Variations in Palatability and Portion Size of Vegetables on Meal Intake of Preschool Children

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1.0 Objectives

1.1 Study Objectives

Aim: To determine the effects of varying both the palatability and portion size of vegetables served to preschool children at a meal on the outcomes of vegetable intake, food intake, energy intake, and energy density at the meal.

Hypotheses:

1. For the outcome of vegetable intake at the meal:
   a. Enhancing the palatability of vegetables served at the meal will increase vegetable intake.
   b. Increasing the portion size of vegetables served at the meal will increase vegetable intake.
   c. Enhancing the palatability of vegetables served at the meal will interact with vegetable portion size to increase its effect on vegetable intake.

2. For the outcome of food intake at the meal:
   a. Enhancing the palatability of vegetables served at the meal will increase food intake.
   b. Increasing the portion size of vegetables served at the meal will increase food intake.

3. For the outcome of energy intake at the meal:
   a. Enhancing the palatability of vegetables served at the meal will increase energy intake.
   b. Increasing the portion size of vegetables served at the meal will increase energy intake.
   c. Enhancing the palatability of vegetables served at the meal will interact with vegetable portion size to increase its effect on energy intake.

4. For the outcome of food energy density at the meal:
   a. Enhancing the palatability of vegetables served at the meal will increase energy density.
   b. Increasing the portion size of vegetables served at the meal will decrease energy density.

1.2 Primary Study Endpoints

1. Weight (grams) of vegetables consumed at the meal

1.3 Secondary Study Endpoints

1. Weight (grams) of food consumed at the meal
2. Energy (kilocalories) consumed at the meal
3. Energy density (kilocalories/gram) of food consumed at the meal

2.0 Background

2.1 Scientific Background and Gaps

The US Dietary Guidelines recommend that 3- to 5-year-old children consume at least one to two servings of vegetables each day (USDA, 2015). The majority of children, however, do not meet these recommendations (Ramsay et al., 2014). This finding has been attributed in part to children's low preference for vegetables compared to other foods (Ishdorj et al., 2015; Nicklaus et al., 2004). As a strategy to increase vegetable intake in children, a number of studies have tested serving larger portions of vegetables at a meal (Mathias et al., 2012; Spill et al., 2010; Kral et al., 2010). The results of these portion size studies, however, have been variable, which might be explained by differences in the palatability of the vegetables that were tested in the studies. It remains to be investigated whether increasing the palatability of vegetables compared to other meal components promotes vegetable intake when larger portions are served. Thus, this experiment aims to assess whether the palatability of vegetables influences vegetable intake in response to increases in vegetable portion size at a meal.

2.2 Previous Data

In a previous study in preschool children (Matthias et al., 2012), the portion size of vegetable side dishes served at a meal was doubled, and it was found that this led to an overall increase in vegetable intake. However, a significant increase was only observed in the children who reported liking the vegetables (57% of children). These findings show that increasing the portion size of vegetables can lead to increases in intake in preschool children, but suggests that the effect depends on the palatability of the vegetables.

2.3 Study Rationale

This study will increase understanding of the effects of vegetable palatability on children's vegetable intake and will assess whether increases in palatability can be used in conjunction with increased portion size to promote vegetable intake in preschool children.

3.0 Inclusion and Exclusion Criteria

3.1 Inclusion Criteria

1. Children who are between the ages of 3 and 5 years old and who are enrolled in a scheduled classroom of the childcare center.

3.2 Exclusion Criteria

1. Children who are allergic to any of the foods served
2. Children whose diets exclude any of the foods served

3. Children who will not be present at the childcare center for all of the scheduled study days (due to scheduled vacations, part-time enrollment at the childcare center, etc.).

3.3 Early Withdrawal of Subjects

3.3.1 Criteria for removal from study

Subjects will be removed from the study if they repeatedly fail to follow study protocol.

All participation is voluntary. Children can refuse to participate in any session and parents, children, and teachers may withdraw from the study at any time.

