans for the weekly sessions. The Instructor will lead and supervise the weekly physical activity/sport sessions for the 12-week intervention and will oversee and support the student assistants during the activity sessions. The Instructor will have regular meetings with the research team to ensure that the intervention is being implemented as planned and to develop strategies to adapt the curriculum and pedagogy as needed. The Physical Activity Instructor will also support and assist the Nutritionist in the weekly food literacy activities as needed. The PA Instructor will participate 5 hours/week for 19 weeks, Years 1 & 2.

Nutritionist will work with the research team under the direct supervision of on of the Co-Is to develop the food literacy curriculum and design the activity plans for the weekly sessions. The Nutritionist will be responsible for preparing the materials for the weekly lessons, including the food for the taste tests. S/he will lead and supervise the weekly food literacy activities over the 12-week intervention and will oversee and support the student assistants during the food literacy activities. The Nutritionist will also support and assist the Physical Activity Instructor in the physical literacy activities as needed. The Nutritionist will have regular meetings with the research team to ensure that the intervention is being implemented as planned. The Nutritionist will participate 5 hours/week for 19 weeks, Years 1 & 2.

Data Analyst will work under the supervision of one of the Co-Is to assist with data management and will implement statistical programming relevant to testing the study hypotheses and for quality control. S/he will participate in data interpretation and manuscript preparation activities, and will have extensive experience in data management and statistical analyses.

Graduate Students from Boston University will work under the supervision of the PI and Co-Is to implement the project, including offering support during the sessions and conducting short activities in breakout rooms.

24. LOCAL RECRUITMENT METHODS

Recruitment.

Participants with ID will be recruited through area special education programs and schools, as well as through the many agencies that serve individuals with ID and their families such as local Arc chapters, city/town recreation programs, Federation for Children with Special Needs, MA Down Syndrome Congress, Department of Developmental Services, and MA Special Education Parent Advisory Councils. We will use our extensive connections in the community and the UMass Chan E.K. Shriver Center's database of participants from previous studies to reach adolescents with ID. We aim to recruit a racially/ethnically diverse sample via postings to listservs, websites, phone, paper mailings, newsletters, and word of mouth. IRB-approved recruitment will be conducted locally using materials that are mailed or distributed via social media to organizations that serve youth with ID. We will continue to submit all recruitment materials via a modification prior to utilizing the recruitment material.

Recruitment materials (e.g. e-brochures, electronic messages) will clearly outline the details of the study and a parent/guardian will directly contact the research staff by telephone or email to express their interest in having their child participating. The intervention will be marketed as a non-competitive and engaging program involving sport skills sampling and healthy eating awareness activities to build physical literacy and food literacy.

Our research plan allows for a 10% drop out rate, which is supported by our previous work in which we have had over 95% retention rates in several intervention studies.

Recruitment – Inclusion/Exclusion Criteria

We will recruit 30 male (n=15) and female (n=15) adolescents with intellectual disabilities (ID) ages 12-16 years. Because the etiology of ID is variable with many known and unknown causes, we expect the sample will include adolescents with various syndromes such as Down syndrome, Fragile X, Williams syndrome, as well as adolescents with ID of unknown etiology. To be included in the study adolescents will be required to have IQ and adaptive functioning scores of ≤75 as measured by the Kaufman Brief Intelligence Test-2 and Vineland Adaptive Behavior Scales-III. Participants must be independently ambulatory and in sufficiently good health to engage in moderate-to-vigorous physical activity, and be able to communicate verbally in English, follow simple instructions, and provide assent/consent. Approval from the primary care physician and medical specialists (as necessary) will be required for participation.

Exclusion criteria include: 1) uncontrolled medical or significant psychiatric condition; 2) insulin-dependent diabetes; 3) physical/orthopedic impairment that would preclude safe participation in physical activity; 4) legally blind or deaf; 5) habitual problem behaviors such as aggression or noncompliance

Screening
Adolescents with ID will be initially screened for eligibility for the study via a telephone or Zoom interview with a parent by the Project Coordinator. During the interview, the intervention will be described and the concepts of physical literacy and food literacy will be explained to parents. Those adolescents who meet the inclusion criteria and a parent will then participate in an enrollment meeting via Zoom. During that meeting, the study protocol will be reviewed in detail and parental permission/informed consent will be obtained and adolescents will sign an assent from that will be administered in the form of a social story. After the consenting and assenting process, we will administer the KBIT-2 to confirm IQ eligibility (i.e., ≤75) and administer the VABS-III to determine if the adolescent meets the criteria for ID (i.e., ≤75) based on their adaptive behavior. If the adolescent meets criteria, demographic characteristics will be ascertained via parent questionnaire on age, sex, race/ethnicity and parent education.

