University at Buffalo
The State University of New York
University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Complete Research Protocol (HRP-503)

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Template Instructions

Sections that do not apply:

- *In several sections, the addition of checkboxes for **Not Applicable** have been added to the template as responses.*
    - *If an N/A checkbox is present, select the appropriate justification from the list.*
    - *If an N/A checkbox is not present, or if none of the existing checkboxes apply to your study, you must write in your own justification.*
- *In addition:*
    - *For research where the only study procedures are records/chart review: Sections 6, 21, 22, 24, 25, 26 and 27 do not apply.*
    - *For exempt research: Section 6 may not apply. Section 6.1 will still apply if there is a study intervention.*

Studies with multiple participant groups:

- *If this study involves multiple participant groups (e.g. parents and children), provide information in applicable sections for each participant group. Clearly label responses when they differ. For example:*

  N/A

  Formatting:

- *Do not remove template instructions or section headings when they do not apply to your study.*

If you are pasting information from other documents using the "Merge Formatting" Paste option will maintain the formatting of the response boxes.

Amendments:

- *When making modifications or revisions to this and other documents, use the **Track Changes** function in Microsoft Word.*

  *Update the version date or number **on Page 3.***

PROTOCOL TITLE:

Include the full protocol title.

Response: AI-Enhanced App-based Intervention for Adolescent E-cigarette Cessation

PRINCIPAL INVESTIGATOR:

Name	*Dr. Eunhee Park*
Department	*School of Nursing*
Telephone Number	*716-829-3701*
Email Address	*eunheepa@buffalo.edu*

Response:

VERSION NUMBER/DATE:

Include the version number and date of this protocol.

Response: 8/11/2024

REVISION HISTORY
FUNDING:

Indicate any funding for this proposal. This should match the Funding Sources page in Click IRB.

Response: Pending the NIH R34 grant: post-council meeting requiring for the Just In Time material submission (JIT).

GRANT APPLICABILITY:

Indicate whether this protocol is funded by a grant (e.g. NIH, foundation grant). For a grant with multiple aims, indicate which aims are covered by this research proposal.

NOTE: This question does not apply to studies funded by a sponsor contract.

Include a copy of the grant proposal with your submission.

Response: Pending the NIH R34 grant: post-council meeting requiring for the Just In Time material submission (JIT).

RESEARCH REPOSITORY:

Indicate where the research files will be kept, including when the study has been closed. The repository should include, at minimum, copies of IRB correspondence (approval, determination letters) as well as signed consent documents. This documentation should be maintained for 3 years after the study has been closed.

Response: The repository will be kept safe in the locked file cabinets of 201 E, Wende Hall, University at Buffalo.

Location: 201 E, Wende Hall, University at Buffalo.

Address: 3435 Mains St., University at Buffalo, Buffalo, NY, 14214.

Department: School of Nursing

1.0 Study Summary

Study Title	AI-Enhanced App-based Intervention for Adolescent E-cigarette Cessation
Study Design	The design for this study will be a qualitative study based on individual interviews.
Primary Objective	To receive feedback from adolescents (n=30) on usability
Secondary Objective(s)	NA
Research Intervention(s)/ Investigational Agent(s)	NA
IND/IDE #	NA
Study Population	Adolescents from 14 to 20 years old who use e-cigarettes
Sample Size	30
Study Duration for individual participants	Each participant will spend approximately take 30 to 60 minutes to complete the interview, including 10 minutes consenting process. There is only one interview for each subject.
Study Specific Abbreviations/ Definitions	N/A

2.0 Objectives*

2.1 Describe the purpose, specific aims, or objectives of this research.

Response: The objective of this study is to develop an effective, user-friendly, app-based intervention for adolescents who use e-cigarettes. We will receive feedback from adolescents on the beta version of the app regarding: 1) functions, 2) design, and 3) content.

2.2 State the hypotheses to be tested, if applicable.

NOTE: A hypothesis is a specific, testable prediction about what you expect to happen in your study that corresponds with your above listed objectives.

Response: There are no hypotheses in this study.

3.0 Scientific Endpoints*

3.1 Describe the scientific endpoint(s), the main result or occurrence under study.

NOTE: Scientific endpoints are outcomes defined before the study begins to determine whether the objectives of the study have been met and to draw conclusions from the data. Include primary and secondary endpoints. Some example endpoints are: reduction of symptoms, improvement in quality of life, or survival. Your response should ***not*** *be a date.*

Response: When there is saturated theme regarding the adolescents' perspectives about the usability of the e-cigarette cessation app-based intervention.

4.0 Background*

4.1 Provide the scientific or scholarly background, rationale, and significance of the research based on the existing literature and how it will contribute to existing knowledge. Describe any gaps in current knowledge. Include relevant preliminary findings or prior research by the investigator.

Response: Among high school students, 19.5% use electronic cigarettes (Miech et al., 2021). There is a critical need for adolescent e-cigarette use prevention and cessation interventions. Although e-cigarettes may be less harmful than traditional cigarettes, they still contain harmful chemicals, and most contain nicotine, which is addictive (Livingston et al., 2020). ENDS use is also associated or co-occurring with other substance use (Park et al., 2020). However, despite the urgency, only a few e-cigarette interventions for adolescents exist, and the current programs have limited evidence (Liu et al., 2020). There is a strong need to develop an adolescent e-cigarette use cessation intervention. Thus, effective and sustainable interventions to address adolescent e-cigarette use are needed. This study aims to develop a scalable e-cigarette use cessation intervention using a smartphone application, which can be deployed to a large pool of adolescents through schools, primary care clinics, and communities.

