VIP-RACE: Developing and Testing Video-feedback Intervention to Promote Racial-Ethnic Socialization Competency in Latino/a/x Families

HRP-591 – Protocol for Human Subject Research

NCT Number: Not Yet Assigned

Date of Last Modification: 03/16/2025

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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).

Developing and Testing a Video-feedback Intervention to Promote Racial-Ethnic Socialization Competency in Latino/a/x Families

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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.

03/16/2025

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 INSTRUCTIONS[1]:**
   - 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.

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).

[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

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…

All locations:
Human Research Protection Program
Office for Research Protections
101 Technology Center
University Park, PA 16802-7014
Phone: 814-865-1775
Fax: 814-863-8699
Email: irb-orp@psu.edu
https://www.research.psu.edu/irb

Table of Contents

1.0 Objectives

1.1 Study Objectives

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

The aim of this study is to develop and iteratively refine the Video-feedback Intervention to Promote Racial-Ethnic Socialization CompEtency (VIP-RACE) to support Latine parents' motivation to engage in racial-ethnic socialization (RES) and strengthen their RES competency (improved skills and confidence, decreased stress). During Phase 1 (Aim 1), we will iteratively refine VIP-RACE in partnership with advisory boards of youth, parents, and RES coaches, as well as expert researchers and clinicians, who will review intervention manual and materials. The refined intervention will be tested with five parents of 10-14-year-old Latine youth to identify gaps in the curriculum and obstacles to implementation that can be addressed prior to a larger pilot. In Phase 2 (Aim 2), we will conduct a proof-of-concept single-arm trial with Latine families to assess the feasibility, acceptability, and preliminary efficacy of VIP-RACE. We hypothesize that VIP-RACE will be shown to be feasible and acceptable to families. We also predict that bolstering parents' RES motivation and competency will result in increased frequency and quality of these conversations between parents and youth which, in turn, are expected to strengthen youth racial-ethnic identity and coping and have cascading effects on mental and behavioral health.

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).

Change in RES motivation and RES competency (confidence, skills, stress) from baseline to 1-month follow-up will serve as the primary indices of VIP-RACE preliminary efficacy. These outcomes will be assessed via parent- and youth-reported measures.

1.3 Secondary Study Endpoints

State the secondary endpoints to be measured in the study.

Secondary outcomes will include changes (from baseline to 1-month follow-up) in parents' frequency and quality of cultural socialization and preparation for bias messages, youth racial-ethnic coping, youth racial-ethnic identity, and youth depressive and anxiety symptoms and conduct problems. These outcomes will be assessed via parent- and youth-reported measures. At baseline and follow-up, parents and youth will also participate in a videotaped parent-child interaction task during which they discuss race-related topics. These data will assess the quality of observed racial socialization and will be used to complement self-reported measures of similar constructs.

Additionally, the feasibility and acceptability of VIP-RACE will be assessed by parent-reported surveys at post-treatment (i.e., immediately finishing the program) and a program evaluation interview conducted separately with parents and RES coaches at the 1-month follow-up. These data will aid in the planning of a larger-scale efficacy trial.

2.0 Background

2.1 Scientific Background and Gaps

Describe the scientific background and gaps in current knowledge.

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.

Experiences of interpersonal and structural racism represent a ubiquitous reality for Latine youth that can have lasting psychological consequences that undergird the profound racial health disparities within the United States. To equip youth with the skills and confidence to navigate and challenge racism, some parents of color use racial-ethnic socialization (RES), or the transmission of implicit and explicit messages about race and racism. Despite decades of research linking RES with reduced mental health symptoms and behavioral problems, as well as positive racial-ethnic identity, in youth of color, few preventive interventions directly target parental RES motivation and RES competency, or parents' skills, confidence, and stress levels around delivering RES messages. Additionally, among the few interventions that have been developed to support parents' RES, all but one have been developed specifically for Black families. Empirically-based intervention strategies that support RES competency in Latine families are urgently needed. To address this gap and disrupt the negative longitudinal effects of racism on Latinx youth, this proposal seeks to develop and pilot a novel RES intervention for Latinx families: VIP-RACE (Video-feedback Intervention to Promote Racial-Ethnic Socialization Competency). VIP-RACE leverages advances in RES theory, along with established intervention approaches in video feedback and motivational interviewing, to bolster Latinx parents' motivation to engage in RES and strengthen their RES competency (improved skills and confidence, decreased stress). Video feedback, which involves reviewing videos of parent-child interactions to strengthen positive dyadic communication, has been shown to improve developmentally salient caregiving strategies across age periods (e.g., responsiveness in early childhood, monitoring in adolescence). However, despite well-documented strengths of video feedback, we have yet to leverage this intervention approach to target culturally-specific parenting practices, such as RES motivation and competency in Latinx parents; this study will be the first to do so.

2.2 Previous Data

Describe any relevant preliminary data.

In developing the conceptual framework and initial draft of the VIP-RACE manual, we have drawn on Motivational Interviewing (MI) approaches for promoting change, past work on RES and resilience theory, and evidence-based video-feedback and family-based interventions aimed at improving parent-child interactions. This includes PI Galán's work with the Family-Check-Up (FCU), an evidence-based program shown to prevent youth behavioral and emotional problems, with most intervention effects mediated by improvements in parenting and family management. For instance, in a randomized controlled trial with 10-13-year-olds and their parents, PI Galán found that the FCU was associated with reduced anxiety and substance use compared to the control. The proposed study leverages key components of the FCU model: 1) using MI and video feedback to promote parenting changes; 2) providing parents with data-based feedback about their behavior; and 3) tailoring treatment to meet families' diverse needs.

2.3 Study Rationale

Provide the scientific rationale for the research.

Racial-ethnic socialization (RES)–or the delivery of messages that promote racial-ethnic pride and prepare youth to cope with racism–is a cultural strength that helps to buffer Latine youth from the damaging effects of racial-ethnic discrimination on mental health and conduct problems. However, discussing race-related topics can be daunting for parents, and the literature is clear that not all parents engage in RES competently. Some Latine parents may engage in racial silence (i.e., avoidance of race-related discussions). These parents may lack skills and confidence in their ability to communicate RES content and/or may not realize the importance of having these conversations with their children. This may be especially true for parents who were born outside of the U.S. and may be new to the idea of being discriminated against (i.e., if they were part of the majority in their country of origin). Parents' racial silence may also be prompted by worries that talking with their children about racism may "fill their heads" with fears. However, research shows the opposite – youth who rarely receive RES messages show worse psychological and behavioral adjustment and may internalize negative stereotypes about their own racial-ethnic group. These findings raise concerns about youth who are unsupported in building the necessary coping skills to respond adaptively to discrimination. Given the negative impact of racial-ethnic discrimination and the protective effects of RES on Latine youth, there is an evident need to identify evidence-based approaches for supporting Latine parents' RES motivation and competency.

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.)

			protocol
Phase 1	Advisory boards	Youth	Youth is 10-to-14-years-old (inclusive); youth are monoracial Latino/a/x/e or Hispanic; able to speak and understand English and/or Spanish have the capacity to provide consent/assent Must be willing to commit to at least a six month appointment. Youth will not need to participate in this board with their parent as a dyad (although they may if they wish to do so)

		Parents	Parent are monoracial Latino/a/x/e or Hispanic able to speak and understand English and/or Spanish have the capacity to provide consent/assent Must be willing to commit to at least a six month appointment Parents will not need to participate in this board with their child as a dyad (although they may if they wish to do so)
		RES coaches	Identifies as monoracial Latino/a/x/e Has substantial experience (2+ years) working with Latino/a/x/e families Has a bachelor's or master's degree or equivalent experience in psychology, social work, or other field related to parenting and child development. Can commit to attending advisory board meetings for at least one year Must be willing to commit to at least a six month appointment
Pilot	Pilot test with 5 families	Youth and Parent dyads	Youth is 10-to-14-years-old (inclusive); Parent and youth are monoracial Latino/a/x/e or Hispanic; One parent is willing to participate; Parent and youth are able to speak and understand English; and Parent and youth have the capacity to provide consent/assent Families must be willing to be video or audio recorded for the parent-child interaction tasks Youth and parent(s) must be willing to participate as dyads.
Phase 2	Test	Youth parent dyads	Youth is 10-to-14-years-old (inclusive); Parent and youth are monoracial Latino/a/x/e or Hispanic; One parent is willing to participate; Parent and youth are able to speak and understand English; and Parent and youth have the capacity to provide consent/assent Families must be willing to be video or audio recorded for the parent-child interaction tasks Youth and parent(s) must be willing to participate as dyads.
	Interview	Coaches	Identifies as monoracial Latino/a/x/e Has substantial experience (2+ years) working with Latino/a/x/e families Has a bachelor's or master's degree or equivalent experience in psychology, social work, or other field related to parenting and child development. Must be willing to commit to at least a one-year appointment. RES coaches can be the same coaches who participated in the Phase 1 advisory board, but they do not need to be.

