—INSTRUCTIONS—

FOR INFORMED CONSENT FORM (ICF) AUTHORS:

- The process of obtaining informed consent must, at a minimum, comply with the regulations of the U.S. Department of Health and Human Services (HHS) found at 45 CFR 46; in particular §46.116 for the general requirements for informed consent and §46.117 for the documentation of the informed consent process. Studies conducted under an Investigational New Drug Application (IND) must also comply with the U.S. Food and Drug Administration's (FDA's) protection of human subjects regulations found at 21 CFR 50, in particular §50.25 and §50.27.
- The content of the protocol/sample informed consent form (ICF) created using this template must match the protocol content. Throughout this template, instructions and examples are provided in ***italics***. Once you have completed the protocol/sample ICF, remove all the instructions italicized in blue.
- The ICF must be written in a language and at a reading and comprehension level understandable to the participant being consented/participant's Legally Authorized Representative (LAR) (usually at an 8th grade or lower reading level).
- When an LAR provides consent, the participant should be informed about the study to the extent possible given his/her understanding. If the participant regains the capacity to consent, consent must be obtained from the participant and the participant must be offered the ability to leave the study if desired.
- The first person "I" and second person "YOU" are used throughout the template to identify the study participant; however, for research with children, these terms should be modified as appropriate (e.g., parental permission forms should use terms such as Your Child, Your Baby, You and Your Child, You and Your Baby, etc.).
- The term "Researchers" used throughout this document refers to protocol chairs, investigators, scientists, or clinical staff, who will be conducting the study. The term "study staff" used throughout this template refers to anyone at the site who is involved with the study at the site level and is listed on the site's delegation log.

FOR LOCAL INVESTIGATORS AND CLINICAL RESEARCH SITE (CRS) PERSONNEL:

- Whenever possible, use language or context specific to the region where the research is being conducted, including the use of local words and sentence structure. Customize language in this template to suit each study. Please ensure that the content of the site-specific ICF matches the protocol/sample ICF.
- Some harms or risks, such as loss or breach of privacy may result in embarrassment, loss of current or future employment, ineligibility for insurance, criminal prosecution, etc. Information regarding alcohol or drug abuse, mental illness, and HIV status are areas of particular sensitivity. Therefore, special attention should be given to augment and specifically define the related risks described in the site-specific ICF. Note – the above examples are not exhaustive.
- The ICF is a tool for the larger informed consent process. It can be supplemented with Institutional Review Board (IRB)/Ethics Committee (EC)/Regulatory Entity (RE)/Regulatory Authority (RA) (as applicable) approved non-written methods of communication (e.g., videos, flipcharts, etc.), as well as additional documents and materials (e.g., participant information sheet, medical glossaries, etc.). A good informed consent process includes some type of "Assessment of Understanding" (AoU) given to participants. Various AoU-methodologies can be used to evaluate understanding (e.g., open ended, true or false, multiple choice questions, or a combination of these).
- For studies that involve children, the IRB/EC of record is responsible for determining: (1) when children are capable of providing assent as well as whether and how assent must be documented; (2) when the permission of one parent or legal guardian is sufficient; and (3) when the permission of both parents or legal guardians is needed (see §46.408). Also see the Division of AIDS (DAIDS) policy, "Enrolling Children (including Adolescents) in Clinical Research".
- HHS regulations require that the consent process be done in a language understandable to the prospective participant/Legally Authorized Representative (LAR) and, in most situations, documented in writing. The prospective participant/LAR should be presented with a complete ICF, such as the form generated using this template. Alternatively, a short ICF written in a language spoken by the prospective participant/LAR could be used. This short form should state that the elements of consent have been presented orally using a written summary. This summary could be the IRB/EC-approved site specific ICF for the study (sample short form consent). When the short form is used, a witness who is fluent in both the language of the summary, and the language of the short consent form, is required. The prospective participant must be given copies of the short form and the summary. The form should be signed or marked by the

prospective participant, or his/her LAR, and the witness. The summary should be signed by the study staff obtaining consent and the witness. If the study staff obtaining consent is assisted by a translator, the translator may serve as the witness (§46.117).

