

RESEARCH CONSENT FORM

Basic Information

Title of Project: **Chronic Stress and Aging**

IRB Number: H36684

Sponsor: Alzheimer's Association

Principal Investigator: Karin Schon, Ph.D.
cogmood@bu.edu
72 E. Concord Street L-1004
Boston, MA 02118

Study Phone Number: (617) 358-2018

Background

This pilot study will examine whether chronic stress due to experiences of racism negatively affects brain function in two subgroups of Black older adults. A larger percentage of African Americans than Americans of European ancestry have Alzheimer's disease. The reasons for this health disparity are unclear. Discrimination related to racial minority status – racism – is a known chronic stressor. The Alzheimer's health gap may, in part, be explained by differences in racism-related chronic stress. Experiences of racism are common among African Americans, the largest minority group in the United States. The hippocampus is a brain area critical for memory formation. It is impacted by both Alzheimer's disease and chronic stress. Hippocampal function is the focus of this study.

We are asking you to take part in this research study because you are between the ages of 50 and 80 years.

Your participation in the study will take place over the course of approximately one week. There will be two separate study visits.

The research study is sponsored by the Alzheimer's Association. The person in charge of this study is Dr. Karin Schon. Dr. Schon can be reached by telephone at 617-358-2118. Or she can be reached by email at kschon@bu.edu. We will refer to this person as the "researcher" throughout this form.

Purpose

The purpose of this study is to understand the relationship between chronic stress and cognition (thinking) in older African American adults. There is an area of the brain called the hippocampus. The hippocampus continuously gives birth to new brain cells, even as we age. This brain area is important for learning and memory. The hippocampus is negatively impacted by chronic stress. This can affect thinking and memory. The purpose of this research study is to investigate whether chronic stress due to

Project Title: Chronic Stress and Aging
Principal Investigator: Karin Schon, Ph.D.

experiences of racism will impact the function of this brain region. To examine this question we will compare two groups of African American older adults.

The purpose of this research is to examine whether African American older adults who experience higher levels of chronic stress due to experiences of racism will show poorer cognition and hippocampal function. In addition, this research will measure elevated salivary cortisol, known as the 'stress' hormone. Cortisol is a physical marker of the stress response. It can be measured in saliva. We will also examine other stressors. These other stressors include those related to socioeconomic status and health. First, we will examine whether racism-related chronic stress in African American older adults could lead to poorer cognition, higher levels of cortisol, and a dysfunctional hippocampus. We will then compare African American older adults living in the City of Boston with those living on St. Croix in the United States Virgin Islands. African Americans living in the City of Boston are members of the racial minority, whereas African Americans living on St. Croix are members of the racial majority. Racial minority status may impact how often people experience discrimination due to race.

What Will Happen in This Research Study

You will be one of approximately 60 subjects to be asked to participate at this location at **Boston University School of Medicine**. A total of up to 120 subjects at all institutions will be asked to participate in this study.

The research will take place at the following location(s): Boston University School of Medicine and the University of the Virgin Islands, St. Croix.

Study Overview

We expect that you will be in this research study for *approximately 1 week, undergoing two study visits*. During this time, we will ask you to complete two visits. The first visit is for informed consent and screening, and obtaining body measures like waist and hip circumference and blood pressure. The second visit is for cognitive testing and further neuropsychological testing. At both study visits you will be asked to fill out several questionnaires.

Overview of Study Visits

Visit #	Description	Duration	Location	Notes
1	Informed consent, screening, questionnaires	Approx. 1.5 - 2 hours	Boston University School of Medicine	Completed during first visit
2	Cognitive testing, saliva sampling, neuropsychological testing, questionnaires	Approx. 1.5 – 2 hours	Boston University School of Medicine	Completed approx. within one week of visit 1

Description of Study Visits

Study Visit 1: Informed consent and screening

Study visit 1 will take about 1.5 to 2 hours to complete. If it is your preference, we may schedule the informed consent and screening separately. At this visit, we will do the following procedures:

Project Title: Chronic Stress and Aging
Principal Investigator: Karin Schon, Ph.D.