4.2 Include complete citations or references.

Response: 1. Miech, R., Leventhal, A., Johnston, L., O'Malley, P. M., Patrick, M. E., & Barrington-Trimis, J. (2021). Trends in use and perceptions of nicotine vaping among US youth from 2017 to 2020. JAMA Pediatrics, 175(2), 185-190. https://doi.org/10.1001/jamapediatrics.2020.5667 PMCID: PMC7739194

Livingston, J., Park, E., Kwon, M., & Chen, C.-h. (2020). Health consequences associated with electronic cigarette use among adolescents and young adults. Nursing Research, 69(3), E139-140.

Park, E., Livingston, J. A., Wang, W., Kwon, M., Eiden, R. D., & Chang, Y.-P. (2020). Adolescent e-cigarette use trajectories and subsequent alcohol and marijuana use. Addictive Behaviors, 103, 106213-106213. https://doi.org/10.1016/j.addbeh.2019.106213 PMCID: PMC6954975

Liu, J., Gaiha, S. M., & Halpern-Felsher, B. (2020). A breath of knowledge: overview of current adolescent e-cigarette prevention and cessation programs. Current Addiction Reports, 1-13. https://doi-org.gate.lib.buffalo.edu/10.1007/s40429-020-00345-5 PMCID: PMC7661014

5.0 Study Design*

5.1 Describe and explain the study design (e.g. case-control, cross-sectional, ethnographic, experimental, interventional, longitudinal, observational).

Response: The design for this study will be a qualitative study based on individual interviews.

6.0 Study Intervention/Investigational Agent

6.1 Describe the study intervention and/or investigational agent (e.g., drug, device) that is being evaluated.

Response: NA

6.2 Drug/Device Handling: If the research involves drugs or device, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

- *If the control of the drugs or devices used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., Research Pharmacy SOP for the Control of Investigational Drugs, etc.), please reference that SOP in this section.*

Response: NA

6.3 If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:

- *Identify the holder of the IND/IDE/Abbreviated IDE.*
- *Explain procedures followed to comply with sponsor requirements for FDA regulated research for the following:*

	Applicable to:		
FDA Regulation	***IND Studies***	***IDE studies***	***Abbreviated IDE studies***
21 CFR 11	***X***	***X***	
21 CFR 54	***X***	***X***	
21 CFR 210	***X***		
21 CFR 211	***X***		
21 CFR 312	***X***		
21 CFR 812		***X***	***X***
21 CFR 820		***X***	

Response: NA

7.0 Local Number of Subjects

7.1 Indicate the total number of subjects that will be enrolled or records that will be reviewed locally.

Response: Approximately 30 adolescents will be recruited.

7.2 If applicable, indicate how many subjects you expect to screen to reach your target sample (i.e. your screen failure rate).

Response: We expect that approximately 100 adolescents will be screened who will be recruited from diverse community settings.

7.3 Justify the feasibility of recruiting the proposed number of eligible subjects within the anticipated recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?

Response: Researchers will leverage the participation of community-based primary care offices using existing relationships developed by Dr. Park in previous studies of low-income populations as well as potentially utilizing the Community Engagement team at the University at Buffalo's Clinical and Translational Science Institute. Researchers will primary target this population, and researchers will access potential subjects within the anticipated recruitment period.

This is an exploratory study. Thus, we are not exactly sure what percentage of those subjects will respond, but the researchers have some connections with local schools and community centers. We believe that this would be a feasible plan.

8.0 Inclusion and Exclusion Criteria*

*8.1 Describe the criteria that define who will be **included** in your final study sample.*

NOTE: This may be done in bullet point fashion.

Response: Response: Inclusion criteria includes:

Adolescents

- Age 14-20 years
- Current e-cigarette users (have used e-cigarettes [vaped] in the past 30 days)
- I-phone users
- Interested in participating in an e-cigarette use cessation program
- Able to read English.

*8.2 Describe the criteria that define who will be **excluded** from your final study sample.*

NOTE: This may be done in bullet point fashion.

Response: Exclusion criteria includes:

Participants

- Age <14 or >20 years
- Current non-e-cigarette users (who have not smoked in the past 30 days)
- Not I-phone users
- Not interested in participating in an e-cigarette use cessation program
- Not able to read English

8.3 2) *Indicate specifically whether you will include any of the following special populations in your study using the checkboxes below.*

NOTE: Members of special populations may not be targeted for enrollment in your study unless you indicate this in your inclusion criteria.

Response: Adolescents who are 14-20 will be included in this study.

☐ Adults unable to consent

☒ Individuals who are not yet adults (infants, children, teenagers)

☐ Pregnant women

☐ Prisoners

8.4 Indicate whether you will include non-English speaking individuals in your study. ***Provide justification if you will exclude non-English speaking individuals.***

*In order to meet one of the primary ethical principles of equitable selection of subjects, non-English speaking individuals may **not** be routinely excluded from research as a matter of convenience.*

In cases where the research is of therapeutic intent or is designed to investigate areas that would necessarily require certain populations who

may not speak English, the researcher is required to make efforts to recruit and include non-English speaking individuals. However, there are studies in which it would be reasonable to limit subjects to those who speak English. Some examples include pilot studies, small unfunded studies with validated instruments not available in other languages, studies with numerous questionnaires, and some non-therapeutic studies which offer no direct benefit.

Response: While subjects may speak other languages, they will all have sufficient command of English to be able to consent and participate in the interviews to communicate with English speaking researchers. This is a pilot study, which do not provide researchers with the capacity of communication in other languages.

9.0 Vulnerable Populations*

If the research involves special populations that are considered vulnerable, ***describe the safeguards included to protect their rights and welfare.***

NOTE: You should refer to the appropriate checklists, referenced below, to ensure you have provided adequate detail regarding safeguards and protections. You do not, however, need to provide these checklists to the IRB.

9.1 For research that involves ***pregnant women,*** *safeguards include:*
NOTE CHECKLIST: Pregnant Women (HRP-412)

Response: N/A

☒ **N/A**: This research does not involve pregnant women.