- Alternatively, an e-consent process may be used to conduct the informed consent discussion (convey study information, ask/answer questions, etc.) and/or document consent (participant/LAR, parental/guardian permission, assent) if permitted by local laws, regulations and guidance and institutional policies (see the 2016 OHRP/FDA guidance: Use of Electronic Informed Consent).
- According to the U.S. Food and Drug Administration (FDA) Guidance, an illiterate prospective participant can be enrolled in a study by "making a mark" on the ICF, as long as this practice is consistent with applicable local law. Similarly, a prospective participant who is physically unable to talk or write, so he/she cannot make a mark, but who understands the spoken language used during the verbal consent process and also understands the study's concepts including risks and benefits, can be enrolled. In this instance, the prospective participant would have to be able to indicate approval or disapproval to enroll in the study, as long as this procedure is consistent with local law. In both these cases, there should be a witness present during the entire consent process who signs the site specific ICF (Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors, August 2023).
- For additional guidance related to the informed consent process and documentation ,see the DAIDS Site Clinical Operations and Research Essentials (SCORE) Manual, Informed Consent of Participants section.
- In all cases where multiple requirements apply, the most stringent requirements must be followed.

FOR LOCAL INVESTIGATORS AND CRS PERSONNEL—NOTES ON SPECIFIC ICF QUESTIONS:

- **Question 2:** Include pertinent information that participants may need to make an informed decision to join the research.
- **Question 4:** List the total amount of blood to be drawn for screening, using easy to understand, commonly used, and locally appropriate units.
- **Question 5:** Use locally appropriate descriptions or metaphors, i.e., "like flipping a coin" for randomization. List the total amount of blood to be drawn using easy to understand, commonly used, and locally appropriate units.
- **Question 7:** Omit the number of participants per CRS if this number may change before full enrollment is reached. Consider adding information about the countries and number of CRSs participating in this study.
- **Question 8:** Consider using supplemental materials (e.g., such as a medical dictionary or handbook) during the informed consent process. Edit to incorporate any other harms known to occur at the local level. Also add qualifiers of frequency, if available, to the described risks, e.g., rarely, seldom, often, at times, etc.
- **Question 9:** Compensation of any kind must not be stated as benefits of research participation.
- **Question 14:** For research studies providing study drugs that may not be available locally, edit to add specific information related to any post-trial access programs.
- **Question 16:** At the CRS's discretion, enter a brief description of additional methods used to maintain privacy and confidentiality of participants' personal (private) information collected for the study and identifiable information, e.g., SOPs for sharing information, coding information, locked file cabinet, limited access to data room/pharmacy, etc. CRSs should use the terminology for describing "personal (private) information" (information collected for the study) that is appropriate for their local setting based on national and/or local regulations and institutional policies.
- **Question 17:** Edit 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.
- **Question 19:** Edit to include clinical trial insurance for injury compensation information if mandatory. Also, edit to meet/add CRS' or Institution's, or local policy, as appropriate.
- **Question 21:** Incidental Findings (IFs) or foreseeable potential "important accidental findings" in clinical research. "Important" means, at a minimum, clinically relevant and actionable for the participant based on locally available clinical standard of care and resources.

DELETE ALL ABOVE INSTRUCTIONS FROM PROTOCOL/SAMPLE ICF

_____ *(Enter DAIDS Network Number or Grant Number here, if applicable.)*

PROTOCOL/SAMPLE INFORMED CONSENT FORM

_____

(Insert complete title above as per protocol; include version number and date.)

APPENDIX___ *(Enter number, if applicable.)*

1. _____ *(Enter a short version of the study title.)*

The person in charge of this study at this site is _____. *[Insert name of the Investigator/Investigator of Record (IoR).]* The U.S. National Institutes of Health (NIH) is _____. *(Revise this sentence as* applicable. *Use "paying for this study" when NIH/DAIDS is only the financial sponsor; use "NIH is the sponsor" when NIH/DAIDS is the regulatory sponsor – i.e., NIH/DAIDS holds the IND. Insert additional funding and other sponsors as applicable.)*

2. What is the key information I should know about this study?

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. This informed consent form tells you about this study. You can ask questions at any time. You can discuss this study with others before deciding to join.

Things you should know:

- Taking part in this research study is voluntary (your choice). You do not have to participate, and you can leave the study at any time. No matter what you decide, any other care that you get at this site will not change.
- The purpose of the study is to ____ (*Briefly describe the purpose of the study.*)
- If you choose to participate, researchers will ask you to agree to _____. (*Briefly summarize the procedures.*) You will be in the study approximately _____. (*Describe the study duration for an individual participant, anticipated # of visits, and other relevant information.)*
- Common risks from this research include____. Rare or significant risks include _____. (*Briefly describe the common/rare/significant risks or discomforts that may affect willingness to participate.*)
- The study will _____ (*Briefly summarize the reasonably expected benefit from the study intervention, including the possibility of no direct benefit.*)
- (*List any alternative procedures or courses of treatment.*)
- *(List any additional information that may be important for participants to make an informed decision such as a "first in human" study, etc.)*

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

The study staff will offer you a *(add "signed" if applicable)* copy of this form.

