Louisiana State University Health Sciences Center in New Orleans

Information on Participating in Research

STUDY TITLE: A qualitative study of factors associated with quitting smoking among African Americans diagnosed with Chronic Obstructive Pulmonary Disease

PRINCIPAL INVESTIGATOR: Michael D. Celestin Jr., PhD

Why is this study being done?

The purpose of this study is to identify factors that make it hard or easy to quit smoking regular or electronic cigarettes or other tobacco products. You are being asked to participate in this study because you self-identify as an adult African American who currently smoke regular or electronic cigarettes or other tobacco products and has received a diagnosis of Chronic Obstructive Pulmonary Disease (COPD) in your lifetime or a healthcare provider that treats this patient population.

What will happen if I take part in this study?

Before you begin the study, you will need to complete a web-based survey for screening or determining eligibility.

If you qualify and agree to take part in this study, you will be asked to complete 1) a supplemental survey, 2) a Phase 1 Interview in-person, over the phone or via videoconference, and 3) a Phase 2 Interview in-person, over the phone or via videoconference. It should take 10 minutes to complete the supplemental survey and 30-45 minutes to complete each interview, depending on your answers.

With your permission, we will interview you face to face, over the phone, or via videoconference and process for audio/video recording and transcription. We will protect your information by storing any information collected in a secure online database or network folder at LSUHSC-NO. Only study investigators will have access to this information.

You may review and edit the media at your discretion. You do not have to agree to audio/video recording in order to participate in the study.

What are the risks of taking part in this study?

We believe that this study presents no risks greater than those experienced in everyday life.

Are there any benefits to participating in this study?

The possible benefits to you include discussing strategies to quit smoking regular or electronic cigarettes or other tobacco products which, if you quit, can improve your health. This study will help the researchers learn more about factors that make it easy or hard to quit smoking regular or electronic cigarettes or other tobacco use. This information may help in the treatment of future patients with COPD who use tobacco products like you.

The alternative is not to participate. You do not have to take part in this research study to be treated for tobacco use. You could get these benefits without being in the study by talking to your doctor or a tobacco treatment specialist at your hospital or calling the Louisiana Tobacco Quitline at 1-800-QUIT-NOW.

How will you keep my private information confidential?

The researchers will protect your information by storing any information collected in a secure online database or network folder at LSUHSC-NO. Only study investigators will have access to this information. We will make every effort to maintain your privacy but we cannot guarantee complete confidentiality. For example, there is always a risk of someone breaking into a computer system where your information may be stored. Federal or state law also may require us to disclose your records. Loss of confidentiality is a potential risk of taking part in this study.

The following people or groups may review your study records for purposes such as quality control or safety:

- The study sponsor and/or representative of the sponsor
- Representatives of LSUHSC-NO and the LSUHSC-NO Institutional Review Board
- Representatives of UMCNO and the UMCNO Research Review Committee
- Other collaborating organizations (i.e., the University of California San Francisco)
- Other organizations or agencies if required by law.

If any publications and/or presentations result from this study, they will not identify you by name.

Will I be paid for my participation?

You will receive a total of $50 for your participation in this study. Payments will include 1) $10 for completing the supplemental survey, 2) $20 for completing the Phase 1 Interview, and 3) $20 for completing the Phase 2 Interview. Payments will occur via an LSUHSC-NO ClinCard based on your completion of the survey and the interview. You will be responsible for any taxes assessed on the compensation.

Whom can I contact if I have questions about this study?

- **The research team:**

You may contact the following individuals with any questions or concerns about the research or your participation in this study.

Principal Investigator Name: Michael D. Celestin, Jr., PhD Site: LSUHSC-NO Address: 2020 Gravier St., N.O., LA 70122 Phone #: 504-568-5742	**Research Administrator** Name: Ty-Runet Bryant Site: LSUHSC-NO Address: 2020 Gravier St., N.O., LA 70122 Phone #: 504-568-5705
Key Study Personnel Name: Debbie Durapau Site: 52579 Highway 51 South, Independent, LA 70443	**Key Study Personnel** Name: Lucretia Young Site: University Medical Center New Orleans

Address: 2020 Gravier St., N.O., LA 70122 Phone #: 985-348-4060	Address: 2000 Canal St., N.O., LA 70112 Phone #: 504-702-5178

- **Office of the Chancellor, LSU Health Sciences Center - New Orleans:**

You may contact the Office of the Chancellor by phone at (504) 568-4801, if

- you have questions about your rights while taking part in this study, or
- you have any concerns or suggestions, and
- want to talk to someone other than the researchers about the study.

