**\_\_\_\_\_\_\_\_\_\_\_\_** *(Enter DAIDS Network here, if applicable)*

PROTOCOL SPECIFIC INFORMED CONSENT FORM

**\_\_\_\_\_\_\_\_STUDY TITLE**

*(Insert complete title above as per protocol, include version number and date)*

**APPENDIX\_\_\_** *(Enter appropriate number)*

# \_\_\_\_\_\_\_\_\_\_\_\_ *(Enter a short version of the study title in lay language).*

The person in charge of this study at this site is \_\_\_\_\_\_\_\_\_\_ .*(****For Local Investigators and CRS Personnel.*** *Insert name of Principal Investigator (PI) and edit this sentence as appropriate).* The U.S. National Institutes of Health (NIH) is paying for this study. *(Revise this sentence and insert additional funding sponsors as applicable).*

This study involves research. Research is not the same as medical care. Research answers scientific questions. These answers can help find new medicines, treatments, vaccines, and even knowledge on how the human body works. Only people who want to participate will be part of this study. This informed consent form tells you about this study. You can ask questions at any time. You can discuss the study with others before deciding to join. No matter what your decision is, any other care that you get at this clinic will not change.

Researchers and study staff are asking you to join this study because you \_\_\_\_\_\_\_\_\_ *(Type a brief description here, e.g., “… are infected with \_\_\_”, “…because you are healthy and have \_\_\_”, etc.).*

The study staff will give you a copy of this form.

# Why are researchers doing this study?

Researchers are doing this study to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

*(Clearly describe in lay language why the study is being done; include the primary objective(s), and the secondary objective(s) if it is/they are safety related, and any investigational issues, e.g., first in humans, new population for study agent, etc.)*

*(Additionally, for studies with investigational agents, describe them in lay language).*

*(Please remember that there is a separate informed consent form template to address the collection and/or use of unused (leftovers) and extra samples that are to be stored for future research use).*

# How do I join this study?

(For studies using a separate informed consent form for screening procedures omit this section).

To see if you can join this study, you will have some lab tests, procedures, and exams. Then researchers will go over the results. If your results meet the study’s requirements, you will be able to join this study.

You will have the following:

*(List and briefly describe exams, tests, and procedures using a bulleted format).*

*(****For Local Investigators and CRS Personnel.*** *List the total amount of blood to be drawn for screening,* ***using easy to understand, commonly used, and locally appropriate units****).*

# What will I need to do during this study?

***(Add the following ONLY for research studies with two or more study groups)***

During this study, you will be in one of \_\_\_\_ (*enter total number of study groups*) study groups.

*(For randomized studies, add the following)*

Researchers will "randomize" you into one of the study groups described here. Randomization means that you are put into a study group by chance. Chance means that \_\_\_\_\_\_. *(****For Local Investigators and CRS Personnel.*** *Complete the above blank using locally appropriate lay language description, i.e. use a culturally appropriate randomization metaphor, for example “Like flipping a coin”).* Neither you nor the study staff can choose your study group.

|  |  |
| --- | --- |
| If you are in Group 1 | *(or the appropriate “group” description as per protocol)*  *(Explain here what will happen to this group’s participants, clearly describing what makes this “group” different from the others in the study)* |
| If you are in Group 2 | *(Continue here as above for each study “group”)* |
| Etc. | *(Continue here as above for each study “group”)* |

*(To avoid the table from becoming repetitive, use a general statement if applicable to multiple rows and/or study groups)*

*[In addition to the group descriptions above,* ***for research studies with “placebo” and/or “control” groups****, include lay language for: (1) definitions for the terms "placebo” and “control”; (2) rationale for using a placebo and/or a control group; (3) information about the degree of chance or possibility of assignment to one of the placebo or control groups; and (4) definitions for terms such as “blinded”, “double blinded”, “placebo controlled trial”, etc. Examples: (1) The clinic staff has no say in whether you get the study vaccine(s) or the placebo/control. They will not know which one you are getting, and neither will you, or (2) Not everyone in this study will get the study vaccine(s). Some participants will get a [placebo / control], a substance that does not contain vaccine. Researchers will compare the results from participants who got the placebo/control with results from participants who got the study vaccine(s)].*

***(For all research studies, add the following)***

Once you join this study, you will need to come for about \_\_\_\_ *(enter the total number of visits)* study visits. You will have the following lab tests, procedures, and exams:

* (List in chronological order and briefly describe the exams, tests, and procedures using a bulleted format. The descriptions should only include information that is necessary for potential participants to make an informed decision about joining the study. For research studies that have repetitive exams, tests, and procedures, a summary approach should be used, e.g. “at most visits you will have…”)
* (Include where the exams, tests, and procedures will be done and their frequency. List sampling amounts, e.g., pelvic samples (biopsies) – the number of samples, approximately what size, etc.)
* (INCLUDE ONLY THOSE EXAMS, TESTS, AND PROCEDURES DONE FOR RESEARCH PURPOSES.)
* (Consider differentiating between test results that are done specifically for this study, from test results collected under standard clinical care and used for this study).
* (Make sure to include information about experimental, invasive, painful, or lengthy exams, tests, and procedures).
* (Indicate if and when results from the exams, tests, and procedures done for research purposes but that affect clinical care will be given to participants).

