



HRP-591 - Protocol for Human Subject Research

Protocol Title:

Provide the full title of the study as listed in item 1 on the “Basic Information” page in CATS IRB (<http://irb.psu.edu>).

Basketball Rx: Game-Changing Health – Combating Adolescent Obesity and Mental Health with Hoops & Health Education

Principal Investigator:

Name: Sarah Inés Ramírez

Department: Family and Community Medicine

Telephone: (717) 232-5443

E-mail Address: sramirez2@pennstatehealth.psu.edu

Version Date:

Provide a version date for this document. This date must be updated each time this document is submitted to the IRB office with revisions. DO NOT revise the version date in the footer of this document.

-08/04/2026

Clinicaltrials.gov Registration #:

Provide the registration number for this study, if applicable. See “HRP-103- Investigator Manual”, under “ClinicalTrials.gov” for more information.

Not applicable

Important Instructions for Using This Protocol Template:

This template is provided to help investigators prepare a protocol that includes the necessary information needed by the IRB to determine whether a study meets all applicable criteria for approval.

1. GENERAL INSTRUCTIONS¹:

- Prior to completing this protocol, ensure that you are using the most recent version by verifying the protocol template version date in the footer of this document with the current version provided in the CATS IRB Library.
- Do not change the protocol template version date located in the footer of this document.
- Some of the items may not be applicable to all types of research. If an item is not applicable, please indicate as such or skip question(s) if indicated in any of the instructional text.
- **GRAY INSTRUCTIONAL BOXES:** Type your protocol responses below the gray instructional boxes of guidance language. If the section or item is not applicable, indicate not applicable.
 - **Do NOT delete the instructional boxes from the final version of the protocol.**
- The protocol should be written in lay language. Do **NOT** copy and paste grant proposal information into the protocol.
- Add the completed protocol template to your study in CATS IRB (<http://irb.psu.edu>) on the “Basic Information” page.

¹ This template satisfies AAHRPP elements 1.7.B, I.8.B, I-9, II.2. A, II.2.I, II.3.A, II.3.B, II.3.C-II.3.C.1, II.3.D-F, II.4.A, III.1.C-F, II.2.D

2. **CATS IRB LIBRARY:**

- Documents referenced in this protocol template (e.g., SOP's, Worksheets, Checklists, and Templates) can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

3. **PROTOCOL REVISIONS:**

- When making revisions to this protocol as requested by the IRB, please follow the instructions outlined in the guides available in the Help Center in CATS IRB (<http://irb.psu.edu>) for using track changes.
- Update the Version Date on page 1 each time this document is submitted to the IRB office with revisions.

If you need help...

Human Research Protection Program

Phone: 814-865-1775

Fax: 814-863-8699

Email: irb-orp@psu.edu

<https://researchsupport.psu.edu/orp/irb/>

Table of Contents

- 1.0 Objectives**
- 2.0 Background**
- 3.0 Inclusion and Exclusion Criteria**
- 4.0 Recruitment Methods**
- 5.0 Consent Process and Documentation**
- 6.0 HIPAA Research Authorization and/or Waiver or Alteration of Authorization**
- 7.0 Study Design and Procedures**
- 8.0 Number of Subjects and Statistical Plan**
- 9.0 Data and Safety Monitoring Plan**
- 10.0 Risks**
- 11.0 Potential Benefits to Subjects and Others**
- 12.0 Sharing Results with Subjects**
- 13.0 Subject Payment and/or Travel Reimbursements**
- 14.0 Economic Burden to Subjects**
- 15.0 Resources Available**
- 16.0 Other Approvals**
- 17.0 Multi-Site Study**
- 18.0 Adverse Event Reporting**
- 19.0 Study Monitoring, Auditing, and Inspecting**
- 20.0 References**
- 21.0 Confidentiality, Privacy and Data Management**
- 22.0 Identifiable Data and Specimen Banking for Future Undetermined Research**

1.0 Objectives

1.1 Study Objectives

Describe the purpose, specific aims, or objectives. State the hypotheses to be tested.

The purpose of this pilot study is to develop the BasketballRx Program, a 3-month long intervention that integrates basketball-skills training with health education to address both obesity and mental health disparities in adolescents. The program will educate participants on nutrition, exercise, and healthy lifestyle habits while promoting mental well-being through physical activity and social connection. This pilot aims to assess the feasibility of expanding the program into larger-scale studies in the future.

The specific aims of the study are to achieve a measurable reduction in Body Mass Index (BMI) through structured physical activity, enhance health literacy on diet, exercise, and lifestyle modifications, and promote community engagement. The program will conclude with a basketball tournament for participants and a youth-led health fair for their families and peers.

Hypothesis: Participation in the BasketballRx intervention will lead to a reduction in BMI, improved health behaviors, and decrease in symptoms of depression and anxiety amongst participating youth.

1.2 Primary Study Endpoints

State the primary endpoints to be measured in the study.

Research typically has a primary objective or endpoint. Additional objectives and endpoints are secondary. The endpoints (or outcomes), determined for each study subject, are the quantitative measurements required by the objectives. Measuring the selected endpoints is the goal of a trial (examples: response rate and survival).

The primary end point is a change in BMI from baseline to post-intervention.

1.3 Secondary Study Endpoints

State the secondary endpoints to be measured in the study.

The secondary study endpoints from baseline to post-intervention include:

Health Behaviors: Change in self-reported physical activity, nutrition, and sleep habits

Body Composition: Change in waist circumference

Engagement and Retention: Program attendance and completion rates

Mental Health: Change in anxiety and depression levels

2.0 Background

2.1 Scientific Background and Gaps

Briefly describe the scientific background and gaps in current knowledge in lay language.

For clinical research studies being conducted at Penn State Health/Penn State College of Medicine, and for other non-PSH locations as applicable, describe the treatment/procedure that is considered standard

of care (i.e., indicate how patients would be treated in non-investigational setting); and if applicable, indicate if the study procedure is available to patient without taking part in the study.

Childhood obesity is a critical public health issue, particularly among Black and Latino inner-city youth, who face compounded barriers to health resources. In Pennsylvania, the obesity prevalence among Black and Latino children is disproportionately high, with rates of 22% and 19% respectively (Pennsylvania Health Policy Coalition, 2020). This higher prevalence is linked to increased risk for diabetes, hypertension, and other chronic diseases (National Health Statistics Reports, 2021). Community-based interventions that combine physical activity with culturally relevant health education have shown promise in addressing childhood obesity. However, few programs effectively integrate sports with structured health education in ways that are both engaging and empowering for youth.

In addition to the physical health concerns associated with obesity, youth mental health is increasingly recognized as a public health priority. Approximately 20% of U.S. adolescents aged 12 to 17 years reported having major depressive disorder in the past year (Sappenfield, 2023). The U.S. Surgeon General has issued a health advisory highlighting the mental health in youths (Office of the Surgeon General, 2021) and annual screening for depression and anxiety is recommended (USPSTF, 2022). Mental health issues, such as anxiety and depression, are exacerbated by stressors related to obesity, social isolation, and a lack of access to mental health resources.

Basketball is an effective way to reduce adolescent anxiety and depression due to its combination of physical activity, social interaction, and cognitive benefits. Physical activity, particularly team sports like basketball, promotes the release of mood-enhancing neurotransmitters such as serotonin and endorphins, which are known to alleviate symptoms of anxiety and depression (Salmon, 2001). The social aspect of basketball helps foster peer support and belonging, which can combat feelings of isolation and loneliness, common contributors to mental health struggles in youth (Werner-Seidler et al., 2017). Furthermore, basketball's structured environment encourages resilience and emotional regulation, teaching adolescents to cope with setbacks, manage frustration, and build self-esteem (Biddle & Asare, 2011). Given its physical, social, and psychological benefits, basketball offers a holistic, evidence-based approach to supporting adolescent health.

Additionally, The Physical Activity Guidelines for Americans, 2nd Edition recommend that children and adolescents ages 6–17 engage in at least 60 minutes of moderate-to-vigorous physical activity daily, including aerobic and skill-based activities such as recreational basketball (Centers for Disease Control and Prevention, 2024a). Similarly, the American College of Sports Medicine (n.d.) advises that school-aged children participate in a minimum of 60 minutes of moderate- to vigorous-intensity exercise per day, incorporating both structured and unstructured play.

The BasketballRx program integrates physical activity with culturally competent health education to address both obesity and mental health disparities in adolescents.

2.2 Previous Data

Describe any relevant preliminary data.

In a preliminary study, 24 overweight and obese primary school children (mean age 10 years) participated in an 8-week basketball program, with sessions held three times per week for 90 minutes. Post-intervention, significant reductions were observed in body weight, BMI, fat mass, and percent body fat, while height remained unchanged. These findings support the potential of basketball as an effective

intervention to improve body composition in overweight children, justifying further research in this area (McGuigan MR, et al., 2009). Additionally, a 12-week school-based basketball intervention involving 171 overweight and obese children not only led to significant reductions in BMI, waist circumference, and body fat percentage, but also resulted in decreased symptoms of depression and anxiety (Liang, 2020).

2.3 Study Rationale

Provide the scientific rationale for the research.

By promoting physical activity and health education in an engaging way, BasketballRx aims to reduce BMI, enhance health literacy, and support mental health. This model, grounded in a culturally relevant sport, offers a scalable and sustainable approach to addressing critical health disparities in underserved populations.

3.0 Inclusion and Exclusion Criteria

Create a numbered list below in sections 3.1 and 3.2 of criteria subjects must meet to be eligible for study enrollment (e.g., age, gender, diagnosis, etc.).

Vulnerable Populations:

You MAY NOT include members of these populations as subjects in your research unless you indicate this in your inclusion criteria because specific regulations apply to studies that involve vulnerable populations.

The checklists referenced below outline the determinations to be made by the IRB when reviewing research involving these populations. Review the checklists as these will help to inform your responses throughout the remainder of the protocol.

- **Children** –Review “HRP-416- Checklist - Children”
- **Pregnant Women** – Review “HRP-412- Checklist - Pregnant Women”
- **Cognitively Impaired Adults**- Review “HRP-417- Checklist - Cognitively Impaired Adults”
- **Prisoners**- Review “HRP-415- Checklist - Prisoners”
- **Neonates of uncertain viability or non-viable neonates**- Review “HRP-413- Checklist - Non-Viable Neonates” or “HRP-414- Checklist - Neonates of Uncertain Viability”

[Do not type here]

3.1 Inclusion Criteria

Create a numbered list of the inclusion criteria that define who will be included in your final study sample (e.g., age, gender, condition, etc.)

1. Ages 10 years old to 15 years old.
2. BMI 85th percentile or higher
3. Patient at the Penn State Health Family and Community Medicine Clinic in Harrisburg, PA
4. Race/ethnicity self-reported as Black or Latino
5. One guardian (as listed in the EHR) must be present during the entirety of all sessions
6. English-speaking
7. Allowable medical conditions: depression, anxiety, adhd, hyperlipidemia, hypercholesterolemia, hypertriglyceridemia, insulin resistance, prediabetes, diabetes, skin conditions, stage 1 hypertension.

3.1.1 Does this research involve collecting data from individuals residing outside of the US?

☒ No

- ☐ Yes – identify the countries where data collection will take place
[Type protocol text here]

3.2 Exclusion Criteria

Create a numbered list of the exclusion criteria that define who will be excluded in your study.

1. Children younger than 10 years old or older than 15 years old
2. Children with a BMI lower than the 85th percentile
3. Children with structural cardiac conditions, respiratory conditions, concussion within the past 30days, Stage 2 hypertension, history of syncope or near syncope, cardiac dysrhythmias/channelopathies (e.g., long QT syndrome, heart block), history of exercise-induced chest pain or heart palpitations, family history of sudden cardiac death in children, seizure disorder, pregnancy.
4. Children with current or past orthopedic conditions/injuries.
5. Children with health conditions/physical limitations that render them unable to participate in any component of the program including but not limited to severe developmental delays, autism, wheelchair dependence.
6. Not cared for at the Penn State Health Family and Community Medicine Clinic in Harrisburg, PA
7. Not of Black/Latino race/ethnicity
8. Unaccompanied children
9. Inability to verify guardianship with the EHR
10. Non-English speaking
11. Participants without sneakers
12. Already enrolled in another formal exercise program
13. An elevated heart rate or newly discovered elevated blood pressure before the start of any of the sessions
14. Parent/guardian is unwilling or unable to provide consent

3.3 Early Withdrawal of Subjects

3.3.1 Criteria for removal from study

Insert subject withdrawal criteria (e.g., safety reasons, failure of subject to adhere to protocol requirements, subject consent withdrawal, disease progression, etc.).

