

**Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT**

TITLE OF RESEARCH: Biological Pathways in Stress Reactivity and Nicotine Addiction among African American and White Smokers

You are being asked to participate in a research study to learn more about how stress and other factors are related to smoking behaviors among men. If you choose to participate, you will be asked to take part in four laboratory study visits that involves providing urine and saliva samples, participating in a social stress test. You will be asked to also complete at home saliva collection and smoking assessments at 4- and 8-weeks after your second laboratory visit. You may experience some mild discomfort with having biospecimens collected, participating in the social stress test, and answering questions about personal factors that impact your life. However, these are minimal risks, and if you do become distressed you will be offered an opportunity to stop your participation at any time and be referred to a medical specialist, if needed. You may also potentially experience a loss of privacy as a result of providing information about your past medical history and personal health behaviors. There will be no direct benefit to you for participating in this study, but the findings from this study will improve our understanding of factors related to smoking among African American and white men. Findings from this research will be used to improve smoking cessation and tobacco use prevention programs. Participating in a research study is voluntary and you can decline to participate in this research.

A. PURPOSE OF THE RESEARCH

Please read this consent form carefully and take your time making your decision. As a study staff member discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand.

You are being asked to participate in this study because you are a current smoker. The study is sponsored by the National Cancer Institute. The investigator in charge of this study at MUSC is Dr. Gayenell Magwood. The study is being done at MUSC as part of a Research Center called the Translational Research Center in Lung Cancer Disparities (TRACER) that also involves Virginia Commonwealth University (VCU), and the City of Hope Comprehensive Cancer Center (COH). Approximately 100 African American and white men will participate in this study.

B. PROCEDURES

We are taking the necessary precautions according to MUSC COVID-19 policies and CDC guidelines to ensure your safety and protect your health during the study procedures described below. We will implement social distancing and you will also be required to wear a mask during the laboratory visits. If you do not have one, one will be provided for you. If you agree to be in this study, the following will happen to examine how stress responses influence smoking behaviors among African American and white men who smoke cigarettes.

Approximately 100 men will take part in the following study activities. This study will involve four laboratory visits that will include a pre-challenge visit (lab visit 1) to collect biospecimens; a stress exposure visit (lab visit 2) that will involve conducting the Trier Social Stress Test (TSST); and two additional visits (lab visits 3 and 4) at 4- and 8-weeks after the TSST visit to collect saliva samples.

1. At your first laboratory visit the following will occur.

- To determine final eligibility to continue study participation, you will be asked to provide a urine sample to examine any traces of drugs or other chemicals in your body. No more than 4 ounces of urine will be obtained for this test. You will also be administered a survey to assess your mental status. If you are found to have any traces of non-prescribed drugs, or are found to have mental distress, you will not be eligible to continue your participation in the study, and no further contact will be made. If eligible, you will be scheduled for the second laboratory visit described below and continue participating in the study.
- You will be asked to provide a swab of your saliva to examine a stress hormone that can be found in your saliva.
- You will also be asked to exhale in a breath monitor to measure levels of a chemical called carbon monoxide that is found in tobacco-related products and associated with cigarette smoking. You will be asked to inhale deeply and hold your breath for 15 seconds, then exhale slowly into the breath monitor.
- If you provide permission, samples of your urine and saliva will also be kept and stored in a biorepository for future research aimed at improving health outcomes. We will obtain saliva using a swab similar to a Q-tip that you will insert underneath your tongue to collect your saliva. Approximately 4 ounces of urine will be obtained in a sterile collection cup.
- No identifiable information pertaining to you will be linked to your urine and saliva samples when it is used in future research.

2. At the second laboratory visit, you will participate in a one-time stress test to examine how you react to stressful situations. During the stress test, the following procedures will happen:

- Your blood pressure, heart rate, and a stress hormone in your saliva will be looked at five times during the visit. Your saliva will be collected by inserting a small sponge stick in your mouth, similar to a Q-tip, and placing it under your tongue for up to 2 minutes.
- You will be asked to participate in an activity that will require you to speak in front of a group of people that includes a mock job interview where you will be asked to describe your dream job for 5 minutes. Immediately after the interview task you will be asked to participate in an oral math task for 5 minutes.

- Additionally, you will be asked to rate your urge to smoke and be given the option to smoke a cigarette through a smoking assessment tool immediately after the stress test is completed.
3. At 4- and 8-weeks following the second laboratory visit, you will be mailed instructions and materials for collecting saliva and completing smoking assessments at home. You will be asked to use a saliva kit to collect your saliva and to keep a collection log to track and keep a record of your smoking behaviors throughout the day. Saliva will be collected at fixed intervals (upon wakening, 30-minutes after wakening, 4:00 pm, and 6:30 pm). Your final saliva sample at 6:30pm will be conducted in-person at the laboratory during visits 3 and 4. During those visits, you will return the saliva samples and smoking assessments collected at home during the course of the day to the study staff.

