

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]: UNC Chapel Hill
Indicate the status of this research project with the other institution's IRB: <input checked="" type="checkbox"/> Pending approval <input type="checkbox"/> Approved <input type="checkbox"/> Other institution does not have a human subject protections review board <input type="checkbox"/> Other, explain:
Will the collaborating institution(s) be engaged in the research? http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Will Virginia Tech's IRB review all human subject research activities involved with this project? <input type="checkbox"/> No, provide the name of the primary institution: <input checked="" type="checkbox"/> Yes <i>Note: primary institution = primary recipient of the grant or main coordinating center</i>

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]: S. Ramey Lab Fund # 234067; C. Ramey Lab Fund #234066; Wellcome Trust # 457530
Is this project receiving federal funds? <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes

If yes,

Does the grant application, OSP proposal, or “statement of work” related to this project include activities involving human subjects that are not 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:

This project is a follow-up to a study known as The Abecedarian Project which was launched in 1972 in Chapel Hill, North Carolina. Dr. Craig Ramey was the original PI and has continued to be PI or later became Co-PI (along with Dr. Frances Campbell at UNC) for follow-up assessments from infancy through age 30. The project was a randomized controlled trial (RCT) designed to test the hypothesis that a systematic, high-quality early educational program provided to children from infancy through kindergarten entry would produce large and enduring benefits in the children's intellectual, academic, and social outcomes (Ramey, Sparling, & Ramey, 2012). The study design involved two treatment groups from birth to age 5: Group 1 (Control Group) was provided free unlimited nutrition in the form of formula (none of the mothers could be convinced to breastfeed), free and individualized social services for the family for the first 5 yrs of the child's life, and free or reduced cost medical care following the American Academy of Pediatrics recommended well-child care protocol; and Group 2 was an Early Education Treatment Group that received the same nutritional, social services, and health care as Group 1 plus was provided free early education at a university-based child development center that had trained teachers and teaching assistants, low teacher:child ratios, a specially constructed curriculum (Learninggames) and offered full-day, 5 days a week, 50 weeks a year care and education until the children entered kindergarten. Children in the Group 2 Early Education Treatment Group showed significant benefits in terms of their cognitive and language development on a variety of different assessments starting at 18 months of age and continuing through kindergarten school entry compared to those in Group 1. In the school years, at ages 6, 8, 12, and 15, the Early Educational Group showed advantages that included significantly higher scores on standardized tests of reading and math, lower rates of grade repetition, and lower rates of placement in special education,

along with many other favorable outcomes (e.g., reduced depression in adolescence, increased sense of academic locus of control). In early adulthood, at age 21, continued benefits for the Early Educational Group appeared, including significantly higher reading and math scores, greater likelihood of being enrolled in a college and/or participating in the workforce, and lower rates of self-reported smoking, drug use, and criminal behavior. At age 30, another set of outcomes revealed benefits in terms of higher rates of successfully completing a 4-yr college degree and employment-related outcomes for the Early Educational Group compared to Group 1. This study has been one of 3 major long-term follow-up studies (the others are the Perry Preschool Project and the Chicago Longitudinal Child-Parent Study) that provide strong empirical support for the hypothesis that early educational experiences can produce major benefits on multiple aspects of the lives of children born into poverty.

The Abecedarian Project enrolled mothers in the greater Chapel Hill, NC area using a High Risk pregnancy screening tool administered when mothers were pregnant or at the time of birth. All mothers gave informed consent and understood that their children were to be randomly assigned to one of the two groups described above. Continued participation rates remained very high (above 90 percent) between the ages of infancy through 30, for both groups. At age 35, a smaller study focused on adult health status involving a lab visit to draw blood, conducted at UNC, and used different recruitment methods and incentives. This age 35 follow-up study resulted in a somewhat lower rate of participation (71%). With the exception of the age 35 biomarker health study, we have relied on re-connecting with the study participants through a well-respected community member who has been part of our research team since 1971 - Ms. Carrie Bynum. For this proposed study, we will engage Ms. Bynum to ensure that the methods are individualized, sensitive, and effective in allowing all study participants to learn about the next "phase" of the study and whether they would like to volunteer to participate. For this proposed follow-up, the primary site for data collection will be the Virginia Tech Carilion Research Institute in Roanoke, VA. For those unable to travel to Roanoke, we will offer the option of participating in part via phone, computer, and/or in-person interviews in North Carolina or their home town (if feasible).