Study participants will be removed from the study if they develop acute medical conditions or illnesses, including elevated resting heart rate and/or newly elevated blood pressure, before the start of any session. Furthermore, they will be removed from the study if they are no longer able to participate in the basketball-based exercise program due to the exacerbation of undisclosed medical conditions or illness.

3.3.2 Follow-up for withdrawn subjects

Describe when and how to withdraw subjects from the study; the type and timing of the data to be collected for withdrawal of subjects; the follow-up for subjects withdrawn from investigational treatment.

Participants will be withdrawn from the study immediately after meeting the withdrawal criteria described above. The study team will advise parents/guardians of these participants to follow up with their Primary Care Provider at the Penn State Health Family and Community Medicine Clinic in Harrisburg, PA. No additional data will be collected from withdrawn participants.

4.0 Recruitment Method

- Upload recruitment materials for your study in CATS IRB (<http://irb.psu.edu>). **DO NOT** include the actual recruitment wording in this protocol.
- StudyFinder: If StudyFinder (<http://studyfinder.psu.edu>) is to be used for recruitment purposes, separate recruitment documents do not need to be uploaded in CATS IRB. The necessary information will be captured from the StudyFinder page in your CATS IRB study.
- Any eligibility screening questions (verbal/phone scripts, email, etc.) used when contacting potential participants must be uploaded to your study in CATS IRB (<http://irb.psu.edu>).

[Do not type here]

4.1 Identification of subjects

Describe the source of subjects and the methods that will be used to identify potential subjects (e.g., organizational listservs, established recruitment databases, subject pools, medical or school records, interactions during a clinic visit, etc.). If not recruiting subjects directly (e.g., database query for eligible records or samples) state what will be queried, how and by whom.

StudyFinder:

- If you intend to use StudyFinder (<http://studyfinder.psu.edu>) for recruitment purposes, include this method in this section.
- Information provided in this protocol, including the description of study procedures, compensation, and recruitment, needs to be consistent with information provided on the StudyFinder page in your CATS IRB study.

For research utilizing **Penn State Health patient data**, please note the following:

- Submissions using **Enterprise Information Management (EIM)** for recruitment, and for non-Hershey locations as applicable, attach your EIM Design Specification form in CATS IRB (<http://irb.psu.edu>). See “HRP-103- Investigator Manual, Study Recruitment” for additional information.
- Direct contact with patients for research recruitment that does not occur in person will require review of the contact list by Penn State Health’s contracted mail company, **Allegra**. See the following for additional information: <https://pennstatehealth.sharepoint.com/COM-IT%20Resources/SitePages/Data%20&%20Analytic%20Services.aspx> (Penn State Health ePass login required).

The study team will hang flyers in the Penn State Health Family and Community Harrisburg (PSH FCM HBG) clinic, allowing patients and their guardians to contact the study team. Flyers will also be hung on site at the YMCA Camp Curtin location.

Additionally, study team members will be on site to review the study with anyone expressing interest in learning more about our study to the provider they are seeing for their appointment that day.

Providers will send a secure email to the Study Team notifying them of anyone expressing interest in learning more about our study.

A list of potentially eligible participants will be generated by the PSCOM Enterprise Information Management (EIM) team. This list will include medical record number, age, date of birth, patient name, guardian name, language, primary care provider, address (street, apartment number, floor, city, state, zipcode), phone number, bmi, and bmi percentile. For participants recruited through EIM, the study team will first send a pre-notification letter detailing the study. A follow-up phone call and letter may also be sent. These communications will describe the goals of the study, risks/benefits of participation, eligibility criteria, and instructions for enrolling in the study.

4.2 Recruitment process

Describe how potential subjects first learn about this research opportunity or indicate 'not applicable' if subjects will not be prospectively recruited to participate in the research.

Subject recruitment can involve various methods (e.g., approaching potential subjects in person, contacting potential subjects via email, letters, telephone, ResearchMatch, or advertising to a general public via flyers, websites, StudyFinder, newspaper, television, and radio).

If applicable, state whether the study team will access medical records before or after engaging the potential subject.

DO NOT include the actual recruitment material or wording in this protocol.

[Do not type here]

4.2.1 How potential subjects will be recruited.

SELF IDENTIFICATION: Potential study participants and their guardians will be recruited via self-identification. The study team will provide contact information on the recruitment fliers that will be posted in the PSH FCM Harrisburg Clinic and the YMCA Camp Curtin location.

ON-SITE RECRUITMENT:

1. The study team member on-site will review the provider's schedule to identify age-eligible patients. The patient's age is automatically listed along with their name on the schedule.
2. Before the start of the patient's visit, the study team member will ask that the provider discuss our study with the study participant.
3. If the patient and guardian express an interest in learning more about our study, the provider will notify the on-site study member.
4. The on-site study team member will discuss the study with the patient and guardian on-site and provide consent.

STUDY TEAM IDENTIFICATION:

1. Members of the study team will remotely review the provider's schedule to identify age-eligible patients. The patient's age is automatically listed along with their name on the schedule.
2. Remote study team members will send a secure email to BasketballRx@pennstatehealth.psu.edu to notify the study team of potentially eligible participants. Study team members will use this data to determine the best days and times to be on site at the recruitment site. In the subject line of the email, the study

team member will write the word [SECURE] to designate a secure email, as this is a Penn State Health (PSH)-approved method of communicating PHI within an email.

3. Study team members are not on site; therefore, before the start of the patient's visit, the study team member will send a Tiger Text via the HIPAA-compliant Tiger Connect application asking that the provider discuss our study with their patient. Tiger Connect is an acceptable and routinely used platform used to communicate PHI at PSH.
4. If the patient and guardian express an interest in learning more about our study, the provider will ask the guardian to notify the study team member of their interest via the study email (BasketballRx@pennstatehealth.psu.edu) posted on our study flyer at the recruitment site.

PROVIDER REFERRAL: Healthcare providers at the recruitment site will make the study team aware of individuals/guardians who have expressed interest to them in participating in our study by sending a secure email to the BasketballRx@pennstatehealth.psu.edu account. This email will be flagged as secure by placing the words [SECURE] in the subject line. This email account is only accessible by the study team. The email will contain the participant's name and MRN, as well as the guardian's name and contact phone number. This is a PSH-approved method of communicating PHI within an email.

OFFICE OUTREACH:

- ~~The Practice Site Manager will contact the guardians of potentially eligible participants by telephone using the EIM Pre-Screening List. During the call, the Practice Site Manager will provide general information about the study based on the content of the study flyer. At the conclusion of the call, the Practice Site Manager will provide the guardian with the study team's contact email (BasketballRx@pennstatehealth.psu.edu) and invite them to contact the study team if they are interested in learning more about the study.~~
- ~~If the guardian prefers to be contacted by the study team via telephone, the Practice Site Manager will obtain permission to share the guardian's contact information and will securely email the guardian's name, phone number, and preferred day and time for a call to the study team at BasketballRx@pennstatehealth.psu.edu. This email will be flagged as secure by placing the words [SECURE] in the subject line. This email account is only accessible by the study team.~~

EIM OUTREACH: For participants recruited through EIM, the study team will first send a pre-notification letter detailing the study. A follow-up phone call and letter may also be sent. These communications will describe the goals of the study, risks/benefits of participation, eligibility criteria, and instructions for enrolling in the study.

OUTREACH TRACKING: The "BasketballRx Recruitment Outreach Tracking Sheet" housed in REDCap will be utilized by authorized study team members to document and monitor recruitment efforts. This tracking tool will record attempts to contact potential participants and their guardian(s), including dates and outcomes of the call, for the purpose of coordinating and managing outreach attempts. Only 5 attempts will be made by the study team to call interested participants and their guardian (s).

4.2.2 Where potential subjects will be recruited.

PSH FCM Harrisburg Clinic, YMCA Camp Curtin

4.2.3 When potential subjects will be recruited.

Subject recruitment will begin after IRB approval is obtained and run through October 01, 2026.

4.2.4 Screening and determining eligibility

Screening involves assessing whether or not a potential subject is eligible for a study based on the inclusion and exclusion criteria. This process only involves assessing eligibility.

Collecting information/data/biospecimens that are not related to eligibility does not meet the definition of screening and requires prior written consent. There are some specific situations in which consent is not required prior to screening activities.

Answer the following items to describe the screening process and determine if prior consent and/or HIPAA authorization is required.

4.2.4.1 For the purpose of screening/determining eligibility, is the potential subject providing information through oral or written communication (e.g. survey or verbally responding to answers)?

- ☒ Yes [NOTE: HIPAA authorization or a waiver of HIPAA authorization may be necessary – see section 6.]

A. SELF IDENTIFICATION: Interested study participant and/or their guardians will make the study team aware of their interest in the study by way of a phone call or email. Upon receipt of this email, a member of the study team will reply requesting a date and time when a call can be scheduled. Study eligibility will be determined through a combination of electronic health record (EHR) review and during the conversation during the aforementioned call with the participant's guardian. During the call, a study team member will verify eligibility using the Eligibility Checklist. If the participant meets all eligibility criteria, they will be invited to participate in the study.

B. ON-SITE:

1. PROVIDER IDENTIFIED: As noted above, providers will be notified if they are seeing a patient who may potentially be eligible to participate in this study. Providers will then discuss this study with the patients. Providers will make the study team member aware of individuals interested in participating in this study. Eligibility will be confirmed by the on-site study team member through a combination of the EHR and during their conversation with the participant and their guardian in the office using the Eligibility Checklist. If they meet the eligibility criteria, they will be invited to participate in the study.
2. STUDY TEAM IDENTIFIED: Study team members will review the [SECURE] email within the BasketballRx@pennstatehealth.psu.edu account listing potentially eligible participants sent by fellow Study Team members as described in Section 4.2.1. and determine the best days and times to be on

site at the recruitment site. Procedures will then follow those outlined in Section B.1. (PROVIDER IDENTIFIED) within section 4.2.4.1.

C. PROVIDER REFERRAL: Study team members will review the [SECURE] email within the BasketballRx@pennstatehealth.psu.edu account listing potentially eligible participants sent by healthcare providers at the recruitment site as described in Section 4.2.1. Procedures will follow those outlined in Section A (SELF IDENTIFICATION) within Section 4.2.4.1.

D. OFFICE OUTREACH: Study team members will review the [SECURE] email within the BasketballRx@pennstatehealth.psu.edu account listing potentially eligible participants sent by the practice site manager at the recruitment site as described in Section 4.2.1. Procedures will follow those outlined in Section A (SELF IDENTIFICATION) within Section 4.2.4.1.

☐ No

4.2.4.2 Is eligibility being determined by obtaining identifiable private information or biospecimens by accessing records or stored identifiable biospecimens?

☒ Yes [NOTE: HIPAA authorization or a waiver of HIPAA authorization may be necessary – see section 6.0]

For those who self-identify, are referred by their providers, and who are identified through office outreach, eligibility will be determined through a combination of electronic health record review and a telephone conversation with the guardian of the interested participant by authorized study team members.

For those who are recruited on site, eligibility will be determined through a combination of electronic health record review and in-person conversation with the guardian of the interested participant by authorized study team members.

☐ No

4.2.4.3 Is the potential subject being asked to do any activity for screening and eligibility purposes beyond what is described above (e.g. fast, blood test)?