C. DURATION

If you decide to participate in this study, you will be asked to participate in four laboratory visits. The first laboratory visit will take approximately 45 minutes and will include saliva and urine collection and completing a mental health assessment.

The second laboratory visit will take approximately 1 hour and 30 minutes and will include clinical tests (i.e. blood pressure, heart rate), saliva collections, a 10-minute stress test, and a smoking assessment that could last up to 20 minutes following the stress test.

The third and fourth laboratory visits will occur at 4- and 8-weeks following the second lab visit and will take approximately 30 minutes to conduct a saliva collection and retrieve samples and assessments collected at home.

D. RISKS AND DISCOMFORTS

Risks associated with this study may include some mild physical discomfort with collecting biospecimens for this study. You may experience some mild discomfort with the saliva collection and briefly holding your breath for the carbon monoxide test that may cause some dizziness.

You may also experience some increased anxiety, discomfort and/or nervousness that may be related to speaking in front of an audience during the mock job interview and verbal math test during the stress test. There is minimal risk that you will experience distress, but if you are distressed you can stop the interview at any time, and you will be offered the opportunity to speak with a licensed clinical psychologist who may make treatment referrals if required.

There is a risk of loss of confidentiality of your information that is used in this study. The institution and the investigative team for this study will take every precaution to ensure that your information is kept confidential during this study. None of your personal health information will be stored with data we collect for this study.

E. MEDICAL RECORDS AND/OR CERTIFICATE OF CONFIDENTIALITY

Information about your study participation will not be stored in your medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record.

This research is covered by a Certificate of Confidentiality from the Federal government. This means that the researchers may not disclose information or biospecimens that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, nor can the information or biospecimens be used as evidence, unless you have consented to this disclosure. Information or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless you have consented to the disclosure. More specifically, identifiable information or biospecimens will not be shared with your medical providers who are not involved in this research unless you authorize the study to disclose information to them, or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Information about your study participation will not be in your MUSC medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record. A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must authorize the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Examples of required disclosure include: child abuse and neglect, or harm to self and others, but there could be others.

Finally, a Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

F. BENEFITS

There will be no direct benefit to you from participating in this study. However, it is hoped that the information gained from the study will help in developing effective interventions to improve smoking cessation and health outcomes among smokers.

G. COSTS

There will be no cost to you as a result of participation in this study.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid \$25.00 for each of the two laboratory visits, and \$25.00 for each of the 4- and 8-week follow-up assessments. If you complete all of these study activities you can receive a total of \$100.00 in addition to the \$25.00 already received for your baseline assessment for an overall total of \$125.00.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds \$600.00 in a calendar year, you will be issued a Form 1099.

Payment for study visits may be made using a gift card or a pre-paid debit card, called a ClinCard. The ClinCard works like a bank debit card and you may use the card to purchase goods or services everywhere Debit MasterCard is accepted. You will be given a ClinCard at the beginning of the study. Each time you receive payment for participation in this study, the money will be added to the card, as outlined in the payment schedule above. Details of the debit card system are explained on an additional sheet.

I. ALTERNATIVES

Your alternative is to not participate in this study.

J. DATA SHARING

Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

Specifically, because this study is being conducted as part of the TRACER Research Center, biospecimens, as well as social and sociodemographic information we collected as part of this study, will be used for future research studies conducted by researchers from MUSC, VCU, and the COH.

Before your information is used by investigators, all identifiable information will be removed. Samples that are donated will not be sold to commercial companies.

K. DISCLOSURE OF RESULTS

Research results from this study will not be disclosed to participants in this study. However, if you have questions about the study or your results, you may contact the Principal Investigator of the study.

L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, the research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study which would include VCU
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:
 - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form.

M. COLLECTION OF SPECIMENS

As part of this study, we would like to store urine and saliva specimens collected from you for future research. This future research may be conducted by Dr. Gayenell Magwood or by other researchers affiliated with TRACER. Urine and saliva samples collected at MUSC will be shipped and housed at a centralized biorepository at VCU until they are either used up or destroyed. Biospecimens will be destroyed at the end of the TRACER project period. The MUSC study principal investigator (Gayenell Magwood) and other TRACER investigators will oversee biospecimen collection and biobanking processes. All biospecimens at MUSC and all TRACER sites will be collected using uniform standard operating procedures.

This research could involve genetic studies. There are several things you should know before allowing your (tissues, cells) to be studied or to be stored.