The current proposed follow-up study will be when study participants are between the ages of 39 - 45 years. This follow-up will focus on testing hypotheses about brain structure and function, as detected in an MRI scanner, associated with two factors: Factor 1 is the participants' preschool education experience (Group 1 vs Group 2); Factor 2 is the participants' prior educational achievement and highest educational attainment (i.e., regardless of their preschool treatment group assignment). In addition, this follow-up study will collect new data about perceived locus of control in the areas of health and economics; and obtain, for the first time ever, personal life narratives from study participants about how they describe the meaning and experience of having been in the Abecedarian Project since birth.

The opportunity to assess the long-term effects of being born into a high-risk poverty environment and of variation in early life experiences, well-documented prospectively for children in both of the treatment groups, is truly unique for this sample. Cooperation and interest in participating has remained high among the study participants, as reflected in their willingness to return for assessments in adulthood and their many informal comments and communication with study staff, including Ms. Bynum. As in the past, all standardized assessments completed in this middle age period will be administered by trained staff who do not know about (i.e., are blinded to) the individuals' treatment group.

We anticipate the study results will provide new findings about the extent to which aspects of the structure and function of the brain in middle age adulthood -- particularly in brain areas and neural networks related to reasoning, planning, language, and self-regulation -- differ significantly as a function of the Early Educational treatment and/or the individual's history of academic achievement and final adult level of educational attainment. Note: for those in Group 1, more than half received at least some community-based preschool (usually one or two years) and previous analyses showed that these educational experiences also produced some benefits, albeit lesser in magnitude, for cognitive and language development. Other anticipated results from the follow-up include learning about the self-reported health practices and behaviors of study participants in middle adulthood and their current life situation. Finally, the story narratives from the Abecedarian Project Study participants will provide valuable qualitative data and be amenable to content analysis for key themes that emerge, and that may relate to individual differences in life trajectories and earlier life experiences.

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

For example - publish or use for dissertation

We plan to publish the results in peer-reviewed scientific journals and to share the findings at scientific meetings and with policy and practice groups interested in long-term effects of high-quality early childhood education. In addition, we propose to summarize and share the findings with communities and parent groups interested in learning about the long-term effects of high-quality early educational interventions for children born into families living in multi-risk, economically impoverished families.

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

The subject pool includes all of the individuals still living from the Abecedarian Study original cohort of 111. At this time, we know of 9 deaths. We will not make efforts to include anyone who is known to be incarcerated or to be seriously ill, since these conditions would preclude participation. Some individuals with certain medical devices or metal implants or who are physically too large or who are claustrophobic cannot be assessed in the scanner, although we would seek to obtain the out-of-scanner data on these individuals from standardized assessments and from interviews.

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?	
<input type="checkbox"/> Public	
<input type="checkbox"/> Private, describe the researcher's privilege to the records:	
Will student, faculty, and/or staff records or contact information be requested from the University?	
<input type="checkbox"/> No	
<input type="checkbox"/> 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:

We will follow the recruitment methods used consistently in the past. Specifically, Ms. Carrie Bynum will be employed for the purposes of initial outreach and contact. She will review the list of participants and the last contact information available for each individual. Sometimes, if she is already aware that a person has moved, she will supplement the list with the more recent information she already has available. For example, if a person has moved to another city and she knows that city, she may look up the address and phone numbers through publicly available sources. Then Ms. Bynum, who is known to all study participants by name and by prior, multiple in-person experiences as a part of the Abecedarian Project over the decades, contacts them - via phone or email or text, as she deems the best way to first reach the person. She will let the person know that there is a new "phase" that will take place and ask if the person would like to learn more about this. If the person says yes, then Ms. Bynum will provide a very general overview of the protocol (see attached letter/telephone script). After answering general questions, Ms. Bynum will ask if the individual feels that he or she would like to give permission to have Dr. Craig Ramey or Dr. Sharon Ramey contact him or her. Then Dr. Craig Ramey or Dr. Sharon Ramey will contact the individual to describe the follow-up study in more detail. The study purpose will be described as learning more about how each person is doing, and contributing to science by being in this follow-up study about the long-term course of their lives, since they have been followed from birth into adulthood. The study focus is on learning what contributes to a person's adult well-being, health, education, income, and family life, and about the

influences on how the brain is structured and how it works around the age 40.