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.

Exclusion criteria for families include:

1. Parents and/or youth do not identify as Latino/a/x/e or Hispanic.
2. Youth or parent has an intellectual disability, autism spectrum disorder, active suicidality, psychotic disorder, or other disorder that may limit ability to complete study (surveys and interviews require sustained attention, mental processing, and comprehension).
3. Members of our parent and youth advisory boards will be ineligible to participate in the Phase 1 pilot and the Phase 2 single-arm trial.
4. Families who participate in Phase 1 will be ineligible to participate in Phase 2.

Exclusion criteria for RES coaches will include:

1. RES coach identifies as any race/ethnicity other than Latino/a/x/e, including multiracial individuals that identify as Latino/a/x/e.

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.).

Families will be removed from the study if either parent or child withdraws consent or if they do not complete study activities.

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.

The withdrawal will be documented and the subject will be replaced if the timeline allows.

4.0 Recruitment Methods

- 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).

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

StudyFinder will not be used. Participants will be self-identified. We will distribute information about the study and provide opportunities for participants to indicate their interest in participating and to provide their contact information. More detail is provided in the next section.

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.

We will employ several recruitment strategies to ensure that we meet our target enrollment numbers. All study phases will use the same recruitment methods.

First, we will leverage the infrastructure of **Penn State's Parents and Children Together (PACT)** research collaborative which has supported and expanded community-engaged research efforts in Harrisburg. PACT has a long-standing relationship with **Latino Connection,** an organization in Harrisburg that primarily works with Latino/a/x families and regularly provides support for research conducted by PACT investigators. Latino Connection has agreed to support recruitment for this project by allowing us to attend their community outreach and programming events to distribute flyers and information about the study. These events may include gathering contact and/or screening information from families. Additionally, PACT has a Director of Community Relations and a Latino Outreach Coordinator who interface regularly with Latino/a/x communities

in the Harrisburg area and will assist with recruitment by referring families and distributing study flyers at community events.

Second, we will partner with other community sites and youth-serving agencies that work with Latino/a/x families, such as the **Latino Hispanic American Community Center in Harrisburg**, which has also been a PACT partner since 2010. These organizations will be asked to disseminate accessible information about the study at their community site locations and during organized events. Depending on the sites' preferences, study personnel will attend these events to provide additional information or conduct on-site screening.

Third, we will provide flyers/brochures describing the study to local businesses that interface with families, such as libraries, places of worship, and salons.

4.2.2 Where potential subjects will be recruited.

Recruitment efforts will target families in Harrisburg, Pennsylvania and the surrounding catchment areas (e.g., Lancaster, PA; York, PA).

4.2.3 When potential subjects will be recruited.

Recruitment for members of our advisory boards is expected to begin in September 2024 (Phase 1). Recruitment for the pilot study is expected to begin around January 2025 and continue through March 2025. Recruitment of families for the proof-of-concept trial (Phase 1) is projected to begin in approximately April 2025 and extend through March2026. However, precise dates of study duration are difficult to predict with certainty, as they will depend on IRB approval and subject flow.

4.2.4 Screening and determining eligibility

Screening involves the process of assessing whether or not a potential subject is eligible for a study based on the inclusion and exclusion criteria. This process only involves assessing the eligibility and collecting information/data/biospecimens that is 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, and otherwise, consent is required prior to screening. Answer the following items in order to describe the screening process and determine if prior consent is required.

4.2.4.1 Is the potential subject providing information through oral or written communication (e.g. survey or verbally responding to answers)?

☒ Yes

The following process will be used to screen for members of our advisory board and for potential participants for the Phase 1 pilot and Phase 2 single-arm trial.

Parents will express interest in participating by contacting the lab through phone or email or by signing up at community events. After contacting the lab, research staff will screen parents over the phone and will obtain contact information from families that are eligible and remain interested in participating. All information collected during this phone call will only be used for screening purposes and contacting families; no information will be used as data for this study.

After confirming eligibility during the screening call, research staff will schedule a virtual appointment (via a Zoom video call) to obtain consent/assent from participants.

☐ 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]

[Describe what is being accessed here]

☒ 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]

[Describe the other purposes here]

☒ 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):

☒ **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']*

☐ **Implied or verbal consent will be obtained – subjects will not sign a consent form (waiver of written documentation of consent)** *[Complete Sections 5.2, 5.3 and 5.6; If this is the only box checked, mark Sections 5.4 and 5.5 as 'Not applicable']*

☐ **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']*

☐ **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, including when and where it will take place.

After confirming eligibility during the screening call, research staff will schedule a virtual appointment (via a Zoom video call) to obtain consent/assent from participants. Consent will be obtained using REDCap e-consent, the REDCap project was created using the CTSI REDCap eConsent Guidance Version 06/29/2022. The consent/assent form will be emailed to participants as a REDCap link so that they can review it independently before their appointment should they wish to do so. Families who do not have access to a device with Wi-Fi will have the option of providing consent/assent during an in-person appointment with research staff. During the appointment, all aspects of the study will be thoroughly explained, and all questions will be answered prior to any research procedures. Participants will be advised of the voluntary nature of the study and the fact that they may withdraw from the study at any time. Participants will also be advised on the contexts in which confidentiality may be broken (e.g., under circumstances of abuse). Study team members will go over each point in the consent document and provide participants with an opportunity to ask questions. Each section of the consent form will be summarized for participants, highlighting the study procedures, participant rights, confidentiality, risks, and benefits. The examiner will provide opportunities to participants to ask questions or gain clarification where necessary. Parents and children will complete the same consent form, and since the research is no more than minimal risk, we will collect one parent's consent and permission for their child to participate, and the assent of the child. All participants will be instructed to type their first and last name and then to click the "Add Signature" button to sign their name to document consent. Upon completion of the consent forms, all participants will be sent an electronic copy of their signed consent forms for their records. As requested in the 'REDCap How To Guide for eConsent' document, the email with the signed consent form will be include the following text:

'Email Confidentiality Notice - This message (including any attachments) contains information intended for a specific individual(s) and purpose which may be privileged, confidential or otherwise protected from disclosure pursuant to applicable law. Any inappropriate use, distribution or copying of the message is strictly prohibited and may subject you to criminal or civil penalty. If you have received this transmission in error, please reply to the sender indicating this error and delete the transmission from your system immediately.'

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.

All participants will be explicitly informed that their participation is voluntary and that they may withdraw from the study at any point. Participants will also be informed that their decision to withdraw will not affect their relationship with Penn State in any way and will have no other negative consequences.

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 that 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:

[Type protocol text here]

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)

5.4 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 Informed consent will not be obtained – request to completely waive the informed consent requirement

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.

For Phase 1:
The other language beside English that is understood by prospective subjects or representatives is Spanish. All study materials for phase 1, including consent forms and advisory board materials, have been created in both English and Spanish to ensure that participants who only speak Spanish are able to participate to the same extent as those who speak English. Participants who do not speak English and only speak Spanish will provide consent in Spanish with the long form of the consent documentation. If we decide to also include Spanish-speaking families in Phase 2, we will submit a modification to reflect these changes.

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."

For Advisory Board Members: 22

Youth members of our advisory board will be 10-14 years old and will provide assent in addition to receiving parental permission. Consent/assent forms will be emailed to parents as a REDCap link. After having a few days to review the document independently, youth and their parents will complete the consent/assent form with research staff via a Zoom video call. Families who do not have access to a device with Wi-Fi will have the option of providing consent/assent during an in-person appointment with research staff. These procedures will be followed, regardless of whether the parent is also participating in the study as a member of our advisory board or not. That is, even in instances in which the child but not the parent is participating, the screening call will still be done with the parent and the parent will still need to meet with their child and research staff to provide permission for their child's participation in this study.

