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

CRS XX: Site Name
(City, Country)
Updated by IMPAACT XXXX CTS as of DD MMM YYYY

Study Activation Requirement	Approval Date	Comments
Preparatory Activities		
Version X.0 protocol registration approval from the DAIDS RSC Protocol Registration Office		*To be confirmed by IMPAACT Ops*
Local Regulatory Approvals		
Institution Approvals		
National Regulatory Approvals		
Completion of protocol signature page by IoR		*Site IoR (or designee) to submit confirmation to IMPAACT Ops**
Completion of study-specific delegation of duties log following the DAIDS Delegation of Duties Log Policy, Effective Date: 03/14/19		*Site IoR (or designee) to submit confirmation to IMPAACT Ops**
Completion of financial disclosure forms by all persons listed on the Form FDA 1572		*Site IoR (or designee) to submit confirmation to IMPAACT Ops**
Confirmation of clinical trial insurance per DAIDS memorandum "DAIDS Requirement for Clinical Trials Insurance" effected 10 August 2018		*Site IoR (or designee) to submit insurance certificate for review and approval by IMPAACT Ops*
Pharmacy Requirements		
DAIDS Pharmaceutical Affairs Branch approval of local pharmacy readiness *[Add any additional pharmacy requirements based on the study needs* [e.g., IMPAACT 2008: DAIDS Pharmaceutical Affairs Branch approval of local pharmacy readiness, based on confirmation of the following: • -20°C freezer remains in good working order • Biosafety cabinet remains in good working order • Site 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*]*		*To be confirmed by DAIDS Protocol Pharmacist*
For non-US Sites: confirmation that supplies of all study drugs [or required study drug materials] are available on site		*Site PoR to submit confirmation to DAIDS Protocol Pharmacist and IMPAACT Ops**

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Data Management Requirements		
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 subject 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 subject enrollment training by at least one site staff member		*To be confirmed by IMPAACT DMC*
Translation and back-translation of study-specific questionnaires • TBA 1 • TBA 2		*To be reviewed and approved by IMPAACT DMC*
Add any additional DMC requirements based on the study needs [e.g., All materials and equipment available for ACASI]		*To be [confirmed or reviewed and approved] by IMPAACT DMC*
Laboratory Requirements		
Approval of local laboratory site readiness, based on confirmation of all items outlined in the: • Non-US IMPAACT XXXX Laboratory Activation Checklist Version X.0, dated DD MMM YYYY, or the • US IMPAACT XXXX Laboratory Activation Checklist Version X.0, dated DD MMM YYYY *[To be sent to sites separately by the IMPAACT Laboratory Center or Westat]*		*To be confirmed by IMPAACT Laboratory Center (for NIAID sites) or Westat (for NICHD sites)*
Study-Specific SOPs		
Participant accrual		• *To fulfill these requirements, sites may either prepare study-specific SOPs or add study-specific addenda (as needed) to pre-existing site SOPs.* • *For each SOP, site IoR (or designee) to submit confirmation to IMPAACT Ops**
Obtaining informed consent		
Eligibility determination		
Determination of blood volume to be collected at each visit		
Study drug adherence counseling		
Safety monitoring and adverse event reporting (including emergency/anaphylaxis plan)		
Critical lab value reporting and management		
Standard of care services to be provided to study participants (maternal and infant)		
Referral for evaluation/treatment/management of maternal mental health conditions		
Participant retention		

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Study Activation Requirement	Approval Date	Comments
Source documentation (to include specification of eCRFs planned to be used as source)		
Collection and processing of pharmacokinetic (PK) samples		
Other Requirements		
[*For all registrational studies*] Confirmation of *site-specific* SOP on regulatory inspection readiness		*Site IoR (or designee) to submit confirmation to IMPAACT Ops**
Participation in study-specific start-up training		*To be confirmed by IMPAACT Ops*
Confirmation of on-site review of [Investigator's Brochures and/or Package Inserts], MOP, and LPC (minimally including IoR and clinicians responsible for participant management)		*Site IoR (or designee) to submit confirmation to IMPAACT Ops**
Resolution of action items identified during study-specific training and/or other site preparatory activities		*To be confirmed by IMPAACT Ops*
[Insert any other study or site-specific requirements] *Example from IMPAACT 2001: Confirmation of ultrasound availability*		*Site IoR (or designee) to submit confirmation to IMPAACT Ops**

**For each item confirmed by the site IoR, corresponding documentation must be on file at the site and available for inspection/monitoring at any time.*

Prepared and verified by [Enter all delegated CTS names], with all elements confirmed on DD MMMM YYY

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