**(For Local Investigators and CRS Personnel.** List the total amount of blood to be drawn using easy to understand, commonly used, and locally appropriate units.)

*(In addition to the bullets above, a simplified schedule of evaluations, in a table or flowchart format, is recommended to be inserted here or to be developed as a separate handout for participants. The schedule of evaluations from the protocol should not be used directly as it is too complex).*

***(Procedures-- First Example: Table format 1)***

| STUDY DAY/STUDY PERIOD  *(Use protocol appropriate units of time and descriptors)* | EXAMS, TESTS, AND/OR PROCEDURES  *(List exams, tests, and procedures and their frequency, as well as the amount of blood to be drawn using easy to understand culturally appropriate units) (If possible, include the length of time per visit)* |
| --- | --- |
| Day 0/Screening | *(e.g. routine blood tests, exams, etc.)* |
| Day 1/Randomization |  |
| Day 1/First Injection (*or first day of study drug, etc.)* | *(e.g. begin taking study medication)* |
| Day 56/Second Injection, etc. |  |

*(It may be helpful to combine both the Visit Schedule, either by week and visit number, visit length, and the Visit Tests/Procedures in the table above. Actual items in the table should be referenced/defined in a separate glossary or as footnotes to the table. For example, if a protocol includes blood draws and DXA scans, they should be defined separately for easy reference: “DXA: A DXA is a ......in which you lie on a table and ......”; “Blood draws: Blood draws involve.... Certain amounts of blood are taken which are measured by milliliters (mL), cubic centimeters (cc), or number of teaspoons)*

***(Procedures-- Second Example: Table format 2)***

| *Procedure* | *Screening visit(s)* | *First injection visit* | *½* | *2* | *2½* | *5* | *8* |
| --- | --- | --- | --- | --- | --- | --- | --- |
| *Injection* |  | *√* |  | *√* |  |  |  |
| *Medical history* | *√* |  |  |  |  |  |  |
| *Complete physical* | *√* |  |  |  |  |  | *√* |
| *Brief physical* |  | *√* | *√* | *√* | *√* | *√* |  |
| *Urine test* | *√* |  | *√* |  |  | *√* |  |
| *Blood drawn* | *√* | *√* | *√* | *√* | *√* | *√* | *√* |
| *Pregnancy test* | *√* | *√* |  | *√* |  |  | *√* |
| *(participants born*  *female)* |  |  |  |  |  |  |  |
| *HIV testing & pretest counseling* | *√* |  |  |  | *√* | *√* | *√* |
| *Risk reduction counseling* | *√* | *√* | *√* | *√* | *√* | *√* | *√* |
| *Interview/questionnaire* | *√* | *√* | *√* | *√* | *√* | *√* | *√* |

***(Procedures-- Third Example: Flowchart format )***

***Modify flowchart below as needed, based on specific study.***

*Enter Study Descriptor*

*Screening*

*Randomization*

*Time window*

***Specifics***

*Specifics*

***Specifics***

*Specifics*

***Specifics***

*Specifics*

***Specifics***

*Specifics*

# How long will I be in this study?

If you decide to join, you will be in this study for about \_\_\_. (Incorporate the appropriate unit of time here. This length of time should include the time for screening, enrollment, and study follow-up).

(It may be necessary to distinguish between study steps, follow ups, or CRS contacts after the completion of the main study. Incorporate language here to ensure these differences are explained.)

# How many participants will be in this study?

\_\_\_\_\_\_\_ (S*tate total accrual goal here)* participants will be in this study. At this site, there will be \_\_\_\_\_\_\_\_\_ participants. *(****For Local Investigators and CRS Personnel.*** *Omit the number of participants per CRS if this number is subject to change before full enrollment is reached. Consider adding information about the countries and number of CRSs participating in this study ).*

# What possible risks can I expect from participating in this study?

***(For HIV-vaccine research studies ONLY, add and edit the following)***

In this study, study staff will take some blood from you and give you some injections. These procedures can, at times, cause bruising, pain, fainting, soreness, redness, swelling, itching, and muscle damage. They rarely can cause an infection. Taking blood from you may cause a low blood cell count or “anemia” and make you feel tired. *(Include the sentence about anemia if the amount of blood to be collected is large)*

*(Enter here the specific known risks of any procedures, such as pelvic exams, rectal exams, biopsies, etc. Describe any reasonably foreseeable risks, discomforts or inconveniences; do not minimize the description of risks; and avoid lengthy complex medical terms).*

Rarely, a vaccine causes an allergic reaction. This reaction can be a rash, hives, or difficulty breathing. You should tell the study staff if you have ever had a bad reaction to an injection or a vaccine. Allergic reactions can be life-threatening.