For Pilot and Phase 2 Participants:

Participating children will be 10-14 years old and will provide assent in addition to receiving parental permission from the participating parent. The consent/assent form will be emailed to participants as a REDCap link. After having a few days to review the document independently, participants will complete the consent/assent form with research staff via

a Zoom video call. Families who do not have access to a device with Wi-Fi will have the option of providing consent/assent during an in-person appointment with research staff.

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.

Assent will be required for the participation of all adolescents. Research staff will thoroughly describe all aspects of the study to parents and youth and address any questions they may have. Parents will then provide consent and youth will provide assent on the same form as their parent.

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.

Not applicable.

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 that is 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.

Not applicable.

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

Provide reasons why this research could not practicably be carried out without access to and use of PHI (that is requested in the waiver and/or related to the alteration of authorization).

Not applicable.

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

Provide reasons why this research could not practicably be carried out without the waiver and/or alternation of authorization. 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.

Not applicable.

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.

Not applicable.

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 study will consist of three parts. First, during Phase 1, we will iteratively refine our VIP-RACE program based on feedback we receive from advisory boards of parents, youth, and RES coaches. Second, we will pilot the VIP-RACE program with five Latine families. After families are recruited, enrolled, and have completed the baseline assessment, parents will complete the VIP-RACE program. Post-treatment assessments will take place with parents at the end of the intervention period and 1-month follow-up assessments will take place with parents and youth. Additionally, all five parents will be asked to provide feedback on the program via a qualitative exit interview. Third, we will conduct a proof-of-concept trial with 40 families. We will follow the same procedures as the pilot, but we will also conduct qualitative interviews with RES coaches at the end of the study to obtain additional feedback on the program.

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.)

Phase 1: VIP-RACE will be iteratively refined in partnership with advisory boards of parents, youth, and RES coaches. Meetings will last approximately 60-90 minutes and will be audio-recorded. Separate meetings will be convened for youth, parents, and RES coaches to maximize privacy, comfort, and authentic engagement.

Pilot: The refined program will be tested with five Latino/a/x/e parents and their 10-14-year-old Latino/a/x/e youth to identify gaps in the curriculum and obstacles to implementation that can be addressed prior to a larger proof-of-concept trial in Phase 2. This pilot will use the same procedures as Phase 2 (see below). The only difference is that RES coaches will not be interviewed at the end of the pilot. Similar to Phase 2, VIP-RACE sessions will be audio-recorded and parent-child discussion tasks will be videotaped.

Phase 2: After screening, eligible parents and children will undergo a baseline assessment, during which they will complete surveys and videotaped discussion tasks. Parents will then complete the VIP-RACE program. VIP-RACE sessions will occur within approximately one week of each other. Immediately post-treatment, at the end of the final session, parents will complete a short assessment battery (with someone

other than their RES coach). Surveys will include repeated measures of parents' RES motivation and competency, as well as feasibility and acceptability measures. Additionally, 10-15 parents will complete qualitative exit interviews over Zoom to further assess feasibility and acceptability. Parent-youth dyads will return for a 1-month follow-up to complete the same surveys as baseline and additional videotaped RES tasks. Visits will be done by staff masked to study hypotheses and family data. RES coaches will also be interviewed at the end of the study to obtain additional feedback.

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.

Advisory board: Advisory board members will receive an email with a draft of the VIP-RACE intervention materials and will be asked to review this content before the first advisory board meeting.

Please note that since the purpose of Phase 1 of this study to further develop and iteratively refine VIP-RACE in collaboration with our advisory board members, we will not know the exact number of sessions or the content of each session until Phase 1 is complete. Below, we describe the current format of the program, with the understanding that much of this will change based on the feedback we receive from our advisory board members. We also want to emphasize that not all of our intervention materials or session guides have been developed yet (again, this will take place in Phase 1 of the project). We will submit an IRB modification to reflect any changes to the program that diverge from what we have outlined below.

Session 1 will be Rose Thorn Bud, where members will share strengths, weaknesses, and areas of opportunity for VIP-RACE. A separate meeting will be convened for parents, youth, and RES coaches to mitigate power inequities. Meetings will take approximately 60-90 minutes and may take place virtually or in person depending on the preferences and availability of each group. This meeting will be audio recorded using a digital recording device if held in person or using Zoom if held virtually.

Session 2 will be a brainstorming meeting during which members generate ideas for intervention refinement using storyboarding and other HCD activities. A separate meeting will be convened for parents, youth, and RES coaches to mitigate power inequities. Meetings will take approximately 60-90 minutes and may take place virtually or in person depending on the preferences and availability of each group. This meeting will be audio recorded using a digital recording device if held in person or using Zoom if held virtually.

Session 3 will be a creation meeting during which advisory board members refine solutions from the previous sessions and produce a list of core recommendations for modifying the program. A separate meeting will be convened for parents, youth, and RES coaches to mitigate power inequities. Meetings will take approximately 60-90 minutes and may take place virtually or in person depending on the preferences and availability of each group. This meeting will be audio recorded using a digital recording device if held in person or using Zoom if held virtually. Subsequent meetings will be focused on obtaining feedback on the revised program.

After advisory board members provide their initial recommendations, PI Galán will integrate feedback into a revised "prototype" or draft of program materials (Draft 2). Advisory board

members will be reconvened to review the revised program and provide additional feedback which will be integrated into Draft 3.

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.

Pilot and Proof-of-Concept Trial: Below we describe the procedures for the pilot and the proof-of-concept trial. We describe them together because procedures are nearly identical, except for an additional qualitative interview that is conducted with RES coaches for the trial but not the pilot. Please note that the pilot and proof-of-concept trial will NOT take place concurrently. Instead, as described in 4.2.3, recruitment for the pilot is expected to begin in November and continue through December 2024; recruitment for the trial is expected to begin in January 2025 and continue through December 2025.

BASELINE ASSESSMENT

Participants will complete an in-person baseline assessment (Session 1 of VIP-RACE) that includes the collection of family demographics, questions about racial-ethnic socialization and racial identity, and ratings of child behaviors (approximately 60 minutes). While one research assistant is interviewing the parent, a second research assistant will conduct an assessment with the adolescent in a separate room. All surveys will be completed on Qualtrics and the measures that each participant will complete are listed below. Parents and youth will also participate together in a series of discussion tasks (approximately 30 minutes). During each videotaped interaction, parents and adolescents will discuss a topic related to race and ethnicity and will be given specific prompts to guide their discussions. These interactions will be recorded during the visit using a research laptop computer with a connected camera (zoom recording). On average, this visit is expected to take approximately 90 minutes. Note that similar to the Family Check-Up model upon which this study draws, the baseline assessment functions as Session 1 of the intervention. Thus, the baseline assessment serves dual purposes: 1) it provides data on baseline levels of outcomes for preliminary efficacy analyses; and 2) it provides data to inform case conceptualization.

Parent Baseline Measures (copies attached):

Demographic questionnaire – Parent (Demographic characteristics)
Racial-Ethnic Socialization Motivation (Parents' motivation to engage in racial socialization)
Racial-Ethnic Socialization Confidence (Parents' confidence to engage in racial socialization)
Racial-Ethnic Socialization Skills and Stress (Parents' skills and stress to engage in racial socialization)
Hughes Parental Ethnic Socialization Scale (HPESS; Parents' frequency of engaging in cultural socialization and preparation for bias)
PROMIS Parent Proxy Bank GenPop v3.0 - Depressive Symptoms (Youth depressive symptoms)
PROMIS Parent Proxy Bank GenPop v3.0 – Anxiety (youth anxiety symptoms)
Child Behavior Checklist (CBCL; youth externalizing problems)

Child Baseline Measures (copies attached):

Demographic questionnaire – Child (Demographic characteristics)
Hughes Parental Ethnic Socialization Scale (HPESS; Parents' frequency of engaging in cultural socialization and preparation for bias)
Discrimination Coping Strategies Scale (DCSS; youth racial-ethnic coping)
Ethnic Identity Scale (EIS; youth racial-ethnic identity)
PROMIS Pediatric Item Bank GenPop 3.0 – Depressive Symptoms (youth depressive symptoms)
PROMIS Pediatric Bank GenPop v3.0 – Anxiety (youth anxiety symptoms)
Youth Self-Report (YSR; youth externalizing problems)

Observational Measures (copy of protocol attached):

Observed Racial Socialization (cultural socialization and preparation for bias quality)

VIP-RACE SESSIONS:

After completing the baseline assessment (which also functions as session 1 of the VIP-RACE program), parents will complete session 2 of VIP-RACE, which entails a 60-minute, rapport-building interview designed to build a collaboration between the RES coach and parent where both members can ask questions and share information. The interview differs from a standard intake, as it offers a relaxed frame for exploring parents' RES concerns and challenges; their motivation to engage in RES; and parenting and family strengths. This session allows RES coaches to build upon the quantitative and observational data collected in the first meeting by learning more about families' lived experiences and using this information to guide case conceptualization and tailoring of the feedback session.