Participants who previously completed study procedures outlined in section 5.1, but did not complete all of the interview questions due to revisions during the enrollment period, will be asked to answer the “new” research questions verbally over the phone. Libbie Sonnier-Netto will contact participants, using phone numbers that they provided to us during their visit to Roanoke, to request verbal consent and if they consent to ask them the new additional research questions that were not on the interview when they first visited but are now included for all future participants to answer. (see interview pages 3 and 4).

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 is a unique study population that has been followed since birth, with research funded by federal, state, and private sources over the decades, and peer-reviewed since its inception. The study has resulted in more than 300 publications that have been instrumental in advancing understanding about many aspects of poverty and children’s educational and health outcomes, starting in infancy. The resources and scientific expertise here at Virginia Tech in the Human Neuroimaging Lab, building upon aspects of the well-tested protocol in the Roanoke Brain Study, led by Dr. Read Montague, with the contributions of the original PI, Dr. Craig Ramey, and co-investigator, Dr. Sharon Ramey, who co-direct the Laboratory for Human Development, and a new collaborator, Dr. Martha Farah at the University of Pennsylvania (an expert in poverty effects on the brain), strengthen the value of this follow-up on the Abecedarian Project sample. We also will continue to engage, as consultants to the project, Drs. Frances Campbell and Margaret Burchinal, longtime collaborators on the Abecedarian Project, who bring special expertise about the earlier developmental outcomes for this sample, as well as Ms. Carrie Bynum who has been employed as the community field coordinator.

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:

We will have the study’s long-term field coordinator, Ms. Carrie Bynum, contact the study participants individually by phone, mail, text, or email following the same procedures that we have successfully employed previously. These procedures involve identifying the study participants based on the last follow-up study and using contact information available currently through public sources and prior information. Ms. Bynum typically makes a phone call to talk about the new opportunity related to follow-up. All study participants are familiar with and have been receptive to this approach. Sometimes Ms. Bynum contacts the

study participants' mothers to be sure she has the most recent contact information. The mothers themselves had given prior written consent to participate, although in the proposed protocol we will not be collecting any data directly from mothers.

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

Drs. Craig Ramey and Sharon Ramey will oversee the process and work closely with Ms. Bynum related to obtaining written informed consent from study participants.

4.4 WHERE WILL THE CONSENT PROCESS TAKE PLACE?

Consent process will take place in Roanoke at the Virginia Tech Carilion Research Institute in the Human Neuroimaging Lab at 2 Riverside Circle. In the event the study participant is interviewed in another city, the consent process will take place in an office or home setting selected by the study participant.

Participants who previously completed study procedures outlined in section 5.1, but did not complete all of the interview questions due to revisions during the enrollment period, will be asked to answer the "new" research questions verbally over the phone. Libbie Sonnier-Netto will contact participants, using phone numbers that they provided to us during their visit to Roanoke, to request verbal consent and if they consent to ask them the new additional research questions that were not on the interview when they first visited but are now included for all future participants to answer. (see interview pages 3 and 4).

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.

All study participants will provide written informed consent before any study procedure takes place. Prior to traveling to Roanoke, study participants will have had opportunities to learn about the details of the study and to receive answers to any early questions they may have. In the event that an individual travels to Roanoke, but then later declines to provide consent, we will offer to reimburse him or her for travel-related expenses. We will ask the individual if he or she is willing to share with us why they declined to provide consent and what we could have done to make things clearer in advance. Based on our extensive prior experience with this study cohort for nearly 40 years, we think this is unlikely to occur.

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.

Before coming to Roanoke, we will have contact with each participant. That is, after the individual tells Ms. Bynum that he or she is interested in learning more about the study, he or she will call or e-mail to speak directly with Dr. Craig Ramey or Dr. Sharon Ramey. If the individual prefers, we can contact him or her at a time that is convenient. We will discuss the study procedures on the phone and we also will send the informed consent statement ahead of time by electronic or postal mail. When the study participant comes to Roanoke, we will let the individual know - during the in-person meeting - that if he or she would like additional time to think about providing written consent, this is fine. We would then offer to have a break, and then re-convene a while later. (Note: We think this unlikely, given the adequate preparation and description ahead of time.)

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:

A phone screening for fMRI eligibility will take place prior to the participant traveling to Roanoke. The screening script is part of the Drs. Ramey's phone script.

Study location: Human Neuroimaging Laboratory site at Virginia Tech Carilion Research Institute in Roanoke, VA.

Subject time commitment: Each visit will take approximately 3.0 - 4.5 hours.