What will happen if I cannot complete the study?

There are several reasons why you may not complete the study.

The researchers or the study sponsor might decide to stop the study at any time.

The researchers may end your participation in this study, without your permission, for a number of reasons including:

- Your safety and welfare are at risk.
- You do not follow instructions.
- You miss scheduled visits.
- You fail to complete study activities.

You also may decide on your own to stop participating in the study. If you are thinking about withdrawing, let the researcher know so he/she may remove you from the study safely. You also should seek medical advice for alternative treatments. The researcher will inform you of any significant new findings during the study that may impact your willingness to continue participation.

If you decide to stop being in the study, or the study is stopped, or you are removed from the study, the researcher will ask you to complete an exit telephone interview.

You are not required to complete these tasks but some of them may be for your own safety.

Information collected about you up to the point of withdrawal will remain part of the study. You may not remove this data from the study database. We will keep this information confidential.

Your Participation in this Study is Voluntary

Taking part in this research study is voluntary; you do not have to participate. If you do take part, you can stop at any time. If you want more information about your rights as a research participant, please visit https://www.lsuhsc.edu/administration/academic/ors/participant_information.aspx.

Your Consent

By choosing to participate in this study, I acknowledge or am aware that:

- The researcher(s) discussed the study with me and answered all my questions.
- I can contact the study team or the Chancellor's Office using the contact information provided above if I have any questions or concerns as the study commences.

INSTRUCTIONS: Include this signature block when a waiver of documentation of informed consent is granted under 45 CFR 67.117(c)(i) The only record linking the subject and the

research would be the signed informed consent form, and the principal risk would be potential harm resulting from a breach in confidentiality, and each subject or LAR will be asked whether the subject wants documentation linking them to the research.

Signature of Participant:

I agree to take part in this study.

_____

Participant Signature Printed Name Date

and/or

Signature of Legally Authorized Representative for Adult:

I am a legally authorized representative of the person named below. I agree for this person to take part in this study.

_____

Name of Participant (Please print)

Type of LAR (Check applicable box):

☐ Court-appointed Guardian

☐ Health Care Proxy

☐ Durable Power of Attorney

☐ Family Member/Next-of-Kin. Relationship: _____

☐ Other: _____

_____

LAR Signature Printed Name Date

Signature of Person Obtaining Verbal Consent:

I have explained the research to the subject and answered all his/her questions.

_____

Signature of Person Obtaining Consent Printed Name Date

Verbal consent was obtained:

☐ In person

☐ Over the phone
☐ By other electronic means: _____

LSU Health NEW ORLEANS
Human Research Protection Program

Louisiana State University Health Sciences Center - New Orleans

Permission to Use Protected Health Information for Research

STUDY TITLE:	**A qualitative study of factors associated with quitting smoking among African Americans diagnosed with Chronic Obstructive Pulmonary Disease**
STUDY IRB#:	**4914**
PRINCIPAL INVESTIGATOR:	**Michael D. Celestin Jr., PhD**
SPONSOR/FUNDING AGENCY:	National Heart, Lung and Blood Institute

1. What is the purpose of this form?

Federal and state privacy laws protect the release and use of your health information. Under these laws, your health care provider, Louisiana State University Health Sciences Center - New Orleans (LSUHSC-NO) cannot release or use your protected health information (PHI) for research purposes unless you give your permission. The purpose of this form is to inform you of the information that will be released and how it will be used or shared, and also for you to give permission.

If you decide to give your permission and to participate in the research study named above, you must provide verbal authorization. Your information will be released to the research team which includes the principal investigator listed above; other researchers hired by the sponsor or LSUHSC-NO; and people with authority to oversee the research. This research team will use and protect your information as described below and in the Consent Document. However, once your health information is released by LSUHSC-NO it may not be protected by the privacy laws and might be shared with others.

If you do not provide verbal authorization, LSUHSC-NO will not obtain, use or share your PHI for research but you will not be able to participate in the research study. Your decision to not provide verbal authorization will not affect any treatment, medical care, enrollment in health plans or eligibility for benefits. If you have questions, please ask a member of the research team.

2. What Protected Health Information will be released or used?

If you give your permission and provide verbal authorization, you are allowing those involved in providing your care and treatment to release the following PHI. Your PHI includes health information in your medical records, financial records and other information that can identify you.

