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| **A. GENERAL STUDY INFORMATION** |
| **Study title:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Protocol and version number:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Principal Investigator:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Country of study:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Target sample size:** \_\_\_ (*P. falciparum*) \_\_\_ (*P. vivax*) |
| **Ethical approval:** [ ]  Yes [ ]  No [ ]  Initiated |
| If Yes, provide ethical approval ID number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Clinical trial registry**: [ ]  Yes [ ]  No [ ]  Initiated |
| If Yes, provide clinical trial registry ID number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Study dates:** mmm-yyyy to mmm-yyyy |
| **Sponsor:** Ministry of Health, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Site Monitor name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | [ ]  Internal [ ]  External  |
| If Site Monitor is External:  |
| [ ]  Sponsor staff member/consultant or [ ]  WHO staff member/consultant |
| Please provide affiliation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **STUDY SITES** |
| **Site Name** | **Drug** | **Hospital** | **Community-based** | **Health centre** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_ | [ ]  | [ ]  | [ ]  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_ | [ ]  | [ ]  | [ ]  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_ | [ ]  | [ ]  | [ ]  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_ | [ ]  | [ ]  | [ ]  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_ | [ ]  | [ ]  | [ ]  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_ | [ ]  | [ ]  | [ ]  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_ | [ ]  | [ ]  | [ ]  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_ | [ ]  | [ ]  | [ ]  |

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| Comments (if needed):  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **B. SITE SPECIFIC INFORMATION** |
| **Site name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  | **Was the site visited?** [ ]  Yes [ ]  No |
| If Yes, indicate date of visit: dd-mmm-yyyy |
| **Name of site focal person:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **1. SITE STAFF** |
| **Name** | **Qualifications** | **Role** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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| **2. TRAINING** – Indicate whether the staff have received training on: | **Yes** | **No** | **N/A** |
| **1** | Protocol requirements: target population and sample size, inclusion and exclusion criteria, definition of severe malaria, follow-up procedure, classification of outcome |[ ] [ ] [ ]
| **2** | Ethical requirements and confidentiality | [ ]  | [ ]  | [ ]  |
| **3** | Clinical assessment: physical examination, temperature, weight, height | [ ]  | [ ]  | [ ]  |
| **4** | Test medicine and rescue medicines: dosage and administration | [ ]  | [ ]  | [ ]  |
| **5** | Test medicine and rescue medicines: handling and storage |[ ] [ ] [ ]
| **6** | List of medications that should not be used during the study period  |[ ] [ ] [ ]
| **7** | Completing the screening form, case report forms, logbooks | [ ]  | [ ]  | [ ]  |
| **8** | Microscopy procedures | [ ]  | [ ]  | [ ]  |
| **9** | Other laboratory procedures (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | [ ]  | [ ]  | [ ]  |
| **10** | Collection, handling and storage of blood slides | [ ]  | [ ]  | [ ]  |
| **11** | Collection, handling and storage of biological samples | [ ]  | [ ]  | [ ]  |
| **12** | Data entry procedures and analysis | [ ]  | [ ]  | [ ]  |
| **13** | Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |

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| **3. SITE FACILITIES** – Indicate whether or not the following facilities exist at the site: | **Yes** | **No** | **N/A** |
| **1** | Clinical examination room |[ ] [ ] [ ]
| **2** | General laboratory | [ ]  | [ ]  | [ ]  |
| **3** | Molecular biology laboratory | [ ]  | [ ]  | [ ]  |
| **4** | Pharmacy or medical store  | [ ]  | [ ]  | [ ]  |
|  | If no pharmacy or medical store available, describe handling and storage of medicines: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |
| **5** | Office space for data management |[ ] [ ] [ ]
| **6** | Is transportation available for patient follow-up? |[ ] [ ] [ ]
|  | [ ] Public transportation |  |  |  |
|  | [ ] Private car |  |  |  |
|  | [ ] Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |

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| **4. STUDY DOCUMENTS** – Are the following essential study documents available at the study site? | **Yes** | **No** | **N/A** |
| **1** | Approved protocol and amendments, if any | [ ]  | [ ]  | [ ]  |
| **2** | Approved informed consent and assent forms | [ ]  | [ ]  | [ ]  |
| **3** | Approved translation of informed consent and assent forms | [ ]  | [ ]  | [ ]  |
| **4** | Approval letters from ethical committees | [ ]  | [ ]  | [ ]  |
| **5** | Screening forms/screening logbook | [ ]  | [ ]  | [ ]  |
| **6** | Case report forms/enrolment logbook | [ ]  | [ ]  | [ ]  |
| **7** | Serious adverse event forms | [ ]  | [ ]  | [ ]  |
| **8** | Laboratory register | [ ]  | [ ]  | [ ]  |
| **9** | Drug inventory log/registry/form | [ ]  | [ ]  | [ ]  |
| **10** | Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |

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| **5. RESOURCES, MATERIAL AND SUPPLIES** **(CLINICAL)** – Are facilities, material and supplies for clinical assessments available and in good working order? | **Yes** | **No** | **N/A** |
| **1** | Clinical examination room (space, cleanliness) | [ ]  | [ ]  | [ ]  |
| **2** | Stethoscopes | [ ]  | [ ]  | [ ]  |
| **3** | Scale for children (calibrated) | [ ]  | [ ]  | [ ]  |
| **4** | Scale for adults (calibrated) | [ ]  | [ ]  | [ ]  |
| **5** | Thermometers (mercury or digital) and battery if electronic thermometer (calibrated) | [ ]  | [ ]  | [ ]  |
| **6** | Medicines for the study including rescue treatment (see 6. Drug inventory) | [ ]  | [ ]  | [ ]  |
| **7** | Syringes 2 ml, 5 ml and needles | [ ]  | [ ]  | [ ]  |
| **8** | Sphygmomanometer (blood pressure monitor) | [ ]  | [ ]  | [ ]  |
| **9** | Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |

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| **6. DRUG INVENTORY** |
|  |  | **Formulation** | **Expiry date** | **Adequate quantity** | **Storage<30°C** |
|  | **Antimalarials** |  |  | **Yes** | **No** | **Yes** | **No** |
| **1** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | mmm-yy | [ ]  | [ ]  | [ ]  | [ ]  |
| **2** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | mmm-yy | [ ]  | [ ]  | [ ]  | [ ]  |
| **3** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | mmm-yy | [ ]  | [ ]  | [ ]  | [ ]  |
|  | **Antipyretics** |  |  |  |  |  |  |
| **4** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | mmm-yy | [ ]  | [ ]  | [ ]  | [ ]  |
| **5** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | mmm-yy | [ ]  | [ ]  | [ ]  | [ ]  |
| **6** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | mmm-yy | [ ]  | [ ]  | [ ]  | [ ]  |
|  | **Rescue treatment** |  |  |  |  |  |  |
| **7** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | mmm-yy | [ ]  | [ ]  | [ ]  | [ ]  |
| **8** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | mmm-yy | [ ]  | [ ]  | [ ]  | [ ]  |
|  | **Other medications** |  |  |  |  |  |  |
| **9** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | mmm-yy | [ ]  | [ ]  | [ ]  | [ ]  |
| **10** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | mmm-yy | [ ]  | [ ]  | [ ]  | [ ]  |

| **7. Resources, material and supplies (laboratory)** – Are facilities, material and supplies for laboratory assessments available and in good working order? | **Yes** | **No** | **N/A** |
| --- | --- | --- | --- |
| **1** | Laboratory facility room (electrical power, sink and running water) | [ ]  | [ ]  | [ ]  |
| **2** | Work bench and stool/chair | [ ]  | [ ]  | [ ]  |
| **3** | Microscopes and eye pieces | [ ]  | [ ]  | [ ]  |
| **4** | Spare microscope light bulbs | [ ]  | [ ]  | [ ]  |
| **5** | Slides | [ ]  | [ ]  | [ ]  |
| **6** | Permanent glass pen or pencils for frosted-edge slides | [ ]  | [ ]  | [ ]  |
| **7** | Slide storage boxes (vertical or horizontal) | [ ]  | [ ]  | [ ]  |
| **8** | Immersion oil  | [ ]  | [ ]  | [ ]  |
| **9** | Lancets | [ ]  | [ ]  | [ ]  |
| **10** | Laboratory timer | [ ]  | [ ]  | [ ]  |
| **11** | Consumables (alcohol, swabs, cotton wool) | [ ]  | [ ]  | [ ]  |
| **12** | Biosafety (rubber gloves, protective clothes, sharp disposal box) | [ ]  | [ ]  | [ ]  |
| **13** | Hand tally counters (at least 2) | [ ]  | [ ]  | [ ]  |
| **14** | Giemsa | [ ]  | [ ]  | [ ]  |
| **15** | Distilled water and buffer solution/tablets | [ ]  | [ ]  | [ ]  |
| **16** | pH meter | [ ]  | [ ]  | [ ]  |
| **17** | Methanol | [ ]  | [ ]  | [ ]  |
| **18** | Drying rack | [ ]  | [ ]  | [ ]  |
| **19** | Measuring cylinders 10 ml and 500 ml | [ ]  | [ ]  | [ ]  |
| **20** | Funnel | [ ]  | [ ]  | [ ]  |
| **21** | Staining jar Coplin or horizontal | [ ]  | [ ]  | [ ]  |
| **22** | Pipettes and pipettes fillers | [ ]  | [ ]  | [ ]  |
| **23** | Bottles and bottle screw-caps 500 ml | [ ]  | [ ]  | [ ]  |
| **24** | Forceps | [ ]  | [ ]  | [ ]  |
| **25** | Dropping bottle | [ ]  | [ ]  | [ ]  |
| **26** | Glass rod | [ ]  | [ ]  | [ ]  |
| **27** | Filter paper for PCR | [ ]  | [ ]  | [ ]  |
| **28** | Plastic bags, desiccant and labels | [ ]  | [ ]  | [ ]  |
| **29** | Absorbent tissue to clean slides | [ ]  | [ ]  | [ ]  |
| **30** | Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |

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| **C. CONCLUSIONS** |
| **8. COMMENTS** – In particular please comment on items from shaded or “N/A” check boxes. Please include the item number. |
| **Item** | **Comment** |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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| **9. ACTION ITEMS** |
| **Item** | **Action required** | **Person responsible** | **Due date** |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | dd-mmm-yyyy |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | dd-mmm-yyyy |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | dd-mmm-yyyy |
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|  |  |  |
| --- | --- | --- |
|   |  | dd-mmm-yy |
| **Name of monitor** | **Signature** | **Date** |