When the volunteer arrives and prior to testing of any kind, informed consent will be obtained. All participants will be informed of the purposes of the study ("to learn more about how early life and school influence middle-age health and brain function" and "to find out what it has been like for you to be in a study since you were born"), the potential value of the study to society ("to identify the family, education, and health factors that can be promoted to improve health and adult well-being"), the lack of value of the study to the subject personally (no treatments are being offered), and all potential risks to the subject. We will explain to the study participant that she or he is under no obligation to participate, and that if he or she wishes to discontinue involvement at any time during the session he or she is free to do so without penalty.

Study staff will review full MRI screening form (see attached MRI Screening Form) to determine MRI eligibility (body girth not too large to fit in scanner, no metallic objects on or in the participant's body, participant not known to be claustrophobic), review safety issues related to being in the MRI scanner with the study participant, provide examples of specific task instructions, and answer any questions. These instructions may also ask the study participant to answer a few simple questions about the tasks. The study staff will inspect the answers, report the results, and answer any questions the individual may have. Prior to the fMRI scan, study participants will be interviewed and complete several brief questionnaires related to physical and mental health and perceptions or strategies related to their everyday lives, such as health locus-of-control and economic locus-of-control.

Scanning procedure:

At this point, study participants will be helped into place in the scanner by a technician and given another opportunity to ask any questions about the fMRI scanning process. Participants will be instructed that they can squeeze a squeeze bulb at any time to alert the technicians to any problem that would necessitate stopping the MRI scan. They will also be instructed about how to use the button boxes to indicate their decisions during the tasks. The participants also can speak to the technician at any time.

One primary procedure is an MRI scan. The MRI scanner we will use differs from conventional scanners only in that the magnet strength is 3.0 T, rather than the more typical 1.5 T magnets used in routine clinical scanning. Note that 3.0 T scanners have been approved for clinical use by the FDA and are currently becoming available for routine clinical applications nationwide. The participants will lie still for about 60 to 70 minutes in the scanner. Resting State scans (see attached resting state instructions document) will be acquired during the scanning session and will last approximately 5 minutes. Additionally, structural scans lasting from approximately 5 up to 18 minutes will be acquired during the first portion of the scanning session. Following structural scanning, functional images will be acquired. As with conventional scanners, the person in the scanner will be in constant voice communication with a technician or investigator via an intercom, in case the study participant wishes to come out of the scanner or has a question. The scanner will detect changes in regional cerebral blood flow that accompany brain activation during these tasks and stimuli.

During the fMRI scan, study participants will perform a series of simple decision-making tasks on the computer in the following categories:

The Trust Game (a neuroeconomic game) (ref. 1, 2) - In this task, study participants will be asked to play a game with a "partner" that involves a series of reciprocal exchanges. The Trust Game necessitates active choices by the study participant in which empathy, fairness, and trust are considered. There are simple rules about investing money and sharing the "wins" or "gains" with a hypothetical partner.
(Time: approximately 10-15 minutes)

Ultimatum Game (ref. 3, 4) - A two-party game where proposers offer a split of money to a responder who either accepts or rejects the offer. Participants will play the role of the responder and the computer will play the role of the proposer in the game for approximately 60 trials. Each trial will begin with a new Proposer

(the computer) proposing how to split \$20 between the Proposer and the participant (Responder), and ends with the participant's response of accepting or rejecting the offer. If the Responder accepts the offer, both sides get the distributed amounts. However, if the Responder rejects, both sides get \$0. In addition, after some of the trials, participants will be asked to rate their feelings about the received offers using emoticons ranging from sad to happy on a 1-9 scale. (Time: approximately 20 minutes)

NOTE: For both neuroeconomic games, the study participant will have a chance to practice on a computer, with a Research Associate helping provide instructions, prior to entering the scanner. This ensures the study participant can read and understand the directions that will appear on the screen when he or she is in the scanner.

NOTE: The fMRI tasks described above represent a subset of the protocol that has been used in the IRB-approved "Roanoke Brain Study" that began in 2011-2012 here at Virginia Tech. Our research team thus has considerable experience in using these tasks and ensuring that study participants feel comfortable and have a positive experience during the assessment session.

