

STAF Beth + Fred one only

AIDS Walk
party 9-11- Compt time
= 2 hrs

Wally Cancelled
Sam

RECEIVED
JUN 25 1992

David
FYI
Pls place in my
ACRC file.
TX

June 22, 1992

Dear Health Service Providers,

I would like to bring your attention to funds available to community-based organizations, in conjunction with UCSF, for the evaluation of HIV/AIDS programs in the community. While the AIDS Office has consistently encouraged program evaluation by service providers, we have generally been unable to provide financial support for such evaluations.

The UCSF AIDS Clinical Research Center has recently issued a request for proposals (RFP) that would enable community-based providers to apply for program evaluation funds, in conjunction with UC researchers. If you are interested, I urge you to read the attached announcement. The contact persons can also provide you with names of interested UC researchers if you are seeking one to work with you on evaluating your programs.

Sincerely,

*Sophia W. Chang*Sophia W. Chang, MD, MPH
Chief, Health Services Branch

Attachment

cc: Program Managers

June 1, 1992

UCSF AIDS CLINICAL RESEARCH CENTER (ACRC)

REQUEST FOR PROPOSALS

The ACRC conducts three funding cycles annually to support clinical research in AIDS. Funds are aimed toward evaluation projects and pilot studies that will assist AIDS investigators to obtain additional funding from other agencies. ACRC also supports student AIDS research, and provides emergency "bridge" funding for investigators between grants or completing grants. ACRC funds are available to UC-affiliated investigators at the three northern California campuses.

As the AIDS epidemic enters its second decade it is abundantly clear that education and behavior change provide the best means of prevention. Prevention efforts must extend directly to the communities and persons at risk.

The ACRC wishes to encourage research proposals that evaluate AIDS interventions at the community level. Examples might include: acceptability of a clean-needle-exchange program for intravenous drug users; social marketing of condom distribution; effect of counselling on risky sexual behaviors in adolescents; access to anonymous HIV testing sites as a determinant of getting tested.

The ACRC also wishes to encourage collaboration between community-based organizations that work with AIDS treatment and prevention and researchers at UCSF. Such collaboration will unite the efforts of community service providers with the skills of a research and evaluation team of epidemiologists and behavior scientists.

In summary, this RFA solicits research proposals from community-based organizations that will study and evaluate the efficacy of HIV intervention and prevention strategies. Applicants are urged to collaborate with a UC faculty member so that fiscal control and human subjects approval can be managed at the appropriate department level.

For further information on submission of research proposals, please contact:

Dr. James Dilley, Center for Positive Care (476-3644)

Ms. Katherine Haynes-Sanstad, Center for AIDS Prevention Studies (597-9205)

Dr. John Ziegler, AIDS Clinical Research Center (750-2048)

Proposal instructions and forms can be obtained from Mr. Layne Ethington, ACRC, telephone 750-6923. Deadlines for submission of completed proposals to the ACRC are August 30, 1992, November 30, 1992, or March 30, 1993. The review and funding period is approximately six weeks after these dates.

**THE
AIDS
HEALTH
PROJECT**

MEMO

FROM: **JAMES W. DILLEY, M.D.**
Project Director

DATE: 3/1/86

TO: _____

Personnel

Sr. Statistician

DS-: _____

Your job title

Supplies (\$25/mo x 12 mos)

\$ 300

Justification

The statistician will be responsible for ~~oversight of~~ ^{all} data management ~~oversight, statistical consulting on appropriate~~ ^{statistical} management of the data, as analyses and ~~will~~ help with the writing of reports and manuscripts. The ~~of~~ administrative supervisor will be responsible for maintaining project files, entering and checking data, producing needed forms and telephoning subjects ~~who do not~~ as needed.

A Project concerned with AIDS prevention and health promotion — University of California, San Francisco and San Francisco Department of Public Health.

Princ. Inves

JWD, MD % time
~~NONE~~

DAVID Silver, PhD "

Ron Stoll, PhD "

Brockel See Attachment 5.

Appendices

NONE.

THE
**AIDS
HEALTH
PROJECT**

A project concerned
with AIDS Prevention
and Health Promotion

MEMO

To: Reese T. Jones, MD
Chairman, Committee on Human Research

From: James Dilley, MD

Date: September 28, 1992

Re: Requested Changes on Approval # H2405-08405-01

Please see attached changes as per your request on page 2, section E. Financial Considerations. A copy of your request for these changes is also included.

Would it be possible for you to return to me a copy of a stamped corrected version of the Consent Form so that I can use this version for all our study participants.

Thank you for your assistance in this matter.

**University of California at San Francisco
San Francisco General Hospital**

Consent to be a Research Subject

A. Purpose

Dr. James Dilley, Dr. David Silven and their colleagues at the UCSF AIDS Health Project are conducting a study of the utilization and effectiveness of the Safer Sex Counseling Project.

Specifically, they are interested in reporting on the kinds of individuals who utilize this program and assessing the kinds of problems identified by those using the program. The researchers are interested in learning more about this population of individuals and their specific needs so that they may improve the overall effectiveness of the program.

B. Procedures

1. Prior to being accepted into the study, an SSPC staff counselor will explain the general purposes of the study and answer any questions I may have.
2. If I agree to participate in this study, I will be asked to complete three questionnaires. The first will be completed before I begin my first counseling session. At this time, I will be asked to do the following:

Complete a questionnaire dealing with general personal information which will include questions about my sexual orientation, sexual practices, my attitudes toward safer sex, and about potentially illegal drug or alcohol use. The questionnaire should take approximately 10 minutes.

3. I will be asked to complete a similar questionnaire at the completion of my counseling sessions with the Safer Sex Counseling Project.
4. If I should decide to not complete my counseling sessions with the Project, I will be phoned by Project staff and asked to complete a brief questionnaire inquiring as to the reasons I have decided to stop. This telephone interview will take approximately 5 minutes.
5. If I complete my counseling sessions, I will be telephoned by Project staff two months after my final session to complete a final interview. This interview will ask questions about my experience of the counseling sessions and ask about my current attitude towards safer sex. This interview will last approximately 5 minutes.

C. Risks

There may be some risks associated with participation in this study.

1. The time involved in completing questionnaires may pose some inconvenience for me.
2. I may experience some anxiety in answering some of the questions.

D. Benefits

While there is no direct benefit to me personally at this time, I may benefit by being asked to consider some of the information being asked on the questionnaire. People infected by HIV and concerned about adopting safer sex practices may benefit in the future from knowledge gained from the study.

E. Financial Considerations

Subjects will be neither paid nor charged for study participation.

F. Confidentiality

While a risk of loss of confidentiality exists, my records will be kept as confidential as possible under the law. Only project staff will have access to records. The data from the study, including data which is collected from and about me, may be shared with other researchers or institutions, but no names will be given out.

G. Alternatives

I may choose not to participate in this study. This would have no effect on my ability to participate in this program now or at any time in the future.

H. Questions

1. I have talked with _____ about this study and she/he has answered my questions. If I have any additional questions, I may call Dr. David Silven at (415) 476-6441.
2. If I experience any worry or distress as a result of participating in the study, I may call Dr. Silven at the above number and schedule a consultation.

I. Consent

Participation in this study is entirely voluntary. Refusal to participate will involve no penalty or loss of benefits to which I might otherwise be entitled. I may withdraw from the study at any time. This will in no way prejudice any future care I may require. This study may be terminated at any time by the investigators at any time they determine it is in my best interest.

I have read and had explained to me all details of my participation in this study.

I have been offered a copy of this consent form and the Experimental Subject's Bill of Rights to keep.

If I wish to participate, I should sign this form.

Subject's Signature

Date

Subject's Name (Printed)

Investigator's Signature

Date

Investigator's Name (Printed)

CHR APPROVAL LETTER

TO: James W. Dilley, M.D.
Box 0884

RE: Evaluation of the Safer Sex Counseling Project

The Committee on Human Research, the UCSF Institutional Review Board holding Department of Health and Human Services Multiple Assurance #M-1169, has reviewed and approved this application to involve humans as research subjects, with the following

CONDITION: As there are no biomedical risks associated with this study, please delete the statement regarding treatment and compensation for injury from the Financial Considerations section of the consent form. In its place, you might wish to state that subjects will be neither paid nor charged for study participation. Please submit two copies of your revised consent form to Box 0962. Once these copies have been received and accepted, the status of this protocol will be changed from Conditional Approval to Approval.

APPROVAL NUMBER: H2405-08405-01. This number is a UCSF CHR number and should be used on all consent forms, correspondence and patient charts.

APPROVAL DATE: September 3, 1992.

Full Committee Review

EXPIRATION DATE: September 1, 1993. If the project is to continue, it must be renewed *by the expiration date*. See reverse side for details.

ADVERSE REACTIONS/COMPLICATIONS: All problems having to do with subject safety must be reported to the CHR within ten working days.

MODIFICATIONS: All protocol changes involving subjects must have prior CHR approval.

QUESTIONS: Please contact the office of the Committee on Human Research at (415) 476-1814 or campus mail stop, Box 0962.

Sincerely,

Scott M. Fields PhD / for R Jones

Reese T. Jones, M.D.
Chairman
Committee on Human Research

COMMITTEE ON HUMAN RESEARCH
FULL COMMITTEE FORMAT
COVER PAGE

13

PRINCIPAL INVESTIGATOR

(UCSF Faculty) James W. Dilley, MD

MAILING ADDRESS

(Campus) Box 0884

UNIVERSITY

TITLE Assoc. Clinical Prof.

PHONE

NUMBER 476-6430

DEPT. Psychiatry

IS P.I. SPONSOR/

ADVISOR ONLY? X

CO-P.I. N/A

TITLE

DEPT.

PHONE

SUBMISSION

NUMBER

DATE

MAILING ADDRESS

PROJECT

TITLE EVALUATION OF THE SAFER SEX COUNSELING PROJECT

NAMES/TITLES OF ALL OTHER INVESTIGATORS:

David Silven, PhD/Psychologist II

Ronald Stall, PhD/Research Psychologist

Donald Chambers, PhD/Senior Statistician

PROCEDURES (List all procedures to be done for purposes of the study):

Completion of self-report questionnaires

HISTORY OF THIS PROJECT:

Previous CHR approval # N/A

X New

 Modification

 Renewal Expiration Date / /

Does this submission differ from the previous submission(s)? Yes No

Explain any differences within protocol.

RADIOISOTOPES:

Will any radioactive materials be used? No

 In vivo

 In Vitro

What materials?

Approval of the Radiation Safety Committee is required prior to final CHR approval.

Number of RSC approval:

Date of RSC approval:

SUBJECTS (Explain in detail in protocol):

Subjects:

Number 25-35

Source(s) UCSF AIDS Health Proj

Reimbursement None

Controls/Normals:

Number None

Source(s)

Reimbursement

DRUGS & DEVICES:

List all new drugs and/or devices and all approved ones being investigated for a new use. Each must have an exemption number from the FDA (unless a non-significant IDE is being sought from the IRB). If applicable, list exemption number.

Will any minors (under 18) be involved? Yes X No

NAME

IND/IDE #

SITE (Check and discuss within protocol):

 Parnassus VAMC SFGH

X Other UCSF site

Other

FUNDING:

Will this study be funded? Yes No

XX Pending

Federally? Other? XX

COSTS: Will there be any charges to the subjects or their third party carriers due to participation in the study? Yes XX No

Specify which costs:

Agency/Sponsor Name

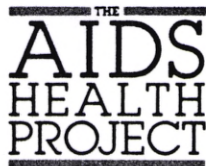
#

AIDS Clinical Research Center

PRINCIPAL INVESTIGATOR'S SIGNATURE

James W. Dilley

Maximum amount (approximate):



*A project concerned
with AIDS Prevention
and Health Promotion*

August 20, 1992

Chair, Committee on Human Research
Office of Research Affairs, Box 0962
University of California, San Francisco

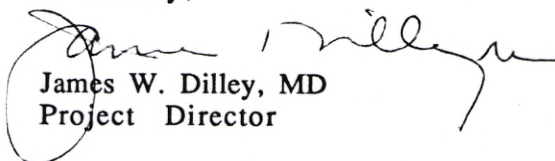
Dear Sir/Madam:

Please find enclosed our full committee review application for a descriptive evaluation study of one of our clinical programs, the Safer Sex Counseling Project.

Please note that we have not concluded our development of Time One and Time Two questionnaires. However, per the CHR guidelines (October 1987), we have included a questionnaire used in a similar study as an Appendix. This questionnaire is a good example of the tone and structure of the kinds of questions we will be using. In fact, this questionnaire, developed by Dr. Ron Stall, will be the basis for our final product. Dr. Stall is a co-investigator on our current project.

We will forward our final questionnaire on to you in the next few weeks.

