

**A Randomized Clinical Trial of the Efficacy of a Behavioral Intervention  
to Prevent Acquisition of HIV Among  
Men who have Sex with Men**

**HIVNET Protocol No. 015**

Sponsored by:

The National Institute of Allergy and Infectious Diseases  
Division of AIDS  
Vaccine and Prevention Research Program

Administered by:

Abt Associates Inc.  
Domestic Master Contractor for  
HIV Vaccine Efficacy Trials

Protocol Co-Chairs:

Margaret Chesney  
Tom Coates  
Beryl Koblin

Protocol Team:

|                  |                |
|------------------|----------------|
| Susan Buchbinder | David McKirnan |
| Connie Celum     | Ken Miller     |
| Sam Clark        | Zeda Rosenberg |
| John Douglas     | Steve Self     |
| Tom LaSalvia     | Jerry Staser   |
| Ken Mayer        |                |

Version 1.0  
6 August 1997

## TABLE OF CONTENTS

|           |  |           |
|-----------|--|-----------|
| <b>1.</b> | <b>INTRODUCTION</b>  | <b>1</b>  |
|           | 1.1 Background   | 1         |
|           | 1.2 Behavioral Intervention  | 1         |
|           | 1.2.1 Intervention Length  | 2         |
|           | 1.2.2 Intervention Tailoring and Delivery                          | 3         |
|           | 1.2.3 Theoretical Framework  | 4         |
|           | 1.3 Study Endpoints  | 4         |
|           | 1.4 Rationale  | 5         |
| <b>2.</b> | <b>STUDY OBJECTIVES</b>  | <b>6</b>  |
|           | 2.1 Primary Objective  | 6         |
|           | 2.2 Secondary Objectives   | 6         |
|           | 2.2.1 STD Outcomes   | 6         |
|           | 2.2.2 Behavior Outcomes  | 6         |
| <b>3.</b> | <b>STUDY DESIGN</b>  | <b>7</b>  |
|           | 3.1 Trial Design   | 7         |
|           | 3.2 Study Duration   | 8         |
|           | 3.2.1 Pilot Phase  | 9         |
|           | 3.2.2 Full Study Implementation                                    | 10        |
|           | 3.3 Timing of Participant Eligibility Screening in Relation to VPS | 10        |
| <b>4.</b> | <b>STUDY POPULATION</b>  | <b>11</b> |
|           | 4.1 Participant Eligibility  | 11        |
|           | 4.1.1 Inclusion Criteria   | 11        |
|           | 4.1.2 Exclusion Criteria   | 12        |
|           | 4.1.3 Withdrawal from Study  | 12        |
|           | 4.1.4 HIV Infection  | 13        |
|           | 4.2 Recruitment  | 13        |
|           | 4.3 Retention Strategies   | 13        |
| <b>5.</b> | <b>BEHAVIORAL INTERVENTION</b>                                     | <b>14</b> |
|           | 5.1 Guidelines   | 14        |
|           | 5.2 Procedures and Schedule of Intervention Contacts               | 16        |
|           | 5.3 Behavioral Intervention Manual and Training Manual             | 16        |
|           | 5.4 Individual Needs Assessment for Tailoring                      | 16        |
|           | 5.5 Description of Intervention: Modules 1-10                      | 17        |
|           | 5.6 Maintenance Modules  | 19        |
| <b>6.</b> | <b>STUDY PROCEDURES</b>  | <b>20</b> |
|           | 6.1 Screening Visit (week -2)                                      | 20        |