☐ Yes [NOTE: consent process or waiver of consent is required – see section 5.0]

[Describe the activity here]

☒ No

4.2.4.4 Is the screening data to be used for purposes other than eligibility or recruitment (e.g. retained for data analysis or for other purposes)?

☐ Yes [NOTE: consent process or waiver of consent is required – see section 5.0]

☒ No

5.0 Consent Process and Documentation

Refer to the following materials:

- The “HRP-090- SOP - Informed Consent Process for Research” outlines the process for obtaining informed consent.
- The “HRP-091– SOP - Written Documentation of Consent” describes how the consent process will be documented.
- The “HRP-314- Worksheet - Criteria for Approval” section 7 lists the required elements of consent.
- The “HRP-312- Worksheet - Exemption Determination” includes information on requirements for the consent process for exempt research. In addition, the CATS IRB Library contains consent guidance and templates for exempt research.
- The CATS IRB library contains various consent templates for expedited or full review research that are designed to include the required information.
- Add the consent document(s) to your study in CATS IRB (<http://irb.psu.edu>). Links to Penn State’s consent templates are available in the same location where they are uploaded. **DO NOT** include the actual consent wording in this protocol.

[Do not type here]

5.1 Consent Process:

Check all applicable boxes below (at least one of the first four boxes must be checked):

- ☒ **Written documentation of consent: Informed consent will be sought and documented with a written consent form** *[Complete Sections 5.2 and 5.6; If this is the only box checked, mark Sections 5.3, 5.4 and 5.5 as ‘Not applicable’]*
- ☐ **Waiver of documentation of consent: Informed consent will be sought but subject signature is not required (e.g. implied or verbal consent will be obtained)** *[Complete Sections 5.2, 5.3 and 5.6; If this is the only box checked, mark Sections 5.4 and 5.5 as ‘Not applicable’]*
- ☐ **Alteration of consent process: 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; If this is the only box checked, mark Section 5.5 as ‘Not applicable’]*
- ☐ **Waiver of consent: Informed consent will not be obtained** *[Complete Section 5.5; If this is the only box checked, mark Sections 5.2, 5.3, 5.4 and 5.6 as ‘Not applicable’]*

If you believe that the research activities outlined meet one or more of the criteria outlined in “HRP-312- Worksheet- Exemption Determination”, check the following box in addition to a consent checkbox above.

- ☐ **Exempt Research - By checking this box, you are verifying that the consent process will disclose the following:**

- **For all research:** Penn State affiliation; name and contact information for the researcher and advisor (if the researcher is a student); the activities involve research; the procedures to be performed; participation is voluntary; that there are adequate provisions to maintain the privacy interests of subjects and the confidentiality of the data; permission for use of data can be withdrawn for research activities involving the collection and use of identifiable data.
- **For research that uses student educational records:** the records that may be used; the purpose of using those records; the party or class of parties to whom the records may be shared; and that if an adult student (or a parent of a student who is not an adult) requests, the school will provide them with a copy of the records shared. Additionally, the parent or adult student will *sign and date* the consent.

Note: If this box has been checked, mark Sections 5.3, 5.4, 5.5, and 5.6 as “Not applicable.” If the investigator’s assessment is inaccurate, an IRB Analyst will request revision to the protocol and ask that consent forms and recruitment materials be submitted. Except for exemptions where Limited IRB Review is required (see “HRP-312- Worksheet- Exemption Determination”) or where otherwise requested by the IRB, consent forms and recruitment materials are generally not reviewed nor approved by the PSU HRPP for research undergoing exempt review.

5.2 Obtaining Informed Consent

5.2.1 Consent Process

Describe the consent process (when, where, and how), including how subjects are provided the consent language and how subjects indicate consent. Describe the HIPAA authorization process (if applicable), making sure to state if authorization occurs during the consent process or describe a standalone authorization process.

Once eligibility is confirmed, an authorized study team member will send the guardian a link to the electronic informed consent form (eConsent) via REDCap, using the HRP 580 – HRPP Consent Form Template (v.05/01/2025). Consent will be obtained electronically through REDCap. The REDCap project was developed in accordance with the CTSI REDCap eConsent Guidance Version 02/28/2025.

During this call, the study team member will ask the guardian to open the eConsent form and will review it together, ensuring the guardian fully understands the study’s purpose, procedures, risks, and their rights. The guardian must electronically sign the eConsent form before participation in the study begins.

Study participation in the BasketballRx program will commence only after the guardian has signed the eConsent form and the child’s verbal assent has been obtained.

Throughout this process, study team members will remain available by phone and email to answer any questions or address concerns from the guardian or participant.

If participants and guardians consent on site, we will make a laptop for the e-Consent process available.

5.2.2 Coercion or Undue Influence during Consent

Describe the steps that will be taken to minimize the possibility of coercion or undue influence in the consent process.

Participation is optional. Participants are free to withdraw from the study at any time. Participants and their guardians will be reminded of the right to end participation at any time throughout the duration of the study. Potential participants will be informed that participation is voluntary and that they are under no obligation or commitment to be part of the study. If they decide to change their minds in the future and withdraw consent, they may do so for any reason and without penalty.

Furthermore, consent language for the study is attached in CATS for IRB review and approval. Study team members have completed human subjects research training requirements regarding ethical consent procedures.

5.3 Waiver of Written Documentation of Consent

Review "HRP – 411 – Checklist – Waiver of Written Documentation of Consent."

5.3.1 Indicate which of the following conditions applies to this research:

- ☐ The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

OR

- ☐ The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. (*Note: This condition is not applicable for FDA-regulated research. If this category is chosen, include copies of a consent form and /or parental permission form for participants who want written documentation linking them to the research.*)

OR

- ☐ If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. (*Note: This condition is not applicable for FDA-regulated research.*)

For distinct cultural groups, describe the alternative mechanism for documenting that informed consent was obtained:

not applicable

5.3.2 Indicate what materials, if any, will be used to inform potential subjects about the research (e.g., a letter accompanying a questionnaire, verbal script, or implied consent form)

not applicable

5.4 Alteration of consent: Informed consent will be sought but some of the elements of informed consent will be omitted or altered (e.g., deception).

Review "HRP-410-Checklist -Waiver or Alteration of Consent Process" to ensure that you have provided sufficient information.

5.4.1 Indicate the elements of informed consent to be omitted or altered

not applicable

5.4.2 Indicate why the research could not practicably be carried out without the omission or alteration of consent elements

not applicable

5.4.3 Describe why the research involves no more than minimal risk to subjects.

Not applicable

5.4.4 Describe why the alteration/omission will not adversely affect the rights and welfare of subjects.

not applicable

5.4.5 If the research involves using identifiable private information or identifiable biospecimens, describe why the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

not applicable

5.4.6 Debriefing

Explain whether and how subjects will be debriefed after participation in the study. If subjects will not be debriefed, provide a justification for not doing so. Add any debriefing materials to the study in CATS IRB.

not applicable

5.5 Waiver of consent: Informed consent will not be obtained

Review "HRP-410-Checklist -Waiver or Alteration of Consent Process" to ensure that you have provided sufficient information.

5.5.1 Indicate why the research could not practicably be carried out without the waiver of consent

not applicable

5.5.2 Describe why the research involves no more than minimal risk to subjects.

not applicable

5.5.3 Describe why the alteration/omission will not adversely affect the rights and welfare of subjects.

not applicable

5.5.4 If the research involves using identifiable private information or identifiable biospecimens, describe why the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

not applicable

5.5.5 Additional pertinent information after participation

Explain if subjects will be provided with additional pertinent information after participation.

not applicable

5.6 Consent – Other Considerations

5.6.1 Non-English-Speaking Subjects

Indicate what language(s) other than English are understood by prospective subjects or representatives.

If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.

Indicate whether the consent process will be documented in writing with the long form of the consent documentation or with the short form of the consent documentation. Review “HRP-091 –SOP- Written Documentation of Consent” and “HRP-103 -Investigator Manual” to ensure that you have provided sufficient information.

Not applicable

5.6.2 Cognitively Impaired Adults

Refer “HRP-417 -CHECKLIST- Cognitively Impaired Adults” for information about research involving cognitively impaired adults as subjects.

5.6.2.1 Capability of Providing Consent

Describe the process to determine whether an individual is capable of consent.

not applicable

5.6.2.2 Adults Unable to Consent

Describe whether and how informed consent will be obtained from the legally authorized representative. Describe who will be allowed to provide informed consent. Describe the process used to determine these individual’s authority to consent to research.

For research conducted in the state of Pennsylvania, review “HRP-013 -SOP- Legally Authorized Representatives, Children and Guardians” to be aware of which individuals in the state of Pennsylvania meet the definition of “legally authorized representative.”

For research conducted outside of the state of Pennsylvania, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of “children” in “HRP-013 - SOP- Legally Authorized Representatives, Children, and Guardians.”

not applicable

5.6.2.3 Assent of Adults Unable to Consent

Describe the process for assent of the subjects. Indicate whether assent will be required of all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not.

If assent will not be obtained from some or all subjects, provide an explanation of why not.

Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.

Not applicable

5.6.3.1 Parental Permission

Describe whether and how parental permission will be obtained. If permission will be obtained from individuals other than parents, describe who will be allowed to provide permission. Describe the process used to determine these individual’s authority to consent to each child’s general medical care.

For research conducted in the state of Pennsylvania, review “HRP-013-SOP- Legally Authorized Representatives, Children and Guardians” to be aware of which individuals in the state of Pennsylvania meet the definition of “children.”

For research conducted outside of the state of Pennsylvania, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of “children” in “HRP-013-SOP- Legally Authorized Representatives, Children, and Guardians.”

Guardians (as listed in the EHR) will be provided with electronic informed consent forms loaded within REDCap. The study team will explain and confirm that the

guardians of the participants fully understand the consent form and what participating in the study involves. Documentation of consent will be recorded in REDCap.

5.6.3.2 Assent of subjects who are not yet adults

Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent. When assent of children is obtained describe whether and how it will be documented.

During the conversation with the guardian described in section 5.2.1, the study team will provide the Assent Handout as an attachment in the same email where the link to the electronic informed consent was sent. For those recruited on site, the Assent Handout will be provided as a paper document. The study team member will ask the guardian to access the Assent Handout and invite the child participant to join in the review of this document. The study team member will then review the study's purpose, procedures, risks, and benefits with the child. An oral explanation of the exercise and health education program will be given in simple, age-appropriate language, supported by the information in the Assent Handout.

Following this explanation, the study team member will assess the child's understanding and willingness to participate, and verbal assent will be requested. This assent will be documented in REDCap.

Participation in the BasketballRx program will begin only after both the guardian has completed the electronic consent form and the child's verbal assent has been obtained.

Throughout this process, the study team will remain available by phone and email to address any questions or concerns from either the guardian or the child participant.

6.0 HIPAA Research Authorization and/or Waiver or Alteration of Authorization

This section is about the access, use or disclosure of Protected Health Information (PHI). PHI is individually identifiable health information (i.e., health information containing one or more 18 identifiers) that is transmitted or maintained in any form or medium by a Covered Entity or its Business Associate. A Covered Entity is a health plan, a health care clearinghouse or health care provider who transmits health information in electronic form. See "HRP-103 -Investigator Manual" for a list of the 18 identifiers.

[Do not type here]

6.1 Authorization and/or Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

Check all that apply:

- ☐ Not applicable, no identifiable protected health information (PHI) is accessed, used, or disclosed in this study. *[Mark all parts of sections 6.2 and 6.3 as not applicable]*
- ☒ Signed authorization will be obtained and documented. *[If this is the only box checked, mark sections 6.2 and 6.3 as not applicable]*

- ☒ **Partial waiver for recruitment purposes only (e.g. if patients' medical records will be accessed to determine eligibility before consent/authorization has been obtained).** *[Complete all parts of sections 6.2 and 6.3]*
- ☐ **Full waiver for entire research study (e.g., medical record review studies).** *[Complete all parts of sections 6.2 and 6.3]*
- ☐ **Alteration to waive requirement for written documentation of authorization (e.g. verbal or implied authorization).** *[Complete all parts of sections 6.2 and 6.3]*

6.2 Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

This section is about the disclosure of PHI as it relates to the requested authorization waiver and/or alteration. Complete each item in this section in relation to each requested waiver of authorization and/or alteration (the last three boxes in Item #6.1). For example, if requesting a partial waiver for recruitment, these items need to address the PHI for recruitment rather than addressing the use of PHI for the entire study.

