

7 HPTN FUNDING, CONFLICT OF INTEREST AND CERTIFICATE OF CONFIDENTIALITY 7-2

- 7.1 HPTN Funding Procedures 7-2
 - 7.1.1 HPTN Funding Process and Timeline 7-2
- 7.2 Conflict of Interest Policy..... 7-4
 - 7.2.1 HPTN Financial Conflict of Interest and Disclosure Policy 7-4
 - 7.2.2 Compliance with 42 CFR 50/F and 45 CFR 94 – NIH Financial Conflict of Interest Policy 7-5
 - 7.2.3 Compliance with 21 CFR 54 – FDA Financial Disclosure by Clinical Investigators 7-5
- 7.3 NIH Certificate of Confidentiality 7-6

7 HPTN FUNDING, CONFLICT OF INTEREST AND CERTIFICATE OF CONFIDENTIALITY

The organizations that comprise the HPTN adhere to relevant US federal regulations and National Institutes of Health (NIH)/National Institute of Allergy and Infectious Diseases (NIAID)/Division of AIDS (DAIDS) policies as a condition of receipt of NIH funding. Each Clinical Trials Unit (CTU)/Clinical research Site (CRS) also adheres to relevant local regulations and policies. In addition, HPTN-specific policies and procedures guide HPTN members in meeting relevant requirements and standardizing site operations for each HPTN study. These include:

- **HPTN Manual of Operations (MOP):** This manual provides general guidelines to all HPTN members and combines HPTN policies and procedures in one document.
- **Site and Study-specific Standard Operating Procedures:** Standard Operating Procedures (SOPs) for site operations and for study operations ensure standard, uniform performance of site and study-related tasks (see Table 10-1) and compliance with HPTN procedures, [International Conference on Harmonisation/Good Clinical Practices](#) (ICH/GCP) guidelines, and [US Food and Drug Administration](#) (FDA) regulations, where applicable.
- **Study-specific Procedures (SSP) Manuals:** In addition to study protocols, conduct of HPTN studies typically is guided by an SSP Manual, an instructional and reference resource developed for each study. SSP Manuals provide links to applicable DAIDS manuals (such as the [Manual for Expedited Reporting of Adverse Events to DAIDS](#)), and provide detailed standardized instructions for conducting protocol-specified procedures (see Section 10.7).

A network oversight committee, the Policy and Procedures Group (PPG), with representation from the Leadership and Operations Center (LOC), Statistical and Data Management Center (SDMC), and the Laboratory Center (LC), is responsible for reviewing the HPTN MOP and releasing revised sections as needed.

7.1 HPTN Funding Procedures

The operational components (CTUs/CRSs, LOC, SDMC, and LC) of the HPTN are funded directly through cooperative agreements (UM1 awards) with the [NIAID](#).

The LOC financial staff collaborate closely with the Prevention Sciences Program (PSP) Chief, PSP financial liaison, [Office of Clinical Site Oversight](#) (OCSO) representative, and the Grants Management Branch (GMB) Officer on all Network financial matters (multiple-funding sources, carryover, release of study-specific funds, progress reports, annual budget renewals, financial status reports), and annual funding levels as recommended by the HPTN Executive Committee (EC). LOC staff also provide guidance to CTU staff on budget questions and issues. When sites receive funding directly from the LOC, invoices are submitted to the LOC for payment based on the payment schedule presented in the subagreement (cost reimbursement, per participant, fee for service, etc.).

7.1.1 HPTN Funding Process and Timeline

The CTUs receive funding through UM1 awards directly from the NIH for their core (infrastructure) funding. Each year, the CTU or institutional recipient of the award must complete a [non-competing grant progress report](#) (PHS 2590 package), including a budget and budget justification for the coming year. Unless otherwise instructed, this package is due to NIAID (or the funding institution, like the LOC) 60 days prior to its annual anniversary date. The format and forms for this report are located on the NIH web site and include:

- Face Page

- Detailed Budget for Next Budget Period
- Budget Justification
- Biographical Sketch (new key personnel only)
- Active Other Support
- Progress Report Summary
- Checklist
- Personnel Report

As part of the renewal package, the CTU provides NIH (or the funding institution) with an overall budget to participate in the development and implementation of the HPTN research agenda for the upcoming funding cycle. This participation requires two types of funds: core and protocol funds.

