Once complete, upload this form as a Word document to the IRB Protocol Management System: https://secure.research.vt.edu/irb

Section 1: General Information

1.1 DO ANY OF THE INVESTIGATORS OF THIS PROJECT HAVE A REPORTABLE CONFLICT OF INTEREST? (http://www.irb.vt.edu/pages/researchers.htm#conflict)

☒ **No**
☐ **Yes,** explain:

1.2 WILL THIS RESEARCH INVOLVE COLLABORATION WITH ANOTHER INSTITUTION?

☒ **No,** go to question 1.3
☐ **Yes,** answer questions within table

IF YES
Provide the name of the institution [for institutions located overseas, please also provide name of country]**:**
Indicate the status of this research project with the other institution's IRB: ☐ Pending approval ☐ Approved ☐ Other institution does not have a human subject protections review board ☐ Other, explain:
Will the collaborating institution(s) be engaged in the research? (http://www.hhs.gov/ohrp/policy/engage08.html) ☐ No ☐ Yes
Will Virginia Tech's IRB review all human subject research activities involved with this project? ☐ No, provide the name of the primary institution: ☐ Yes *Note: primary institution = primary recipient of the grant or main coordinating center*

1.3 IS THIS RESEARCH FUNDED?

☐ **No,** go to question 1.4
☒ **Yes,** answer questions within table

IF YES
Provide the name of the sponsor [if NIH, specify department]: Virginia Tech Department of Human Nutrition, Foods and Exercise
Is this project receiving federal funds? ☒ No ☐ Yes

If yes,

Does the grant application, OSP proposal, or "statement of work" related to this project include activities involving human subjects that are <u>not</u> covered within this IRB application?

- ☐ No, all human subject activities are covered in this IRB application
- ☐ Yes, however these activities will be covered in future VT IRB applications, these activities include:
- ☐ Yes, however these activities have been covered in past VT IRB applications, the IRB number(s) are as follows:
- ☐ Yes, however these activities have been or will be reviewed by another institution's IRB, the name of this institution is as follows:
- ☐ Other, explain:

Is Virginia Tech the primary awardee or the coordinating center of this grant?

- ☐ No, provide the name of the primary institution:
- ☐ Yes

1.4 DOES THIS STUDY INVOLVE CONFIDENTIAL OR PROPRIETARY INFORMATION (OTHER THAN HUMAN SUBJECT CONFIDENTIAL INFORMATION), OR INFORMATION RESTRICTED FOR NATIONAL SECURITY OR OTHER REASONS BY A U.S. GOVERNMENT AGENCY?

For example – government / industry proprietary or confidential trade secret information

- ☒ **No**
- ☐ **Yes,** describe:

1.5 DOES THIS STUDY INVOLVE SHIPPING ANY TANGIBLE ITEM, BIOLOGICAL OR SELECT AGENT OUTSIDE THE U.S?

- ☒ **No**
- ☐ **Yes**

Section 2: Justification

2.1 DESCRIBE THE BACKGROUND, PURPOSE, AND ANTICIPATED FINDINGS OF THIS STUDY:

Effectiveness of Community Gardens (CG). Two recent reviews highlight the lack of empirical evidence related to the effectiveness and impact of CG on health outcomes. These reviews highlight numerous opportunities for research and practice, including the need for theory-driven hypotheses and use of validated metrics, control sites, adequately powered studies, assessment of health-related outcomes, longitudinal research to evaluate changes over time, and process data. Specific to youth, a 2009 garden-based review included four in-school, three afterschool, and three community-based nutrition education programs. The impacts on individual level youth outcomes, including FV intake, willingness to try FV, preference for FV, self-efficacy, and knowledge were mixed across studies. These inconsistencies in study findings are highlighted, in part, by lack of scientific rigor in the study design and evaluation methods. Although the Social Cognitive Theory (SCT), which is based on reciprocal determinism among individual, behavioral and environmental factors has been the most consistent theory used in these education programs, none of these studies examined socioenvironmental factors (e.g. availability of fresh FV in the community and home). Furthermore, none of the studies examined distal health outcomes (e.g. weight status). Since the 2009 review, two pre-post survey designs with no control group have examined the effectiveness of garden-based nutrition interventions in increasing FV availability in the home of youth with mixed results. Importantly, CG provide numerous benefits beyond health, such as promotion of community building, beautification, civic engagement, social capital, and social well-being. These key social processes (e.g. collective efficacy, connection, reciprocity, mutual trust, and social norms) are integral to health promotion. On a broader scale, they can progress community supported agriculture programs and positively impact the community food system by improving food security. These important social and