6.2.1 Access, use or disclosure of PHI representing no more than a minimal risk to the privacy of the individual

6.2.1.1 Plan to protect PHI from improper use or disclosure

Include the following statement as written – DO NOT ALTER
If the research does not involve a waiver or alteration of authorization, remove the statement and indicate as not applicable.

Information is included in the "Confidentiality, Privacy and Data Management" section of this protocol.

6.2.1.2 Plan to destroy identifiers or a justification for retaining identifiers

Describe the plan to destroy the identifiers (associated with the waiver and/or alteration of authorization) at the earliest opportunity consistent with the conduct of the research. Include when and how identifiers will be destroyed.

If identifiers are to be retained, provide the legal, health or research justification for retaining the identifiers.

Each study participant will be assigned a masked study ID number. The study team will use HIPAA-compliant electronic storage provided by Penn State Health such as REDCap and Microsoft SharePoint, to collect and store electronic study data. Data will be de-identified before analysis. Participant-level identifiers will be stripped from the dataset after publication of the study findings.

6.2.2 Explanation for why the research could not practicably be conducted without access to and use of PHI

Provide reasons why the research or the portion of the research could not be conducted without access to and use of PHI (for which the study team is requesting the waiver and/or related to the alteration of authorization).

Access to PHI is necessary to determine participant eligibility based on clinical criteria, including age, BMI, and the absence of chronic health conditions noted in section 3.2. These data elements are typically documented in the medical record and are not reliably self-reported or available through other means.

6.2.3 Explanation for why the research could not practicably be conducted without the waiver or alteration of authorization

Provide reasons why the research or the portion of the research could not be conducted without a signed authorization from the subjects. If more than one waiver and/or alteration of authorization (e.g. waiver for recruitment and alteration for verbal authorization) is requested, make sure to provide reasoning for each request.

We are requesting a partial waiver of HIPAA authorization for recruitment purposes because we must review limited elements of the participant's medical record prior to obtaining full HIPAA authorization in order to determine eligibility. Specifically, during the recruitment process, we will be speaking with the student's guardian to obtain preliminary information, such as the student's BMI and other relevant health data. However, in order to confirm the accuracy of that information and ensure the participant meets the study's inclusion criteria, we need to access the electronic medical record (EMR) at the same time.

This limited access is essential to verify eligibility before proceeding with the full consent and authorization process. Without the ability to confirm key data points in the EMR during this initial stage, we risk enrolling participants who do not meet eligibility criteria, which could compromise the integrity of the study and result in unnecessary burden on the participants and their families.

Therefore, the waiver is necessary solely to allow for this limited medical record review during recruitment and prior to obtaining signed HIPAA authorization. Full HIPAA authorization will be obtained from participants/guardians before any additional access to medical records or study procedures are conducted.

6.3 Waiver or alteration of authorization statements of agreement

By submitting this study for review with a waiver of authorization, you agree to the following statement – DO NOT ALTER.

If the research does not involve a waiver or alteration of authorization, remove the statement and indicate as not applicable.

Protected health information obtained as part of this research will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other permitted uses and disclosures according to federal regulations.

The research team will collect only information essential to the study and in accord with the 'Minimum Necessary' standard (information reasonably necessary to accomplish the objectives of the research) per federal regulations.

Access to the information will be limited, to the greatest extent possible, within the research team. All disclosures or releases of identifiable information granted under this waiver will be accounted for and documented.

7.0 Study Design and Procedures

Data collection materials that will be seen or used by subjects in your study must be uploaded to CATS IRB (<http://irb.psu.edu>). **DO NOT** include any actual data collection materials in this protocol (e.g., actual survey or interview questions).

[Do not type here]

7.1 Study Design

Describe and explain the study design.

This prospective pilot study will follow a one-arm, pre-/post-test design. A total of 30 children, aged 10 to 15 years, with obesity will be recruited through the PSH FCM HBG Clinic. Study activities will take place at the YMCA Camp Curtin location, situated within a mile of the clinic and geographically central to the participants' residences. The study aims to evaluate the feasibility and preliminary effectiveness of a community-based lifestyle intervention for pediatric obesity and mental health.

• **BasketballRx Intervention:** Participants will engage in 6 sessions in a 2 month period. Sessions 1 through 5 will last 90 minutes and will be composed of two parts: (1) 40 minutes of interactive health education focused on nutrition, sleep hygiene, and mental well-being; (2) 50 minutes of structured physical activity, specifically basketball drills. Sessions will be facilitated by trained members of the study team. Session 6 will last 180 minutes; details noted below.

1. Sessions 1 through 5:

- **Health Education Component:** This curriculum is a youth-centered wellness program that uses basketball as a platform to teach lifelong habits for physical, mental, and social health. Students engage in interactive lessons that cover nutrition, hydration, food label literacy, injury prevention, sleep hygiene, mindfulness, and stress management. Each session connects these concepts to athletic performance and daily life, helping students understand the impact of their choices on energy, focus, and overall health. The program promotes a holistic approach to well-being, equipping participants with practical tools to thrive on and off the court.
- **Basketball Skills Component:** Participants will take part in a structured basketball skills curriculum. Each session is designed to promote physical activity and teamwork in a supportive, age-appropriate environment. Activities are led by trained study personnel. Each session will incorporate a warm-up, skill-focused drills, and group-based games. Collectively, these activities represent age-appropriate, moderate-intensity exercise consistent with CDC definitions.

- #### 2. Session 6 (Final Session) BasketballRx: Hoops for Health Fair:
- This event will provide participants with the opportunity to demonstrate skills learned in Sessions 1 through 5 and to lead brief presentations on key health topics for family and community members. This event will allow participating youth to demonstrate the basketball skills, teamwork, and health knowledge gained during the program, reinforcing links between physical activity, nutrition, and overall wellness.

Family members, study team members, and community partners will be invited to attend, fostering social support and celebrating participants' progress. The event will also serve as positive reinforcement, integrating physical skills with health literacy to advance the study's goals of improving physical activity and wellness behaviors in youth.

- **Event Structure:**
 - i. **Basketball Skills Demonstration:** Teams will compete in age-appropriate, friendly games and skill challenges (e.g., shooting, dribbling, passing drills).
 - ii. **Health Education Fair:** Participants will present short demonstrations or interactive displays summarizing key concepts from the curriculum, which include nutrition and hydration strategies, food label literacy, injury prevention, sleep hygiene, mindfulness, and stress management. These presentations will highlight the connection between healthy lifestyle choices and athletic performance.
 - iii. **Supervision and Safety:** All activities will be led and supervised by trained study personnel, including licensed healthcare professionals and medical student volunteers, ensuring adherence to safety protocols and age-appropriate competition.
 - iv. **Community Engagement:** The event will be open to guests to foster family involvement, reinforce social support networks, and celebrate the participants' progress.

• **Data Collection:** Weight, height, and waist circumference will be collected at session 1 and then again at session 6. Blood pressure and heart rate will be collected at the start of every session, before engaging in any physical activity. Health-related knowledge on nutrition, sleep habits, screen time, and mindfulness, as well as self-reported physical activity, will be assessed using structured surveys. As an additional psychosocial measure, anxiety and depression will be assessed by SCARED (Screen for Child Anxiety Related Disorders) and PHQ-2 (Patient Health Questionnaire-2) scores, respectively. Pre-intervention scores will be obtained at session 1 before the start of the curricular components, while the research team will collect post-intervention scores to assess changes in depression- and anxiety-related symptoms at session 6. Participants with SCARED scores greater than 3 will be referred to their Primary Care Provider (PCP), and PHQ-2 scores of 3 or greater will trigger follow-up screening with the PHQ-A (modified for adolescents). A PHQ-A score of 5 or more will result in a referral to their PCP at the PSH FCM HBG Clinic. The difference between pre- and post-intervention scores will be calculated.

• **Data Analysis:** Weight and height will be used to calculate BMI. Quantitative data will be analyzed using paired t-tests to assess pre- and post-intervention changes in BMI, waist circumference, health knowledge scores, PHQ-2, PHQ-A, and SCARED scores. As a pilot study, the primary objectives are to assess feasibility, acceptability and to generate preliminary effect size estimates to inform the design of future larger-scale studies. Feasibility will be assessed through recruitment and retention rates, session attendance, and participant engagement. Practicality and fidelity will be tracked by monitoring staff effort, space and supply use, and facilitator checklists to ensure the program is delivered as intended. Acceptability will be evaluated with the post-intervention survey. These data will be summarized descriptively.

7.2 Study Procedures

Provide a step-by-step description of all research procedures being conducted (broken down by visit, if applicable) including such information as below (where and when applicable); describe the following:

- **HOW:** (e.g., data collection via interviews, focus groups, forms such as surveys and questionnaires, medical/school records, audio/video/digital recordings, photographs, EKG procedures, MRI, mobile

devices such as electronic tablets/cell phones, observations, collection of specimens, experimental drug/device testing, manipulation of behavior/use of deception, computer games, etc.) For surveys, indicate if subjects are able to skip questions that they don't want to answer.

- WHERE: (e.g., classrooms, labs, internet/online, places of business, medical settings, public spaces, etc.)

[Do not type here]

7.2.1 Visit 1 or Day 1 or Pre-test, etc.

Provide a description of what procedures will be performed on visit 1 or day 1 or pre-test in order of how these will be done. If your study only involves one session or visit, use this section only and delete 7.2.2.

Consent Confirmation and Eligibility Verification: Refer to sections 4.2.4. and 5.0 for procedures related to the determination of eligibility and the consent and assent processes.

On the day of session 1, study staff will confirm that signed informed consent from the guardian and verbal assent from the participant have been obtained. Before beginning the educational content of the session, the following steps will be completed and data collected using the Data Collection document:

- Height and weight will be measured to calculate BMI
- Waist circumference will be measured
- Blood pressure and heart rate will be measured
- Participants will complete the SCARED and PHQ-2 questionnaires. Additionally, the PHQ-A questionnaire will be completed by participants with elevated PHQ-2 scores.
- Participants will complete the pre-intervention survey

Guardians will be asked to remain for the duration of the session.

Supervision and Safety: Before each session, a study team member will assess participants' blood pressure and heart rate. Any participant with elevated heart rate or newly elevated blood pressure outside of the age-appropriate range will be excluded from physical activity for that session and referred to their primary care provider (PCP) as appropriate. Additionally, participants who score above the clinical threshold on either the SCARED or PHQ-A will be referred to their PCP for further evaluation and follow-up.

All basketball drills and games will be conducted under the supervision of trained study team members. Safety protocols will be strictly enforced, including adequate spacing between participants, appropriate footwear, and scheduled hydration breaks. Each child will receive a water bottle at the start of session 1.

The physical activity component of the study is designed to meet national guidelines for moderate-intensity physical activity in youth, as defined by the CDC (2024b). This level of intensity is characterized by increased breathing while still allowing for conversation and generally corresponds to 50–70% of a participant's maximum heart rate (MHR), calculated as 220 minus the participant's age.

To support monitoring of exertion, each participant will be provided with a fitness tracker at the first session, which will be used to monitor heart rate in real-time during all physical activities. Participants will be informed of their age-specific MHR at the beginning of each session and instructed to pause and rest if their heart rate exceeds this threshold. Study team members will monitor fitness tracker data during sessions to ensure heart rate remains within the target range.

In addition to objective heart rate monitoring, perceived exertion will be assessed using the OMNI 0–10 scale and the "talk test" (i.e., the ability to speak while exercising). All exertion-related observations will be recorded systematically using the study's Exertion Monitoring Checklist.