A. ☐ **Complete Medical Record** (Complete health record(s) may contain all of the records, as well as "other" notes or documents relating to my treatment or hospitalization, as listed below);

OR

B. **One or more of the specific records checked below.**

☐ Ambulatory Clinic Records
☐ Progress Notes
☐ Hospital Inpatient Records
☐ Other Test Reports
☐ Dental Records
☐ Operative Reports
☐ Discharge Summary
☐ Consultations
☐ Emergency Department Records
☐ Imaging Reports
☐ Photographs, Videotapes
☐ History & Physical Exams
☐ Psychological Tests
☐ Lab & Pathology Reports
☐ Financial Records
☒ Diagnosis & Treatment Codes
☐ Other

Describe "Other": Click or tap here to enter text.

3. Do I have to give my permission for certain specific uses?

Yes. The following information will only be released if you give your specific permission verbally.

_____ I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment.

_____ I agree to the release of HIV/AIDS testing information.

_____ I agree to the release of genetic testing information.

_____ I agree to the release of information pertaining to mental health diagnosis or treatment.

4. Who will release and/or receive my Protected Health Information?

Your Protected Health Information may be obtained, used or shared with these individuals or organizations for the following purposes:

- To the Principal Investigator listed above and the research team described in the Consent Document;
- To others with authority to oversee the research (i.e., Institutional Review Board (IRB), safety monitoring committee, oversight board, etc.);

- To healthcare providers who provide services to you or analyze your health information in connection with the research study;
- To insurance companies or others responsible for your medical bills in order to secure payment;
- To others who are required by law to review the quality and safety of the research, including: U.S. government agencies, such as the Food and Drug Administration or the Office of Human Research Protections; the research sponsor or the sponsor's representatives; other federal or state agencies; or government agencies in other countries.

LSUHSC-NO is required by law to protect your health information. By providing verbal authorization, you authorize LSUHSC-NO to collect, release use or share your health information for this research. Those 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, if permitted by laws governing them.

5. How will my Protected Health Information be shared for the research?

If you agree to be in this study, the research team may share your PHI in the following ways:

- To perform the research;
- Share it with researchers in the U.S. or other countries;
- Use it to improve the design of future studies;
- Share it with business partners of the sponsor; and/or
- File applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

6. Am I required to provide verbal consent?

No. You are **not** required to provide verbal authorization. If you decide not to provide authorization, you will still receive the same clinical care, or any services you were already entitled to receive. However, if you do not provide verbal authorization, you will not be able to participate in this research study.

7. What about optional research activity

If the research you are agreeing to participate in has additional optional research activity such as the creation of a database, a tissue repository or other activities, as explained to you in the informed consent process, you can choose to agree or not agree to have my information shared for those activities.

☐ I agree to allow my information to be disclosed for the additional optional research activities explained in the informed consent process.

8. Does my permission expire?

This permission to release, retain, use or share your Protected Health Information:

☒ Expires when the research ends and all required study monitoring is over.

☐ Does not expire. [**NOTE:** If researchers want to retain PHI indefinitely, a justifiable rationale for doing so must be described in the IRB application.]

9. Can I cancel my permission?

You can cancel your permission at any time. You can do this by writing to a member of the research team. Please send your written request to:

Name:	Michael D. Celestin Jr., PhD
Title/Role:	Principal Investigator
Physical Address:	2020 Gravier St., New Orleans, LA 70112
Email Address:	mceles@lsuhsc.edu
Phone Number:	504-568-5742

If you cancel your permission, you will no longer be in the research study. You may want to ask someone on the research team if canceling will affect your medical treatment.

If you cancel, no more health information about you will be collected. However, information that has already been collected and disclosed about you may continue to be used as necessary to maintain the integrity of the study (i.e. complete the research). Also, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

10. What if I have more questions about my privacy rights?

Any privacy rights not specifically mentioned in this form are contained in the Notice of Privacy Practices that you received or will receive from the Principal Investigator or at the facility that you attend.

If you still have further questions about your privacy rights, you may contact the individual listed in Section 9.

11. Permission

Signature of Person Obtaining Verbal HIPAA Authorization:

The subject or their LAR has agreed to the release and use of the subject's Protected Health Information.

_____

Signature of Person Obtaining Consent Printed Name Date

Verbal HIPAA Authorization was obtained:

- ☐ In person
- ☐ Over the phone
- ☐ By other electronic means: _____

Verification of Legally Authorized Representative:

_____

Relationship to Participant/LAR type