(If the key information section also satisfies the elements of informed consent under 45 CFR 46.116(b) and (c), this information does not need to be repeated in the body of the consent.)

3. Why are researchers doing this study?

Researchers are doing this study to _____.

(Identify the study intervention and describe the purpose of the study; include the primary objective(s), and the secondary objective(s) if it is/they are safety related, and any experimental or investigational issues, e.g., first in humans, new population for the study drug, etc.)

4. 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.)

5. 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 _____. Neither you nor the study staff can choose your study group.

(Consider adding a metaphor for randomization such as "like flipping a coin)

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 cover multiple rows and/or study groups.)

[For research studies with "placebo" and/or "control" groups, include: (1) definitions for "placebo" and "control"; (2) rationale for using a placebo and/or a control group; (3) information about the chance or possibility of assignment to one of the placebo or control groups; and (4) definitions for "blinded", "double blinded", "placebo controlled trial", etc.]

(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; briefly describe the exams, tests, and procedures using a bulleted format.)*
- *(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.)*
- *(Include information on test results that will be given to participants because of their effect on clinical care.)*

- *(Include information about experimental, invasive, painful, or lengthy exams, tests, and procedures.)*

(Consider including a simplified schedule of evaluations in a table or flowchart format. Three examples are shown below.

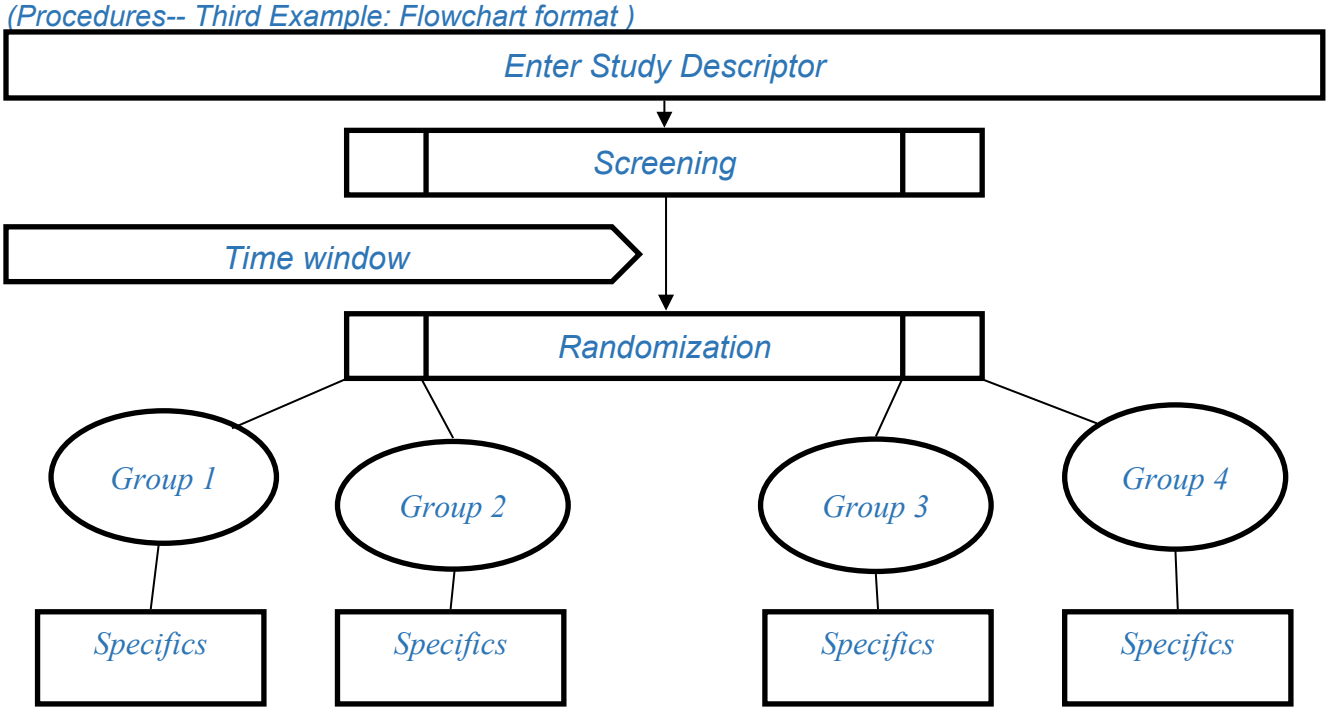
STUDY DAY/STUDY PERIOD *(Use protocol appropriate units of time and descriptors.)*	EXAMS, TESTS, AND/OR PROCEDURES *(List exams, tests, and procedures and their frequency, as well as the amount of blood to be drawn using easy to understand locally appropriate units.) (If possible, include the length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

(Consider combining the Visit Schedule and the Visit Tests/Procedures in the table above.)