3.3.2 Follow-up for withdrawn subjects

N/A

4.0 Recruitment Methods

4.1 Identification of subjects

Children who are enrolled in the scheduled classroom at the childcare center, along with their parents or guardians, will be invited to participate.

Teachers in the classrooms of participating children will be invited to participate.

4.2 Recruitment process

4.2.1 How potential subjects will be recruited

We will recruit using a parent letter placed in each child's mailbox at the childcare center. A trained staff member who is approved to do recruitment and consenting of subjects will be available in the center during child pick up or drop off to explain the study and answer any questions parents may have.

Teachers in classrooms of participating children will be verbally invited to participate by study staff.

4.2.2 Where potential subjects will be recruited

At the childcare center.

4.2.3 When potential subjects will be recruited

We will work with local child care centers to identify times which we can come in to collect data. 2 – 4 weeks before data collection begins, we will recruit participants.

4.2.4 Describe the eligibility screening process and indicate whether the screening process will occur before or after obtaining informed consent

Children with allergies to foods served, or whose diets exclude these foods, will not be eligible to participate in this study. Children with > 1 previously planned absence during any of the study days will also be excluded from participation.

A screening questionnaire regarding food allergies, dietary exclusions, food intolerances, and attendance during planned study days will be included with the consent form.

5.0 Consent Process and Documentation

5.1 Consent Process:
Check all applicable boxes below:

☒ **Informed consent will be sought and documented with a written consent form *[Complete Sections 5.2 and 5.6]***

☐ **Implied or verbal consent will be obtained – subjects will not sign a consent form (waiver of written documentation of consent) *[Complete Sections 5.2, 5.3 and 5.6]***

☐ **Informed consent will be sought but some of the elements of informed consent will be omitted or altered (e.g., deception). *[Complete section 5.2, 5.4 and 5.6]***

☐ **Informed consent will not be obtained – request to completely waive the informed consent requirement. *[Complete Section 5.5]***

5.2 Obtaining Informed Consent

5.2.1 Timing and Location of Consent

The consent form will be signed by the parent prior to their child's enrollment in the study. Consent will be obtained at the childcare center with a trained member of the lab staff present.

Teachers will consent (to fill out questionnaires about enrolled children) at the childcare center during the first study week in their classroom.

5.2.2 Coercion or Undue Influence during Consent

Parents will be given the consent form to take home to review on their own and can decide whether they want their child to participate.

Teachers will be given the opportunity to review the consent from on their own and can decide if they wish to participate.

5.3 Consent – Other Considerations

5.3.1 Non-English-Speaking Subjects

It is not anticipated that there will be any non-English speaking or illiterate parent participants.

5.3.2 Cognitively Impaired Adults

5.6.2.1 Capability of Providing Consent

N/A

5.6.2.2 Adults Unable to Consent

N/A

5.6.2.3 Assent of Adults Unable to Consent

N/A

5.3.3 Subjects who are not yet adults (infants, children, teenagers)

5.6.3.1 Parental Permission

Parents will sign consent for their child to participate. Two copies of the consent form will be provided, one to be signed and returned to study staff, and one to be kept for parents' records.

5.6.3.2 Assent of subjects who are not yet adults

Children can refuse to eat any meal if they choose. Before beginning measurement of height and weight or the Tasting Game, children will be asked if they want to participate and can refuse to do so.

6.0 Study Design and Procedures

6.1 Study Design

This study will have a within-subject design with four experimental conditions. Once a week for four weeks, children will be served a meal consisting of a main dish, fruit, vegetables, and milk. On different occasions, the vegetables served at the meal will be varied in both palatability and portion size. The palatability will be either standard (steamed, plain vegetables) or enhanced (vegetables with added flavoring) and the portion size will be either baseline (100%) or larger (200% of baseline).

The experimental conditions will be as follows:
1. Standard palatability of vegetables and 100% portion size of vegetables
2. Standard palatability of vegetables and 200% portion size of vegetables
3. Enhanced palatability of vegetables and 100% portion size of vegetables
4. Enhanced palatability of vegetables and 200% portion size of vegetables

The order of presenting the conditions across study weeks will be counterbalanced by classroom. All meals will meet the minimum guidelines outlined by the USDA and Child and Adult Care Food Program (CACFP).