environment determinants are key to understanding and improving the health among low-income populations, yet do not replace the need for stronger study designs and evaluation methods to rigorously assess the socioenvironmental effects directly related to the availability of FV, as well as longer term health outcomes associated with CG. Our proposed theory-grounded, two-group experimental intervention targeting at-risk youth will begin to address many of these shortcomings identified in the current CG literature.

Profile and health needs of one of Virginia's and North Carolina's most health disparate regions. The Dan River Region (DRR) is situated in south central Virginia and north central North Carolina. All counties in this region meet the medically underserved area/population classification with high indices of poverty, low educational attainment and health disparities. Historically, this rural area relied largely on agriculture, manufacturing, and textile mills for its economic foundation. In recent years, many of the manufacturing and textile jobs have disappeared, creating the highest rates of unemployment in the Commonwealth of Virginia. At the end of 2010, unemployment in the region ranged from 12.3-18.9%, well exceeding state (6.7%) and national (9.4%) averages. Low SES, rural, and African American populations in Virginia consistently experience higher mortality rates and poorer health status across a variety of outcomes (e.g. heart disease, cancer, infant mortality, diabetes mellitus) when compared to higher SES, urban, and non-black Virginians. Thus the geographic profile, socio-demographics, and current economic strain creates a vulnerable situation for residents and makes the DRR one of the most health disparate regions of the Commonwealth. According to the 2011 County Health Report, the largest city in the region (Danville) is 122nd in overall health out of 132 counties in the Commonwealth. Three recent comprehensive needs assessments conducted in the DRR conclusively recognized obesity and obesity among youth as a serious health concern for the DRR. Furthermore, these needs assessments indicated the need for community partnerships to promote community design and policy changes that promote healthy living. Collectively, these reports led to community efforts to unify stakeholders in November 2009, at which time regular meetings began with the intent to develop a cohesive and organized obesity task force.

Community-Based Participatory Research (CBPR). Community-based participatory research (CBPR), a process that builds equitable community-academic partnerships, is recognized as an important approach to develop and execute health interventions among marginalized populations, promote program sustainability, and a key strategy to translate research into practice to help reduce health disparities. Importantly, applying CBPR efforts is a recent recommendation for implementing and evaluating gardenbased youth programs. A CBPR framework has guided the organization and development of the regional obesity task force, recently named The Dan River Partnership for a Healthy Community (DRPHC), and includes committed community leaders and organizations of the Dan River Region and research expertise from the Virginia Tech Department of Human Nutrition, Foods, and Exercise (VT-HNFE).

Significance. While CG and CBPR have grown in popularity, both fields of literature are limited by the lack of theory-guided controlled experimental research designs addressing health behaviors and health related outcomes. This proposal will address both of these identified shortcomings through a theoretically driven intervention and it will measure health outcomes, specifically intake and access to fruits and vegetables and weight status. In large part, the CG research field is being driven by either shortterm individual level-behaviors or social- and environmental-level processes (community building, beautification, civic engagement, social capital, and social well-being), but not on health outcomes. Therefore, little is understood about CG being a viable intervention strategy for obesity prevention. The long-term goal of this proposal is to understand if CG efforts are a viable approach to improve and sustain changes in the nutrition, health, and weight status of low-income youth and their caregivers. The significance of this proposal is further highlighted by addressing numerous short-comings in the current literature. For example, we propose to evaluate changes in health-related outcomes, to use a controlled research design and previously validated instruments, and to apply principles in communitybased participatory research. Each of these has been recently recommended to advance the evidence surrounding CG research. Furthermore, despite prior CG studies being grounded in the Social Cognitive Theory, there has been little focus on reciprocal determinism and most notably the socioenvironmental factors (e.g. availability of fresh FV in the community and home) that impact fruit and vegetable intake. Our effort to thoroughly apply the Social Cognitive Theory and to include but move beyond individual determinants of fruit and vegetable intake among youth is critical to advance the scientific-evidence related to obesity prevention programs for youth. In addition to scientific advancement, this application is grounded in CBPR, promoting equitable and strong collaborations among the identified partners (VT-HNFE, Virginia Cooperative Extension, and Cardinal Village and Cedar Terrace housing

