SUMMARY OF CHANGES

A Randomized, Placebo-Controlled Trial of HPV Vaccination to Reduce Cervical High-Grade Squamous Intraepithelial Lesions among HIV-Infected Women Participating in an HPV Test-and-Treat Program (COVENANT)
Version 5.0

NCI Protocol #: AMC-099
Local Protocol #: AMC-099

NCI Version Date: 07AUG2023
Protocol Date: 07AUG2023

I. Administrative and Editorial Changes by Principal Investigator

#	Section	Comments
1.	Global	The model informed consent form was updated to version 5.0, and the date was updated to 07AUG2023.

MODEL INFORMED CONSENT

Study Title for Study Participants: HPV test-and-treat with or without HPV vaccine to reduce cervical pre-cancer

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: AMC PROTOCOL #099: A Randomized, Placebo-Controlled Trial of HPV Vaccination to Reduce Cervical High-Grade Squamous Intraepithelial Lesions among HIV-Infected Women Participating in an HPV Test-and-Treat Program (COVENANT)

A Clinical Trial of the AIDS Malignancy Consortium (AMC)

WHAT IS THE USUAL APPROACH FOR PREVENTING CERVICAL CANCER?

You are being asked to take part in the study because you are a woman with HIV infection. Cervical HSIL is tissue in the cervix, part of the uterus or womb, that has been damaged by infection with human papillomavirus (HPV) and is at risk for turning into cancer.

Some of the ways doctors prevent cervical cancer:

- Look for cervical HSIL by examining the cervix for damaged areas, Pap smears (rubbing cells off the cervix), or biopsies of the cervix (cutting small pieces of tissue from the cervix)
- Removing cervical HSIL if found or damaged areas are seen.

WHAT ARE MY OTHER CHOICES IF I DO NOT TAKE PART IN THIS STUDY?

If you decide not to take part in this study, you have other choices. For example:

- You may choose to have the usual approach described above.
- You may choose to take part in a different study, if one is available.
- You may choose not to have cervical cancer prevention.

WHY IS THIS STUDY BEING DONE?

Cervical cancer is a common cancer among women living with HIV. This study will test women for HPV infection of the cervix, and treat the cervix of women who have types of HPV infection that are most likely to cause HSIL. We will see whether giving a vaccine against HPV (9-valent HPV vaccine or 9vHPV) will make HSIL less likely to occur after a cervical treatment. We expect 1 out of 5 women to have HSIL diagnosed after the cervical treatment. 9vHPV is approved by the US Food and Drug Administration for cervical cancer prevention in females age 9-45 years.

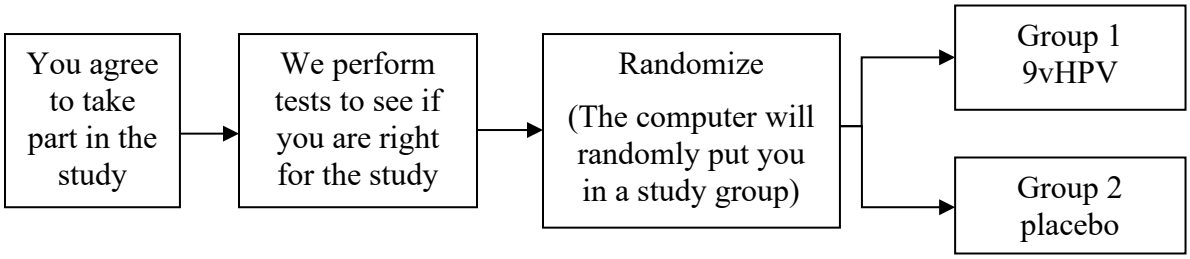
WHAT ARE THE STUDY GROUPS?

This study has two groups.

- Group 1 will get injections with the 9vHPV into your upper arm muscle or thigh
- Group 2 will get injections with salt water, which does nothing for HPV (this is known as a placebo) into your upper arm muscle or thigh

There will be 3 injections that occur at entry, 4 weeks and 26 weeks later. A computer will assign you to one of the study groups by chance. This is called randomization. This is done by chance because no one knows if one treatment is better than the other. You have an equal chance of being in any group. You and the study staff will not know whether you are in Group 1 or 2.