6.2 Study Procedures

1. On one day a week for four weeks, enrolled children will be served a lunch of foods commonly served in the childcare center and following the regular meal schedule. Menus have been developed from the childcare center menus to be as similar as possible to the foods that children are served regularly. Milk will be served as beverage. Meals will be served at tables of 3 to 6 children and one adult, which is a standard practice at the childcare centers. The adults at the table will be instructed not to discuss the food or to encourage the children to eat. Each participant will be served an individual pre-weighed meal. All food and beverage items will be weighed with an electronic food scale before and after meals in order to determine the amount consumed. Participants will be told they can eat as much or as little of the foods as they would like. Trained research personnel will observe each mealtime and will document food and beverage spillage and any comments made about the food.

2. After all study meals are completed, trained research personnel will return to the childcare center to measure the height and weight of enrolled children. Body weight will be measured in triplicate using a portable digital scale. Height will be measured in triplicate using a portable stadiometer. Enrolled children will also be invited to participate in the Tasting Game. They will be asked to taste a small amount of each food served in the study and indicate their liking of the food by pointing to one of three cartoon faces (Yummy, Just OK, and Yucky). Children will also be asked to rank their liking of each food in the meal and to indicate their preference for the vegetables with enhanced palatability compared to those with standard palatability.

3. Parents will be asked to complete a demographic questionnaire, the Children and Adult Eating Behavior Questionnaire, the Vegetable Questionnaire, and a portion of the Child Feeding Questionnaire. These questionnaires (4 total) will assess whether certain child eating behaviors or parental feeding behaviors influence food intake. All will be administered and completed via paper and pencil.

4. Photographs may be taken in the childcare center of children eating meals, participating in the Tasting Game, and having their height and weight measured. Taking such photographs will be subject to the consent provided by each parent concerning their child.

5. For each enrolled child, the classroom teacher who is most familiar with the child's eating behavior will complete one questionnaire (Children's Eating Behaviour Questionnaire). All will be administered and completed via paper and pencil.

6.2.1 Visit 1

Enrolled children will be served a lunch of foods commonly served in the childcare center and following the regular meal schedule. Milk will be served as beverage. Meal 1 will be served at tables of 3 to 6 children and one adult, which is a standard practice at the childcare centers.

Each participant will be served an individual pre-weighed meal. All food and beverage items will be weighed with an electronic food scale before and after meals in order to determine the amount consumed. Participants will be told they can eat as much or as little of the foods as they would like. Trained research personnel will observe each mealtime and will document food and beverage spillage and any comments made about the food.

6.2.2 Visit 2 (If applicable)

Enrolled children will be served a lunch of foods commonly served in the childcare center and following the regular meal schedule. Milk will be served as beverage. Meal 2 will be served at tables of 3 to 6 children and one adult, which is a standard practice at the childcare centers.

Each participant will be served an individual pre-weighed meal. All food and beverage items will be weighed with an electronic food scale before and after meals in order to determine the amount consumed. Participants will be told they can eat as much or as little of the foods as they would like. Trained research personnel will observe each mealtime and will document food and beverage spillage and any comments made about the food.

6.2.3 Visit 3 (If applicable)

Enrolled children will be served a lunch of foods commonly served in the childcare center and following the regular meal schedule. Milk will be served as beverage. Meal 3 will be served at tables of 3 to 6 children and one adult, which is a standard practice at the childcare centers.

Each participant will be served an individual pre-weighed meal. All food and beverage items will be weighed with an electronic food scale before and after meals in order to determine the amount consumed. Participants will be told they can eat as much or as little of the foods as they would like. Trained research personnel will observe each mealtime and will document food and beverage spillage and any comments made about the food.