Narrative collection:

The "Narrative" is an opportunity for the Abecedarian Study participants to share, in their own words, what being part of this study since they were very young has meant to them. We decided to include this for two important reasons: (1) First and foremost, many study participants previously have told us and Ms. Carrie Bynum that this study has been very influential in their lives, for them and their families. This perception has been reported by those who participated in both of the study groups. We think collecting their narratives will provide an informative and unique qualitative dimension to this longitudinal study. Further, participants may feel this allows them to contribute in a way that has not been offered systematically in the past. Finally, there will be an opportunity to explore whether the participants' own "life narratives" and perceptions about being in the study relate to some aspects of their brain structure and functioning during decision-making neuroeconomic tasks.

Other Non-scanning activities:

Study participants will complete the following tools via interview and self-administration.

- 1) Current life situation information about self, family, and residence: employment and income, and general health.
- 2) The Multidimensional Health Locus of Control Scale (ref. 5) (MHLC) that addresses a person's perception of what influences his or her health and getting sick or well, items include choices such as:
 - If I become sick, I have the power to make myself well again.
 - I am directly responsible for my health.
 - My physical well-being depends on how well I take care of myself.
 - When I feel ill, I know it is because I have not been taking care of myself properly.
 - If I see an excellent doctor regularly, I am less likely to have health problems.
 - Other people play a big part in whether I stay healthy or become sick.
 - The type of care I receive from other people is what is responsible for how well I recover from an illness.
- 3) Economic Locus of Control (ref. 6) that focuses on a person's perception of how their financial well-being relates to individual choices versus other factors. Items include choices such as:
 - Saving and careful investing is a key factor in becoming rich.
 - I am usually able to protect my personal interests.
 - When I get what I want, it's usually because I worked hard for it.
 - My life is determined by my own actions.
 - Regarding money, there isn't much you can do for yourself when you are poor.
 - It's not always wise for me to save because many things turn out to be a matter of good or bad fortune.
 - It is chiefly a matter of fate whether I become rich or poor.

The study procedures will involve two phases: 1) an interview about the person's narrative (being in the Abecedarian Study since birth), current life situation, and administration of several standardized tools about health and economics (lasting about 90-120 minutes); and 2) a protocol in the MRI full body scanner (lasting about 60-70 minutes). The session will take place on one day. If the participant would like, a brief rest or meal time break can occur between the phases.

Each phase is described in detail below:

1) Interview and Assessment

We begin by asking the person to share with us what being in this research project since birth has been like. Next, we update information about the person's current residence, employment, income, relationship status, family composition, use of public welfare services, disability status, health status, health care (type and adequacy).

2) Neuroimaging protocol

During scanning, the individual will have structural measures collected, as well as images acquired during a resting state, when the individual is asked to simply relax and remain still (see resting state instructions attachment). Also, the individual will play two of the neuroeconomic games used in The Roanoke Brain Study and many other studies of adult decision-making and brain function.

In the event that the participant is ineligible (based on the MRI Screening form responses) or does not wish to complete the scanning portion, the participant will be provided the opportunity to play the games outside of the scanner at a computer in the lab. This will be an expansion of the "practice" session provided for all study participants.

References

1. Krueger, F., Grafman, J., & McCabe, K. (2008). Neural correlates of economic game playing. *Philosophical Transactions of the Royal Society B*, 363: 3859-74.
2. Kishida, K. T., & Montague, P. R. (2012). Imaging models of valuation during social interaction in humans. *Biological Psychiatry*, 72: 93-100.
3. Güth, et al. 1982. An experimental analysis of ultimatum bargaining. *Journal of Economic Behavior and Organization*, 3, 367-88.
4. (Book) Camerer, Colin F. *Behavioral Game Theory: experiments in strategic interaction*. 2003. Princeton University Press, Princeton, NJ.
5. Wallston, K. A., Wallston, B. S., & DeVellis, R. (1978). Development of the multidimensional health locus of control (MHLC) scales. *Health Education Monographs*, 6(2): 160-170.
6. Furnham, A. (1986). Economic locus of control. *Human Relations*, 39(1): 29-43.

5.2 DESCRIBE HOW DATA WILL BE COLLECTED AND RECORDED:

Study participants will be assigned a coded designation. Actual names and contact information will be kept in a locked file cabinet in our laboratory. Only personnel who are direct members of the research team will have access to personally identifiable information.

