IMPAACT [####], [Full Study Title]
Site-Specific Study Activation Checklist

CRS [####]: [Site Name], [City, Country]

Study Activation Requirements

Each requirement is confirmed, with applicable documentation, by the signatories below.

To Be Confirmed by Clinical Research Manager (CRM):
Version 1.0 protocol registration approval received from the DAIDS RSC Protocol Registration Office
Include if applicable to any participating sites: Clinical trial insurance verified, based on site's insurance certificate, with DAIDS Clinical Trials Insurance Certificate Checklist filed *Include as applicable to reflect selected sites for which CTI is required and selected sites for which CTI is not required:* (Required for sites in [enter relevant countries]; not required for sites in [enter relevant countries])
Resolution of action items identified during study-specific training and/or other preparatory activities (confirmed resolved or determined to be not applicable)
Teams may consider additional requirements to be confirmed with the CRMs. Depending on the nature of the requirements, some may be confirmed by the CRM; those that the site will need to confirm should be included in requirements for Site Investigator of Record (IoR) Confirmation (e.g., confirmation of ultrasound or ECG machine availability).
CRM Signature:
To Be Confirmed by DAIDS Pharmaceutical Affairs Branch (PAB) Protocol Pharmacist:
PAB approval of local pharmacy readiness, minimally including a PAB-approved DAIDS PAB Pharmacy Establishment Plan
For non-US sites, using applicable terminology to reference study drug(s), product(s), etc., consistent with protocol language: Study drug[s] [or required study drug materials] are available on site, in consultation with the site IoR: • [Indicate formulations or different study drugs, if multiple options/types/drugs] • [e.g., IMPAACT 2034: Pretomanid 200 mg tablets, 50 mg dispersible tablets, and 10 mg dispersible tablets]
If applicable: Ancillary supplies are available on site, in consultation with the site IoR: • [Indicate any required ancillary supplies] • [e.g., for IMPAACT 2034: Pharmacy vials, Pill splitters, Dosing cups and/or oral syringes]

Study Activation Requirements

Each requirement is confirmed, with applicable documentation, by the signatories below.

If applicable: Local pharmacy readiness, in consultation with the site IoR:

- [Indicate any required local pharmacy readiness requirements]

[e.g., for IMPAACT 2008:

- -20°C freezer in good working order
- Biosafety cabinet in good working order
- Site Pharmacist of Record (PoR) has completed training in aseptic technique
- Site PoR has attended study-specific training for IMPAACT 2008 (in-person or webinar) or for the AMP study]

Teams may consider additional requirements to be confirmed with the protocol pharmacists. Depending on the nature of the requirements, some may be confirmed by the protocol pharmacist; those that the site will need to confirm should be included in requirements for Site IoR Confirmation.

Protocol Pharmacist Signature:

To Be Confirmed by Protocol Data Manager (PDM):

IMPAACT Data Management Center (DMC) approval of local data management readiness, based on confirmation of the following:

- Creation of DMC portal accounts for relevant site staff with level 2 access and study enrollment privileges
- Creation of accounts in Medidata Rave for relevant site staff
- Completion of required Medidata Rave eLearning courses by at least one site staff member
- Participation in study enrollment training by at least one site staff member

If any study-specific eCRFs will be translated into local languages: Translation and back-translation of study-specific questionnaires are completed

- [Indicate the questionnaires to be translated]

[e.g., for IMPAACT 2010:

- Routine Adherence Assessment
- Barriers of Adherence
- Facilitators of Adherence
- Edinburgh Postnatal Depression Scale
- Generalized Anxiety Disorder 7-Item Scale
- Pittsburgh Sleep Quality Index Questionnaire (including validation of translation if applicable)]

Teams may consider additional requirements to be confirmed by the PDMs (e.g., all materials and equipment available for ACASI). Depending on the nature of the requirements, some may be confirmed by PDMs; those that the site will need to confirm should be included in requirements for Site IoR Confirmation.

Study Activation Requirements

Each requirement is confirmed, with applicable documentation, by the signatories below.