All vaccines can cause fever, chills, rashes, pains, nausea, headache, dizziness, and sleepiness. Most people are still able to do their daily activities after getting a vaccine. Rarely do they need to go to the doctor. Frequently, vaccines cause pain and swelling where you get the injection. These local reactions are usually minor.

The body’s immune system protects the body from infections. Sometimes, this system attacks the body instead, causing an “autoimmune disease”. A vaccine can cause this type of disease or make it worse, but it happens hardly ever.

*[Enter here the specific known risks of the study vaccine(s) using the risk summary table guidelines located at the end of the entire risk section and highlighted in purple]*

**For Local Investigators and CRS Personnel.** Consider using supplemental medical glossaries during the informed consent process.

The vaccine*(s)* may cause “vaccine-induced sero-positivity” or “VISP”. So you may test HIV positive when you really do not have HIV. If you have VISP, you cannot donate blood. You may be unable to join the military, or to get medical or dental care, employment, health insurance, or a country visa. This clinic’s HIV test can tell the difference between real HIV infection and VISP. Researchers do not know how long you may have VISP. You will have free HIV testing at this clinic and any documentation you need to prove that you have VISP for as long as you need it. Study staff will give you a brochure that tells you more about VISP, and how to avoid related problems. **(*For Local Investigators and CRS Personnel.*** *Modify this paragraph as needed.)*

Also, if you become pregnant and have the baby while you have VISP, your baby may have VISP too. This clinic’s HIV test can tell the difference between real HIV infection and VISP in your baby as well. You will have access to this free HIV testing at this clinic for as long as you need it. **(*For Local Investigators and CRS Personnel.*** *Delete this paragraph if local HIV testing of newborns is done via nucleic acid testing).*

Researchers do not know how the vaccine(*s*) may affect your risk of getting HIV. If you get HIV, they do not know if the vaccine(*s*) would affect how bad your HIV infection will be. Also, they do not know if the vaccine(*s*) would change how you may respond to other HIV vaccines in the future. Currently, there is no vaccine for HIV.

*(For studies enrolling women of child bearing potential and using vaccines that may have possible risks in pregnancy, add the following)*

Researchers do not know if the vaccine(s) may harm unborn babies. You should not become pregnant during this study. If you are having sex that can make you pregnant, you should use birth control. Researchers will talk with you about acceptable birth control methods. You should use them from\_\_\_\_\_\_\_\_\_\_ *days/weeks* before your first injection until \_\_\_\_\_\_\_ *days/weeks/months* after your last study injection [*Modify language to meet protocol specific requirements for birth control pre, during, and post receiving study vaccine(s)].* Researchers will also test you for pregnancy before each injection and at some other study visits.

If you become pregnant during this study, you will stop getting the study injections. Study staff will help you find out about available care for you and your baby. This study will not pay for this care. Knowing the results of your pregnancy is important, so study staff may ask you to come back for visits or may call you. (*Modify as per protocol requirements*)

You should not breastfeed while on this study. Researchers do not know if the vaccine(*s*) may pass through breast-milk and may harm your baby. (*Modify as per protocol requirements*).

***(For prevention, social, behavioral, and epidemiological studies, add and edit the following as appropriate)***

In this study, study staff will take some blood from you. This procedure rarely can cause an infection. Taking blood from you may cause a low blood cell count or “anemia” and make you feel tired. *(Include the sentence about anemia if the amount of blood to be collected is large)*

*(Enter here the specific known risks of any procedures, such as pelvic exams, rectal exams, biopsies, injections, etc. Describe any reasonably foreseeable risks, discomforts or inconveniences; do not minimize the description of risks; and avoid lengthy complex medical terms).*

*[Enter here any risks for any study agent(s) used for prophylactic purposes, use the risk summary table guidelines located at the end of the entire risk section and highlighted in purple]*

**(For Local Investigators and CRS Personnel.** Consider using supplemental medical glossaries during the informed consent process).

*(Enter here the possible risk of developing drug resistance when a participant HIV-seroconverts if testing an ARV-containing study agent, e.g., If you become infected with HIV while using the study drug xxxx, it is possible that the medications in the anti-HIV medication, drug xxxx would not work against the HIV in your body).*

*(For prevention studies enrolling women of child bearing potential and that may have possible pregnancy risks, add and modify the following as appropriate)*

Researchers do not know if the \_\_\_\_\_ [*Enter study agent(s) here*] may harm unborn babies. You should not become pregnant during this study. If you are having sex that can make you pregnant, you should use birth control. Researchers will talk with you about acceptable birth control methods. You should use them from \_\_\_\_*days/weeks* until \_\_\_\_ *days/weeks/months [Modify language to meet protocol specific requirements for birth control pre, during, and post receiving study agent(s)].* Researchers will also test you for pregnancy at some study visits.

