

Attachment 7a

Medical Release and Healthcare Source Forms, English

[Registry logo]

[State cancer registry name and address]

HIPAA - Medical Records Release Authorization

The researchers conducting this study are interested in learning about the experiences of women with cervical cancer prior to and including their diagnosis. To learn more about your personal experiences, we hope that you will allow us to contact your medical providers so that we can review your medical records to learn more about your condition.

We need your written authorization to review your medical records. The medical record reviews will provide data about the medical care you received prior to and including the date of your clinical diagnosis of invasive cervical cancer. We are asking to review your medical records because we would like to obtain detailed clinical information from your healthcare providers about your screening and follow-up visits, like the type of Pap or HPV test, the clinical results, and the type of treatment if any that was done prior to your diagnosis. You are not required to allow us to access your records, but **this information can be very important to better understand ways to prevent cervical cancer.**

Background on HIPAA

The *Health Insurance Portability and Accountability Act* (HIPAA) is a federal law. The Privacy Rule of HIPAA went into effect on April 14, 2003. The purpose of this rule is to limit your health care providers' use and disclosure of your health information. Health care providers are your doctors and the clinics or hospitals where you were diagnosed and/or treated. Protected health information includes your medical history, diagnosis, treatment, and payment information. It also includes identifiable information such as your date of birth. This form describes the information the researchers will ask your health care providers to release. It also explains how we will use that information.

What information would be released?

- Records or information related to your screening and treatment up to and including the date of your cancer diagnosis including information on clinical factors, symptoms, therapy, outcomes, and follow-up care of abnormal test results.
- Copies of your medical records and medical reports (i.e., pathology or test results) from 5 years prior to and including the date of your cervical cancer diagnosis. The researchers will only collect information related to the cancer.

Who will see my information?

- Research Study Team: This team includes researchers from the _____ Cancer Registry, Battelle Memorial Institute and the Centers for Disease Control and Prevention (CDC).
- Research Sponsor: Centers for Disease Control and Prevention (CDC). The Research Sponsor will not have access to any information that could personally identify you.

- Members of the Institutional Review Board (IRB). The IRB is a committee of people who review and approve human subjects research studies to make sure that the studies are conducted ethically. The IRB has approved this study. The IRB would only access your records to assure that your information was being protected correctly. The IRB will not have access to any information that could personally identify you.

Your name, address, telephone and social security number(s) and other data that could reasonably identify you will be deleted from your medical record by a designated member of the research study team at the cancer registry before your health information is shared with other members of the research study team, research sponsor, or the Institutional Review Board (IRB).

Limits of this authorization

The research study team and research sponsor may not use the information for purposes other than this study. We will not disclose information to any other persons or entities other than those who are part of the research study team, research sponsor, or IRB as listed above. As indicated, all information that identifies you personally will be removed as required by HIPAA regulations as part of the study protocol.

There are no consequences to you if you refuse to sign this authorization.

How long the information will be used and your right to cancel your authorization

This authorization will expire two years after the completion of the study, *mm/dd/yyyy*, and *all abstraction records will be destroyed*. However, you have the right to cancel your authorization at any time. To cancel, you must send a written request that is signed by you or your personal representative. Contact the *Principal Investigator: name and address* and we will send you a form that you can use for this purpose. Canceling your authorization will not affect your medical care in any way.

Questions regarding your privacy rights

The address of the Institutional Review Board is:

ATTN: IRB Administrator
Institutional Review Board
Address

Tel: (____) ____-____

Please keep a signed copy of the completed Authorization for your future reference.

AUTHORIZATION FOR RELEASE OF MEDICAL RECORDS

Study ID

Case Investigation of Cervical Cancer (CICC) Study

Patient Name:		Birthdate:	
Street:			
City:		State:	Zip:

To: Health Care Providers, Facilities and Medical Records

By signing this document, I request and authorize (give permission to) you to release the following information about me to the researchers at the *state* Cancer Registry, Battelle Memorial Institute and the Centers for Disease Control and Prevention (CDC) so that they may review medical records related to my cervical cancer screening history, treatment and follow-up of precancers, and cancer diagnosis from my health care providers:

- Records, copies of my medical records, medical reports (i.e., pathology or test results), and other information, including information on screening history (Pap tests, HPV history, biopsies, ECC, surgery) and symptoms of cervical cancer five (5) years prior to my diagnosis of cancer through the date of my diagnosis.

Records can be mailed to: *Study director name and address.*

Information for the patient

The research team and sponsor will not use the information for purposes other than this study except as otherwise permitted by law. We will not disclose information to any persons or entities other than those who are part of the research study team, research sponsor, or human subjects committees. All information that identifies you personally will be removed as required by HIPAA regulations as part of the study protocol.

You have the right to revoke this Authorization. Unless previously revoked in writing, this authorization will expire two years after the completion of the study, *mm/dd/yyyy.*

Agreement

I have read (or someone has read to me) the information provided above. I have been given the opportunity to ask questions and all of my questions have been answered to my satisfaction.

(Signature of Patient)

(Date)

PLEASE RETURN THIS FORM in the postage paid envelope.

In order to make sure that we know the medical screenings and care that you received prior to your diagnosis, we are asking you to list the healthcare providers you saw for your gynecological care and *well woman* routine exams for a period of five years before your diagnosis, as well as providers you saw for the diagnosis of cervical cancer.

We do not have your medical providers listed in the cancer registry so we need your help to identify them so that we can better understand the full experience of medical care that you received prior to your diagnosis. This may help us better understand possible ways to prevent cervical cancer

Please provide the name and location of the medical providers, clinics and hospitals you saw for gynecologic and well woman preventive care in the 5 years leading up to and including your diagnosis.

If you cannot remember back for all of the 5 years or are missing some providers, please list what you do remember and make notes in the *Comment Box* about what information might be missing.

We will contact the medical providers you identify, give them a copy of the HIPAA-Medical Records Release Authorization you gave us, and ask them to share your medical information.

Do you recall all of the providers that you saw for gynecologic and well woman preventive care in the 5 years prior to and including your diagnosis? Yes No Not sure

Comment Box: _____

1. Provider/Clinic/Hospital Name:

Address: _____

City, State _____

Phone: (____) ____-_____

2. Provider/Clinic/Hospital Name:

Address: _____

City, State _____

Phone: (____) ____-_____

Space for additional medical providers, clinics or hospitals, is provided on the next page.

3. Provider/Clinic/Hospital Name: _____

Address: _____

City, State _____

Phone: (____) ____ - _____

4. Provider/Clinic/Hospital Name: _____

Address: _____

City, State _____

Phone: (____) ____ - _____

5. Provider/Clinic/Hospital Name: _____

Address: _____

City, State _____

Phone: (____) ____ - _____

6. Provider/Clinic/Hospital Name: _____

Address: _____

City, State _____

Phone: (____) ____ - _____

7. Provider/Clinic/Hospital Name: _____

Address: _____

City, State _____

Phone: (____) ____ - _____

8. Provider/Clinic/Hospital Name: _____

Address: _____

City, State _____

Phone: (____) ____ - _____

If you have additional providers, please include them on another sheet of paper.

PLEASE RETURN THIS FORM in the postage paid envelope.