Another way to find out what will happen to you during this study is to read the chart below. Start reading at the left side and read across to the right, following the lines and arrows.



HOW LONG WILL I BE IN THIS STUDY?

You will be in the study for about two years.

WHAT EXTRA TESTS AND PROCEDURES WILL I HAVE IF I TAKE PART IN THIS STUDY?

Before you begin the study

We will ask you about your medical history and perform tests to confirm that you can take part. Your first visit will include the following unless done recently by a health care provider:

- Questions about your medical history, including :
- Information about your HIV disease and any Pap smears.
- Whether you ever had an HPV vaccine (like Gardasil® or Cervarix®).

Extra tests and procedures

A study calendar that describes these tests and how often they are done is attached.

- Cervical colposcopy and collection of cervical swabs for HPV and Pap tests.

If HPV infection that puts you at risk for HSIL is found, then you will enter the study.

- You will have blood drawn.
- You will have a swab of your anus to test for HPV infection.
- You will answer a brief questionnaire about sex you have had recently.

If you are a woman who is able to become pregnant, you will have a test of your urine for pregnancy at each study visit.

Four weeks after your first injection, you will receive a cervical treatment. If you have cervical cryotherapy, you will have at least two biopsies to look for HSIL just prior to the treatment.

After this, study staff will follow you with cervical colposcopy with biopsies, cervical HPV and Pap testing, and blood draws to look for HPV antibodies.

WHAT POSSIBLE RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?

If you choose to take part in this study, there is a risk that:

- You may lose time at work or home and spend more time at the clinic than usual.
- You may be asked sensitive or private questions which you normally do not discuss.
- 9vHPV may not be better, and could possibly be worse, than the salt water injection.

There is also a risk that you could have side effects from the study vaccine. Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.

Here are important points about how you and the study doctor can make side effects less of a problem:

- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust the study drugs to try to reduce side effects.

The lists below show the most common and the most serious side effects that researchers know about. There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Table of Possible Side Effects of 9vHPV and salt water injection.

COMMON, SOME MAY BE SERIOUS In 100 people receiving 9vHPV, more than 20 and up to 100 may have:
• Pain, redness, swelling and bruising at the injection site

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving 9vHPV, from 1 to 20 may have:	
• Headache • Fever • Nausea • Dizziness	• Tiredness • Muscle aches • Itching at the injection site • Sore throat • Stomach pain

RARE, AND SERIOUS In 100 people receiving 9vHPV, 1 may have:
• Allergic reactions • Dizziness and passing out. Shaking or seizure like movements can occur.

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

Reproductive risks: You should not get pregnant while in this study. The cervical treatment used in this study could be damaging to the pregnancy or the unborn baby. Check with the study doctor about what types of birth control, or pregnancy prevention, to use while in this study. If you are a woman and become pregnant or suspect you are pregnant while participating in this study, please inform your treating doctor or nurse immediately.

Risks to privacy: Your privacy is very important and the researchers will make every effort to protect it. Your test results will be identified by a unique code and the list that links the code to your name will be kept separate from your sample and health information.

WHAT IF I BECOME PREGNANT WHILE ON THIS STUDY?

We will continue to follow you on the study. You will not receive any study vaccine, cervical treatments or cervical biopsies while you are pregnant.

WHAT POSSIBLE BENEFITS CAN I EXPECT FROM TAKING PART IN THIS STUDY?

It is not possible to know at this time if the study drug/study approach is better than the usual approach so this study may or may not help you. This study may help researchers learn things that may help other people in the future.

CAN I STOP TAKING PART IN THIS STUDY?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest.
- If new information becomes available.
- If you do not follow the study rules.
- If the study is stopped by the U.S. National Cancer Institute (the study sponsor), AIDS Malignancy Consortium, the ethics committee, or any other agency responsible for oversight of the study.