HEALTH EDUCATION TRAINING:

Session 1a: Fuel for the Court & Snack Attack

In this session, students will explore the importance of nutrition and a healthy lifestyle habit in a fun, engaging way. Through interactive discussions and activities, they will learn food groups, macronutrients, micronutrients, and how food choices can support their energy levels, especially snack choices. They will be learning key times to snack before workouts and games to develop habits that can help keep them healthy.

Learning Objectives:

- Identify the major food groups and their functions.
- Describe three macronutrients
- Understand the concept of a balanced meal
- Recognize the best snack for athletic performance.

Procedures:

1. Anticipatory Set/ Engage learner (5 minutes)
 - Ask students what they ate for breakfast or lunch.
 - Display MyPlate and prompt "Where do the foods you ate belong?"
2. Pre-Instruction/ formative: Q&A (5 minutes)
 - Name a carbohydrate. What do carbohydrates do for your body?
 - Name a protein. What do proteins do for your body?
 - Name a fat. What does fat do for your body?
3. Direct Instruction: Teach 5 food groups (10 minutes)
 - Discuss nutrients and their roles (carbohydrates, proteins, fats)
 - Show how to build a balanced meal with MyPlate
 - Discuss common unhealthy habits (sugary snacks, too large portion sizes, prepackaged foods)
4. Guided & Independent Practice (10 minutes)
 - Game – Macronutrient Match
 - Worksheet or journal reflection that asks them to identify a snack that they currently consume that may be unhealthy and how changing that into a healthy snack may impact their health: "Once I change ____ to _____ I can make snacking healthier...."
5. Post-Instruction Assessment: Q&A from pre-instruction (5 minutes)
6. Exit ticket: "Why does nutrition matter in your everyday life?" (5 minutes)

BASKETBALL SKILLS TRAINING:

Session 1b: Introduction & Basketball Fundamentals

Session Title: "Get in the Game" – Program Orientation and Foundational Basketball Skills

Estimated Duration: 50 minutes

Objectives: To establish rapport between participants and staff, introduce program expectations, assess basic motor and basketball skill levels, and teach foundational basketball movements in a supportive, team-oriented environment.

Procedures (in order of implementation):

1. Welcome and Icebreaker Activity (5 minutes):
The session will begin with a brief welcome from the study staff and volunteer coaches. Participants will be invited to share their name and their favorite basketball player or team in a round-robin format. This segment is designed to promote social engagement, build group cohesion, and set a positive tone for the program.
2. Warm-Up Relay Races (10 minutes):
Participants will be divided into small, evenly sized teams. Relay activities will take place using 4–5 cones set approximately 5–10 feet apart in a straight line. Movements include:
 - Forward sprints to the final cone and return
 - Backpedals to the final cone and return
 - Side shuffles down and back
 - Zig-zag sprints through cones
 Emphasis will be placed on dynamic warm-up, proper body mechanics, and communication within teams.
3. Dribble Tag (5 minutes):
All participants will be assigned a basketball and confined to a designated play area (e.g., half court). One or two participants will begin as “taggers” and attempt to tag others while maintaining dribble control. If tagged, participants must complete three jumping jacks before re-entering the game. This drill reinforces dribbling while moving, spatial awareness, and multitasking.
4. Partner Passing Drills (10 minutes):
Participants will pair up and form two facing lines spaced approximately 8–10 feet apart. Drill progression will include:
 - Chest passes: focus on stepping into the pass and follow-through (thumbs down)
 - Bounce passes: ball should bounce 2/3 of the way to the receiver
 - Optional progression: introduce light movement between passes to simulate in-game motion
5. Zig-Zag Dribbling Through Cones (10 minutes):
Participants will complete a zig-zag or slalom-style dribbling course using cone markers. Each player will dribble from one end of the course to the other, switching hands at each cone. Coaching emphasis will include:
 - Keeping the dribble low
 - Maintaining eye contact with the environment (head up)
 - Using both dominant and non-dominant hands
6. “Around the World” Passing Game (10 minutes):
Participants will form a circle and begin with one basketball. Each player must call out the name of the recipient before passing. A second basketball will be added to increase complexity and require faster reaction time. This activity is designed to reinforce communication, spatial awareness, and team cohesion.

7.2.2 Visit 2 or Day 2 or Post-test, etc. (If applicable)

Provide a description of what procedures will be performed on visit 2 or day 2 or post-test in order of how these will be done. If your study involves more than two sessions or visits replicate

this section for each additional session or visit (e.g., 7.2.3, 7.2.4, etc.). If your study involves only one session or visit, delete this section.

Photographs will be taken during each of the health education and basketball skills sessions while the participants are learning about healthy eating and playing basketball. Photos will only be taken of participants who opt in during the consent process. Facial images may be captured in these photographs. The mobile phone of study team members will be used to capture the image. The image will immediately be uploaded to the PSH Sharepoint folder and the image deleted from the phone. If backup to cloud is enabled on the phone, it will be turned off while capturing the photos and will not be turned back on until after photos have been uploaded to PSH servers. These photographs will be used for future publications and presentations.

Supervision and Safety: Before each session, a study team member will assess participants' blood pressure and heart rate. Any participant with elevated values outside of the age-appropriate range will be excluded from physical activity for that session and referred to their primary care provider (PCP) as appropriate. Additionally, participants who score above the clinical threshold on either the SCARED or PHQ-A will be referred to their PCP for further evaluation and follow-up.

All basketball drills and games will be conducted under the supervision of trained study team members. Safety protocols will be strictly enforced, including adequate spacing between participants, appropriate footwear, and scheduled hydration breaks. Each child will receive a water bottle at the start of session 1.

The physical activity component of the study is designed to meet national guidelines for moderate-intensity physical activity in youth, as defined by the CDC (2024b). This level of intensity is characterized by increased breathing while still allowing for conversation and generally corresponds to 50–70% of a participant's maximum heart rate (MHR), calculated as 220 minus the participant's age.

To support monitoring of exertion, each participant will be provided with a fitness tracker at the first session, which will be used to monitor heart rate in real-time during all physical activities. Participants will be informed of their age-specific MHR at the beginning of each session and instructed to pause and rest if their heart rate exceeds this threshold. Study team members will monitor fitness tracker data during sessions to ensure heart rate remains within the target range.

In addition to objective heart rate monitoring, perceived exertion will be assessed using the OMNI 0–10 scale and the "talk test" (i.e., the ability to speak while exercising). All exertion-related observations will be recorded systematically using the study's Exertion Monitoring Checklist.

HEALTH EDUCATION TRAINING:

Session 2a: Label Detectives + Hydration = Performance

In this session, students build on their nutrition knowledge by learning how to read and understand food labels. They practice identifying key ingredients and sugar content, assisting them in making more informed snack and drink choices. The session also highlights the link between proper hydration and physical performance. Overall, students are encouraged to apply these skills in their daily lives and support long-term health.

Lesson Objectives:

- Identify proper healthy ways to hydrate your body.
- Describe how to figure out natural sugars from the nutrition facts label.
- Understand the nutrition facts label components

Procedures:

1. Anticipatory Set/ Engage learner (5 minutes)
 - Display popular sugary and health drinks and measure out the amounts of sugar in each of them and facilitate a discussion about the nutritional content and benefits/risks of each drink.
2. Pre-Instruction/ formative (5 minutes)
 - Who knew that the drinks contained that much sugar?
 - Who knows what sugar does to your body?
 - What is hydration?
3. Direct Instruction (10 minutes)
 - Describe aspects of the nutrition facts label, including serving size, %DV, total sugar, added sugar, natural sugar, and proteins
 - Teach how to calculate natural sugars for total and added sugars.
4. Guided & Independent Practice (10 minutes)
 - Use different popular snacks nutrition facts labels and have students measure out how much sugar is in one serving.
 - Compare this to the amount of sugar in protein ball snack they will make.
 - Worksheet or journal reflection "What is something I eat that contains high amounts of sugar?"
5. Post- Instruction Assessment (10 minutes)
 - Q&A from pre-instruction
 - Exit ticket "Why does nutrition matter in your everyday life?"

Session 3a: Mental Health & Social Cohesion

In this session, participants build awareness of their emotions, explore the impact of stress, and practice positive coping strategies. They learn how sports, friendships, and mindfulness can support mental well-being. Through interactive discussions and activities, students strengthen empathy, teamwork, and relationship skills that foster resilience and social connection.

Lesson Objectives

- Recognize emotions and express them in healthy ways.
- Understand stress, anxiety, and depression in simple terms.
- Identify and practice positive coping strategies.
- Build empathy, teamwork, and respectful conflict resolution skills.

Procedures

1. Mood Warm-Up (5 minutes)
 - Circle check-in using color cards or emojis.
 - Prompt: 'How are you feeling today?'
 - Brief discussion: Emotions affect how we play and interact.
2. Understanding Stress, Anxiety & Depression (10 minutes)
 - Define stress, anxiety, and depression
 - Explain how basketball and social connections can reduce stress.
3. Stress Management (5 minutes)
 - Group brainstorm: positive coping strategies (deep breathing, journaling, talking to a friend, exercise, music).

- Pair activity: read stressful scenarios and discuss how to respond using coping strategies.
- 4. Healthy Relationships (10 minutes)
 - Circle discussion: 'What does a healthy friendship look like?'
 - Identify traits of good friends and brainstorm respectful conflict resolution strategies.
 - In pairs: role-play conflict resolution scenarios.
- 5. Mindfulness Cooldown (5 minutes)
 - Lead a short guided breathing or meditation session.
- 6. Wrap-Up & Reflection (5 minutes)
 - Quick review questions:
 - - What is one coping strategy you can use this week?
 - - How can basketball or friendships help with stress?
 - Exit ticket: Share (verbally or written) one coping or friendship skill to practice this week.

Session 4a: Mindfulness, Relationships & Warm-Up Basics

In this session, students learn skills that support both social and physical wellness. They practice mindfulness to enhance self-regulation, explore what healthy relationships look like, and build foundational knowledge about warming up and stretching to prevent injury. The session emphasizes emotional balance, respectful conflict resolution, and the importance of preparing the body for safe physical activity.

Lesson Objectives

- Understand the purpose of warming up and stretching before physical activity.
- Practice mindfulness techniques to support self-regulation.
- Identify traits of healthy relationships and practice positive conflict resolution.

Procedures

1. Pre-Instruction Questions (5 minutes)
 - What does it mean to calm your mind?
 - What makes someone a good friend?
 - Why do athletes stretch before they play?
3. Lets Stretch (10 minutes)
 - Begin with a quick stretch or simple movement (e.g., shaking out arms/legs).
 - Ask:
 - Why do athletes stretch before they play
 - How do you feel after taking a moment to pause or stretch?
 - Why is warming up before gameplay important?
 - Teach examples of stretches, naming the body parts they target.
 - Stretching: Participants pair up and demonstrate stretches to each other while explaining why warming up is important.
3. Calming the Body and Mind (10 minutes)
 - Mindfulness Cooldown: Lead a short, guided breathing or meditation. Option: play calming music or nature sounds.
 - Ask:
 - What does it mean to calm your mind?
4. Relationship Building (10 minutes)
 - Healthy Relationships: Facilitate a circle discussion on "What does a healthy friendship look like?" and list student responses on the board.

- Relationships: In pairs, role-play scenarios to practice resolving conflicts respectfully.
5. Post-Instruction Assessment (5 minutes)

Quick review questions:

- What is one way to calm your body and mind?
- Name one trait of a good friend.
- Why do we warm up before playing sports?
- Exit ticket: Write or share one new skill they will use this week (mindfulness, friendship, or stretching).

Session 5a: Injury Awareness, Nutrition Check-In, and Sleep Hygiene

Objective: Participants will learn the components of a balanced meal, strategies for fueling performance, basic injury prevention tips, and the importance of sleep for health and athletic performance.

Procedures:

Welcome and Warm-Up (5 minutes)

- Facilitators welcome participants and lead introductions with a fun question (e.g., favorite food or meal).
- Emphasis is placed on teamwork, participation, and respect.