Data management
The names of the participants will be obtained to ensure that the data are organized during data collection and for the intervention. Names will be transferred to a participant number when the data are entered into the computer and no names will ever be published. Age and birthdate will also be required as will sex. The addresses and telephone numbers of the parent(s) of each participant will be required in order to maintain contact during the intervention. There will be no attempt to link the personal identification information to the study data. Data from participants who screened but did not enroll will not be included as study data, except to track information as needed for a Consort diagram. Their identifying information will be destroyed/deleted upon the start of the intervention, unless they have indicated a desire to be contacted for future research opportunities. Anyone who indicates a desire to be contacted for future research opportunities will have their information shared with the Clinical & Translational Research Support Core at the Shriver Center that maintains a database of participant information for the purposes of recruitment (Curtin, PI). This information is housed in a password protected database that is available only to Core staff.

Recruitment Materials
We will continue to submit recruitment material via a protocol modification prior to utilizing.

Compensation
Participants will not receive compensation for participation, but will be permitted to keep the sports equipment (e.g., balls, bats, etc.), and tablet after the intervention. If a participant does not have reliable internet, they will be provided with a Wi-Fi hotspot, which they will also be permitted to keep (however, we will not continue to pay for data service).

25. LOCAL NUMBER OF SUBJECTS
We will recruit 30 male (n=15) and female (n=15) adolescents with intellectual disabilities (ID) ages 12-16 years.

26. CONFIDENTIALITY
Confidentiality of participants will be protected in several ways. All participants will receive an identifying number for coding and analyzing data. Informed consent and identifying code numbers will be kept in a separate file from completed data questionnaires. Data will be reported

in group format only; if any need should arise to report individual data, it will be accessible only to the research team and identifying information will not be reported that might allow the individual's identity to be discerned.

Data will consist of a recording of and performance on the TGMD-3 test, completion of questionnaires by participants and parents, and recording of the virtual intervention sessions on Zoom. All video recordings will be stored in a password-protected, HIPAA-compliant, cloud-based server. Questionnaires will be administered by paper or electronically using REDCap. All paper-based data will be kept in a locked file cabinet and will be accessible only to the research team. Individual names and identifying characteristics will not be shared with others outside of the research team. Requests or discussions regarding participation in the study will be made by letter or phone calls in a separate, private room.

Subjects will be provided with an Amazon Fire Tablet for use during the study. No identifying information will be stored on these devices during the duration of the study however we will allow participants to keep these devises after the intervention at which point they can choose to disclose personal information. The privacy statement for the Amazon Fire tablets can be found here: https://www.amazon.com/gp/help/customer/display.html?

Additionally, this study will utilize the Remind App to provide SMS reminders of study tasks to participants' parents. Remind was originally designed to facilitate communication, including texting, emailing and phone calls, from educators to students without sharing personal contact information. Remind is now commonly used in research to facilitate communication between research staff and participants or participants' caregivers if applicable. Remind complies with all privacy laws applicable to public schools including FERPA and COPPA. Remind is ISO 27001:2013 certified and has also obtained iKeepSafe certification for the FERPA Assessment, COPPA Safe Harbor Program, and California Student Privacy Badge. Remind is a certified signatory of Privacy Shield, administered by the US Department of Commerce, which allows Remind to lawfully transfer the data of European Union residents to the United States. To meet these program guidelines, Remind employs two kinds of security features: those that are user-facing, and those that are embedded in the service. Users can receive messages via text message, smartphone app, or email, but contact information like phone numbers and email addresses are only visible to research administrators and not exposed to other parents or participants. Instead, Remind uses third-party phone numbers to protect users' privacy.

If participants opt-out of using the Remind app, we will ask them to consent to receiving notifications about the study via email or text message with the provided Text Message / Email Consent document.