If you become pregnant during this study, researchers may ask you to stop using \_\_\_\_ [*Enter study agent(s) here*]. Study staff will help you find out about any available care for you and your baby. This study will not pay for this care. Knowing the results of your pregnancy is important, so study staff may ask you to come back for visits or may call you. (*Modify as per protocol requirements*)

*[For ARVs and other drug-intervention studies add here the DAIDS approved template language or standard guideline for birth control depending on the drug’s FDA pregnancy risk category (****See attached Appendix\_???****). There may be rare exceptions that require revision to this wording. Any revision should only be made after discussion with the DAIDS Medical Officer]*

Researchers want know if any of the HIV drugs you took during your pregnancy affected your baby. This information may help find the best HIV drugs to use in pregnant women. So, researchers will report this information to the "Antiretroviral Pregnancy Registry". This computer database will not use your name or information that can identify you. (*Modify as per protocol requirements*).

You should not breastfeed while on this study. Researchers do not know if the study agent may pass through breast-milk and may harm your baby. (*Modify as per protocol requirements*).

***(For therapeutic research studies ONLY, add and edit the following as appropriate)***

In this study, study staff will take some blood from you. This procedure rarely can cause an infection. Also, taking blood from you may cause a low blood cell count or “anemia” and make you feel tired. *(Include the sentence about anemia if the amount of blood to be collected is large)*

*(Enter here the specific known risks of any procedures, such as pelvic exams, rectal exams, biopsies, etc. Describe any reasonably foreseeable risks, discomforts or inconveniences; do not minimize the description of risks; avoid lengthy complex medical terms).*

**(For Local Investigators and CRS Personnel.** Consider using supplemental medical glossaries during the informed consent process).

*[Describe any reasonably foreseeable risks, discomforts or inconveniences of study agent(s) using risk summary table guidelines located at the end of the entire risk section and highlighted in purple]*

The following is a summary of the known risks of the \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[*enter study agent(s)]*. You may experience all, some, or none of these risks.

***(For Local Investigators and CRS Personnel.*** *DAIDS-approved risks lists will need to be part of the package for submission to the local IRBs/ECs and DAIDS PRO).*

*(For studies enrolling women of child bearing potential and that are using study agents that may have possible pregnancy risks, add the following)*

Researchers do not know if the \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *[Enter study agent(s) here]* may harm unborn babies. You should not become pregnant during this study. If you are having sex that can make you pregnant, you should use birth control. Researchers will talk with you about acceptable birth control methods *[Modify language to meet protocol specific requirements for birth control pre, during, and post receiving study agent(s)]*. You should use them from \_\_\_\_*days/weeks* until \_\_\_\_ *days/weeks/months [Modify language to meet protocol specific requirements for birth control pre, during, and post receiving study agent(s)].* Researchers will also test you for pregnancy at some study visits. (*Modify as appropriate for each protocol).*

If you become pregnant during this study, researchers may ask you to stop using \_\_\_\_ [*Enter study agent(s) here*]. Study staff will help you find out about any available care for you and your baby. This study will not pay for this care. Knowing the results of your pregnancy is important, so study staff may ask you to come back for visits or may call you. (*Modify as per protocol requirements*)

*[For ARVs and other drug-intervention studies add here the DAIDS approved template language or standard guideline for birth control depending on the drug’s FDA pregnancy risk category (****See attached Appendix\_???****). There may be rare exceptions that require revision to this wording. Any revision should only be made after discussion with the DAIDS Medical Officer]*

Researchers want know if any of the HIV drugs you took during your pregnancy affected your baby. This information may help find the best HIV drugs to use in pregnant women. So, researchers will report this information to the "Antiretroviral Pregnancy Registry". This computer database will not use your name or information that can identify you. (*Modify as per protocol requirements*).

You should not breastfeed while on this study. Researchers do not know if the study agent may pass through breast-milk and may harm your baby. *(Modify as per protocol requirements).*

*[Consider the following risks and add information* ***as appropriate:***

* *Risk of being in a placebo or a control group: (1) Include a lay language explanation of the degree of discomfort and potential risk due to not receiving the standard of care, i.e., not receiving any treatment or receiving a sub-optimal treatment/intervention for the disease or condition being studied; (2) Include a lay language explanation of the consequences of delaying active treatment/intervention; and (3) Include a lay language explanation of how the participant’s condition may worsen while on a placebo or a control group.*
* *Risk of changing or not providing an effective standard of care for a condition under study: Include a lay language explanation of how the participation in research may interfere with an effective standard of care, e.g., new dose finding and dosing schedule research for an approved and effective TB drug regimen.*
* *Risks related to stopping study agent/intervention/interaction early.*
* *Risk of developing immune reconstitution inflammatory syndrome (IRIS).*
* *Risks related to poor adherence to study intervention/interaction, e.g., drug resistance.]*

***(For ALL research studies, add and carefully edit the following as appropriate to account for social harms)***

You may face personal problems because of being in this study. Family, friends, and others may worry, get upset, or treat you unfairly. People may think that you have HIV or are likely to get it (*delete or modify this sentence as appropriate)*. You could lose your job because your employer thinks that you have HIV (*delete or modify this sentence as appropriate)*, or because you take too much time away from work to be in this study, but it is really unlikely.