The third (and currently final) session of VIP-RACE is a 90-minute feedback session in which the parent and RES coach review pre-selected clips from the videotaped tasks (collected during session 1). Video feedback highlights parent RES strengths and provides opportunities for self-reflection. As they review the tape, parents are prompted to reflect on the content of their RES messages, as well as the emotional tenor and relational context in which these messages are delivered. To frame this discussion, the RES coach uses a family feedback form summarizing strengths and areas for growth. Content on the form is based on videotaped recordings, questionnaires, and the parent interview. This information is organized into three domains: a) parent RES competency (RES confidence, skills, and stress); b) parent RES frequency and quality (cultural socialization, preparation for bias); and c) parent-child relationship quality. While reviewing videoclips and the feedback form, the RES coach summarizes what research says about how each domain affects youth well-being--e.g., *"research shows that when parents avoid talking to their children about discrimination, Latinx youth don't develop the skills to cope with these experiences, and they show worse mental health and behavioral problems."* The strategic use of research can educate parents about the effects of racism on youth adjustment, increase awareness of the consequences of racial silence, and highlight protective effects of RES. Throughout, the coach communicates hope and uses MI to enhance RES motivation. Importantly, feedback and psychoeducation are reinforced by examples from parents' own interactions with their child. At the end of the feedback, parents develop a personalized action plan with goals and concrete actions to meet these goals.

POST-TREATMENT ASSESSMENT AND PARENT QUALITATIVE INTERVIEWS:

After finishing the VIP-RACE program, parents will complete a brief, 30-minute battery of questionnaires via Qualtrics. Surveys will include repeated measures of parents' RES motivation and competency, as well as feasibility and acceptability measures. We will also conduct in-depth qualitative interviews with a subgroup of parents (n = 10-15) to obtain additional feedback on the feasibility and acceptability of VIP-RACE). Interviews will probe parents' views of the program, including what they found most and least useful, how the program helped them navigate RES conversations, and suggestions on improving implementation. To select cases with divergent perspectives, purposive sampling will be utilized to include participants with variation in RES practices, treatment engagement, and demographics (e.g., sex, ethnicity, age, language). Interviews will be conducted and recorded via Zoom. They will follow a semi-structured format, will last approximately an hour, and will be conducted by a research team member.

Parent measures (copies attached):

- *Racial-Ethnic Socialization Motivation* (Parents' motivation to engage in racial socialization) – copy is attached, but please note that this is the same as the baseline measure so it has only been uploaded once
- *Racial-Ethnic Socialization Confidence* (Parents' confidence to engage in racial socialization) -) - copy is attached, but please note that this is the same as the baseline measure so it has only been uploaded once
- *Racial-Ethnic Socialization Skills and Stress* (Parents' skills to engage in racial socialization) -) - copy is attached, but please note that this is the same as the baseline measure so it has only been uploaded once
- *Feasibility and Acceptability of Intervention Measure* (program feasibility and acceptability)

Interview Measure (copy attached):

- *Program Evaluation Interview – Parents* (implementation, feasibility, acceptability)

ONE-MONTH FOLLOW-UP ASSESSMENT:

Four weeks after finishing the program, families will participate in an in-person follow-up assessment. The procedures will be the same as the baseline assessment including parent and child surveys and parent-child discussion tasks. Most of the surveys will be the same as baseline minus the demographics questionnaire. The directions for the parent-child interaction task will be modified slightly to avoid repetition with the baseline version of this task, but the type of interaction (discussion of race-related topics) will be the same.

All measures administered at the 4-week follow-up are listed below:

Parent Measures (copies are attached, but please note that these are the same as the measures administered at baseline so they have only been uploaded once):

Racial-Ethnic Socialization Motivation (Parents' motivation to engage in racial socialization)
Racial-Ethnic Socialization Confidence (Parents' confidence to engage in racial socialization)
Racial-Ethnic Socialization Skills (Parents' skills and stress to engage in racial socialization)
Hughes Parental Ethnic Socialization Scale (HPESS) (Parents' frequency of engaging in cultural socialization and preparation for bias)
PROMIS Parent Proxy Bank GenPop v3.0 - Depressive Symptoms (Youth depressive symptoms)

PROMIS Parent Proxy Bank GenPop v3.0 – Anxiety (youth anxiety symptoms)
Child Behavior Checklist (CBCL; youth externalizing problems)

Child Measures (copies are attached, but please note that these are the same as the measures administered at baseline so they have only been uploaded once):

Hughes Parental Ethnic Socialization Scale (HPESS) (Parents' frequency of engaging in cultural socialization and preparation for bias)
Discrimination Coping Strategies Scale (DCSS; youth racial-ethnic coping)
Ethnic Identity Scale (EIS; youth racial-ethnic identity)
PROMIS Pediatric Item Bank GenPop 3.0 – Depressive Symptoms (youth depressive symptoms)
PROMIS Pediatric Bank GenPop v3.0 – Anxiety (youth anxiety symptoms)
Youth Self-Report (YSR; youth externalizing problems)

Observational Measures (copy of protocol attached)

Observed Racial Socialization (cultural socialization and preparation for bias quality)

QUALITATIVE INTERVIEWS (FOR PROOF-OF-CONCEPT TRIAL ONLY):
At the end of the study (after completing all VIP-RACE sessions), we will conduct semi-structured interviews with RES coaches to learn about challenges with implementation, lessons learned, and perceptions of program impact. Interviews will be conducted over Zoom and will be recorded.

Interview Measure (copy attached):
Program Evaluation Interview – RES Coaches (implementation, feasibility, acceptability)

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.

Advisory board members: Advisory board meetings will last approximately 60-90 minutes (7 meetings x 60-90 minutes/meeting = 7-10/5 hours) Initial meetings will focus on further developing and iteratively refining the VIP-RACE program (see descriptions detailed above). Subsequent meetings will focus on providing input on study materials and procedures, such as questionnaires, flyers, and recruitment strategies.

VIP-RACE participants: Participation requires four steps: (1) parents and youth will each complete a baseline assessment that takes approximately 1.5 hour to complete; (2) parents will complete the VIP-RACE program. The exact number of sessions is TBD based on the development/refinement process in Phase 1 of this project. However, we expect that there will be no more than four 1-1.5-hour sessions (4-6 hours) that occur weekly; (3) after finishing the program, parents will complete a 30-minute assessment battery assess primary outcomes, feasibility, and acceptability; and (4) 1 month after finishing the program, parents and children will complete their follow-up assessment, which will take approximately

1.5 hour to complete. Thus, in total, families will be involved for approximately 7.5-9.5 hours over the course of approximately 9 weeks.

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.)

We hope to have a total sample of 55 parent-youth dyads complete the study (5 for Phase 1 and 50 for Phase 2). We may have some families drop out so we will recruit some additional families. Anticipated total number enrolled is estimated to be 75 parents/75 youth, but recruitment will be ongoing until the goal sample size of 55 is met.

For our advisory boards, we hope to recruit 10-15 parents, 10-15 youth, and 7-10 RES coaches.

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.

Given concerns regarding the use of pilot studies to calculate effect sizes, sample size estimates for the pilot were calculated with the goal of establishing the feasibility and acceptability of the intervention, rather than having sufficient power to detect effects at specified criterion levels. However, a sample size of 50 will provide greater than 80% power to detect a medium effect size. Sample sizes needed to detect small effects exceed the scope of a project focused on piloting a new intervention in a proof-of-concept trial.

