RESEARCH SUBJECT INFORMATION AND CONSENT FORM	
Title	A phase 1 clinical trial of the safety and immunogenicity of an oral, replicating adenovirus 26 vector vaccine for HIV-1 (rcAd26.MOS1.HIV-Env) in healthy HIV-1-uninfected adults

This consent form contains important information to help you decide whether to participate in a research study.

The study staff will explain this study to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

- **Being in a study is voluntary – <u>your choice</u>.**
- **If you join this study, you can still <u>stop at any time</u>.**
- **<u>No</u> one can <u>promise</u> that a study will help you.**
- **Do not join this study unless all of your <u>questions</u> are <u>answered</u>.**

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the study;
- Any possible benefits to you;
- The possible risks to you;
- Other options you could choose instead of being in this study;
- How your personal health information will be treated during the study and after the study is over;
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

<u>Please read this consent form carefully.</u>

HOUSEHOLD CONTACT INFORMATION AND CONSENT FORM

TITLE: A phase 1 clinical trial of the safety and immunogenicity of an oral, replicating adenovirus 26 vector vaccine for HIV-1 (rcAd26.MOS1.HIV-Env) in healthy HIV-1-uninfected adults

PROTOCOL NO.: rcAd001/IAVI 001
WIRB® Protocol #
RSRB

SPONSOR: International AIDS Vaccine Initiative
125 Broad Street, 9th Fl
New York, NY 10004
United States

INVESTIGATOR: John J. Treanor, MD
Box 689
601 Elmwood Avenue
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SITE(S): Vaccine Research Unit
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Vaccine Research Unit Inpatient Facility
St. Mary's Campus
89 Genesee Street
Rochester, NY 14611
United States

STUDY RELATED PHONE NUMBER(S): John J. Treanor, MD
585-275-5871 (Office Hours)
585-327-3466 (24 Hours)

You have been asked to take part in a research study. First, we want you to know that taking part in a research study is entirely voluntary. Second, you need to know that there are important differences between being cared for in a research study and being cared for by your doctor outside of a research study. Taking part in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information. Being in this study does not replace your regular medical care. Therefore, it is important that you understand the difference between the regular care you get from your doctor and what is involved in this research study.

About the study

The University of Rochester is doing a study on a new type of HIV vaccine. HIV is the virus that causes AIDS. You are learning about this study because you live with someone who wants to be a research volunteer in the study. We refer to you as a "household contact" of the research volunteer.

The vaccine is made of a live, weakened virus called adenovirus and is given by mouth in a capsule. The vaccine is not made from actual HIV. Because it is a live vaccine, there is a chance that it may be excreted in the stool of the research volunteer after he or she takes the capsule. If this happens, there is also a chance that others might have contact with that stool and accidentally transfer the vaccine to their mouths, where the vaccine might be swallowed again. It is actually very easy to have contact with someone else's stool, especially if you live with someone and share a bathroom.

We think the vaccine will most likely be found in the stool of volunteers about 7 days after they take the capsule. All volunteers will therefore have to stay in the Vaccine Research Isolation Unit for 9 days following vaccination for a total of 12 days. Once the volunteer is discharged from the Isolation Unit, we believe that the risk of spreading the weakened virus in the vaccine to others is very low. Still, there is a small risk that people who live with the volunteer might be exposed to the vaccine.

We are asking you if you agree to participate in this study because you are a household contact of a research volunteer, and may be exposed to the study vaccine. If you do not agree to participate in this research study as a household contact, then the research volunteer who you live with will not be allowed to participate either.

About 24 people will take part in this study as research volunteers. We are testing 4 different doses. The researcher in charge of this study at University of Rochester is John J. Treanor, MD. We are collaborating with Beth Israel Deaconess Medical Center and researchers at Harvard University who helped design the study vaccine, and the International AIDS Vaccine Initiative (IAVI), who has helped to organize the study. The Bill and Melinda Gates Foundation is paying for the study.

