Maintaining Confidentiality

Ensuring the confidentiality of a participant and program, and the data we collect, are of the utmost importance to the project. This section outlines the guidelines and procedures for maintaining confidentiality.

Data collection
On-site data collection will be conducted by a team of trained data collectors from the in-country investigator’s institution. The data will be collected during interviews, where information will be obtained directly from the respondent. Often, the site will provide records to the data collectors to review on site.

The data will usually be recorded directly in the database using laptop computers. The database contains an ID code with no identifying information for the facility or the respondent. The data files will be saved and then sent to UCSF for analysis and storage.

In some cases, data may be recorded onto paper forms. The paper questionnaires will be kept secure by the data collectors while onsite, and marked only with the designated ID codes. These will then be transported back to the data collectors’ institution for data entry. Once the data from the paper questionnaires have been entered into the database, the forms and database file will be sent to UCSF for analysis and storage.

Data storage
In order to maintain the data in a secure, confidential way, the following steps have been taken to maintain confidentiality during and after data collection:

- Facility names and personal contact information will be kept separate from questionnaires and the database. The database will only contain ID codes; no names will be associated with a site and the data collected at that site.

- A separate file, accessed only by the in-country PI or data collection supervisor will contain facility-identifying information and facility reports.

- A master database at UCSF will re-integrate facility data with facility-identifying information. This will be kept on site at UCSF only and secured with a password.

- Subsequent exports of the data and the data analysis to collaborators will remove any facility-identifying information.

- All non-UCSF sites will send data to UCSF to be maintained in the master database.

Purpose of Consent
When people are involved in research, it is vitally important that the individual in the study give an informed consent to participate in the research study.

The PANCEA project is approved by the Committee on Human Research (CHR) at the University of California, San Francisco (UCSF). Because the project is collecting data on programs and not on individuals, and there is minimal risk involved in the study, the project is considered exempt from federal Human Subjects Research oversight. This low risk status
allows for data collection at programs without the use of a signed human subjects consent form. However, we do need to explain the study and obtain oral consent. We have developed letters to the programs for this purpose.

Program Data

Programs that have been interviewed for data collection will normally remain anonymous in that the information they provide will not be cited with any reference to their HIV prevention program and under no conditions will the personal identity of an individual be revealed.

However, if the PANCEA project finds it important and potentially beneficial to reveal and site a particular study program in a publication or report, the project will go to the program director and request written permission to mention the name of the program. In no case will the PANCEA project use the name or other personal identifying information of an individual interviewed. Refer to “Consent for HIV Prevention Organization or Facility to be Mentioned by Name.”

Exit Interview

For intervention clients being administered the exit interview, no personal identifiers will be collected, allowing the individuals to remain anonymous. Since a signed consent form would provide a record linking a subject’s name to the research, a signed consent form will not be obtained. Rather, an information sheet (an unsigned consent document), read out loud to the prospective participant, will serve to inform the individual of the nature of the questions in the exit interview and thus allow him or her to decline participation. Refer to “Information Sheet for Exit Interviews.”

The individual will be told about the purpose, procedures, risks and benefits of the study, the subject's rights in participating in research, and the freedom to decline to participate without any jeopardy. The individual will also be given the opportunity to obtain further information and answers to questions related to the study. The exit interview questions will be asked by an interviewer in confidential settings and recorded on the instrument which is kept under research team control at all times.
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

CONSENT FOR HIV PREVENTION ORGANIZATION OR FACILITY TO BE MENTIONED BY NAME

STUDY OF THE COSTS AND EFFICIENCY OF HIV PREVENTION PROGRAMS IN DEVELOPING COUNTRIES

A. PURPOSE AND BACKGROUND

The Institute for Health Policy Studies at the University of California, San Francisco, is funded by the NIH to study the determinants cost and efficiency of HIV Prevention interventions in 8 countries. The Principal Investigator of this study is James G. Kahn, MD, MPH (415) 476-6642, jgkahn@itsa.ucsf.edu. The project director is Elliot Marseille, DrPH, MPP. Other Investigators include Stef Bertozzi, PhD, MD; Nancy Padian, PhD; Joseph Saba, MD (Axios International); Mead Over, MD (World Bank); and Geoff Garnett, PhD, (Imperial College School of Medicine, London). The overall goal is to provide new data on HIV prevention costs and outputs to be used in conjunction with an existing epidemiologic model. With the addition of these data, the model can predict the effect of prevention activities on HIV incidence, and it can estimate the cost-effectiveness of these activities. Further, the study will identify the conditions most closely linked with high levels of efficiency.