8.3 Statistical or Analytic Methods

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

Preliminary efficacy of VIP-RACE will be evaluated by calculating change scores for parents' RES motivation and competency (primary outcomes) from baseline to post-treatment and follow-up. VIP-RACE will be judged of adequate efficacy if there is a significant improvement in median RES motivation and RES competency (confidence, skills, and stress), with significance based on a Wilcoxon signed-rank test using one-sided $p < .05$. Secondary outcomes will be assessed by comparing changes in parents' frequency and quality of cultural socialization and preparation for bias messages from baseline to follow-up, as measured through survey data and dyadic videotaped interaction tasks. Summary statistics of change scores for youth racial-ethnic identity, racial-ethnic coping, depressive and anxiety symptoms, and conduct problems will also be calculated. Improvement in each measure will be judged by a Wilcoxon signed-rank test. Participants who withdraw or are lost to follow-up will be analyzed assuming that they did not experience an improvement.

To assess feasibility and acceptability, we will compute basic descriptive statistics (i.e., means and standard deviations) for the Feasibility of Intervention Measure (FIM) and Acceptability of Intervention Measure (AIM).

Transcripts from qualitative interviews with caregivers and RES coaches will be imported into Dedoose, a qualitative data analysis software. After open-coding transcripts, the team will finalize a codebook with definitions, rules, and examples. All transcripts will be re-coded, and 50% will be randomly assigned for double-coding to confirm adequate inter-rater reliability (kappa ≥ 0.80). Axial coding will be used to combine codes to identify broader themes. Content analysis will be used to identify themes related to feasibility and acceptability, and the constant comparison method will be applied to illuminate patterns by salient factors (e.g., biological sex, age, nativity). For parents, we will assess perceptions of the program and coaches and what aspects of program implementation were most and least impactful. For RES coaches, we will focus on strategies used to implement the program, perceptions of program, impact on parents and families, and modifications that can be made to maximize implementation in the future. After analyzing quantitative and qualitative data separately, data will be triangulated using convergence and expansion to allow for a more comprehensive evaluation of feasibility and acceptability.

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, as this research involves only minimal risks.

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.

This study uses measures and protocols that have been used in prior research without adverse effects on participants. Further, the components of the intervention are similar to those already utilized by many parenting programs, including the evidence-based intervention – the Family Check-Up. However, throughout the study, participants will be asked questions about subjects such as race, racism, and discrimination, which may be sensitive topics for some participants. Participants may request discontinuation of any procedure at any time if they experience undue distress, and participants may choose to skip questions that they are uncomfortable answering.

Participants will be providing screening information (email addresses, names, etc.) and recorded discussions about race. All recordings and screening information will be saved on password protected documents within OIS approved storage servers, such as OneDrive or Sharepoint, so there is minimal risk of participants' confidentiality being violated.

All data will be associated with coded subject IDs, and any forms linking PII to a participant's data will be destroyed after completion of data analysis. Only research staff will have access to any sensitive documents.

The digital videos from the discussion task portion of the study and the audio recordings of VIP-RACE sessions will have no identifying information beyond the audio/video that they contain and will be directly uploaded to an OIS approved storage server, such as One Drive or Sharepoint, after recording. Once uploaded to the server, the audio/video will be deleted from the recording device. The content of the recordings themselves (e.g., parents and children talking together) is not highly sensitive, although the videos will show the faces of both parents and children. We will not modify the footage to obscure the participants' identities; however, these videos will be labeled only with the participants' coded study ID numbers. As described below, recordings will be subsequently transcribed by a professional service company (Rev.com) with protected private account access with 2-factor authentication and encryption for communication transmissions. Recordings will be coded by authorized research staff who access them within the research lab folder, preventing any access to unauthorized personnel.

Qualitative interviews with parents and RES coaches will take place over Zoom. Zoom recordings are stored in a dedicated research lab folder in Sharepoint; only authorized research staff have access. As described below, we will enable the audio transcription on Zoom to automatically transcribe the audio from these interviews. Zoom includes several levels of security for data including private account access with 2-factor authentication and encryption for communication transmissions. At the beginning of each recording, we will have participants replace their Zoom name with their study ID number so that the transcript does not have any identifiable information. Zoom recordings are coded by authorized research staff who access them within the research lab folder, preventing any access to unauthorized personnel.

Advisory board meetings will take place in person or remotely via Zoom, depending on members' preferences. If procedures take place in-person, meetings will be recorded using a digital recording device. Immediately after each session, the recording will be uploaded to a secure folder on Sharepoint, saved using participants' ID numbers, and then destroyed from the recorder. If meetings take place over Zoom, the procedures detailed above for qualitative interviews will be implemented.

All participants are told that we will protect their confidentiality regarding their input on measures to the degree possible, and only a violation of our protocols would result in a breach of confidentiality or privacy, and we have protections in place to protect against that risk. Participation will not prevent participants from accessing other educational or professional supports that might be available and beneficial to them.

Participants will be informed of all risks above, as well as the measures taken to ameliorate those risks. Confidentiality will not be maintained if there are any indications of abuse, neglect, or other safety risks; in these cases, we serve as mandated reporters and report the concerns to the appropriate authorities. Participants will also be informed of this limit to their privacy and confidentiality in the consent.

In sum, the risks to participants are minimal.

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.

The overall risk involved in the project is considered to be minimal, whereas the information gained could greatly improve our knowledge base of how cultural strengths can be leveraged to protect Latino/a/x/e youth from the pernicious effects of racial-ethnic discrimination. PI Galán has conducted previous studies using parent-adolescent videotaped discussion tasks. Many families report that they enjoy participating in these discussion tasks, as they provide a space for positive dyadic interaction and self-reflection on personal experiences and beliefs. Furthermore, parents will receive several direct benefits. For example, they will receive critical psychoeducation

and feedback to a) promote positive RES with their children and b) bolster their parenting strengths more broadly. During the feedback session, parents will develop a personalized action plan where they set realistic goals and identify specific steps that they can take towards these goals. They will also receive resources to support them in these efforts. In addition to potential benefits for parent participants, the proposed research may have benefits for youth participants. Specifically, the intervention may buffer the detrimental effects of racial-ethnic discrimination on Latino/a/x/e youth participants via increased parental RES motivation and competency. Additionally, RES coaches may benefit from receiving training in and access to a program that targets culturally-specific parenting practices in Latino/a/x/e families.

11.2 Potential Benefits to Others

Describe the potential benefits to society or others.

This research may produce important knowledge relevant to reducing mental health symptoms and conduct problems in Latino/a/x/e adolescents exposed to racial-ethnic discrimination. This study will be the first to develop, refine, and test a video-feedback intervention to promote RES motivation and competency among Latino/a/x/e parents. Leveraging advances in RES theory, along with established approaches in video feedback, motivational interviewing, and social learning theory, the proposed study represents a key step toward understanding and targeting parents' dynamic RES processes with their children. Such an intervention has potential to strengthen youth racial-ethnic coping and buffer poor mental and behavioral health outcomes. Feasibility, acceptability, and preliminary efficacy findings will lay necessary groundwork for a future randomized controlled trial of VIP-RACE. Findings from this project will ultimately inform the evidence base of culturally sensitive interventions available to improve mental health and reduce conduct problems in Latino/a/x/e adolescents. Due to the expected benefits of this study and the extensive precautions that will be taken to minimize the risk of harm to subjects, we believe that the anticipated benefits of this study outweigh the potential risks.

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.

Not Applicable. Results will not be shared with subjects or others.

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 university's policy regarding payments to human participants in research will be adhered to: https://policy.psu.edu/policies/rpg03#D4

Advisory Boards (Phase 1):
All advisory board members, both English and Spanish speaking, will receive $40 in cash per meeting attended. Meetings will occur twice during the first month and then once a month for the subsequent five months; each

meeting will last approximately 60-90 minutes (7 meetings x 60-90minutes/meeting = 7-10.5 hours). Thus, each member may earn up to $280 for attending all advisory board meetings. If meetings take place in person, members will be reimbursed for travel expenses to attend advisory board meetings (up to $50 per member across the entire study period).