9.2 For research that involves ***neonates of uncertain viability or non-viable neonates,*** *safeguards include:*
NOTE CHECKLISTS: Non-Viable Neonates (HRP-413), or Neonates of Uncertain Viability (HRP-414)

Response: NA

☒ **N/A:** This research does not involve non-viable neonates or neonates of uncertain viability.

9.3 For research that involves ***prisoners****, safeguards include:*
NOTE CHECKLIST: Prisoners (HRP-415)

Response: NA

☒ **N/A:** This research does not involve prisoners.

9.4 For research that involves ***persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children")****, safeguards include:*
NOTE CHECKLIST: Children (HRP-416)

Response: We will include participants who are below 18. We reviewed the checklist. We expect that there will be minimal risks involved in this research.

We will provide explanation to minimize the risks, such as breaches of confidentiality, and will make an effort to prevent those risks.

☐ **N/A:** This research does not involve persons who have not attained the legal age for consent to treatments or procedures ("children").

*9.5 For research that involves **cognitively impaired adults**, safeguards include: NOTE CHECKLIST: Cognitively Impaired Adults (HRP-417)*

Response: NA

☒ **N/A:** This research does not involve cognitively impaired adults.

*9.6 Consider if other specifically targeted populations such as students, employees of a specific firm, or educationally or economically disadvantaged persons are vulnerable. **Provide information regarding their safeguards and protections, including safeguards to eliminate coercion or undue influence.***

Response: Contact information of Institutional Review Board will be provided during the consenting and interview processes to ensure their safeguards and protections, particularly for adolescents. Information regarding their safeguards to eliminate coercion or undue influence will be provided. Anytime when they do not want to participate in this study, they will be able to withdraw anytime, and this will be emphasized.

10.0 Eligibility Screening*

*10.1 Describe **screening procedures** for determining subjects' eligibility. Screening refers to determining if prospective participants meet inclusion and exclusion criteria.*

📎 *Include all relevant screening documents with your submission (e.g. screening protocol, script, questionnaire).*

Response: When the potential participants contact the researchers via mail, email, phone calls, program directors, research team members will make an appointment for an interview. Before making an appointment for an interview, researchers will determine participants' eligibility by asking the following questions via email, phone calls, or text:

To adolescents:

- How old are you? (To screen if they are between 14 and 20 years old)
- Are you a current e-cigarette user? (Yes to the following question, "Have you used an electronic vaping product such as PuffBar, ElfBar, Lost Mary, JUUL, Vuse, e-cigarettes, vapes, vape pens, e-cigars, e-hookahs, hookah pens, or mods at least 1 day in the last 30 days?")
- Are you an iPhone user?

- Can you read English?

☐ **N/A:** There is no screening as part of this protocol.

11.0 Recruitment Methods

☐ **N/A:** This is a records review only, and subjects will not be recruited. NOTE: If you select this option, please make sure that all records review procedures and inclusion/exclusion screening are adequately described in other sections.

11.1 Describe when, where, and how potential subjects will be recruited.

NOTE: Recruitment refers to how you are identifying potential participants and introducing them to the study. Include specific methods you will use (e.g. searching charts for specific ICD code numbers, Research Participant Groups, posted advertisements, etc.).

Response: The PI will oversee all study recruitment and enrollment activities. To recruit participants who are 18 or older than 18, researchers will recruit potential participants through those listed in the IRB approved large research registry of families (Buffalo Research Registry [BRR] via email, mail, and phone. In addition, flyers will be distributed to healthcare settings, such as local free clinics, primary clinics, urgent care, retail clinics, WIC office, and Medicaid offices, as well as other non-healthcare settings, such as grocery stores, malls, cafeteria, libraries, universities, and churches, and youth community centers with persmission from the establishment. Moreover, social network sites such as Facebook, Twitter, Instagram, Snapchat, Linkedin will be considered for recruitment to broaden the reach, and the flyers will be posted in their original format. Univeristy at Buffalo sites will be used and a new account will be created for this study. Study flyers will be posted on the websites or online discussion boards which adolescdent e-cigartte users may frequently use. We will distribute the flyers through the listserves at the universities. The study team will utilize the University at Buffalo's Clinical and Translational Science Institute (CTSI) for recruitment assistance and consultation. The CTSI's Recruitment Team provides resources and guidance on appropriate recruitment strategies, and assistance in linking our study team with commnity partners to effectively reach recruitment goals and target populations.

We will be also working with the Clinical and Translational Science Institute (CTSI) Community Engagement Team (CET) to create awareness of the study through their professional and community contacts. The tools they have available may include the Buffalo Research Registry (BRR, IRB Approved STUDY00000806), the Patient Voices Network (PVN), the Conventus CTSI/PVN and Evergreen Research Tables, i2b2 and TriNetX, Department of Emergency Medicine Research Assistant Program, and conducting outreach at various community events. These tools are methods by which the CET distributes IRB-approved recruitment information to community members. Through networks of CTSI, this study can be introduced to eligible participants of other reserach being conducted at University at Buffalo. In addition, we will announce

our study through ResearchMatch.org site. ResearchMatch.org is a national electronic, web-based recruitment tool that was created through the Clinical & Translational Science Awards Consortium. Thus, volunteers who registered on the ResearchMatch site will be able to see the announcement about our study.

To recruit participantsd who are younger than 18 years old, we will mainly recruit participants from schools and hospitals. We want to ask the staff at the hospitals and schools to introduce the app and this study to the potentailly eligible participants who attend their schools or hospitals. We will contact the personnel, including school nurses of local middle and high schools in and around the Buffalo area, such as Heim Middle School and Amherst Middle School, to request permission to distribute the fliers.

11.2 Describe how you will protect the privacy interests of prospective subjects during the recruitment process.

NOTE: Privacy refers to an individual's right to control access to him or herself.

