|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| START QA/QC CHECKLIST & SITE ASSESSMENT | | | | | | | | | | |
| 1 | Clinic Name: |  | | | | | | | | |
| 2 | Reviewer Name: |  | | | | | | | | |
| 3 | Date of Site Visit: |  | | | | | | | | |
| 4 | In-Charge on Duty: |  | | | | | | | | |
| 5 | Notes from meeting with In-Charge |  | | | | | | | | |
| **Availability of Study Documents and Forms** | | | | | | | | | | |
| 6 | Is there a copy of the training manual and SOP available on-site | | YES: | NO: | | Notes | | | | |
| 7 | Are copies of the study eligibility criteria available for clinicians? | | YES: | NO: | | Notes | | | | |
| 8 | Please report the supply of blank study forms available: | | Approx. Count Available (check each form) | | | | | | | |
| Form | | None | | Less than 25 | | More than 25 | |
| Informed Consent Information Sheet | |  | |  | |  | |
| Informed Consent Comprehension Assessment | |  | |  | |  | |
| Informed Consent Cover Sheet | |  | |  | |  | |
| Infographic | |  | |  | |  | |
| Study Enrolment | |  | |  | |  | |
| Time & Motion | |  | |  | |  | |
| ART Assessment | |  | |  | |  | |
| CD4 Log | |  | |  | |  | |
| **Appropriate Completion and Storage of Study Forms** | | | | | | | | | | |
| 9 | Review the enrolment/eligibility Excel file | | Is it complete? YES:  NO: | | | | | Notes: | | |
| How many people have been enrolled to date? \_\_\_\_\_\_\_\_\_\_\_ | | | | |  | | |
| 10 | Have Informed Consent QC checklists been completed for all enrolled patients? | | YES: | NO:  If any ICF QC checklists have not been completed, please complete them now or indicate plan for completion. | | | | Notes: | | |
| 11 | Review study forms on file (at least 5 of each type): Are they complete? If not, note fields most often incomplete or filled incorrectly.  *(Provide immediate feedback to study team on any errors noted)* | | Form: | | | Complete? | | NOTES | | |
| Study Enrolment | | | YES:  NO: | |  | | |
| Time & Motion | | | YES:  NO: | |  | | |
| ART Assessment | | | YES:  NO: | |  | | |
| CD4 Log | | | YES:  NO: | |  | | |
| 12 | Please indicate whether these forms can be easily located and whether they have been stored securely | | Form: | | | Easily located? | | Stored securely? | | NOTES: |
| Informed Consent Documents | | | YES:  NO: | | YES:  NO: | |  |
| Study Enrolment | | | YES:  NO: | | YES:  NO: | |  |
| Time & Motion | | | YES:  NO: | | YES:  NO: | |  |
| ART Assessment | | | YES:  NO: | | YES:  NO: | |  |
| CD4 Log | | | YES:  NO: | | YES:  NO: | |  |
| **PIMA Point of Care (POC) CD4 Assessment** | | | | | | | | | | |
| 13 | Is the Point-of-Care (CD4) PIMA machine operational (functioning)? | | YES: | NO: | | Notes: | | | | |
| 14 | Is the Point-of-Care (CD4) instrument stocked? How many cartridges remain (be sure to check expiration dates). | | YES: | NO: | | Cartridges  Remaining: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| 15 | Have study staff reported any problems running the PIMA machine? | | YES: | NO: | | Notes: | | | | |
| 16 | How many results have been recorded in the Point of Care Log Book to date? | | Count: \_\_\_\_\_\_\_\_ | | | | | | | |
| 17 | Pick 5 ART charts of enrolled START patients. Does the CD4 value on the PIMA generated slip match the value written in the CD4 Log book? *[Alternatively, check: Do the the last five values in the PIMA CD4 memory correspond to the last five entries in the CD4 log book]* | | YES: | NO: | | Notes: | | | | |
| 18 | Please complete the DBS field assessment form on the next page. *Write any general comments based on what you observed.* | | Notes: | | | | | | | |
| **GENERAL COMMENTS** | | | | | | | | | | |
| 19 | Other Notes: Please provide additional narrative regarding the state of the project at the clinic be sure to outline in detail specific challenges or successes of the project (i.e. changes in the clinic staff/infrastructure/etc.): | | | | | | | | | |

**PIMA FIELD ASSESSMENT FORM**

1. Did study team member engage participant in activities and was participant aware of what was happening?

Yes No

1. Did study team member wear gloves before touching the Pima machine and any other blood collection supplies?

Yes No

1. Were all the supplies removed before the beginning of blood collection procedure?

|  |  |
| --- | --- |
| Pima machine |  |
| Pima cartridge |  |
| Alcohol swabs |  |
| Cotton wool |  |
| Lancet |  |
| Plasters |  |
| Sharps boxes |  |
| Biohazard bag |  |

1. Was the cartridge removed from the foil bag before sample collection?

Yes No

1. Did study team member ensure that the participant’s hands were warm?

Yes No

1. Did study team member enquire from the participant which finger can be pricked?

Yes No

1. Did study team member wipe participant’s hands with alcohol swab?

Yes No

1. Was the positioning of the lancet on the participants finger correct?

Yes No

1. Did the study team member wipe off the first drop of blood to encourage blood flow?

Yes No

1. Did study team member message participant’s hand correctly?

Yes No

1. Was the blood sample collected in the cartridge sufficient?

Yes No

1. Was the patients hand below the heart during blood collection?

Yes No

1. Did study team member have a strong grip of the participant’s hand?

Yes No

1. After removing cartridge from foil bag, did study team member keep the foil bag until results from the Pima machine were obtained?

Yes No