- Core funds are provided to HPTN CTUs in order to maintain the scientific and administrative expertise as well as the infrastructure to support the CTU and each affiliated CRS. Continued support will be based on a satisfactory evaluation at the end of a time period designated as appropriate by each Network. Costs in this category include:
 - CTU Principal Investigators (PI) to maintain CTU administration and an ongoing contribution to the HPTN
 - Personnel for CTU administration, oversight and evaluation, including CTU Coordinator, financial and administrative staff
 - Regulatory, pharmacy, data management, and laboratory oversight staff
 - Community education and engagement structures and activities
 - Clinical quality management activities
 - Maintenance and replacement of equipment
 - Travel to attend HPTN meetings
 - Mentoring and training of staff
- Protocol Funds (PF) are an additional amount provided to support protocol-related expenses attributable to protocol development, implementation or close-out of trial. PF will be calculated annually and will be determined in collaboration with the networks responsible for the protocols. Costs in this category that are protocol specific include:
 - Salary for additional staff or expanded commitment of core staff to carry tasks attributable to the specified protocol
 - Participant recruitment and retention
 - Protocol required tests and evaluations
 - Participant reimbursement
 - Equipment and supplies
 - Community education and engagement structures and activities
 - Additional support for regulatory, pharmacy, data management, and laboratory activities

For direct funding from NIAID, the OCSO representative and Grants Management Specialist send a letter to the CTU Principal Investigators (PIs) to provide guidance on budget development for their annual 2590 package representing the upcoming year. In the future CTUs will be funded directly from FHI 360.

Each year, the HPTN leadership provides an annual PF funding plan based on study-specific budgets. The plan takes into consideration anticipated study initiation dates, number of trials implemented by each CTU, number of participants, and other factors that have cost implications. The recommendations are submitted to appropriate NIH personnel. The LOC will work closely with all NIH partners to ensure adequate review and compliance. NIH will

inform the HPTN leadership of the PF level they intend to fund and request a plan to allocate the funding across the Network sites. Given the role of the NIH in the funding of the HPTN scientific portfolio, HPTN and NIH leadership engage in an ongoing dialogue to ensure adequate funding levels to advance the science.

In addition to submitting a renewal package 60 days prior to its anniversary date (i.e., October 1 for a December 1 date) of each year, CTUs must account for expenditures by funding source(s) through their annual Federal Financial Report (FSR). The FFR includes information on unliquidated balances (funds obligated to the CTU, but not expended). The CTU is required to file the FFR within 90 days of the end of the funding cycle. This report is submitted directly to [NIH's Office of Financial Management](#) (OFM).

The OFM will review and accept the FFR. The OFM reviews electronic submissions first. If sites are submitting paper copies, they should send a copy directly to the OCSO Program Officer and the NIH GMB Officer who can expedite OFM's review and acceptance. GMB staff are notified by the OFM when the FFR has been accepted. Only then can GMB staff act on any carryover requests received. This process will continue for all core funded activities provided directly from NIAID. If funding for protocol funds is made available through the LOC, sites are required to provide monthly invoices to the LOC.

Most importantly, if a site identifies a need for additional funds, they should first review the existing budget in the current CTU award and determine if there are funds that can be rebudgeted/reallocated, which they can manage given their expanded authority.

7.2 Conflict of Interest Policy

Key members of protocol teams and HPTN committees are required to complete a Financial Disclosure Form. Annually, the [Office of HIV AIDS Network Coordination](#) (HANC) distributes the "Statement of Financial, Equity, and Intellectual Property Interests" (Appendix A of the cross-network SOP) to Network members who are required to disclose financial information. Included in this distribution is a list of Network-affiliated companies (referred to as relevant entities in the cross-network SOP) and their related products to serve as a guide to Network members completing their Statements. This list must not be regarded as an exhaustive list of relevant entities. It is the responsibility of Network members to report all significant financial interests as outlined in the cross-network SOP. A cover letter accompanying the distribution provides a deadline for submission.

7.2.1 HPTN Financial Conflict of Interest and Disclosure Policy

The HPTN seeks to maintain objectivity in all of its research by ensuring that the selection of products for testing, as well as the design, conduct and reporting of research is not biased by conflicting financial interests of HPTN leaders and/or investigators who are responsible for the research.

In accordance with the provisions of the US Code of Federal Regulations (CFR) 42 CFR 50/F and 45 CFR 94 and with 21 CFR Part 54, HPTN is required to ensure that:

- Investigators have disclosed any significant financial interests
- Records of financial disclosure are maintained according to the sponsor's requirements
- Conflicting interests of investigators are managed, reduced or eliminated

Specifically, all individuals who meet the definition of "key personnel" as defined in the [NIH HIV/AIDS Clinical Trials Networks Financial Disclosure Policy and Procedure](#) described below must provide the required financial disclosure information annually. In addition, as a study-specific requirement, all individuals listed on a [Form FDA 1572](#) for a study inducted under

an Investigational New Drug (IND) application with the US Food and Drug Administration must have on file at the site a completed [financial disclosure form](#) prior to enrollment of any participants in that study; likewise, any new personnel added to the Form FDA 1572 must complete a disclosure form within the specified timeframe.

