

Division of AIDS (DAIDS) Protocol Risk Worksheet

Protocol DAIDS # Version # Total Sample Size

Protocol Title

----- To be completed by the DAIDS Medical Officer (MO) ----- [To access the Protocol Risk Worksheet Guidelines, please click here](#)

Please note that **blue text*** has a pop-up definition for all enabled (non-grey) questions.

Protocol MO Name MO Completion Date*
 Initial Assessment Reassessment (use DD-Mon-YYYY or click down arrow for calendar)

1. Protocol Information

1.1. Will the clinical sites be monitored by a **non-DAIDS** entity (i.e., other than DAIDS Monitoring Contract)? Yes No Decision is pending

1.2. Will this protocol be **risk ranked**? Yes No

1.3. Is this a **Clinical Trial**? Yes No

1.4. Select Study Risk Category: Minimal Risk Greater than Minimal Risk

1.5. In general, minimal risk studies are not monitored. Is an exception recommended to request monitoring of this minimal risk study?
 Yes
 No

1.6. **Highest Phase of the study:**
 NA
 Phase I, Ib
 Phase II, IIa, IIb (for therapeutic studies, including therapeutic vaccines) and II/III
 Phase III, IIIb (for vaccine and prevention studies) and III/IV
 Phase IV (study product approved by FDA for indication and population)

1.7. **IND/IDE status:**
Are data intended to be used for a regulatory purpose (such as submission to an IND/IDE or NDA), or to alter standard of care recommendations? Yes No

1.8. Level of potential harm/toxicity related to intervention within the study population:
 Low Moderate High

2. Human Subjects Protection

2.1. Will the protocol have any **Vulnerable Populations**? Yes No

2.2. Are there additional privacy/confidentiality concerns? Yes, **Low** Yes, **Moderate to High** No

3. Study Complexity

3.1. Level of study design complexity: Low Moderate to High

3.2. **Study visit intensity:** Low Moderate High

4. Additional Factors

4.1. Specify factors to be considered for possible adjustment up or down of the priority level for the study:
 No additional factors Non-network study

4.2. Other issues - Specify and/or Notes to OCSO (below):