Pilot (Phase 1) and Single-Arm Trial (Phase 2):
Parents and youth will each be paid $45 at baseline ($90 per family) and $50 at follow-up ($100 per family). Additionally, immediately post-treatment, parents will receive $25 for completing a limited number of self-report measures to index shifts in proximal outcomes relevant to racial socialization motivation and competency. Thus, in total, participating families may earn $215 for completing baseline, post-treatment, and follow-up assessments. Families will be reimbursed for travel expenses to attend study appointments (up to $50 in cash per family across the entire study period).

All RES coaches and a subset of 10-15 parents will participate in individual qualitative interviews to further assess intervention feasibility and acceptability and guide refinements for a larger trial. These participants will be compensated $50 for participating in this interview.

All payments will be in the form of cash.

14.0 Economic Burden to Subjects

14.1 Costs

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

Not applicable, there are no costs to participants.

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.

Families will have the option of completing assessments and treatment sessions in Dr. Galan's laboratory space at Penn State (University Park) or the PACT lab or Latino Connection community building in Harrisburg.

Penn State Lab Space. PI Galán's DREAM (Dismantling Racial inEquities Around Mental health) laboratory is located at Penn State's University Park campus at the Child Study Center and is affiliated with the Department of Psychology's Child Clinical area. The laboratory space includes a waiting/reception area for participants, two observation rooms designed for recording treatment sessions or parent-child interactions or collecting survey measures; a control room; and office space for a lab manager, graduate students, and undergraduate research assistants. These offices have multiple computer workstations and laptops for data storage and engaging in coding, data processing, statistical analysis, and support services. PI Galán and other lab personnel use Macintosh and IBM compatible computers with Microsoft Office, R, Mplus, SAS, SPSS and internet productivity tools (software for e-mail and internet browsing). The laboratory also has coding stations that include a computer, monitor, and relevant software (e.g., Noldus Observer Pro for coding videotaped parent-adolescent interactions; Dedoose for coding qualitative interviews). All computer workstations have high-speed, secure Internet connections and are equipped with the latest antivirus software available through IT/Computing Services. The user's "rights" are set by the PI.

PI Galán has a dedicated office located on the same floor as her laboratory space (2nd floor of Moore Building). Her office is fully equipped with a phone, a new Mac computer, a desk, and a conference table for meetings with students and lab staff.

PACT Offices and Child-Family Observation Lab. Parents and Children Together (PACT) is a key resource for the proposed project. PACT is an interdisciplinary research collaborative committed to promoting community-university partnerships in the service of fostering healthy families. As a PACT investigator since July 2023, PI Galán has access to PACT facilities. The PACT lab is located in the capital area of Harrisburg, PA, approximately 1.5 hours from PSU-UP. This research space/lab has become a critical component of infrastructure support for research projects in Harrisburg. It has grown as a result of interdisciplinary collaborative efforts of several Penn State child and family researchers with funded grants; the Child Study Center (Dr. Karen Bierman, Director); the Prevention Research Center (Dr. Max Crowley, Director); and seed money from the Penn State Children, Youth and Family Consortium. The space available for the current project include office space with desks, computers, phones, wireless computing, and printer; a waiting/reception area for participants; observation and control rooms equipped with cameras with high-resolution and microphone capabilities for recording audio and video of parent-adolescent interactions or treatment sessions; and a large multi-use room that can be used for focus groups, survey data collection, interviews, trainings, or meetings.

15.1.1 Penn State Health (PSH) Research Locations

Indicate if any Penn State Health location where this research may take place OR select 'Not Applicable'.

- ☒ Not applicable – research will not take place any at PSH locations
- ☐ Milton S. Hershey Medical Center
- ☐ St. Joseph's Medical Center
- ☐ Berks Cardiology
- ☐ Andrews and Patel
- ☐ Holy Spirit Medical Center
- ☐ Hampden Medical Center
- ☐ Lancaster Medical Center
- ☐ Pennsylvania Psychiatric Institute
- ☐ Community Medical Group
- ☐ Other: [please identify]

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.

Recruitment efforts will target families in Harrisburg, Pennsylvania, and the surrounding regions (e.g., York, PA; Lancaster, PA). According to the 2021 US Census, Harrisburg has a population of approximately 51,000 people, 25.1% of whom identify as Hispanic/Latino/a/x/e (~12,801 people) and 7.8% of whom are 10-14 years old (~3900). A 2020 analysis by Pew Research found that Hispanic/Latino population growth accounts for about half of overall population growth in Harrisburg since 2010. In York, PA (population size of ~44,845), approximately 34% of people are Hispanic (~15,247) and 7.9% are 10-14 years old (~3543). In Lancaster, PA (population size of ~56,348 people), approximately 30.8% of people Hispanic or Latino/a/x/e (~17,355) and 7.6% are 10-14 years old (~4282).

Unfortunately, we were unable to find statistics on the intersection of race and age for individuals living in these regions (e.g., the number of Latino/a/x/e children between 10-14 years old). Thus, the total number of potential subjects to which our study team has access is difficult to calculate with precision. However, based on the numbers above, we conservatively estimate that at least 4,000 of people who live in the regions that we'll be recruiting from are 10–14-year-old White youth. Thus, recruiting 55 Latino/a/x/e families with 10–14-year-old children (1.38% of 4000) to participate in our study is more than feasible.

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 is budgeted for 20% time for the duration of the study. This will be a sufficient amount of time to conduct and complete the 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.

Not applicable.

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.

The project coordinator and the PI will conduct training for any new research assistant hires and provide regular supervision and oversight to assure all research protocols are followed.

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.).

Prior to distributing and posting recruitment materials (e.g., flyers/brochures) in private spaces, such as community locations, we will reach out to community agencies, organizations, event leaders, and other businesses asking them to distribute recruitment materials to their list-serves or asking for permission to post our recruitment materials within their organization's space.

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 Future Undetermined Research: Data and Specimen Banking

If this study is collecting **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 section 22 below OR the "HRP-598 – Research Data Plan Review Form" 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]

20.1 Data and/or specimens being stored

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

Not applicable; we will not be banking data or specimens for future undetermined research.

20.2 Location of storage

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

Not applicable.

20.3 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.

20.4 Access to data and/or specimens

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

Not applicable.

20.5 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.

20.6 Process for returning results

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

Not applicable.

21.0 References

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

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22.0 Confidentiality, Privacy and Data Management

IMPORTANT: The following section is required for all locations EXCEPT Penn State Health and the College of Medicine. Penn State Health and College of Medicine should skip this section and complete "HRP-598 Research Data Plan Review Form." In order to avoid redundancy, for this section state "See the Research Data Plan Review Form" if you are conducting Penn State Health research. Delete all other sub-sections of section 22.

For research being conducted at Penn State Health or by Penn State Health researchers only: The research data security and integrity plan is submitted using "HRP-598 – Research Data Plan Review Form."

In order to avoid redundancy, for this section state "See the Research Data Plan Review Form" if you are conducting Penn State Health research. Delete all sub-sections of section 22.

For all other research: Complete the following section. Please refer to PSU Policy AD95 for information regarding information classification and security standards and requirements. It is recommended that you work with local IT staff when planning to store, process, or access data electronically to ensure that your plan can be carried out locally and meets applicable requirements. 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.

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

	Hard Copy Data	Electronic Stored Data

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

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

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

Not applicable - All data will be collected electronically.

22.2.2 How will the paper records be secured?

Not applicable - All data will be collected electronically.

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

Not applicable - All data will be collected electronically.

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

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

☒ Penn State REDCap

☐ Other – Specify - provided and approved database application:
[Type protocol text here if box checked]

☐ Penn State, College, or Department IT file server
☒ Penn State OneDrive or SharePoint
☐ Penn State GoogleDrive
☐ Web-based system provided by the sponsor or cooperative group - Specify URL and contact information:
[Type protocol text here if box checked]

☐ Other – Specify the database application or server:
[Type protocol text here if box checked]

Provide details about the data security features or attach security documentation provided by sponsor or group:
[Type protocol text here if box checked]

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.

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.