(Procedures- Second Example: Table format 2)

Procedure *(Use protocol appropriate procedures and timing of procedures.)*	*Screening visit(s)*	*First injection visit*	*Week ½*	*Week 2*	*Week 2½*	*Week 5*	*Week 8*
Injection (add local term: "shot", "jab", etc.)		√		√			
Medical history	√						
Complete physical	√						√
Brief physical		√	√	√	√	√	
Urine test	√		√			√	
Blood drawn	√	√	√	√	√	√	√
Pregnancy test (for female participants)	√	√		√			√
HIV testing & pretest counseling	√				√	√	√
Risk reduction counseling	√	√	√	√	√	√	√
Interview/questionnaire	√	√	√	√	√	√	√

(Procedures-- Third Example: Flowchart format)



6. How long will I be in this study?

If you decide to join, you will be in this study for about _____. *(This length of time should include the time for screening, enrollment, and study follow-up.)*

7. How many participants will be in this study?

_____ *(enter study total accrual goal)* total participants will be in this study. At this site, there will be _____ participants.

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

(For vaccine research studies only, add and edit the following. Describe foreseeable risks and do not minimize them. Avoid medical terms; use lay language.)

The following is a summary of the known risks of the _____. You may experience all, some, or none of these risks.

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 *(add local term: "shot", "jab", etc.)* 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 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 hardly ever happens.

[Enter here the specific known risks of the study vaccine(s) using the Risk Summary Table Guidelines box below.]

[For HIV Vaccines, include the following section.]

HIV vaccine(s) may cause "vaccine-induced sero-positivity" or "VISP". This means that you may test positive for HIV when you really do not have HIV. If you have VISP, you cannot donate blood. You also may not be able to join the military, or to get medical or dental care, employment, health insurance, or a country visa. This site'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 site 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.

Also, if you become pregnant and have the baby while you have VISP, your baby may have VISP too. This site's HIV test can tell the difference between real HIV infection and VISP in your baby as well. Your baby will have access to this free HIV testing at this site for as long as needed.

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 your HIV disease. 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 approved vaccine for HIV.

[For studies using ARVs and other study drugs, enter specific known risks of the study drug(s) based on the DAIDS Drug Risk Lists, if available, and using the Risk Summary Table Guidelines below. Any revision to the DAIDS Drug Risk List should only be made after discussion with the DAIDS Medical Officer.]

The following is a summary of the known risks of _____. You may experience all, some, or none of these risks. These risks are what researchers know so far. They may change when the researchers learn more about from this or other studies.

Risk Summary Table Guidelines — Consider the following for language on risk frequency. Frequency is based on the information available at the time of ICF development and may be dependent on study phase, etc. This information may need to be revised as more information becomes known about the study intervention(s):

- *"Common, some may be Serious" – Use for risks occurring in greater than 20% (2 out 10) of participants receiving the study intervention(s).*
- *"Occasional, some may be Serious" – Use for risks occurring in 4% to 20% (4 to 20 out of 100) of participants receiving the study intervention(s).*
- *"Rare, and Serious" – Use for risks occurring in 3% (3 out 10) or fewer participants and are not foreseeable but serious. Modify per protocol for interventions that have not been widely investigated.*
- *"Possible, some may be Serious" – Use to inform study participants of possible risks related to study interventions for which the frequency of individual risks has not yet been determined.*

Also indicate when risks may be life-threatening and may be irreversible.

Note: "Serious" is defined as any untoward medical occurrence related to the study intervention that: results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect [ICH E6(R2), section 1.50].

(For studies enrolling women of child bearing potential with potential pregnancy risks, add and edit the following based on the study intervention.)

(For studies using ARVs and other study drugs, add the pregnancy-related risk language from the DAIDS Drug Risk Lists, if available. See also the Therapeutics Research Program Guidance for the Development of Protocol Procedures to Address Reproductive Risk.)