You may feel embarrassed when answering personal questions about sex or having a physical exam. You may feel anxious when waiting for your HIV test results. If you have these feelings, please tell the study staff so that they can find a way to help you.

Researchers and study staff try hard to protect your privacy. They also have a duty to maintain your privacy. But there is a risk that others, including your partner, may find out that you are participating in this study. So, they may treat you badly or discriminate against you. Your partner may decide to insult you, leave you, or hit you. Your partner may stop paying for things. Another social risk is that someone may use your personal information in a bad way. For example, someone finds out your test results and shares them with others. You could then have problems getting or keeping a job. You may no longer have your family’s or your community’s support. These situations may cause you stress and embarrassment. Researchers have ways to reduce these social risks. Some of these ways include limiting access to your study records, having your study visits in private, and using codes to identify you and your samples. If you have any of these problems, please talk to the study staff, so that they can try to help you. ***(For Local Investigators and CRS Personnel.*** *Modify this paragraph to incorporate any other social harms known to occur at the local level. Also add qualifiers of frequency, if available, to the risks already described here, e.g. rarely, seldom, often, at times, etc.).*

There may be other risks that researchers do not know now. If you feel something bad that you think is because of being in this study, you should tell the study staff. Researchers will tell you about any new risks from this study or other studies that can affect your decision to stay in this study.

***Risk Summary Table Guidelines: (The following text is highlighted in purple)***

*DAIDS Medical Officers, working with protocol teams, and clinical trial specialists, should incorporate summary tables of any reasonably foreseeable risks, discomforts or inconveniences of study agent(s). Risks should not be minimized and lengthy complex medical terms should be avoided. Include only information that is necessary for potential participants to make an informed decision about study participation. Descriptions of risks of individual non-specified drugs or agents do not need to be included; however, general statements regarding common risks for relevant drug classes or referral to package inserts could be included.*

*Use a summary table format for study agent(s) risks, including lab value changes that could be perceived by study participants or could be indicative of harm. The following guidelines of frequency of risks should be used; however, DAIDS Medical Officers, working with protocol teams, should revise the guideline percentages as appropriate for each protocol:*

* ***“Common, some may be Serious”*** *– There is no standard definition of the frequency of risks included in this category. However, as a guideline, this category can be viewed as occurring in greater than 20% of participants receiving the study agent(s).*
* ***“Occasional, some may be Serious”*** *– There is no standard definition of the frequency of risks included in this category. However, as a loose guideline, this category can be viewed as occurring in 4% to 20% of participants receiving the study agent(s).*
* ***“Rare, and Serious”*** *– Risks that occur in 3% or fewer participants and that are not considered reasonably foreseeable but are serious. This category, in particular, would need to be modified for each protocol when the research study agent(s) has(have) not been widely investigated.*
* ***“Possible, some may be Serious”*** *– This frequency category may be used, when appropriate, for informing study participants of possible risks related to IND agents for which the frequency of individual risks has not yet been determined.*

***Notes:***

* ***“Serious”*** *is defined as risks that may require hospitalization or may be irreversible, long-term, or life-threatening.*
* *A DAIDS working group is in the process of developing summary tables of possible risks of study agents or combinations commonly used in DAIDS therapeutic or prophylactic trials. For research studies using a study agent with a DAIDS-Approved Standardized Risk List, check first at \_\_\_\_\_\_ to see if a summary risk table for that agent has been issued. If no summary risk table exists, use the agent’s DAIDS-Approved Standardized Risk List to create one following the guidelines above and using the Risk Summary Table Manual also found at the previous link. Additionally, the DAIDS-Approved Risk List for each study agent would need to be attached as an appendix to the protocol as supplemental supportive information to be submitted to IRBs/ECs, and not as a patient informational sheet. (This ends the highlighted purple text)*

# What possible benefits can I expect from participating in this study?

*(For research studies where* ***there is no potential*** *for direct benefit to participants from the study agent/intervention/interaction, add the following)*

Researchers do not know if \_\_\_\_\_ (add study agent/intervention/interaction here) will have a direct benefit to you. However, researchers may learn some information from this study that may help others.