6.2.4 Visit 4 (If applicable)

Enrolled children will be served a lunch of foods commonly served in the childcare center and following the regular meal schedule. Milk will be served as beverage. Meal 4 will be served at tables of 3 to 6 children and one adult, which is a standard practice at the childcare centers.

Each participant will be served an individual pre-weighed meal. All food and beverage items will be weighed with an electronic food scale before and after meals in order to determine the amount consumed. Participants will be told they can eat as much or as little of the foods as they would like. Trained research personnel will observe each mealtime and will document food and beverage spillage and any comments made about the food.

6.2.5 Visit 5 (If applicable)

After all study meals are completed, trained research personnel will return to the childcare center to measure the height and weight of enrolled children. Body weight will be measured in triplicate using a portable digital scale. Height will be measured in triplicate using a portable stadiometer. Enrolled children will also be invited to participate in the Tasting Game. They will be asked to taste a small amount of each food served in the study and indicate their liking of the food by pointing to one of three cartoon faces (Yummy, Just OK, and Yucky). Children will also be asked to rank their liking of each food in the meal and to indicate their preference for the vegetables with enhanced palatability compared to those with standard palatability.

6.3 Duration of Participation

Children's study meals will be served during their usual meal time at the childcare center and will take no more than the usual time (30 minutes). The height and weight measurements and the Tasting Game on the final visit will require an additional hour of time. Completion of questionnaires will take approximately 30 minutes for parents and approximately 20 minutes per questionnaire for teachers.
Total time commitment for parent and child should be no more than 3 hours.

7.0 Subject Numbers and Statistical Plan

7.1 Number of Subjects

We estimated that we will need 49 children to complete the study in order to detect significant effects of vegetable palatability on vegetable intake. In order to allow for absences and withdrawal of participants, we will aim to enroll 65 children.

7.2 Sample size determination

A power analysis was performed to determine the sample size needed to detect the effect on vegetable intake of enhancing the vegetables with small amounts of salt and butter; this effect was considered to be more difficult to detect than that of portion size. The variability in vegetable intake was estimated from a study in which toddlers were served vegetables with different amounts of butter and salt at different lunches (Bouhlal et al., 2011), as well as from our previous studies in 3- to 5-year-old children (Smethers et al., 2019; Sanchez et al., 2019). The difference in vegetable intake to be detected was set at 10 g, which is about one-third of the minimum vegetable serving size of the Child and Adult Care Food Program (CACFP) for lunch in this age group. In order to detect this difference in vegetable intake, the required sample size was estimated to be 49 children using a Type 1 error rate of 5% and a power of 80%. In order to allow for absences and withdrawals, we will aim to enroll at least 65 children in the study.

7.3 Statistical methods

The primary outcome of this crossover study will be children's vegetable intake by weight. Secondary outcomes will be meal food and milk intake, meal energy intake, and the energy density of the food consumed at the meal. Differences in mean outcomes across the two experimental factors will be analyzed using linear mixed models with repeated measures. The fixed factors in the model will be the experimental conditions of portion size (100% or 200%) and flavor (plain or enhanced), as well as study week, classroom, and sex of the child. The interaction between the factors of portion size and flavor will be tested for significance in all models and removed if not significant. Participants will be treated as a random effect. The Tukey-Kramer method will be used to adjust the significance level for multiple pairwise comparisons between means. Children who left <7 g of vegetables uneaten at ≥3 meals will be identified as "plate cleaners", and vegetable intake will be analyzed both with and without these children.

Analysis of covariance with linear mixed models will be used to assess the influence of continuous participant characteristics (age, body weight, height, BMI-for-age percentile, BMI z-score, questionnaire subscales) on the relationship between experimental factors and vegetable intake. Categorical subject characteristics (sex, preference ratings for both versions of vegetables, and liking and ranking ratings of all meal components) will be tested as factors in the models. Ordinal logistic regression will be used to evaluate whether the distribution of the liking ratings of the vegetables differed significantly between the plain and enhanced versions; results will be reported as odds ratios with 95% confidence levels. Differences between boys and girls in age, body weight, height, BMI-for-age percentile, and BMI z-score will be evaluated by using t-tests. Outcomes from statistical models will be considered significant at $p < 0.05$. All data will be analyzed with SAS software (SAS 9.4, SAS Institute, Inc.).

