RUSH

SCRIPT FOR TELEPHONE CONSENT/AUTHORIZATION FOR PARTICIPATION IN PRESERVING COGNITIVE RESILIENCE: A BIRACIAL PARENT-OFFSPRING STUDY

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Protocol Title: **Preserving Cognitive Resilience: A Biracial Parent-Offspring Study**
Sponsor(s): **The University of California, Davis and The National Institute on Aging**

Name of Participant: _____

The <u>Key Information</u> Is:
You are being invited to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

I will now give you information about the study to help you decide whether you want to participate. Please ask any questions you have, before agreeing to be in the study.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study at a later time, your health care, benefits, or relationship with Rush University Medical Center will not change or be affected.
The purpose of this study is to better understand how to maximize and preserve cognition, the ability to think and reason, by studying the connections between people's cognition and the cognition and other characteristics of their parents and themselves. These characteristics include whether these connections differ between men and women or between blacks and whites, or differ according to differences in diet, health habits, genetic factors, life experiences and events, social factors, neighborhood characteristics, heart and vascular factors, medication use, and personality and feelings.

If you agree to participate in this study, your participation may last up to five years, and you will be asked to complete two telephone interviews and two brief in-person visits in your home or in a study office as you choose. It is possible that you will be asked to continue for a longer period if warranted by the initial results.

During the telephone interviews you will be asked about your health, and activities that may affect your health such as smoking and physical activity, and your feelings, and brief tests of your thinking (cognition) will be administered. The visits will include a

measurement of how fast blood flows from your chest to your legs, measurement of your blood pressure and weight, identifying any medications you take, and drawing about two tablespoons of blood.

You will also be asked to have a two-tablespoon sample of blood drawn (Those unwilling or unable to comply with this blood collection request will be asked to provide a specimen of DNA for genetic analyses via a swab of the inside of the cheek.) and to have a magnetic resonance imaging (MRI) examination of the head. This examination is used to detect damage to the brain, such as damage from a stroke, as well as changes that may occur with aging For a detailed list of study procedures, please see the "What are the activities you will be doing if you participate in this study?" section of this consent form.

There are risks to you for participating in this study. In drawing a blood sample, you may experience pain or discomfort, and/or bleeding, and bruising at the site the needle enters the body, and in rare cases, fainting or infection. The tests of your memory and thinking and the evaluation of the function of your nerves and of your emotions may make you uncomfortable at times, despite being designed to be comfortable and highly acceptable. If health problems are found at the MRI examination, discussing them may give rise to feelings of stress, especially if the finding of a problem is later found to be incorrect in any way. You will be excluded from the MRI procedure if you have a heart pacemaker, a history of surgery for an aneurysm or blood vessel surgery, ear surgery, any embedded metallic foreign objects, or other metallic implants. There is a remote possibility of loss of confidentiality of the information you provide or of the results of the laboratory examinations of the blood sample, including results of the genetic tests, despite the safeguards to confidentiality noted below.

I will give you a detailed list of risks you should know about in a few moments in the "What are the risks and discomforts of participating in this study?" section.
You may not directly benefit from taking part in this study, but we hope that knowledge gained from this study may benefit others through a better understanding of the connections between people's cognition and the cognition and other characteristics of their parents or themselves

This is not a treatment study. Your only other option to participating in this study is not to participate.

<u>The Detailed Information Is</u>: I will now give you additional information about the study to help you decide whether you want to participate.

<u>Why are you being invited to participate in this study?</u>
You are being asked to participate in this study because one or both of your parents participated in the Chicago Health and Aging Project (CHAP).

<u>How many participants will take part in this study?</u>
Approximately 1100 participants are expected to take part in this study

Does this study involve tissue/blood banking?
Yes, it does. Tissue and/or blood banking is the long-term storage of your samples into a repository (or sample bank).