Or

*(For research studies where* ***there is potential*** *for direct benefit**to participants from study agent/intervention/interaction, add the following).*

Researchers believe that \_\_\_\_\_\_ (*describe any reasonably* ***foreseeable potential direct*** *benefits for participants due to the study agent/intervention/interaction*) may have a direct benefit to you. Also, researchers may learn some information from this study that may help others.

(Additionally, when appropriate, edit the last sentence of either paragraph above by describing specifically any **known** **ancillary** **benefits** (1) to participants, e.g., additional monitoring, increased health awareness, access to early treatment for any secondary diagnoses, etc.; and (2) to society, e.g., future knowledge about the condition, etc.). **(Make sure to have a clear separation between the direct benefits and the ancillary benefits and do not include incidental findings language here).**

(For research studies with placebo groups, also add the following)

Also, if you are in one of the treatment groups, there is a possibility of benefit to you if \_\_\_\_\_\_\_\_\_ (add study agent/intervention/interaction here) is later proven to work.

(**For Local Investigators and CRS Personnel.** Payments of any kind **MUST NOT** be stated as benefits of research participation).

(If appropriate, add the following paragraph about **incidental findings** or foreseeable potential “important accidental findings”. “Important” means, at a minimum, clinically relevant and actionable for the participant).

Researchers may discover by chance something important about your health that has nothing to do with the study goals. For example, they might find out that you have a liver problem from a lab test result used to see if you could join the study. You may be able to do something about this finding. So researchers will refer you for care. At the end of this form, you will be able to choose if you want researchers to tell you about these kinds of findings. *(****For Local Investigators and CRS Personnel.*** *“Important” means, at a minimum, clinically relevant and actionable for the participant. These conditions should be based on locally available standard of care and resources).*

# What other choices do I have?

*(For treatment/intervention/procedure studies ONLY, add the following and edit as appropriate)*

If you choose not to participate in this study:

* You could choose to get the available local standard of care
* You could choose to get other research\_\_\_\_ (*treatments/interventions/procedures, choose as appropriate*) in another study
* You may choose to do nothing

*(For prevention studies ONLY, including vaccines, add the following and edit as appropriate)*

If you choose not to participate in this study:

* You could choose to participate in other studies
* You may choose to get HIV counseling and testing outside this study

***(For all research studies, add the following)***

If you would like more information about the risks and benefits of each one of these choices, feel free to talk to the study staff. You can also discuss these options with your doctor. Regardless of your choice, any care that you get at this clinic outside of this study will not change.

# Can I change my mind about participating in this study?

Yes, you can change your mind at any time. Your participation in this study is completely voluntary. Tell the study staff if you are thinking about leaving or have decided to leave this study. Again, any care that you get at this clinic outside of this study will not change.

Study staff may want you to do some follow up visits and testing before you leave this study.

# Can researchers take me off this study early?

Yes, researchers can take you off this study at any time:

* If they believe it is the best thing for you
* If you do not follow the study requirements
* If one of the groups watching over the study stops it

Study staff may want you to do some follow up visits and testing before you are off this study.

*(In the paragraph above, add more qualifiers to “best thing for you” as appropriate, e.g., continuing the study agent/intervention/interaction may be harmful to you, you need an intervention that you may not have while on the study, you become pregnant, you become infected with HIV, etc.)*

*[For research studies involving children (including neonates and adolescents) that require parental permission from both parents/guardians add the following]*

This study needs permission from both parents or legal guardian(s). Your child will not be able to participate in this study, if one of them does not give permission.

*(For research studies involving pregnant women or fetuses where there is a prospect of direct benefit solely to the fetus, add the following)*

This study needs permission from you and the father of your unborn baby. You may not be able to participate in this study, if he does not give his permission.

*(For prevention studies ONLY, including vaccines, add the following question and edit as appropriate)*

# What happens if I become HIV infected during this study?

If you become HIV infected during this study, study staff will tell about any available care. Study staff will counsel you about your HIV infection. They will also tell you how to lower the risks of giving HIV to others. Researchers may ask you to continue with this study for up to \_\_\_\_months. (*Modify as per protocol requirements*)

# What happens at the end of this study?

*(Add information on the study agent/intervention/interaction availability and when the study is completed. If applicable, explain any plans for long-term follow-up, e.g., tests, procedures, exams, etc.).*

*(For studies providing a drug, agent or device add the following and edit as appropriate)*

Once you finish this study, researchers cannot give you \_\_\_ *(insert drugs/agents, etc.)*. If \_\_\_\_ *(insert drugs/agents, etc.)* is helping you, the study staff may be able to tell you how to get it. But, it could be that you can only get something similar.

