

HIV PREVENTION TRIALS NETWORK MANUAL OF OPERATIONS

Supported by:

Division of AIDS
National Institute of Allergy and Infectious Diseases
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Developed by:

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INTRODUCTION

HIV PREVENTION TRIALS NETWORK MANUAL OF OPERATIONS

This Manual of Operations (MOP) describes the HIV Prevention Trials Network (HPTN) structure; operating policies; roles and responsibilities of entities and individuals within the HPTN; protocol development and approval processes; standardized study operations procedures; data and specimen collection and processing procedures; and quality management, monitoring, and evaluation in studies conducted by the HPTN. The HPTN MOP is to be used as a reference document for current HPTN policies and procedures. Clinical Trials Units are expected to maintain a hard copy of the current HPTN MOP at all clinical research sites.

The HPTN MOP does not replace the study-specific procedures (SSP) manual that is developed for each HPTN study. The SSP contains detailed guidance on study implementation (see Section 10-14 for more information on SSP manuals). All study procedures within the HPTN must be conducted in accordance with the study protocol, the SSP manual, and this MOP. In the event that there are inconsistencies between these documents, follow this precedent:

- If the MOP is inconsistent with the SSP manual, the SSP manual must be followed
- If the SSP manual is inconsistent with the study protocol, the protocol must be followed.

HPTN members are encouraged to contact the relevant individuals within the Network with procedural questions. For study-specific questions related to proper implementation, data collection, and laboratory concerns for a study protocol, contact the HPTN Coordinating and Operations Center (CORE) Clinical Research Manager/ Protocol Specialist (CRM/PS), the HPTN Statistical and Data Management (SDMC) Protocol Project Manager (PM), and the HPTN Network Laboratory (NL) Quality Assurance/Quality Control Coordinator.

For more general questions related to the HPTN policies and procedures, the following contacts are suggested:

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ORGANIZATION AND UTILIZATION OF THE MOP

The HPTN MOP is intended to pull together, in one document, guidelines for the governance and administration of the HPTN and for the development, review, approval, conduct, and dissemination of research within the Network. The work of the HPTN is guided by regulations and requirements from various sources: the HPTN leadership, the National Institutes of Health (NIH) Division of AIDS (DAIDS), US federal regulations, and regulations of the countries in which HPTN studies are conducted. The MOP includes references to relevant regulations from the first three sources; HPTN investigators are expected to be knowledgeable about and adhere to specific country regulations.

AVAILABILITY OF THE MOP

Copies may be provided to the CTU Principal Investigators, Investigators of Record, CRS Leaders, and Study Coordinators or designees on request. The document also can be downloaded from the HPTN web site at <http://www.hptn.org>.

MODIFICATIONS TO THE MOP

Each section of the MOP is presented and managed as an individual, controlled document. Each section will be identified by its date of issue. Each appendix will be handled the same way. This will allow individual sections and appendices to be modified or updated as needed.

A special email address (mopissues@hptn.org) has been created to facilitate the MOP update process. All additions, corrections, or comments on the MOP contents should be sent directly to this address. Prior to each MOP update, assigned staff review each email and incorporate modifications as appropriate.

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Frequently Used Acronyms

Acronym	Definition
ACASI	Audio-Computer Assisted Self Interview
ACTG	AIDS Clinical Trials Group
AE	Adverse Event
AER	Adverse Event Report
AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral
BSWG	Behavioral Science Working Group
CAB	Community Advisory Board
CDC	US Centers for Disease Control and Prevention
CFR	US Code of Federal Regulations
CIP	Community Involvement Program
CLIA	Clinical Laboratory Improvement Amendments
CM	Clarification Memo
CoC	Certificate of Confidentiality
COI	Conflict of Interest
CORE	Coordinating and Operations Center (FHI 360)
CRF	Case Report Form
CRM/PS	Clinical Research Manager/Protocol Specialist
CRPMC	Clinical Research Products Management Center
CRRB	Clinical Research Resources Branch
CRS	Clinical Research Site
CTA	Clinical Trials Agreement
CTU	Clinical Trials Unit
CWG	Community Working Group
DAIDS	Division of AIDS
DAIDS-ES	DAIDS Enterprise System
DHHS	US Department of Health and Human Services
DOT	US Department of Transportation
DPRS	DAIDS Protocol Registration System
DSMB	Data and Safety Monitoring Board

Acronym	Definition
EC	Executive Committee
EWG	Ethics Working Group
FDA	US Food and Drug Administration
FHCRC	Fred Hutchinson Cancer Research Center
FHI 360	Formerly Family Health International
FIC	Fogarty International Center
FWA	Federal Wide Assurance
GCP	Good Clinical Practices
GMB	NIH Grants Management Branch
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human Immunodeficiency Virus
HPTN	HIV Prevention Trials Network
HSP	Human Subjects Protection
HVTN	HIV Vaccine Trials Network
IATA	International Air Transport Association
ICH	International Conference on Harmonization
IND	Investigational New Drug
IoR	Investigator of Record
IRB/EC	Institutional Review Board/Ethics Committee
JHU	Johns Hopkins University
LDMS	Laboratory Data Management System
LoA	Letter of Amendment
MOP	Manual of Operations
MRC	Manuscript Review Committee
NDA	New Drug Application
NoA	Notice of Award
NIAID	National Institute of Allergy and Infectious Diseases
NICHD	National Institute of Child Health and Human Development
NIDA	National Institute on Drug Abuse
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NL	Network Laboratory

Acronym	Definition
OAR	Office for AIDS Research
OCPL	Office of Communications and Public Liaison
OCR	Office for Civil Rights
OCISO	Office of Clinical Site Oversight
OHRP	US Office of Human Research Protections
OPCRO	Office for Policy in Clinical Research Operations
PAB	Pharmaceutical Affairs Branch
PEC	Performance Evaluation Committee
PHI	Protected Health Information
PI	Principal Investigator
PM	Project Manager
PMG	Prevention Management Group
PRO	Protocol Registration Office
PRP	Prevention Research Program
PSP	Prevention Sciences Program
PSRC	Prevention Science Review Committee
PSRT	Protocol Safety Review Team
PTID	Participant Identification Number
QA	Quality Assurance
QC	Quality Control
QMP	Quality Management Plan
RAB	Regulatory Affairs Branch
RSC	Regulatory Support Center
SAE	Serious Adverse Event
SC	Scientific Committee
SCHARP	Statistical Center for HIV/AIDS Research and Prevention
SDMC	Statistical and Data Management Center (SCHARP/FHCRC)
SMC	Study Monitoring Committee
SOAP	Subjective-Objective-Assessment-Plan
SOP	Standard Operating Procedure
SRC	Science Review Committee
SSP	Study-specific Procedures Manual

Acronym	Definition
STD	Sexually Transmitted Disease
SU	Substance Use
VCT	Voluntary Counseling and Testing
VPDSMB	Vaccine and Prevention Data and Safety Monitoring Board
VRP	Vaccine Research Program
WG	Working Group
WHO	World Health Organization