As the overall study is collaborative, with this subcontract from the University of California, Davis (UCD) to Rush University Medical Center (RUMC) for data collection and study leadership of the overall study at UCD, there will be repositories for both information and tissue at both RUMC and UCD. This includes all relevant existing information from previous studies including the Chicago Health and Aging Project (CHAP), information from interviews and testing, including the results of tests of memory and thinking, blood test results, blood pressure measurements, measurement of carotid femoral pulse wave velocity (CFPWV), blood pressure (BP), height, weight, waist circumference, and magnetic resonance imaging (MRI). Frozen samples of blood serum and DNA extracted from cheek swab specimens will also be deposited and stored at both RUMC and UCD.

This information will be stored in restricted access computer files and the specimens in locked freezers or storage cabinets at both RUMC and UCD for as long as possible and may be used in future studies. Information and specimens will be available only to scientists who have approval to do research studies.

The purpose of these repositories is to collect information and blood and tissue specimens that have the potential to be useful in examining a very broad range of issues relevant to the health of older persons for storage and future research.

These repositories will consist of information in computerized and paper records and of blood specimens. No one has access to the storage bank for research purposes except for Dr. Denis A. Evans and persons working directly under his supervision for the RUMC repository and Kumar B. Rajan and persons working directly under his supervision for the UCD repository.
If you agree, all information you provide through your participation in this research project will be deposited in these repositories. This includes information from your interview and testing, including the results of tests of memory and thinking, blood test results, blood pressure measurements, measurement of how fast blood flows from your chest to your legs, magnetic resonance imaging (MRI), measurement of height and weight. The cells and all other materials included in all blood samples you provide while participating in this study also will be deposited in the repository. This includes red blood cells, white blood cells, blood plasma, blood serum and DNA extracted from white blood cells and cheek swab specimens. This information will be stored in restricted access computer files and the specimens in locked freezers or storage cabinets at RUMC or UCD. Since we do not yet know the exact questions that will be studied by scientists in the future, we cannot tell you what specific information they will be looking at or what that might mean to you. The information and tissue specimens in the storage bank will be available only to scientists who have approval to do research studies

Does this study involve genetic testing?
Yes, this study involves use of DNA from some of the blood sample that you provide for genetic testing. The genetic material will be stored for use in studying these health problems for as long as possible, at least a period of several years. (See Section: Does this study involve tissue/blood

banking? above.)The use of genetic material in research to study the causes of disease and to help understand how individuals respond to drug treatments is called genetic research. The cells of your body contain a molecule called deoxyribonucleic acid (DNA). DNA is received from your parents and carries a code in the form of genes, which determine your physical characteristics such as the color of your hair and eyes. Ribonucleic acid or RNA for short also acts as a messenger to tell your cells to produce certain features. Just as differences in our genetic codes help explain why we all look different, these differences can also help explain why some people develop certain diseases and others do not. They may also help explain why some drugs are safe and effective for some people but not for others.

What do you need to know regarding the collection of biospecimens?
Biospecimens may include blood, tissue, urine, bone marrow, saliva, cells, etc. In this study, we will collect blood samples and cheek swabs. Most biospecimens contain DNA. We may use biospecimens collected as a part of this study for whole genome sequencing, which involves mapping (identifying the location of genes and the distance between them) of all of your DNA. Information from genetic testing will not be provided back to you. Information will be stored in repositories at RUMC and UCD a repository as I mentioned in the "Does this study involve tissue/blood banking?" Section.

Will your information or biospecimens be used for research in the future?
Information or biospecimens collected from you for this study may be used for future research or shared with other researchers. If this happens, information which could identify you will be removed before any information or biospecimens are shared. Since identifying information will be removed, you will not be asked for additional consent as I mentioned in the "Does this study involve tissue/blood banking?" Section.

