IMPAACT Template Site-Specific Study Activation Checklist

CRS XX: Site Name
(City, Country)

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*
Completion of study-specific delegation of duties log		*Site IoR (or designee) to submit confirmation to IMPAACT Ops**
Completion of financial disclosure forms by all persons listed on the Form FDA 1572 *(for studies being conducted under an IND only)*		*Site IoR (or designee) to submit confirmation to 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**
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] by IMPAACT DMC*

Study Activation Requirement	Approval Date	Comments
Laboratory Requirements		
Approval of local laboratory site readiness, based on confirmation of the following: <u>*All laboratories*</u> • Confirmation of *[applicable population, e.g., mothers and infants]* HIV testing algorithms • Confirmation of current IATA training certificates for at least two individuals <u>*Additionally, for US site laboratories*</u> • Submission of current CAP/CLIA certificates for labs that will perform study testing • Submission of current *[applicable population, e.g., maternal and pediatric]* reference ranges (must be reviewed, approved, and signed by Laboratory Medical Director) <u>*Additionally for non-US site laboratories*</u> • DCLOT approval of laboratory readiness based on – Completion of relevant IMPAACT Critical Items from DAIDS Audit Action Plan, if applicable – Approval of protocol analyte list (PAL) – Confirmation of acceptable EQA status (pSMILE, VQA, IQA) for protocol analytes for both primary and backup laboratories – Submission of current *[applicable population, e.g., maternal and pediatric]* reference ranges (must be reviewed, approved, and signed by Laboratory Medical Director)		*To be confirmed by IMPAACT Laboratory Center (for NIAID sites) or Westat (for NICHD sites)*
<u>*Additionally for non-US site laboratories*</u> • Have obtained all required permits and fully executed M/STAs for shipping specimens to [insert lab] OR • Have made significant progress toward obtaining required permits and S/MTAs for shipping specimens to [insert lab]		*To be confirmed by IMPAACT Laboratory Center (for NIAID sites) or Westat (for NICHD sites)*
Study-Specific SOPs *(will be determined with protocol team but may include the following)*		***(Requirements will be determined with the protocol team but may include the following)***
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		
Participant retention		
Source documentation (to include specification of eCRFs planned to be used as source)		
Collection and processing of pharmacokinetic (PK) samples		

Study Activation Requirement	Approval Date	Comments
Other Requirements		
Confirmation of <u>*site-specific*</u> SOP on regulatory inspection readiness *(for registration studies only)*		*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.*