Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Participant's Name________________________________

Principal Investigator:	Dr. Christopher Moskaluk, University of Virginia Health System, PO Box 800214, Charlottesville, VA, 22908, Phone: 434-982-4408
Sponsor:	The University of Virginia Department of Pathology The Adenoid Cystic Carcinoma Research Foundation

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a signed copy of this form.

Who is funding this study?

This study, the Adenoid Cystic Carcinoma Registry, is being funded by a grant from the Adenoid Cystic Carcinoma Research Foundation, and by the University of Virginia Department of Pathology.

Why is this research being done?

The purpose of this study is to establish a registry and specimen bank at the University of Virginia, in order to collect health information and tissue samples from patients with adenoid cystic carcinoma, to be used for future research studies.

You are being asked to be in this study, called the Adenoid Cystic Carcinoma Registry (ACCR) because you have been diagnosed with adenoid cystic carcinoma. This is a rare cancer, so its research is difficult by the small number of cases available. The purpose of the Registry is to bring health information and any donated specimens together in one place so they can be made available to researchers studying adenoid cystic carcinoma. This knowledge may lead to the development of new diagnostic tests, new treatments or insights into the causes of this disease.

Up to 500 people will be in this study at UVa.

IRB-HSR
APPROVAL DATE 9|9|16
EXPIRATION DATE 9|8|17

What will happen if you participate in this registry?

If you decide to participate in the Adenoid Cystic Carcinoma Registry, you will sign this consent form and send it back to us. We will then send you a copy of this consent, after it has been signed by a member of the study team.

Then, you will be asked to:

- complete a short questionnaire about your demographics (age, gender, ethnicity), demographics (age, gender, ethnicity), risk exposure, medical history, family cancer history, symptoms, and information about the diagnosis and treatment of your adenoid cystic carcinoma. Based on your responses, a member of the study team may contact you by telephone or mail to clarify your answers, if needed. Completion of the questionnaire should take less than 30 minutes of your time.
- give permission for your doctor(s) to release information to the physicians and staff of the Registry about your treatment and present health status. We will ask you to sign an additional form so that we may receive this information.

There is also one optional thing you can agree to if you decide to join the Registry:

- you can decide to donate a tissue specimen to the Registry. After the tests for your medical care are completed, there may be samples left over. Normally, these leftover samples would be thrown away. We are asking you to allow us to collect this leftover material for specimen banking and/or genetic research. If you decide to donate tissue we will ask you to sign a separate form that will allow the hospital where you had your surgery to send us any tumor sample available. We will also ask you to sign a separate consent form so that the hospital where you had your surgery will be willing to release your tissue for this registry.

Your health information and tissue will then be used in future approved research regarding the biology of adenoid cystic carcinoma.

Collection of Samples and Health Information for Genetic Research and/or Specimen Banking

What Sort of Research Will Be Done On Your Sample(s)?

Specimens collected for research will be added to a research specimen bank the ACC Registry). The purpose of a specimen bank is to process, and store samples until researchers need them for future research. The long term goals of the samples collected in this bank will be mainly used for research on adenoid cystic carcinoma. Is it not possible, however, to list every research project that will include the samples because we cannot predict all of the research questions that will be important over the coming years. As we learn more, new research questions and new types of research may be done.

You are being asked to provide samples of your tissue, taken during for clinical purposes for the diagnosis and treatment of your adenoid cystic carcinoma. We will only ask for leftover tissue – tissue which is no longer needed for your diagnosis, care, or treatment.

If you agree, genetic research on the DNA in your specimen sample may be performed according to future approved research projects. DNA is the material that makes up your genes. All living things are made of cells. Genes are the part of cells that contain the instructions which tell our bodies how to grow and work, and determine physical characteristics such as hair and eye color. Genes are passed from parent to child.

Your specimen sample may be used to create a living specimen sample (called a "cell line") that can be grown in the laboratory. This allows researchers to have an unlimited supply of your cells in the future without asking for more samples from you.

If you decide to donate your leftover tissue to the Registry tissue bank, no additional time will be required. We will simply ask you to sign a form so that the place where you had your surgery will allow the tissue to be sent to the Registry here at the University of Virginia.

It is important to know that treatment decisions for your care have been made independent of this research project. Procedures such as biopsies and removal of a tumor are being done as part of routine medical care and would be done whether or not you give your permission for your samples to be used for genetic research and/or specimen banking. No extra material will be taken for this research.

How Will Your Sample(s) Be Labeled for Specimen Banking?

Dr. Christopher Moskaluk, the leader of the research specimen bank, will be responsible for storing your sample and for protecting your privacy.

Your sample(s) will not be labeled with your name or other information that would identify you directly. Instead, it will have a unique code that allows for it to be linked to your health information. This link means that your specimen can be identified but only indirectly.