Will your cells, tissues, blood or other biological materials (biospecimens) be used to develop commercial products?
Yes, your biospecimens may be used to develop a commercial product. Such use is unlikely and not presently planned, but if a commercial product is developed from the biospecimens collected as part of this study (even if your identifying information is removed), you will not profit financially from such a product as I mentioned in the "Does this study involve tissue/blood banking?" Section.

Will you be contacted about participating in future research?
If you agree, we may contact you after your participation in this study about participating in future research.

If you agree to be contacted about future research, please indicate this by saying "yes" at this time. If you do not agree to be contacted about future research, please indicate this by saying "no" at this time.

Initial and date the option chosen:
YES agrees to be contacted about future research: Initials Date _____ _____
NO does not agree to be contacted about future research: Initials Date _____ _____

What are the risks and discomforts of participating in this study?

Side effects, risks, and/or discomforts from participation in this study may include: • In drawing a blood sample, you may experience pain or discomfort, and/or bleeding, and bruising at the site the needle enters the body, and in rare cases, fainting or infection.

- The tests of your memory and thinking and the evaluation of the function of your nerves and of your emotions may make you uncomfortable at times, despite being designed to be comfortable and highly acceptable.
- If health problems are found at the MRI examination, discussing them may give rise to feelings of stress, especially if the finding of a problem is later found to be incorrect in any way. You will be excluded from the MRI procedure if you have a heart pacemaker, a history of surgery for an aneurysm or blood vessel surgery, ear surgery, any embedded metallic foreign objects or other metallic implants.
- There is a remote possibility of loss of confidentiality of the information you provide or of the results of the laboratory examinations of the blood sample, including results of the genetic tests, despite the safeguards to confidentiality noted below even though records of participation in this research project will be maintained and kept confidential to the extent permitted by law. Some of the steps in this research will be conducted at the University of California, Davis, and identifiable information will be shared with University of California, Davis researchers. An identification number will be assigned to the data you provide, and the link between this number and your identity will be maintained in a separate restricted file.

What are the risks involving genetic information?

While we believe that the risks to you and your family are very low, we are not able to know all of the risks from taking part in genetic research. Your privacy will be protected to the fullest extent possible. Certain health concerns that affect you and your blood relatives might be found as inherited traits are studied. Even though your genes are unique, you share some of the same genes with your blood relatives. Genetic information is considered health information and is protected under the Health Insurance Portability and Accountability Act (HIPAA) as is your other health information. While very rare, information could be misused by employers, insurance companies and others. For example, life insurance companies may charge a higher rate based on this information. A federal law called the Genetic Information Non-Discrimination Act (GINA) should help lower the risk from unfair health insurance or employment policies. To learn more about the GINA Law, please go to http://www.ginahelp.org/GINAhelp.pdf or ask the study staff.

What if there is new information that may affect your decision to participate in this study?

During this study, you will be told about important findings (either good or bad), such as changes in the risks or benefits of participation in the study or new choices to participation that might cause you to change your mind about being in the study. If new information is shared with you, you may be asked to sign a revised consent form in order to continue participating in this study.

Will you receive your individual results from the study?

Generally, activities performed for research purposes are not meant to provide clinical information. We may learn things about you from this study which could be important to your health or treatment. If this happens, this information will be shared with you. Your blood pressure and blood cholesterol results will be shared with you. The study will not cover the costs of any follow-up actions outside of the study.

Can you leave or be removed from this study?

You have the right to leave a study at any time without penalty. For your safety, however, you should consider the study doctor's advice about how to leave this study. If you leave this study before the final study visit, the study doctor may ask you to complete the final steps.

The researchers and sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You do not follow the instructions;
- The study is cancelled for any reason.

What about confidentiality of your medical information?

This authorization is voluntary. Rush University Medical Center and its affiliates ("Rush") will not withhold or refuse your treatment, payment, enrollment, or eligibility for benefits if you sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study or receive study-related treatment.

