

CONSENT OF AN ADULT TO BE IN A TUMOR REGISTRY

Participant's Name _____

What is an Informed Consent?

You are being asked to be in a tumor registry. The purpose of this form is to give you the information you will need to help you decide if you want to be in this registry. Please read this form carefully. Please ask questions about anything you do not understand. When all your questions have been answered, you can decide if you want to be in this registry. If you do decide to be in this registry, you will get a copy of this signed form to keep for your records.

Introduction

You are being asked to join the Adenoid Cystic Carcinoma Registry (ACCR), which is maintained at the University of Virginia.

Because you are an adult (over age 18) and have been diagnosed with adenoid cystic carcinoma (ACC) of the head, neck or thorax (chest), you are eligible to join the Adenoid Cystic Carcinoma Registry (ACCR).

The Adenoid Cystic Carcinoma Registry is a list of many people who have been diagnosed or treated for adenoid cystic carcinoma and who wish to share their medical information and tissue specimens for research. Participants in the ACCR provide information about their illness and usually donate tissue specimens, which are placed in a repository at the University of Virginia. The purpose of the ACCR is to bring this health information and any donated specimens together in one place so they can be made available to researchers studying adenoid cystic carcinoma. Submission of your tissue and health information to the ACCR gives physicians and scientists valuable information and material to understand the biology of adenoid cystic carcinoma. This knowledge may lead to the development of new diagnostic tests, new treatments or insights into the causes of this disease.

Scientists and physicians who request data from the ACCR will be given information that is identified only by a code number. Your name, address or any other information that could be used to identify you will not be released for research purposes in order to protect your privacy.

If you decide to participate in the Adenoid Cystic Carcinoma Registry, you will be asked to:

- ∞ complete a short questionnaire about your risk exposure, medical history, family cancer history, and information about the diagnosis and treatment of your adenoid cystic carcinoma.
- ∞ give permission for your doctor(s) to release information to the physicians and staff of the ACCR about your treatment and present health status

There are two optional things you can agree to if you decide to join the Registry:

- ∞ you can decide to be contacted for information about your progress in the future
- ∞ you can decide to donate a tissue specimen to the ACCR

Follow-up information over time and tissue specimens are very important resources that the ACCR would like to make available to researchers studying adenoid cystic carcinoma.

Up to 500 people will be in the Registry at UVA.

The decision to be in the Adenoid Cystic Carcinoma Registry is up to you. Your medical information will remain with the ACCR indefinitely so it can be used for future studies. If you give your permission, the Registry physician or his/her staff may contact you or your physician(s) in the future to update records of your progress.

Are there some people who should not be in the Registry?

The person in charge of the Registry or a member of the Registry staff will talk with you about the requirements to be in this registry. It is important that you are truthful with them about your history. You should not join if you do not meet all the qualifications.

You should not join this registry if:

- ∞ You are not able to grant consent to participate
- ∞ You are under 18 years of age
- ∞ You have not been diagnosed with or treated for Adenoid Cystic Carcinoma (ACC) by your doctor(s)

How much time will being in the Registry take?

The time necessary to join the Adenoid Cystic Carcinoma Registry is minimal. You will not have to come to the University of Virginia or visit your doctor to participate, and you are not restricted from participating in any other research study. All participants in the ACCR must fill out a short questionnaire about your exposure to common cancer risk factors, medical history, family cancer history, and about your adenoid cystic carcinoma diagnosis and treatment. This will usually take less than 30 minutes to complete. Based on your responses, a physician or staff member of the ACCR may contact you by telephone or mail for additional information or to clarify your answers.

The physicians and staff of the Adenoid Cystic Carcinoma Registry will be responsible for obtaining copies of medical records from your doctor(s) or hospital(s) where you were or will be treated for your adenoid cystic carcinoma for the Registry. This will usually not require additional time on your part.

If you also agree to be contacted in the future, you may be contacted by mail or telephone by the ACCR to update records of your progress.

What are the risks of being in this Registry?

The risk of being in this registry is accidental disclosure of your health information. This could expose you or family members to risk of discrimination or psychological harm. A number of safeguards are in place to protect the confidentiality of this information, so that risk is considered to be slight. We cannot guarantee, however, that the risk is nonexistent.

Could you be helped by being in this Registry?

You will not be directly helped by being in this registry, however the information in the ACCR may be used in studies which help others in the future. If you decide to join the Registry, you will not be granted any special access to additional treatment options, such as experimental drugs or therapies. The information in the ACCR will not be used to invite you to participate in other studies. It will not be possible to provide you or your physician with any information about your personal results from any study which uses samples or information from the Adenoid Cystic Carcinoma Registry. These results will not be placed in your medical record. You will not benefit financially if your information or specimen is used in research that leads to the development of any commercial product.

What are your other choices?

You do not have to be in this registry to be treated for your illness or condition. If you want to participate in a research study, such as an experimental treatment, you do not have to be in the Adenoid Cystic Carcinoma Registry.

Your other choice is not to join the ACCR.

Will you be paid for being in the Registry?

You will not get any money for being in the Registry.

What are the costs of being in the Registry?

Taking part in the ACCR does not involve any added procedures or tests which you or your insurance company must pay for. The ACCR will arrange to obtain copies of your medical records and any tissue or histology specimens you give permission for us to have from your doctor(s) or hospital where you were treated without cost to you.

You or your insurance company will be responsible for paying for your usual tests and care that would be done if you join the Adenoid Cystic Carcinoma Registry or if you do not.

What happens if you are hurt while participating in this Registry?

You should talk to the Registry physician if you have questions about being paid for an unexpected injury/loss of confidentiality caused by participating in this registry. You do not give up legal rights for personal injury by signing this form.

What happens if you change your mind?

You do not have to be in the Registry if you do not want to be. You may choose to not be in this registry or to be removed from the Registry at any time. You are not required to be in this registry in order to receive services normally available to you at the University of Virginia.

If you do decide to be removed from the Registry you will be asked to send a letter stating you wish to withdraw your registration and your permission to release your information to Dr. Christopher Moskaluk, University of Virginia Health System, Box 800214, Charlottesville, VA, 22908.

The registry physician may remove you from the registry at any time. Some reasons for removing you would be if you do not follow instructions.

How will information about you be used and protected?

University of Virginia policies require that your personal health information be protected as required by law.

Signing this form gives your health care providers permission to release, and the researchers your permission to obtain, use, and give out health information about you for the Adenoid Cystic Carcinoma Registry as described in this form. You do not have to sign this form. However, if you do not sign it, you cannot participate in the Registry.

Information about you may include information about your health and your medical care before, during, and after you start participating in the Registry, even if that information wasn't collected for the purposes of the Registry. Information about you may be obtained from any hospital, doctor or other health care provider involved in your care. It may include information that identifies you, like your name, address, telephone and Social Security numbers, and date of birth. It also may include:

- ∞ Complete hospital and doctor's office records, including all test results (X-rays, blood tests, urine tests, etc.)
- ∞ Information obtained from your participation in the Registry, such as information we learn in phone calls, surveys, and other medical information we learn from you as a participant.
- ∞ Billing information.

Your information will be used and given out to carry out the objectives of the Registry, to see whether it is being maintained and used correctly, and to evaluate the Registry's efforts. University of Virginia staff who may use and give out your information include the researchers and research staff, the institutional review board and others who oversee research projects, including auditors and compliance monitors.

Other organizations involved with or overseeing the Registry may receive your information, including:

- ∞ Government agencies and accrediting organizations that have oversight duties regarding the research or the University
- ∞ Organizations that are funding the Registry and groups working for them
- ∞ Safety monitors or committees

Your information may also be used to meet the reporting requirements of governmental agencies. The results of studies using materials or information provided by the Registry could be published in an article, but would not include any information that would let others know who you are.

Those persons outside of the University of Virginia 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.

Information collected about you for this registry will be kept in a record that is separate from your medical record.

Your permission to use and give out health information for this registry does not end unless you cancel it. If you cancel your permission you will no longer be able to be a participant in the Registry. You may cancel your permission at any time by writing to the researchers listed in this form.