*(****For Local Investigators and CRS Personnel.*** *For research studies providing drugs that may not be available locally, edit the paragraph above adding specific information related to any post-trial access programs).*

*(If applicable, please add below information on any plans for informing participants of the study results.)*

*(For research studies with blinded groups, edit and add the following as appropriate)*

During this study, study staff will not know if you are getting the study agent, a placebo, or a control agent. You will not know, either. You will have to wait until this study ends to find out what you got. It could take several years. But, if you have a serious medical problem and need to know what you got before the end of this study, researchers can get this information. *(Edit this paragraph as applicable for each study)*.

# What will happen to my samples at end of this study?

*[For research studies with* ***NO*** *plans for using leftover (unused) specimens of any kind for future research beyond this study (main study), edit and add the following paragraph]*

Once this study ends, researchers will destroy all of your unused *\_\_\_\_\_\_\_\_\_\_\_\_\_ (Insert generic type of specimen, i.e., blood/body fluid/tissue).*  Researchers will not store any unused samples for future research.

*(Or)*

*[For research studies with* ***MANDATORY*** *storage of leftover (unused) specimens of any kind for future research beyond this study (main study), edit and add the following paragraph]*

Once this study ends, researchers may store some of your unused *\_\_\_\_\_\_\_\_\_\_\_\_\_ (Insert generic type of specimen, i.e., blood/body fluid/tissue)*. Researchers may use these samples for future research. You need to let researchers store these samples to participate in this study. There \_\_\_\_ (*insert “is” or “will be”’ as appropriate per protocol*) another informed consent form that explains what researchers may do with these samples.

# How will researchers protect the privacy of my information?

Researchers have protections in place to maintain your privacy. They keep your study records in a secure place. They do not use your name in publications, meetings, or stored samples. They use a code to identify you and your samples. They do not share any information that could identify you.

***(For Local Investigators and CRS Personnel.*** *Enter here, at CRS’s discretion, a brief description of additional methods used to maintain privacy and confidentiality of participants’ private and identifiable information, e.g., SOPs for sharing information, coding information, locked file cabinet, limited access to data room/pharmacy, etc.).*

There are some organizations watching over this study. They want to make sure that researchers are protecting your rights and keeping you safe. They also want to see if researchers follow the approved study. People from these organizations may review your records. These people have a duty to maintain your privacy. Some of these organizations are:

* The local Institutional Review Board (IRB) or Ethics Committee (EC)
* The U.S. National Institutes of Health (NIH)
* The U.S. Office for Human Research Protections (OHRP)
* The U.S. Food and Drug Administration (FDA) *(Omit if not applicable)*
* Other local, US, or international regulatory authorities/entities [*Insert any specific name(s), if applicable]  (****For Local Investigators and CRS Personnel.*** *Edit the sentence as needed).*
* The \_\_\_\_\_\_\_\_\_\_\_\_ *(insert name applicable national/local IRB/EC)*
* The \_\_\_\_\_\_\_\_\_\_\_\_ *(List any other relevant organizations like study sponsor(s), other pharmaceutical companies, network leadership, any collaborators, etc.)*
* Study monitors*(Omit if not applicable)*

***(For research studies being implemented at U.S. clinical research CRSs ONLY, where certificate of confidentiality are being requested, add the following).***

Researchers in the U.S. have "Certificates of Confidentiality" from NIH. Researchers can use these certificates as a tool to legally refuse to give information to others that would identify you. For example, researchers can say "No" to a court that is trying to get information about you. But, the courts can make researchers give information about you to prevent serious harm to you or others.

This tool does not stop you, or people close to you, from telling others about you or your being in the study. For example, you can give written consent for your boss, or your insurer, or others to get study information. Then researchers cannot use this tool to withhold the information. So, you and people close to you need to protect your information.

*[For research studies that need to be reported to clinicaltrials.gov add the following paragraph. This paragraph complies with the new FDA regulation found at 21 CFR 50.25(c) and must be included verbatim in all informed consent documents. Do not revise. TO DETERMINE IF A STUDY IS AN APPLICABLE CLINICAL TRIAL go to* [*NIH Implementation of FDAAA*](http://grants.nih.gov/ClinicalTrials_fdaaa/ACTs_under_FDAAA.htm) *]*

A description of this study will be available on [https://clinicaltrials.gov/](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.

# Will I have to pay anything to participate in this study?

You will not have to pay for any study lab tests, procedures, or exams. Your insurance provider will not have to pay either.(***For Local Investigators and CRS Personnel.***  *Edit this sentence to remove insurance provider if applicable. Also, add information on any extra costs to study participants or their insurance companies, e.g., information on any drugs or required procedures, any routine care that is part of the study, etc)*

# Will I receive any payment for my participation in this study?

*(Select one of the two following statements as appropriate)*

No, you will not receive any payment. You will need to spend some time and maybe some money to participate in this study. Researchers will not reimburse you for these expenses.

