**Study Activation Checklist**

**MTN-042B: Assessing Baseline Pregnancy Outcomes in Sub-Saharan Africa**

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| **Site Name** |  | **Site Location** |  |
| **Site Investigator of Record** |  | **Site Number** |  |

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| **Study Activation Requirement** | | **Approval**  **Date** | **Comments** |
| **Required Preparatory Activities** | | | |
|  | Confirmation of DAIDS site approval (per the site’s Office of Clinical Site Oversight Program Officer) (if applicable) |  | ***Instruction:*** *Approval date to be completed as applicable prior to distribution to sites (i.e. for sites that already have OCSO approval)* |
| **Required Regulatory Activities** | | | |
|  | Approval of study protocol and any data collection/abstraction forms (as needed, per local IRB requirements) by local and in-country regulatory authority(ies) |  | ***Instruction:*** *List all site IRBs/Regulatory Bodies and upcoming submission deadlines.* |
|  | Protocol Registration Approval received from the DAIDS RSC Protocol Registration Office |  | ***Instruction:*** *includes submission and approval of all regulatory documentation required to be uploaded to the DAIDS Protocol Registration System (DPRS) [DAIDS IoR Form, signed and dated Protocol Signature Page, Investigator of Record (IoR) qualifications and training documentation (CV, Good Clinical Practice/Human Subjects Protection certifications and, if applicable, medical license or equivalent), Institutional Review Board (IRB)/Independent Ethics Committee approval – refer to the DAIDS Protocol Registration Manual for additional information* |
|  | Confirmation that all regulatory procedures required by MTN LOC (Pitt) have been completed |  | ***Instruction:*** *Includes completion of the HANC Financial Disclosure by IoR, submission of IRB/IEC roster(s), sub-investigator qualifications and training documentation (GCP, HSP, and MTN IoR training), and other items as requested)* |
| **Data Management Requirements** | | | |
|  | Availability of required internet-enabled equipment for study data submission and management |  | *The MTN-042B management team is working on obtaining tablets for data collection and will provide more information when available.* |
|  | Confirmation of site staff access, registration, and setup of study database |  |  |
|  | Successful mock data submission |  |  |
|  | Completion of training for site staff on utilization of study database |  |  |
|  | Approval of data-management readiness by the SDMC |  |  |

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| **Study and/or Site-Specific SOP Approvals** *NOTE: Site institutional SOPS may be used to fulfill study-activation SOP requirements with approval from FHI 360. Sites are required to include an addendum as needed to cover all additional protocol-required procedures for the MTN-042B that are not reflected in the established institutional SOP.* | | | |
|  | IRB/EC communications |  |  |
|  | MTN-042B SOP (topics should include chart tracking, data extraction/management, maintenance of confidentiality, communications with healthcare facilities) |  | *A template SOP is in draft and the MTN-042B team will provide when available.* |
| **Other Requirements** | | | |
|  | Adequate staffing in place for study implementation, as determined by study management team |  |  |
|  | Completion of a study staff signature sheet/roster/delegation of duties (DoD) log |  | *A template MTN-042B DoD log will be provided. Note: the MTN template contains all required information as per the recently released DAIDS DoD Policy.* |
|  | Availability of site-specific PTID tracker/link log |  | *A template PTID Link Log is in draft and the MTN-042B team will provide when available.* |
|  | Completion of required study specific training |  | *Training will be web based. Scheduling TBD.* |
|  | Resolution of any other issues or action items identified during preparatory activities |  |  |

**Signatures** *(to be obtained after site-specific completion of all activation items):*

**FHI 360 Approval, on behalf of the Management Team**

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**Final DAIDS Prevention Sciences Program Approval for Study Activation**

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