1. The specimens will be labeled with a code that only study personnel can link back to you. Researchers outside of this study will not be given a link between the code number and your name or any other identifying information. While we hope this will prevent any potential loss of privacy or confidentiality, we cannot make any guarantees.
2. In addition to your name, other information about you might be connected to your sample. For instance, information about race, ethnicity, sex, your medical history, and so forth might be available to investigators studying your specimen. Such information might be important for

research or public health. It is possible that this information might come to be associated with your racial or ethnic group.

3. In this study, investigators will not tell you what they find out about you, nor will they contact you if a test becomes available to diagnose a condition you might have or later develop.

You may request at any time that your research samples be removed from storage and not be used for future research. If you decide you want your samples removed, you may contact Dr. Gayenell Magwood via written communication at the following address:

**99 Jonathan Lucas Street
Charleston, SC 29425**

Once the request is received, and if your samples have not already been used for other research, they will be destroyed. If you do not make such a request, your specimens will be stored indefinitely or until completely used.

Please initial by your choice below:

Yes, I agree to allow my samples to be kept and used for future research.

No, I do not agree to allow my samples to be kept and used for future research.

N. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below:

Yes, I agree to be contacted

No, I do not agree to be contacted

O. CLINICAL TRIALS.GOV

A description of this clinical trial will be available on clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Virginia Commonwealth University Office of Research (800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298) at (804) 827-2157; <https://research.vcu.edu/human-research/> or the

NOTICE OF PRIVACY PRACTICES

MUSC Organized Health Care Arrangement (OHCA)

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

The Medical University of South Carolina and its affiliates (including but not limited to the Medical University Hospital Authority, MUSC Physicians, and MUSC Physicians Primary Care) participate in a clinically integrated health care setting. As a result of this clinical integration, these organizations function as an Organized Health Care Arrangement (OHCA) as defined by the Health Insurance Portability and Accountability Act (HIPAA). For purposes of this notice, the members of the MUSC OHCA are collectively referred to in this document as "MUSC." **We collect or receive this information about your past, present or future health condition to provide health care to you, to receive payment for this health care, or to operate the hospital and/or clinics.**

HOW WE MAY USE AND RELEASE YOUR PROTECTED HEALTH INFORMATION (PHI)

A. The following uses do NOT require your authorization, except where required by SC law:

- 1. For treatment.** Your PHI may be discussed by caregivers to determine your plan of care. For example, the physicians, nurses, medical students and other health care personnel may share PHI in order to coordinate the services you may need.
- 2. To obtain payment.** We may use and disclose PHI to obtain payment for our services from you, an insurance company or a third party. For example, we may use the information to send a claim to your insurance company.
- 3. For health care operations.** We may use and disclose PHI for hospital and/or clinic operations. For example, we may use the information to review our treatment and services and to evaluate the performance of our staff in caring for you.
- 4. For public health activities.** We report to public health authorities, as required by law, information regarding births, deaths, various diseases, reactions to medications and medical products.
- 5. Victims of abuse, neglect, domestic violence.** Your PHI may be released, as required by law, to the South Carolina Department of Social Services when cases of abuse and neglect are suspected.
- 6. Health oversight activities.** We will release information for federal or state audits, civil, administrative or criminal investigations, inspections, licensure or disciplinary actions, as required by law.
- 7. Judicial and administrative proceedings.** Your PHI may be released in response to a subpoena or court order.
- 8. Law enforcement or national security purposes.** Your PHI may be released as part of an investigation by law enforcement.
- 9. Uses and disclosures about patients who have died.** We provide coroners, medical examiners and funeral directors necessary information related to an individual's death.
- 10. For purposes of organ donation.** As required by law, we will notify organ procurement organizations to assist them in organ, eye or tissue donation and transplants.
- 11. Research.** We may use your PHI if the Institutional Review Board (IRB) for research reviews, approves and establishes safeguards to ensure privacy.

12. To avoid harm. In order to avoid a serious threat to the health or safety of a person or the public, we may release limited information to law enforcement personnel or persons able to prevent or lessen such harm.

13. For workers compensation purposes. We may release your PHI to comply with workers compensation laws.

14. Marketing. We may send you information on the latest treatment, support groups and other resources affecting your health.

15. Fundraising activities. We may use your PHI to communicate with you to raise funds to support health care services and educational programs we provide to the community. You have the right to opt out of receiving fundraising communications with each solicitation.

16. Appointment reminders and health-related benefits and services. We may contact you with a reminder that you have an appointment.

B. You may object to the following uses of PHI:

1. Hospital directories. Unless you object, we may include your name, location, general condition and religious affiliation in our patient directory for use by clergy and visitors who ask for you by name.

2. Information shared with family, friends or others. Unless you object, we may release your PHI to a family member, friend, or other person involved with your care or the payment for your care.