WHAT ARE MY RIGHTS IN THIS STUDY?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the _____ *(insert name of center)* Institutional Review Board at _____ *(insert telephone number). (Note to Local Investigator: Contact information for patient representatives or other individuals at a local institution who are not on the IRB or research team but take calls regarding clinical trial questions can also be listed here.)*

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

You will not be charged for study-related visits, physical exams, laboratory tests or other procedures. *(Modify the prior statement to local requirements if subjects will be expected to cover the cost of any research-related care, tests, or supplies.)*

You will also not be charged for the HPV vaccine or salt water injection. These will be provided to study participants free of charge.

You, your insurance company, or your health care system will need to cover the cost of anti-HIV drugs. The study is not providing anti-HIV drugs. *(Delete references to insurance company or health care system if not applicable at site)*. In some cases, it is possible that your insurance company or health care system will not pay for these costs because you are participating in a research study. *(Insert site/country policy.)*

You will not be paid for taking part in this study. But you will receive *(Insert information on local currency amount for transportation and related costs)* to cover the costs of your time and transportation to the clinic.

WHAT HAPPENS IF I AM INJURED OR HURT BECAUSE I TOOK PART IN THIS STUDY?

If you are injured as a result of taking part in this study, please tell your study doctor. (*Institution name)* will give you immediate treatment. The doctor will refer you for further treatment if necessary. However, you may/may not *(per site/country policy)* have to pay for this care as (*Institution name)* and the AMC have not set aside funds for any treatment for injuries *(per site/country policy.*

If you have medical insurance, your insurance company may not be willing to pay for study-related injury. If you have no insurance (or if your insurance is not willing to pay), you may be responsible for any costs *(per site/country policy).*

You will not give up any of your legal rights to seek payment for injury by signing this consent form.

WHO WILL SEE MY MEDICAL INFORMATION?

Your privacy is very important to us and the researchers will make every effort to protect it. Your information may be given out if required by law. For example, certain laws require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information, and/or information about your specimens from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The AIDS Malignancy Consortium (AMC)
- Any drug company supporting the study (Merck, the company providing the vaccine)
- The Institutional Review Board (IRB) or ethics committee – this is a group of people who review research studies with the goal of protecting the people who take part in the study.

- *(insert name of authority for clinical research and/or investigational drugs for country)*
- The National Cancer Institute in the U.S.
- The Food and Drug Administration in the U.S.

WHERE CAN I GET MORE INFORMATION?

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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

WHO CAN ANSWER MY QUESTIONS ABOUT THIS STUDY?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor _____ *(insert name of study doctor[s])* at _____ *(insert telephone number).*

ADDITIONAL RESEARCH STUDIES SECTION

This part of the consent form is about optional studies that you can choose to take part in. You will not get health benefits from any of these studies. The researchers leading this optional study hope the results will help other people with cancer in the future.

The results will not be added to your medical records and you or your study doctor (specify: will/will not) know the results.

You will not be billed for these optional studies. You can still take part in the main study even if you say 'no' to any or all of these studies. If you sign up for but cannot complete any of the studies for any reason, you can still take part in the main study.

Circle your choice of "yes" or "no" for each of the following studies.

OPTIONAL SAMPLE COLLECTIONS FOR LABORATORY STUDIES AND DONATION OF LEFTOVER TISSUE SAMPLES TO THE AIDS AND CANCER SPECIMEN RESOURCE (ACSR)

Researchers are trying to learn more about cancer, HIV/AIDS, and other health problems. Much of this research is done using samples from your tissue, blood, urine, or other fluids. Through these studies, researchers hope to find new ways to prevent, detect, treat, or cure health problems.

- **Donation of left over study specimens to the ACSR for all study participants:** If you choose to take part in this clinical trial, the researchers would like to collect unused blood and biopsy tissue left over after the study is done. The researchers ask your permission to store and use your samples and related health information (for example, your response to cancer treatment, results of study tests and medicines you are given) for medical research. The research that may be done is unknown at this time. Storing samples for future studies is called "biobanking." The Biobank is being run by the **AIDS and Cancer Specimen Resource** and is supported by the National Cancer Institute.

WHAT IS INVOLVED?