Sincerely,



James W. Dilley, MD
Project Director

Committee on Human Research
Full Committee Format
Safer Sex Counseling Project
UCSF AIDS Health Project

I. Study Aim/Purpose

The aim of this project is to perform an evaluation study of a counseling intervention program, the Safer Sex Counseling Project (SSCP) of the University of California AIDS Health Project. This program, which endeavors to help gay men who self-identify as in need of help maintaining safer sexual practices, provides one to four individual counseling sessions to help them regain their commitment to practicing safer sex. This study aims to answer several questions, including:

1. What are the characteristics of the sample of gay and bisexual men who seek the services of the SSCP? More specifically, what is the distribution in terms of age, ethnicity, education, sexual orientation (gay or bisexual self-identified), HIV antibody status, income, education, substance use, relationship status (single or in a steady relationship) and type (monogamous or nonmonogamous), types of unsafe sex behaviors concerned about, factors to which risk of unsafe sex is attributed, and recent history of unsafe sexual behaviors?
2. For those who have unsafe sex lapses after entering the SSCP, to what factors are these lapses attributable?
3. What is the average number of SSCP sessions that each client receives?
4. For those who drop out of the SSCP without their counselor's consent that intervention goals have been sufficiently met, what are the factors to which dropping out is attributable?
5. What is the impact of participation in the SSCP in terms of attitudes and behavior relevant to safer sex? More specifically:

- a. Does participation in the SSCP increase the level of clients' perceived self-efficacy in being able to stick to the safer sex guidelines and avoid unsafe lapses?
 - b. Does it decrease the frequency in which they actually engage in unsafe sexual behavior?
 - c. Does it increase clients' level of confidence in being able to identify the factors to which risk of unsafe sex is attributable in their particular cases?
 - d. Does it lead to increased perceived self-efficacy or actions taken to deal effectively with the factors to which risk of unsafe sex is attributed, such as seeking treatment for alcohol abuse, or talking with sex partners about the need to stick to the safer sex guidelines?
 - e. What patterns can be identified in terms of any changes over time in these effects, both during the course of participation in the SSCP, and during the two-month follow-up period?
6. Are there variables that are predictive of positive change in terms of the above-mentioned effects?
 7. Do clients who attend only one SSCP session show more or less effects of the intervention compared to those who attend multiple sessions?

II. Background

The UCSF AIDS Health Project (AHP) has been in the forefront of providing AIDS prevention counseling since early 1984. AHP has served over 60,000 clients since that time and has pioneered efforts to provide people at risk for HIV disease the information, skills and abilities needed to remain free of infection. The intervention model utilized by AHP is based on cognitive-behavioral approaches to behavior change. This model has proven successful in helping self-identified individuals at risk for HIV infection make necessary behavior changes to reduce their risk.

AHP provides a range of HIV related services in San Francisco. Our single largest program is the Anonymous Testing Program where we have provided testing and counseling services to roughly 1,000 people each month since the opening of the program in 1985. Since that time, AHP has been acutely aware of the many men and women who make commitments to practicing safer sex, but who later "fall off the wagon". These clients are regularly seen in the

safer sex, but who later "fall off the wagon". These clients are regularly seen in the Anonymous Testing Program when they return to be tested after a "slip" has made them want to re-check their antibody status. This phenomenon of "relapse" was expected and as the phenomenon began to appear, AHP and other AIDS agencies lobbied for special services for those clients who self-identified as those having difficulty remaining safe. The Safer Sex Counseling Project (SSCP) was created in response to this need.

The SSCP provides gay and bisexual men with individualized sex-positive counseling sessions aimed at helping to restore a commitment to safer sex practices. Clients are offered one to four individual sessions designed to help them identify and overcome their difficulties with remaining safe. The sessions provide clients safer sex information, identify factors associated with increased potential for unsafe sex lapses, and helps them to develop strategies for addressing these factors so as to reduce their risk for future lapses. This evaluation study will help us to identify client variables predictive of program success or failure.

III. Significance

Despite major reductions in high-risk sexual behavior among gay and bisexual men in San Francisco since the early 1980s, relapse into unsafe sex has been consistently found to occur in large numbers in this population. In a 1990 study by Ekstrand and Coates at San Francisco's Center for AIDS Prevention Studies (CAPS) evaluating data from the San Francisco Men's Health Study, 16% of the sample reported having reinitiated unprotected insertive anal intercourse, and 12% reinitiated unprotected receptive anal intercourse, following a period of exclusively safe sex. Stall, Ekstrand, Pollack, McKusick, and Coates at CAPS (1990), evaluating data from the cohort of men in San Francisco's AIDS Behavioral Research Project, reported that a pattern of return to unsafe sex was eight times more common than that of consistent high risk sex at every period of measurement. In a 1990 report by the San Francisco AIDS Foundation (SFAF), 30% of 401 subjects surveyed in late 1989 reported having engaged in unsafe sex within the previous month. Unsafe sex in that survey was defined more broadly than in the 1990 CAPS study, as unprotected anal intercourse, oral-anal contact, fisting, or oral sex with ejaculation. Approximately 18% of the men in the SFAF survey reported having engaged specifically in unprotected anal intercourse within the previous year.

For the past year, The AIDS Health Project's Safer Sex Counseling Project (SSCP) has been providing individual consultation sessions to gay and bisexual men concerned about their risk of relapsing into unsafe sex. Because of limited funding, no formal program evaluation has been conducted to date. Evaluation is needed to help better identify the types of clients being served by the program including their needs, and the impact of the intervention. Furthermore, evaluation can help to discriminate and describe those who benefit from the intervention and those who do not. This information is critical in terms of future program planning.

IV. Methods

a. General Study Design

The current proposal involves a prospective descriptive evaluation study. Written questionnaires will be administered to SSCP clients at the start (pre-treatment) and the conclusion (post-treatment) of their participation in the program, and at two-month follow-up. A two-month follow-up period, rather than a longer one, was chosen in order to minimize loss of contact with subjects over time. Key variables will include sexual activities engaged in, perceived self-efficacy to stick to the safer sex guidelines and avoid unsafe sex lapses, and level of commitment to following the safer sex guidelines and avoiding unsafe sex in the future. For those clients who drop out of the SSCP without their counselor's consent that intervention goals have been sufficiently met, a structured telephone interview will be used to assess clients' reasons for leaving the program.

b. Methods of data analysis

Prior to any statistical analyses, questionnaire items will be grouped and summary scales created for the study's primary variables (e.g., types and levels of sexual risk behaviors, level of confidence in identifying personal risk factors to which unsafe sex is attributable, degree of commitment to safer sex, perceived self-efficacy in avoiding unsafe sex). Published research by Dr. Stall and his colleagues (1992), based upon data collected using a longer form of the proposed evaluation questionnaires, documents the development of a series of similar scales.

Factor analysis and internal-consistency reliability coefficients will be used as data reduction methods for scale creation for the proposed questionnaire.

Much of the research is primarily descriptive (Questions #1-4). Summary data will be provided for the entire participating sample, as well as separate group descriptions for those subjects who report unsafe sex lapses and those who drop out of the intervention without their counselor's consent that goals have been sufficiently met. In each of these latter two subgroups, group comparisons with "successful" subjects will help identify factors associated with decreased sexual risk behavior and increased confidence, commitment, and personal self-efficacy.

Research question 5 involves an assessment of attitudes and behaviors over time (i.e., pre- and post-intervention, two-month follow-up) will be examined using repeated measures analyses. By comparing the post-intervention and follow-up assessments to baseline (pre-intervention), the presence of short-term change and stability of change over time can be investigated. Research question 7 involves a similar set of repeated measures analyses, but with the inclusion of group comparisons between those completing a single session and those completing multiple sessions, plus the interaction of group with time (i.e., are changes, if any, the same for the two groups over time).

Research question 6 focuses on identifying independent variables (e.g., age, ethnicity, education, substance use) and baseline levels of dependent variables (e.g., degree of confidence, commitment, and personal self-efficacy in avoiding unsafe sex) that are related to positive change (e.g., increased self-efficacy, decreased sexual risk behavior).

Given the relatively small expected sample size of 25-35 clients, statistical analyses will be primarily univariate or bivariate. Group comparisons will be performed using t-tests and analysis of variance (ANOVA) for continuous variables, Mann-Whitney and Kruskal-Wallis tests for ordered categorical and non-normal continuous variables, and Fisher's exact and chi-square tests for unordered categorical variables. Measures of association will be calculated using Pearson product-moment or Spearman rank-order correlations, based upon whether or not the variables are continuous, ordered, and/or non-normally distributed.

c. Subject Selection

1. Who and Why

The subjects selected for evaluation in this proposal are the clients in our ongoing Safer Sex Counseling Project. These clients are self-identified gay or bisexual men who have stated that they have had difficulty remaining committed to safer sex practices. Gay and bisexual men are targeted by this program because they make up the single largest group at risk of HIV infection in San Francisco. Generally, these men also have expressed a desire to change high-risk behaviors and have volunteered to take advantage of the program to help them make the changes needed.

2. Total Number

We expect to sample 25 to 35 men in our study.

3. Inclusion/Exclusion Criteria

Inclusion criteria for this proposed project include: membership in the Safer Sex Counseling Project; self-identified gay or bisexual males; willingness to participate in the program; English speaking.

Exclusion criteria include: clients judged to be acutely suicidal or actively psychotic at time of intake; mono-lingual non-English speakers.

d. Subject Recruitment

1. Source(s)

As mentioned above, the AIDS Health Project currently runs the Anonymous Testing Program for the City and County of San Francisco. In addition, the Project offers educational support services for gay and bisexual men through a range of group activities. During an average week, AHP provides services to some 300 to 350 gay or bisexual men. These men are made aware of the Safer Sex Counseling Project as a resource and those who identify relapse as a problem in

their lives are referred. Other AIDS service organizations throughout the city sometimes also refer clients to this program.

2. Initial Contact Method

The majority of referrals to the SSCP come from the AIDS Health Project's Anonymous Test Site counseling staff. During the post-test results sessions, clients often relate that their reason for testing at this time is related to an episode of unsafe activity. This gives counselors the opportunity to describe the SSCP and encourage clients to take advantage of the program. Clients are anonymous throughout this entire procedure and frequently decide that despite their problems with relapse, they are not interested in pursuing the issue further. Counseling staff give clients wishing to enter the SSCP the telephone number of the program. Clients then are asked to contact the intake worker for the program at their convenience.

e. Consent Process and Documentation

At the first meeting between the client and his counselor, the AHP counselor will explain the purpose and requirements of the study, and ask the client if he is willing to participate. If he agrees, the counselor will give the client a copy of the consent form to sign (see Attachment One), one copy to keep and a copy of the "Subjects' Bill of Rights". The signed consent form will then be returned to the study data manager for filing.

f. Procedures

1. Study Procedures

If consent to participate in the study is obtained, the client will be asked to complete the study Time one questionnaire packet. The questionnaire packet will be developed, in collaboration with Ron Stall, Ph.D., M.P.H. at CAPS, who has designed similar protocols. A copy of the questionnaire Dr. Stall helped to develop for an evaluation study now being conducted of the Stop AIDS Project in San Francisco is attached (see Attachment Two). The measures developed for the study proposed here will use a similar format to the measures in that instrument, shortened to focus on the primary dependent variables in the present study.

The client will be allowed to ask any questions he may have during the completion of the forms and he will return the completed forms to the counselor prior to the start of his counseling session. The counselor will then turn in the completed forms to the study data manager. If consent is not obtained, the client will go directly into his counseling session.

At the completion of the agreed upon number of counseling sessions, the client will be asked to complete the Time two questionnaire packet, which, like the Time one questionnaire packet, will use a similar format to the instrument developed by Dr. Stall and his colleagues for the Stop AIDS evaluation (See Attachment Three). The completion of these forms will occur at the end of the final counseling session. The counselor will deliver the completed forms to the data manager.

If the client should drop out of the program prior to completing the agreed upon number of sessions, the data manager will contact the client by telephone and complete a brief telephone interview (See "Phone Questionnaire", Attachment Four) to document the clients' attitudes towards the program and his reasons for not completing the agreed number of sessions.

For clients who have completed the Time two packet of questionnaires, the data manager will log the client's end date. Two months later, the data manager will contact the client by telephone and complete the Time three questionnaire (See Attachment Five).

2. Time

Time one (pre-treatment), two (end of treatment) and three (follow-up) questionnaires will take approximately 10 minutes to complete. Note that Times one and two will be written and Time three will be a telephone interview.

The "Drop-out" telephone questionnaire will take approximately 10 minutes to complete.

3. Study Site

The study will be completed at the Center for Positive Care and at the offices of the AIDS Health Project, 1855 Folsom St, Mission Center Building.

g. Risks/Discomforts

There may be some risks associated with participation in this study. These include:

1. The time involved in completing questionnaires may pose some inconvenience for the subject, and,
2. The subject may experience some anxiety in answering some of the questions.

h. Treatment and Compensation for Injury

If the subject is injured or experiences distress as a result of participation in the study, treatment will be available. The costs of such treatment may be covered by the University of California depending upon a number of factors. The University does not normally provide any other form of compensation for injury. For further information the subject may contact the Committee on Human Research at (415) 476-1814.

i. Alternatives

Since this proposed study is an evaluation study of an existing program, the subject may simply decline to be a part of the study. He will still of course, be eligible for the program and his refusal to participate in the study will in no way effect his course of treatment.

J. Costs to the Subject

There are no costs to the subject for participating in the SSPC program, just as there are no costs associated with participation in this study.

k. Reimbursement of Subjects

No reimbursement is available to subjects for participation in this study.

l. Confidentiality of Records

Every effort will be made to keep all client records confidential. All client records other than the consent form will be coded. The signed consent forms will be kept in a locked file cabinet in the office of the Principal Investigator. Once the signed consent form is returned to the study office, a code will be matched with the client's name. This list will be kept in a password protected file on the Principal Investigator's computer.

When a client drops out of the study or needs to be contacted to complete the Time three telephone interview, the Principal Investigator will give the subject's phone number and first name only to the data manager who will then call the subject and complete the questionnaire.

Data will be reported in aggregate only. No identifying information will be linked with an individual's results.

5. Qualifications of Investigators

James W. Dilley, MD, is an Associate Clinical Professor of Psychiatry at UCSF. Dr. Dilley has been the Director of the UCSF AIDS Health Project since 1984 and has authored many articles on various aspects of the mental health and psychosocial aspects of AIDS care. Dr. Dilley has served on the American Psychiatric Association's AIDS Commission and has been either a member of the Scientific Advisory Committee to the International AIDS Conference or a member of the Review panel for the past six years. Finally, Dr. Dilley has recently completed a four year study of the neuropsychological aspects of HIV infection funded by the National Institute on Drug Abuse.