- Ask you to fill out questionnaires about your overall physical health. This will include questions about your brain health, cognition, heart and blood circulation, oral health, vision, mood and anxiety, mental and emotional health, exercise and physical activity habits, and stress; biographical and socio-demographic information
- Ask about your medical and mental health history
- Ask about your prescription medications
- Ask you to complete questionnaires on the computer
- Measure your height, weight, waist circumference, and hip circumference. You will keep your clothes on for the measurements, but you will be asked to remove shoes, jackets, and heavy sweaters.
- Brief screening for dementia
- Interview you about your experiences with discrimination.

Location: We will perform the screening at the Boston University School of Medicine, General Clinical Research Unit. Access is through the Instructional Building at 72 East Concord Street, L Building.

What will happen next? If you are eligible to participate in the research study, we will continue with cognitive and neuropsychological testing and schedule you for the second study visit. The following section describes the remaining study visit.

Study Visit 2: Saliva sample collection, cognitive testing, and neuropsychological assessment

Study visit 2 will take approximately one and a half to two hours to complete. At this visit, we will do the following procedures:

- Collect saliva only, using the passive drool method
- You will perform cognitive (thinking) tasks associated with learning and memory and with forming unconscious associations
- Undergo neuropsychological testing to assess your cognitive functioning. This assessment will include tests of memory, processing speed, attention, visual-spatial functioning, executive functioning, and language
- Complete a questionnaire on self-perceived social status and socioeconomic status

We will ask you not to eat a major meal (e.g. breakfast) within one hour of saliva collection. We will also ask you not to eat foods with high sugar or acidity or drink caffeinated beverages immediately before the saliva collection. We will also ask you not to engage in strenuous physical activity for 24 hours before the tests.

Location: Study visit 2 will take place at the Boston University School of Medicine campus, General Clinical Research Unit (GCRU). The address of the GCRU is 72 East Concord, Boston, MA.

What is the time commitment? The time commitment is approximately three to four hours across two study visits. These visits will be scheduled within a week of each other.

If you agree to take part in this study, we will ask you to sign the consent form before we do any study procedures.

Risks and Discomforts

Risks of completing tasks and questionnaires:

You may get tired during the cognitive tasks. The testing procedures include breaks and you can rest at any time, except during timed tasks. You may feel emotional or upset when answering some of the

Project Title: Chronic Stress and Aging
Principal Investigator: Karin Schon, Ph.D.

questions. We will ask you to let the interviewer know at any time if you want to take a break or stop the interview. You will not be required to answer any questions that make you feel uncomfortable. However, you may be excluded from participating in this study if we cannot determine whether you meet the study criteria.

Risks associated with obtaining and storing saliva samples and loss of confidentiality.

There are no physical risks associated with providing a saliva sample. The risks associated with obtaining and storing saliva samples are primarily related to a potential loss of confidentiality. That is, if the data obtained from the sample were linked to you personally, it could potentially have undesirable consequences. The main risk of using and storing information for research is a potential loss of confidentiality.

Other Risk/Discomforts:

There may be unknown risks/discomforts involved. Study staff will update you in a timely way on any new information that may affect your health, welfare, or decision to stay in this study.

Protections against Risks and Discomforts

Risks associated with completing tasks and questionnaires

We will ask you to let the interviewer know at any time if you want to take a break or stop the interview. You are not required to answer any questions that make you feel uncomfortable. However, you may be excluded if it cannot be established whether or not you meet the inclusion and/or exclusion criteria. The testing procedures include breaks and you can rest at any time, except during timed tasks.

Risks associated with saliva sample collection and loss of confidentiality

We will code all biomarker data. We keep the code in a password-protected computer separate from the research data or as a paper file in a locked file cabinet. We will protect the confidentiality of the biomarker data by storing them on secure servers or on a password-protected desktop computer or secure fileserver. All research staff are trained in human subject protection. We will protect each participant's confidentiality by labeling identifiable information with a code and keeping the key to the code separately from the research data either in a password-protected computer or as a paper file in a locked file cabinet. The master code is limited to Boston University investigators, and we will not release it to anyone outside the institution. Information will be stored on secure servers or on a password-protected desktop computer or secure fileserver.