22.4 Is there a list/key that links code numbers to identifiers?
☒ Yes - explain how the list that links the code to identifiers is stored separately from coded data:

All instruments are coded with a participant ID number to ensure strict confidentiality. The master list linking ID numbers with identifiable information (e.g., names, contact information) will be kept on SharePoint. Access to the list will be password protected and restricted to authorized project personnel. All other data will be stored in separate documents on SharePoint, including the de-identified survey data and video-recordings of observational data (i.e., these will labeled with ID numbers only).

☐ Not applicable, there is no list that links code numbers to identifiers. Skip to section 22.6.

22.5 Is there a list of people who have access to the list/key?
☒ Yes – explain how access to that list is restricted and why certain persons require access.

Only the PI and project coordinator will have access to the master list linking code numbers to identifiers. The project coordinator is responsible for oversight assurance that participant data has all been entered in alignment with the proper identification code.

☐ No – explain why not:
[Type protocol text here if box is checked]

22.6 Describe the mechanism in place to ensure only approved research personnel have access to the stored research data (electronic and paper).
☒ Password-protected files

☒ Role-based security
☒ Specify all other mechanisms used to ensure only permitted users have access to the stored research data:

The PI and project coordinator have private locked offices to ensure security.

The use of mobile devices or wireless activity trackers to collect identifiable research data may have to be approved by Penn State IT - Information Security.

22.7 Will research data be collected and/or stored on a wireless activity tracker or mobile application or will the study team enter research data on a mobile device, such as an electronic tablet or cell phone?

☒ No – skip to 22.8
☐ Yes - answer the following questions:

22.7.1 Specify the provider of the tracker or mobile devices(s)/application

☐ Supplied by the sponsor
☐ Penn State owned device
☐ A personal device
☐ Other – Please specify source: [Type protocol text here if box is checked]

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

[Type protocol text here]

22.7.3 Specify the type of data collected on the tracker or mobile devices(s)/application.

[Type protocol text here]

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

[Type protocol text here]

22.7.5 Describe the measures taken to protect the confidentiality of the data collected on the tracker or mobile device(s)/application. Please address physical security of the device(s), electronic security, and secure transfer of data from device(s) to the previously indicated data/file storage location provided in section 22.3.

[Type protocol text here]

The use of online survey tools and email to collect or send research data containing identifiers that represent more than minimal risk to subjects may have to be approved by Penn State IT - Information Security.

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

☐ No – skip to 22.9
☒ Yes - answer the following questions:

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

The only identifiers collected over the internet or via email will be the virtually signed consent forms, the qualitative interviews conducted with parents and RES coaches at follow-up, and advisory board meetings (if they take place virtually).

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

All questionnaire data for phase 1 will be collected over the internet via REDCap while all questionnaire data for the pilot and phase 2 will be collected over the internet via Qualtrics. Questionnaires will relate to race, racism, racial-ethnic socialization, identity, and the VIP-RACE program. Qualitative interviews with parents and RES coaches will be recorded on a Zoom video call on a secure network. Advisory board meetings may take place virtually or in person depending on the preferences and availability of each group. If meetings take place virtually, sessions will be recorded via Zoom.

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

All data will be associated with a coded subject ID. All data collected through REDCap and Qualtrics contain only the ID code, with no individual identifiers. At the beginning of Zoom meetings (for qualitative interviews), we will have families replace their Zoom name with their study ID number. Further, all identifying data will be saved on OIS approved software such as Sharepoint and OneDrive, and access will be restricted through the use of password protection. A firewall is secured and access to specific areas is restricted to authorized study personnel included on the IRB protocol.

Any documents with names on them (e.g., consent forms, payment receipts) will be kept separate from any documents with ID codes (e.g., survey forms). The master list linking ID numbers with identifiable information (e.g., names, contact information) will be kept on SharePoint. Access to the list will be password protected and restricted to authorized project personnel. All other data will be stored in separate documents, including the coded survey data and video-recordings of observational data (i.e., these will labeled with ID numbers only).

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

REDCap and Qualtrics surveys will be downloaded by the PI or the project manager who will use participants' study code ID to merge parents', youths', and RES coaches' ratings into a single datafile that will be uploaded to SharePoint.

22.8.5 If the research involves online surveys, list the name(s) of the service provider(s) that will be used for the survey(s) (e.g., REDCap, Penn State licensed Qualtrics, Survey Monkey, Zoomerang)? (Note: The IRB strongly recommends the use of REDCap for online surveys that obtain sensitive identifiable human subjects data.)

☒ Penn State REDCap
Penn State Qualtrics
☐ Penn State Microsoft Forms
☐ Penn State Google Forms
☐ Other - Please specify:
Application: [Type protocol text here]
URL (If applicable): [Type protocol text here]

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

Not applicable.

Depending on the nature of the subject matter involved, certain security requirements must be in place for the audio and/or video recording or photographing of subjects. If the subject matter presents more than minimal risk to the subjects, then, before completing the section below, please contact Penn State IT - Information Security at security@psu.edu to confirm whether these requirements are required.

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

☐ No - skip to section 22.10
☒ Yes - answer the following questions:

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

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

VIP-RACE sessions with parents will be audio-recorded for supervision and fidelity monitoring purposes. Sessions will focus on building rapport with parents, exploring parents' RES concerns and challenges, and providing parents with feedback on their strengths and areas for growth as it pertains to RES.

Advisory board meetings will be audio recorded using a digital voice recorder if held in person or using Zoom if held virtually. These meetings will focus on obtaining feedback from board members on the content and structure of the intervention and study materials (e.g., wording of questionnaires).

☒ Video – Describe the intended content of the video recording:
Qualitative interviews with parents and RES coaches will be recorded via Zoom.
During these interviews, parents and RES coaches will be asked to provide in-depth feedback on the VIP-RACE program.

Additionally, at baseline and the follow-up assessment, parents and youth will complete video-taped parent-child interaction tasks. Families will be given discussion task prompts about race-related topics and will be asked to discuss the topics as they normally would. These interactions will be recorded during the visit using a research laptop computer with a connected camera (zoom recording).

☐ Photographs of the subjects – Describe the intended content of the photographs:
[Type protocol text here]

☐ 3-D Images – Describe the intended content of the of 3-D images:
[Type protocol text here]

☐ Other - Specify:
[Type protocol text here]

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

They will be stored electronically.

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

On Penn State SharePoint

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

Authorized study personnel who will code the recordings.

22.9.5 Will any of the recordings be transcribed?

☐ Not applicable
☐ No
☒ Yes – indicate who will be doing the transcribing?

We will enable the audio transcription on Zoom to automatically transcribe the audio from recorded qualitative interviews, parent-child interaction tasks, and advisory board meetings (if they take place virtually). Zoom includes several levels of security including private account access with 2-factor authentication and encryption for communication transmissions. At the beginning of each recording, we will have participants replace their Zoom name with their study ID number so that the transcript does not have any identifiable information. The content of the videos themselves (e.g., parents and children talking together) is not highly sensitive, although the videos will show the faces of both parents and RES coaches.

To transcribe audio recordings of VIP-RACE sessions, we will use an on-line transcribing service, Rev.com, that includes several levels of security for data including private account access with 2-factor authentication and encryption for communication transmissions.

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

☐ No
☒ Yes - specify purpose(s) (e.g., publication, presentations, educational training, future undetermined research):

As the goal of this study is to assess the preliminary efficacy of VIP-RACE in a proof-of-concept single arm trial, data from this project will be used to inform a larger randomized controlled trial. Audio recordings of VIP-RACE sessions will be used to train future RES coaches in this intervention program. These recordings will only be utilized for educational training purposes and access will be restricted to authorized study personnel.

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

☒ Yes - check one of the following:

- ☒ The research involves human subjects as defined by the DHHS regulations (See Worksheet HRP-310).
- ☐ The research involves collecting or using biospecimens that are identifiable to an individual.
- ☐ If collecting or using biospecimens as part of the research, there is a small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual.
- ☐ The research involves the generation of individual level, human genomic data.

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

☐ No - answer the following question.