By signing this document, you voluntarily authorize (give permission to) Dr. Denis A. Evans, his study team, and other Rush personnel involved with the conduct and review of this study (which may include off-site personnel) to use or disclose (release) health information that identifies you for the study described in this document.

During the study, Dr. Denis A. Evans and his study team will collect Protected Health Information (PHI) about you for the purposes of this research. PHI is your health information that includes your medical history and new information obtained as a result of this study. Some of this information will come from your medical record. The health information that Rush may use or disclose for this research includes all information in your medical record.

Dr. Denis A. Evans and his study team may share your health information and the results of your study-related procedures and tests with people outside of Rush who assist with the conduct and review of this study. The persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. Your health information described above may be used or disclosed to:

- To the Researchers at the University of California, Davis.
- The study Sponsor, the University of California, Davis, and its representatives
- Monitoring agencies such as the Food and Drug Administration (FDA), the National Institutes of Health and the Rush Institutional Review Board (IRB).
- Quest Diagnostics
- Franciscan Health

While you participate in the study you will have access to your medical record, but Dr. Denis A. Evans is not required to release your study information that is not part of your medical record. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. The results of study tests/procedures performed as part of this study may become part of your medical record. Any study information in your medical record will be kept indefinitely. Your identity will not be revealed on any report, publication, or at scientific meetings. You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed above.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. Denis A. Evans at Rush University Medical Center, Suite 245, 1700 W. Van Buren, Chicago IL 60612. If the authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.
This authorization is valid for the entirety of this research study. It will expire upon completion of the study or if you revoke (take back) the authorization.
If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.
Records of participation in this study will be maintained and kept confidential as required by law. An identification number will be assigned to the data you provide, and the link between this number and your identity will be maintained in a separate restricted file.
The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

If you disclose actual or suspected abuse, neglect, or exploitation of a child, or disabled or elderly adult, the researcher or any member of the study staff must, and will, report this to Child Protective Services (such as the Department of Family and Human Services), Adult Protective Services, and/or the nearest law enforcement agency.

What are the costs to participate in this study?
There are no costs to you for participating in this research.

Will you be paid for your participation in this study?
You will be paid $50.00 by check for the time and inconvenience involved in providing a blood sample and $50.00 by check for the time and inconvenience of undergoing an MRI examination. If you do not finish this study, you will be paid for the study blood draw or MRI Examination you have completed. You will be paid within approximately 60 days. You will be paid in full after the Blood draw or MRI examination. We may need to collect your social security number or Taxpayer Identification Number (TIN) in order to pay you and for tax reporting purposes to the United States Internal Revenue Service (IRS).

What if you are injured as a result of your participation in this study?
If you get ill or injured from being in the study, Rush University Medical Center will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Denis A. Evans at telephone number (312) 942-3350.
You should let any health care provider who treats you know that you are in this study. If you do seek medical treatment, please take a copy of this document with you because it may help the

doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact your study doctor.
You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial.
Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.
By signing this form, you are not giving up any legal rights to seek compensation of injury.

Who can you contact for more information about this study?
Questions are encouraged. If you have further questions about this study, you may call Ms. Colleen Plunkett, the Study Coordinator, at (312) 942-3350 or email her at Colleen_M_Plunkett@Rush.edu.

Who can you contact if you have concerns about your rights as a study participant?
Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?
Taking part in this study is voluntary. If you choose not to participate in this study or to leave the study at any time, your health care, benefits or relationship at Rush University Medical Center will not change or be affected.

If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Denis A. Evans in writing. Dr. Denis A. Evans may still use your information that was collected prior to your written notice.

If you wish to participate in this research project, please indicate this by saying "yes" at this time. If you do not wish to participate, please indicate this by saying "No" at this time.

_____ _____
Print name of subject Date

_____ _____
Signature of study staff member obtaining this Informed Consent via telephone Date

SIGNATURE OF THE PRINCIPAL INVESTIGATOR:
I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

_____ _____
Signature of the Principal Investigator Date of Signature