3. Health plan. You have the right to request that we not disclose certain PHI to your health plan for health services or items when you pay for those services or items in full.

C. Your prior written authorization is required (to release your PHI) in the following situations:

You may revoke your authorization by submitting a written notice to the privacy contact identified below. If we have a written authorization to release your PHI, it may occur before we receive your revocation

1. Any uses or disclosures beyond treatment, payment or healthcare operations and not specified in parts A & B above.

2. Psychotherapy notes.

3. Any circumstance where we seek to sell your information.

WHAT RIGHTS YOU HAVE REGARDING YOUR PHI

Although your health record is the physical property of MUSC, the information belongs to you, and you have the following rights with respect to your PHI:

A. The Right to Request Limits on How We Use and Release Your PHI. You have the right to ask that we limit how we use and release your PHI. We will consider your request, but we are not always legally required to accept it. If we accept your request, we will put any limits in writing and abide by them except in emergency situations. Your request must be in writing and state (1) the information you want to limit; (2) whether you want to limit our use, disclosure or both; (3) to whom you want the limits to apply, for example, disclosures to your spouse; and (4) an expiration date.

B. The Right to Choose How We Communicate PHI with You. You have the right to request that we communicate with you about PHI in a certain way or at a certain location (for example, sending information to your work address rather than your home address). You must make your request in writing and specify how and where you wish to be contacted. We will accommodate reasonable requests.

C. The Right to See and Get Copies of Your PHI. You have the right to inspect and receive a copy of your PHI (including an electronic copy), which is contained in a designated record set that may be used to make decisions about your care. You must submit your request in writing. If you request a copy of this information, we may charge a fee for

copying, mailing or other costs associated with your request. We may deny your request to inspect and receive a copy in certain very limited circumstances. If you are denied access to PHI, you may request that the denial be reviewed.

D. The Right to Get a List of Instances of When and to Whom We Have Disclosed Your PHI. This list may not include uses such as those made for treatment, payment, or health care operations, directly to you, to your family, or in our facility directory as described above in this Notice of Privacy Practices. This list also may not include uses for which a signed authorization has been received or disclosures made more than six years prior to the date of your request.

E. The Right to Amend Your PHI. If you believe there is a mistake in your PHI or that a piece of important information is missing, you have the right to request that we amend the existing information or add the missing information. You must provide the request and your reason for the request in writing. We may deny your request in writing if the PHI is correct and complete or if it originated in another facility's record.

F. The Right to Receive a Paper or Electronic Copy of This Notice: You may ask us to give you a copy of this Notice at any time. For the above requests (and to receive forms) please contact: Health Information Services (Medical Records), Attention: Release of Information / 169 Ashley Avenue / MSC 369 / Charleston, SC 29425. The phone number is (843) 792-3881.

G. The Right to Revoke an Authorization. If you choose to sign an authorization to release your PHI, you can later revoke that authorization in writing. This revocation will stop any future release of your health information except as allowed or required by law.

H. The Right to be Notified of a Breach. If there is a breach of your unsecured PHI, we will notify you of the breach in writing.

HEALTH INFORMATION EXCHANGES

MUSC, along with other health care providers belongs to health information exchanges. These information exchanges are used in the diagnosis and treatment of patients. As a member of these exchanges, MUSC shares certain patient health information with other health care providers. Should you require treatment at another location that is a part of one of these exchanges, that provider may gather historical health information to assist with your treatment. You have the option of saying that this cannot be done. If you choose not to take part in these alliances, please contact the MUSC Privacy Office at 792-4037.

HOW TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you think your privacy rights may have been violated, or you disagree with a decision we made about access to your PHI, you may file a complaint with the office listed in the next section of this Notice. **Please be assured that you will not be penalized and there will be no retaliation for voicing a concern or filing a complaint. We are committed to the delivery of quality health care in a confidential and private environment.**

PERSON TO CONTACT FOR INFORMATION ABOUT THIS NOTICE OR TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you have any questions about this Notice or any complaints about our privacy practices please call the Privacy Officer (843) 792-4037, the Privacy Hotline (800) 296-0269, or contact in writing: HIPAA Privacy Officer / 169 Ashley Avenue / MSC 332 / Charleston SC 29425. You also may send a written complaint to the Office of Civil Rights. The address will be provided at your request.

CHANGES TO THIS NOTICE

We reserve the right to change the terms of this Notice at any time. We also reserve the right to make the revised or changed Notice effective for existing as well as future PHI. This Notice will always contain the effective date. You may view this notice and any revisions to it at: <http://www.musc.edu/privacy>.

EFFECTIVE DATE OF THIS NOTICE

This Notice went into effect on April 14, 2003.
Revised September 2013.