|            |  |           |
|------------|--|-----------|
| 6.1.2      | Informed Consent for HIV Testing and HIV Pre-Test Counseling<br>(see Appendix B-1) | 21        |
| 6.1.3      | Laboratory Procedures  | 22        |
| 6.2        | Enrollment and Randomization Visit (week 0)  | 22        |
| 6.2.1      | Enrollment Post-test Counseling Part 1 (Appendix B-2)<br>-All Participants         | 23        |
| 6.2.2      | Randomization  | 23        |
| 6.2.3      | Enrollment post-test counseling Part 2 for Controls<br>(see Appendix B-3)          | 24        |
| 6.3        | Routine Semiannual Follow-up Visits (month 6, 12, 18, 24, 30 and 36)               | 24        |
| 6.3.1      | Follow-Up Pre-Test Visits  | 24        |
| 6.3.1.2    | Control Pre-test and risk reduction counseling<br>[same as Section 6.1.2]          | 25        |
| 6.3.1.3    | Laboratory Procedures [same as Section 6.1.3]                                      | 25        |
| 6.3.1.4    | Behavioral intervention maintenance session<br>[same as Section 5.6]               | 26        |
| 6.3.2      | Follow-up Post-test Visits   | 26        |
| 6.4        | Interim Visits   | 26        |
| 6.5        | Training   | 27        |
| 6.5.1      | Supervision and Quality Assurance  | 28        |
| 6.5.2      | Nature of the Counseling Relationship  | 28        |
| <b>7.</b>  | <b>EVALUATION OF OUTCOMES</b>  | <b>29</b> |
| 7.1        | Primary Outcomes   | 29        |
| 7.2        | Secondary Outcomes   | 30        |
| 7.2.1      | HSV-2  | 30        |
| 7.2.2      | Gonorrhea  | 30        |
| 7.2.3      | Self-report HIV Risk Behaviors   | 30        |
| 7.3        | Additional Secondary Outcomes: Psychosocial Mediators                              | 31        |
| <b>8.</b>  | <b>DATA COLLECTION</b>   | <b>31</b> |
| 8.1        | Introduction   | 31        |
| 8.2        | Data Collection Forms  | 32        |
| 8.2.1      | Forms used   | 32        |
| 8.2.2      | Form Completion and Submission   | 32        |
| 8.3        | A-CASI Data Collection   | 33        |
| 8.4        | Locator Forms  | 33        |
| 8.5        | Baseline and Follow-Up Questionnaires  | 33        |
| 8.6        | Medical records  | 33        |
| 8.7        | Record Storage and Archive   | 33        |
| <b>9.</b>  | <b>STATISTICAL CONSIDERATIONS</b>  | <b>34</b> |
| 9.1        | Overview of Study Design   | 34        |
| 9.2        | Sample Size, Accrual and Loss to Follow-up   | 34        |
| 9.3        | Analytic Issues and Trial Operating Characteristics                                | 35        |
| 9.4        | Analysis Plan  | 38        |
| 9.4.1      | Primary Analyses   | 38        |
| 9.4.2      | Secondary Analyses   | 38        |
| 9.5        | Relationship to other HIVNET Trials  | 40        |
| 9.6        | Data Monitoring  | 41        |
| <b>10.</b> | <b>HUMAN SUBJECTS</b>  | <b>41</b> |
| 10.1       | Institutional Review   | 41        |
| 10.2       | Informed Consent   | 41        |

|            |   |   |   |
|------------|---|---|---|
| 10.3       | Confidentiality                                       | 42  |   |
|            | 10.3.1  | Local Protections   | 42  |
|            | 10.3.2  | Statistical and Clinical Coordinating Center (SC) Protections   | 42  |
|            | 10.3.3  | Federal Protections   | 43  |
| 10.4       | Benefits  | 43  |   |
|            | 10.4.1  | Support for HIV Prevention  | 43  |
|            | 10.4.2  | Access to Care  | 43  |
|            | 10.4.3  | Remuneration  | 44  |
|            | 10.4.4  | Benefits to Humanity  | 44  |
| 10.5       | Risks   | 44  |   |
|            | 10.5.1  | Health Risks  | 44  |
|            | 10.5.2  | Psychosocial Risks  | 44  |
| 10.6       | Study Withdrawal and Discontinuation                  |   | 44  |
| 10.7       | Communicable Disease Reporting                        |   | 45  |
| 10.8       | Incentives to Participation                           |   | 45  |
| 10.9       | Community Preparedness                                |   | 45  |
| <b>11.</b> | <b>LABORATORY SPECIMENS AND BIOHAZARD CONTAINMENT</b> |   | <b>46</b>                                       |
|            | 11.1  | Local Laboratory (LL)   | 46  |
|            | 11.2  | Central Laboratory (CL)   | 46  |
|            | 11.3  | Biohazard Containment   | 47  |
| <b>12.</b> | <b>ADMINISTRATIVE PROCEDURES</b>                      |   | <b>47</b>                                       |
|            | 12.1  | Study Coordination  | 47  |
|            | 12.2  | Intervention Coordinating Center (ICC)  | 47  |
|            | 12.3  | Domestic Master Contractor (DMC) and Statistical and Clinical Coordinating Center (SC) Responsibilities | 48  |
|            |   | 12.3.1  | Domestic Master Contractor (DMC) 48             |
|            |   | 12.3.2  | Statistical and Clinical Coordinating Center 49 |
|            | 12.4  | Study Site Monitoring   | 50  |
|            | 12.5  | Protocol Compliance   | 50  |
|            | 12.6  | Investigator Records  | 50  |
|            | 12.7  | Use of Information and Publications   | 51  |
|            | 12.8  | Signatures and Timetable  | 51  |
|            | <b>REFERENCES</b>                                     |   | <b>52</b>                                       |