Potential Benefits

You may or may not benefit from taking part in this study.

Others may benefit in the future from the information that the investigators will learn from this study. These potential benefits may include knowledge about how chronic stress due to experiences of racism affects the brain and cognitive (thinking) processes. However, you may not receive any benefit from participating.

Costs

There are no costs to you for being in this research study.

Project Title: Chronic Stress and Aging
Principal Investigator: Karin Schon, Ph.D.

Payment

For your participation in this study, you will be compensated either via check, gift card, or cash in the amount of \$30.00 per visit. If you withdraw, compensation for each study visit completed will be sent via check for each study visit completed.

There are no costs to you for participating in this research study, but you will be compensated for your time.

We will compensate you the following amount for each study visit that you complete:

- | | |
|------------------|------|
| - Study visit 1: | \$30 |
| - Study visit 2: | \$30 |

Transportation and parking: You will be compensated for public transportation or metered parking costs as needed. You will receive reimbursement up to \$20, \$10 per study visit.

Confidentiality

We will do our best to keep your information safe. However, we cannot guarantee confidentiality.

Federal and state agencies, if they are required by law or are involved in research oversight, may access information about you from this study. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.

We will protect each participant's confidentiality by labeling identifiable information with a code and keeping the key to the code separately from the research data in a password-protected computer and/or as paper files in a locked file cabinet. The master code is limited to investigators at Boston University Medical Center (BUMC). We will not release it to anyone outside the institution. Information will be stored on secure servers.

We will keep the data for a minimum of seven years and possibly longer following the completion of the research study. We will shred paper data and non-erasable media (e.g. CD-ROMs, DVDs). We will destroy electronic data on media intended for reuse (e.g. hard disk drives, USB storage devices, etc.) using specialized software.

Information from this study may be reviewed and photocopied by the Food and Drug Administration (FDA) and/or state and federal regulatory agencies such as the Office of Human Research Protection as applicable, and the Institutional Review Board of Boston University Medical Center. Information from this study may be used for research purposes and may be published. However, your name will not be used in any publications. Your information may also be used by non-research staff within BUMC who need this information to do their jobs (for example, for processing payments) and by people or groups who we hire to do work for us, such as data storage companies, insurers, and lawyers.

We might use our research data and data from your biological samples in future studies. These future studies might be done by us or by other investigators. Before we use your data or data from your biological samples, we will remove any information that shows your identity.

Re-Contact

Project Title: Chronic Stress and Aging
Principal Investigator: Karin Schon, Ph.D.

We would like to ask your permission to contact you again in the future. This contact would be after the study has ended. Please initial your choice below:

____ Yes ____ No You may contact me again to ask for additional information related to this study

____ Yes ____ No You may contact me again to ask for additional biological samples related to this study

____ Yes ____ No You may contact me again to let me know about a different research study

Subject's Rights

By consenting to be in this study you do not waive any of your legal rights. Consenting means that you have been given information about this study and that you agree to participate in the study. You will be given a copy of this form to keep.

If you do not agree to be in this study or if at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you. Your decision will not affect your ability to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

We may decide to have you stop being in the study even if you want to stay. Some reasons this could happen are if staying in the study may be bad for you, or if the study is stopped.

Questions

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact Dr. Karin Schon at (617) 358-2118 during the day and at (617) 744-9023 after hours. Also call if you need to report an injury while being in this research.

You may also call 617-358-5372 or email medirb@bu.edu. You will be talking to someone at the Boston Medical Center and Boston University Medical Campus IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

Project Title: Chronic Stress and Aging
Principal Investigator: Karin Schon, Ph.D.

Subject: _____
Printed name of subject

By signing this consent form, you are indicating that you have read this form (or it has been read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study.

Signature of subject
Date

Researcher: _____
Printed name of person conducting consent discussion

I have personally explained the research to the above-named subject and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.

Signature of person conducting consent discussion	Date
---	------

Project Title: Chronic Stress and Aging
Principal Investigator: Karin Schon, Ph.D.

OPTIONAL - Study Visit 2: Brain Imaging (fMRI)

You may also have an MRI if you meet certain requirements and are interested in participating in this portion of the study. If you opt to have an MRI, we will do the following additional procedures at this visit, **lasting an additional hour**:

- During the MRI, we may monitor your heart rate, breathing rate, and pulse.

Description of MRI procedures: An MRI is a test that uses a magnetic field and pulses of radio wave energy to make pictures of organs and structures inside the body. During the MRI, we will ask you to lie still on a table that slides into a tunnel-shaped machine. The machine is slightly wider than your body. The top and sides of the tunnel will be very close to your body. The MRI machine makes loud noises as it takes pictures of the insides of your body. We will give you earplugs to reduce the noise. You will be able to hear and speak to the research staff at all times during the MRI procedures. However, we will ask you not to speak during any scans unless there is an emergency (for example, you feel claustrophobic or sick). The researcher and/or the MR technologist will be in contact with you throughout the study. You may terminate your participation in the study at any time (even during a scan). We can stop the procedure at any time, if necessary. The MRI will take about one hour.

When in the scanner, please breathe quietly and stay still. We will begin by taking some preliminary pictures of your brain. During this time, the scanner will make some knocking noises; do not be alarmed. Soon after this, functional MRI scans will begin, at which time the noises will become louder and higher-pitched. We will ask you to look at a fixation dot while you are inside the MRI scanner.

We may take measurements of blood pressure, heart rate, and/or pulse immediately before entering and immediately after exiting the fMRI scanner room.

Location: We will meet at the General Clinical Research Unit on the Boston University Medical Campus. The General Clinical Research Unit is located at 88 East Newton Street, Evans Building, eighth Floor, Boston, MA (access is through the Instructional Building at 72 East Concord Street, L Building). Note this is the same location as that of the first study visit. We will then escort you to the nearby Center for Biomedical Imaging. The Center for Biomedical Imaging is located at 650 Albany Street (X-B01) on the Boston University Medical Campus. The imaging center is a short walk from the General Clinical Research Unit.

Payments

Participants who complete the optional MRI will receive a 25-dollar finishing bonus.

MRI risks

There are no known harmful effects from the strong magnetic field used for MRI. However, the magnet is very powerful. The magnet may affect pacemakers, artificial limbs, and other medical devices that contain iron. The magnet will stop a watch that is close to the magnet. Any loose metal object has the risk of causing damage or injury, because the magnet can pull it toward its center. You may experience claustrophobia (fear of small spaces) or anxiety while in the magnet, because the top and sides of the machine will be very close to the body. During the MRI scan the MRI scanner will make loud, knocking

Project Title: Chronic Stress and Aging
Principal Investigator: Karin Schon, Ph.D.

sound that may cause hearing damage without protection. The MRI scan that you will be undergoing is for research purposes and has no clinical diagnostic value. If the members of the imaging center or researchers on this project notice any unexpected, gross abnormalities in the scan, they will be pointed out to you. In this event, you will be provided with a copy of the relevant scans and encouraged to follow up with your own physician.

Protection against MRI Risks

We will ask you to let the interviewer know at any time if you want to take a break or stop the MRI. If you have any metal in or on your body that you cannot remove we will exclude you from participating in the study. The MR technologist will screen you for metal with a metal wand. You should not participate in this study if you are claustrophobic. Because of the loud knocking sounds during the MRI, you will be required to wear earplugs. Earplugs will be provided to you. If you feel anxious during the procedure, you may ask us to stop the MRI at any time. The MR technologist and the study staff are trained in magnet safety.

Subject: _____
Printed name of subject

By signing this consent form, you are indicating that you have read this form (or it has been read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study.

Signature of subject _____ Date _____

Researcher: _____
Printed name of person conducting consent discussion

I have personally explained the research to the above-named subject and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.

Signature of person conducting consent discussion	Date
---	------