1. **We are doing this study to answer several questions.**

   - Is the study vaccine safe to give to people?
   - Will the study vaccine cause any symptoms?
   - How do people's immune systems respond to the study vaccine? (Your immune system protects you from disease.)
   - Do people excrete the vaccine in their stool or in their throat? (In other words, can we detect the vaccine in people's stool or throat?)
   - What is the highest dose of the vaccine that is safe and well-tolerated by people?

2. **The study vaccine cannot give you HIV.**

The study vaccine is not made from actual HIV. If you are exposed to the vaccine, it is impossible for the study vaccine to give you HIV. Also, it cannot cause you to give HIV to someone else.

3. If you are exposed to the study vaccine, we do not know if the vaccine will decrease, increase, or not change your chance of becoming infected with HIV.

Several studies have tested whether HIV vaccines can reduce the risk of getting HIV from another person. In some studies, people who got the vaccine seemed to have the *same* risk of getting HIV as people who did not get the vaccine. In one study, people who got the vaccine seemed to have a *lower* risk of getting HIV than people who did not get the vaccine. In another study, some men who got the vaccine had a *higher* risk of getting HIV than men who did not get the vaccine. This study differs from the studies in which people who got the vaccine had a higher or lower risk of getting HIV. The study staff can tell you about the differences.

If you are exposed to the vaccine, we do not know whether the vaccine in this study will affect your risk of getting HIV from another person. The risk could be higher, lower, or unchanged. It's very important to avoid exposure to HIV during and after the study. We will tell you how to avoid HIV.

4. The study vaccine is experimental. There is no HIV vaccine that has been approved for use.

Because you live with someone who is participating in this vaccine study, there is a small chance you will be exposed to the study vaccine too. In this section we describe some of the risks associated with being exposed to the study vaccine. We will tell you if we learn anything new that may affect your willingness to stay in the study.

Side Effects

We do not expect any significant side effects if you are exposed to the study vaccine. Some mild symptoms might include:

- Nausea
- Abdominal discomfort
- Loose stools
- Fever

In other studies of similar vaccines, about 1 in 10 people had diarrhea. About 1 in 100 people had a fever. If you have these symptoms, we think they will not last long and will not require treatment. Rarely, a vaccine can cause an allergic reaction, including a rash, hives, or difficulty breathing. Allergic reactions can be life-threatening. You should tell us if you have ever had a bad reaction to any vaccine.

False Positive HIV Tests

Most vaccines cause the body to make antibodies as a way of preventing infection. If you are exposed to the study vaccine, your body may make antibodies to HIV. This might cause you to test positive on some types of HIV tests, even if you are not infected with HIV. This is called vaccine-induced seroreactivity (VISR). For this reason, you should plan to get HIV tests only at this clinic during the study. Our tests can tell the difference between true HIV infection and a positive result that is caused by the study vaccine.

If you are exposed to the vaccine and develop a false-positive HIV test (VISR), here are some of the risks:

- If someone believes you are infected with HIV even if you are not, you could face discrimination and other problems. For example, you could be denied medical or dental care, employment, insurance, a visa, or entry into the military.
- You will not be able to donate blood or organs.
- Your family and friends may treat you differently.
- If you become pregnant, the baby may also have a false-positive HIV test. (The antibodies may be passed to the baby but are not a danger to the baby.) For most babies, antibodies from the mother last for about six months.

If you develop a false-positive HIV test because you were exposed to the vaccine, we can provide you with free HIV testing for as long as you need it. If this happens, we do not know how long you will test positive due to exposure to the study vaccine. If you receive a positive HIV test result and we determine it is because you have HIV, we will refer you for follow-up care.

It is unlikely, but you could test negative at the end of the study and positive some time later, even though you don't have HIV. This could happen if different HIV tests come into use. We will give you a phone number to call for more information.