*(Or)*

No, you will not receive any payment. You will need to spend some time and maybe some money to participate in this study. Researchers will reimburse you for some of these expenses. You will receive a total of (1) \_\_\_\_\_\_ for \_\_\_\_\_\_(2). You will receive this reimbursement every \_\_\_\_\_\_\_\_ (3).

(**For Local Investigators and CRS Personnel.**  (1) enter CRS specific amount in appropriate currency; (2) list and briefly describe the types of expenses being covered by this reimbursement, e.g., transportation to CRS, time away from work, etc.; and (3) enter the specifics about how reimbursement will be made, include frequency and amount, revise if the planned reimbursement will include more than money, e.g. meals, bus passes, etc. Also, if applicable include information about reporting income to authorities, for example in the U.S. add tax info for reimbursement over $600 USD per year)

# Who should I contact if I think that I am hurt because of my participation in this study?

(For studies for which the researchers believe to be minimal risk, omit this section. **However, remember that the final determination of risk level is made by the local IRB/EC**).

If you think you are hurt because of your participation in this study, please tell (1) \_\_\_\_\_\_\_\_. You can do it in person or call (2) \_\_\_\_\_\_\_.

*(****For Local Investigators and CRS Personnel.*** *Enter (1) researcher(s) name or names, and (2) the complete contact information).*

If you are hurt because of your participation in this study, the (3) \_\_\_\_ will give you immediate necessary treatment. You (4) \_\_\_\_\_ have to pay for this treatment. The U.S. NIH is not able to reimburse you for these treatment expenses. You can use the court system to look for reimbursement for these expenses. Researchers will tell you where to get additional treatment. Finally, you may wish to talk to others who are not in this study to ask for advice.

*(****For Local Investigators and CRS Personnel.*** *In number (3) enter name of the institution, and in number (4) choose “will” or “will not”)*

*(****For Local Investigators and CRS Personnel.*** *In countries where insurance for injury compensation is mandatory, revise the above paragraph to include the relevant information. Also, edit the paragraph above to meet/add CRS’ or Institution’s, or local policy, as appropriate , for example the CRS or Institution may have procedures in place to determine the probability that the injury is related to research; thus, this information would need to be added).*

# What are my rights and who should I contact if I have questions?

You have the right to leave this study at any time and for any reason. The study staff will continue to treat you the same no matter what you decide. You will not give up your legal rights by signing this informed consent form. You also have the right to know about any new information from this study or other studies. This information may affect your health, welfare, or decision to stay in this study.

If you have any questions about your rights, you should contact \_\_\_\_\_ at \_\_\_\_\_. *(****For Local Investigators and CRS Personnel.*** *Enter appropriate name or names, titles, and complete contact information here. This person should be an individual other than the Study PI or anyone on this study team. The IRB/EC Chair or any IRB/EC member would likely be the most appropriate contact).*

# Do I want researchers to tell me about important findings that are not part of the study goals and that were found by chance?

Findings are important if they impact your health, welfare, or decisions about your health care.

|  |  |
| --- | --- |
| \_\_\_\_ (Initials) Yes, I want researchers to tell me. | \_\_\_\_ (Initials) No, I don’t want researchers to tell me. |

[For Local Investigators and CRS Personnel. The above option is about Incidental Findings (IFs) or foreseeable potential “important accidental findings” in clinical research. “Important” means, at a minimum, clinically relevant and actionable for the participant. These conditions should be based on locally available clinical standard of care and resources. Additionally, since disclosure of IFs is optional and not directly related to the aim of the study, some IRBs/ECs may find it more appropriate to place this section after the Question 20 below].

# How do I confirm my decision to be in this study?

My signature below confirms:

* that I voluntarily decided to participate in this study
* that I had the opportunity to read this form or that it was read to me
* that this form was explained to me
* that I had the opportunity to ask questions
* that I had the opportunity to discuss my study participation with others

*(Edit the bullets above as applicable. However, maintain all three elements, i.e. voluntary participation, understanding of the information, and satisfaction with responses)*

***(For Local Investigators and CRS Personnel.*** *The following block of signatures should be modified as suitable for each protocol. See the Instructions Page of this template for details. Remember, it is the responsibility of the local IRB/EC to determine the appropriate procedures for obtaining and documenting informed consent).*

|  |  |  |
| --- | --- | --- |
| **Participant’s Name (print)** |  | **Participant’s Signature/Mark/Thumb Print and Date** |
| **Participant’s Authorized Legal Representative’s Name (Print)** |  | **Authorized Legal Representative’s Signature and Date** |
| **Study Staff’s Name Conducting Consent Discussion (Print)**  ***Or***  **Study Staff’s Name Obtaining Consent (Print)** |  | **Study Staff’s Signature and Date** |
| **Witness’ Name (Print)** |  | **Witness’s Signature and Date** |
| **Mother’s Name (Print)** |  | **Mother’s Signature and Date** |
| **Father’s Name (Print)** |  | **Father’s Signature and Date** |