

## Attachment 5. Recruitment Script

*When called by a potential volunteer, please make introductions and answer any questions that the volunteer may have concerning the study. If the potential volunteer is still interested, please read the following statement:*

Thank you for calling about information on volunteering to participate in a study entitled “A Randomized, Observer-blind, Placebo-controlled, Two-part, Phase 2 Study to Evaluate the Safety, Tolerability and Immunogenicity of Two Prime-boost Regimens of the Candidate Prophylactic Vaccines for Ebola Ad26.ZEBOV and MVA-BN-Filo”. We appreciate your interest. I will provide you some information that will help you determine if you can participate in the study.

### Background:

This study involves 2 experimental vaccines for the Ebola virus. Ebola is a contagious and often fatal infection affecting people in several countries, particularly in Central and Western Africa. The study is evaluating the safety, tolerability and immune response of 2 different ebola vaccines given 14 days apart. This combination may boost the immune system more effectively than either vaccine given alone. This 2-vaccine regimen is being studied in humans in multiple studies in Africa, Europe and US, and each has been studied in humans individually.

In this study, you will receive either 2 injections of vaccine or 2 injections of placebo, which is normal saline or sterile salt water. You cannot contract Ebola by receiving these vaccines. You have an 80% chance of receiving actual vaccine product, or 4 out of 5 people. You will have blood tests to measure how your immune system is responding to the vaccines. Only the vaccine preparers will know which one you receive; Neither you nor your doctor or coordinator will know what you are given.

Everyone that enters the study will be followed for at least 6 and ½ months. You will receive study injections on Day 1 and again on Day 15. You will be asked to record any symptoms in a diary for 7 days after each vaccine.



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There are 7 required visits in 6 and ½ months. When all participants have achieved the 6 months visit after the second injection, you will be told if you received vaccine or placebo injections. If you received vaccine, you will be asked to return for a final visit, which will be 1 year from the second injection.

We will enroll a total of 75 volunteers. Of those, 25 will be HIV-positive.

### Entry Criteria:

To qualify for this study, you must be:

- Age 18-70
- In good health
- Available for up to one year
- Willing to use effective birth control for at least the first 6 and ½ months of the study. Males in the study with female partners of childbearing potential must make sure that their partner is using effective birth control, and must also agree to use condoms.
- If you are HIV-positive, you must be on anti-retroviral medications at stable doses for at least 4 weeks.

You cannot be in this study if you have:

- Prior history of ebola infection or exposure
- Traveled to Ebola-endemic area in past 30 days
- Previous Ebola vaccine or any Ad26- or MVA-based vaccine
- Allergy to eggs, some vaccine products, or certain antibiotics
- Received any experimental vaccine or device in the past 3 months
- History of eczema
- History of chronic or recurring hives
- Newly-positive for HIV at screening
- Any history of organ or stem-cell transplant
- History of cancer that was cured with anything other than surgery.  
(Squamous cell and basal cell skin cancers are ok)



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- Concurrent participation in another study while in this one, unless it's only observational

If you decide you wish to screen for this study, we will schedule you for a screening visit in our clinic. You will attend a briefing where the study will be explained in detail and you will be given time to ask any questions you may have. You will read a document explaining the study. If you wish to continue and complete the screening requirements, you will need to pass a 'test of understanding' to ensure you have understood what this study is about and what is expected of you. Once you have passed (you are allowed to re-take the test twice) you can sign the consent form. This does not obligate you to do the study – signing it simply means that the study has been explained to you and you wish to participate.

At the screening visit, after watching the briefing, reading and signing the consent form, you will have:

- Vital signs taken
- Electrocardiogram (if you are over 50)
- Medical history and physical exam by a study doctor
- Blood and urine tests
- Urine pregnancy test if you are female

Once your test results are obtained (usually around a week's time), a study coordinator will call to tell you if you qualify and if so, if you wish to continue to the next visit. You will also be informed if you do not qualify, and the reason why.

Each study visit is compensated at the end of the visit. The maximum amount of compensation you can receive is \$1675 if all visits and requirements are completed. A smaller group of enrolled subjects may be asked to complete 3 optional blood donation visits for additional testing. These optional visits are compensated at \$300 each. The total compensation available for those volunteers completing these optional visits is \$2,575.

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