Which researchers can use your samples and what information about you can they have?

Your sample may be shared with researchers at the University of Virginia and at other institutions. Dr. Moskaluk will not give your name to other researchers who want to use your sample, and will only give the following information

Type of cancer
Histologic grade of cancer
Clinical stage of cancer at time of surgery
Your gender
Your age at time of procurement

Anatomic site of tumor
Anatomic site of primary tumor (if tissue procured was a metastasis)
Your race/ethnicity
Initial diagnosis, or recurrence
Treatments (radiation, chemo, or surgery)

Those who would see the information would include researchers and the others listed under "Who will see your private information?" section of this consent document.

Some of the people who receive your information may not have to follow the privacy laws and may share or release your information because they do not have to follow the privacy laws.

What Are the Benefits To Donating Your Sample(s) For Genetic Research and/or Specimen Banking?

It is very unlikely that any future research performed using your specimen(s) would benefit you directly, but it may provide important medical knowledge that could help other patients with your medical condition or other medical problems in the future.

What Are The Risks of Donating Your Sample(s) For This Study?

Risks to Privacy from Genetic Research and/or Specimen Banking:
The main risk of allowing us to store and use your samples and certain limited health information for research is a potential loss of privacy. One of the risks to you is the release of information from your health records. The University of Virginia will do its best to protect your records so that facts about you and your health will be kept private. The chance that information identifying you will be given to someone else is very small. However, we cannot *guarantee* it will be safe. To further safeguard your privacy, information obtained from future research will not be placed in your medical record.

There are certain risks of having health information given to other people by mistake. In the unlikely event that this happens, it could cause discrimination or mental harm to you or your family members if others were to see this information. The results could be that you may not be able to get or keep certain kinds of insurance. It could also hurt family relationships.

Your doctor will explain the risks of any medical procedure you are having. In some cases, your doctor will ask you to sign a separate clinical consent form that explains the risks of the procedure. Allowing your samples to be placed in the bank for future research will not change the risks of the medical procedure itself.

Because everyone has unique DNA, it is also possible, although very unlikely, that someone could identify you through your DNA if they have another sample of your DNA.

Information about your genetic make-up could mean that you and your family members could face problems that could lead to getting or keeping some kinds of insurance or affect your ability to get or keep a job. There is no way to predict all the possible risks of this research.

Will You Find Out the Results of the Research on Your Sample(s) for Genetic Research and/or Specimen Banking?

Neither you, your health care provider, nor anyone in your family, will receive the results of any research done on your sample(s). The results will not be put in your health records. Therefore, results from any research done on your sample(s) will not affect your medical care. This helps protect you and other members of your family from harm that might be caused by this information.

What If You Change Your Mind About Donating Your Sample(s) for Genetic Research and/or Specimen Banking?

If you decide now that your sample(s) can be kept for genetic research and/or specimen banking, and later change your mind, you can simply withdraw the sample(s) at that time. To withdraw you will need to write to the Principal Investigator listed on the first page of this form. We will then destroy any of your tissue that has not already been used. If your tissue has been sent to another medical center for use in research, we will not be able to destroy it. Also, if your sample has been used in genetic research, the information that we have learned will remain in the study, even if you withdraw. Unless you withdraw from the study, permission for researchers to use your tissue and to use and share your private health information for this study will never end.

Will You Be Paid For Donating Your Sample(s) for Genetic Research and /or Specimen Banking?

You will not be paid to donate your sample(s) for genetic research and /or specimen banking.

Will Donating Your Sample(s) Cost You Any Money?

There is no cost to you to have your samples collected or used for genetic research and/or specimen banking.

Genetic Testing and/or Specimen Banking Options:

You do not have to participate and agree for specimens to be collected for genetic research and/or specimen banking in order to be in the main part of this study. No matter what you decide to do, your decision will not affect your medical care. You can tell us your choice by placing your initials in one of the options below:

GENETIC RESEARCH:

Please indicate your choice by placing your initials below (if applicable):

___ YES **Your sample(s) may be used for genetic research**

___ NO **Your sample(s) may not be used for genetic research**

SPECIMEN BANKING:

Please indicate your choice by placing your initials below (if applicable):

___ YES **Your sample(s) may be saved for future research and stored in a specimen bank.**

___ NO **Your sample(s) may not be saved for future research and stored in a specimen bank.**

Could you be helped by being in this study?

You will not benefit from being in this study. However the information researchers get from this study may help others in the future.

What are your other choices if you do not join this study?

You do not have to be in this study to be treated for your illness or condition. You can get the usual treatment even if you choose not to be in this study, including participation in other research studies.