authorities). Engaging local expertise and experiences will promote sustainable efforts targeting at-risk families in the public housing communities. The outcomes of this research will be used to inform regional policy development related to the funding and allocation of land for CGs and programming to support youth and family participation in the CG by the local public housing authority.

2.2 EXPLAIN WHAT THE RESEARCH TEAM PLANS TO DO WITH THE STUDY RESULTS:

For example - publish or use for dissertation

It is anticipated that the results from this study will be submitted for publication in a peer review journal, submitted for a master's thesis and doctoral dissertation and submitted for presentation at academic and research conferences.

Section 3: Recruitment

3.1 DESCRIBE THE SUBJECT POOL, INCLUDING INCLUSION AND EXCLUSION CRITERIA AND NUMBER OF SUBJECTS:

Examples of inclusion/exclusion criteria - gender, age, health status, ethnicity

Participants: Youth and parents will be recruited from the two participating public housing authorities (N=200, n=50 youth and n=50 primary caregivers at two sites). At both sites, the youth will be recruited from ongoing after school and summer programs offered at no cost to parents. This is a community-based trial our inclusion criteria broadly includes any fulltime resident of the housing community, parent and youth that provides parent informed consent, and child assent. Given the proposed study utilizes ongoing afterschool and/or summer programs at both sites it is likely that more than one parent or caregiver may be present with the child and a parent(s) could have multiple children enrolled in the program. No family members will be excluded from the programming at either the intervention or control site. Youth whose parents do not consent to the study activities will still participate in the program, but no data will be collected from them. For analytic purposes, the parent with primary caretaking role will be used for analysis. Data from all enrolled children from the primary caretaker will be analyzed. All measures are validated for youth 5 years or older.

Inclusion criteria:
Child and parent must be full-time resident of public housing community, defined as >50% of nights. Child must be ages 5-14. Parent must provide consent and the child must be willing to participate (child assent). Adult caregiver (>18 years) resident of the public housing community. Consent to all data collection periods.

Exclusion criteria:
If no child meets the age/grade requirements, that parent will not be eligible to participate.
Child or caregiver only lives at public housing community part-time(spend <50% of nights).

3.2 WILL EXISTING RECORDS BE USED TO IDENTIFY AND CONTACT / RECRUIT SUBJECTS?

Examples of existing records - directories, class roster, university records, educational records

☒ **No,** go to question 3.3
☐ **Yes,** answer questions within table

IF YES
Are these records private or public? ☐ Public ☐ Private, describe the researcher's privilege to the records:
Will student, faculty, and/or staff records or contact information be requested from the University? ☐ No ☐ Yes, visit the following link for further information: http://www.policies.vt.edu/index.php (policy no. 2010)

3.3 DESCRIBE RECRUITMENT METHODS, INCLUDING HOW THE STUDY WILL BE ADVERTISED OR INTRODUCED TO SUBJECTS:

The site coordinator at each community will be responsible for recruiting youth, parents, and community residents to participate in the study activities. Additionally, the Danville Public Housing Authority Newsletter, website, and internal information systems will be utilized to advertise and recruit participants. Graduate student researchers will assist the site coordinators as needed.

3.4 PROVIDE AN EXPLANATION FOR CHOOSING THIS POPULATION:

Note: the IRB must ensure that the risks and benefits of participating in a study are distributed equitably among the general population and that a specific population is not targeted because of ease of recruitment.

This application focuses on CG efforts targeting at-risk youth in The Dan River Region, a health disparate region situated in south central Virginia and north central North Carolina. The Dan River Partnership for a Healthy Community (DRPHC), an established community-based participatory research (CBPR) team, is the dynamic partnership behind emerging efforts to promote, evaluate, and understand health outcomes and regional policy implications of CG efforts. Increasing access to healthy food among at-risk youth and families via CG efforts has been identified as a top priority.