Nutrition Check-In (10 minutes)

- Discussion: “What does a healthy diet look like?”
- Review components of a balanced meal (3+ food groups or 2 macronutrients; emphasis on color and variety).
- Group activity: Each participant shares one healthy food and one affordable snack; facilitator records on the board to build a team list.
- Game Time – Nutrition Review
 - Interactive nutrition games such as MyPlate Bingo, Macronutrient Matching, or Label Reading Challenge.
 - Reinforcement that healthy foods provide strength, energy, and performance benefits.

Fueling for Performance & Injury Prevention (10 minutes)

- Discussion of pre- and post-practice snacks (e.g., banana with peanut butter, yogurt with granola, turkey sandwich, low-fat chocolate milk).
- Injury prevention tips: adequate protein for muscle repair, calcium and vitamin D for bone health, hydration, and rest.

Sleep Hygiene – Why Sleep Matters (10 minutes)

- Education on recommended sleep (8–10 hours for teens) and consequences of insufficient sleep (mood, cognition, behavior, academic performance, sports outcomes).
- Discussion of barriers to adequate sleep (late body clock, early school schedules, screens).
- Review of strategies for sleep hygiene: consistent sleep/wake times, cool/dark/quiet room, avoiding screens and caffeine before bed, and creating a bedtime routine.
- Interactive True/False Quiz on sleep habits to reinforce content.

Reflection & Goal Setting (5 minutes)

- Each participant identifies one new thing learned about nutrition, injury prevention, or sleep.
- Participants set a personal goal for the week and either share aloud or write it down.

BASKETBALL SKILLS TRAINING:

Session 2b: Introductory Basketball Skills & Physical Activity

Session Title: “Get in the Game” – Fundamentals & Engagement

Estimated Duration: 50 minutes

Objectives: To build rapport, assess baseline skill levels, and introduce foundational basketball movement and coordination exercises.

Step-by-Step Procedures (in order of implementation):

1. Welcome and Icebreaker (5 minutes):

Participants are welcomed by study personnel. A brief introduction is conducted where each participant shares their name and favorite basketball team or player. The session begins with emphasis on fun, teamwork, and respectful participation.

2. Warm-Up Relay Drills (10 minutes):

Participants are divided into small teams and complete a series of movement-based relays, including forward running, backpedaling, side shuffling, and zig-zag sprinting using cone markers. This segment promotes dynamic stretching, neuromuscular activation, and cardiovascular warm-up.

3. Ball Handling – Dribble Tag (10 minutes):

Each participant is given a basketball and plays a controlled game of “Dribble Tag” within a designated area. One or two participants are designated as “taggers,” and all participants must maintain dribble control while avoiding being tagged. Players who are tagged complete a brief fitness task (e.g., 3 jumping jacks) before rejoining.

4. Fundamental Passing Drills (10 minutes):

In pairs, participants practice chest and bounce passes while emphasizing form (stepping into pass, follow-through, eye contact). The drill progresses to include light movement between passes to simulate game conditions.

5. Zig-Zag Dribbling (10 minutes):

Participants complete a slalom-style dribbling course using cones. Focus is placed on hand transitions, maintaining control, and dribbling with the head up. Progression includes use of the non-dominant hand.

6. “Around the World” Passing Game (5 minutes):

Participants form a circle and engage in a rapid passing game where each player must call out the name of the recipient prior to passing. This activity is designed to build court awareness, communication, and reaction time. A second ball may be introduced for increased challenge and engagement.

Session 3b: Ball Control & Conditioning Skills

Session Title: “Hustle & Handle” – Ball Control, Fitness, and Layup Fundamentals

Estimated Duration: 50 minutes

Objectives: To improve ball control, cardiovascular fitness, and introduce proper layup technique.

Procedures:

1. Dynamic Warm-Up (10minutes):

Group warm-up consisting of high knees, butt kicks, lateral lunges, arm circles, and basketball-specific hand control exercises (ball slaps, finger taps).

2. Cone Dribbling Challenges (10 minutes):

Each participant completes individual dribbling circuits using dominant and non-dominant hands, with progression to crossover or through-the-legs movements for advanced participants.

3. “Red Light, Green Light” Dribble Game (10 minutes):

A reaction-time drill where participants dribble in response to verbal cues: “green”

(advance), “red” (stop), and “yellow” (slow dribble in place). Focus is on control and decision-making under pressure.

4. Partner Layup Practice (10 minutes):

Paired participants rotate between shooter and rebounder roles. Emphasis is placed on proper layup footwork, using the backboard, and switching hands when needed.

5. “Dribble Knockout” Game (10 minutes):

Participants attempt to maintain dribble control while displacing others’ balls. Eliminated players complete a brief physical activity (e.g., jumping jacks) and return. This promotes agility, ball protection, and endurance.

Session 4b: Defensive Skills & Rebounding Techniques

Session Title: “Lock In on Defense” – Defensive Fundamentals and Rebounding

Estimated Duration: 50 minutes

Objectives: To introduce participants to core defensive principles, including footwork, positioning, and rebounding mechanics.

Procedures:

1. Slide & Sprint Circuit (10 minutes):

Participants rotate through a cone-marked circuit that involves lateral slides, forward sprints, and backpedaling to simulate defensive movement patterns. Proper defensive stance, spacing, and balance are emphasized throughout.

2. Mirror Drill (10 minutes):

Working in pairs, one participant performs lateral movements while the partner mimics their motion. In advanced rounds, the leader incorporates ball-handling to add complexity. This drill promotes reaction time, defensive anticipation, and visual tracking.

3. Closeout Drill (10 minutes):

Each defender starts in the paint and sprints out to challenge an offensive player on the perimeter. Emphasis is placed on controlled deceleration, hand positioning, and closing the gap without fouling. Progressions may include shot defense or drive containment.

4. Box-Out Battles (10 minutes):

Two participants position under the basket while a third person (coach or peer) simulates a shot. Players engage in controlled physical contact to gain inside rebounding position. Drill reinforces boxing out, spatial awareness, and rebound securing.

5. “Steal the Bacon” Game (10 minutes):

Participants are assigned numbers and placed on opposing baselines. When a number is called, the designated players race to the center for ball possession and initiate a 1-on-1 offensive/defensive play. Progressions include 2v2 or 3v3 for team coordination.

Session 5b: Team Integration & Program Celebration

Session Title: “Teamwork Day” – Game Play, Application, and Recognition

Estimated Duration: 50 minutes

Objectives: To allow participants to apply learned skills in a team-based context, reinforce collaboration and sportsmanship, and celebrate progress and participation.

Procedures:

1. Warm-Up with Ball Movement Drill (10 minutes):

Participants form small-sided groups and engage in continuous pass-and-move drills designed to encourage communication, decision-making, and spacing awareness.

2. Mini-Games (15 minutes):

Participants engage in short-sided basketball games (3-on-3 or 4-on-4) with rotating teams every 5–6 minutes. This structure maximizes playtime and inclusivity while reinforcing all fundamental skills developed during the program.

3. Fast Break Challenge (10 minutes):

Players rotate through 2v1 and 3v2 fast-break scenarios, focusing on offensive spacing, defensive recovery, and quick decision-making under pressure. All participants experience offensive and defensive roles.

4. Prepare for Health Fair & Reflections (15 minutes):

- Participants are divided into 5 groups of 6 participants. Each group is assigned a health education topic discussed during sessions 1-4. With the help of a study team member and using the Health Fair Presentation templates, each group prepares a 5-minute presentation for the Health Fair in Session 6.
- A brief closing circle is held where participants are invited to share reflections on their experience and encouraged to continue practicing healthy habits.

Session 6: BasketballRx: Hoops for Health Fair

Session Title: "Play Strong, Live Well"

Objectives: To engage participants, their families, and peers in a basketball tournament and health fair to showcase their learned knowledge and skills in basketball and health education. The event aims to celebrate youth participation, raise awareness about healthy behaviors, and provide a supportive space for learning, movement, and community building.

- Data Collection (20 minutes) Of note, data will be recorded using the Data Collection document.
 - See Section 7.1 for details. In summary, before the beginning of the tournament and health fair, study team members will obtain blood pressure and heart rate for each participant. Any participant with an elevated blood pressure or heart rate will be excluded from playing in the tournament. They will be allowed to participate in the other portions of the event.
 - Participants will complete the post-intervention survey as well as the PHQ-2 and SCARED questionnaires. Additionally, the PHQ-A questionnaire will be completed by participants with elevated PHQ-2 scores. Participants will also complete the "Youth Reflection Survey."
 - Post-intervention BMI and waist circumference will be measured.
- Team Huddle (20 minutes)
 - The study team will distribute uniforms to the participants, and the agenda for the event will be reviewed with them and their guardians.
- AGENDA for Tournament and Health Fair (140 minutes)
 1. Welcome (10 minutes) - Welcoming of participants and guest attendees. Brief overview of the event schedule and activities. Introduction of the study team, community partners. Share the purpose of the event and a summary of the BasketballRx program. Group cheer to kick off the event. Light music and games are available. Informal mingling.
 2. Health Fair (30 minutes) – Interactive session on nutrition, physical activity, and mental health, designed to be culturally relevant and youth-friendly. This session will be facilitated by all members of the study team and will allow the participants to demonstrate acquired knowledge through participation in the BasketballRx program through brief presentations to attendees.
 3. Basketball Tournament (30 minutes) – 5-on-5 rotating half-court games. Emphasis on participation, teamwork, and physical activity.
 4. Award Ceremony & Social (70 minutes)
 - a. Certificates of completion will be awarded to all participants.
 - b. Attendees enjoy music, healthy snacks, games, and informal socializing to close the event on a positive, inclusive note.

7.3 Duration of Participation

Describe how long subjects will be involved in this research study. Include the number of sessions and the duration of each session - consider the total number of minutes, hours, days, months, years, etc.

The study participants will attend 6 sessions across 3 months. Sessions 1 through 5 will be 90 minutes long, while session 6 will be 180 minutes long.

8.0 Number of Subjects and Statistical Plan

8.1 Number of Subjects

Indicate the maximum number of subjects to be accrued/enrolled, to include all persons who sign consent for the study. If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.)

The maximum number of subjects to be enrolled in the study is 30.

8.2 Sample Size Determination

If applicable, provide a justification of the sample size outlined in section 8.1 to include reflections on, or calculations of, the power of the study.

As this is an exploratory study, formal power calculations were not conducted. Instead, the primary goal is to generate preliminary effect size estimates for key outcome variables (e.g., change in BMI, waist circumference, health knowledge, depression, and anxiety symptoms), which will inform a future, adequately powered study.

8.3 Statistical or Analytic Methods

Describe the statistical methods (or non-statistical methods of analysis) that will be employed.

Quantitative data will be analyzed using paired t-tests to evaluate within-subject changes in primary outcomes, including BMI, waist circumference, and survey-based measures (e.g., health knowledge, behaviors, depression, and anxiety symptom scores) from pre- to post-intervention.

9.0 Data and Safety Monitoring Plan

This section is required when research involves more than Minimal Risk to subjects as defined in “HRP-001 SOP- Definitions.”

Minimal Risk is defined as the probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For research involving prisoners, Minimal Risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

Please complete each section below if the research involves more than minimal risk to subjects or indicate not applicable.

[Do not type here]

9.1 Periodic evaluation of data

Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

Not applicable.

9.2 Data that are reviewed

Describe the data that are reviewed, including safety data, untoward events, and efficacy data.

Not applicable.

9.3 Method of collection of safety information

Describe the method by which the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls and with subjects).

Not applicable.

9.4 Frequency of data collection

Describe the frequency of data collection, including when safety data collection starts.

Not applicable.

9.5 Individuals reviewing the data

Identify the individuals who will review the data. The plan might include establishing a data and safety monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.

Not applicable.

9.6 Frequency of review of cumulative data

Describe the frequency or periodicity of review of cumulative data.

Not applicable.

9.7 Statistical tests

Describe the statistical tests for analyzing the safety data to determine whether harms are occurring.

Not applicable.

9.8 Suspension of research

Describe any conditions that trigger an immediate suspension of research.

Not applicable. .