Response: When adolescents are interested in participating in the study by promotion flyer, they can directly contact the research team. When researchers are communicating with potential participants via phone or in person, the communication will be occurring at a private place. In that way, other people will not overhear or witness research activities. When we advertise the study via social media, comments will be shut off to protect participants' confidentiality and privacy. When participants contact the researchers through ResarchMatch site, their contact information will be shared with the research team only when they choose to do so. Participants will then have the option of replying yes or no through a set of quick links available in the notification. If a participant choose to respond in the affirmative, they will authorize ResearchMatch to release their contact information.

11.3 Identify any materials that will be used to recruit subjects.

NOTE: Examples include scripts for telephone calls, in person announcements / presentations, email invitations.

For advertisements, include the final copy of printed advertisements with your submission. When advertisements are taped for broadcast, attach the final audio/video tape. NOTE: You may submit the wording of the advertisement prior to taping to ensure there will be no IRB-required revisions, provided the IRB also reviews and approves the final version.

Response: Recruitment materials are attached.

12.0 Procedures Involved*

*12.1 Provide a description of **all research procedures or activities** being performed and when they are performed once a subject is screened and determined to be eligible. Provide as much detail as possible.*

NOTE: This should serve as a blueprint for your study and include enough detail so that another investigator could pick up your protocol and replicate the research. For studies that have multiple or complex visits or procedures, consider the addition of a schedule of events table in in your response.

Response: When the potential participants contact the researchers via email, phone calls, text, research team members will ask for eligibility. If they are eligible, we will ask about available times and places for interview and make an appointment. Participants will be provided with the link for the exiting apps in advance of the interviews and we will ask them to download it before the interview day. Private places, such as an office at the University at Buffalo will be used for in-person interview. Or if the participants prefer, the interviews will occur via Zoom or phone call. Before the interview begins, researchers will explain the purpose of the study and potential risks of participating in this research and obtain consent if the participants are 18 or older than 18 years old. We will obtain parent consent and minor assent if they are younger than 18 years old. We will obtain written consent. We will also ask if we can keep their contact information for five years to ask if they want to participate in future research. After obtaining consent, the researchers will ask participants to complete online survey (10 minutes), and ask participants to complete specific tasks on the app (task test performance test) (e.g., creating a personal profile). Then, the researchers will start interviews. For in-person interviews, we will use audio-recorders and for phone and Zoom interviews, we will use a record function on the Zoom application. Each interview will take about 30 to 60 minutes. Before the participants begin interviews, they will compete the survey (18 question) via phone or computer. After the interview is conducted, the recorded files will be transcribed by transcription services and double checked by the research team. All recorded audio files and transcribed files will be saved in the secure computer. All recordings and transcribed copies will be deleted once all the study procedures, including data analysis and reporting is completed.

12.2 Describe what data will be collected.

NOTE: For studies with multiple data collection points or long-term follow up, consider the addition of a schedule or table in your response.

Response: This study has a one-time data collection point. We will conduct the usability survey and task performance test during the interview meeting. After the survey and task performance test, we will conduct the interviews. The audio recording and the transcripts will be the obtained. In addition, the contact information, including name, phone number and email address, if they agree, will be collected to schedule the interviews.

12.3 List any instruments or measurement tools used to collect data (e.g. questionnaire, interview guide, validated instrument, data collection form).

Include copies of these documents with your submission.

Response: This will be semi-structured interview. The basic interview questions that will be used are included in the interview guide (attached). As part of the interview, we will ask participants to conduct specific tasks within the app and the prompt is included in the interview guide file. Further follow-up questions will be used for probing. In addition, we will conduct a brief survey using mHealth App Usability Questionnaire.

12.4 Describe any source records that will be used to collect data about subjects (e.g. school records, electronic medical records).

Response: NA

*12.5 Indicate whether or not **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 physician) and if so, describe how these will be shared.*

Response: Individual subject results will not be shared with subjects or others.

*12.6 Indicate whether or not **study** results will be shared with subjects or others, and if so, describe how these will be shared.*

Response: Study results will be shared via publication. Subjects or others may have access to published findings of the study.

13.0 Study Timelines*

13.1 Describe the anticipated duration needed to enroll all study subjects.

Response: 12 months

13.2 Describe the duration of an individual subject's participation in the study. Include length of study visits, and overall study follow-up time.

Response: Each participant will spend approximately take 30 to 60 minutes to complete the interview, including 10 minutes consenting process, completing the survey, and task performance test. There is only one interview for each subject.

13.3 Describe the estimated duration for the investigators to complete this study (i.e. all data is collected and all analyses have been completed).

Response: This study is expected to take one year to complete data collection and data analysis.

14.0 Setting

14.1 Describe all facilities/sites where you will be conducting research procedures. Include a description of the security and privacy of the facilities (e.g. locked facility, limited access, privacy barriers). Facility, department, and type of room are relevant. Do not abbreviate facility names.

NOTE: Examples of acceptable response may be: "A classroom setting in the Department of Psychology equipped with a computer with relevant survey administration software," "The angiogram suite at Buffalo General Medical

Center, a fully accredited tertiary care institution within New York State with badge access," or, "Community Center meeting hall."

Response: Meeting rooms at University at Buffalo will be considered first to meet for participants for an interview upon making an appointment. Available meeting rooms or classrooms of community centers or other places which ensures privacy may be used for data collection. If the participant prefers, virtual interviews, using application, Zoom can be used for an interview. Or phone interviews can be conducted if participants prefer.

14.2 For research conducted outside of UB and its affiliates, describe:

- *Site-specific regulations or customs affecting the research*
- *Local scientific and ethical review structure*

NOTE: This question is referring to UB affiliated research taking place outside UB, i.e. research conducted in the community, school-based research, international research, etc. It is not referring to multi-site research. UB affiliated institutions include Kaleida Health, ECMC, and Roswell Park Cancer Institute.

Response:

☒ **N/A:** This study is not conducted outside of UB or its affiliates.

15.0 Community-Based Participatory Research

15.1 Describe involvement of the community in the design and conduct of the research.

NOTE: Community-Based Participatory Research (CBPR) is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.

Response:

☒ **N/A:** This study does not utilize CBPR.

15.2 Describe the composition and involvement of a community advisory board.

Response:

☒ **N/A:** This study does not have a community advisory board.

16.0 Resources and Qualifications

*16.1 Describe the qualifications (e.g., education, training, experience, expertise, or certifications) of the Principal Investigator **and** staff to perform the research. When applicable describe their knowledge of the local study sites,*

culture, and society. Provide enough information to convince the IRB that you have qualified staff for the proposed research.

NOTE: If you specify a person by name, a change to that person will require prior approval by the IRB. If you specify a person by role (e.g., coordinator, research assistant, co-investigator, or pharmacist), a change to that person will not usually require prior approval by the IRB, provided that the person meets the qualifications described to fulfill their roles.

Response:

The PI, Eunhee Park, PhD, RN, APHN-BC, is an assistant professor of School of Nursing at the University at Buffalo. Dr. Park has completed research and publications on adolescent health behavior and health promotion, including adolescent smoking and substance use prevention. She received her PhD at the University at Virginia. She received her Master's degree in the Public Health Nursing Leadership (PHNL) specialty track, and her PhD degree at the University of Virginia. As a certified Advanced Public Health Nurse, she has community experience in a variety of community settings. Before entering the graduate school, she worked as a RN at the Pediatrics Unit in a general hospital. These experiences will allow her to work effectively as a partner with youth to promote health.

RA (TBD): doctoral student in the School of Nursing at University at Buffalo who have skills and knowledge about qualitative interviews with young research adolescents.

Describe other resources available to conduct the research.

16.2 Describe the time and effort that the Principal Investigator and research staff will devote to conducting and completing the research.

NOTE: Examples include the percentage of Full Time Equivalents (FTE), hours per week. The question will elicit whether there are appropriate resources to conduct the research.

Response: 30 percent of Full Time Equivalents will be spent by PI. Also, there will be two RAs (10 hours per week over 1 year each) to assist recruitment, data collection, and data analysis.

16.3 Describe the availability of medical or psychological resources that subjects might need as a result of anticipated consequences of the human research, if applicable.

NOTE: One example includes: on-call availability of a counselor or psychologist for a study that screens subjects for depression.

Response: NA

16.4 Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

Response: The PI will train and provide supervision to the Research Assistant who has completed the training on human subjects and ethics in research (CITI). During the initial meetings, the PI will provide handouts or files to inform the protocol, the research procedures, and RAs' duties and functions. There will be biweekly meetings among RAs and the PI to ensure all research members follow the research procedures.

17.0 Other Approvals

17.1 Describe any approvals that will be obtained prior to commencing the research (e.g., school, external site, funding agency, laboratory, radiation safety, or biosafety).

Response:

☒ **N/A:** This study does not require any other approvals.

18.0 Provisions to Protect the Privacy Interests of Subjects

18.1 Describe how you will protect subjects' privacy interests during the course of this research.

NOTE: Privacy refers to an individual's right to control access to him or herself. Privacy applies to the person. Confidentiality refers to how data collected about individuals for the research will be protected by the researcher from release. Confidentiality applies to the data.

Examples of appropriate responses include: "participant only meets with a study coordinator in a classroom setting where no one can overhear", or "the participant is reminded that they are free to refuse to answer any questions that they do not feel comfortable answering."

Response: There will be no attempt to reveal participants' identities in any part of this study, and all data collected will not be shared with anyone except the research team members.

During the recruitment and interview phase, researchers will try to protect participants' privacy and confidentiality. When researchers are communicating with participants via phone or in person, communication will be occurring at a private place. In that way, other people will not overhear or witness research activities. When we advertise the study via social media, comments will be shut off to protect participants' confidentiality and privacy.

The data files, including audio files and participants' contact information will be shared using UB Box site, which only research members have access to. Data analysis will be performed and stored in the firewall,

encrypted, password protected computers provided by the School of Nursing. All computer databases and files will be maintained at the University at Buffalo. No data will be reported for individuals, and names of participants will not be identified in any reports on this study. Pseudonyms and ID numbers will be used during the interview. The file links the pseudonyms and participants' names and contact information will be saved in the password protected file and this file will be only shared with the research team members as necessary during the recruitment phase.

During the interviews, researchers will explain that there are risks of breaches of confidentiality and privacy in spite of the effort to protect them. The participants can stop participating in the study at any point. Participants will be reminded that they are free to refuse to answer any questions that they do not feel comfortable answering.

18.2 Indicate how the research team is permitted to access any sources of information about the subjects.

NOTE: Examples of appropriate responses include: school permission for review of records, consent of the subject, HIPAA waiver. This question ***does apply*** *to records reviews.*

Response: We will obtain parental permission, consent, and assent of the subjects.

19.0 Data Management and Analysis*

19.1 Describe the data analysis plan, including any statistical procedures. This section applies to both quantitative and qualitative analysis.

Response: Quantitative data including demographic questions and survey questions will be analyzed with descriptive statistics. For the qualitative data from the interviews, a content analysis approach will be used with a deductive approach.

19.2 If applicable, provide a power analysis.

NOTE: This may not apply to certain types of studies, including chart/records reviews, survey studies, or observational studies. This question is asked to elicit whether the investigator has an adequate sample size to achieve the study objectives and justify a conclusion.

Response: No power analysis is needed.

19.3 Describe any procedures that will be used for quality control of collected data.

19.4 Response: *data.*

Response: Research team members will meet biweekly to check the research procedures and ensure the quality of the data.

20.0 Confidentiality*

A. Confidentiality of Study Data

*Describe the local procedures for maintenance of confidentiality of **study data and any records that will be reviewed for data collection**.*

*20.1 A. Where and how will all data and records be stored? Include information about: password protection, encryption, physical controls, authorization of access, and separation of identifiers and data, as applicable. Include physical (e.g. paper) **and** electronic files.*

Response: The data files will be stored in secure computers that are firewall and password protected. All paper documentation (including consent forms) will be stored in locked filing cabinets of the researchers' office and Center for Nursing Research office. The file containing participants' name and contact information, interview data (audio files and transcribed data), and consent forms will be stored in locked filing cabinets of the researchers' office and Center for Nursing Research office and/or saved as a password protected file in the PI's computer located in the PI's office at campus and the UB Box folder. All computer databases and files will be maintained at the University at Buffalo. No data will be reported for individuals, and names of participants will not be identified in any reports on this study. Pseudonyms and ID numbers will be used during the interview. The file links the pseudonyms and participants' names and contact information will be saved in the password protected file and this file will be only shared with the research team members as necessary during the recruitment phase.

The data files will be shared using UB Box site, which only research members have access to. Data analysis will be performed and stored in the firewall, encrypted, password protected computers provided by the School of Nursing.

20.2 A. How long will the data be stored?

Response: All files, including transcribed data, audio files, and links between the participants' identifying information will be deleted when the study is complete. Contact information for participants who want to be notified about future studies, their contact information will be stored for five years.

20.3 A. Who will have access to the data?

Response: Only the research members who are given permission.

20.4 A. Who is responsible for receipt or transmission of the data?

Response: The PI is responsible for the data receipt or transmission.

20.5 A. How will the data be transported?

Response: The data files without participants' names and contact information will be shared using UB Box site, which only research members have access to.

B. Confidentiality of Study Specimens

*Describe the local procedures for maintenance of confidentiality of **study specimens**.*

☒ **N/A:** No specimens will be collected or analyzed in this research. *(Skip to Section 21.0)*

20.6 B. Where and how will all specimens be stored? Include information about: physical controls, authorization of access, and labeling of specimens, as applicable.

Response: NA

20.7 B. How long will the specimens be stored?

Response: NA

20.8 B. Who will have access to the specimens?

Response: NA

20.9 B. Who is responsible for receipt or transmission of the specimens?

Response: NA

20.10 B. How will the specimens be transported?

Response: NA

21.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

NOTE: Minimal risk studies may be required to monitor subject safety if the research procedures include procedures that present unique risks to subjects that require monitoring. Some examples include: exercising to exertion, or instruments that elicit suicidality or substance abuse behavior. In such cases, N/A is not an acceptable response.

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

Response: During the whole sessions and data collection periods, research team members will meet regularly to check the research procedures and ensure the safety of the subjects. There is no unique risk to subjects that require monitoring.

21.2 Describe what data are reviewed, including safety data, untoward events, and efficacy data.

Response: NA

21.3 Describe any safety endpoints.

Response: NA

21.4 Describe how the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).

Response: NA

21.5 Describe the frequency of safety data collection.

Response: NA

21.6 Describe who will review the safety data.

Response: NA

21.7 Describe the frequency or periodicity of review of cumulative safety data.

Response: NA

21.8 Describe the statistical tests for analyzing the safety data to determine whether harm is occurring.

Response: NA

21.9 Describe any conditions that trigger an immediate suspension of the research.

Response: NA

22.0 Withdrawal of Subjects*

☐ **N/A:** This study is not enrolling subjects. This section does not apply.

*22.1 Describe **anticipated** circumstances under which subjects may be withdrawn from the research without their consent.*

Response: NA

22.2 Describe any procedures for orderly termination.

NOTE: Examples may include return of study drug, exit interview with clinician. Include whether additional follow up is recommended for safety reasons for physical or emotional health.

Response: NA

22.3 Describe procedures that will be followed when subjects withdraw from the research, including retention of already collected data, and partial withdrawal from procedures with continued data collection, as applicable.

Response: When the participants want to withdraw from the research, researchers will identify whether the participants want to retain in the data analysis process. If they do not want researchers to use the data they already provided, the researchers will not include the data the participants provided at the request of that subject. Otherwise, researchers will notify the subjects that the data already collected will be retained.

23.0 Risks to Subjects*

23.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to their participation in the research. Consider physical, psychological, social, legal, and economic risks. Include a description of the probability, magnitude, duration, and reversibility of the risks.

NOTE: Breach of confidentiality is always a risk for identifiable subject data.

Response: This study is of minimum risk due to some possible experience of discomfort in answering the questions during the interview. Moreover, as with most research studies, participants are at risk of a breach of confidentiality.

23.2 Describe procedures performed to lessen the probability or magnitude of risks, including procedures being performed to monitor subjects for safety.

Response: Subjects will be told that they may choose not to answer any interview questions that make them uncomfortable or is unduly sensitive. Participants will also be told that they are free to drop out of the study at any time. It will be completely voluntary to participate in the interview.

See section 20.1 for procedures to mitigate the risk of breach of confidentiality.

Data files will be stored on a secure computer protected by a firewall and password. Files containing participant names and contact information, interview data (audio files and transcribed data) will be stored in locked file cabinets in the investigator's office and the Nursing Research Center office and/or as password protected files on the PI's computer and in the UB Box folder. The computer will be turned off and kept in PI's office that no other people has access to when it's not being used. All computer databases and files will be stored at the University at Buffalo. No personal data will be reported, and participants will not be identified by name in any reports about this study. Pseudonyms and identification numbers will be used during interviews. Files linking pseudonyms and participant names and contact information will be kept in a password-protected file that will only be shared with members of the research team as necessary during the recruitment phase.

Data files will be shared using the UB Box website and will only be accessible by study members. Data analysis will be conducted and stored in a firewalled, encrypted, password-protected computer provided by the School of Nursing.

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

Response: NA

23.4 If applicable, indicate which research procedures may have risks to an embryo or fetus should the subject be or become pregnant.

Response: NA

23.5 If applicable, describe risks to others who are not subjects.

Response: NA

24.0 Potential Benefits to Subjects*

24.1 Describe the potential benefits that individual subjects may experience by taking part in the research. Include the probability, magnitude, and duration of the potential benefits. Indicate if there is no direct benefit.

*NOTE: Compensation **cannot** be stated as a benefit.*

Response: There is no direct benefits to the individual participants.

25.0 Compensation for Research-Related Injury

☐ **N/A:** The research procedures for this study do not present risk of research related injury (e.g. survey studies, records review studies). This section does not apply.

*25.1 **If the research procedures carry a risk of research related injury,** describe the available compensation to subjects in the event that such injury should occur.*

Response: No risk is anticipated.

25.2 Provide a copy of contract language, if any, relevant to compensation for research related injury.

*NOTE: If the contract is not yet approved at the time of this submission, submit the current version here. If the contract is later approved with **different language regarding research related injury**, you must modify your response here and submit an amendment to the IRB for review and approval.*

Response: N/A

26.0 Economic Burden to Subjects

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

NOTE: Some examples include transportation or parking.

Response: There is no cost that subjects may be responsible for because of participation in the research. When participants are interviewed on campus, the parking permit will be provided.

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

27.0 Compensation for Participation

27.1 Describe the amount and timing of any compensation to subjects, including monetary, course credit, or gift card compensation.

Response: $25 gift cards (Target gift card) will be provided for participating in the study on the meeting day after participants finish interviewing.

For participants who conduct interviews via phone or Zoom, the gift cards can be transferred via their email address or phone number.

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

☐ **N/A:** There is no compensation for participation. This section does not apply.

28.0 Consent Process

28.1 Indicate whether you will be obtaining consent.

NOTE: This does not refer to consent documentation, but rather whether you will be obtaining permission from subjects to participate in a research study. Consent documentation is addressed in Section 29.0.

☒ ***Yes*** *(If yes, Provide responses to each question in this Section)*
☐ ***No*** *(If no, Skip to Section 29.0)*

28.2 Describe where the consent process will take place. Include steps to maximize subjects' privacy.

Response: When adolescents are interested in participating in the study by promotion flyer, they can directly contact the research team. When the potential participants contact the researchers via mail, email, phone calls, research team members will make an appointment for an interview if they are eligible.

For in-person interviews, meeting rooms at University at Buffalo will be considered first to meet for participants for an interview upon making an appointment. Available meeting rooms or classrooms of community centers or other places which ensures privacy may be used for consenting and data collection. For in-person interviews, signs on the written consent forms will be obtained.

If the participant prefers, Zoom or phone interviews can be conducted. For Zoom or phone interviews, researchers will obtain written consent from parents of participants and written assents from participants if participants are between 13 and 17 and written consent from participants if they are older than 18 years old or 18 years old before the interviews.

28.3 Describe how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study.

NOTE: It is always a requirement that a prospective subject is given sufficient time to have their questions answered and consider their participation. See "SOP: Informed Consent Process for Research (HRP-090)" Sections 5.5 and 5.6.

Response: Participants will take time as much as they want before they contact researchers to participate in the study, within the overall time-frame of the study.

28.4 Describe any process to ensure ongoing consent, defined as a subject's willingness to continue participation for the duration of the research study.

Response: When participants consent to the study, they will be told that they are free to stop participating at any time.

28.5 Indicate whether you will be following "SOP: Informed Consent Process for Research (HRP-090)." Pay particular attention to Sections 5.4-5.9. If not, or if there are any exceptions or additional details to what is covered in the SOP, describe:

- *The role of the individuals listed in the application who are involved in the consent process*
- *The time that will be devoted to the consent discussion*
- *Steps that will be taken to minimize the possibility of coercion or undue influence*
- *Steps that will be taken to ensure the subjects' understanding*

Response:

☒ We have reviewed and will be following "SOP: Informed Consent Process for Research (HRP-090)."

Non-English Speaking Subjects

☒ **N/A:** This study will not enroll Non-English speaking subjects. *(Skip to Section 28.8)*

28.6 Indicate which language(s) other than English are likely to be spoken/understood by your prospective study population or their legally authorized representatives.

NOTE: The response to this Section should correspond with your response to Section 8.4 of this protocol.

Response: NA

28.7 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, how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study, and any process to ensure ongoing consent. Indicate the language that will be used by those obtaining consent.

NOTE: Guidance is provided on "SOP: Informed Consent Process for Research (HRP-090)."

Response: NA

Cognitively Impaired Adults

☒ **N/A**: This study will not enroll cognitively impaired adults.
(Skip to Section 28.9)

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

Response: NA

Adults Unable to Consent

☒ **N/A**: This study will not enroll adults unable to consent.
(*Skip to Section 28.13)*

When a person is not capable of consent due to cognitive impairment, a legally authorized representative should be used to provide consent (Sections 28.9 and 28.10) ***and, where possible, assent of the individual should also be solicited*** *(Sections 28.11 and 28.12).*

28.9 Describe how you will identify a Legally Authorized Representative (LAR). Indicate that you have reviewed the "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" for research in New York State.

NOTE: Examples of acceptable response includes: verifying the electronic medical record to determine if an LAR is recorded.

Response: NA

☒ We have reviewed and will be following "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."