PDM Signature:

To Be Confirmed by Laboratory Center (LC; for NIAID-supported sites) or Westat (for NICHD-supported sites):

Approval of local laboratory site readiness, based on confirmation of all items outlined in the IMPAACT [####] [US and/or non-US] Laboratory Activation Checklist *(to be sent separately by the IMPAACT Laboratory Center or Westat)*

For primary objectives, key secondary objectives, or results for participant management, teams should consider when agreements are needed for specimens requiring specialized laboratory testing (e.g., PK, resistance) outside of the approved local laboratory and modify or adapt the following options as applicable:

Required for sites in [enter relevant countries]; not required for sites in [enter relevant countries]

Option a: specimens need to be tested in real-time, close to real-time, or at the beginning of study participation OR when specialized testing laboratory(ies) agree to store specimens (second option is less common):

- Fully executed STA/MTA and other applicable documentation to ship samples to [indicate specialized testing laboratory(ies)]

Option b: specimens are tested in batches, well into study participation, and/or at the end of the study (one or more of the following may be applicable):

- *When specialized testing lab is in the US:* Initiated process to obtain STA/MTA and other applicable documentation to ship samples to [as applicable: BRI (NIAID sites) or Fisher (NICHD sites)]
- *When specialized testing lab is in South Africa:* Initiated process to obtain STA/MTA and other applicable documentation to ship samples to BARC SA (NIAID and NICHD sites)
- *When specialized testing laboratory(ies) agree to store specimens (less common):* Initiated process to obtain STA/MTA and other applicable documentation to ship samples to [indicate specialized testing laboratory(ies)]

LC or Westat Signature:

To Be Confirmed by Site Investigator of Record (IoR):

For all studies conducted under an IND: Financial disclosure forms completed by all persons listed on the Form FDA 1572 and filed at the site

Site staff reviewed [Investigator's Brochure(s) and/or Package Insert(s)], study-specific Manual of Procedures (MOP), and Laboratory Processing Chart (LPC), minimally including the site IoR and clinicians responsible for participant management, with documentation filed at the site

For non-US sites: MTA tracker completed within the DMC portal for IMPAACT [####]

Study Activation Requirements

Each requirement is confirmed, with applicable documentation, by the signatories below.

Study-specific standard operating procedures (SOPs) finalized and/or site-specific SOPs reviewed and, as needed, updated to ensure alignment with IMPAACT [####] requirements, minimally describing the following procedures: *Teams may modify/add/remove requirements below based on study-specific needs*

- Participant recruitment, accrual, and retention
- Obtaining informed consent, permission, and/or assent
- Eligibility determination
- *Particularly for studies enrolling children where blood volume limits may be close:* Determination of blood volume to be collected at each visit
- *For studies with PK evaluations for primary or secondary objectives especially:* Collection and processing of pharmacokinetic (PK) samples
- Study drug adherence counseling [and any other applicable counseling SOPs]
- Safety monitoring, critical lab value reporting and management, and adverse event reporting *(if study includes management for emergency care, e.g., anaphylaxis, teams should consider adding requirement for related SOP)*
- Standard of care services to be provided to study participants
- Referral for evaluation/treatment/management of [mental health conditions, contraception, etc.]
- Source documentation
- *For studies expected to submit data for registrational purposes:* Site-specific regulatory inspection readiness
- Site-specific SOPs for:
  - CRS process to verify participant age and identity
  - CRS process to identify and prevent co-enrollment

Appropriate study-specific training completed by all applicable staff, per their respective roles as indicated in the Delegation of Duties log, with documentation of completed training filed at the site

Study-specific delegation of duties log completed and filed at the site

Teams may consider additional requirements to be confirmed by the site. Depending on the nature of the requirements, some may be confirmed by protocol team members (as above); those that the site will need to confirm should be included in requirements for Site IoR Confirmation (e.g., confirmation of ultrasound or ECG machine availability). It is expected that the indicated member will maintain documentation confirming each requirement.

Site IoR Signature: