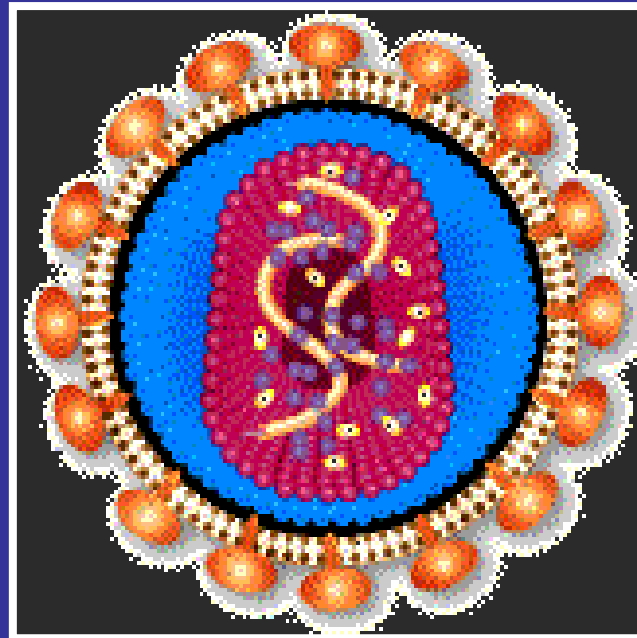
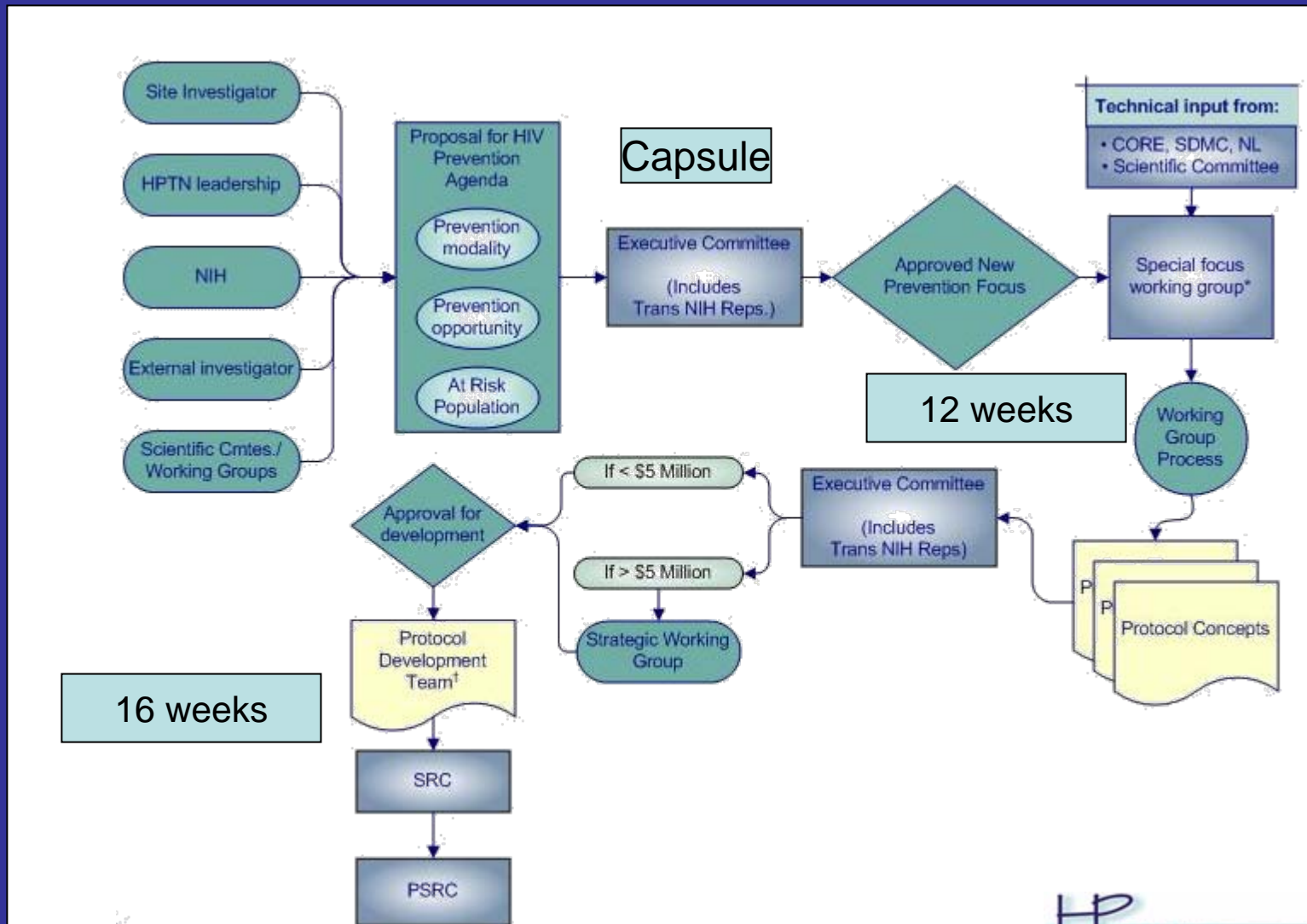