If you agree to take part, here is what will happen next:

a) **Donation of left over study specimens to the ACSR for all study participants:** Your sample and some related health information will be stored in the ACSR Biobank, along with samples and information from other people who take part. The samples will be kept until they are used up. Information from your medical record may be updated after the study is over.

b) **Donation of screening visit materials if found to be ineligible for study:** Your samples from your screening visit and some health related information will be used by the researchers for future research.

1) Qualified researchers can submit a request to use the materials stored in the ACSR. A science committee at the ACSR will review each request. There will also be an ethics review to ensure that the request is necessary and proper. Researchers will not be given your name or any other information that could directly identify you.

2) Neither you nor your study doctor will be notified when research will be conducted or given reports or other information about any research that is done using your samples.

3) Some of your genetic and health information may be placed in central databases that may be public, along with information from many other people. Information that could directly identify you will not be included.

WHAT ARE THE POSSIBLE RISKS?

1) There is a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.

2) There is a risk that someone could trace the information in a central database back to you. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.

3) In some cases, this information could be used to make it harder for you to get or keep a job or insurance. There are laws against the misuse of genetic information, but they may not give full protection. There can also be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a study. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?

Your privacy is very important to the researchers and they will make every effort to protect it. Here are just a few of the steps they will take:

1) When your sample(s) is sent to the researchers, no information identifying you (such as your name) will be sent. Samples will be identified by a unique code only.

2) The list that links the unique code to your name will be kept separate from your sample and health information. The ACSR and AMC staff with access to the list must sign an agreement to keep your identity confidential.

3) Researchers to whom the ACSR and the AMC send your sample and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.

4) Information that identifies you will not be given to anyone, unless required by law.

5) If research results are published, your name and other personal information will not be used.

WHAT ARE THE POSSIBLE BENEFITS?

You will not benefit from taking part. The researchers, using the samples from you and others, might make discoveries that could help people in the future.

ARE THERE ANY COSTS OR PAYMENTS?

There are no additional costs to you or your insurance for these optional studies. [Insert any local stipends]. If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

WHAT IF I CHANGE MY MIND?

If you decide you no longer want your samples to be used, you can call the study doctor, _____, *(insert name of study doctor for main trial)* at _____ *(insert telephone number of study doctor for main trial)* who will let the researchers know. Then, any sample that remains in the bank will no longer be used and related health information will no longer be collected. Samples or related information that have already been given to or used by researchers will not be returned.

WHAT IF I HAVE MORE QUESTIONS?

If you have questions about the use of your samples for research, contact the study doctor, _____, *(insert name of study doctor for main trial)*, at _____ *(insert telephone number of study doctor for main trial)*.

Please circle your answer to show whether or not you would like to take part in each option:

Samples for future research studies:

My samples and related information may be donated to ACSR Biobank for use in future health research.

Initial _____ YES _____ NO

If I am ineligible for the study, or choose not to participate in the study, the researchers may use my study data and samples collected during the screening visit for future research.

Initial _____ YES _____ NO

MY SIGNATURE AGREEING TO TAKE PART IN THE MAIN STUDY

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed copy of this form. I agree to take part in the main study *and any additional studies where I circled 'yes'.*

_____	_____
Participant's Signature	Date of Signature
_____	_____
Signature of Person(s) conducting the Informed Consent Discussion	Date of Signature

AMC-099: STUDY CALENDAR FOR VOLUNTEERS

Screening

At this visit, we will ask you about the following information and perform these exams:

- Medical history including a history of HIV medications
- Urine test for pregnancy (if woman able to become pregnant)
- Cervical swabs for HPV testing and cytology
- Cervical colposcopy and vulvar examination
- Anal swab

Entry

- Your medical history will be updated for any changes since your last visit. This includes any side effects from the study exam, and any changes in your medications. A brief physical exam may be performed.
- Blood draw
- 9vHPV or placebo injection
- Baseline questionnaire

Week 4

- Your medical history will be updated for any changes since your last visit. This includes any side effects from the study exams and study vaccine, and any changes in your medication. A brief physical exam may be performed.
- Urine test for pregnancy (if woman able to become pregnant)
- 9vHPV or placebo injection
- Cervical colposcopy
- Cryotherapy or LEEP therapy. If you undergo cervical cryotherapy, at least 2 cervical biopsies will be taken prior to the cryotherapy.