8.0 Data and Safety Monitoring Plan

8.1 Periodic evaluation of data

N/A

8.2 Data that are reviewed

N/A

8.3 Method of collection of safety information

N/A

8.4 Frequency of data collection

N/A

8.5 Individuals reviewing the data

N/A

8.6 Frequency of review of cumulative data

N/A

8.7 Statistical tests

N/A

8.8 Suspension of research

N/A

9.0 Risks

There are minimal risks associated with participation in this study. The risks are no greater than those associated with the children's usual attendance and consumption of meals at the childcare center, which include the risk of food allergy, food-borne illness, and choking on food.

The amounts of food served in all experimental conditions meet or exceed minimum requirements for calorie and nutrient content for this age group as specified by the USDA and Child and Adult Care Food Program (CACFP).

Teachers, children and parents risk loss of confidentiality. Measures will be taken to minimize this risk and include keeping all documents with personal information in a locked closet in the lab manager's office. Only those listed on the IRB application will have access to those records.

10.0 Potential Benefits to Subjects and Others

10.1 Potential Benefits to Subjects

None

10.2 Potential Benefits to Others

The research will benefit society by advancing understanding of children's eating behavior and identifying meal-related strategies for the prevention of obesity in children.

11.0 Sharing Results with Subjects

N/A

12.0 Subject Payment and/or Travel Reimbursements

Parents will be paid $20 upon completion of the study. Parents will receive an additional $40 for returning 4 questionnaires ($10 per questionnaire). If a participant does not, for any reason, complete all study meals, payment will be prorated at $5/meal. Total parent payment will be $60.

Teachers will be paid $5 per questionnaire returned.

13.0 Economic Burden to Subjects

13.1 Costs

N/A

14.0 Other Approvals

14.1 Other Approvals from External Entities

The Bennett Family Center, Hort Woods Child Care Center at Hort Woods, and Step by Step School for Early Learning have given permission to conduct our research in the facilities.

14.2 Internal PSU Committee Approvals

N/A

15.0 Adverse Event Reporting

15.1 Reporting Adverse Reactions and Unanticipated Problems to the Responsible IRB

In accordance with applicable policies of The Pennsylvania State University Institutional Review Board (IRB), the investigator will report, to the IRB, any observed or reported harm (adverse event) experienced by a subject or other individual, which in the opinion of the investigator is determined to be (1) unexpected; and (2) probably related to the research procedures. Harms (adverse events) will be submitted to the IRB in accordance with the IRB policies and procedures.

16.0 Study Monitoring, Auditing and Inspecting

16.1 Auditing and Inspecting

The investigator will permit study-related monitoring, audits, and inspections by the Penn State quality assurance program office(s), IRB, the sponsor, and government regulatory bodies, of all study related documents (e.g., source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g., pharmacy, diagnostic laboratory, etc.).

17.0 Future Undetermined Research: Data and Specimen Banking

17.1 Data and/or specimens being stored

N/A

17.2 Location of storage

N/A

17.3 Duration of storage

N/A

17.4 Access to data and/or specimens

N/A

17.5 Procedures to release data or specimens

N/A

17.6 Process for returning results

N/A

18.0 References

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Kral, T.V., Kabay, A.C., Roe, L.S., & Rolls, B.J. (2010). Effects of doubling the portion size of fruit and vegetable side dishes on children's intake at a meal. *Obesity*, 18(3), 521-527.

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Nicklaus, S., Boggio, V., Chabanet, C., & Issanchou, S. (2004). A prospective study of food preferences in childhood. *Food Quality and Preference*, 15(7-8), 805-818.

Ramsay, S.A., Eskelsen, A.K., Branen, L.J., Armstrong Shultz, J., & Plumb, J. (2014). Nutrient intake and consumption of fruit and vegetables in young children. *ICAN: Infant, Child, & Adolescent Nutrition*, 6(6), 332-344.

