

HPTN 052

**A Randomized Trial to Evaluate the Effectiveness of
Antiretroviral Therapy plus HIV Primary Care versus
HIV Primary Care Alone to Prevent the Sexual
Transmission of HIV-1 In Serodiscordant Couples**

Study-Specific Procedures Manual



Sponsored by:

**Division of AIDS, US National Institute of Allergy
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List of Abbreviations and Acronyms

3TC	lamivudine
ABC	Abacavir
ACTG	AIDS Clinical Trials Group
AD	associate director
AE	adverse event
AIDS	acquired immunodeficiency syndrome
ALK Phos	alkaline phosphatase
ALT	alanine aminotransferase
APV	Amprenavir
ART	antiretroviral therapy
AST	aspartate aminotransferase
ATV	atazanavir
BID	twice daily
BV	bacterial vaginosis
CAB	Community Advisory Board
CBC	complete blood count
CD4	antigenic marker on helper/inducer T cells
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CK	creatinine kinase
CLIA	Clinical Laboratory Improvement Amendments
CM	clarification memo
CMC	Clinical Management Committee
CORE	Coordinating and Operations Center
CRF	case report form
CRM	clinical research manager
CRPMC	Clinical Research Products Management Center
CT	<i>Chlamydia trachomatis</i>
CTA	Clinical Trials Agreement
CTU	clinical trials unit
CV	curriculum vitae
d4T	stavudine
DAIDS	Division of AIDS
ddC	Zalcitabine
ddI	didanosine
ddI-EC	didanosine, delayed release
dL	deciliter
DLV	Delavirdine mesylate
DMSO	dimethyl sulfoxide
DNA	deoxyribonucleic acid
DSMB	Data and Safety Monitoring Board
EAE	expedited adverse event
EDTA	ethylenediaminetetracetic acid

EC	ethics committee
EFV	efavirenz
EIA	enzyme immunoassay
ENF	Enfuvirtide
FAO	Food and Agriculture Organization of the United Nations
FBS	fetal bovine serum
FDA	Food and Drug Administration
FHI	Family Health International
FPV	Fosamprenavir
FSTRF	Frontier Science Foundation
FTC	emtricitabine
FWA	Federalwide Assurance
GC	<i>Neisseria gonorrhoea</i>
GCP	good clinical practices
GCLP	good clinical laboratory practices
gp	glycoprotein
HBSS	Hank balanced salt solution
HEENT	head, eyes, ears, nose, and throat
HIV	human immunodeficiency syndrome
HPTN	HIV Prevention Trials Network
HSV	herpes simplex virus
IATA	International Air Transport Association
ICF	informed consent form
ICH	International Conference on Harmonization
ID	identification
IDV	Indinavir
IFA	immunofluorescent assay
IND	Investigational New Drug Application
IoR	Investigator of Record
IRB	institutional review board
KOH	potassium hydroxide
kg	kilogram
LDMS	laboratory data management system
LFT(s)	liver function test(s)
LN2	liquid nitrogen
LoA	Letter of Amendment
LPV/r	lopinavir/ritonavir
MedDRA	Medical Dictionary for Regulatory Activities
mg	milligram
mL	milliliter
mm	millimeter
MOP	Manual of Operations
MTCT	mother-to-child transmission
NA or N/A	not applicable
NASBA	Nucleic Acid Sequence Based Amplification
NAT	nucleic acid testing

NCS	not clinically significant
NFV	Nelfinavir
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NL	Network Laboratory
nPEP	non-occupational post-exposure prophylaxis
NVP	nevirapine
OCSO	Office of Clinical Site Oversight
OHRP	Office for Human Research Protection
PAB	Pharmaceutical Affairs Branch
PBMC	peripheral blood mononuclear cell
PBS	phosphate-buffered saline
PCR	polymerase chain reaction
PID	partner identification
PM	project manager
PMN	polymorphonuclear neutrophil
p	protein
pMTCT	prevention of mother-to-child transmission
PPD	Pharmaceutical Product Development
PRO	Protocol Registration Office
prn	as needed
PRS	prevention research specialist
PS	protocol specialist
PSB	Prevention Sciences Branch
PSRT	Protocol Safety Review Team
PTID	participant identification number
PTN	Prevention Trials Network
QA	quality assurance
QC	quality control
QD	once daily
QOL	quality of life
RCC	Regulatory Compliance Center
RNA	ribonucleic acid
RTV	Ritonavir
SADR(s)	suspected adverse drug reaction(s)
SCHARP	Statistical Center for HIV/AIDS Research and Prevention
SDMC	Statistical and Data Management Center
SEP	site establishment plan
SGOT	Serum glutamic oxaloacetic transaminase (also called AST)
SGPT	Serum glutamic pyruvic transaminase (also called ALT)
SOAP	subjective, objective, assessment, plan
SOP	standard operating procedure
SQV	Saquinavir
SSP	study-specific procedures
STD	sexually transmitted disease
STI	sexually transmitted infection

TDF	tenofovir
TV	<i>Trichomonas vaginalis</i>
U/L	Units/Liter
ULN	upper limit of normal
U.S.	United States
VCT	voluntary counseling and testing
VQA	Virology Quality Assurance
WB	Western Blot
WHO	World Health Organization
WTS	when-to-start
ZDV	zidovudine (also called AZT)
μL	microlitre