Week 26

- Your medical history will be updated for any changes since your last visit. This includes any side effects from the study exams and study vaccine, and any changes in your medication. A brief physical exam may be performed.
- Urine test for pregnancy (if woman able to become pregnant)
- 9vHPV or placebo injection
- Cervical swabs for HPV testing and cytology
- Cervical colposcopy with at least two cervical biopsies obtained, and vulvar examination
- Blood draw

Week 52

- Your medical history will be updated for any changes since your last visit. This includes any side effects from the study exams and study vaccine, and any changes in your medication. A brief physical exam may be performed.
- Urine test for pregnancy (if woman able to become pregnant)
- Cervical swabs for HPV testing and cytology
- Cervical colposcopy with at least two cervical biopsies obtained, and vulvar examination
- Blood draw
- Anal swab
- Questionnaire

Week 78

- Your medical history will be updated for any changes since your last visit. This includes any side effects from the study exams, and any changes in your medication. A brief physical exam may be performed.
- Urine test for pregnancy (if woman able to become pregnant)
- Cervical swabs for HPV testing.
- Cervical colposcopy if your study provider feels it is necessary.
- Blood draw

Week 104

This will be the final visit for this study. At this visit, we will ask you about the following information and perform these exams:

- Your medical history will be updated for any changes since your last visit. This includes any side effects from the study exams, and any changes in your medication. A brief physical exam may be performed.
- Urine test for pregnancy (if woman able to become pregnant)
- Examination of the vulva. Biopsies of the vulva may be done if the provider feels HPV damage is present.
- Cervical swabs for HPV testing and cytology
- Cervical colposcopy with at least 2 cervical biopsies and vulvar examination.
- Anal swab
- Blood draw
- Follow-up questionnaire

Treatment of Cervical HSIL

If you are diagnosed with cervical HSIL at any point after week 4, we will ask you to return for LEEP treatment. Your provider may recommend an alternative treatment if he or she feels this is best for you.

Description of COVENANT Procedures

Cervical Swabs for HPV and Pap Testing

The study doctor or nurse will insert a speculum into your vagina to gently stretch the opening. A swab will be used to rub cells off the cervix to be tested for HPV. A small plastic broom will be used rub and sweep cells from the cervix. For a Pap test, the cells are looked at under a microscope to check for any problems.

Cervical Colposcopy

While the speculum is inserted, acetic acid (common table vinegar) is placed on the cervix. This causes cervical cells that are not normal to appear white in color. A doctor or nurse then uses a colposcope to look at the cervix. A colposcope is a large microscope with a bright light that is positioned approximately 30 centimeters from the vagina to allow the doctor or nurse to clearly see the cervix. It will take about 15 minutes to do this procedure.

Cervical Biopsy

This is done during a cervical colposcopy. A doctor or nurse pinches a small amount of skin from areas of the cervix that appear to be damaged by HPV. If no damage is seen, then random biopsies will be obtained. It will take about 5 minutes to do this procedure. The biopsy is sent to the laboratory to look for abnormal cells.

Cervical Cryotherapy

This is a treatment that freezes a section of the cervix. A doctor or nurse will insert a speculum into the vagina. For this treatment, the doctor or nurse will not inject the cervix with medication to numb the cervix. A special instrument called a probe is placed against the cervix and the cervix is frozen for 3 minutes, thawed for 5 minutes and frozen again for 3 minutes.

LEEP (Loop Electrosurgical Excision Procedure)

This procedure uses a thin wire loop to remove abnormal areas from the cervix. A doctor or nurse will insert a speculum into the vagina and will inject the cervix with medication to numb the cervix. The wire loop is attached to a machine that gives off small electric current. The wire is passed under the areas damaged by HPV to remove them. It will take about 20 minutes to do this procedure.