7.2.2 Compliance with 42 CFR 50/F and 45 CFR 94 – NIH Financial Conflict of Interest Policy

The HPTN is a party to the NIH HIV/AIDS Clinical Trials Networks Financial Disclosure Policy and Procedure: https://www.hanc.info/smctl/Documents/Cross-network%20FDCOI_SOP.pdf which describes the requirements and procedures for financial disclosure for all named networks. These policies and procedures were developed to identify significant financial interests of researchers in the NIH HIV/AIDS Clinical Trials Networks and avoid conflicts of interest, or the appearance of such conflicts, in the networks' activities.

HPTN members required to disclose under this policy include:

- All members of the Scientific Leadership Group
- All members of a Study Monitoring Committee and Endpoint Review Committee.
- Protocol Chairs, Co-Chairs, Vice-Chairs, and other protocol team members who make direct and significant contributions to the study and/or the study data, as determined by network leadership (e.g., protocol virologist, immunologist, pharmacologist, LC and SDMC personnel)

Members of a protocol team who do not have key decision-making roles, including industry representatives and federal government employees (who are required to report under other federal guidelines) are not required to disclose under this policy.

Annually, the [Office of HIV AIDS Network Coordination](#) (HANC) distributes the "Statement of Financial, Equity, and Intellectual Property Interests" ([Appendix A](#) of the cross-network SOP) to Network members who are required to disclose financial information. A Review Committee including the Network Chair, Vice Chair, Operations Center Director or designee, and the DAIDS Program Officer is responsible for review and mitigation of potential conflicts. This process and the responsibilities of the Operations Center are detailed in the cross-network SOP.

7.2.3 Compliance with 21 CFR 54 – FDA Financial Disclosure by Clinical Investigators

As part of marketing applications for new human drugs and biological products, and marketing applications and reclassification petitions for medical devices, sponsors of clinical research studies are required to disclose to the US Food and Drug Administration (FDA) certain financial arrangements between sponsors and clinical investigators and certain interests of clinical investigators in the product under study or in the sponsor of the study. To fulfill this requirement, Clinical Research Sites (CRSs) involved in the conduct of HPTN studies conducted under an Investigational New Drug (IND) application with the FDA are required to maintain documentation of certain financial arrangements and interests.

This is not a new requirement; however, DAIDS is expected to issue a new policy related to this requirement in the near future and HPTN has established procedures to ensure compliance with the forthcoming policy network-wide. Further guidance will also be provided in an expected update of the DAIDS Protocol Registration Manual, as sites will be required to complete the required documentation prior to enrolling participants in any study for which financial disclosure is required.

HPTN has developed a [Financial Disclosure Form](#) for accessibility on the HPTN website, which may be used to record the required financial disclosure information at each site. Alternatively, an equivalent form provided by a pharmaceutical company co-sponsoring a study may be used.

For each study being conducted under an IND, the designated form must be completed by the CRS Investigator of Record (IoR) and all other investigators and study staff listed on the Form FDA 1572, to disclose their own financial interests as well as those of their spouses and dependent children, prior to enrolling any study participants. IoRs will be required to confirm that the forms have been completed by all applicable CRS staff and placed on file as a condition for site-specific study activation. As new CRS personnel are added to the Form FDA 1572, these personnel must also complete the designated form. Upon completion of the study, as part of study close-out procedures, all forms will be reviewed and updated as needed to add any new financial interests that may have occurred since initial completion of the forms. All forms must be available for review by site monitors and other sponsor and HPTN representatives, as well as FDA representatives.

The deadline for submission by the solicited Network members is May 31. The final report to the Review Committee is due no later than June 30.

7.3 NIH Certificate of Confidentiality

The HPTN has obtained a US Government Certificate of Confidentiality (CoC) that covers US-based CTUs that have been listed by protocol under the CoC. Coverage under the HPTN CoC is applied for by the LOC prior to study implementation.

The CoC does not cover voluntary disclosures (e.g., voluntary disclosure by the participant to his/her health provider or insurer) or suspected harm to a child or self. Site staff will inform participants of the limitations of coverage of the CoC. The LOC Clinical Research Manager (CRM) works with US sites to ensure that language describing the CoC is included in the informed consent form, as needed. Once the protocol has been approved by the local Institutional Review Board (IRB), documentation of the IRB approval is submitted to the LOC clinical operations staff with accompanying application materials from the CTU PI. When CoC coverage has been obtained for the site, the LOC CRM notifies the site.

For more information on the CoC, refer to the law pertaining to the [Certificate of Confidentiality \[Public Health Service Act 301\(d\)\]](#), the [NIH Certificates of Confidentiality Kiosk](#), including information on 42 U.S.C. 241(d), as amended by Public Law No. 100-607, Section 163 (November 4, 1988)].