Sanchez C.E., Roe L.S., Keller K.L., Smethers A.D., Meehan C.T., Rolls B.J. (2019). Does serving a larger proportion of vegetables and fruit influence children's intake over 5 days? *Poster presented at Obesity Week*.

Smethers, A.D., Roe, L.S., Sanchez, C.E., Zuraikat, F.M., Keller, K.L., Kling, S.M., & Rolls, B.J. (2019). Portion size has sustained effects over 5 days in preschool children: A randomized trial. *American Journal of Clinical Nutrition*, *109*(5), 1361-1372.

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U.S. Department of Health and Human Services and U.S. Department of Agriculture. 2015–2020 Dietary Guidelines for Americans. 8th ed. December 2015. Available at: http://health.gov/dietaryguidelines/2015/.

19.0 Confidentiality, Privacy and Data Management

19.1 Which of the following identifiers will be recorded for the research project? Check all that apply. If none of the following identifiers will be recorded, do not check any of the boxes.

	Hard Copy Data	Electronic Stored Data
Names and/or initials (including on signed consent documents)	☒	☐
All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes,	☐	☐
All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older	☒	☐
Telephone numbers	☐	☐
Fax numbers	☐	☐
Electronic mail addresses	☐	☐
Social security numbers	☐	☐
Medical record numbers	☐	☐
Health plan beneficiary numbers	☐	☐
Account numbers	☐	☐
Certificate/license numbers	☐	☐
Vehicle identifiers and serial numbers, including license plate numbers	☐	☐
Device identifiers and serial numbers	☐	☐
Web Universal Resource Locators (URLs)	☐	☐
Internet Protocol (IP) address numbers	☐	☐
Biometric identifiers, including finger and voice prints	☐	☐
Full face photographic images and any comparable images	☒	☐
Any other unique identifying number, characteristic, or code (such as the pathology number)	☐	☐
Study code number with linking list	☒	☐
Genomic sequence data	☐	☐
State ID numbers	☐	☐
Passport numbers	☐	☐
Driver's license numbers	☐	☐

19.2 If storing paper records of research data, answer the following questions:

19.2.1 Where will the paper records, including copies of signed consent forms, associated with this research study will be stored?

Paper records of data (food intake, food preference, height and weight, and questionnaires) will be stored without identifiers in locked offices in the laboratory.

Consent forms will be stored in a locked closet in the lab manager's office within the laboratory office. Only those listed on the IRB application will have access to these files.

19.2.2 How will the paper records be secured?

Consent forms will be stored in a locked closet in the lab manager's office within the laboratory office. Only those listed on the IRB application will have access to these files.

Paper records of data (food intake, food preference, height and weight, and questionnaires) will be stored without identifiers in locked offices in the laboratory.

19.2.3 How will access to the paper records be restricted to authorized project personnel?

Consent forms will be stored in a locked closet in the lab manager's office within the laboratory office. Only those listed on the IRB application will have access to these files.

Paper records of data (food intake, food preference, height and weight, and questionnaires) will be stored without identifiers in locked offices in the laboratory

19.3 If storing electronic records of research data, indicate where the electronic data associated with this research study will be stored. Check all that apply.

☒ Penn State-provided database application. Check which of the following database applications are being used (check all that apply):

☐ Penn State REDCap

☐ Other – Specify - provided and approved database application:

☒ Penn State, College, or Department IT file server

Our lab has a networked storage drive which only allows access to those on the IRB application. Users must enter their PSU email and password to access this drive. Photos are kept on this drive. This drive is only visible to those who have permission to access it.