Describe the steps that will be taken to secure data and/or specimens during data collection, storage, use, and transmission. For example:

- *Which staff roles will be responsible for their receipt or transmission? How will they be collected and transported?*
  The Research Assistant will be responsible for the receipt and transmission of the data and for transporting it by vehicle. Any transported data will be kept in a locked container while it's being transported.

- *Where and how will they be stored?*
  How long will they be stored?
  Will any portable devices (e.g., laptops, thumb drives) be used?
  All data will be kept in a locked file cabinet accessible only to the research team and UMass Chan IRB representatives, on password-protected computers and in REDCap. Data will be stored for 5 years from the completion of the study. Laptops and thumb drives will be used and will be encrypted per UMass Chan policies.

- *Which staff roles will have access?*
  All study staff will have access to the data.

- *How will you limit access?*
  Only study staff will have keys to the file cabinets and passwords to the computers and REDCap.

- *Will staff undergo any special training or require special authorizations?*
  No, this will not be necessary, as the procedures followed in this protocol are standard procedures for projects of this nature.

- *Will you implement electronic controls, such as password protection? Encryption?*
  Yes – drives and databases (REDCap) will be password protected, and laptops/thumb drives will be encrypted.

- *Will you use physical controls, such as locked offices?*
  Yes – all paper-based forms will be stored in locked cabinets within locked offices.

- *If data or specimens are coded, how will you store the key that links the code to subject identifiers separately from the data and specimens?*
  The key that links the code to subject identifiers will be stored in REDCap, separate from the data.

- *When and how will you securely destroy identifiers to anonymize data?*
  In order to securely destroy identifiers to anonymize data, we will remove the study code from the database that links the participant's name to the study code. This will be done within 5 years of study completion.

- *When and how will you securely destroy the data and specimens in full?*
  All coded, printed data will be shredded 5 years from the completion of the study. All electronic, coded data will be destroyed 5 years from the completion of the study using the most secure methods at that time, in order to make sure the data is completely destroyed.

- *Have you obtained or will you seek a Certificate of Confidentiality?*
  No

Research personnel from University of Massachusetts Chan Medical School Eunice Kennedy Shriver Center, Tufts University, Boston University, and the University of Massachusetts-Boston who are listed with the IRB as UMass personnel engaged in the design, conduct, or reporting of the research will have access to local data. In addition, people that have an identified role in oversight of this study may inspect subjects' medical and research records. This includes the National Institute of Health (NIH), the UMass Chan Institutional Review Board (IRB), and UMass representatives. Finally, PHI may be entered into databases at the University of Massachusetts Chan Medical School, including the Institutional Review Board (IRB), the Medical School's research management system and the research, billing and compliance office.

27. PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF SUBJECTS

Participants and their parents will be interviewed to ensure that they understand the intervention, its purpose, and the information to be collected. Ample time will be given to provide participants an opportunity to ask questions and express any concerns. If it appears that the adolescent participants are reluctant to participate (even if their parents wish them to), we will make it clear that their agreement to be involved is key, and we will not proceed with enrolling them if it is apparent that they are resistant. We will explain this to the parents and let them know that it would not be in their child's best interest, or in line with research ethics, to involve them in the study without their full agreement.

28. COMPENSATION FOR RESEARCH-RELATED INJURY

N/A – This project does not pose more than minimal risk to participants.

29. ECONOMIC BURDEN TO SUBJECTS

There is very little economic burden to the subjects. All materials and equipment will be covered by the study.

30. CONSENT PROCESS

Potential participants who meet the inclusion criteria and a parent will be invited to a remote enrollment meeting with the Project Coordinator. At that meeting, the purpose of the study will be explained in detail and we will interview the adolescent to discern their interest and motivation for participating in the program. Parental permission/informed consent will be obtained from parents and assent will be obtained from adolescents. The assent form will be verbally administered in the form of a social story over Zoom to accommodate potential limited reading skills of participants. The adolescent will then be asked to verbally assent to the study, with that verbal assent being documented in REDCap. A parent will be present for the assenting process to help ensure that adolescents with ID understand the details of the study and what they are agreeing to. Participants may elect to decline participation at any point during the project, even after giving informed assent, as described above.

31. PROCESS TO DOCUMENT CONSENT IN WRITING

As indicated above, we will obtain written consent from parents and a simple signed assent from the adolescents/youth.

32. DRUGS OR DEVICES – N/A