David Silven, PhD, has been the Coordinator of the AIDS Health Project's Educational Support Services unit for the past three years. Dr. Silven is a clinical psychologist with previous research experience on the process of psychotherapy and the use of cognitive approaches in the treatment of depression.

6. Special Requirements and Attachments

See Attachments One through Five.

7. Bibliography

Ekstrand, M.L., & Coates, T.J. (1990). Maintenance of safer sexual behaviors and predictors of risky sex: The San Francisco Men's Health Study. *American Journal of Public Health, 80*, 973-977.

San Francisco AIDS Foundation, & Communication Technologies (1990). HIV-related knowledge, attitudes, and behaviors among San Francisco gay and bisexual men: Results from the fifth population-based survey. Unpublished manuscript.

Stall, R. Barrett, D., Bye, L., et al. (1992). Younger and older gay men's HIV risk-taking behaviors: The Communication Technologies 1989 cross-sectional survey. *Journal of AIDS, 5*, 682-87.

Stall, R., Ekstrand, M., Pollack, L., McKusick, L., & Coates, T.J. (1990). Relapse from safer sex: The next challenge for AIDS prevention efforts. *Journal of Acquired Immune Deficiency Syndromes, 3*, 1181-87.

CHR APPROVAL LETTER

TO: James W. Dilley, M.D.
Box 0884

RE: Evaluation of the Safer Sex Counseling Project

The Committee on Human Research, the UCSF Institutional Review Board holding Department of Health and Human Services Multiple Assurance #M-1169, has reviewed and approved this application to involve humans as research subjects, with the following

CONDITION: As there are no biomedical risks associated with this study, please delete the statement regarding treatment and compensation for injury from the Financial Considerations section of the consent form. In its place, you might wish to state that subjects will be neither paid nor charged for study participation. Please submit two copies of your revised consent form to Box 0962. Once these copies have been received and accepted, the status of this protocol will be changed from Conditional Approval to Approval.

APPROVAL NUMBER: H2405-08405-01. This number is a UCSF CHR number and should be used on all consent forms, correspondence and patient charts.

APPROVAL DATE: September 3, 1992.

Full Committee Review

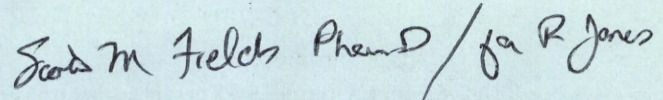
EXPIRATION DATE: September 1, 1993. If the project is to continue, it must be renewed *by the expiration date*. See reverse side for details.

ADVERSE REACTIONS/COMPLICATIONS: All problems having to do with subject safety must be reported to the CHR within ten working days.

MODIFICATIONS: All protocol changes involving subjects must have prior CHR approval.

QUESTIONS: Please contact the office of the Committee on Human Research at (415) 476-1814 or campus mail stop, Box 0962.

Sincerely,

A handwritten signature in dark ink, appearing to read "Reese T. Jones", with a stylized flourish at the end.

Reese T. Jones, M.D.
Chairman
Committee on Human Research

GENERAL INFORMATION FOR APPROVALS

EXPIRATION DATE:

An expiration date of either the first or the 15th of the month is given on the front of this form. Although the office of the Committee on Human Research will, as a courtesy, send a reminder about 6 to 8 weeks in advance of the expiration date, it is the investigator's responsibility to initiate the renewal process sufficiently early. The Department of Health and Human Services and the University of California require *at least* annual review of all projects involving humans as subjects. Please allow a minimum of 4 weeks for the CHR to review and renew your application.

EXTRAMURAL FUNDING AGENCY CERTIFICATION:

The majority of the funding agencies require the University have an Institutional Review Board and that the principal investigator have appropriate IRB approval. For most funding agencies certification of IRB approval is accomplished by signing the face page of most applications. The Institutional Officer signing for the application organization is the Director, Office of Research Affairs. Non-federal agencies utilize a variety of certifications including their own certification format. Questions regarding extramural agency requirements should be directed to the Contracts and Grants Office, 476-2977.

Before a principal investigator submits an extramural funding proposal he/she should have the appropriate IRB approval(s) in place. To submit a grant or contract proposal which proposes the use of human subjects the Office of Research Affairs, Division of Contracts and Grants, requests that you attach one copy of this IRB approval letter to the Contracts and Grants Approval Form. If you are using more than one assurance, please submit one copy of each approval letter.

PAYMENT OF SUBJECTS:

The University Purchasing Department will issue blanket requisition numbers. The General Requisition should cite the following information:

- a copy of the Approval letter;
- the approved rate for each class of subjects and/or each procedure, or
- the protocol page clearly stating the rates; and
- a copy of the consent form showing the reimbursement statement.

With a blanket number, Form 5's can be submitted to Accounting. The Form 5 should include:

- the blanket number;
- the subject's name and address for mailing;*
- the subject's social security number.*

* Because the use of names and social security numbers can create a confidentiality problem, this point should be addressed both in the protocol and in the consent form.

**University of California at San Francisco
San Francisco General Hospital**

Consent to be a Research Subject

A. Purpose

Dr. James Dilley, Dr. David Silven and their colleagues at the UCSF AIDS Health Project are conducting a study of the utilization and effectiveness of the Safer Sex Counseling Project.

Specifically, they are interested in reporting on the kinds of individuals who utilize this program and assessing the kinds of problems identified by those using the program. The researchers are interested in learning more about this population of individuals and their specific needs so that they may improve the overall effectiveness of the program.

B. Procedures

1. Prior to being accepted into the study, an SSPC staff counselor will explain the general purposes of the study and answer any questions I may have.
2. If I agree to participate in this study, I will be asked to complete three questionnaires. The first will be completed before I begin my first counseling session. At this time, I will be asked to do the following:

Complete a questionnaire dealing with general personal information which will include questions about my sexual orientation, sexual practices, my attitudes toward safer sex, and about potentially illegal drug or alcohol use. The questionnaire should take approximately 10 minutes.

3. I will be asked to complete a similar questionnaire at the completion of my counseling sessions with the Safer Sex Counseling Project.
4. If I should decide to not complete my counseling sessions with the Project, I will be phoned by Project staff and asked to complete a brief questionnaire inquiring as to the reasons I have decided to stop. This telephone interview will take approximately 5 minutes.
5. If I complete my counseling sessions, I will be telephoned by Project staff two months after my final session to complete a final interview. This interview will ask questions about my experience of the counseling sessions and ask about my current attitude towards safer sex. This interview will last approximately 5 minutes.

C. Risks

There may be some risks associated with participation in this study.

1. The time involved in completing questionnaires may pose some inconvenience for me.
2. I may experience some anxiety in answering some of the questions.

D. Benefits

While there is no direct benefit to me personally at this time, I may benefit by being asked to consider some of the information being asked on the questionnaire. People infected by HIV and concerned about adopting safer sex practices may benefit in the future from knowledge gained from the study.

E. Financial Considerations

Subjects will be neither paid nor charged for study participation.

F. Confidentiality

While a risk of loss of confidentiality exists, my records will be kept as confidential as possible under the law. Only project staff will have access to records. The data from the study, including data which is collected from and about me, may be shared with other researchers or institutions, but no names will be given out.

G. Alternatives

I may choose not to participate in this study. This would have no effect on my ability to participate in this program now or at any time in the future.

H. Questions

1. I have talked with _____ about this study and she/he has answered my questions. If I have any additional questions, I may call Dr. David Silven at (415) 476-6441.
2. If I experience any worry or distress as a result of participating in the study, I may call Dr. Silven at the above number and schedule a consultation.

I. Consent

Participation in this study is entirely voluntary. Refusal to participate will involve no penalty or loss of benefits to which I might otherwise be entitled. I may withdraw from the study at any time. This will in no way prejudice any future care I may require. This study may be terminated at any time by the investigators at any time they determine it is in my best interest.

I have read and had explained to me all details of my participation in this study.

I have been offered a copy of this consent form and the Experimental Subject's Bill of Rights to keep.

If I wish to participate, I should sign this form.

Subject's Signature

Date

Subject's Name (Printed)

Investigator's Signature

Date

Investigator's Name (Printed)

University of California at San Francisco
San Francisco General Hospital

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*This Form
must be
used &
CHR stamp.*

University of California at San Francisco
San Francisco General Hospital

Consent to be a Research Subject



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E. Financial Considerations

If I am injured or experience distress as a result of participation in the study, treatment will be available. The costs of such treatment may be covered by the University of California depending upon a number of factors. The University does not normally provide any other form of compensation for injury. For further information I may contact the Committee on Human Research at (415) 476-1814.

F. Confidentiality

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I have been offered a copy of this consent form and the Experimental Subject's Bill of Rights to keep.

If I wish to participate, I should sign this form.

Subject's Signature

Date

Subject's Name (Printed)

Investigator's Signature

Date

Investigator's Name (Printed)

1. Have you had sex with anyone in the past 6 months?

No ☐ → [If No, please skip to QUESTION 7, PAGE 5]
 Yes ☐ → [If YES, continue on with the Next Questions]

By lover or "primary" partner, we mean a person to whom you feel committed more than anyone else AND with whom you have had sex.
 This does not necessarily mean that you are monogamous.

2a. How many different men in total did you have sex with, including your lover or primary partner, if you have one?

Write number of different men in the box:
 If none, write in zero (0).

Number of men
in past 30 days

Number of men
in past 6 months

2b. How many different women in total did you have sex with, including your primary partner, if you have one?

Write number of different women in the box:
 If none, write in zero (0).

Number of women
in past 30 days

Number of women
in past 6 months

3. During the PAST 30 DAYS, how many TIMES did you have sex:

[IF NOT AT ALL OR NON-APPLICABLE, check "Zero (0) Times."]

	Number of times	Zero (0) Times
a. With your lover or primary partner, if you have one?		
b. With a man other than your primary partner?		
c. With a woman?		
d. With more than one other or others (group sex, 3-ways)?		
e. With others at a J/O club or bathhouse?		

4. Are you currently in a primary relationship with a man?

(By "primary", we mean a relationship with a man where you feel committed to him more than anyone else AND where you have had sex together. This does not necessarily mean that you are monogamous.)

No ☐ [If No, please skip to QUESTION 6, PAGE 4]
Yes ☐

→ If YES, answer the following:

4a. How long ago did you meet this man?

Number of years

Number of months

4b. How long ago did you first have sex with this man?

Number of years

Number of months

4c. Which of the following best describes sex in your relationship?
[Check only one box]

a. Neither of us has sex with other people.

☐

b. Only he has sex with other people.

☐

c. Only I have sex with other people.

☐

d. We both have sex with other people.

☐

5. In the PAST 30 DAYS, how often did you do each of the sexual activities listed below with your LOVER OR PRIMARY PARTNER?

[Please write the number of times in each box. Write zero (0) if not at all.]

WITH YOUR LOVER OR PRIMARY PARTNER:

Oral Sex Without Condoms (Rubbers):

- a. Oral sex where you suck his cock; he doesn't cum in your mouth.
- b. Oral sex where you suck his cock; he cums in your mouth.
- c. Oral sex where he sucks your cock; you do not cum in his mouth.
- d. Oral sex where he sucks your cock; you cum in his mouth

Oral Sex With Condoms (Rubbers):

- e. Oral sex where you suck his cock; he wears a condom.
- f. Oral sex where he sucks your cock; you wear a condom.

Anal Intercourse Without Condoms (Rubbers):

- g. You fuck your partner; you cum up his ass.
- h. Your partner fucks you; he cums up your ass.
- i. Your partner withdraws before he cums during anal intercourse.
- j. You withdraw before you cum during anal intercourse.

Anal Intercourse With Condoms (Rubbers):

- k. You fuck your partner while you wear a condom.
- l. Your partner fucks you while he wears a condom

Rimming (oral/anal sex) Without Latex

- m. You rim your partner
- n. Your partner rims you

If your partner was your only sexual partner in the past 30 days,
SKIP TO QUESTION 7, PAGE 5

Please complete this page if you:

- (a) are single and had sex with another man in the past 30 days, OR
(b) are in a relationship but had sex in the past 30 days with someone who isn't your primary partner

ALL OTHERS SKIP TO QUESTION 7, PAGE 5

6. In the PAST 30 DAYS, how often did you do each of the sexual activities listed below with a man (or men) who were NOT your lover or primary partner?

[Please write the number of times in each box. Write zero (0) if not at all.]

OUTSIDE A PRIMARY RELATIONSHIP:

Oral Sex Without Condoms (Rubbers):

- a. Oral sex where you suck his cock; he doesn't cum in your mouth.
b. Oral sex where you suck his cock; he cums in your mouth.
c. Oral sex where he sucks your cock; you do not cum in his mouth.
d. Oral sex where he sucks your cock; you cum in his mouth

Oral Sex With Condoms (Rubbers):

- e. Oral sex where you suck his cock; he wears a condom.
f. Oral sex where he sucks your cock; you wear a condom.

Anal Intercourse Without Condoms (Rubbers):

- g. You fuck your partner; you cum up his ass.
h. Your partner fucks you; he cums up your ass.
i. Your partner withdraws before he cums during anal intercourse.
j. You withdraw before you cum during anal intercourse.

Anal Intercourse With Condoms (Rubbers):

- k. You fuck your partner while you wear a condom.
l. Your partner fucks you while he wears a condom

Rimming (oral/anal sex) without Latex

- m. You rim your partner
n. Your partner rims you

7. In the **PAST SIX MONTHS**, have you had anal intercourse where neither you nor your sexual partner used a condom? (This includes all anal intercourse with and without orgasm.)