If you are an employee of UVa your job will not be affected if you decide not to participate in this study.

If you are a student at UVa, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?

You will not get any money for being in this study.

By agreeing to be in this study, you are donating your information and, if you agree to Specimen Banking, tissue samples for research, and giving up any property rights you may have in them. The results of this research using your donated materials may have commercial value. However, you will not receive any payments.

Will being in this study cost you any money?

All of the procedures in this study (collection and storage of data and leftover specimens) will be provided at no cost to you or your health insurance. You will continue to be responsible for all of the care for your adenoid cystic carcinoma.

What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader can take you out of the study. Some of the reasons for doing so may include

e) You do not follow instructions
f) The study is closed for safety, administrative or other reasons

If you decide to stop being in the study, we will ask you to send a letter to Dr. Christopher Moskaluk, University of Virginia Health System, Box 800214, Charlottesville, VA, 22908. If your sample and information have been sent to other investigators, we will not be able to retrieve them.

How will your personal information be shared?

The UVa researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address and date of birth
- Social Security number ONLY IF you are being paid to be in this study
- Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.
- Tissue or blood samples if you agree to provide them for tissue banking and/or genetic testing for this study

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- The sponsor(s) of this study, and the people or groups it hires to help perform or review this research
- Insurance companies or other organizations that may need the information in order to pay your medical bills or other costs of your participation in the study
- Tax reporting offices (if you are paid for being in the study)
- People who evaluate study results, which can include sponsors and other companies that make the drug or device being studied, researchers at other sites conducting the same

study, and government agencies that provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.

Some of the people outside of UVa who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator:
Dr. Christopher Moskaluk
Pathology, School of Medicine
P.O. Box 800214
Charlottesville, VA 22908

Telephone: (434)982-4408

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22908

Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

______________________	______________________	________
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

______________________	______________________	________
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Consent from Impartial Witness

If this consent form is read to the subject because the subject is blind or illiterate, an impartial witness not affiliated with the research or study doctor must be present for the consenting process and sign the following statement. The subject may place an X on the Participant Signature line above.

I agree the information in this informed consent form was presented orally in my presence to the **identified individual(s)** who has had the opportunity to ask any questions he/she had about the study. I also agree that the **identified individual(s)** freely gave their informed consent to participate in this trial.

IMPARTIAL WITNESS (SIGNATURE)	IMPARTIAL WITNESS (PRINT)	DATE

IRB-HSR #8804
ADENOID CYSTIC CARCINOMA REGISTRY
at
The University of Virginia
Charlottesville, Virginia

Authorization for Disclosure of Protected Health Information and Release of Tissue and Pathology Specimens

I, ______________________, hereby authorize _________________________________
(Print your name) (Name of Hospital)

located in ____ to disclose the protected
(Location of Hospital: City & State)

health information, pathology materials, and tissue described below to the Adenoid Cystic Carcinoma Registry (ACCR) at The University of Virginia for research purposes.

This authorization covers all past, present, and future periods.

I authorize the disclosure and release of:

- pathology reports and laboratory results about my adenoid cystic carcinoma
- information from my medical records about my diagnosis and treatment for adenoid cystic carcinoma (clinic notes, surgical reports, case summaries, chemotherapy and radiation therapy reports)
- pathology materials from my adenoid cystic carcinoma procedures which are longer needed for my diagnosis, care, or treatment (glass histology slides, paraffin tissue blocks)
- any tissue left over from my surgery procedures for adenoid cystic carcinoma which is not needed for my diagnosis, care, or treatment

I understand that I may revoke this authorization, in writing, at any time. I understand that my treatment, payment, enrollment, or eligibility for benefits will not be conditioned on whether I sign this authorization.

____ ____________
(Signature) (Today's Date)

____ ____________
(Medical Record Number or Last 4 Digits of SSN) (Date of birth)

If you have pathology samples at more than one hospital, please fill out one copy of this form for each hospital.

PLEASE DO NOT SEND THIS FORM DIRECTLY TO YOUR HOSPITAL! Please send the completed signed form to the ACCR and we will use it to request the samples after we have entered your information into the registry.

IRB-HSR #8804
ADENOID CYSTIC CARCINOMA REGISTRY
at
The University of Virginia
Charlottesville, Virginia

Contact information

This information will be used only for the purpose of scientific and clinical studies.