☐ Box.psu.edu

☐ Web-based system provided by the sponsor or cooperative group - Specify URL and contact information:

☐ Other – Specify the database application or server:
Provide details about the data security features or attach security documentation provided by sponsor or group:

19.4 Is there a list/key that links code numbers to identifiers?

☒ Yes - explain how the list that links the code to identifiers is stored separately from coded data:

A master list of participant ID, letter, and first name will be kept as a password-protected document on the study coordinator's computer. Only those listed on the IRB application will have access to this. A paper copy will also be kept in a locked closet in the lab manager's office. This closet is locked when not occupied and only those listed on the application will have access to this. The code list will be destroyed 5 years after study completion or when the results are published, whichever comes first.

☐ Not applicable, there is no list that links code numbers to identifiers. Skip to section 19.6.

19.5 Is there a list of people who have access to the list/key?

☒ Yes – explain how access to that list is restricted and why certain persons require access.

Those listed on the IRB application have access to this master list.

☐ No – explain why not:

19.6 Describe the mechanism in place to ensure only approved research personnel have access to the stored research data (electronic and paper).

☒ Password-protected files

☐ Role-based security

☒ Specify all other mechanisms used to ensure only permitted users have access to the stored research data.

Only those listed on the IRB application will have access to these files.

19.7 Will any research data (such as survey data) be collected on a mobile device, such as an electronic tablet, cell phone, or wireless activity tracker?

☒ No

☐ Yes - answer the following questions:

19.7.1 Specify the provider of the mobile devices(s)

☐ Supplied by the sponsor

☐ Penn State owned device

☐ A personal device

☐ Other – Please specify source:

19.7.2 Specify the type(s) of mobile device(s) that will be used to capture data and all identifiers captured on the mobile device(s). Please list all devices, and if more than one, the identifiers to be collected on each.

19.7.3 Specify the type of data collected on the mobile devices(s).

19.7.4 Specify the application or website used to collect the data from the mobile device, if applicable.

19.7.5 Describe the measures taken to protect the confidentiality of the data collected on mobile device(s). Please address physical security of the device(s), electronic security, and secure transfer of data from device(s) to the previously indicated data/file storage location provided in section 19.3.

19.8 Will any research data be directly entered/sent by subjects over the internet or via email (e.g., data capture using on-line surveys/questionnaires, surveys via email, observation of chat rooms or blogs)?

☒ No

☐ Yes - answer the following questions:

19.8.1 Specify the identifiers collected over the internet or via email (Including IP addresses if IP addresses will be collected).

19.8.2 Specify the type of data collected over the internet or via email.

19.8.3 Describe the measures taken to protect the confidentiality of the data collected?

19.8.4 Describe how the research team will access the data once data collection is complete.

19.8.5 If the research involves online surveys, list the name(s) of the service provider(s) that will be used for the survey(s)

☐ Penn State REDCap

☐ Penn State Qualtrics (de-identified data only)

☐ Other - Please specify:
Application:
URL (If applicable):

19.8.6 If the answer above is "Other" contact security@psu.edu for approval of an alternative data capture method

19.9 Will any type of recordings (e.g., audio or video) or photographs of the subjects be made during this study?

☐ No - skip to section 19.10

☒ Yes - answer the following questions:

19.9.1 What will be used to capture the audio/video/images? Give a brief description of content.

☐ Audio – Describe the intended content of the audio recording:

☐ Video – Describe the intended content of the video recording:

☒ Photographs of the subjects – Describe the intended content of the photographs:

Photographs may be used in presentations at scientific meetings. Only photographs will be used – names or other identifiable information will not be used with photographs.

There is a place on the consent form for parents to indicate whether or not they give permission for the use of their child's photograph.

Our lab has a networked storage drive which only allows access to those on the IRB application. Users must enter their PSU email and password to access this drive. Photos are kept on this drive. This drive is only visible to those who have permission to access it.

☐ 3-D Images – Describe the intended content of the of 3-D images:

☐ Other - Specify:

19.9.2 How will the recordings/photographs/images be stored (electronically or physically)?

Electronically.

19.9.3 Where will the recordings/photographs/images be stored?

Images will be stored on the laboratory's networked storage drive. Only those listed on the IRB application have access to this.

19.9.4 Who will have access to the recordings/photographs/images?

Only those listed on the IRB application will have access to the photographs.