Vulvar Examination

The vulva is the area around the vagina. This skin can also be damaged by HPV infection. The doctor or nurse will carefully examine the skin. If any areas of the vulva appeared damaged by HPV, then he or she will inject the area with numbing medicine and then a small piece of skin will be pinched off.

Anal Swab

The doctor or nurse will insert a small swab into your anus. The swab will be rubbed in a circular motion against the skin inside the anus.

Additional Risks of Study Procedures Other than Vaccination

Blood draw: Taking blood may cause some discomfort, bleeding, or bruising where the needle enters the body, lightheadedness; and in rare cases, fainting or infection.

Cervical colposcopy, speculum exam, Pap test, and HPV testing: These tests can be uncomfortable. Occasionally there can be some bleeding, a tingling feeling, or slight stinging. These tests may cause embarrassment. Some people may feel anxiety while waiting for the test results.

Cervical Biopsy

- Pain during biopsy
- Mild bleeding similar to a menstrual period
- Rarely, the following problems can occur
    - Heavy bleeding can occur requiring treatment to stop the bleeding
    - Infection of the cervix requiring antibiotics (drugs used to stop or slow down the growth of bacteria and germs)
    - Damage to the cervix making it more difficult to carry a pregnancy

Cervical Cryotherapy

- Pain and cramping during the procedure
- Heavy, watery discharge from the vagina for 1 to 2 weeks
- Heavy, foul-smelling discharge from the vagina
- Mild bleeding similar to a menstrual period
- Infection of the cervix requiring antibiotics
- Rarely, the following problems can occur
    - Severe cramps and stomach pain requiring pain medications
    - Infection of your uterus and surrounding areas
    - Heavy bleeding requiring treatment to stop the bleeding
    - Narrowing of the cervix making it difficult for menstrual bleeding to occur
    - Accidental freezing of the vagina during the procedure
    - Dizziness or fainting during the procedure
    - Damage to the cervix making it more difficult to carry a pregnancy
    - Damage to the cervix making it difficult to become pregnant

LEEP

- Pain from injections of numbing medication into the cervix
- Blood tinged or dark brown mucus from the vagina for 1 or 2 weeks
- Dull ache or cramping during the procedure

- Pain or cramping after the procedure
- Infection of the cervix requiring antibiotics
- Rarely, the following reactions can occur
    - Dizziness, fainting or allergic reaction to the numbing medications
    - Severe bleeding of the cervix requiring sewing of the cervix
    - Accidental damage of the vagina
    - Accidental damage of the uterus
    - Infection of the uterus and surrounding areas
    - Narrowing of the cervix making it difficult for menstrual bleeding to occur
    - Damage to the cervix making it more difficult to carry a pregnancy
    - Damage to the cervix making it difficult to become pregnant

Spreading HIV

For some time after you have cryotherapy or LEEP, it is possible the condition of the cervix may make it more likely to spread HIV to a sexual partner. For this reason, we ask that you not have vaginal sex for 6 weeks after the procedure. If you choose to have vaginal sex, we ask that your sexual partner use a condom.

Anal swab

The anal swab may cause pain or irritation in the anus.

AMC-099: AMC CERTIFICATE OF CONFIDENTIALITY

HPV Test and Treat With or Without HPV Vaccine to Reduce Cervical Pre-Cancer

The NIH has given the AMC a Certificate of Confidentiality. The Certificate does not mean that the NIH or the U.S. Government recommend that you take part in this study. This Certificate helps us keep your health information private.

Your records for this study will have information that may identify you. This Certificate lets us turn down legal demands for your study records. We can use the Certificate to turn down demands for records from a U.S. court. The Certificate can be used in any federal, state, or local legal matters. We will use the Certificate to turn down any demands for your study records. The cases where we cannot use the Certificate are explained below.

We cannot use the Certificate to turn down a demand from the U.S. Government for study records. This applies to audits or reviews of the AMC. This also applies to study records that we have to report to the FDA.

The Certificate does not stop you or your family members from sharing your health information. It does not stop you from talking about taking part in this study. You may give written permission for an insurer, employer, or other person to get copies of your study records. If you give permission, we cannot use the Certificate to say no to a request for your study records.