No ☐ → [If No, please **SKIP TO QUESTION 10, PAGE 7**]

Yes ☐

→ 7a. Had you previously made a decision or a commitment that you would only have anal intercourse with a condom?

Yes ☐ No ☐

7b. Approximately how many times did you have unprotected anal intercourse during the past six months?

1-5 ☐ 6-10 ☐ 11-15 ☐ 16-20 ☐ 21+ ☐

8. In the **PAST SIX MONTHS**, how important were the following reasons for having anal sex without a condom?

	Not at all Important	Not very Important	Important	Very Important
a. You were afraid to bring up the topic of condoms?	☐	☐	☐	☐
b. You knew you were positive, so why bother?	☐	☐	☐	☐
c. You wanted to bond with your partner?	☐	☐	☐	☐
d. Your sex partner told you he was HIV antibody negative?	☐	☐	☐	☐
e. You thought that once without a condom would be OK?	☐	☐	☐	☐
f. There weren't any condoms around at the time?	☐	☐	☐	☐
g. You were really sexually turned on and didn't stop to put on a condom?	☐	☐	☐	☐
h. You wanted both of you to have the same HIV status?	☐	☐	☐	☐
i. Using a condom caused the loss of a hard-on?	☐	☐	☐	☐
j. You knew you and your partner had the same HIV status?	☐	☐	☐	☐
k. It felt better to have sex without a condom?	☐	☐	☐	☐
l. You agreed not to cum in each other?	☐	☐	☐	☐
m. You figured that you were bound to get infected anyway?	☐	☐	☐	☐
n. You were in love?	☐	☐	☐	☐
o. You had been drinking or using other drugs?	☐	☐	☐	☐
p. You were tired of having safe sex?	☐	☐	☐	☐
q. The two of you had always fucked without a condom so you thought that there was no reason to start using one now.	☐	☐	☐	☐

9. The next set of questions are about how you felt the last time you had unprotected anal sex.

AFTER the LAST TIME you had unprotected anal intercourse did you:

	Not True	Somewhat True	Mostly True	Definitely True
a. not think much about it at all?	☐	☐	☐	☐
b. talk to that sex partner about it later?	☐	☐	☐	☐
c. feel you had a good reason for having unsafe sex?	☐	☐	☐	☐
d. feel guilty?	☐	☐	☐	☐
e. blame yourself?	☐	☐	☐	☐
f. talk to a friend about it?	☐	☐	☐	☐
g. promise yourself that you would never had unsafe sex again?	☐	☐	☐	☐
h. worry about whether you or your partner had been infected with HIV?	☐	☐	☐	☐
i. lose sleep over it?	☐	☐	☐	☐
j. feel scared?	☐	☐	☐	☐
k. feel discouraged about always trying to have have safe sex since you end up having unsafe sex anyway?	☐	☐	☐	☐
l. feel sure that you would never have unsafe sex again?	☐	☐	☐	☐
m. feel closer to your partner?	☐	☐	☐	☐
n. question your ability to always stay safe sexually?	☐	☐	☐	☐
o. feel worthless?	☐	☐	☐	☐
p. worry, but not talk to anyone about it?	☐	☐	☐	☐
q. decide not to think about it?	☐	☐	☐	☐

r. Did you have any other reaction? Please pause for a minute to remember. Then write it down:

CONTINUE ON WITH THE NEXT QUESTIONS

10. Have you ever been tested for antibodies to the AIDS virus (the AIDS antibody blood test)?

No ☐ → [If No, SKIP to Question 13, Page 8]
Yes ☐ → [Please continue]

10b. When was the most recent time you were tested?

Date of last test:

____/____/____
month/year

11. What was the result of your most recent test? [Please check ONE box]

Negative ☐ → [Go on to QUESTION 12]
Positive ☐ → [Go on to QUESTION 12]
Don't know ☐ → [Skip to QUESTION 13, PAGE 8]

12. We are interested in knowing who gay men talk to about their antibody status. Please indicate whether you've told any of the following people about your antibody test result, whether it is positive or negative.

PLEASE CIRCLE YOUR ANSWER

Have you told your:

closest friends?

YES NO NOT APPLICABLE

any of your other friends?

YES NO NOT APPLICABLE

lover?

YES NO NOT APPLICABLE

any of your other sex partners?

YES NO NOT APPLICABLE

a psychologist or counselor?

YES NO NOT APPLICABLE

ALL MEN WHO KNOW THEIR HIV STATUS,
SKIP TO QUESTION 14, PAGE 9

13. We are interested in the reasons people have for not finding out their HIV (AIDS) antibody status. Below are reasons people have given for not getting tested or not finding out their test results. Please rate how much each of the following has influenced your decision to not finding out your HIV status.

[Please circle only one number per item.]

	<u>Not at all</u>	<u>A little</u>	<u>Some</u>	<u>Very much</u>
Knowing the results of the test is too stressful.	1	2	3	4
I am already doing all that I can to stay healthy; I don't need to know my antibody status.	1	2	3	4
I never had as much risky sex as men who test positive for HIV, so I'm sure I'm negative.	1	2	3	4
I am afraid the test results might be used against me (for example, to deny me health insurance).	1	2	3	4
I am already sure that I am antibody positive, so I don't need to get tested.	1	2	3	4
I am afraid how the test results would affect my personal relationships.	1	2	3	4
Other blood tests I have had indicate I am healthy.	1	2	3	4
My friends don't think I should get tested.	1	2	3	4
I don't think that knowing your test results does you much good medically.	1	2	3	4
I'd like to get tested, but I just can't force myself to go through with it.	1	2	3	4

Have you felt any other reasons? If so, please describe and rate these reasons:

_____	1	2	3	4
_____	1	2	3	4

EVERYONE ANSWER QUESTION 14

14. How much do the following statements describe you?
 Circle the number which BEST fits your response to each item:

	Does Not Describe Me Very Well			Describes Me Very Well
a. When I talk to my friends about my sexual experiences, I tell them whether or not it was safe	1	2	3	4
b. I tell all my sexual partners my HIV status before I have sex with them	1	2	3	4
c. I tell my HIV status to partners with whom I'm thinking of having a relationship, but not casual sex partners.	1	2	3	4
d. I only have sex with people of my own HIV status.	1	2	3	4
e. I feel very much a part of the gay community.	1	2	3	4
f. I don't pay much attention to HIV-status when deciding to have sex with someone.	1	2	3	4
g. Knowing someone's HIV status is one of the factors that determines whether or not I'll have a relationship with someone.	1	2	3	4
h. I have made a commitment to myself to only have safe sex.	1	2	3	4
i. I have made a commitment to other people to only have safe sex.	1	2	3	4

15. FILL IN THE REST OF THIS SENTENCE: When someone tells me he had unsafe sex, my reaction is:

and I tell him: _____

IF YOU ARE HIV ANTIBODY POSITIVE OR ASSUME YOU ARE HIV ANTIBODY POSITIVE, PLEASE COMPLETE THIS SECTION

IF YOU ARE HIV ANTIBODY NEGATIVE, SKIP TO QUESTION 17, PAGE 11

16. Which of the following strategies are you pursuing for your HIV infection?

Check all that apply:

YES

NO

I am taking care of myself.

☐☐

I am monitoring my immune system with blood tests.

☐☐

I am getting drugs or other treatments through the medical system.

☐☐

I am following an alternative treatment strategy (i.e. acupuncture, herbs).

☐☐

I am following a metaphysical strategy (i.e. meditation, spiritual healing).

☐☐

Other:

I'm doing nothing

☐☐

EVERYBODY CONTINUE ANSWERING THE FOLLOWING QUESTIONS

17. How much do you agree or disagree with each of the following statements?

Circle the number which BEST fits your response to each item:

	Strongly Disagree	Disagree	Agree	Strongly Agree
a. Most gay men have unprotected anal sex.	1	2	3	4
b. Some of my sexual partners want to have unsafe sex when they're with me.	1	2	3	4
c. My current behavior could put me at risk of infection or reinfection.	1	2	3	4
d. When gay men slip and have unsafe sex, they talk to a friend about it.	1	2	3	4
e. I am capable of having sex that will not infect or reinfect my sexual partner with AIDS.	1	2	3	4
f. During really hot sex, I am not able to stop doing risky things.	1	2	3	4
g. Most gay men who slip and have unsafe sex are too embarrassed to talk to anyone about it.	1	2	3	4
h. All of my friends use condoms.	1	2	3	4
i. My friends encourage me to practice safe sex.	1	2	3	4
j. My friends tell me when they slipped and had unsafe sex.	1	2	3	4
k. My friends think that it is important to use a condom when having sex.	1	2	3	4
l. Most gay men think that it is impossible to always have safe sex until there is a cure for AIDS.	1	2	3	4
m. I feel confident that I will never slip from safe sex in the future.	1	2	3	4

[QUESTION 17, CONTINUED]

	Strongly Disagree	Disagree	Agree	Strongly Agree
n. Most gay men are now using condoms when they have anal sex.	1	2	3	4
o. People who <u>always</u> use condoms during anal sex will probably not transmit the AIDS virus.	1	2	3	4
p. If I were to slip and have unsafe sex, I would talk to my friends about it.	1	2	3	4
q. AIDS can be transmitted to the "top" (the insertive sexual partner) during unprotected anal sex.	1	2	3	4
r. I am likely to have unsafe sex in the next six months.	1	2	3	4
s. I believe that most of my gay friends support practicing safe sex.	1	2	3	4
t. If I'm going to have anal sex, I'm going to use a rubber.	1	2	3	4
u. I feel confident in my ability to talk about safe sex and slipping with a partner.	1	2	3	4
v. Sometimes I get so frustrated that I have sex in ways that I know are unsafe.	1	2	3	4
w. I have unsafe sex to relieve tensions.	1	2	3	4
x. It's embarrassing to buy condoms in a store.	1	2	3	4
y. Talking about the possibility of slipping to unsafe sex helps me to stay safe.	1	2	3	4
z. If I insist on using a condom for anal sex, a sex partner will think less of me.	1	2	3	4
aa. Sooner or later I will become infected with HIV.	1	2	3	4

18. Have you ever attended any of the following activities as a participant (not as a volunteer) to address HIV or HIV-related issues?

	NO	YES	IF YES, # of meetings in the last 6 months?
a. STOP AIDS meetings	☐	☐	_____
b. The Buddy Connection	☐	☐	_____
c. Positives Being Positive	☐	☐	_____
d. Other HIV positive support group Specify: _____	☐	☐	_____
e. HIV negative support group Specify: _____	☐	☐	_____
f. Caregivers support group	☐	☐	_____
g. Gay/Lesbian support group	☐	☐	_____
h. Substance abuse group	☐	☐	_____
i. People of color support group	☐	☐	_____
j. Other Specify: _____	☐	☐	_____

19. Did you attend a STOP AIDS meeting in San Francisco between 1985 and 1987?

☐	☐
--------------------------	--------------------------

20. Have you served as a volunteer for any of the following groups in the last 6 months?

HIV-Related Activities

	NO	YES
a. ACT-UP	☐	☐
b. AIDS Health Project	☐	☐
c. AIDS Legal Referral Panel	☐	☐
d. 18th Street Services	☐	☐
e. Coming Home Hospice	☐	☐
f. GAPA Community Health Project	☐	☐
g. Most Holy Redeemer	☐	☐
h. BAHSES/ BWMT/ MACT	☐	☐
i. Open Hand	☐	☐
j. Project Inform	☐	☐
k. Shanti Project	☐	☐
l. S.F. AIDS Foundation	☐	☐
m. STOP AIDS Project	☐	☐
n. Visiting Nurses and Hospice of S.F.	☐	☐
o. Other HIV-related volunteer activity: (SPECIFY)	☐	☐

Gay/Lesbian Activities

	NO	YES
p. Athletic Clubs (Running, baseball, swimming...)	☐	☐
q. Court System	☐	☐
r. Cultural clubs (Frameline etc.)	☐	☐
s. Gay/Lesbian Environmental groups	☐	☐
t. Motorcycle clubs	☐	☐
u. Parade	☐	☐
v. Political Party affiliated clubs	☐	☐
w. Other Gay/Lesbian affiliated political organizations	☐	☐
x. Queer Nation	☐	☐
y. Religious groups	☐	☐
z. Gay/Lesbian affiliated Service organizations	☐	☐
aa. University/College affiliated organizations	☐	☐
bb. Other Gay/Lesbian activities: (SPECIFY)	☐	☐

21. Your zipcode: _____

22. Date of birth: _____ / _____
month year

23. How would you describe yourself: Please check only one box.

- a. American Indian or Alaskan native
- b. Asian, Asian-American, or Pacific Islander
- c. Black, African-American (but not Hispanic/Latino)
- d. Hispanic, Latino, Puerto Rican or Mexican-American
- e. White, not of Hispanic/Latino origin
- f. Other (Please specify: _____)

☐
☐
☐
☐
☐
☐

24. What is the highest level of education you have COMPLETED?
Check only one box.

- a. Did not complete high school
- b. High school graduate (or GED)
- c. Technical school
- d. Some college
- e. College graduate (Bachelor's degree)
- f. Some graduate or professional school
- g. Graduate/professional degree

☐
☐
☐
☐
☐
☐
☐

25. How many years have you lived in San Francisco since 1980?

Number of Years

26. Do you have a job (or jobs) for which you get paid?

No

☐

Yes

☐

27. Check the amount that comes closest to your total income before taxes from all sources for 1990.

Less than \$10,000

☐

\$10,000 - \$19,999

☐

\$20,000 - \$29,999

☐

\$30,000 - \$39,999

☐

\$40,000 - \$49,999

☐

\$50,000 - \$59,999

☐

\$60,000 - \$69,999

☐

\$70,000 - \$79,999

☐

\$80,000 - \$89,999

☐

\$90,000 - \$99,999

☐

\$100,000 or more

☐

THANK YOU FOR YOUR HELP!!!

