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7 HPTN FUNDING, CONFLICT OF INTEREST AND CERTIFICATE OF CONFIDENTIALITY

The organizations that comprise the HPTN adhere to relevant United States (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. These regulations and policies are referenced throughout this Manual of Procedures (MOP), as well as within site and Network operations Standard Operating Procedures (SOPs) and Study-Specific Procedures (SSP) manuals.

7.1 HPTN Funding Procedures

The operational components (Clinical Trials Units (CTUs)/Clinical Research Sites (CRSs), HPTN Leadership and Operations Center (LOC), Statistical and Data Management Center (SDMC), and Laboratory Center (LC)) of the HPTN are funded directly through cooperative agreements (UM awards) with NIAID.

The HPTN 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). HPTN LOC staff also provide guidance to CTU staff on budget questions and issues. When sites receive funding directly from the HPTN LOC, invoices are submitted to the HPTN LOC for payment based on the payment schedule presented in the sub-agreement (cost reimbursement, per participant, fee for service, etc.).

7.1.1 HPTN Funding Process and Timeline

The CTUs receive funding through a UM award directly from the NIH for their core (infrastructure) funding. The CTUs may also receive salary in their NIH direct funded UM award - this is determined by DAIDS OSCO in close collaboration with the HPTN LOC. 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 HPTN LOC) 60 days prior to its annual anniversary date. The format and forms for this report are located on the NIH website and include:

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

As part of the renewal package, the CTU provides NIH (and other funding partners) 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 Funds and Protocol Funds (PF):

- Core Funds are provided directly to CTUs by NIAID in order to maintain the scientific and administrative expertise and 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, protocol implementation, and protocol close-out. PFs 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
    - Clinical Trial Insurance (CTI), as is appropriate. (Sites should work with the HPTN LOC finance team to request approval from the Grant Manager at NIAID to use protocol funds for CTI.)

For direct core funding from NIAID, the OCSO representative and Grants Management Specialist send a letter to the CTU PIs to provide guidance on budget development for their annual PHS 2590 package representing the upcoming year.

Each year, HPTN leadership provides an annual PF plan based on study-specific budgets. Based on the PF plan, some sites receive salary directly from the HPTN LOC based on being identified as a protocol-specific site. The plan takes into consideration the anticipated study initiation dates, number of studies implemented by each CTU, number of participants, and other factors that have cost implications. The recommendations are submitted to appropriate NIH personnel. The HPTN LOC will work closely with all NIH partners to ensure adequate review and compliance. NIH will inform 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 the anniversary date of each year (i.e., October 1 for a December 1 due date), CTUs must account for expenditures by funding source(s) through their annual Federal Financial Report (FFR). 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 PF is made available through the HPTN LOC, sites are required to provide monthly invoices to the HPTN 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 re-budgeted/reallocated, which they can manage given their expanded authority.

7.2 Financial Conflict of Interest and Disclosure Policies

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, 45 CFR 94, and 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

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

The HPTN is subject to the NIH HIV/AIDS Clinical Trials Networks Financial Disclosure and Conflict of Interest SOP 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.

Annually, the Office of HIV/AIDS Network Coordination (HANC) distributes a link by email to Network members who are required to disclose financial information to complete the online "Statement of Financial, Equity, and Intellectual Property Interests."

Individuals who meet the reporting requirement are defined in Section 3.1 in the NIH HIV/AIDS Clinical Trials Networks Financial Disclosure Policy and Procedure and must provide the required financial disclosure information annually.

Specific to HPTN members, this includes, but is not limited to:

- All members of leadership (executive), study monitoring, endpoint, and scientific review committees
- Protocol Chairs, Co-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., pharmacologist, LC and SDMC personnel)

Network members who are not required to disclose under this policy include:

- Members of a protocol team who do not have key decision-making roles
- Industry representatives and federal government employees who are required to report under other federal guidelines)
- Community representatives

The deadline for solicited Network members to complete their disclosure statement is approximately 30 days after the solicitation email is distributed.

The HPTN Conflict of Interest Review Committee, including the HPTN PIs and HPTN LOC Executive Director/designee, is responsible for the review and mitigation of potential conflicts. This process and the responsibilities of the committee are detailed in the NIH HIV/AIDS Clinical Trials Networks Financial Disclosure and Conflict of Interest SOP.

7.2.2 Compliance with 21 CFR 54 – FDA Financial Disclosure by Clinical Investigators (for IND Studies ONLY)

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, 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.

HPTN has developed a Financial Disclosure Form for accessibility on the DAIDS Regulatory Support Center 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 saved in the CRS regulatory files. As new CRS personnel are added to the Form FDA 1572, these personnel must also complete the designated form. These disclosures may only need to be completed once by a staff person if nothing changes for that staff person throughout the course of the study.

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.

7.3 NIH Certificate of Confidentiality

NIH provides Certificates of Confidentiality (CoCs) automatically to any NIH-funded recipients conducting research applicable to the NIH Policy for Issuing Certificates of Confidentiality, for which all HPTN research is applicable.

Certificates will be issued to recipients for applicable research regardless of the country where the investigator or the protected information resides. However, Certificates may not be effective for data held in countries outside of the US.

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. The HPTN LOC Clinical Research Manager (CRM) ensures that language describing the CoC is included in the informed consent form, as needed. Site staff will inform participants of the limitations of coverage of the CoC as part of the informed consent process.

For more information on the CoC, refer to: https://grants.nih.gov/policy/humansubjects/coc.htm.