Researchers do not know if the _____ may harm unborn babies. *(Edit if there are known risks to the embryo, fetus, and/or mother.)* You should not become pregnant during this study. If you are having sex that can make you pregnant, you should use contraception (ways to prevent pregnancy). Researchers will talk with you about acceptable methods. You should use them from ____ *(days/weeks)* until ____ *(days/weeks/months). (Edit to meet protocol requirements.)* Researchers will also test you for pregnancy at some study visits *(Edit to meet protocol requirements, e.g., before each injection, etc.)*

If you become pregnant during this study, you will stop _____. *(Edit to meet protocol requirements, e.g. getting injections, etc.)* 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. *(Edit to meet protocol requirements.)*

You should not breastfeed while on this study. Researchers do not know if the _____ may pass through breast milk and may harm your baby. *(Edit as per protocol requirements and what is known about the study intervention.)*

Researchers want to 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. And researchers have procedures to protect this information. *(Edit or omit paragraph as per protocol requirements.)*

(For all studies, consider the following risks. Edit to meet protocol requirements.)

- *Risk of being in a placebo or a control group:*
  - *Describe potential risks 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*
  - *Describe the consequences of delaying active treatment/intervention*
  - *Describe 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, e.g., impact of new dose finding and dosing schedule research for an approved and effective TB drug regimen.*
- *Risks related to stopping study intervention/interaction early*
- *Risk of developing immune reconstitution inflammatory syndrome (IRIS)*
- *Risks related to poor adherence to study intervention/interaction, e.g., drug resistance*
- *Risks of sharing sensitive information with parents/guardians for studies involving minors*

(For all research studies, add and edit the following as applicable.)

(Risks of Blood Draws)

In this study, study staff will take some blood from you and give you some injections (*add local term: "shot", "jab", etc.*). *(Edit as per protocol requirements.)* These procedures can cause bruising, pain, fainting, soreness, redness, swelling, itching, bleeding, a small blood clot, and muscle damage. They rarely cause an infection. Taking blood from you may cause a low blood cell count (known as "anemia") and make you feel tired. *(Include information about anemia for large volume.)*

(Risks of procedures, such as pelvic exams, rectal exams, biopsies, etc. Describe foreseeable risks and do not minimize them. Avoid medical terms.)

In this study, you will have the following_____. You may feel _____.

(Risks of harms and other related risks.)

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 edit this sentence as appropriate)*. You could lose your job because your employer thinks that you have HIV *(delete or edit this part of the sentence as appropriate)*, or because you take too much time away from work to be in this study.

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 and treat you badly. Your partner may decide to insult you, leave you, or hit you. Your partner may stop paying for things. Another risk is that someone may use your personal (private) information (information collected about you for the study) in a bad way. For example, someone could find out your test results and share 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 risks. Some of these ways include limiting access to your study records, having your study visits in private, and using codes to link 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.

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.

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

(For research studies with no prospect of direct benefit from the study intervention, add the following.)

There are no expected direct benefits from_____ . However, researchers may learn some information from this study that may help others.

(For research studies with the prospect of direct benefit from study intervention/interaction, add the following.)

Researchers believe that _____ *(describe the prospect of direct benefit from study intervention)* may have a direct benefit to you. Also, researchers may learn some information from this study that may help others.

(Add known ancillary benefits, e.g., additional monitoring, increased health awareness, access to early treatment for any secondary diagnoses, future knowledge about the condition, etc. Compensation should not be included as a benefit.)

(When appropriate, add the following paragraph about important incidental findings and revise as applicable [i.e., 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.

10. What other choices do I have?

(Edit the following list as appropriate.)

If you choose not to participate in this study:

- You could choose to get the locally available standard of care
- You could choose to join another research study
- You may choose to do nothing
- You may choose to get HIV *(edit as appropriate, e.g., SARS-CoV-2)* counseling (have someone talk to you about HIV *(edit as appropriate, e.g., SARS-CoV-2)* and testing outside this study

If you would like more information about the risks and benefits of each one of these choices, talk to the study staff. You can also discuss these options with your doctor. Regardless of your choice, any other care that you get at this site will not change. Your decision not to participate will not lead to any penalty, or loss of benefits or rights that you would normally have otherwise.

11. 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 up to you (voluntary). Tell the study staff if you are thinking about leaving this study. Again, any other care that you get now or in the future at this site will not change. Your decision to leave the study will not lead to any penalty, or loss of benefits or rights that you would normally have otherwise.

