Table of Contents for MTN 016 Study-Specific Procedures Manual

List of Abbreviations and Acronyms

HIV Prevention Agent Pregnancy Exposure Registry: EMBRACE Study

3TC	lamivudine
ACASI	audio computer-assisted self interview
AE	adverse event
AIDS	Acquired Immunodeficiency Syndrome
ALP	alkaline phosphatase
ALT	alanine transaminase
AP	anterior-posterior
ARV	antiretroviral
AST	aspartate aminotransferase
AUC	area under the curve
BID	twice a day
BMD	bone mineral density
BV	bacterial vaginosis
CDC	Centers for Disease Control
CFR	Code of Federal Regulations
CONRAD	Contraceptive Research and Development Organization
d4T	didehydro-deoxythymidine (stavudine)
DAIDS	Division of AIDS
DHHS	(United States) Department of Health and Human Services
DNA	deoxyribonucleic acid
DSMB	Data and Safety Monitoring Board
E. coli	Eschericia coli
EAE	expedited adverse event
EC	Ethics Committee
EFV	efavirenz
EMBRACE	Evaluation of Maternal and Baby outcome Registry After Chemoprophylactic Exposure
FDA	(United States) Food and Drug Administration
FHI	Family Health International
FTC	emtricitabine
GCP	Good Clinical Practices
HBV	hepatitis B virus
HIV	human immunodeficiency virus
HPTN	HIV Prevention Trials Network
IATA	International Air Transport Association
IGF	insulin-like growth factor
IND	investigational new drug application
IoR	Investigator of Record
IRB	Institutional Review Board
LC-MS	liquid chromatography-mass spectrometry
LDMS	Laboratory Data Management System
LLOQ	lower limit of quantification
LPV	lopinavir
mg	milligram
mL	milliliter
mm	millimeter

MTN	Microbicide Trials Network
NIAID	National Institute of Allergy and Infectious Disease
NICHD	National Institute of Child Health and Human Development
NIH	National Institutes of Health
NOAEL	no-observed-adverse-effect-level
NNRTI	non-nucleoside reverse transcriptase inhibitor
OHRP	Office of Human Research Protections
PACTG	Pediatric AIDS Clinical Trials Group
PK	pharmacokinetic
PMPA	9-R-2-phosphonomethoxypropyl adenine
PMPApp	tenofovir diphosphate
PMTCT	prevention of mother-to-child transmission
PPD	Pharmaceutical Product Development Inc.
PrEP	pre-exposure prophylaxis
PSRT	Protocol Safety Review Team
PTID	participant identification number
RCC	Regulatory Compliance Center
RNA	ribonucleic acid
RT	reverse transcriptase
RTV	ritonavir
SAE	serious adverse event
SCHARP	Statistical Center for HIV/AIDS Research and Prevention
SDMC	Statistical Data Management Center
SHIV	simian/human immunodeficiency virus
SMC	Study Monitoring Committee
SOP	standard operating procedure (s)
TDF	tenofovir disoproxil fumarate
ULN	upper limit of normal
UNAIDS	United Nations Joint Programme on HIV/AIDS
ZDV	zidovudine