Section 4: Consent Process

For more information about consent process and consent forms visit the following link: http://www.irb.vt.edu/pages/consent.htm

If feasible, researchers are advised and may be required to obtain signed consent from each participant unless obtaining signatures leads to an increase of risk (e.g., the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting in a breach of confidentiality). Signed consent is typically not required for low risk questionnaires (consent is implied) unless audio/video recording or an in-person interview is involved. If researchers will not be obtaining signed consent, participants must, in most cases, be supplied with consent information in a different format (e.g., in recruitment document, at the beginning of survey instrument, read to participant over the phone, information sheet physically or verbally provided to participant).

4.1 CHECK ALL OF THE FOLLOWING THAT APPLY TO THIS STUDY'S CONSENT PROCESS:

- ☒ Verbal consent will be obtained from participants
- ☒ Written/signed consent will be obtained from participants
- ☐ Consent will be implied from the return of completed questionnaire. Note: The IRB recommends providing consent information in a recruitment document or at the beginning of the questionnaire (if the study only involves implied consent, skip to Section 5 below)
- ☐ Other, describe:

4.2 PROVIDE A GENERAL DESCRIPTION OF THE PROCESS THE RESEARCH TEAM WILL USE TO OBTAIN AND MAINTAIN INFORMED CONSENT:

An information and recruitment packet will be distributed by the site coordinator to parents in the housing authority. The packet will include an informed consent form that will be returned to the researchers for the baseline assessment at which point a researcher will review the informed consent document with the parent and answer any questions. Separate consent forms will be obtained for each child for parents with multiple children enrolled in the program. Verbal assent will be obtained from the children under 18 years old prior to obtaining baseline measures.

4.3 WHO, FROM THE RESEARCH TEAM, WILL BE OVERSEEING THE PROCESS AND OBTAINING CONSENT FROM SUBJECTS?

Under the direction of Drs. Zoellner and Hill graduate student researchers Karissa Grier and Felicia Reese will oversee the process and obtain consent from caregivers and assent from children. Each of these

individuals have been trained in IRB procedures.

4.4 WHERE WILL THE CONSENT PROCESS TAKE PLACE?

In Danville, Virginia at each housing authority: Cardinal Village and Cedar Terrace.

4.5 DURING WHAT POINT IN THE STUDY PROCESS WILL CONSENTING OCCUR?

Note: unless waived by the IRB, participants must be consented before completing any study procedure, including screening questionnaires.

Consent from the parent will be obtained prior to baseline measures. Similarly, parent or guardian informed consent will take place before the survey is administered to the child. Assent will take place before the interview-administered survey is given to the child.

4.6 IF APPLICABLE, DESCRIBE HOW THE RESEARCHERS WILL GIVE SUBJECTS AMPLE TIME TO REVIEW THE CONSENT DOCUMENT BEFORE SIGNING:

Note: typically applicable for complex studies, studies involving more than one session, or studies involving more of a risk to subjects.

The parent or guardian will have ample time to review the consent form. They will be allowed to ask questions of the researcher prior to becoming involved in the program. Upon request, the parents or guardians will also be provided with a copy of the informed consent document. The child assent statement will be read aloud and slowly by one of the researchers. Children will also have ample time to ask questions before the survey is administered.

☐ Not applicable

Section 5: Procedures

5.1 PROVIDE A STEP-BY-STEP THOROUGH EXPLANATION OF ALL STUDY PROCEDURES EXPECTED FROM STUDY PARTICIPANTS, INCLUDING TIME COMMITMENT & LOCATION:

The research will take place at the Cedar Terrace and Cardinal Village Housing Authority sites in Danville, VA. Parent or guardian consent will be obtained prior to interaction with the children. If parent or guardian consent is given, children will be asked to participate in the survey. After assent is obtained, the interview-administered survey will begin. The parent or guardian will be asked for their written consent before filling out a self-administered survey. The data will only be used for research purposes for children who have signed the assent form and whose parent or guardian has given permission. The time commitment for the surveys and height and weight measuresments will be approximatley 30 minutes for the parent or guardian and 30 minutes for the child. Children will also participate in the Junior Master Garden curriculum which will be held weekly for one hour for approximately 10 weeks.