Sometimes it may be necessary for information about you to continue to be used or given out, even if you have canceled your permission. Examples of reasons for this include:

- ∞ To avoid losing study results that have already included your information
- ∞ To help University and government officials oversee the Registry.

If you are a patient at the University of Virginia, a copy of this consent form will be placed in your medical record. This means that everyone who is authorized to see your records will be able to find out that you are in the Registry.

Please contact the researchers listed below to:

- ∞ Obtain more information about the Adenoid Cystic Carcinoma Registry
- ∞ Ask a question about the Registry procedures
- ∞ Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- ∞ Leave the Registry
- ∞ Express a concern about the Registry

Principal Investigator/Registry Physician: Dr. Christopher Moskaluk
Telephone: 434-982-4408

You may also express a concern about a study by contacting the Institutional Review Board listed below.

University of Virginia Human Investigation Committee
PO Box 800483
Charlottesville, Virginia 22908
Telephone: 434-924-2620
Fax: 434-924-2932

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the HIC 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 unless you want to.

Conclusion

Please check one of the following (permission to obtain updates about your progress):

_____ You agree to be contacted in the future by physicians or staff of the Adenoid Cystic Carcinoma Registry for follow up information about your progress.

_____ You do not agree to be contacted in the future by physicians or staff of the Adenoid Cystic Carcinoma Registry for follow up information about your progress.

What does your signature mean?

Before you sign this form, please ask questions about any part of the Registry that is not clear to you. Dr. Chris Moskaluk [cam5p@virginia.edu, (434) 982-4408] or Dr. Henry Frierson Jr. [hff@virginia.edu, (434) 982-4404] are familiar with the Registry and will explain anything you need clarified. Your signature below means that you understand the information given to you about the Registry and in this form. If you sign the form it means that you agree to join the Registry.

PARTICIPANT
(SIGNATURE)

PARTICIPANT
(PRINT)

DATE

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

PERSON OBTAINING CONSENT
(SIGNATURE)

PERSON OBTAINING
CONSENT
(PRINT)

DATE

Tissue Banking

In addition to placing your medical information in the Adenoid Cystic Carcinoma Registry as we have told you about, the Registry would like to obtain some of your tissue and store it for a long time. The purpose of collecting these specimens is to make them available for use in later research studies. Donating your specimen may give researchers valuable material necessary for developing new tests or treatments and understanding the causes of adenoid cystic carcinoma. This is a very important function of the Adenoid Cystic Carcinoma Registry, since many research studies make use of tissue specimens and benefit when there is specific health information about them available. You may be in the Registry already described without agreeing to have your tissue stored for a long time.

If you agree to donate your specimen, you will not have to have any additional medical procedures. We will only take leftover tissue from your surgery or biopsy procedures which is not required for your medical care. These specimens may include glass histology slides, paraffin tissue blocks, and left over tissue.

If your biopsy or surgery did not or will not take place at the University of Virginia, we will give you a release form to sign. This form gives permission for your doctor(s) or hospital to transfer any available specimens not needed for your medical care to the Adenoid Cystic Carcinoma Registry. We will submit this authorization with a request for any unneeded tissue specimens to your doctor(s) or hospital(s) on your behalf. You will not have to arrange or pay for transfer of any specimens to the ACCR from outside the University of Virginia.

Your specimen will be stored in a tissue repository, along with specimens from many other people. These specimens will be stored in the Pathology Department at the University of Virginia. Your specimen may be stored with some clinical information, such as your age, sex, and diagnosis, which will be made available to the researchers who use your specimen. Your name and personal information which can identify you, such as your address, will only be known to the physicians and staff of the ACCR. Dr. Christopher Moskaluk and the staff of the Adenoid Cystic Carcinoma Registry will be responsible for storing your specimen and for protecting your privacy. Scientists who request specimens from the ACCR for a study will only receive a code number with your specimen. Your name and most other information that could be used to identify you, except for certain dates and general geographic information, will be removed. Anyone who receives the specimen will sign an agreement to keep the remaining information confidential.