Address at which we may contact you by mail:

____

____

Daytime phone number:____________________________

Email: __________________

Name of physician primarily responsible for your care:

____

Address of physician (or name and location of hospital/clinic)

____

____

Phone number of physician: _________________________

IRB-HSR #8804
ADENOID CYSTIC CARCINOMA REGISTRY
at
The University of Virginia
Charlottesville, Virginia

Registry data

We are currently collecting information on adenoid cystic carcinoma that has arisen in the head, neck and thorax (trachea and lungs) in individuals 18 years of age or older. The following information may help us establish an overlooked association that can give us a clue to the cause of adenoid cystic carcinoma or find currently unidentified risk factors. Your privacy will be maintained by the use of code numbers when the data is released to researchers. No person contacting the ACCR will be given any information that could identify you.

Date of birth:_____________
Your age at the time of diagnosis with ACC:____________
Your sex:__________
Your race and ethnic background:_________________________________
Your height at the time of diagnosis:_____________
Your approximate weight at the time of diagnosis:______________
Which of the following environments have you lived in most of your life?
______Rural
______Suburban
______Urban
______Other______________________________________

Occupation/exposure history

Your occupation over the majority of your life:_____________________________
Have you had exposure to any chemicals or irritating substances over a long time?______
If yes, what are they? ____
Have you been exposed to radiation *prior* to your diagnosis of ACC?If yes, please explain. ____
____

Tobacco use:

___no significant tobacco use
Type of tobacco product:
___cigarettes ___cigars ___chewing tobacco ___snuff ___other___________________

Age when I started using tobacco:_________
Age when I stopped using tobacco:________
I am still using tobacco:___________

Over the time you used tobacco, how much did you use per day (number of cigarette packs, number of cigars, etc.)?____

Alcohol use:

Consider a serving as one can of beer, one glass of wine or one mixed drink.
____never or seldom drink alcohol
____1-6 servings per week
____7-14 servings per week
____15-21 servings per week
____more than 21 servings per week

Most common form of alcoholic beverage consumed:
____beer
____wine
____distilled alcohol (whisky, rum, vodka, etc. straight or in mixed drinks)

Medical history

Did you have other medical conditions unrelated to adenoid cystic carcinoma, prior to this diagnosis?______
If yes, what are they, and how long have you had the conditions prior to your diagnosis with adenoid cystic carcinoma?
____
____
____
Did you use any medications for a significant amount of time prior to your diagnosis?
____
If yes, what was(were) the medication(s)?____

Location of the origin of adenoid cystic carcinoma:
______Don't know
______Side of face
______Inside mouth: under, in or around my tongue
______Inside mouth: the roof or the back of mouth
______Lips
______Nose or sinuses
______Inside neck
______Inside chest or lungs
______Other location____

IRB-HSR #8804
ADENOID CYSTIC CARCINOMA REGISTRY
at
The University of Virginia
Charlottesville, Virginia

Which of the following symptoms preceded your diagnosis of ACC? (check all that apply)
______No symptoms, my doctor or dentist discovered it

	YES	NO	Length of time before diagnosis
A swelling or lump	___	___	___________________________
A non-healing sore	___	___	___________________________
Pain	___	___	___________________________

(Where was the pain, and what did it feel like?____________________________________
____

______Other symptom (Please describe____
____

	Month	Year	Part of body
First diagnosis of ACC			
Surgery for initial cancer			
Surgery for recurrent cancer			
Radiation therapy			
Chemotherapy			

If the radiation and chemotherapy were at a hospital other than the one in which you received surgery, please tell us its name and location: ______________________________
____
____

If your cancer has recurred or spread, and you have not already listed it above, please tell us in what part of your body this has happened, and when this was detected.____
____
____

Family history:
Has there been any one else in the history of your family diagnosed with adenoid cystic carcinoma? _______________
If yes, what relation are they to you?_________________________
Has there ever been any one else in the history of your family who has been diagnosed with any other kind of cancer? _________________
If yes, please fill out the following for each person with cancer as best you can:

Relationship to you	Type and/or location of cancer	Age of diagnosis

Total number of your first degree relatives (your parents, brothers, sisters, and children), living or dead:______
Total number of your first degree relatives who have or had cancer:____________

If you didn't have room to fully answer any of the above questions, please continue on another piece of paper. If there is anything else that you feel might have been a factor in developing cancer, please let us know. Please send these forms to:

Adenoid Cystic Carcinoma Registry
c/o Christopher A. Moskaluk M.D., Ph.D.
UVA Health System Dept. of Pathology
PO Box 800214
Charlottesville, VA 22908

We prefer regular mail, but if for some reason you wish to use a courier or express mail service please use:

Adenoid Cystic Carcinoma Registry
c/o Christopher A. Moskaluk M.D., Ph.D.
UVA Health System Dept. of Pathology
Room 3024 Hospital Expansion, 1215 Lee Street
Charlottesville, VA 22908

PLEASE BE SURE THAT YOU HAVE SIGNED AND DATED THE CONSENT AND TISSUE RELEASE FORMS or we cannot enter you into the registry.