10.0 Risks

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include as may be useful for the IRB's consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Consider all types of risk including physical, psychological, social, legal, and economic risks. **Note: Loss of confidentiality is a potential risk when conducting human subject research and must be listed here.**

- If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.

- If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.
- If applicable, describe risks to others who are not subjects.

All study procedures have been designed to pose no more than minimal risk to participants in that they fall within the normal basketball drills during physical education classes at school. Nonetheless, to protect participant well-being, any adverse events—such as physical injuries, signs of distress, or discomfort—will be documented in real time by study personnel.

Licensed physicians will be present at all intervention sessions to monitor safety and respond to any issues that arise. Guardians will also be present throughout all sessions.

Should a participant experience an injury and the participant or guardian believe emergency care is required, they will be directed to seek immediate medical attention. If emergency care is not deemed necessary by the participant or guardian, the study team will instruct them to contact their Primary Care Provider at the Penn State Health Harrisburg Clinic (recruitment site) to schedule follow-up as appropriate.

The study team will periodically review documentation of adverse events and participant feedback to assess for any trends that may indicate emerging risks. If patterns of harm or discomfort are identified, the study team will evaluate and, if necessary, modify study procedures to ensure continued participant safety. This ongoing evaluation will inform decisions regarding whether participants should continue, modify, or discontinue their participation.

Subjects may experience distress or discomfort when answering certain questions in the survey—to mitigate this, they will be told that they do not have to answer any questions that make them uncomfortable.

The loss of confidentiality is a risk when participating in research, but the study team will use best research practices to reduce the chances that this will happen. The study data will be housed in Penn State's REDCap, which is a secure, HIPAA-compliant research database. Access to the study database will be restricted to study team members for whom access is essential. Information gathered from participation in the study will not place subjects at risk of criminal or civil liability or cause damage to their finances, employability, or reputation.

11.0 Potential Benefits to Subjects and Others

11.1 Potential Benefits to Subjects

Describe the potential benefits that individual subjects may experience from taking part in the research. If there is no direct benefit to subjects, indicate as such. Compensation is not considered a benefit. Compensation should be addressed in section 13.0.

Participants may experience several potential direct benefits because of their involvement in this study including:

- Improved health literacy through structured education on nutrition, physical activity, and sleep hygiene, which may support healthier lifestyle choices.
- Increased physical activity via guided basketball sessions, which provide opportunities for regular exercise in a supportive, supervised environment.
- Reductions in BMI and waist circumference due to engagement in the physical activity component and adoption of healthier behaviors.

- Enhanced self-efficacy and engagement in health-promoting behaviors because of repeated exposure to positive reinforcement, team-based activities, and structured goal setting.

11.2 Potential Benefits to Others

Describe the potential benefits to society or others.

If successful, this pilot study has the potential to contribute to broader public health efforts by informing the development of scalable, community-based interventions for pediatric obesity. The integration of age-appropriate, culturally responsive basketball-based physical activity with structured nutrition education offers a promising and engaging model that could be replicated in similar urban and underserved communities.

The findings from this study may guide clinicians, educators, and community health practitioners in implementing effective lifestyle interventions that not only address obesity but also promote mental health and social engagement among youth. By generating preliminary data on feasibility, acceptability, and impact, this study may serve as a foundation for larger trials aimed at reducing childhood obesity and improving psychosocial outcomes at the population level.

12.0 Sharing Results with Subjects

Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how information will be shared.

Upon study completion, each participant will receive a certificate of completion, which will include their individual pre- and post-intervention weight measurements as documented during the study.

13.0 Subject Payment and/or Travel Reimbursements

Describe the amount, type (cash, check, gift card, other) and timing of any subject payment or travel reimbursement. If there is **no** subject payment or travel reimbursement, indicate as not applicable.

Extra or Course Credit: Describe the amount of credit **and** the available alternatives. Alternatives should be equal in time and effort to the amount of course or extra credit offered. It is not acceptable to indicate that the amount of credit is to be determined or at the discretion of the instructor of the course.

Approved Subject Pool: Indicate which approved subject pool will be used; include in response below that course credit will be given and alternatives will be offered as per the approved subject pool procedures.

The guardian of each participant will receive a \$50 gift card at session 1 and \$50 gift card at session 6. They will also receive \$50 gift cards at sessions 3 and 4. Participants must attend at least 4 sessions including session 6, to receive the fourth \$50 gift card. The PI and study team will obtain an exception from the Controller's Office to provide compensation via gift card instead of Greenphire.

14.0 Economic Burden to Subjects

14.1 Costs

Describe any costs that subjects may be responsible for because of participation in the research.

Participation in the study will involve no financial cost to participants or their guardians.

14.2 Compensation for research-related injury

If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.

If there is no sponsor agreement that addresses compensation for medical care for research subjects with a research-related injury, include the following text as written - DO NOT ALTER OR DELETE:

It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Costs for the treatment of research-related injuries will be charged to subjects or their insurance carriers.

For sponsored research studies with a research agreement with the sponsor that addresses compensation for medical care for research-related injuries, include the following text as written - DO NOT ALTER OR DELETE:

It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Such charges may be paid by the study sponsor as outlined in the research agreement and explained in the consent form.

not applicable

15.0 Resources Available

15.1 Facilities and locations

Identify and describe the facilities, sites, and locations where recruitment and study procedures will be performed.

If research will be conducted outside the United States, describe site-specific regulations or customs affecting the research, and describe the process for obtaining local ethical review. Also, describe the principal investigator's experience conducting research at these locations and familiarity with local culture.

Recruitment will occur from the PSH FCM Harrisburg clinic.

Recruitment will also occur by way of flyers posted at the YMCA Camp Curtin site where interested individuals will be able to contact that study team by the included contact information on the flyer.

The BasketballRx program and data collection will take place at the YMCA Camp Curtin in Harrisburg, PA.

15.2 Feasibility of recruiting the required number of subjects

Indicate the number of potential subjects to which the study team has access. Indicate the percentage of those potential subjects needed for recruitment.

The study team has access to approximately 300 potential subjects through the PSH FCM Harrisburg Clinic. To achieve the target enrollment of 30 participants, we aim to recruit approximately 10% of this population.

15.3 PI Time devoted to conducting the research

Describe how the PI will ensure that a sufficient amount of time will be devoted to conducting and completing the research. Consider outside responsibilities as well as other on-going research for which

the PI is responsible. Please only provide a response for the principal investigator – do **not** include information about any other study team members.

The PI will utilize dedicated research time to conduct this research.

15.4 Availability of medical or psychological resources

Describe the availability of medical or psychological resources that subjects might need as a result of their participation in the study.

Participants will be referred to their Primary Care Physician at the PSH FCM Harrisburg Clinic for any care needed, including psychological, as this is within the scope of practice of these healthcare providers.

15.5 Process for informing Study Team

Describe the training plans to ensure members of the research team are informed about the protocol and their duties.

All study team members will maintain current certification through the CITI program. Additionally, the research team will convene monthly to review study protocols, assess study progress, and discuss any necessary protocol modifications that may occur during the study.

16.0 Other Approvals

16.1 Other Approvals from External Entities

Describe any approvals that will be obtained prior to commencing the research (e.g., from engaged cooperating institutions IRBs who are also reviewing the research and other required review committees, community leaders, schools, research locations where research is to be conducted by the Penn State investigator, funding agencies, etc.).

The YMCA has provided the study team with support granting access to their facilities for the implementation of the BasketballRx program.

16.2 Internal PSU Ancillary Reviews

DO NOT ALTER OR DELETE:

Ancillary reviews are reviewed by other compliance groups or individuals within Penn State that inform the IRB's review of a new study or a modification to an existing study.

PSU IRB may set applicable ancillary reviews for your study. Please refer to the "HRP-309 Worksheet – Ancillary Review Matrix" for more information (found in the CATS Library).

[Do not type here]

17.0 Multi-Site Study

If this is a multi-site study (i.e., a study in which two or more institutions coordinate, with each institution completing all research activities outlined in a specific protocol) and **the Penn State PI is the lead investigator**, describe the processes to ensure communication among sites in the sections below.

[Do not type here]

17.1 Other sites

List the name and location of all other participating sites. Provide the name, qualifications and contact information for the principal investigator at each site and indicate which IRB will be reviewing the study at each site.

not applicable

17.2 Communication Plans

Describe the plan for regular communication between the overall study director and the other sites to ensure that all sites have the most current version of the protocol, consent document, etc. Describe the process to ensure all modifications have been communicated to sites. Describe the process to ensure that all required approvals have been obtained at each site (including approval by the site's IRB of record). Describe the process for communication of problems with the research, interim results, and closure of the study.

not applicable

17.3 Data Submission and Security Plan

Describe the process and schedule for data submission and provide the data security plan for data collected from other sites. Describe the process to ensure all engaged participating sites will safeguard data as required by local information security policies.

not applicable

17.4 Subject Enrollment

Describe the procedures for coordination of subject enrollment and randomization for the overall project.

not applicable

17.5 Reporting of Adverse Events and New Information

Describe how adverse events and other information will be reported from the clinical sites to the overall study director. Provide the timeframe for this reporting.

not applicable

17.6 Audit and Monitoring Plans

Describe the process to ensure all local site investigators conduct the study appropriately. Describe any on-site auditing and monitoring plans for the study.

not applicable

18.0 Adverse Event Reporting

18.1 Reporting Adverse Reactions and Unanticipated Problems to the Responsible IRB

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

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.

19.0 Study Monitoring, Auditing, and Inspecting

19.1 Auditing and Inspecting

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

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.).

20.0 References

List relevant references in the literature which highlight methods, controversies, and study outcomes.

- Biddle, S. J. H., & Asare, M. (2011). Physical activity and mental health in children and adolescents: A review of reviews. *British Journal of Sports Medicine*, 45(11), 886–895. <https://doi.org/10.1136/bjsports-2011-090185>
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- Office of the Surgeon General. (2021). Protecting youth mental health: The U.S. Surgeon General’s advisory. U.S. Department of Health and Human Services. Accessed July 17, 2025. <https://www.hhs.gov/sites/default/files/surgeon-general-youth-mental-health-advisory.pdf>
- Pennsylvania Health Policy Coalition. (2020). Obesity. Accessed February 12, 2025. <https://pahealthpolicy.org/obesity>
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- Centers for Disease Control and Prevention. (2024, June). Physical activity guidelines for Americans, 2nd edition. U.S. Department of Health & Human Services. <https://www.cdc.gov/physical-activity-education/guidelines/index.html>
- Centers for Disease Control and Prevention. (2024, June). Measuring physical activity intensity. U.S. Department of Health & Human Services. <https://www.cdc.gov/physical-activity-basics/measuring/index.html>
- American College of Sports Medicine. (n.d.). Physical activity guidelines for children. Retrieved August 22, 2025, from <https://www.acsm.org/physical-activity-guidelines-children>

21.0 Confidentiality, Privacy and Data Management

For data level classification: <https://security.psu.edu/awareness/icdt/>

For approved UP/Commonwealth storage platforms:

<https://security.psu.edu/awareness/storage/>

<https://datastoragefinder.psu.edu/computing/backup-storage/finder>

Please visit datastoragefinder.psu.edu and <https://security.psu.edu/awareness/storage/> for assistance with identifying appropriate data storage options. If the software to be used does not appear on that site, please visit <https://procurement.psu.edu/electronic-click-through-contracts> to consider whether a software request form must be completed.

NOTE: Please refer to [PSU Policy AD95](#) for information regarding information classification and security standards and requirements. **UP/Commonwealth campuses:** If you have questions about Penn State's Policy AD95 or standards or need a consultation regarding data security, please contact Penn State IT – Information Security at security@psu.edu. **College of Medicine:** If you have questions about Penn State's Policy AD95 or standards or need a consultation regarding data security, please contact Jason Hughes in the Penn State IT Security Group at jhughes7@pennstatehealth.psu.edu.

21.1 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
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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	☐	☐

21.2 Are the identifiers above linked (directly or indirectly via code list) to research data?

If there is a list/key that links indirect identifiers (code numbers, participant IDs, etc.) to direct identifiers, that list must **not** be comingled (i.e., stored in the same location) as the identifiable data, including copies of signed informed consent forms. Additionally, access to that list/key must be restricted to authorized project personnel.