Research studies often involve some risks. Any time you donate a specimen to a tissue bank that can be linked to your identity, you are providing a sample that could reveal health information about you. This could expose you or family members to risk of discrimination or psychological harm. A number of safeguards are in place to protect the confidentiality of this information, so that risk is considered to be slight. We cannot guarantee, however, that the risk is nonexistent.

There will be no direct benefit to you for donating your specimen, although others may someday benefit from the research that might be performed using your specimen. It will not be possible to provide you or your physician with any information or results from the research conducted with

your specimen. These results will not be placed in your medical record. You will not benefit financially if your specimen is used in research that leads to the development of any commercial product.

The only alternative is not to donate your specimen.

Most of the research that will use your tissue poses only minimal risk in terms of revealing personal information about you. Some research may pose greater risks to you because it may reveal personal information about you that has greater privacy risks. For example, hereditary genetic testing that can be linked to your identity often raises greater privacy risks. In order to protect your rights, that kind of research can't be done without your specific permission. This means that you may be contacted in the future and asked to give consent to a certain research protocol if you have not already consented to that kind of research in this consent.

If your specimen is used for any type of genetic research, the results will not be put in your medical record. The research will not change the care you receive. Although the University of Virginia will do its best to assure that any personal information remains confidential, there can be no absolute guarantee. The risk of having personal health information accidentally released to other people includes loss of insurability, ability to get or keep a job, and/or damage to family relationships.

You will receive no payment for donating your tissue. Any profit that comes from commercial application of this research will go to the University of Virginia. You will not profit in any way if your specimen is used in research that leads to the development of a commercial product. There will be no additional cost to you for donating your tissue.

Your specimen will be kept until it is used up or destroyed. If you or your physician(s) determine that your specimen may contain information necessary for your care, you may request that any specimens which have not already been distributed for research be returned. You or your doctor should contact Dr. Christopher Moskaluk at (434)982-4408 as soon as possible to expedite this.

If you do decide to withdraw from the Registry and end this agreement, please send a letter stating you wish to withdraw your specimen to Dr. Christopher Moskaluk, University of Virginia Health System, Box 800214, Charlottesville, VA, 22908. We will destroy any remaining tissue that has not already been distributed for research. However information already obtained from your tissue will continue to be used. You are free to decide to have it withdrawn at any time without hurting your future medical care at the University of Virginia.

Please check ONE of the following:

I agree to have my tissue stored long term for future research uses.

I do not agree to have my tissue stored long term for future research uses.

Please check ONE of the following regarding future contact about additional consent for research involving greater privacy risks such as hereditary genetic traits.

_____ I agree to be contacted in the future with information about research studies involving greater privacy risks such as hereditary genetic testing.

_____ I do not want to be contacted in the future about participating in studies involving greater privacy risks such as hereditary genetic testing.

PARTICIPANT
(SIGNATURE)

PARTICIPANT
(PRINT)

DATE

PERSON OBTAINING CONSENT
(SIGNATURE)

PERSON OBTAINING CONSENT
(PRINT)

DATE

Dr. Moskaluk will review this consent form and will return a signed copy to you.

HIC#8804
ADENOID CYSTIC CARCINOMA REGISTRY
at
The University of Virginia
Charlottesville, Virginia

Release of tissue and pathology specimens

I, _____, hereby authorize the Pathology Department or
(Print your name)

Service, and its employees, of _____
(Name of Hospital)

in _____ to release all pathology material
(Location of Hospital: City & State)

(glass histology slides, paraffin tissue blocks) and any tissue left over from my surgery

to the Adenoid Cystic Carcinoma Registry (ACCR) at The University of

Virginia.

(Signature)

(Today's Date)

(Social Security Number)

(Date of birth)

If you have pathology samples at more than one institution, please fill out a form for each institution.

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

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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: _____

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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 about 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.)? _____

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at
The University of Virginia
Charlottesville, Virginia

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 _____

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 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			X
			X
			X

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: _____

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at
The University of Virginia
Charlottesville, Virginia

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 **mail** 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 the street address is Room 3024 Hospital Expansion, 1215 Lee Street

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