Study staff may ask you to come back for follow-up visits before you leave to make sure everything is ok. *(Revise this sentence as applicable to address the type of withdrawal and potential follow-up: complete withdrawal, withdrawal from the interventional portion of the study but with continued study follow-up and data collection, or a final visit for premature study discontinuation)*

If you decide or need to leave the study early, any personal (private) information that was already collected about you for the study needs to stay in the study records . Your information and any samples previously collected for the study will be included in the analysis of the study's results. *(Revise as applicable for non-FDA regulated (non-IND) studies where the participant may request that previously collected data be removed and samples be destroyed.)*

[Please ensure that this section matches the corresponding section(s) of the protocol]

12. Can researchers take me off this study early?

(Edit the following list as appropriate to match the protocol.)

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

- If researchers believe it is the best thing for you
- If you do not follow the study requirements
- If the study is stopped or cancelled for any reason

Study staff may ask you to come back for follow-up visits before you are off the study to make sure everything is ok.

13. What happens if I get HIV during this study? *(For prevention studies, including vaccine trials for HIV,SARS-CoV-2 and other infections, add this question. Edit as appropriate.)*

If you get HIV during this study, study staff will tell you about any available care. Study staff will talk to you about your HIV. They will also tell you how to lower the risks of giving HIV to others. Researchers may ask you to continue in this study.

14. What happens at the end of this study?

(Add information on the post-trial availability of the study intervention. If applicable, explain any plans for long-term follow-up, e.g., tests, procedures, exams, etc.)

(For studies testing a study intervention that will not be available immediately post-trial, add the following and edit as appropriate.)

Once you finish this study, researchers cannot give you ____. If ____ 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 or nothing at all.

(For studies testing a study intervention found to be efficacious that may/will be offered to study participants who did not receive the "active" study intervention, add the following and edit as appropriate.)

If researchers learn that the _____ is helpful, researchers may ask you if you want to get the _____ once you finish the study.

(Select one of the following statements.)

You will receive important research results about your health that researchers learn from the study (*Add information about the types of health information that will be shared and when these results will be given.)*

(OR)

You will not receive any health-related research results from the study.

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

During this study, study staff will not know if you are getting the study drug, a placebo, or a control drug. 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.

15. Will my samples and personal (private) information be used, stored, or shared after this study is over?

[For research studies with no plans for using leftover (unused) samples for future research other than for this study, use the following after editing as appropriate.]

Once this study ends, researchers will destroy all of your unused _____ *(Insert generic type of samples, i.e., blood/body fluid/tissue)*. Researchers will not use, store, or share any of your unused samples or your linked coded personal (private) information (information collected about you for the study) for future research, even if information that could identify you is removed from your personal (private) information or your samples. There are no plans for the NIH to sell your samples for commercial profit (to make money), even if information that could identify you is removed.

(For research studies with mandatory or with optional storage of leftover and/or additional samples collected for future research other than for this study, use the following paragraph after editing as appropriate.)

Once this study ends, researchers *(may/will)* store with your permission *(Delete "with your permission" if storage is mandatory)* some of your unused _____ *(Specify leftover and/or additionally collected samples; also insert generic type of sample, i.e., blood/body fluid/tissue)* samples for future _____ research. *(Insert whether future research is unspecified and/or*

study-related) These samples *(will/may/will not)* be shipped or stored outside of the country. *(Revise this sentence as applicable).* This research may include either limited or a more complete genetic testing such as Whole Genome Sequencing (WGS). WGS is a way to look at all of your genes (the basic "instruction book" for the cells that make up our bodies). *(If WGS testing will not be done, revise as applicable.)*

(For research conducted at U.S. Clinical Research Sites that may include genetic testing and may be subject to the Genetic Information Nondiscrimination Act – GINA, add the following.)

In the event that your genetic information becomes linked to your name, the U.S. federal law called the Genetic Information Nondiscrimination Act (GINA) would help protect you. This law prohibits health insurance companies, group health plans, and most employers from denying services based on your genetic information. However, GINA does not protect against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

(Revise this paragraph as applicable)

Also, information that could identify you may be removed from your samples and personal (private) information (information collected about you for the study) and *(may/will)* be replaced with a code. Researchers from this study may then use your coded information or coded samples for future research, or share your coded personal (private) information or your coded samples with other researchers for future research. Researchers will not ask you again if it is okay to use your coded personal (private) information and coded samples for these future studies.

(For instances when there are/may be/are no plans to use or sell samples for commercial profit, revise this section as applicable.)

Researchers *(may/will/will never)* sell your samples for commercial profit (to make money), even if information that could identify you is removed. The NIH has no plans to sell participant samples for commercial profit. Some of this research may lead to new discoveries, such as new medicines or tests. You will not receive any money or other type of compensation from the discovery and sale of these new medicines or tests.