Please place this questionnaire in its envelope and either:

- a. Bring it to your STOP AIDS meeting
- b. Mail it back to us in the envelope provided

1. Have you had sex with anyone in the past 6 months?

No ☐ → [If No, please skip to QUESTION 7, PAGE 5]
 Yes ☐ → [If YES, continue on with the Next Questions]

By lover or "primary" partner, we mean a person to whom you feel committed more than anyone else AND with whom you have had sex. This does not necessarily mean that you are monogamous.

2a. How many different men in total did you have sex with, including your lover or primary partner, if you have one?

Write number of different men in the box:
 If none, write in zero (0).

Number of men
 in past 30 days

Number of men
 in past 6 months

2b. How many different women in total did you have sex with, including your primary partner, if you have one?

Write number of different women in the box:
 If none, write in zero (0).

Number of women
 in past 30 days

Number of women
 in past 6 months

3. During the PAST 30 DAYS, how many TIMES did you have sex:

[IF NOT AT ALL OR NON-APPLICABLE, check "Zero (0) Times."]

	Number of times	Zero (0) Times
a. With your lover or primary partner, if you have one?		
b. With a man other than your primary partner?		
c. With a woman?		
d. With more than one other or others (group sex, 3-ways)?		
e. With others at a J/O club or bathhouse?		

4. Are you currently in a primary relationship with a man?

(By "primary", we mean a relationship with a man where you feel committed to him more than anyone else AND where you have had sex together. This does not necessarily mean that you are monogamous.)

No ☐ [If No, please skip to QUESTION 6, PAGE 4]
Yes ☐

→ If YES, answer the following:

4a. How long ago did you meet this man?

Number of years

Number of months

4b. How long ago did you first have sex with this man?

Number of years

Number of months

4c. Which of the following best describes sex in your relationship?
[Check only one box]

a. Neither of us has sex with other people.

b. Only he has sex with other people.

c. Only I have sex with other people.

d. We both have sex with other people.

☐
☐
☐
☐

5. In the PAST 30 DAYS, how often did you do each of the sexual activities listed below with your LOVER OR PRIMARY PARTNER?

[Please write the number of times in each box. Write zero (0) if not at all.]

WITH YOUR LOVER OR PRIMARY PARTNER:

Oral Sex Without Condoms (Rubbers):

- a. Oral sex where you suck his cock; he doesn't cum in your mouth.
- b. Oral sex where you suck his cock; he cums in your mouth.
- c. Oral sex where he sucks your cock; you do not cum in his mouth.
- d. Oral sex where he sucks your cock; you cum in his mouth

Oral Sex With Condoms (Rubbers):

- e. Oral sex where you suck his cock; he wears a condom.
- f. Oral sex where he sucks your cock; you wear a condom.

Anal Intercourse Without Condoms (Rubbers):

- g. You fuck your partner; you cum up his ass.
- h. Your partner fucks you; he cums up your ass.
- i. Your partner withdraws before he cums during anal intercourse.
- j. You withdraw before you cum during anal intercourse.

Anal Intercourse With Condoms (Rubbers):

- k. You fuck your partner while you wear a condom.
- l. Your partner fucks you while he wears a condom

Rimming (oral/anal sex) Without Latex

- m. You rim your partner
- n. Your partner rims you

If your partner was your only sexual partner in the past 30 days,
SKIP TO QUESTION 7, PAGE 5

Please complete this page if you:

- (a) are single and had sex with another man in the past 30 days, OR
(b) are in a relationship but had sex in the past 30 days with someone who isn't your primary partner

ALL OTHERS SKIP TO QUESTION 7, PAGE 5

6. In the PAST 30 DAYS, how often did you do each of the sexual activities listed below with a man (or men) who were NOT your lover or primary partner?

[Please write the number of times in each box. Write zero (0) if not at all.]

OUTSIDE A PRIMARY RELATIONSHIP:

Oral Sex Without Condoms (Rubbers):

- a. Oral sex where you suck his cock; he doesn't cum in your mouth.
b. Oral sex where you suck his cock; he cums in your mouth.
c. Oral sex where he sucks your cock; you do not cum in his mouth.
d. Oral sex where he sucks your cock; you cum in his mouth

Oral Sex With Condoms (Rubbers):

- e. Oral sex where you suck his cock; he wears a condom.
f. Oral sex where he sucks your cock; you wear a condom.

Anal Intercourse Without Condoms (Rubbers):

- g. You fuck your partner; you cum up his ass.
h. Your partner fucks you; he cums up your ass.
i. Your partner withdraws before he cums during anal intercourse.
j. You withdraw before you cum during anal intercourse.

Anal Intercourse With Condoms (Rubbers):

- k. You fuck your partner while you wear a condom.
l. Your partner fucks you while he wears a condom

Rimming (oral/anal sex) without Latex

- m. You rim your partner
n. Your partner rims you

7. In the **PAST SIX MONTHS**, have you had anal intercourse where neither you nor your sexual partner used a condom? (This includes **all** anal intercourse with and without orgasm.)

No ☐ → [If No, please **SKIP TO QUESTION 10, PAGE 7**]

Yes ☐

→ 7a. Had you previously made a decision or a commitment that you would only have anal intercourse with a condom?

Yes ☐ No ☐

7b. Approximately how many times did you have unprotected anal intercourse during the past six months?

1-5 ☐ 6-10 ☐ 11-15 ☐ 16-20 ☐ 21+ ☐

8. In the **PAST SIX MONTHS**, how important were the following reasons for having anal sex without a condom?

	Not at all Important	Not very Important	Important	Very Important
a. You were afraid to bring up the topic of condoms?	☐	☐	☐	☐
b. You knew you were positive, so why bother?	☐	☐	☐	☐
c. You wanted to bond with your partner?	☐	☐	☐	☐
d. Your sex partner told you he was HIV antibody negative?	☐	☐	☐	☐
e. You thought that once without a condom would be OK?	☐	☐	☐	☐
f. There weren't any condoms around at the time?	☐	☐	☐	☐
g. You were really sexually turned on and didn't stop to put on a condom?	☐	☐	☐	☐
h. You wanted both of you to have the same HIV status?	☐	☐	☐	☐
i. Using a condom caused the loss of a hard-on?	☐	☐	☐	☐
j. You knew you and your partner had the same HIV status?	☐	☐	☐	☐
k. It felt better to have sex without a condom?	☐	☐	☐	☐
l. You agreed not to cum in each other?	☐	☐	☐	☐
m. You figured that you were bound to get infected anyway?	☐	☐	☐	☐
n. You were in love?	☐	☐	☐	☐
o. You had been drinking or using other drugs?	☐	☐	☐	☐
p. You were tired of having safe sex?	☐	☐	☐	☐
q. The two of you had always fucked without a condom so you thought that there was no reason to start using one now.	☐	☐	☐	☐

9. The next set of questions are about how you felt the last time you had unprotected anal sex.

AFTER the LAST TIME you had unprotected anal intercourse did you:

	Not True	Somewhat True	Mostly True	Definitely True
a. not think much about it at all?	☐	☐	☐	☐
b. talk to that sex partner about it later?	☐	☐	☐	☐
c. feel you had a good reason for having unsafe sex?	☐	☐	☐	☐
d. feel guilty?	☐	☐	☐	☐
e. blame yourself?	☐	☐	☐	☐
f. talk to a friend about it?	☐	☐	☐	☐
g. promise yourself that you would never had unsafe sex again?	☐	☐	☐	☐
h. worry about whether you or your partner had been infected with HIV?	☐	☐	☐	☐
i. lose sleep over it?	☐	☐	☐	☐
j. feel scared?	☐	☐	☐	☐
k. feel discouraged about always trying to have have safe sex since you end up having unsafe sex anyway?	☐	☐	☐	☐
l. feel sure that you would never have unsafe sex again?	☐	☐	☐	☐
m. feel closer to your partner?	☐	☐	☐	☐
n. question your ability to always stay safe sexually?	☐	☐	☐	☐
o. feel worthless?	☐	☐	☐	☐
p. worry, but not talk to anyone about it?	☐	☐	☐	☐
q. decide not to think about it?	☐	☐	☐	☐

r. Did you have any other reaction? Please pause for a minute to remember. Then write it down:

CONTINUE ON WITH THE NEXT QUESTIONS

10. Have you ever been tested for antibodies to the AIDS virus (the AIDS antibody blood test)?

No ☐ → [If No, SKIP to Question 13, Page 8]
Yes ☐ → [Please continue]

10b. When was the most recent time you were tested?

Date of last test:

____/____/____
month/year

11. What was the result of your most recent test? [Please check ONE box]

Negative ☐ → [Go on to QUESTION 12]
Positive ☐ →
Don't know ☐ → [Skip to QUESTION 13, PAGE 8]

12. We are interested in knowing who gay men talk to about their antibody status. Please indicate whether you've told any of the following people about your antibody test result, whether it is positive or negative.

PLEASE CIRCLE YOUR ANSWER

Have you told your:

closest friends?

YES NO NOT APPLICABLE

any of your other friends?

YES NO NOT APPLICABLE

lover?

YES NO NOT APPLICABLE

any of your other sex partners?

YES NO NOT APPLICABLE

a psychologist or counselor?

YES NO NOT APPLICABLE

ALL MEN WHO KNOW THEIR HIV STATUS,
SKIP TO QUESTION 14, PAGE 9

13. We are interested in the reasons people have for not finding out their HIV (AIDS) antibody status. Below are reasons people have given for not getting tested or not finding out their test results. Please rate how much each of the following has influenced your decision to not finding out your HIV status.

[Please circle only one number per item.]

	<u>Not at all</u>	<u>A little</u>	<u>Some</u>	<u>Very much</u>
Knowing the results of the test is too stressful.	1	2	3	4
I am already doing all that I can to stay healthy; I don't need to know my antibody status.	1	2	3	4
I never had as much risky sex as men who test positive for HIV, so I'm sure I'm negative.	1	2	3	4
I am afraid the test results might be used against me (for example, to deny me health insurance).	1	2	3	4
I am already sure that I am antibody positive, so I don't need to get tested.	1	2	3	4
I am afraid how the test results would affect my personal relationships.	1	2	3	4
Other blood tests I have had indicate I am healthy.	1	2	3	4
My friends don't think I should get tested.	1	2	3	4
I don't think that knowing your test results does you much good medically.	1	2	3	4
I'd like to get tested, but I just can't force myself to go through with it.	1	2	3	4

Have you felt any other reasons? If so, please describe and rate these reasons:

_____	1	2	3	4
_____	1	2	3	4

EVERYONE ANSWER QUESTION 14

14. How much do the following statements describe you?
Circle the number which BEST fits your response to each item:

	Does Not Describe Me Very Well			Describes Me Very Well
a. When I talk to my friends about my sexual experiences, I tell them whether or not it was safe	1	2	3	4
b. I tell all my sexual partners my HIV status before I have sex with them	1	2	3	4
c. I tell my HIV status to partners with whom I'm thinking of having a relationship, but not casual sex partners.	1	2	3	4
d. I only have sex with people of my own HIV status.	1	2	3	4
e. I feel very much a part of the gay community.	1	2	3	4
f. I don't pay much attention to HIV-status when deciding to have sex with someone.	1	2	3	4
g. Knowing someone's HIV status is one of the factors that determines whether or not I'll have a relationship with someone.	1	2	3	4
h. I have made a commitment to myself to only have safe sex.	1	2	3	4
i. I have made a commitment to other people to only have safe sex.	1	2	3	4

15. FILL IN THE REST OF THIS SENTENCE: When someone tells me he had unsafe sex, my reaction is:

and I tell him: _____

IF YOU ARE HIV ANTIBODY POSITIVE OR ASSUME YOU ARE HIV ANTIBODY POSITIVE, PLEASE COMPLETE THIS SECTION

IF YOU ARE HIV ANTIBODY NEGATIVE, SKIP TO QUESTION 17, PAGE 11

16. Which of the following strategies are you pursuing for your HIV infection?

Check all that apply:

YES

NO

I am taking care of myself.

☐☐

I am monitoring my immune system with blood tests.

☐☐

I am getting drugs or other treatments through the medical system.

☐☐

I am following an alternative treatment strategy (i.e. acupuncture, herbs).

☐☐

I am following a metaphysical strategy (i.e. meditation, spiritual healing).

