HPTN Financial Program

Kathy Hinson
Family Health International (FHI 360)
HPTN Investigator Meeting
16 June 2014
Presentation Outline

• Overview of HPTN fiscal portfolio
• Protocol costing approach
• Contractual management – timeline for funding and reporting
## Sources of Funding

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**Pending:**
- HPTN 078
- HPTN 079
- HPTN 080
Additional Funding Sources

- OGAC/PEPFAR
- Bill and Melinda Gates Foundation
- CDC
- Product contributions from pharmaceutical companies
Fiscal Program Principles

• LOC ensure integrity of financial program with following principles:
  – *Cost containment* and resource sharing
  – *Accountability* at all levels (NIH, Network, sites), with clear lines of fiscal and programmatic authority
  – *Partnerships* and collaborations
  – *Transparency* in decision making, documentation and communication
  – *Flexibility* to shift funds based on study needs and performance milestones
Protocol Costing

- Planning
- Implementing
- Reporting
Protocol Funding

- PF
  - support to cover protocol-related expenses attributable to protocol development, implementation or close-out of a clinical trial.
  - support for LOC, LC and SDMC for central resources to support study

- PF include funds for (but are not limited to):
  - Salary for additional staff or expanded commitment of staff working on the 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
Protocol Costing Approach

- Centralized process includes protocol leadership and site engagement
- Costing Models
  - per participant/capitation
  - cost reimbursement
  - fixed obligation methods
  - May use combination of approaches (for development versus implementation)
- Life of project budgeting – final approval by EC
- Site + central resources
Criteria for Determining Site PF Needs

• Costing template based on study needs
  – Schedule of evaluations
  – Target enrollments per site
  – Screen to enroll ratios (based on historical data/performance)
  – Local needs (international versus US)
  – Laboratory assays

• Build budget based on timeline for development, implementation, closeout activity
Budget Template Development

LOC and SDMC

Protocol chair

CTU and CRS input

CTU and CRS

Leader-ship
Collaborative Arrangement
Between NIAID, Network, CTU and CRS
CTU
• CTU history of fiscal performance
• Fully funded, affiliated CTUs with HPTN
• CTU administrative office has primary responsibility for PF accounting and performance (CTU and CRSs)
• Cost leveraging and efficiencies
• Effective planning

CRS....if
• Protocol-specific, not affiliated to CTU
Communication

• Communications (to both CTU and CRS)
  – Budget guidance
  – FAQ document
  – Investigator call
  – Annual meetings (or investigator meetings)
  – HPTN funding policy manual
  – MOP Section 7
Study Agreement Mechanisms

• Cost reimbursement
  – development costs
  – implementation costs obligated after meeting milestone (i.e, site activation)

• Per participant

• Fixed cost, milestone driven
Payment Methods

• Payment
  – US: bank wire or check
  – International: bank wire
  – Payment made upon review and approval of monthly invoice and required documentation
Protocol Expenditures

Reporting/Tracking

• CTU: Monthly invoicing or milestone driven reports/ invoices
  – per participant invoice: confirm PTIDs with SDMC

• CTU also responsible for reporting PF expenditures to NIAID
Timeline for PF Distribution

- Protocol budget developed in parallel with protocol development (concept → v 1.0)
- Development/pre-implementation funds
  - Central resources: upon EC approval of concept
  - Sites: v. 1.0 or as determined by study needs
- Implementation funds:
  - If per participant, milestone driven payment schedule
  - Cost reimbursement
Clinical Trial Insurance
Clinical Trial Insurance

- In PF budget, if allowable (presents “risks peculiar to the project”)
- Site submit CTI request forms including DAIDS checklist and 3 vendor quotes to LOC
- LOC to submit documentation to PO and GMO on per protocol basis
- Funds not awarded from LOC until NIH approval is in place
Consortium/Subagreement Management