5.2 DESCRIBE HOW DATA WILL BE COLLECTED AND RECORDED:

Parents or guardians will answer a self-administered questionnaire that will be completed on-site or at home and returned the day of baseline measures. After parental consent and child assent, the children will answer an interview administered survey. Parents/guardians and children will be measured for height and weight by trained researchers and measures will be recorded in a folder along with survey responses. Both parent and child survey will have a cover sheet that is removed from the survey, thereby identifying each survey by number only. All cover sheets and informed consents will be transported and stored separately from the surveys in locked filing cabinets.Attendance data will also be collected from the children on days when the cirriculum is offered. The attendance sheet will be locked separate from the files that contain the numbered identification. All data will be entered into a data analysis software identified by the survey number only.

5.3 DOES THE PROJECT INVOLVE ONLINE RESEARCH ACTIVITES (INCLUDES ENROLLMENT, RECRUITMENT, SURVEYS)?

View the "Policy for Online Research Data Collection Activities Involving Human Subjects" at http://www.irb.vt.edu/documents/onlinepolicy.pdf

☒ **No,** go to question 6.1
☐ **Yes,** answer questions within table

IF YES
Identify the service / program that will be used: ☐ www.survey.vt.edu, go to question 6.1 ☐ Blackboard, go to question 6.1 ☐ Center for Survey Research, go to question 6.1 ☐ Other **IF OTHER:** Name of service / program: URL: This service is… ☐ Included on the list found at: http://www.irb.vt.edu/pages/validated.htm ☐ Approved by VT IT Security ☐ An external service with proper SSL or similar encryption (https://) on the login (if applicable) and all other data collection pages. ☐ None of the above (note: only permissible if this is a collaborative project in which VT individuals are only responsible for data analysis, consulting, or recruitment)

Section 6: Risks and Benefits

6.1 WHAT ARE THE POTENTIAL RISKS (E.G., EMOTIONAL, PHYSICAL, SOCIAL, LEGAL, ECONOMIC, OR DIGNITY) TO STUDY PARTICIPANTS?

The potential risks in completing the parent or guardian survey and child survey is low. There are no known sensitive questions. The only known risk is the time and inconvenience of answering the survey questions. The potential risks in participating in the cirriculum are low.

6.2 EXPLAIN THE STUDY'S EFFORTS TO REDUCE POTENTIAL RISKS TO SUBJECTS:

We will not force subjects to answer any questions or participate in the cirriculum if they do not want to. Participants will not be penalized if they decide not to participate in the evaluation process or if they decide to withdraw from the survey or cirriculum after they gave their consent. Appropriate efforts will be taken to protect confidentiality of data.

6.3 WHAT ARE THE DIRECT OR INDIRECT ANTICIPATED BENEFITS TO STUDY PARTICIPANTS AND/OR SOCIETY?

The anticipated direct benefit to the participants is to increase fruit and vegetable availability in the home, increase nutrition knowledge and self-efficacy for gradening.
The indirect benefit to the community is the assessment of a possible future garden intervention. The program will provide data in order to evaluate the effectiveness of increasing fruit and vegetable availability through community gardening.

Section 7: Full Board Assessment

7.1 DOES THE RESEARCH INVOLVE MICROWAVES/X-RAYS, OR GENERAL ANESTHESIA OR SEDATION?

☒ **No**
☐ **Yes**

7.2 DO RESEARCH ACTIVITIES INVOLVE PRISONERS, PREGNANT WOMEN, FETUSES, HUMAN IN VITRO FERTILIZATION, OR MENTALLY DISABLED PERSONS?

☒ **No,** go to question 7.3
☐ **Yes,** answer questions within table →

IF YES
This research involves: ☐ Prisoners ☐ Pregnant women ☐ Fetuses ☐ Human in vitro fertilization ☐ Mentally disabled persons

7.3 DOES THIS STUDY INVOLVE MORE THAN MINIMAL RISK TO STUDY PARTICIPANTS?

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily activities or during the performance of routine physical or psychological examinations or tests. Examples of research involving greater than minimal risk include collecting data about abuse or illegal activities. Note: if the project qualifies for Exempt review (http://www.irb.vt.edu/pages/categories.htm), it will not need to go to the Full Board.