The primary data collected will be three types: personal narratives, structural and fMRI images, and interview and standardized assessment data. For structural and fMRI data, these will be collected on Siemens 3T MRI machines and stored onsite using secured servers. The behavioral stream of data and images acquired during the sessions be collected and recorded using NEMO, the lab's in-house software package. NEMO is the software that was developed at Baylor College of Medicine which allows us to create and execute multi-subject experiments via a TCP/IP network. NEMO is a client-server application written in Java and maintained by VT staff. This software has been used in thousands of experiments and has paved the way for groundbreaking results in the field of Neuroscience. Before the functionality of NEMO, it was difficult, if not impossible, to gather data in a perfectly synchronized, simultaneous manner.

Data from interviews and assessments will be recorded on laptops, directly online (for the literacy assessment), or via video documentation. For the MRI sessions, all data are recorded electronically. The story narratives will be recorded via videotape. In the event that a participant would prefer audio-recording only, we can accommodate this preference.

The additional research questions that Libbie Sonnier-Netto will ask over the phone, after receiving verbal consent, will be recorded on the data sheet and added to the data already on file for the participant.

5.3 DOES THE PROJECT INVOLVE ONLINE RESEARCH ACTIVITIES (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:	
<input type="checkbox"/>	www.survey.vt.edu , go to question 6.1
<input type="checkbox"/>	Blackboard, go to question 6.1
<input type="checkbox"/>	Center for Survey Research, go to question 6.1
<input type="checkbox"/>	Other
IF OTHER:	
Name of service / program:	
URL:	
This service is...	
<input type="checkbox"/>	Included on the list found at: http://www.irb.vt.edu/pages/validated.htm
<input type="checkbox"/>	Approved by VT IT Security
<input type="checkbox"/>	An external service with proper SSL or similar encryption (https://) on the login (if applicable) and all other data collection pages.
<input type="checkbox"/>	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 risks associated with fMRI are the same as those with conventional MRI. Movement or heating of metallic implants is a potential risk, and so subjects will be screened to exclude people with metallic implants, fragments, or pacemakers. Some individuals experience claustrophobic reactions in the scanner. Subjects will be informed of this prior to the study, but because it is sometimes difficult to predict who will have such a reaction. Any subject experiencing claustrophobia will be removed from the scanner immediately. There is no invasive component to this study, such as IV catheters, and so discomfort, bruising, or infection are not risks. The Siemens 3 T scanner has been approved by the FDA. However, there may be additional risks associated with scanning at 3 T compared to the conventional clinical scanners in the 1.5-2.0T range. These include:

1. Effect of the static field. There is no conclusive evidence for irreversible or hazardous bio-effects to acute, short-term exposures of humans up to 2.0 T (Shellock and Kanal, 1996). Studies have indicated some side effects at 4.0 T, namely unusual sensations including nausea, vertigo, and metallic taste (Schenck, 1991). However, there is no evidence that this is either irreversible or harmful. If subjects experience unusual sensations, they will be withdrawn from the scanner immediately.

2. Effect of the gradient field. MRI operates by rapidly changing small additional fields, called gradients. This will induce small electrical currents in any conductor, and thus could theoretically induce mild peripheral nerve stimulation. However, this is not substantially different at higher magnetic fields since the gradients are separate from the main magnet. There is no evidence that the effect of the gradients is any different at 3T than at 1.5 T. However, if subjects experience peripheral nerve stimulation, e.g. tingling or twitching, they will be withdrawn from the scanner immediately.

3. Effect of the RF electromagnetic field. The higher magnetic field strength requires that higher RF frequency pulses are used to excite the protons in the subject's brain. The limits of RF energy that can be

safely given to humans has been clearly defined by the FDA: a. The exposure to RF energy below the level of concern is an SAR of 0.4 W/kg or less averaged over the body, and 8.0 W/kg or less spatial peak in any 1 g of tissue, and 3.2 W/kg or less average over the head; or b. The exposure to RF energy that is sufficient to produce a core temperature increase of 1 degree C and localized heating to no greater extent than 38 degrees C in the head, 39 degrees C in the trunk, and 40 degrees C in the extremities, except for patients with impaired systemic blood flow and/or perspiration. We will adhere to the recommendations for the head. The scanner has a large monitor indicating the RF power level which can be limited to a specific maximum.

4. There is a small risk of the loss of subject confidentiality, but this risk will be minimized by the study staff, as explained in Section 5.2.

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

Every effort will be made to ensure that the subject is comfortable and to minimize risk during the study visit. A screening form will be collected to prevent any risk associated with metallic implants. As stated above, any subjects who experience claustrophobia, dizziness, or peripheral nerve stimulation will be withdrawn from the scanner. Subjects are provided with an emergency squeeze bulb to indicate to the operator that they would like to be removed from the scanner. The purpose of the emergency signal will be explained to all subjects prior to entering the scanner. The risk of loss of confidentiality for personal information, and fMRI images will be minimized by study staff as outlined in section 5.2.