☐☐

Other:

I'm doing nothing

☐☐

EVERYBODY CONTINUE ANSWERING THE FOLLOWING QUESTIONS
--

17. How much do you agree or disagree with each of the following statements?

Circle the number which BEST fits your response to each item:

	Strongly Disagree	Disagree	Agree	Strongly Agree
a. Most gay men have unprotected anal sex.	1	2	3	4
b. Some of my sexual partners want to have unsafe sex when they're with me.	1	2	3	4
c. My current behavior could put me at risk of infection or reinfection.	1	2	3	4
d. When gay men slip and have unsafe sex, they talk to a friend about it.	1	2	3	4
e. I am capable of having sex that will not infect or reinfect my sexual partner with AIDS.	1	2	3	4
f. During really hot sex, I am not able to stop doing risky things.	1	2	3	4
g. Most gay men who slip and have unsafe sex are too embarrassed to talk to anyone about it.	1	2	3	4
h. All of my friends use condoms.	1	2	3	4
i. My friends encourage me to practice safe sex.	1	2	3	4
j. My friends tell me when they slipped and had unsafe sex.	1	2	3	4
k. My friends think that it is important to use a condom when having sex.	1	2	3	4
l. Most gay men think that it is impossible to always have safe sex until there is a cure for AIDS.	1	2	3	4
m. I feel confident that I will never slip from safe sex in the future.	1	2	3	4

[QUESTION 17, CONTINUED]

	Strongly Disagree	Disagree	Agree	Strongly Agree
n. Most gay men are now using condoms when they have anal sex.	1	2	3	4
o. People who <u>always</u> use condoms during anal sex will probably not transmit the AIDS virus.	1	2	3	4
p. If I were to slip and have unsafe sex, I would talk to my friends about it.	1	2	3	4
q. AIDS can be transmitted to the "top" (the insertive sexual partner) during unprotected anal sex.	1	2	3	4
r. I am likely to have unsafe sex in the next six months.	1	2	3	4
s. I believe that most of my gay friends support practicing safe sex.	1	2	3	4
t. If I'm going to have anal sex, I'm going to use a rubber.	1	2	3	4
u. I feel confident in my ability to talk about safe sex and slipping with a partner.	1	2	3	4
v. Sometimes I get so frustrated that I have sex in ways that I know are unsafe.	1	2	3	4
w. I have unsafe sex to relieve tensions.	1	2	3	4
x. It's embarrassing to buy condoms in a store.	1	2	3	4
y. Talking about the possibility of slipping to unsafe sex helps me to stay safe.	1	2	3	4
z. If I insist on using a condom for anal sex, a sex partner will think less of me.	1	2	3	4
aa. Sooner or later I will become infected with HIV.	1	2	3	4

18. Have you ever attended any of the following activities as a participant (not as a volunteer) to address HIV or HIV-related issues?

	NO	YES	IF YES, # of meetings in the last 6 months?
a. STOP AIDS meetings	☐	☐	_____
b. The Buddy Connection	☐	☐	_____
c. Positives Being Positive	☐	☐	_____
d. Other HIV positive support group Specify: _____	☐	☐	_____
e. HIV negative support group Specify: _____	☐	☐	_____
f. Caregivers support group	☐	☐	_____
g. Gay/Lesbian support group	☐	☐	_____
h. Substance abuse group	☐	☐	_____
i. People of color support group	☐	☐	_____
j. Other Specify: _____	☐	☐	_____

19. Did you attend a STOP AIDS meeting in San Francisco between 1985 and 1987?

☐	☐
--------------------------	--------------------------

20. Have you served as a volunteer for any of the following groups in the last 6 months?

HIV-Related Activities

	NO	YES
a. ACT-UP	☐	☐
b. AIDS Health Project	☐	☐
c. AIDS Legal Referral Panel	☐	☐
d. 18th Street Services	☐	☐
e. Coming Home Hospice	☐	☐
f. GAPA Community Health Project	☐	☐
g. Most Holy Redeemer	☐	☐
h. BAHSES/ BWMT/ MACT	☐	☐
i. Open Hand	☐	☐
j. Project Inform	☐	☐
k. Shanti Project	☐	☐
l. S.F. AIDS Foundation	☐	☐
m. STOP AIDS Project	☐	☐
n. Visiting Nurses and Hospice of S.F.	☐	☐
o. Other HIV-related volunteer activity: (SPECIFY)	☐	☐

Gay/Lesbian Activities

	NO	YES
p. Athletic Clubs (Running, baseball, swimming...)	☐	☐
q. Court System	☐	☐
r. Cultural clubs (Frameline etc.)	☐	☐
s. Gay/Lesbian Environmental groups	☐	☐
t. Motorcycle clubs	☐	☐
u. Parade	☐	☐
v. Political Party affiliated clubs	☐	☐
w. Other Gay/Lesbian affiliated political organizations	☐	☐
x. Queer Nation	☐	☐
y. Religious groups	☐	☐
z. Gay/Lesbian affiliated Service organizations	☐	☐
aa. University/College affiliated organizations	☐	☐
bb. Other Gay/Lesbian activities: (SPECIFY)	☐	☐

21. Your zipcode: _____

22. Date of birth: _____ / _____
month year

23. How would you describe yourself: Please check only one box.

- a. American Indian or Alaskan native
- b. Asian, Asian-American, or Pacific Islander
- c. Black, African-American (but not Hispanic/Latino)
- d. Hispanic, Latino, Puerto Rican or Mexican-American
- e. White, not of Hispanic/Latino origin
- f. Other (Please specify: _____)

☐
☐
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☐
☐
☐

24. What is the highest level of education you have COMPLETED?
Check only one box.

- a. Did not complete high school
- b. High school graduate (or GED)
- c. Technical school
- d. Some college
- e. College graduate (Bachelor's degree)
- f. Some graduate or professional school
- g. Graduate/professional degree

☐
☐
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☐
☐
☐
☐

25. How many years have you lived in San Francisco since 1980?

Number of Years

26. Do you have a job (or jobs) for which you get paid?

No

☐

Yes

☐

27. Check the amount that comes closest to your total income before taxes from all sources for 1990.

Less than \$10,000

☐

\$10,000 - \$19,999

☐

\$20,000 - \$29,999

☐

\$30,000 - \$39,999

☐

\$40,000 - \$49,999

☐

\$50,000 - \$59,999

☐

\$60,000 - \$69,999

☐

\$70,000 - \$79,999

☐

\$80,000 - \$89,999

☐

\$90,000 - \$99,999

☐

\$100,000 or more

☐

THANK YOU FOR YOUR HELP!!!

Please place this questionnaire in its envelope and either:

- a. Bring it to your STOP AIDS meeting
- b. Mail it back to us in the envelope provided

Phone Questionnaire
*Evaluation of clients who "dropped out" of the
Safer Sex Counseling Project*

Date: ____/____/____

Subject's code number: _____

Interviewer: _____

Note to Interviewer: Begin by reading the following instructions:

Hello. My name is _____. I am calling from the AIDS Health Project's Safer Sex Counseling Project. You recently met with a counselor from the Safer Sex Counseling Project. I'd like to spend a few minutes talking with you now, as part of an evaluation study to follow-up with people who received counseling through the Project. Do you have a few minutes to talk?

I'd like to ask you a series of questions. If there's something you don't understand, don't hesitate to ask. All information you give will be entirely confidential.

1. How many times did you meet with a counselor from the Safer Sex Counseling Project?

2. How long ago was the last time you met with the counselor?

3. How would you rate your level of satisfaction with the help you received from the program, on a 1-7 scale, where 1 = very dissatisfied, and 7 = very satisfied?

1	2	3	4	5	6	7
Very Dissatisfied						Very Satisfied

4. We want to know why you decided to stop meeting with your counselor. I'm going to read a series of statements. After I read each one, say "yes" if the statement is true for you, and "no" if it is not true.

Y N One reason I stopped was because I felt I had gotten the help I was looking for.

Y N One reason I stopped was because I did not feel the meetings with the counselor adequately addressed my issues.

- Y N One reason was because I was dissatisfied with the counselor.
- Y N One reason was because I had problems attending meetings due to my schedule or other responsibilities.
- Y N One reason was because the location of the meetings was inconvenient for me.
- Y N One reason was because the length of each meeting was more than I wanted or felt comfortable with.
- Y N One reason was because I no longer felt concerned about the risk of my having unsafe sex.
- Y N One reason was because, although I still feel concerned about the risk of my having unsafe sex, I no longer felt the motivation to take the time to work on those issues.

4. Are there any other reasons why you decided to stop meeting with your counselor, other than the reasons I just listed?

5. On a 1-7 scale, how would you rate your level of commitment to avoiding unsafe sex 100% of the time during the next six months, where "1" means you don't feel very committed to that at all, and "7" means that you feel extremely committed?

Response: _____

6. On a 1-7 scale, how would you rate your level of confidence in your ability to avoid unsafe sex 100% of the time during the next six months, where "1" means you don't feel very confident about that at all, and "7" means that you feel extremely confident?

Response: _____

Phone Questionnaire
*Evaluation of clients who completed the
Safer Sex Counseling Project
(Time Three Questionnaire)*

Date: ____ / ____ / ____

Subject's code number: _____

Interviewer: _____

Note to Interviewer: Begin by reading the following instructions:

Hello. My name is _____. I am calling from the AIDS Health Project's Safer Sex Counseling Project. You recently completed a number of sessions with a counselor from the Safer Sex Counseling Project. I'd like to spend a few minutes talking with you now, as part of an evaluation study to follow-up with people who received counseling through the Project. Do you have a few minutes to talk?

I'd like to ask you a series of questions. If there's something you don't understand, don't hesitate to ask. All information you give will be entirely confidential.

1. How many times did you meet with a counselor from the Safer Sex Counseling Project?

2. How long ago was the last time you met with the counselor?

3. How would you rate your level of satisfaction with the help you received from the program, on a 1-7 scale, where 1 = very dissatisfied, and 7 = very satisfied?

1	2	3	4	5	6	7
Very Dissatisfied						Very Satisfied

4. On a 1-7 scale, how would you rate your level of commitment to avoiding unsafe sex 100% of the time during the next six months, where "1" means you don't feel very committed to that at all, and "7" means that you feel extremely committed?

Response: _____

5. On a 1-7 scale, how would you rate your level of confidence in your ability to avoid unsafe sex 100% of the time during the next six months, where "1" means you don't feel very confident about that at all, and "7" means that you feel extremely confident?

Response: _____

6. On a 1-7 scale, how would you rate your level of understanding about factors that are associated with your engaging in unsafe sex, where "1" means you are very clear about those factors, and "7" means that you are not very clear?

Response: _____

RECEIVED
OCT 9 1992

DS-
pls file -
cc: David

October 6, 1992

James W. Dilley, M.D.
Department of Psychiatry
Box 0884

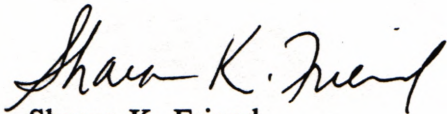
Re: Evaluation of the Safer Sex Counseling Project
(CHR Approval #H2405-08405)

Dear Dr. Dilley:

The revised consent form for the above protocol was recently received in our office. Because the change requested in our letter of September 3, 1992 has been made and approved, the condition has now been removed from your approval. Your approval number remains H2405-08405 and the expiration date September 1, 1993.

A copy of the revised consent form has been stamped and is being returned to you with this letter. This is the officially approved version of the consent form. Please destroy all previous versions of the form in order to avoid their inadvertent use.

Sincerely,



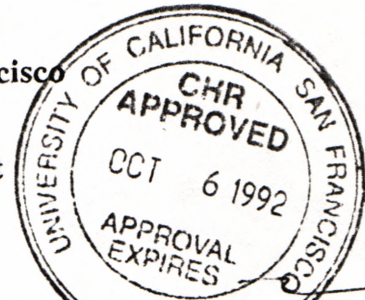
Sharon K. Friend
Principal Analyst
Committee on Human Research

fog

Enc.

University of California at San Francisco
San Francisco General Hospital

Consent to be a Research Subject



A. Purpose

Dr. James Dilley, Dr. David Silven and their colleagues at the UCSF AIDS Health Project are conducting a study of the utilization and effectiveness of the Safer Sex Counseling Project.

Specifically, they are interested in reporting on the kinds of individuals who utilize this program and assessing the kinds of problems identified by those using the program. The researchers are interested in learning more about this population of individuals and their specific needs so that they may improve the overall effectiveness of the program.

B. Procedures

1. Prior to being accepted into the study, an SSPC staff counselor will explain the general purposes of the study and answer any questions I may have.
2. If I agree to participate in this study, I will be asked to complete three questionnaires. The first will be completed before I begin my first counseling session. At this time, I will be asked to do the following:

Complete a questionnaire dealing with general personal information which will include questions about my sexual orientation, sexual practices, my attitudes toward safer sex, and about potentially illegal drug or alcohol use. The questionnaire should take approximately 10 minutes.

3. I will be asked to complete a similar questionnaire at the completion of my counseling sessions with the Safer Sex Counseling Project.
4. If I should decide to not complete my counseling sessions with the Project, I will be phoned by Project staff and asked to complete a brief questionnaire inquiring as to the reasons I have decided to stop. This telephone interview will take approximately 5 minutes.
5. If I complete my counseling sessions, I will be telephoned by Project staff two months after my final session to complete a final interview. This interview will ask questions about my experience of the counseling sessions and ask about my current attitude towards safer sex. This interview will last approximately 5 minutes.

C. Risks

There may be some risks associated with participation in this study.

1. The time involved in completing questionnaires may pose some inconvenience for me.
2. I may experience some anxiety in answering some of the questions.

D. Benefits

While there is no direct benefit to me personally at this time, I may benefit by being asked to consider some of the information being asked on the questionnaire. People infected by HIV and concerned about adopting safer sex practices may benefit in the future from knowledge gained from the study.

E. Financial Considerations

Subjects will be neither paid nor charged for study participation.

F. Confidentiality

While a risk of loss of confidentiality exists, my records will be kept as confidential as possible under the law. Only project staff will have access to records. The data from the study, including data which is collected from and about me, may be shared with other researchers or institutions, but no names will be given out.

G. Alternatives

I may choose not to participate in this study. This would have no effect on my ability to participate in this program now or at any time in the future.

H. Questions

1. I have talked with _____ about this study and she/he has answered my questions. If I have any additional questions, I may call Dr. David Silven at (415) 476-6441.
2. If I experience any worry or distress as a result of participating in the study, I may call Dr. Silven at the above number and schedule a consultation.

