APPENDIX I:
HPTN 083-02 Qualitative Sub-Study Site Activation Checklist

HPTN 083-02 Qualitative Sub-Study Site Activation Checklist

CRS Name:

CRS Number:

Investigator of Record:

Activation Requirement	Investigator's Initials
IRB/EC approval for the HPTN 083-02 Sub-Study	
Approval for the HPTN 083-02 Sub-Study by any other applicable national or local regulatory authorities	
Staff hired/assigned to execute qualitative interviews with documentation in regulatory file of appropriate education, training and experience, to include:	
CV	
GCP training	
HSP training	
Study-specific training from the main HPTN 083 trial, including study design, AE and Social Harm reporting and relevant SSP manual sections	
Qualitative interview training, including 083-02 specific training	
Completed Delegation of Duties Log (per new DAIDS DoD template)	
SOPs in place for conduct and recording of confidential interviews, confidential storage of recordings, transcript generation, confidential storage and transmission of transcripts, and, as applicable, translation of transcripts.	
Equipment in place and operational for recording of qualitative interviews.	
Protocol registration approval has been received from the DAIDS Regulatory Support Center (RSC)	
Investigator of record has signed the protocol signature page and it is on file at the site	

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[INSERT INVESTIGATOR NAME HERE AND SIGNATURE ABOVE]
Investigator of Record

Date