☒ **No**
☐ **Yes**

IF YOU ANSWERED "YES" TO ***ANY ONE*** OF THE ABOVE QUESTIONS, 7.1, 7.2, OR 7.3, THE BOARD MAY REVIEW THE PROJECT'S APPLICATION MATERIALS AT ITS MONTHLY MEETING. VIEW THE FOLLOWING LINK FOR DEADLINES AND ADDITIONAL INFORMATION: http://www.irb.vt.edu/pages/deadlines.htm

Section 8: Confidentiality / Anonymity

For more information about confidentiality and anonymity visit the following link: http://www.irb.vt.edu/pages/confidentiality.htm

8.1 WILL PERSONALLY IDENTIFYING STUDY RESULTS OR DATA BE RELEASED TO ANYONE OUTSIDE OF THE RESEARCH TEAM?

For example – to the funding agency or outside data analyst, or participants identified in publications with individual consent

☒ **No**
☐ **Yes,** to whom will identifying data be released?

8.2 WILL ANY STUDY FILES CONTAIN PARTICIPANT IDENTIFYING INFORMATION (E.G., NAME, CONTACT INFORMATION, VIDEO/AUDIO RECORDINGS)?

Note: if collecting signatures on a consent form, select "Yes."

☒ **No,** go to question 8.3
☐ **Yes,** answer questions within table →

IF YES
Describe if/how the study will utilize study codes:
If applicable, where will the key [i.e., linked code and identifying information document (for instance, John Doe = study ID 001)] **be stored and who will have access?**

Note: the key should be stored separately from subjects' completed data documents and accessibility should be limited.

The IRB strongly suggests and may require that all data documents (e.g., questionnaire responses, interview responses, etc.) do not include or request identifying information (e.g., name, contact information, etc.) from participants. If you need to link subjects' identifying information to subjects' data documents, use a study ID/code on all data documents.

8.3 WHERE WILL DATA BE STORED?

Examples of data - questionnaire, interview responses, downloaded online survey data, observation recordings, biological samples

Questionnaires and attendance will be stored in locked cabinets in the HNFE Behavioral Research Team office located in the Integrated Life Sciences Building. The survey key will be stored separately (e.g., in separate locked filing cabinets) from one another.

8.4 WHO WILL HAVE ACCESS TO STUDY DATA?

Only the investigative research team who have been trained in IRB procedures will have access to the survey data, as well as research assisstants who enter the data into the statistical program.

8.5 DESCRIBE THE PLANS FOR RETAINING OR DESTROYING THE STUDY DATA

The data will be stored for at least three years or until research findings are published. Then child assent forms, parent or guardian permission forms, self-administered surveys, and interview-administered questionnaires and baseline and followup data will be shredded.

8.6 DOES THIS STUDY REQUEST INFORMATION FROM PARTICIPANTS REGARDING ILLEGAL BEHAVIOR?

☒ **No,** go to question 9.1
☐ **Yes,** answer questions within table →

IF YES
Does the study plan to obtain a Certificate of Confidentiality? ☐ No ☐ Yes (Note: participants must be fully informed of the conditions of the Certificate of Confidentiality within the consent process and form) *For more information about Certificates of Confidentiality, visit the following link:* *http://www.irb.vt.edu/pages/coc.htm*

Section 9: Compensation

For more information about compensating subjects, visit the following link: http://www.irb.vt.edu/pages/compensation.htm

9.1 WILL SUBJECTS BE COMPENSATED FOR THEIR PARTICIPATION?

☐ **No,** go to question 10.1
☒ **Yes,** answer questions within table →

IF YES
What is the amount of compensation? $30
Will compensation be prorated? ☒ Yes, please describe: **Parents will receive a $15 gift card upon completion of data collection at baseline and at followup.** ☐ No, explain why and clarify whether subjects will receive full compensation if they withdraw from the study? *Unless justified by the researcher, compensation should be prorated based on duration of study participation. Payment must not be contingent upon completion of study procedures. In other words, even if the subject decides to withdraw from the study, he/she should be compensated, at least partially, based on what study procedures he/she has completed.*

Section 10: Audio / Video Recording

For more information about audio/video recording participants, visit the following link: http://www.irb.vt.edu/pages/recordings.htm

10.1 WILL YOUR STUDY INVOLVE VIDEO AND/OR AUDIO RECORDING?

☒ **No,** go to question 11.1
☐ **Yes,** answer questions within table →

IF YES
This project involves: ☐ Audio recordings only ☐ Video recordings only ☐ Both video and audio recordings
Provide compelling justification for the use of audio/video recording:
How will data within the recordings be retrieved / transcribed?
How and where will recordings (e.g., tapes, digital data, data backups) be stored to ensure security?
Who will have access to the recordings?
Who will transcribe the recordings?
When will the recordings be erased / destroyed?

Section 11: Research Involving Students

11.1 DOES THIS PROJECT INCLUDE STUDENTS AS PARTICIPANTS?

☒ **No,** go to question 12.1
☐ **Yes,** answer questions within table →

IF YES

Does this study involve conducting research with students of the researcher?

☐ No

☐ Yes, describe safeguards the study will implement to protect against coercion or undue influence for participation:

Note: if it is feasible to use students from a class of students not under the instruction of the researcher, the IRB recommends and may require doing so.

Will the study need to access student records (e.g., SAT, GPA, or GRE scores)?

☐ No

☐ Yes

11.2 DOES THIS PROJECT INCLUDE ELEMENTARY, JUNIOR, OR HIGH SCHOOL STUDENTS?

☐ **No,** go to question 11.3

☒ **Yes,** answer questions within table

IF YES

Will study procedures be completed during school hours?

☒ No

☐ Yes

If yes,

Students not included in the study may view other students' involvement with the research during school time as unfair. Address this issue and how the study will reduce this outcome:

Missing out on regular class time or seeing other students participate may influence a student's decision to participate. Address how the study will reduce this outcome:

Is the school's approval letter(s) attached to this submission?

☐ Yes

☐ No, project involves Montgomery County Public Schools (MCPS)

☒ No, explain why: **The program does not interfere with regular school hours as it will be conducted after school hours and during the summer while the children are not in school.**

You will need to obtain school approval (if involving MCPS, click here: http://www.irb.vt.edu/pages/mcps.htm). Approval is typically granted by the superintendent, principal, and classroom teacher (in that order). Approval by an individual teacher is insufficient. School approval, in the form of a letter or a memorandum should accompany the approval request to the IRB.

11.3 DOES THIS PROJECT INCLUDE COLLEGE STUDENTS?

☒ **No,** go to question 12.1

☐ **Yes,** answer questions within table

IF YES

Some college students might be minors. Indicate whether these minors will be included in the research or actively excluded:

☐ Included

☐ Actively excluded, describe how the study will ensure that minors will not be included:

Will extra credit be offered to subjects?

☐ No
☐ Yes

If yes,

What will be offered to subjects as an equal alternative to receiving extra credit without participating in this study?

Include a description of the extra credit (e.g., amount) to be provided within question 9.1 ("IF YES" table)

Section 12: Research Involving Minors

12.1 DOES THIS PROJECT INVOLVE MINORS (UNDER THE AGE OF 18 IN VIRGINIA)?

Note: age constituting a minor may differ in other States.