(Include the following for research studies that have a separate stored samples consent. Recommend using a separate consent when information and samples will be shared outside of the main study .)

There ____ *(is/will be)* another informed consent form that explains what researchers may do with these samples.

16. How will researchers protect my samples and personal (private) information (information collected about me for the study)?

Researchers have plans and procedures in place to protect your samples and your personal (private) information. They keep your study records in a secure place. They do not use your name in publications, meetings, or on your samples. Instead, they use a code to link your personal (private) information and your samples to you. The key to the code will be kept separate from your samples and information. Only the researchers can match your name to the code if needed. Any information collected about you for the study will be kept confidential and will be shared only with your permission, or as required by law. *(Revise the above section as applicable if samples and information will be completely delinked from the participant.)*

There are some groups watching over this study. They want to make sure that researchers and their staff are protecting your rights and keeping you safe. They also want to see if researchers are following the approved study plan. People from these groups may review your records. Researchers may also share any information collected for this study ("personal/private information") with the groups that are listed below (*Revise the list to include relevant collaborators)*. But these groups will only use your personal (private) information for legitimate business, public health, research, regulatory, and

commercial purposes. For example, this information may include any side effects (reactions) you had from the _____*(list the type of study intervention, drug, vaccine, etc.)* and the date it happened. It is important for researchers and the other groups to also share this type of information with regulatory authorities (RAs)/entities (REs) so that they can decide if this new _____ *(study intervention, drug, vaccine, etc.)* is safe and works the way it is supposed to.

These groups watching over this study and the groups your information is shared with, have a duty to keep your information confidential. Some of these groups are:

- The Institutional Review Board (IRB) or Ethics Committee (EC) of record
- The U.S. National Institutes of Health (NIH) and its collaborators *(List known collaborators such as the DAIDS networks, etc.)*
- The U.S. Office for Human Research Protections (OHRP)
- The U.S. Food and Drug Administration (FDA) *(Omit if not applicable.)*
- The Pharmaceutical companies supporting this study, including their affiliates, collaborators, and contractors *(Revise/omit as applicable.)*
- Other local, U.S., or international regulatory authorities (RAs)/entities (REs) [*Insert any specific name(s), if applicable, including any applicable national REs/RAs. Edit the sentence as needed.)]*
- Study monitors
- The _____ *(List any other relevant organizations not already listed.)*

(Revise this section as applicable)

For your safety, researchers will verify your age and identity before you can join this study and at every study visit while you are on this study. For example, they may take a photo of you or a fingerprint. (Revise as applicable; list here any specific methods to be used at the site such as any biometric system/fingerprints, identity numbers, etc.) They may also use and store some of your personal (private) information to check to see if you have already enrolled in this study or any other study here or at another research site. By agreeing to be part of this study, you give the researchers permission to use your personal (private) information for these purposes.

(Include the following paragraph for US covered entities only if HIPAA language is not included in the site-specific consent.)

U.S. Federal laws protect the privacy of your protected health information ("personal/private information"). However, there are exceptions to these laws. The Researchers will ask you to sign a form ("HIPAA Authorization") to give your permission for certain uses and sharing of your personal (private) information for the study. That form provides more details about the types of information that may be used and shared, and how it will be protected.

(Include the following for sites in South Africa only.)

In addition, the Protection of Personal Information Act (POPIA) ensures that all South African institutions conduct themselves in a responsible manner when collecting, processing, storing and sharing your personal information by holding them accountable should they abuse or compromise your personal information in any way.

(Include any relevant country-specific data-sharing requirements as applicable.)

(For research studies being conducted at U.S. Clinical Research Sites and at all sites when samples will be stored in the U.S. only, add the following paragraph.)

Researchers have a Certificate of Confidentiality from the U.S. National Institutes of Health. This certificate is a tool to help protect your personal (private) information (information collected about you for the study) and your samples. Researchers can use this tool to legally refuse to give your information or samples to others. For example, researchers can say "No" to a court that is trying to get information about you. The court system cannot force researchers to talk about you being in the study.

But the courts can make researchers give personal (private) information about you to prevent serious harm to you or others. And researchers have to give your information to people paying for this study or the U.S. FDA when asked. In this case, the information will be used to check or evaluate the study.

Researchers can release personal (private) information about you when you say it is okay. You can tell others about you being in the study. For example, you can allow your boss, insurer, doctor, or others to get study information. Then researchers cannot use this tool to withhold the information. This tool does not prevent you from having access to your own study information.