B. PROCEDURES

I have just completed an interview on the topic of my program’s costs, outputs, and operation. Also, I have helped the research team collect data about my program.

If I choose to do so, I can allow the name of the HIV prevention organization or facility with which I am associated to be mentioned in reports, publications and other documents, including web-based documents that are generated by the study team. Consent is indicated by my signature at the bottom of this form. In no case will the research team use my name or other personal identifying information.

C. RISKS/DISCOMFORTS

Providing consent may increase the chances that others will figure out that I was interviewed as part of this study and may thus result in a loss of privacy. If the information or opinions I provided upsets people in a position to affect my career, there is some risk of negative consequences to me personally or to the organization to which I am associated.

D. BENEFIT

There may be no direct benefit to me from participating in this study. However, it is possible that interview or the later analyses may help me improve my program’s management. Also, the
information I provide may help improve the efficiency of HIV prevention activities in my country and elsewhere.

E. COSTS AND PAYMENTS

There will be no costs or payments to me as a result of taking part in this study. The project I am associated with may receive compensation for participating in this study.

F. QUESTIONS

If I have any comments or concerns about this study, I should talk with the investigator visiting my program, or with the Principal Investigator:

Professor James G. Kahn, MD, MPH
Email: jgkahn@itsa.ucsf.edu
Tel: 415/476-6642, fax: 415/476-0705
Institute for Health Policy Studies
University of California San Francisco, Box 0936
San Francisco CA 94143
USA

If for some reason I do not wish to do this, I may contact the Committee on Human Research which is concerned with the protection of volunteers in research projects. I may reach the committee office between 8:00 and 5:00 U.S. Pacific time, Monday through Friday, by calling (415) 476-1814, or by writing: Committee on Human Research, Box 0962, University of California, San Francisco, CA 94143 USA

G. CONSENT

I will be given a copy of this consent form to keep.

Giving consent to the use of my organization’s name is voluntary. I am free to decline this request.

If I agree to give consent, I should sign below.

_________________ ____________________________
Date Signature of Study Participant

_________________ ____________________________
Date Project researcher

Version 2/6/2004
PAN_man_ConfidConsent_v4
To be read to exit interview respondents, who are clients of HIV prevention projects.

“Thank you for agreeing to meet with us. We appreciate your helping us with this research. I want to give you information about this project, and about the questions we would like to ask you. We will then ask you if you agree to continue with this interview.

We are doing a study about HIV prevention programs in developing countries. The overall goal is to provide information on the costs of the programs and their services. This will be used to understand how HIV prevention programs can do more to stop the spread of HIV with the money they have. An important part of the research is understanding the client’s opinion about the program. That is why we would like to interview you.

We wish to ask you questions about the HIV prevention services you received and what you paid for them; what you thought of the quality of those services; how effective you believe these services are in reducing risk of contracting or transmitting HIV, and a little about your background.

Your privacy will be fully protected. No one from this research project will ask for your name or for any other information that would allow others to identify you. The information you provide will not be linked to you in any report. You will not be contacted by this project in the future to answer additional questions.

There will be no costs or payments to you as a result of taking part in this study. There may be no direct benefit to you from participating in this study. However, it is possible that this interview or the study may help improve the delivery of HIV services in your country and elsewhere.

Some people might consider some of the questions we want to ask you to be of a personal or intimate nature. It is possible that you may feel some discomfort in hearing or responding to some of the questions. You are free to refuse to answer any question, or you can stop this interview at any time, and your wishes will be respected without question. This interview will take about 10-15 minutes of your time.

Do you have any questions about what we have just explained?

Are you willing to participate in this interview?”