I. Consent

Participation in this study is entirely voluntary. Refusal to participate will involve no penalty or loss of benefits to which I might otherwise be entitled. I may withdraw from the study at any time. This will in no way prejudice any future care I may require. This study may be terminated at any time by the investigators at any time they determine it is in my best interest.

I have read and had explained to me all details of my participation in this study.

I have been offered a copy of this consent form and the Experimental Subject's Bill of Rights to keep.

If I wish to participate, I should sign this form.

Subject's Signature

Date

Subject's Name (Printed)

Investigator's Signature

Date

Investigator's Name (Printed)

**University of California at San Francisco
San Francisco General Hospital**

Consent to be a Research Subject

A. Purpose

Dr. James Dilley, Dr. David Silven and their colleagues at the UCSF AIDS Health Project are conducting a study of the utilization and effectiveness of the Safer Sex Counseling Project.

Specifically, they are interested in reporting on the kinds of individuals who utilize this program and assessing the kinds of problems identified by those using the program. The researchers are interested in learning more about this population of individuals and their specific needs so that they may improve the overall effectiveness of the program.

B. Procedures

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F. Confidentiality

While a risk of loss of confidentiality exists, my records will be kept as confidential as possible under the law. Only project staff will have access to records. The data from the study, including data which is collected from and about me, may be shared with other researchers or institutions, but no names will be given out.

G. Alternatives

I may choose not to participate in this study. This would have no effect on my ability to participate in this program now or at any time in the future.

H. Questions

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2. If I experience any worry or distress as a result of participating in the study, I may call Dr. Silven at the above number and schedule a consultation.

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Participation in this study is entirely voluntary. Refusal to participate will involve no penalty or loss of benefits to which I might otherwise be entitled. I may withdraw from the study at any time. This will in no way prejudice any future care I may require. This study may be terminated at any time by the investigators at any time they determine it is in my best interest.

I have read and had explained to me all details of my participation in this study.

I have been offered a copy of this consent form and the Experimental Subject's Bill of Rights to keep.

If I wish to participate, I should sign this form.

Subject's Signature

Date

Subject's Name (Printed)

Investigator's Signature

Date

Investigator's Name (Printed)

Deleted 9/28/92 per CHR request from Section E. Financial Security:

If I am injured or experience distress as a result of participation in the study, treatment will be available. The costs of such treatment may be covered by the University of California depending upon a number of factors. The University does not normally provide any other form of compensation for injury. For further information I may contact the Committee on Human Research at (415) 476-1814.

COMMITTEE ON HUMAN RESEARCH
FULL COMMITTEE FORMAT
COVER PAGE

PRINCIPAL INVESTIGATOR

(UCSF Faculty)

MAILING ADDRESS

(Campus)

UNIVERSITY

TITLE

PHONE

NUMBER

DEPT.

IS P.I. SPONSOR/

ADVISOR ONLY?

CO-P.I.

TITLE

ONE

NUMBER

DEPT.

SUBMISSION

DATE

MAILING ADDRESS.

PROJECT

TITLE

Title:
Evaluation of the
Safer Sex Counseling
Project

NAMES/TITLES OF
INVESTIGATORS:

Dr David Silver, PhD

Psychologist II

Re Ronald Stall, PhD

Research Psychologist

Dr Donald Chambers, PhD

Statistical

PROCEDURES (List all procedure
purposes of the study):

ISOTOPES:

radioactive materi

In vivo

materials?

Completion of
self-report
questionnaires

TO

Does this submission differ from the
previous submission(s)? ☐ Yes ☐ No

Explain any differences within protocol.

Approval of the Radiation Safety Committee
is required prior to final CHR approval.

Number of RSC approval:

Date of RSC approval:

SUBJECTS (Explain in detail in protocol):

Subjects:

Number 25-35

Source(s)

Reimbursement

Controls/Normals:

Number

Source(s)

Reimbursement

UCSF
AIDS Health Project

- NONE

- NONE

DRUGS & DEVICES:

List all new drugs and/or devices and all
approved ones being investigated for a new use.
Each must have an exemption number from
the FDA (unless a non-significant IDE is being
sought from the IRB). If applicable, list
exemption number.

Will any minors (under 18) be
involved? ☐ Yes ☐ No

NAME

IND/IDE #

SITE (Check and discuss within protocol):

☐ Parnassus ☐ VAMC ☐ SFGH

☐ Other UCSF site

Other

NO minors
site

COSTS: Will there be any charges to
subjects or their third party
carriers due to participation in the
study? ☐ Yes ☐ No

Specify which costs:

NO costs

FUNDING:

Will this study be funded? ☐ Yes ☐ No

Federally? ☐ Other? ☒ Pending

Agency/Sponsor Name

AIDS Clinical Research Center

PRINCIPAL INVESTIGATOR'S SIGNATURE

COMMITTEE ON HUMAN RESEARCH
FULL COMMITTEE FORMAT
COVER PAGE

PRINCIPAL INVESTIGATOR

(UCSF Faculty)

MAILING ADDRESS

(Campus)

UNIVERSITY

TITLE

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IS P.I. SPONSOR/

ADVISOR ONLY?

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TITLE

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NUMBER

DEPT.

SUBMISSION

DATE

MAILING ADDRESS

PROJECT

TITLE

Title:
Evaluation of the
Safer Sex Counseling
Project

NAMES/TITLES OF
INVESTIGATORS:

David Silver, PhD

Psychologist II

Ronald Stall, PhD

Research Psychologist

Donald Chambers, PhD

Senior Statistician

ECT:

#

ation Date 1/1

PROCEDURES (List all procedure
purposes of the study):

Completion of
self-report
questionnaire

RADIOISOTOPES:

Will any radioactive materials

_____ In vivo

What materials? _____

Does this submission differ from the
previous submission(s)? Yes No

Explain any differences within protocol.

SUBJECTS (Explain in detail in protocol):

Subjects:

Number 25-35

Source(s)

Reimbursement

UCSF
AIDS Health Project

— NONE

Controls/Normals:

Number

Source(s)

Reimbursement

— NONE

Will any minors (under 18) be
involved? Yes No

NO minors

SITE (Check and discuss within protocol):

___ Parnassus ___ VAMC ___ SFGH

___ Other UCSF site

Other

✓ other UCSF
site

COSTS: Will there be any charges to
subjects or their third party
carriers due to participation in the
study? Yes No

Specify which costs:

NO costs

Approval of the Radiation Safety Committee
is required prior to final CHR approval.

Number of RSC approval: _____

Date of RSC approval: _____

DRUGS & DEVICES:

List all new drugs and/or devices and all
approved ones being investigated for a new use.
Each must have an exemption number from
the FDA (unless a non-significant IDE is being
sought from the IRB). If applicable, list
exemption number.

NAME

IND/IDE #

FUNDING:

Will this study be funded? Yes No

Federally? Other? Pending

Agency/Sponsor Name

AIDS Clinical Research Center

PRINCIPAL INVESTIGATOR'S SIGNATURE

COMMITTEE ON HUMAN RESEARCH
FULL COMMITTEE FORMAT
COVER PAGE

PRINCIPAL INVESTIGATOR

(UCSF Faculty)

MAILING ADDRESS

(Campus)

UNIVERSITY

TITLE

PHONE

NUMBER

DEPT.

IS P.I. SPONSOR/
ADVISOR ONLY?

CO-P.I.

TITLE

ONE

NUMBER

DEPT.

SUBMISSION

DATE

MAILING ADDRESS

PROJECT

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Title:
Evaluation of the
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Project

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INVESTIGATORS:

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Psychologist II

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Research Psychologist

Donald Chambers, PhD

Senior Statistician

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#

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purposes of the study):

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self-report
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What materials? _____

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SUBJECTS (Explain in detail in protocol):

Subjects:

Number 25-35

Source(s)

Reimbursement

UCSF
AIDS Health Project

— NONE

Controls/Normals:

Number

Source(s)

Reimbursement

— NONE

Will any minors (under 18) be
involved? Yes No

NO minors

SITE (Check and discuss within protocol):

___ Parnassus ___ VAMC ___ SFGH

___ Other UCSF site

Other

✓ other UCSF
site

COSTS: Will there be any charges to
subjects or their third party
carriers due to participation in the
study? Yes No

NO costs

Specify which costs:

Maximum amount (approximate):

Approval of the Radiation Safety Committee
is required prior to final CHR approval.

Number of RSC approval: _____

Date of RSC approval: _____

DRUGS & DEVICES:

List all new drugs and/or devices and all
approved ones being investigated for a new use.
Each must have an exemption number from
the FDA (unless a non-significant IDE is being
sought from the IRB). If applicable, list
exemption number.

NAME

IND/IDE #

FUNDING:

Will this study be funded? Yes No

Federally? Other? ☒ Pending

Agency/Sponsor Name

AIDS Clinical Research Center

PRINCIPAL INVESTIGATOR'S SIGNATURE

III. SPECIFIC OBJECTIVES (List)

IV. PROJECT SIGNIFICANCE (Brief statement of background data, justification, and anticipated result relative to prevention, morbidity, and mortality)

- o Overview of design, (1-2 sentences summarizing the classification [randomized controlled trial, time series, etc.], the subjects, the key variables)

- o Study subjects (specify who will be studied and to whom the findings will be generalized)
 - inclusion and exclusion criteria that define the accessible population
 - design for sampling from the accessible population (consecutive, convenience, etc.)

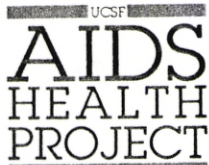
- o Variables (specify approaches to standardizing, blinding, validating, etc.)
 - intervention (include technical approach to randomization, if appropriate)
 - other predictor and confounding variables
 - outcome variables

- o Results to date/Pretest strategies

- o Statistical issues
 - statistical hypotheses to be tested
 - plans for analysis
 - sample size estimates

- o Quality control and data management plans (specify systems for assuring completeness and accuracy of the data)

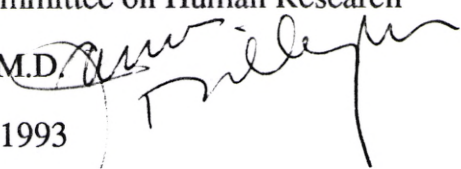
- o Timetable and organization chart (indicate areas of responsibility and lines of authority)
- o Ethical considerations (be brief)
- o Resources, equipment and physical facilities
- o Consultants and arrangements between institutions (if relevant)



A project concerned
with AIDS Prevention
and Health Promotion

MEMO

To: Reese T. Jones, M.D.
Chairman, Committee on Human Research

From: James Dilley, M.D. 

Date: September 6, 1993

Re: Cancellation of CHR Assigned Number: H2405-08405-1

The above referenced CHR assigned approval number entitled "Evaluation of the Safer Sex Counseling Project" should be retired on the expiration date of September 1st. It was never funded, therefore, no final report is necessary.

Thank you for your assistance in this matter.

RENEWAL OF FULL COMMITTEE APPLICATION

DATE: July 6, 1993

JUL 8 1993

TO: James W. Dilley, M.D.
Box 0884

FROM: Reese T. Jones, M.D.
Chairman, Committee on Human Research

RE: Title: Evaluation of the Safer Sex Counseling Project

Number assigned: H2405-08405-01

Expires: September 1, 1993

This is a courtesy reminder to inform you that your currently approved protocol is about to expire. The Department of Health and Human Services and the University of California require at least annual review of all projects involving humans as subjects. **AFTER THE EXPIRATION DATE NO FURTHER WORK CAN BE DONE ON THIS STUDY. YOUR CURRENT APPROVAL WILL BE TERMINATED. THIS IS YOUR FINAL REMINDER.**

Please let us know the status of your project by indicating the following:

☒ This protocol should be retired on the expiration date.
RETURN ATTACHED FINAL REPORT.

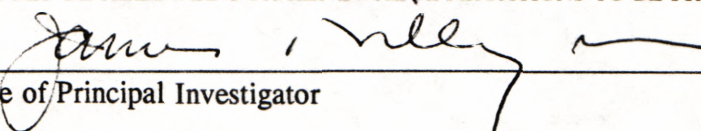
☐ This protocol should be kept active. **THE COMPLETE RENEWAL APPLICATION SHOULD BE ATTACHED TO THIS LETTER**, including **FIVE** identical sets of material, stapled and containing, but not necessarily limited to the following:

- 1) a status report (see p. 23 of the *CHR Guidelines* for details);
- 2) a short statement of the research plan for the coming year;
- 3) the completed, updated cover page (enclosed);
- 4) the approved protocol, *highlighting any proposed modifications*; and
- 5) consent documents (consent forms, information sheets, initial contact letters), *highlighting any modifications to be made at this time.*

For complete instructions on how to renew an approved protocol, please refer to the *Guidelines for Research Involving Human Subjects at UCSF* (October 1987), Part VI, "Renewal Applications." If you do not have a copy of the *Guidelines*, call the CHR office and a copy will be forwarded to you.

Please sign and return this form, along with the renewal application if the protocol is to be kept active, to the Committee on Human Research, Box 0962. If you have any questions, please call the office at (415) 476-1814. Copies of currently used forms are available from the office. **FOUR WEEKS BEFORE THE EXPIRATION DATE SHOULD BE ALLOWED FOR RENEWAL APPLICATIONS TO BE PROCESSED.**

9.7.93
Date


Signature of Principal Investigator

HEPC Project # 92008405

**COMMITTEE ON HUMAN RESEARCH
FULL COMMITTEE FORMAT
COVER PAGE**

PRINCIPAL INVESTIGATOR (UCSF Faculty)

(Name & Degree) _____

Mailing Address

(Campus) _____

CO-P.I.