Joining the study

5. It is completely up to you whether or not to join the study.

Take your time in deciding. If it helps, talk to people you trust, such as your doctor, friends or family. If you decide not to join this study, or if you leave it after you have joined, your other care at this clinic and the benefits or rights you would normally have will not be affected.

6. If you were born female and could become pregnant, you must agree to use birth control to join this study.

Because you live with someone who is participating in this vaccine study, there is a small chance you will be exposed to the study vaccine too. For this reason, you should not become pregnant during the study. If you are exposed to the vaccine, we do not know how the vaccine could affect the developing baby.

If you were born female and are sexually active in a way that could lead you to get pregnant, you

must agree to use effective birth control from 3 weeks before to 4 months after you receive the vaccine. Effective birth control means using any of the following methods every time you have sex:

- Birth control drugs that prevent pregnancy—given by pills, shots, patches, vaginal rings, or inserts under the skin;
- Male or female condoms, with or without a cream or gel that kills sperm;
- Diaphragm or cervical cap with a cream or gel that kills sperm;
- Intrauterine device (IUD); or
- Any other contraceptive method approved by the researchers.

If you were born female, you do not have to use birth control if:

- You are only having sex with a partner or partners who have had a vasectomy. (We will ask you some questions to confirm that the vasectomy was successful.);
- You have reached menopause, with no menstrual periods for one year;
- You have had a hysterectomy (your uterus removed);
- You have had your ovaries removed;
- You have a tubal ligation (your "tubes tied") or confirmed successful placement of a product that blocks the fallopian tubes;
- You are having sex only with a female partner or partners;
- You are sexually abstinent (no sex at all).

Remember: If you are having sex, you need to use male or female condoms to protect yourself from HIV infection.

If you join the study, we will test you for pregnancy at screening and at 4 months.

Being in the study

If you meet the study requirements and want to join, here is what will happen:

7. You will be screened to determine your health status.

At this visit a study investigator will take a complete medical history. We will also draw about 10 mL of blood (1 tablespoon) to perform an HIV test and a test for exposure to the adenovirus included in the vaccine.

If you test positive for HIV at the time of screening, we are required by law to report this information to the New York State Health Department. Counseling will be made available to you to discuss your positive test result. Persons who test positive for HIV will not be able to participate in this study.

8. You will come to the clinic for scheduled visits about 4 times over about 1 year.

Visits can last from 30 to 45 minutes. You may have to come for more visits if you have a lab or health issue. We may contact you after the study ends (for example, to tell you about the study results), and request additional visits if necessary.

9. We will pay you for each study visit you complete.

You will receive $50.00 for each clinic visit you complete, to cover the costs of transportation and the time you spend at the clinic. Although you will have more than one screening visit, this counts as only one visit per the payment schedule.

You do not have to pay anything to be in this study.

10. We will counsel you on how to avoid contact with the stool of the person you live with.

Once the research volunteer has been discharged from the Isolation Unit, we believe that the risk of spreading the weakened virus in the vaccine to you or others is very low. The main way that we think it might be spread is if you have contact with the stool of the person you live with (the research volunteer). This can happen very easily when people share a bathroom. You can help reduce the risk of being exposed to the vaccine by observing proper personal hygiene, such as frequent hand washing, especially following bowel movements. We will counsel you on the best methods to minimize the risk of being exposed to the vaccine.

11. Research volunteers in this study will get either the vaccine or a placebo.

Most research volunteers in this study will get the study vaccine, but some volunteers will also get a placebo. Whether the volunteer gets the study vaccine or placebo is completely random, like flipping a coin. If the person you live with receives placebo, you have no risk of being exposed to the study vaccine. However, you will not know if the person you live with has received the study vaccine or placebo until the end of the study.

The study design:

Study Group	1	2	3	4
# of Volunteers Getting Vaccine	5	5	5	5
# of Volunteers Getting Placebo	1	1	1	1
# of Capsules	1	10	1	10
How Vaccine is Taken	By Mouth	By Mouth	By Mouth	By Mouth
# of Viral Particles Ingested (Total)	10^8	10^9	10^{10}	10^{11}

12. The research volunteer will receive the study vaccine only once.

The person you live with will be staying in the Vaccine Research Isolation Unit when he or she receives the study product. He or she will stay in the Isolation Unit for the 9 days afterwards to reduce the risk of exposing you to the vaccine.

13. As a household contact, we will:

- Do regular HIV testing, as well as counseling on your results and on how to avoid getting HIV;
- Take blood samples;
- Do pregnancy tests if you were born female; persons who have had a complete hysterectomy (removal of the uterus and ovaries, verified by medical records), are not required to have pregnancy tests;
- Ask questions about your health, including medications you may be taking;
- Ask questions about any personal problems or benefits you may have from being in the study; and
- Ask questions about whether you have had any HIV tests outside the study.

When we take blood, the amount will depend on the lab tests we need to do. It will be an amount between 10 mL and 15 mL (a little less than 1 tablespoon). Your body will make new blood to replace the blood we take out.

We will review the results of these tests with you at your next visit, or sooner if necessary. If any of the results are important to your health, we will tell you. We will also offer you counseling and referral for needed care.

Here is a schedule of what you will be asked to do if you are eligible and agree to participate in the study:

Study Month				**1**	**4**	**8**
Study Week		**2**	**3**	**4**	**16**	**34**
Study Day	**Scr**	**17** ***phone ok***	**21** ***phone ok***	**28**	**112**	**240**
Visit Windows (Days)	**-56, -3**	**±2**	**±2**	**+14**	**±14**	**± 14**
Screening Assessment	**X**					
Informed Consent	**X**					
Assessment of Understanding	**X**					
HIV Risk Assessment	**X**					
HIV Risk Reduction Counseling	**X**	**X**	**X**	**X**	**X**	**X**
HIV Test Counseling	**X**			**X**	**X**	**X**
Pregnancy Prevention Counseling	**X**	**X**	**X**	**X**	**X**	
Comprehensive Medical History	**X**					
Intercurrent Illness		**X**	**X**	**X**	**X**	
Adverse Event Evaluation	**X**	**X**	**X**	**X**	**X**	SAE Only
HIV Screening	**X**			**X**	**X**	**X**
HIV Diagnostics				**X**	**X**	**X**
Ad26 Serology	**X**			**X**	**X**	**X**
Urine Pregnancy Test	**X**				**X**	

14. We will counsel you on avoiding HIV infection.

We will ask you personal questions about your HIV risk factors such as sexual behavior and drug use. We will talk with you about ways of lowering your risk of getting HIV. If you become infected with HIV, we will talk with you about ways to avoid giving the virus to someone else. We will help you develop a risk reduction plan. Some topics we may discuss include:

- What you think causes risky behavior for you.
- Methods to avoid getting HIV or giving it to someone else.

These may include using condoms and other safe sex practices, or behavioral changes, such as cutting down on alcohol. We will talk about new methods of HIV prevention, and can give you information on how to access them.

15. We will test your samples for this study.

We will send your samples (without your name) to a lab to see how your immune system responds to the study products. The analysis of your samples will be led by a research team at Beth Israel Deaconess Medical Center (BIDMC).

These tests are for research purposes only. The lab will not give the results to you, your primary provider or this clinic, and the results will not become part of your study record.

16. We may take you out of the study at any time. We may do this even if you want to stay in the study.

This may happen if:

- You do not follow instructions,
- The researcher thinks that staying in the study might harm you,
- You get HIV,
- You enroll in a different research study where you receive another study product, or
- The study is stopped for any reason.
- The research volunteer leaves the study prior to vaccination.

If the research volunteer leaves the study after vaccination, we will continue to keep you in the study.

17. If you become pregnant during the study, we will continue with some procedures.

We will do this for as long as it is safe for you and your developing baby.