HIV Prevention Trials Network



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Family Health International*

Concept Development Process



Capsule Development

- Multidisciplinary collaboration
- Idea could be generated by individual or multidisciplinary team e.g. EC, sponsor, investigators, region, community etc
- Capsule should be brief and succinct (2 -3 pages)

HPTN Study Capsule for EC Review

(2-3 pages)

Template on HPTN web

- STUDY TITLE
- STUDY CHAIR(S) (IF DETERMINED)
- PURPOSE
- RATIONALE
- STUDY DESIGN
- NATURE OF INTERVENTION(S)
- STUDY POPULATIONS
- STUDY SIZE
- OBJECTIVES
- Primary, secondary and, if applicable, tertiary objectives.
- STUDY DURATION AND PARTICIPATION REQUIREMENTS
- PROPOSED SITES WITH SUITABLE POPULATIONS
- TIMEFRAME/PRACTICAL CONSIDERATIONS
- ESTIMATED BUDGET

Capsule Review Process

- Capsule submitted to EC for review
- EC designates primary, secondary and NIH reviewers and has a Yes/No vote
- Capsule discussed in a closed session
- Authors of capsule answer questions in a following open session
- If approved by EC, capsule proceeds to concept development

Criteria for Review

- scientific merit
- importance/public health impact
- research advantage of the HPTN

Concept Generation

- Concept team created
- Team includes a designated PI, representation from scientific committees/working groups, Trans-NIH steering committees, CORE, SDMC, and NL.
- Concept submitted to the HPTN EC for review and approval at least 2 weeks before meeting.
- Maximum of 10 pages and should include estimated budget
- Timeline from capsule to concept is 12 weeks

Concept review

Reviewers:

Primary and secondary (assigned by EC Chair)
statistical, community, ethics, and laboratory

Trans-NIH Steering Committee consensus review

Assigned reviewers submit written comments in advance of the review, and the concept and reviewers' comments are discussed on a full EC call or at a face-to-face meeting.

Concept Review

- Confidential and anonymous votes by all EC members that are present
- More than 80% “Yes” vote = Yes to proceed to protocol development
- Conflict of Interest Policy: any conflicting EC member recuses from discussion and vote

Prioritization of concepts

If concepts get prioritized due to budget constraints, they will be scored from 1 to 5 based on the following criteria:

- scientific merit (50%)
- importance/public health impact (30%)
- research advantage of the HPTN (20%)

Protocol Development and Review

- EC approved concepts are developed into protocol within 12 to 16 weeks
- Protocols are reviewed by the HPTN SRC and the DAIDS PSRC