(Name & Degree) _____

Mailing Address

(Campus) _____

PROJECT TITLE

(Up to 150 Spaces) _____

University

Title _____

Phone

Number _____

Title _____

Phone

Number _____

Dept. _____

Is P.I. Sponsor/

Advisor Only? _____

University

Dept. _____

SUBMISSION

DATE _____

**NAMES/DEGREES OF ALL OTHER
INVESTIGATORS:**

HISTORY OF THIS PROJECT:

Previous CHR approval # _____

☐ New

☐ Modification (Highlight changes in protocol.)

☐ Renewal (Expiration Date _____)

SITE (Check and discuss in protocol.):

☐ Parnassus ☐ VAMC ☐ SFGH ☐ MtZION

☐ Other UCSF site ☐ Foreign

☐ Other _____

SUBJECTS (Discuss in protocol.)

Estimate total number of subjects at all sites checked above.

(If multicenter, discuss overall number of subjects in protocol.)

Number (This Year) _____ (Total for Study) _____

Source(s) _____

Reimbursement per subject: _____

Special Subject Populations:

(Check and discuss in protocol. See Appendix G of *CHR Guidelines*.)

☐ HIV-Infected Individuals

☐ Minors

☐ Fetuses, Pregnant Women

☐ Those Unable to Speak or Read English

☐ Those Unable to Consent for Themselves

☐ Prisoners

COSTS: Who will pay for study procedures and treatment?

(Check all that apply. Specify and discuss which costs in protocol.)

☐ Study Sponsor

☐ Third Party Carriers (Insurance, etc.)

☐ Subject

☐ Other (name) _____

Maximum amount for which a subject might be held responsible (approximate): \$ _____

FUNDING: Will this study be funded?

☐ Yes ☐ No ☐ Pending

☐ Federal Gov. ☐ Other Gov. (i.e., State, City, WHO)

☐ Pharmaceutical/Device Co. ☐ Other Private

☐ Campus & University-wide Programs ☐ Departmental

Agency/Sponsor Name (Grant/Contract #, if known): _____

PROCEDURES (List all procedures to be done for purposes of the study, including surveys, chart reviews, etc.): _____

Will HIV testing be performed for research purposes?

☐ Yes ☐ No (If yes, discuss in detail in protocol.)

RADIOISOTOPES:

Will any radioactive materials be administered to humans? ☐ Yes ☐ No

If yes, what materials? _____

Current number of RSC approval: # _____

Note: Approval of the Radiation Safety Committee (RSC) is required prior to final CHR approval.

DRUGS & DEVICES:

List all approved drugs and/or devices being studied:

List all new drugs and/or devices and all approved ones being investigated for a new use. Each drug or Significant-Risk device must have an exemption number from the FDA. *Note:* Investigator's Brochure for each must be submitted for review with application.

NAME

IND/IDE #

Is a Non-Significant Risk device exemption being sought from the IRB? ☐ Yes ☐ No

If yes, discuss in detail within the protocol. (See Appendix D of *CHR Guidelines*.)

PRINCIPAL INVESTIGATOR'S SIGNATURE & DATE

INSTRUCTION FOR FULL COMMITTEE APPLICATION

Fifteen (15) identical sets of material are required. Each set must be identical and should contain:

- 1) Cover Letter (optional)
- 2) CHR Cover Page (12/91 version), signed by the Principal Investigator;
- 3) Protocol written according to Full Committee Format (FCF), within ten-page limit with pages numbered;
- 4) All information sheets and/or consent forms to be used; and
- 5) All special attachments/requirements (i.e., interview guides, non-standard questionnaires, letters of support).

For detailed information regarding the Full Committee Format (FCF), standard consent form format, and special requirements and attachments, please refer to the *Guidelines for Research Involving Human Subjects at the University of California, San Francisco* (October 1987 or revised December 1991).

If consultation with a senior staff member is desired for a Full Committee Format protocol and/or consent form, appointments may be made by calling the CHR office at 476-1814.

At present, it takes approximately FOUR TO SIX WEEKS to complete the CHR review process of a Full Committee application. It is the investigator's responsibility to make submissions early enough to meet deadlines such as those of granting agencies, sponsoring companies, or CHR expiration dates. Factors such as University holiday periods, summer vacation schedules, and major granting agency deadlines, when the volume of applications submitted to the CHR increases greatly, should also be taken into consideration in planning to allow a sufficient amount of time for CHR review.

A copy of the *Guidelines for Research Involving Human Subjects at the University of California, San Francisco* (December 1991), all current forms, and information regarding submission and review schedules can be obtained in person at the Committee on Human Research, Suite 11, Laurel Heights Campus, or by calling 476-1814.

If an investigational drug or device is being used, submit one copy of Investigator's Brochure. If this is an industry-sponsored study or multicenter trial, submit one copy of full protocol. *Do not submit grant application.*

Submit applications to: Committee on Human Research (CHR)
Box 0962
UCSF
San Francisco, CA 94143-0962

RECEIVED
JUL 21 1993

COMMITTEE ON HUMAN RESEARCH
OFFICE OF RESEARCH AFFAIRS, Box 0962
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

RENEWAL OF FULL COMMITTEE APPLICATION

DATE: July 19, 1993

TO: James W. Dilley, M.D.
Box 0884

FROM: Reese T. Jones, M.D.
Chairman, Committee on Human Research

RE: Title: Evaluation of the Safer Sex Counseling Project

Number assigned: H2405-08405-01 Expires: September 1, 1993

This is a courtesy reminder to inform you that your currently approved protocol is about to expire. The Department of Health and Human Services and the University of California require at least annual review of all projects involving humans as subjects. **AFTER THE EXPIRATION DATE NO FURTHER WORK CAN BE DONE ON THIS STUDY. YOUR CURRENT APPROVAL WILL BE TERMINATED. THIS IS YOUR FINAL REMINDER.**

Please let us know the status of your project by indicating the following:

_____ This protocol should be retired on the expiration date.
RETURN ATTACHED FINAL REPORT.

_____ This protocol should be kept active. **THE COMPLETE RENEWAL APPLICATION SHOULD BE ATTACHED TO THIS LETTER**, including **FIVE** identical sets of material, stapled and containing, but not necessarily limited to the following:

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- 2) a short statement of the research plan for the coming year;
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For complete instructions on how to renew an approved protocol, please refer to the *Guidelines for Research Involving Human Subjects at UCSF* (October 1987), Part VI, "Renewal Applications." If you do not have a copy of the *Guidelines*, call the CHR office and a copy will be forwarded to you.

Please sign and return this form, along with the renewal application if the protocol is to be kept active, to the Committee on Human Research, Box 0962. If you have any questions, please call the office at (415) 476-1814. Copies of currently used forms are available from the office. **FOUR WEEKS BEFORE THE EXPIRATION DATE SHOULD BE ALLOWED FOR RENEWAL APPLICATIONS TO BE PROCESSED.**

Date

Signature of Principal Investigator

HEPC Project # 92008405

**COMMITTEE ON HUMAN RESEARCH
FULL COMMITTEE FORMAT
COVER PAGE**

PRINCIPAL INVESTIGATOR (UCSF Faculty)

(Name & Degree) _____

Mailing Address

(Campus) _____

CO-P.I.

(Name & Degree) _____

Mailing Address

(Campus) _____

PROJECT TITLE

(Up to 150 Spaces) _____

University

Title _____

Phone

Number _____

Title _____

Phone

Number _____

Dept. _____

**Is P.I. Sponsor/
Advisor Only?** _____

University

Dept. _____

**SUBMISSION
DATE** _____

**NAMES/DEGREES OF ALL OTHER
INVESTIGATORS:**

HISTORY OF THIS PROJECT:

Previous CHR approval # _____

- ☐ New
☐ Modification (Highlight changes in protocol.)
☐ Renewal (Expiration Date _____)

SITE (Check and discuss in protocol):

- ☐ Parnassus ☐ VAMC ☐ SFGH ☐ MtZION
☐ Other UCSF site ☐ Foreign
☐ Other _____

SUBJECTS (Discuss in protocol.)

Estimate total number of subjects at all sites checked above.

(If multicenter, discuss overall number of subjects in protocol.)

Number (This Year) _____ (Total for Study) _____

Source(s) _____

Reimbursement per subject: _____

Special Subject Populations:

(Check and discuss in protocol. See Appendix G of *CHR Guidelines*.)

- ☐ HIV-Infected Individuals
☐ Minors
☐ Fetuses, Pregnant Women
☐ Those Unable to Speak or Read English
☐ Those Unable to Consent for Themselves
☐ Prisoners

COSTS: Who will pay for study procedures and treatment?

(Check all that apply. Specify and discuss which costs in protocol.)

- ☐ Study Sponsor
☐ Third Party Carriers (Insurance, etc.)
☐ Subject
☐ Other (name) _____

Maximum amount for which a subject might be held responsible (approximate): \$ _____

FUNDING: Will this study be funded?

- ☐ Yes ☐ No ☐ Pending
☐ Federal Gov. ☐ Other Gov. (i.e., State, City, WHO)
☐ Pharmaceutical/Device Co. ☐ Other Private
☐ Campus & University-wide Programs ☐ Departmental
Agency/Sponsor Name (Grant/Contract #, if known): _____

PROCEDURES (List all procedures to be done for purposes of the study, including surveys, chart reviews, etc.): _____

Will HIV testing be performed for research purposes?

☐ Yes ☐ No (If yes, discuss in detail in protocol.)

RADIOISOTOPES:

Will any radioactive materials be administered to humans? ☐ Yes ☐ No

If yes, what materials? _____

Current number of RSC approval: # _____

Note: Approval of the Radiation Safety Committee (RSC) is required prior to final CHR approval.

DRUGS & DEVICES:

List all approved drugs and/or devices being studied:

List all new drugs and/or devices and all approved ones being investigated for a new use. Each drug or Significant-Risk device must have an exemption number from the FDA. *Note:* Investigator's Brochure for each must be submitted for review with application.

NAME

IND/IDE #

Is a Non-Significant Risk device exemption being sought from the IRB? ☐ Yes ☐ No

If yes, discuss in detail within the protocol. (See Appendix D of *CHR Guidelines*.)

PRINCIPAL INVESTIGATOR'S SIGNATURE & DATE

INSTRUCTION FOR FULL COMMITTEE APPLICATION

Fifteen (15) identical sets of material are required. Each set must be identical and should contain:

- 1) Cover Letter (optional)
- 2) CHR Cover Page (12/91 version), signed by the Principal Investigator;
- 3) Protocol written according to Full Committee Format (FCF), within ten-page limit with pages numbered;
- 4) All information sheets and/or consent forms to be used; and
- 5) All special attachments/requirements (i.e., interview guides, non-standard questionnaires, letters of support).

For detailed information regarding the Full Committee Format (FCF), standard consent form format, and special requirements and attachments, please refer to the *Guidelines for Research Involving Human Subjects at the University of California, San Francisco* (October 1987 or revised December 1991).

If consultation with a senior staff member is desired for a Full Committee Format protocol and/or consent form, appointments may be made by calling the CHR office at 476-1814.

At present, it takes approximately FOUR TO SIX WEEKS to complete the CHR review process of a Full Committee application. It is the investigator's responsibility to make submissions early enough to meet deadlines such as those of granting agencies, sponsoring companies, or CHR expiration dates. Factors such as University holiday periods, summer vacation schedules, and major granting agency deadlines, when the volume of applications submitted to the CHR increases greatly, should also be taken into consideration in planning to allow a sufficient amount of time for CHR review.

A copy of the *Guidelines for Research Involving Human Subjects at the University of California, San Francisco* (December 1991), all current forms, and information regarding submission and review schedules can be obtained in person at the Committee on Human Research, Suite 11, Laurel Heights Campus, or by calling 476-1814.

If an investigational drug or device is being used, submit one copy of Investigator's Brochure. If this is an industry-sponsored study or multicenter trial, submit one copy of full protocol. *Do not submit grant application.*

Submit applications to: Committee on Human Research (CHR)
Box 0962
UCSF
San Francisco, CA 94143-0962

**THE
AIDS
HEALTH
PROJECT**

MEMO

FROM: **JAMES W. DILLEY, M.D.**
Project Director

DATE: 78-96

TO: DS.

Proposed Budget

104
-12
92

0.05 IWD, WOS

6K
Can Row 80?
(stated)

0.10 Donald Silver

~~0.05~~ ~~Don Ch.~~ (TB Confirmed).
4K

0.15 2 gyp leaders. x $\frac{11}{11}$ yr.
only.

~~0.30~~
~~0.30~~ AA II

Operations
mailing Costs →
Salary Fees

4,800 ~~4,888~~

3X
Post pg

6,5005

Rent

Common Cost.

120

0.12 / 5/yr. → 3/6 mos.
(2)

From Springer Supply. ↓

**THE
AIDS
HEALTH
PROJECT**

MEMO

FROM: **JAMES W. DILLEY, M.D.**
Project Director

DATE: _____

TO: _____

.10 FTE Travel 4200
.25 FTE Project Asst. 1500
.30-.40

Statistical Consultant \$500

July Fees 2,000

$$\begin{aligned} 4055 \times 2 &= 80 \\ 20 &= 3 \times 10 = 600 \\ 60 &= 2 \times 20 = 1200 \\ 20 &= 1 = 200 \end{aligned}$$

13,500

Mailing Q's & mailing
Ferox. 300
500
Groups 55 : 50 $\triangleright$ 20 wire mail 13
Controls : 50 $\times$ 2 = 100 pieces
20 $\times$ 1 = 20 pieces
200 pieces $\times$ 1.50

Ferox ✓