19.9.5 Will any of the recordings be transcribed?

☒ Not applicable

☐ No

☐ Yes – indicate who will be doing the transcribing?

19.9.6 Will the recordings/photographs be used for purposes other than this research study?

☐ No

☒ Yes - specify purpose(s) (e.g., publication, presentations, educational training, future undetermined research):

Presentations at scientific meetings.

19.10 Certificate of Confidentiality (COC) - Is the research biomedical, behavioral, clinical or other research that is funded by the National Institutes of Health (NIH)?

☒ Yes - check one of the following:

☒ The research involves human subjects as defined by the DHHS regulations (See Worksheet HRP-310).

☐ The research involves collecting or using biospecimens that are identifiable to an individual.

☐ If collecting or using biospecimens as part of the research, there is a small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual.

☐ The research involves the generation of individual level, human genomic data.

Note: If <u>any</u> of the 4 items above are checked, a COC is automatically issued by NIH and applies to the research. Information about the COC must be included in the consent form.

☐ No - answer the following question.

If the research is not funded by NIH, will the investigator apply for a COC for this research study?

☐ No

☐ Yes

Note: For research not funded by NIH, the IRB may require a COC if the research is collecting personally identifiable information and the information is sensitive and/or the research is collecting information that if disclosed could significantly harm or damage the subject.

19.11 What steps will be taken to protect subjects' privacy interests? (Check all that apply.)

☐ Identification and recruitment of potential subjects follows procedures consistent with privacy standards

☐ Consent discussion and research interventions will take place in a private setting

☒ Limiting the information being collected to only the minimum amount of data necessary to accomplish the research purposes

☒ Limiting the people with access to the identifiable research data to the minimum necessary as specified in the application and consent process

☐ Other – Specify:

19.12 What is the process for ensuring correctness of data entry?

☒ Double data entry to reduce risk of errors

☐ Electronic edit checks to ensure data being entered are not obviously incorrect

☐ Random internal quality and assurance checking of research data

☐ Direct entry by subjects

☐ Other - Specify:

19.13 Does this research involve the generation of large-scale human genomic data as defined in NIH Genomic Data Sharing Policy (http://gds.nih.gov)?

☒ No

☐ Yes – If Yes, describe the plan for de-identifying the dataset before sharing it with NIH-designated data repositories.

19.14 The European Union (EU) General Data Protection Regulation (GDPR)

19.14.1 To determine if the research is subject to the GDPR answer the following questions:

19.14.1.1 Will the Penn State principal investigator, or another entity under the Penn State principal investigator's direction, be collecting, recording, storing, using, any personal data* of any subjects physically located in the European Economic Area (EEA) at the time of data collection (even if the subject is NOT an EEA resident) or any EEA citizens? (This includes recruitment through social media sites, use of third party internet sites, mobile devices or apps to collect data, and/or direct receipt of data from subjects.)**

☒ No

☐ Yes (This research may be subject to the GDPR)

19.14.1.2 Does this research involve the transfer of personal data collected under the GDPR from an EEA country? (This includes direct transfer of data from research collaborators.)

☒ No

☐ Yes (This research may be subject to the GDPR)

19.14.2 If the research may be subject to the GDPR as indicated in the answers to the questions above, answer the following:

19.14.2.1 Will any of the data fall into one of the following categories: health data, racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic data, biometric data used for purpose of identifying an individual, sex life or sexual orientation?

☐ No

☐ Yes

19.14.2.2 Will any of the data be related to criminal convictions or offenses?

☐ No

☐ Yes

Comments on any of the above responses:

* “Personal data” means any information relating to an identified or identifiable natural person; an identifiable natural person is one who can be identified, directly or indirectly, by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

** European Economic Area (EEA) – Includes the 28-member states of the European Union (Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia Spain, Sweden, UK) and Norway, Iceland, Lichtenstein.

19.15 Does this research involve transfer or disclosure of data and/or specimens to and/or from Penn State?

☒ No - skip the remainder of section 19.15.