(Include the following information for ex-US sites and revise as applicable. Clarify if the data and samples storage is for this study and/or for future use. Ensure that the information in this section matches relevant sections of the protocol.)

Your personal (private) information collected for the study will *(revise as applicable)* be sent to the U.S. for processing and storage. Also, your samples will *(revise as applicable)* be sent the U.S. to a place called a "bio-bank" for storage and future analysis.

[For research studies that are applicable clinical trials as per 42 CFR 11.22(b) and need to be included on the ClinicalTrials.gov website, add the following paragraph verbatim. See the Checklist for Evaluating Whether a Clinical Trial or Study is an Applicable Clinical Trial (ACT).] [For research studies that only meet the requirements of the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information and are not subject to 42 CFR 11.22(b), "as required by U.S. law" can be omitted from the following paragraph.]

A description of this clinical trial will be available on https://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.

17. Will I have to pay anything to participate in this study?

(Edit to remove insurance provider if applicable)

You will not have to pay for any study related lab tests, procedures, or exams. Your insurance provider will not have to pay for these either. You and/or your insurance company will be responsible for any other lab tests, procedures, or exams that are a part of your standard care.

18. Will I receive any compensation for my participation in this study?

(Select one the following statements.)

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

(OR)

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

[In (1) enter site specific amount in appropriate currency.]

[In (2) list and briefly describe the types of expenses being covered, e.g., transportation to site, time away from work, etc.]

[In (3) enter how the 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, e.g., in the U.S. add tax info for reimbursement over $600 USD per year.]

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

If you think you are hurt because of your participation in this study or have questions about an injury, please tell (1) _____. You can do it in person or call (2) _____. The (3) ____ will give you immediate necessary treatment. You (4) _____ have to pay for this treatment. Your insurance company (5) _____ have to pay for this treatment. The U.S. NIH is not able to reimburse you (pay you back) for these treatment expenses. There is no option for money or other forms of compensation through NIH. *(For studies conducted in countries other than the United States, please include related information if Clinical Trial Insurance is an in-country requirement.)* 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

[In (1) enter researcher(s) name or names.]

[In (2) enter the complete contact information.]

[In (3) enter name of the institution.]

[In (4) enter "will" or "will not", e.g., in countries with mandated clinical trial insurance, "will" must be entered.]

[In (5) enter "may", "will", or "will not".]

(For applicable declared U.S. Public Health Emergencies [such as COVID-19], please add the following information; for U.S. sites only)

Due to the public health crisis, the U.S. Federal government has issued an order that may limit your right to sue if you are injured or harmed while participating in this COVID 19-related clinical study.

If the order applies, it limits your right to sue the researchers, healthcare providers, any Sponsor or manufacturer or distributor involved with the Study. You may be prevented from making claims for injuries that have a causal relationship with the use of the investigational product in this Study, including, but not limited to, claims for death; physical, mental, or emotional injury, illness, disability, or condition; fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and loss of or damage to property, including business interruption loss.

However, the U.S. Federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death. If funds are appropriated by U.S. Congress, compensation for injuries may be available to you under this Countermeasures Injury Compensation Program. To find out more about the Countermeasures Injury Compensation Program" go to https://www.hrsa.gov/cicp/about/index.html or call 1-855-266-2427.

20. 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. Any other care that you get now or in the future at this site will not change *(revise as applicable)*. 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 related studies. This information may affect your health, well-being (welfare), or decision to stay in this study.

If you have any questions about your rights, you should contact _____ at _____. *(Enter the name(s), title(s), and complete contact information of the IRB/EC contact or other organization appropriate for the site. This contact should be an individual other than the Study PI/study team.)*

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

(Omit this section if there are no plans to provide if important incidental findings to participants.)

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.

22. Do I give researchers permission to contact me?

Sometimes researchers may want to contact you to get more information or to clarify information about you for this study. They may also want to contact you to see if you are interested in joining future studies.

____ (Initials) Yes, researchers may contact me.	____ (Initials) No, researchers may not contact me.

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

My signature/mark/thumb print below confirms that the study and this form was explained to me and:

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

[The signature blocks should be modified per protocol requirements. However, It is the responsibility of the IRB/EC of record to determine the appropriate procedures for obtaining and documenting informed consent. For example, for research studies involving children (including neonates and adolescents) the U.S. regulations may require parental permission from both parents/guardians depending on the pediatric risk category designation, thus include both signature blocks. Also for example, for research studies involving pregnant women, the U.S. regulations require parental permission from both parents/guardians, thus include both signature blocks].

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