- Procedure
- Negotiations
- Communication
- Compliance
Types of Mechanisms

• Master agreement
  – Contractual terms and conditions, special provisions negotiated at start of grant cycle, FCOI
  – Pre-award assessment of CTU
  – With CTU organization

• Subaward
  – Specific scope of work, period of performance, $, any project specific terms and conditions, deliverables, milestones, FCOI
  – With CTU organization
  – Linked to master agreement

• Consortium agreement
  – Similar to master agreement but $0
  – Terms and conditions, scope of work, period of performance, deliverables, states funding from CTU, Network expectations, milestones, FCOI
  – With CRS organization, if a lower tier to CTU
Pre-Award Assessment

• Assesses organization’s ability to perform successfully under the terms and conditions of proposed award
• Takes into consideration integrity, record of past performance, financial and technical resources
• Desk review based on audit or financial statements
• Can include site visit utilizing FHI 360 country office fiscal staff
Timeline and Factors Influencing Timelines

- Development and review timeline (2-4 weeks)
- Factors influencing timely execution
  - Administrative clearances
  - Release of funds
  - Pre-award assessment indicates minimal risk with subrecipient
  - Comprehensive submission from sites
  - Limited negotiation of institution or study-specific requirements done with master agreement
Monitoring Site Performance

- Subaward scope of work including milestones
- Study operations report
- Protocol team conference calls
- Study Monitoring Committee
- Network evaluation
- Quarterly leadership review of study progress
- Internal LOC audits (fiscal performance)
Status of PF Funding
NOA has arrived!

Notice of Award
Multi-Component Research Project Co-op Agreements
Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Grant Number: 2UM1AI068619-08 REVISED
FAIN: UM1AI068619

Principal Investigator(s):
MYRON S COHEN
WAFAA M EL-SADR (contact), MD

Project Title: LOC: HIV Prevention Trials Network
Direct Funding from NIH

- HPTN 068
- HPTN 073
Current PF Awards from LOC

- HPTN 065
- HPTN 071
- IPrEX OLE
Master Agreements from LOC (N=20)

- Centre for AIDS Programme of Research in SA
- Chiang Mai University/ RIHES
- Columbia University
- George Washington University
- Harvard University
- Hospital Geral de Nova Iguaçu
- Johns Hopkins University
- National AIDS Research Institute
- Fundaçao Oswaldo Cruz
- Public Health Foundation Enterprises
- RS Cipto Mangunsumo Hospital
- SF Dept. of Public Health
- Ukrainian Institute on Public Health Policy
- University of Cape Town
- University of California
- University of North Carolina
- University of Pennsylvania
- Vanderbilt University
- Weill Medical College of Cornell
- Wits Health Consortium
New PF Grants from LOC

- HPTN 052 (N=11)
- HPTN 074 (N=3)
- HPTN 076 (N=4)
- HPTN 077 (N=8)
- HPTN 075 (N=4)

New Consortium Agreements N=7
New Grants from LOC

• Protocol Chairs, Executive Committee, Committee Chair (N=7)
• Scholars (N=4)
Consortium Agreements (N=7)

• Blantyre Health Research and Training Trust
• Botswana Harvard AIDS Institute
• Hospital Nossa Senhora da Conceição
• Parirenyatwa
• Rutgers, the State University of New Jersey
• Spilhaus
• YRG Care
Proposed Year 9 Funding Process

March 24: Yr 9 PF plan

May 28: NIH confirms PF

July 1: Budget guidance to sites

Sept 1: Site PF PHS packages to LOC

Oct 1: Annual progress report and budget to NIH

Oct-Nov: Negotiate and draft and/or modify subs

Nov –Dec: LOC internal review process

Dec 1: Yr 9 subs in place
ACKNOWLEDGEMENTS

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NIAID: Sheryl Zwerski, David Burns, Michael Gilbreath

NIAID Grants Management: Maggie Wells, Donna Sullivan

NIAID OCSO Liaisons: Patricia Jones, Jane Bupp

NIMH: Dianne Rausch

NIDA: Katherine Davenny