The interviewer will remind each study participant that he or she may skip answering any questions that he or she chooses, and may end the session at any time. Similarly, while in the scanner, the study participant is encouraged to speak directly to us and let us know if he or she is uncomfortable and would like to stop or have a brief break and return. This can be readily accommodated. Most individuals adapt quite well, because the feelings related to being in the scanner are discussed with each participant in advance.

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

Benefits to study participants are primarily related to their feeling of contributing to science and the understanding of the important influences on a child's and adult's life in terms of having greater (or lesser) health and life adjustment. In the past, these study participants have expressed their enjoyment in continuing to be part of the Abecedarian Project. (Note: a number of the study participants and their mothers who are in the Control group have shared spontaneously with us that they have received many benefits from the help offered to them throughout the study. At all ages, whenever potential problems were detected, referrals and follow through occurred, in addition to the earlier benefits of nutrition, social services, and pediatric care in the first 5 years of life offered to both study groups. For society, the benefits extend to many aspects of public policy and delivery of high-quality early education programs to children born into poverty and high-risk family situations. The findings from prior assessments of the Abecedarian Project sample at younger ages have contributed to shaping early educational programs, policy standards, and monitoring more recent efforts to improve school readiness, social-emotional well-being, and health among children living in poverty. If these findings affirm the major hypotheses - namely, that there will be significant differences in brain structure and function, in middle age associated with the first 5 years of educational experience, then this will inform theories about brain development and about the importance of early education in contributing to more optimal brain development across the lifespan. Similarly, if there are differences related to educational attainment (regardless of the early educational treatment), these will be valuable additions to knowledge about brain health and function in middle age. To our knowledge, this would be the first prospective study that links brain development and function in middle age to early life experiences that were systematically manipulated (via the original RCT study design) and in a sample studied prospectively (rather than through retrospective recall or records only).

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:	
<input type="checkbox"/> Prisoners	
<input type="checkbox"/> Pregnant women	<input type="checkbox"/> Fetuses
<input type="checkbox"/> Mentally disabled persons	<input type="checkbox"/> Human in vitro fertilization

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: Each study participant will have an identifying number with the key stored in secured files in our lab. Contact information will be stored separately and not in the same location as the raw data to be collected. Videotapes will have a unique and different identifier that only links to brain imaging and other assessment data via the master key. This will prevent most research staff from being able to make any comparisons

across types of data that could violate the coders staying unaware (i.e., blinded) to the early life history of the study participants or to other outcome data obtained at this follow-up assessment.

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? The key will be stored in the Ramey and Ramey Human Development Lab master office on the second floor of the VTCRI in a locked file accessible only to the primary investigators and the local study coordinator, Ms. Laura Bateman. This will be in a room and file cabinets that are separate from all other completed data documents and videotapes.

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

In the central offices of the Ramey and Ramey Human Development Lab, all videotapes and interview and standardized assessment data will be stored in a secured physical file and in electronic files that are password protected and highly secure and available only to designated research staff on this project, The neuroimaging data will be stored in the VTCRI Human Neuroimaging Lab and accessible only to designated research staff for this project.

8.4 WHO WILL HAVE ACCESS TO STUDY DATA?

Only research staff named as part of this IRB submission (with possible future additions that would be pre-approved before joining and participating in any aspect of this research) and who maintain current IRB certification. We will maintain a record of all individuals who work on this project and have any form of access to these data. As an integral part of all our research, we convene all research staff at the start of a project and at least once a year to review the protection of human subjects for this study protocol. We also review responsible conduct and integrity in conducting research.

8.5 DESCRIBE THE PLANS FOR RETAINING OR DESTROYING THE STUDY DATA

Because this has been a landmark study in the field of human development, we propose that the final dataset to be collected will be retained and archived permanently. This is described in the informed consent statement. Earlier datasets from this project have already been stored at the University of Michigan where there is repository of longitudinal datasets with documentation about the studies.