If you leave the study while you are still pregnant, we will contact you after your due date to ask some questions about your pregnancy and delivery.

18. If you get infected with HIV during the study, we will help you get care and support.

You will not be able to stay in this study. We will counsel you about your HIV infection and about telling your partner(s). We will tell you where you can get support and medical care, and about other studies you may want to join. We will not provide or pay for any of your HIV care directly.

Other Risks

19. There are other risks to being in this study.

Even if you don't get exposed to the vaccine, there are other risks to participating in this study:

- In this study we will take some blood samples. These procedures can cause sometimes cause bruising, pain, fainting, soreness, redness, swelling, itching, muscle damage, and (rarely) infection where the needle was inserted.
- You may feel embarrassed when we ask about your HIV risks, such as having sex and using drugs.
- You may feel anxious waiting for your HIV test results or other health test results.
- Although the risk is very low, it is possible that your personal information could be given to someone who should not have it. We can tell you more about how we will protect your personal information if you would like it.

Benefits

20. The study might not benefit you.

You might not benefit from participating in this study, except that you will get information about your health and HIV status, and get HIV risk reduction counseling. The information we collect from this study may help develop an effective HIV vaccine.

Your responsibilities as a study volunteer

21. If you join the study, you have responsibilities such as:

- Be informed about the study and ask questions if you don't understand something.
- Give the study staff complete and accurate study-related information. Update the staff about any symptoms or illnesses you are experiencing. Inform the staff of any problems or discrimination you experience because of your participation in this study.
- Do not donate blood or tissue during this study.
- Receive HIV testing only at this clinic during the study.
- Use birth control methods as described earlier.
- Follow the instructions of the study staff to reduce your chances of being exposed to the vaccine.

Leaving the study

22. Tell us if you decide to leave the study.

You are free to leave the study at any time and for any reason, but it is very important that you tell us. We will also ask you to come back to the clinic one last time for a physical exam, and we may ask to take some blood and urine samples. We will also ask about any personal problems or benefits you have experienced from being in the study. We believe these steps are important to protecting your health, but it is up to you whether to complete them. If you leave the study before the research volunteer has been vaccinated, then we will require the research volunteer to also drop out of the study. If you leave the study after the research volunteer has been vaccinated, then we will not ask the research volunteer to drop out.

Injuries

23. If you get sick or injured during the study, contact us immediately.

If you are directly injured by the study vaccine that is being studied, or by clinical procedures

solely required to participate in the study, you may need to pay for treatment of your injuries, but you will be reimbursed for the reasonable and necessary medical expenses for such treatment. You will not be required to pay for emergency medical treatment provided at Strong Memorial Hospital or Highland Hospital. The University may seek payment for treating study-related injuries from your health insurer or the study sponsor.

Use of Samples and Information

24. After the study is completed, we may want to use your samples to answer additional research questions.

When samples are no longer needed for this study, Beth Israel Deaconess Medical Center wants to keep them for use in other studies. This form gives you information so you can decide if you want your extra samples and information used in other studies. You will mark your decision at the end of the form.

If you decide that we may keep extra samples for use in other studies, here are some things you should know:

- Extra samples will be stored in a secure place at Beth Israel Deaconess Medical Center in Boston, MA.
- We will keep your samples for five years and then destroy them.
- You will not be paid for the use of your samples.
- You will not benefit from any studies we do with your samples. The studies are only being done for research purposes. Results from these other studies will not be given to you, this clinic, or your doctor.
- Beth Israel Deaconess Medical Center will not sell your samples or information.
- Your samples and information may be shared with other researchers. They will need to have their research plan approved by Beth Israel Deaconess Medical Center, as well as the researcher's institutional review board (IRB) or ethics committee (EC).
- If your samples are shared with other researchers, they will be labeled with a code number. Your name will not be a part of the information.
- Your samples might be used for studies related to HIV, vaccine, the immune system, and other diseases.