- ☐ No – skip to 21.3
☒ Yes – complete 21.2.1

21.2.1 Explain how the list that links the code to identifiers is stored separately from coded data and include who has access:

The study team will use REDCap to store research data.
Each study participant will be assigned a masked study ID number.
A linking list of study participants' study id numbers and their identifying information will be stored on a password-protected Excel spreadsheet, saved on a Penn State Health HIPAA compliant SharePoint that only study team members will be able to access.

21.3 Are paper records of research data (including copies of signed consent forms) being collected or stored:

- ☐ No – skip to 21.4
☒ Yes – complete 21.3.1 and 21.3.2

21.3.1 Where will the paper records be securely stored?

Paper records will be stored in a locked drawer in a locked office at the PSH HBG Clinic which has a security system.

21.3.2 Will everyone on the study team have access to the stored paper records?

- ☒ Yes – skip to 21.4
☐ No – Explain what limitations are in place:

21.4 Are electronic records of research data being collected or stored?

- ☐ No – skip to 21.5
☒ Yes – Complete rest of 21.4

Use of one of the IT-approved solutions listed is strongly recommended. If “Other” is chosen for storage of identifiable data, the IRB may set an ancillary review for further assessment of compliance with institutional data security policy.

21.4.1 How is the data being collected? (e.g., data capture using online surveys/questionnaire, surveys via email, observation of chat rooms or blogs, application, or device)

- Informed consent will be documented in REDCap by members of the study team.
- Participant survey responses will be collected on paper and subsequently entered into REDCap by trained study personnel.
- Anthropometric measures (weight, height, and waist circumference) will be obtained through chart review and reassessed at the start of Sessions 1 and 6. These data will also be entered into REDCap by study team members.
- Heart rate and blood pressure will be measured at the beginning of each session, recorded on paper by the study team, and later entered into REDCap.
- Standardized mental health measures, including the SCARED, PHQ-2, and PHQ-A questionnaires, will be administered at the start of Sessions 1 and 6, with results documented in REDCap.
- Adherence to the study protocol will be monitored through completion of the Facilitator Checklist.
- Safety monitoring will include both direct observation by the study team and participant self-report.
- Exertion levels will be tracked using the Exertion Monitoring Checklist by the study team.
- Any adverse events or concerns will be documented in the Incident Log by the study team.

21.4.1.1 If you've indicated that data is being collected via a device or application (e.g. FitBit, Apple Watch, eye tracker, etc.), will the developer/external entity have access to the research data?

- ☒ No
☐ Yes

21.4.2 Specify the level of data that will be stored electronically (refer to definitions at the top of this section – links to levels/storage: <https://security.psu.edu/awareness/storage/>)

- ☐ Level 1 (e.g. public data, de-identified)
☐ Level 2 (e.g. identifiable not sensitive)
☒ Level 3 (e.g. PHI, or identifiable sensitive data)
☐ Level 4 (e.g. Classified data)

21.4.3 Indicate where the electronic data associated with this research study will be stored (Check all that apply)

21.4.3.1 Penn State University and Commonwealth Campuses

- Penn State IT provided database application:
 - ☐ Penn State REDCap
 - ☐ Penn State Qualtrics
 - ☐ Penn State, College, or Department IT managed file server, OneDrive, or SharePoint
 - ☐ Penn State GoogleDrive
- Other – Specify the database application or server:
 - ☐ Provide details about the data security features or attach security documentation provided by sponsor or group.

Please visit datastoragefinder.psu.edu for assistance with identifying appropriate data storage options. If the software to be used does not appear on that site, a [software request form](#) must be completed.

21.4.3.2 Penn State Health/College of Medicine

- Penn State IT provided database application:
 - ☒ Penn State REDCap
 - ☐ Penn State Qualtrics
 - ☒ Penn State Health, College of Medicine, or Department IT managed file server
 - ☒ Office365, OneDrive, or SharePoint
 - Specify the O365 tenant to be used (PSU, PSH) PSH
 - ☐ Oncore (Penn State Cancer Institute only)
 - ☐ Florence eBinders
 - ☐ External Institution's REDCap
 - ☐ Web-based system provided by the sponsor or cooperative group via contract
- Other – Specify the database application or server:
 - ☐ Provide details about the data security features or attach security documentation provided by sponsor or group.

21.5 Will any type of recordings (e.g., audio or video) or photographs of the subjects be made during this study or will you interact with subjects via live video streaming(video chat)?

- ☐ No – skip to 21.6
- ☐ Yes – Live video chat ONLY without recording. If this is the ONLY box checked, complete 21.5.1 only.
- ☒ Yes – Recording (audio, video, photographs, recording of video chat). If this is the ONLY box checked, skip to 21.5.2:

21.5.1 Select the video chat platform:

- ☐ PSH HIPAA Compliant Teams
- ☐ PSU Zoom
- ☐ Other: Specify:
[Type text here if box is checked]

21.5.2 Select the type of recording or image being made and what is being used to record or capture the image:

- ☐ Audio – Describe what will be used to capture the audio:
[Type text here if box is checked]

- ☐ Video – Describe what will be used to capture the video:
[Type text here if box is checked]

- ☒ Photographs of the subjects – Describe what will be used to photograph the subjects and whether facial images will be captured or collected:

Photographs will be taken of participants during the sessions. Facial images may be captured in these photographs. The mobile phone of study team members will be used to capture the image. The image will immediately be uploaded to the PSH Sharepoint folder and the image deleted off of the phone. If backup to cloud is enabled on the phone, it will be turned off while capturing the photos and will not be turned back on until after photos have been uploaded to PSH servers.

- ☐ Recording of video chat
- ☐ PSH HIPAA Compliant Teams
- ☐ PSU Zoom
- ☐ Other: Specify:
[Type text here if box is checked]

- ☐ Other - Specify:
[Type text here if box is checked]

21.5.3 Will any of the recordings be transcribed?

Note: If a transcription service outside of Penn State will be used, a business associate agreement or data transfer agreement may be needed.

- ☐ No
- ☐ Yes – indicate who will be doing the transcribing? (Ex: Zoom, Rev.com, Datagain, 3Play Media). If necessary, please clarify if the transcription service is HIPAA compliant or not.

Not applicable.

21.5.4 Will the recordings be destroyed or cleaned (removed of all identifiers)? If so, describe below.

Not applicable.

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

- ☐ Yes – this means at least one of the following is true:
- 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 any of the 4 items above are true, 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.

21.7 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 – describe the plan for de-identifying the dataset before sharing it with NIH-designated data repositories.

[Type protocol text here]

Note: Data sharing with an NIH-designated data repository may require execution of an institutional certificate. Please review the 'Institutional Certification for NIH Genomic Data Sharing' section of the Investigator's Manual for information about seeking institutional certification.

21.8 Does this research involve data sharing to public/restricted data repositories or as part of a journal requirement?

Data sharing is an important part of rigorous scientific discovery and the validation of results. Planning for data sharing is *strongly recommended*. Please refer to:
<https://libraries.psu.edu/about/departments/research-informatics-and-publishing/services/data-management-and-sharing>

Data sharing includes sharing of identifiable, coded, or de-identified data. The data can be shared with public or restricted data repositories. Increasingly, journals require the sharing of data as a stipulation for publication. NIH-funded studies **require data sharing**, unless explicitly granted an exception from the NIH.

- ☒ No – skip to section 21.9
☐ Yes (*strongly recommended* as may be required for publication and future grant submission)

21.8.1 What type of data will be shared: De-identified, coded, identifiable (if identifiable, list the identifiers that will be shared)

- ☐ De-identified
☐ Coded (there is a study code ID being sent, but no identifiers with the study code)
☐ Identifiable – Specify the identifiers that will be shared:

[Type protocol text here]

21.8.2 What type of repository will be used to share the data: Public, controlled, etc. Note: The specific name of the repository is not necessary.

[Type protocol text here]

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

- ☒ No - skip to section 22.0
☐ Yes - answer the following questions:

21.9.1 Specimen and/or data are being transferred or disclosed (electronically or physically) **TO** Penn State. Please insert study information in first blank row. Please add additional rows as necessary for each individual entity, do not have more than one entry in a row. (Example provided in grey)

Sharing Entity	Data or Specimen Type	Method of Transfer	Storage Location	Identifiers (Refer to table 1 in 22.1)	Linking List Location	Additional notes, if needed.
Johns Hopkins	Consent forms, questionnaires, activity data from FitBit, liver biopsy sample, biopsy results, audio recordings.	Aspera, Office 365, REDCap, Sponsored platform/location	REDCap, Lab, CRC	Study code, Date of birth	☐ ONLY with External Entity ☐ External Entity and Penn State ☐ Penn State ONLY	

21.9.2 Specimen and/or data are being transferred or disclosed (electronically or physically) **FROM** Penn State. Please insert study information in first blank row. Please add additional rows as necessary for each individual entity, do not have more than one entry in a row. (Example provided in grey)

Sharing Entity	Data or Specimen Type	Method of Transfer	Storage Location	Identifiers (Refer to table 1 in 22.1)	Linking List Location	Additional notes, if needed.
Temple	Consent forms, questionnaires, activity data from FitBit, liver biopsy sample, biopsy results, audio recordings.	Aspera, Office 365, REDCap, Sponsored platform/location	REDCap, Lab, CRC	Study code, Date of birth	☐ ONLY with External Entity ☐ External Entity and Penn State ☐ Penn State ONLY	

UP/Commonwealth Data Transfer:

Office of Sponsored Programs - Data transfers or disclosures may require a Data Use Agreement (DUA). If the third party is requiring us to sign a contract regarding the data, this contract must go through the Office of Sponsored Programs <https://www.research.psu.edu/osp/overview-pages/data-use-agreements>.

PSU/Commonwealth Material Transfer:

Office of Technology Transfer - All material transfers, either sending or receiving, require a Material Transfer Agreement (MTA). Please contact the Office of Technology Transfer for more information. <https://ott.psu.edu/>

Penn State Health/College of Medicine Data transfer:

Office of Research Affairs - Data transfers or disclosures may require a Data Use Agreement (DUA). If the Office of Research Affairs has not yet been contacted, please email e-contracts@pennstatehealth.psu.edu. If a third party is requiring us to sign a contract regarding the data, the contract must go through the Office of Research Affairs. Please submit at the following link: <https://pennstatehershey.tfaforms.net/267>.

Penn State Health/College of Medicine Material transfer:

Center for Medical Innovation - All material transfers, either sending or receiving, require a Material Transfer Agreement (MTA). If a MTA Intake Form has not been completed for this material transfer, please go to <https://pennstatehershey.tfaforms.net/744> and complete the on-line MTA intake form. If you have any questions, please email CMI@pennstatehealth.psu.edu.

22.0 Identifiable Data and Specimen Banking for Future Undetermined Research

If this study is banking **identifiable** data and/or specimens that will be banked for **future undetermined research**, please describe this process in the sections below. This information should not conflict with information provided in the above sections regarding whether or not data and/or specimens will be associated with identifiers (directly or indirectly). If there are no plans to use identifiable data/specimens for future, undetermined research, then this section is **NOT applicable**.

[Do not type here]

22.1 Data and/or specimens being stored

Identify what data and/or specimens will be stored, and the data associated with each specimen.

not applicable

22.2 Location of storage

Identify the location where the data and/or specimens will be stored.

not applicable

22.3 Duration of storage

Identify how long the data and/or specimens will be stored. If data and/or specimens will be stored indefinitely, indicate such.

not applicable

22.4 Access to data and/or specimens

Identify who will have access to the data and/or specimens.

not applicable

22.5 Procedures to release data or specimens

Describe the procedures to release the data and/or specimens, including: the process to request a release, approvals required for release, who can obtain data and/or specimens, and the data to be provided with the specimens.

not applicable

22.6 Process for returning results

Describe the process for returning results about the use of the data and/or specimens.

not applicable