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? Compensation spans both direct remuneration for the study participant's time and direct payment or reimbursement for costs of transportation, meals, and snacks, and possible modest costs to bring a companion. We will pay each study participant a total of \$550 this includes \$260 for their time and effort to travel here and to participate in the personal narratives and the interview portion of the follow-up study; \$290 to cover the round trip mileage from the Raleigh/Durham area (where the majority of the participants will be traveling from, if a participant travels from a different area (farther distance) we will need to compensate the difference using the TEM system) and 2 travel days of meals and incidentals for the participant and a friend or family member. (Note: before coming to Roanoke, we will discuss the specific travel and lodging arrangements with the participant.) Although direct assessments are projected to be 4 hours, many study participants may choose to spend most of the day here, with a lunch or snack break that could last an hour or so. The majority of the study participants are likely to come in the day before and spend the night at a local hotel (we propose the Cambria Suites that is a short walk from the VTCRI data collection site). We project many study participants will need to take two days off work to participate. Payments at prior adult assessments have been \$150, although we think this higher amount is justified given the large time investment and the need to travel out of town.

Neuroeconomic Games/Scanning Tasks: Participants may earn an additional \$0-\$40, based on their performance in the games. Thus, a participant may earn a total of \$260-\$300, depending on task payment.

Will compensation be prorated?

Yes, please describe:

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
<p>This project involves:</p> <p><input type="checkbox"/> Audio recordings only <input type="checkbox"/> Video recordings only <input checked="" type="checkbox"/> Both video and audio recordings</p>
<p>Provide compelling justification for the use of audio/video recording: We seek to collect a unique set of narratives, a form of data collection that is showing increasing promise as a complementary form of data of high potential value in longitudinal studies. The Abecedarian Study has data on the study participants' since birth; they will be in their early 40s at the time of obtaining these videotapes.</p>
<p>How will data within the recordings be retrieved / transcribed? We propose to develop a standardized method for identifying and coding key themes and expressions (verbal and affective) throughout the study participants' narratives. These will involve content analysis, inter-rater agreements, and data reduction. We also plan to create a full written transcript of the narratives.</p>
<p>How and where will recordings (e.g., tapes, digital data, data backups) be stored to ensure security? These will be stored in locked and secured physical and electronic files in the VTCRI Human Development Lab.</p>
<p>Who will have access to the recordings? Only trained research staff on this project will have access to these recordings. In the event that we later seek to show any portion of the video recordings, we would obtain prior written photo release from the study participants. This potential is mentioned in the informed consent statement as an option.</p>
<p>Who will transcribe the recordings? Trained research staff will do the transcriptions although we will explore whether existing voice-to-text programs can provide a reliable initial transcription. If so, we would have this be part of the transcription with a follow-up verification for the accuracy.</p>
<p>When will the recordings be erased / destroyed? We propose to include these in the permanent archive for the study.</p>

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
<p>Does this study involve conducting research with students of the researcher?</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes, describe safeguards the study will implement to protect against coercion or undue influence for participation:</p> <p><i>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.</i></p>

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:

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
<p>Does the project reasonably pose a risk of reports of current threats of abuse and/or suicide?</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes, thoroughly explain how the study will react to such reports:</p> <p><i>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.</i></p>
<p>Are you requesting a waiver of parental permission (i.e., parent uninformed of child's involvement)?</p> <p><input type="checkbox"/> No, both parents/guardians will provide their permission, if possible. <input type="checkbox"/> No, only one parent/guardian will provide permission. <input type="checkbox"/> 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:</p>
<p>Is it possible that minor research participants will reach the legal age of consent (18 in Virginia) while enrolled in this study?</p> <p><input type="checkbox"/> No <input type="checkbox"/> 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:</p> <p><i>For more information about minors reaching legal age during enrollment, visit the following link: http://www.irb.vt.edu/pages/assent.htm</i></p>
<p><i>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.</i></p>

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:
<p>Provide an explanation of how the study meets <u>all</u> the following criteria (A-D) for an alteration of consent:</p> <p>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):</p> <p><i>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.</i></p> <p><i>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.</i></p>

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? From prior funded assessments of this longitudinal cohort. Informed consent from study participants will permit data linking.
Provide a detailed description of the existing data that will be collected or studied/analyzed: Child's treatment group, participation level, and scores on standardized assessments of cognition, language, social-emotional development, and academic or educational attainment from ages 6 months – 35 years of age.
<p>Is the source of the data public?</p> <p><input checked="" type="checkbox"/> No, continue with the next question <input type="checkbox"/> Yes, you are finished with this application</p>
<p>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:</p> <ul style="list-style-type: none"> ▪ 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.

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