25. Confidentiality of records and authorization to use and disclose information for research purposes

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, your personal information will be stored securely and is kept separate from your research chart. Sometimes, however, researchers need to share information that may identify you with people that work for the University, collaborators, regulators or the study sponsor. This information will be used to do the research, study the results, or to see if the research was done right. If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

Here are some additional things you should know:

- If you decide not to give permission to use or give out your health information, then you will not be able to be in this study.
- You may review or copy your information when the research is over.
- If the results of this study are made public, information that identifies you will not be used.
- You may cancel your permission to use and disclose your health information at any time.
- If you withdraw from the study, no new health information identifying you will be gathered after that date.
- Your study records and samples will be kept in a secure location. We will not share your name with the lab that does the tests on your samples, or with anyone else who does not need to know your name.
- We cannot guarantee absolute privacy. At this clinic, we have to report the following information:
    - If you have a disease that we must report to the health department, such as certain sexually transmitted infections.
    - If we suspect that you may be harming yourself or others or planning to do so.

Questions

26. If you have questions or problems at any time during your participation in this study, use the following important contacts.

If you have questions about this study, contact

- Catherine Bunce RN, MS, CCRC, Study Coordinator
  Telephone: (585) 275-5744

- Doreen M. Francis, RN, CCRC
  Telephone: (585) 275-3473

- Or you may ask the study staff to give you the name and phone number of a Community Advisory Board member

If you have any symptoms that you think may be related to this study, contact

- John Treanor M.D., Principal Investigator
  Telephone: (585) 275-5871, after hours you may call (585) 327-3466

If you have questions about your rights as a research volunteer, or any concerns or complaints, you may contact

- Western Institutional Review Board
  1019 39th Avenue SE, Suite 120, Puyallup, WA, 98374-2115
  Telephone: (360) 252-2500 or (800) 562-4789
  Fax: (360) 252-2498
  Email: help@wirb.com

Your permissions and signature

In Section 13 of this form, we told you about possible other uses of your extra samples and limited information, outside this study. Please write your initials or make your mark in the box next to the option you choose.

☐ I allow my extra samples combined with limited information for other studies related to HIV, the immune system, and other diseases to be used.

OR

☐ I do not allow my extra samples to be used in any other studies.

INFORMED CONSENT FORM

Subject's Full Name *(please print)*: _____

By signing this form, I certify to all of the following:

- I have read this entire Information Sheet and Informed Consent Form (or had the information read to me) and received explanations regarding what will be done to me and what I am being asked to do. I have had the opportunity to ask questions, and I understand that I may ask additional questions about this research study at any time.
- I agree to participate in this research study and will fully cooperate with the research study doctor, and I will be in contact with him/her immediately in case of any unusual or unexpected symptoms during the research study. During the period of the research study, I will inform the research study doctor about any other medical treatment that might be needed.
- I will be given a copy of this Information Sheet and Informed Consent Form to keep for my reference.
- I consent to make my confidential personal information available for review by the Sponsor or its representative or to any health authorities, institutions, or governmental agencies assigned this task in this country or in another country where the study vaccine may be considered for approval, or, if applicable, the Institutional Review Board or Ethics Committee.
- I understand that I am free to withdraw from the research study at any time without explaining my decision to do so and without it affecting my medical care.
- I understand that I will be informed of any new information that may affect my willingness to continue participation in this research study.
- I voluntarily consent to take part in this research study.

_____ _____

Signature Date

Statement of Investigator (or person designated by the Investigator to perform the Informed Consent procedure):

I certify that I have explained the nature and purpose of this research study, and the potential benefits and reasonably foreseeable risks associated with participation, to the above volunteer, on the date stated on this consent form. I have answered any questions that were raised, and have witnessed the above signature.

Full name of the person performing the Informed Consent procedure (PI or his/her designee)
(please print)

_____ _____

Signature Date