28.10 ***For research conducted outside of New York State****, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "legally authorized representative" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response: NA

28.11 Describe the process for ***assent of the adults****:*

- *Indicate whether assent will be obtained from all, some, or none of the subjects.* ***If some, indicate which adults will be required to assent and which will not.***

Response: NA

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

Response: NA

28.12 Describe whether ***assent of the adult*** *subjects will be documented and the process to document assent.*

NOTE: The IRB allows the person obtaining assent to document assent on the consent document using the "Template Consent Document (HRP-502)" Signature Block for Assent of Adults who are Legally Unable to Consent.

Response: NA

Subjects who are not yet Adults (Infants, Children, and Teenagers)

☐ **N/A**: This study will not enroll subjects who are not yet adults. *(Skip to Section 29.0)*

28.13 Describe the criteria that will be used to determine ***whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research*** *under the applicable law of the jurisdiction in which the research will be conducted* ***(e.g., individuals under the age of 18 years)****. For research conducted in NYS, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children."*

NOTE: Examples of acceptable responses include: verification via electronic medical record, driver's license or state-issued ID, screening questionnaire.

Response: Parents who are a legal guardian will be only able to consent and the record of consenting will be kept, following "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)." The participant age will be determined by a screening questionnaire.

28.14 ***For research conducted outside of New York State****, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved 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 the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."

Response: N/A

28.15 Describe whether parental permission will be obtained from:

Response:

☒ One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

☐ Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

☐ Parent permission will not be obtained. A waiver of parent permission is being requested.

NOTE: The requirement for parent permission is a protocol-specific determination made by the IRB based on the risk level of the research. For guidance, review the "CHECKLIST: Children (HRP-416)."

*28.16 Describe whether permission will be obtained from individuals **other than parents**, and if so, who will be allowed to provide permission. Describe your procedure for determining an individual's authority to consent to the child's general medical care.*

Response: N/A

*28.17 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.*

Response: Assent will be obtained from all children.

28.18 When assent of children is obtained, describe how it will be documented.

Response: We will obtain he signature on the assent form.

29.0 Waiver or Alteration of Consent Process

Consent will not be obtained, required information will not be disclosed, or the research involves deception.

☐ **N/A:** A waiver or alteration of consent is not being requested.

29.1 If the research involves a waiver or alteration of the consent process, please review the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" to ensure that you have provided sufficient information for the IRB to make the determination that a waiver or alteration can be granted.

NOTE: For records review studies, the first set of criteria on the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" applies.

Response: N/A

29.2 If the research involves a waiver of the consent process for planned emergency research, please review the "CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)" to ensure you have provided sufficient information for the IRB to make these determinations. Provide any additional information necessary here:

Response: N/A

30.0 Process to Document Consent

☐ **N/A:** A Waiver of Consent is being requested.
(Skip to Section 31.0)

30.1 Indicate whether you will be following "SOP: Written Documentation of Consent (HRP-091)." If not or if there are any exceptions, describe whether and how consent of the subject will be obtained including whether or not it will be documented in writing.

NOTE: If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent. This is sometimes referred to as 'verbal consent.' Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information.

If you will document consent in writing, attach a consent document with your submission. You may use "TEMPLATE CONSENT DOCUMENT (HRP-502)". If you will obtain consent, but not document consent in writing, attach the script of the information to be provided orally or in writing (i.e. consent script or Information Sheet).

Response: We will follow "SOP: Written Documentation of Consent (HRP-091)."

☒ We will be following "SOP: Written Documentation of Consent" (HRP-091).

31.0 Multi-Site Research (Multisite/Multicenter Only)*

☒ **N/A:** This study is not an investigator-initiated multi-site study. This section does not apply.

31.1 Indicate the total number of subjects that will be enrolled or records that will be reviewed across all sites.

Response: N/A

*31.2 If this is a multi-site study **where you are the lead investigator**, describe the processes to ensure communication among sites, such as the following.*

- *All sites have the most current version of the IRB documents, including the protocol, consent document, and HIPAA authorization.*
- *All required approvals have been obtained at each site (including approval by the site's IRB of record).*
- *All modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.*
- *All engaged participating sites will safeguard data as required by local information security policies.*
- *All local site investigators conduct the study appropriately in accordance with applicable federal regulations and local laws.*
- *All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.*

Response: N/A

31.3 Describe the method for communicating to engaged participating sites.

- *Problems (inclusive of reportable events)*
- *Interim results*
- *Study closure*

Response: N/A

*31.4 If this is a multicenter study **where you are a participating site/investigator**, describe the local procedures for maintenance of confidentiality.*

- *Where and how data or specimens will be stored locally?*
- *How long the data or specimens will be stored locally?*
- *Who will have access to the data or specimens locally?*
- *Who is responsible for receipt or transmission of the data or specimens locally?*
- *How data and specimens will be transported locally?*

Response: N/A

31.5 If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods. Local recruitment methods are described elsewhere in the protocol.

- *Describe when, where, and how potential subjects will be recruited.*
- *Describe the methods that will be used to identify potential subjects.*
- *Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)*

Response: N/A

32.0 Banking Data or Specimens for Future Use*

☐ **N/A:** This study is not banking data or specimens for future use or research outside the scope of the present protocol. This section does not apply.

*32.1 If data or specimens will be banked (stored) for **future use, that is, use or research outside of the scope of the present protocol**, describe where the data/specimens will be stored, how long they will be stored, how the data/specimens will be accessed, and who will have access to the data/specimens.*

NOTE: Your response here must be consistent with your response at the "What happens if I say yes, I want to be in this research?" Section of the Template Consent Document (HRP-502).

Response: Contact information for participants who want to be notified about future studies will be kept.

32.2 List the data to be stored or associated with each specimen.

Response: N/A

32.3 Describe the procedures to release banked data or specimens for future uses, including: the process to request a release, approvals required for

release, who can obtain data or specimens, and the data to be provided with specimens.

Response: N/A