☐ **No,** go to question 13.1
☒ **Yes,** answer questions within table

IF YES
Does the project reasonably pose a risk of reports of current threats of abuse and/or suicide? ☒ No ☐ Yes, thoroughly explain how the study will react to such reports: *Note: subjects and parents must be fully informed of the fact that researchers must report threats of suicide or suspected/reported abuse to the appropriate authorities within the Confidentiality section of the Consent, Assent, and/or Permission documents.*
Are you requesting a waiver of parental permission (i.e., parent uninformed of child's involvement)? ☐ No, **both** parents/guardians will provide their permission, if possible. ☒ No, **only one** parent/guardian will provide permission. ☐ Yes, describe below how your research meets **all** of the following criteria (A-D): Criteria A - The research involves no more than minimal risk to the subjects: Criteria B - The waiver will not adversely affect the rights and welfare of the subjects: Criteria C - The research could not practicably be carried out without the waiver: Criteria D - (Optional) Parents will be provided with additional pertinent information after participation:
Is it possible that minor research participants will reach the legal age of consent (18 in Virginia) while enrolled in this study? ☒ No ☐ Yes, will the investigators seek and obtain the legally effective informed consent (in place of the minors' previously provided assent and parents' permission) for the now-adult subjects for any ongoing interactions with the subjects, or analysis of subjects' data? If yes, explain how: *For more information about minors reaching legal age during enrollment, visit the following link:* *http://www.irb.vt.edu/pages/assent.htm*
*The procedure for obtaining assent from minors and permission from the minor's guardian(s) must be described in **Section 4** (Consent Process) of this form.*

Section 13: Research Involving Deception

For more information about involving deception in research and for assistance with developing your debriefing form, visit our website at http://www.irb.vt.edu/pages/deception.htm

13.1 DOES THIS PROJECT INVOLVE DECEPTION?

☒ **No,** go to question 14.1
☐ **Yes,** answer questions within table

IF YES
Describe the deception:
Why is the use of deception necessary for this project?
Describe the debriefing process:
Provide an explanation of how the study meets <u>all</u> the following criteria (A-D) for an alteration of consent: Criteria A - The research involves no more than minimal risk to the subjects: Criteria B - The alteration will not adversely affect the rights and welfare of the subjects: Criteria C - The research could not practicably be carried out without the alteration: Criteria D - (Optional) Subjects will be provided with additional pertinent information after participation (i.e., debriefing for studies involving deception): *By nature, studies involving deception cannot provide subjects with a complete description of the study during the consent process; therefore, the IRB must allow (by granting an alteration of consent) a consent process which does not include, or which alters, some or all of the elements of informed consent.*
The IRB requests that the researcher use the title "Information Sheet" instead of "Consent Form" on the document used to obtain subjects' signatures to participate in the research. This will adequately reflect the fact that the subject cannot fully consent to the research without the researcher fully disclosing the true intent of the research.

Section 14: Research Involving Existing Data

14.1 WILL THIS PROJECT INVOLVE THE COLLECTION OR STUDY/ANALYSIS OF EXISTING DATA DOCUMENTS, RECORDS, PATHOLOGICAL SPECIMENS, OR DIAGNOSTIC SPECIMENS?

Please note: it is not considered existing data if a researcher transfers to Virginia Tech from another institution and will be conducting data analysis of an on-going study.

☒ **No,** you are finished with the application
☐ **Yes,** answer questions within table

IF YES
From where does the existing data originate?
Provide a detailed description of the existing data that will be collected or studied/analyzed:
Is the source of the data public? ☐ No, continue with the next question ☐ Yes, you are finished with this application

Will any individual associated with this project (internal or external) have access to or be provided with existing data containing information which would enable the identification of subjects:

- **Directly** (e.g., by name, phone number, address, email address, social security number, student ID number), or
- **Indirectly through study codes** even if the researcher or research team does not have access to the master list linking study codes to identifiable information such as name, student ID number, etc or
- **Indirectly through the use of information that could reasonably be used in combination to identify an individual** (e.g., demographics)

☐ No, collected/analyzed data will be completely de-identified
☐ Yes,

If yes,

Research will not qualify for exempt review; therefore, if feasible, written consent must be obtained from individuals whose data will be collected / analyzed, unless this requirement is waived by the IRB.

Will written/signed or verbal consent be obtained from participants prior to the analysis of collected data? -select one-

This research protocol represents a contract between all research personnel associated with the project, the University, and federal government; therefore, must be followed accordingly and kept current.

Proposed modifications must be approved by the IRB prior to implementation except where necessary to eliminate apparent immediate hazards to the human subjects.

Do not begin human subjects activities until you receive an IRB approval letter via email.

It is the Principal Investigator's responsibility to ensure all members of the research team who interact with research subjects, or collect or handle human subjects data have completed human subjects protection training prior to interacting with subjects, or handling or collecting the data.

----------END----------