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

☐ No
☐ Yes

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

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

☒ Identification and recruitment of potential subjects follows procedures consistent with privacy standards
☒ Consent discussion and research interventions will take place in a private setting
☒ Limiting the information being collected to only the minimum amount of data necessary to accomplish the research purposes
☒ Limiting the people with access to the identifiable research data to the minimum necessary as specified in the application and consent process
☐ Other – Specify:

[Type protocol text here]

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

☐ Double data entry to reduce risk of errors
☐ Electronic edit checks to ensure data being entered are not obviously incorrect
☐ Random internal quality and assurance checking of research data
☒ Direct entry by subjects
☐ Other - Specify:

[Type protocol text here]

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

☒ No
☐ Yes – 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.

22.14 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*.

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
☒ Yes (*strongly recommended* as may be required for publication and future grant submission)

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

Advisory Board Meetings: Meetings with advisory board members will be transcribed, de-identified, and summarized using rapid qualitative analysis and matrix analysis. De-identified transcripts and the resulting descriptive matrix will be uploaded to the openICPSR repository.

Survey Data: De-identified individual and aggregate survey data (including raw and recoded data) will be shared. The de-identification process will remove direct and indirect respondent identifiers.

Attendance Data: We will share data on the number of VIP-RACE sessions attended.

Interview and Observational Data. Sharing qualitative data such as transcriptions from interviews or parent-child interactions can potentially reveal sensitive information and identify individual participants. These concerns are particularly pronounced for studies working with historically marginalized communities such as Latino/a/x families and studies assessing sensitive topics such as experiences of racial-ethnic discrimination, immigration, and mental health. Thus, prior to sharing any qualitative data, we will first obtain feedback from our parent and youth advisory boards about whether doing so may limit families' full participation and honest responses in this study. If sharing these data is deemed appropriate, then the following steps will be taken:

Interview Data: Following generation and quality check of raw transcripts from interviews, digital voice recordings will be permanently deleted to protect participant privacy. Respondent identifiers will not be shared. Raw transcripts will be maintained but not shared. Transcripts from interviews will be de-identified and sensitive content redacted where identification is plausible. These de-identified and redacted transcripts and coding summaries will be shared.

Observational Data: Transcripts from parent-child discussion tasks will be de-identified and sensitive content redacted where identification is plausible. These de-identified and redacted transcripts and coding summaries will be shared. Video recordings of parent-child discussion tasks will be maintained but will not be shared publicly because of the difficulty of masking the identity of participants.

Metadata, other relevant data, and associated documentation: In addition to the raw and aggregate data described above, to facilitate interpretation of the data, we will upload the data dictionary, survey instruments (with proprietary measures redacted), interview guides and codebooks, the discussion task protocol and codebook, and a log of decisions related to methods, coding, and data analyses.

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

The data and metadata from this project will be archived and made available free of charge through the openICPSR repository hosted at the Inter-university Consortium of Political and Social Research (ICPSR). ICPSR is a CoreTrustSeal certified repository providing long-term access to and preservation of data packages curated by domain specialists.

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

☐ No - skip the remainder of section 22.15
☒ Yes - answer the following questions:

Check all that apply:

22.15.1 ☐ **Data** are being transferred or disclosed **to** Penn State

What is the name of the third party(ies) (the institution, sponsor, etc.) sending or providing the data?

[Type protocol text here]

22.15.1.1 Is the third party requiring us to sign a contract regarding the data?

☐ Yes - this contract must go through the Office of Sponsored Programs
https://www.research.psu.edu/osp/overview-pages/data-use-agreements
☐ No

22.15.2 ☒ **Data** are being transferred or disclosed **from** Penn State

What is the name(s) of the third party(ies) (the institution, sponsor, etc.) receiving or accessing the data?

Rev.com

Note: Data transfers or disclosures may require a Data Use Agreement (DUA).

22.15.3 ☐ **Specimens** are being transferred **to** Penn State

What is the name(s) of the third party(ies) (the institution, sponsor, etc.) sending the specimens?

[Type protocol text here]

22.15.4 ☐ **Specimens** are being transferred **from** Penn State

What is the name(s) of the third party(ies) (the institution, sponsor, etc.) receiving the specimens?

[Type protocol text here]

Note: All material transfers, either sending or receiving, require a Material Transfer Agreement (MTA). Please contact the Office of Technology Management for more information.

22.15.5 Describe how the data/specimens will be securely transferred or disclosed to/from the third party(ies).

We will use an on-line transcribing service, Rev.com, that includes several levels of security for data including private account access with 2-factor authentication and encryption for communication transmissions. Rev.com is compliant with the European Union's General Data Protection Regulation (GDPR) directive. Digital voice recordings from VIP-RACE sessions will be saved using participants' IDs before uploading to Rev.com. The master list linking IDs to identifiers will not be shared with Rev.com.

22.15.6 How are the research data/specimens being transferred from and/or sent to the third party(ies)? Complete the appropriate section(s) and check all that apply within each completed section.

22.15.6.1 Data being transferred or disclosed **to** Penn State**:**

- ☐ Data are being received in aggregate/metrics (just counts, no individual data)
- ☐ De-identified individual data are being received and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)
- ☐ Coded research data without any identifiers are being received and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list
- ☐ Coded research data with identifiers (such as dates and/or any of the identifiers listed in section 22.15.7 aside from Study Code) are being received and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list
- ☐ Data with identifiers (such as dates and/or any of the identifiers listed in section 22.15.7) are being received and the linking list remains with the entity sending the data; the recipient of the data will have access to the linking list
- ☐ Data with identifiers along with the linking list are being received
- ☐ Other – Specify:
  [Type protocol text here if box is checked]

22.15.6.2 Data being transferred or disclosed **from** Penn State**:**

- ☐ Data are being sent in aggregate/metrics (just counts, no individual data)
- ☐ De-identified individual data are being sent and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)
- ☒ Coded research data without any identifiers are being sent and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list
- ☐ Coded research data with identifiers (such as dates and/or any of the identifiers listed in section 22.15.7 aside from Study Code) are being sent and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list
- ☐ Data with identifiers (such as dates and/or any of the identifiers listed in section 22.15.7) are being sent and the linking list remains with the entity sending the data; the recipient of the data will have access to the linking list
- ☐ Data with identifiers along with the linking list are being sent
- ☐ Other – Specify:
  [Type protocol text here if box is checked]

22.15.6.3 Specimens being transferred or disclosed **to** Penn State**:**

- ☐ De-identified specimens are being received and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)
- ☐ Coded specimens without any identifiers are being received and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list
- ☐ Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.15.7 aside from Study Code) are being received and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list
- ☐ Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.15.7) are being received and the linking list remains with the entity sending the specimens; the recipient of the specimens will have access to the linking list
- ☐ Coded specimens with identifiers along with the linking list are being received
- ☐ Other – Specify:
  [Type protocol text here if box is checked]

22.15.6.4 Specimens being transferred or disclosed **from** Penn State**:**

- ☐ De-identified specimens are being sent and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)
- ☐ Coded specimens without any identifiers are being sent and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list
- ☐ Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.15.7 aside from Study Code) are being sent and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list
- ☐ Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.15.7) are being sent and the linking list remains with the entity sending the specimens; the recipient of the specimens will have access to the linking list
- ☐ Coded specimens with identifiers along with the linking list are being sent
- ☐ Other – Specify:
  [Type protocol text here if box is checked]

22.15.7 If transferring data/specimens with identifiers to or from Penn State, which of the following identifiers will be included with the data/specimens? Check all that apply:

☐ Names	☐ Medical record numbers
☐ Initials	☐ Health plan beneficiary numbers
☐ Street address	☐ Account numbers
☐ City	☐ Certificate/license numbers
☐ Driver's License numbers	☐ Passport numbers
☐ State	☐ State ID numbers
☐ Zip Codes	☐ Vehicle identifiers and serial numbers, including license plate numbers
☐ County	☐ Device identifiers and serial numbers
☐ Geocodes	☐ Web Universal Resource Locators (URLs)
☐ Precincts	☐ Internet Protocol (IP) address numbers

☐ All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death	☐ Biometric identifiers, including finger and voice prints
☐ Ages > 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	☐ Full face photographic images and any comparable images
☐ Telephone numbers	☐ Any other unique identifying number, characteristic, or code (such as the pathology number) Specify: [Type protocol text here if box is checked]
☐ Fax numbers	☐ Study code numbers
☐ Electronic mail addresses	☐ Master list linking study code numbers to subject(s)
☐ Social security numbers	☐ Genomic sequence data
	☐ Other – specify: [Type protocol text here if box is checked]