Key HPTN Processes
Nirupama Sista, PhD
Key Network Processes

HPTN processes are outlined in the Manual of Operations: available at www.hptn.org (new version released after the annual meeting)

Key Processes:
• Science Generation (Section 9)
• Site Selection (Section 20)
Science Generation Process

Five Scientific Committees (SC)
- Men Who Have Sex With Men
- Women at Risk
- Adolescents
- Substance Users
- Integrated Strategies

Two Working Groups (WG)
- Community Working Group
- Ethics Working Group
CONCEPT SUBMITTED

HPTN EC Review

CONCEPT APPROVED

Schema Finalized by Protocol Team

Protocol developed by protocol team

HPTN SRC review & approval

- DAIDS PSRC review & approval
- DAIDS regulatory review & approval
- DAIDS Medical or Program Officer review & approval
- DAIDS RAB Chief sign-off on final version 1.0

Final protocol version to sites for preparation of site-specific consent forms and submission to IRBs/ECs
Science Generation Process- Review

SCIENTIFIC MERIT
- Hypothesis scientifically sound/answerable by proposed design
- Study design and methods will yield the proposed outcomes
- Analysis plan for data is adequate and appropriate
- Population is appropriate for research/research is relevant to the community considered

IMPORTANCE/PUBLIC HEALTH IMPACT
- Relevance of planned research to HIV infection prevention
- Proposed study is or would potentially lead to an efficacy trial

HPTN CAN OFFER A RESEARCH ADVANTAGE
- Study is aligned with the scientific agenda and priorities of the Network (i.e., integrated strategies for prevention and PrEP)
- Proposed research will benefit from a multi-site, multidisciplinary collaboration involving different populations either in the initial or subsequent phase

YES
Protocol Development

NO
Concept Plan Rejected
Section 9: Protocol Development

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<tr>
<th>Adolescents at Risk</th>
<th>Women at Risk</th>
<th>Substance Users</th>
<th>MSM</th>
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<tr>
<td>Audrey Pettifor</td>
<td>Ada Adimora</td>
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<td>Raquel de Boni</td>
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<td>Gina Brown</td>
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<td></td>
<td>Chitra Singh</td>
<td>Vu Minh Quan</td>
<td>Patrick Sullivan</td>
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<table>
<thead>
<tr>
<th>Integrated Strategies</th>
<th>Ethics</th>
<th>Community</th>
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<tr>
<td>Connie Celum</td>
<td>Jeremy Sugarman</td>
<td>Janet Frohlich</td>
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<td>Susan Buchbinder</td>
<td>Jerome Singh</td>
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<td>Peter Cherutich</td>
<td>Mark Barnes</td>
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<td>Anant Bhan</td>
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<td>Mina Hosseinipour</td>
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<td>Fatima Zulu</td>
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<td>Steven Wakefield</td>
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### Scientific Committee Liaisons

<table>
<thead>
<tr>
<th>Adolescents at Risk</th>
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<tr>
<td>LOC: Phil Andrew</td>
<td>LOC: Bonnie Dye</td>
<td>LOC: Maria Fawzy</td>
<td>LOC: Phaedrea Watkins</td>
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<td>CW Agnes Nondo</td>
<td>CW: Fatima Zulu</td>
<td>CW: Shipeng “Steven” Chen</td>
<td>CW: Craig Hutchinson</td>
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<td>FS: Jim Hughes</td>
<td>FS: James Dai</td>
<td>FS: Deborah Donnell</td>
<td>FS: Ying Chen</td>
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<tr>
<td>SDMC: Diana Lynn</td>
<td>LC: TBD</td>
<td>LC: Bill Clark &amp; Paul Richardson</td>
<td>LC: Vanessa Cummings</td>
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<tr>
<td>LC: Charlotte Gaydos</td>
<td>SDMC: Corey Kelly</td>
<td>SDMC: Huguette Redinger</td>
<td>SDMC: Lynda Emel</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Integrated Strategies</th>
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<th>Community</th>
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<tbody>
<tr>
<td>LOC: Theresa Gamble</td>
<td>LOC: Elizabeth Greene</td>
<td>LOC: Jonathan Lucas</td>
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<td>CW: Ernest Moleki</td>
<td>CW: David Galetta</td>
<td>EC: Melissa Turner</td>
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<td>EC: Wafaa El-Sadr</td>
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<td>LC: Estelle Piwowar-Manning</td>
<td>LC: Paul Richardson</td>
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<tr>
<td>SDMC: Jim Huhges</td>
<td>SDMC: Deborah Donnell</td>
<td></td>
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</tbody>
</table>
Study Site Selection
Study Site Selection: Process

- Concept approved for protocol development
- Site questionnaire to assess capacity sent to Sites
- Site Selection Committee discusses completed questionnaires and select site(s)
- Pre-site selection assessment visit (if required)
- Site Selection Committee recommends to HPTN EC
- HPTN EC votes and recommends to NIH
- Sites Final
Study Site Selection: Questionnaire

Example Criteria in the Site Selection Questionnaire

• HIV prevalence and incidence
• Experience in performing similar clinical studies
• Site capacity, staff experience, work load, education
• Infrastructure for regulatory support
• Community Advisory Boards (CABs)
• Laboratory facilities and expertise
Study Site Selection: Committee

• Protocol Specific Site Selection Committee (SSC)

• Voting Members:
  • Protocol Chair(s) (if conflict, protocol chair abstains from discussion of their site)
  • Representatives from LOC, LC, SDMC

• Non-voting members:
  • DAIDS Program, OCSO, and other NIH representatives
Study Site Selection: Prioritization

Process of prioritization for site solicitation:
1. HPTN approved CRSs (based on study design)
2. Other Network approved CRSs
3. CRSs that were affiliated to selected CTUs but were not selected
4. New Non-Network sites
Where in the World is HPTN?

★ Funded HPTN CRS ★ Protocol Specific Sites
Study Site Selection: Non-network Sites

Non-Network sites: when do we need these?

- Studies needing unique populations:
  - HPTN 074
- Studies that are community randomized:
  - HPTN 071
  - Vanguard studies in development
- Studies that require specific settings
  - HPTN 065
  - Vanguard studies in development

Discussion with OCSO and DAIDS Program to define the basic site requirement (HPTN 065 and HPTN 071)
Study Site Selection: Non-network Sites

Non-Network sites: how are they identified?

• Availability of relevant epidemiologic data
• Research conducted by site relevant to proposed study
• Experience and expertise of site researchers
• Available infrastructure
• Ability to meet DAIDS and HPTN requirements
Site Selection process

MOP Section 20

20 SELECTION OF SITES

20.1 Selection Questionnaire

20.2 Addition of New Sites to Ongoing Studies

20.3 Referenced Web Links
Acknowledgements

Sponsored by NIAID, NIDA, NIMH under Cooperative Agreement # UM1 AI068619

NIAID: Sheryl Zwerski, David Burns, Michael Gilbreath

NIAID Grants Management: Maggie Wells and Donna Sullivan

NIAID OCSO Liaisons: Patricia Jones, Jane Bupp

NIMH: Dianne Rausch

NIDA: Katherine Davenny
Questions?
Science Generation Process - Review and Scoring

**SCIENTIFIC MERIT (50%)**
- Hypothesis scientifically sound/answerable by proposed design
- Study design and methods will yield the proposed outcomes
- Analysis plan for data is adequate and appropriate
- Population is appropriate for research/research is relevant to the community considered

**IMPORTANCE/PUBLIC HEALTH IMPACT (30%)**
- Relevance of planned research to HIV infection prevention
- Proposed study is or would potentially lead to an efficacy trial

**HPTN CAN OFFER A RESEARCH ADVANTAGE (20%)**
- Study is aligned with the scientific agenda and priorities of the Network (i.e., integrated strategies for prevention and PrEP)
- Proposed research will benefit from a multi-site, multidisciplinary collaboration involving different populations either in the initial or subsequent phase

- **YES**
  - Protocol Development
  
- **NO**
  - Concept Plan Rejected