STUDY TO MONITOR THE RESULTS OF THE PROGRAM: QUALITY OF LIFE, POSITIVE PREVENTION, AND SOCIAL INCLUSION FOR PEOPLE LIVING WITH HIV AND AIDS

1. INTRODUCTION

This proposal is for a study to monitor the results of a program implemented in partnership with the National STD/AIDS Program (NAP), the United States Agency for International Development (USAID) and the Centers for Disease Control (CDC).

The activities of the Program are based on the following four objectives: 1) Strengthen health promotion and HIV transmission prevention activities that target PLHIV; 2) Promote the social inclusion of PLHIV by investing in integrated initiatives with the private sector and civil society; 3) Contribute to the sustainability and institutional strength of CSOs working with PLHIV; 4)Increase access to strategic information related to the Brazilian government's HIV/AIDS treatment and care patterns and practices.

To monitor the results of the activities of this Program, Pact Brasil plans to conduct a study about the quality of life of PLHIV who will benefit through the program actions. A Monitoring and Evaluation Plan (M&E Plan) was developed and the following outcome indicators were identified:

1) Level of satisfaction with one's quality of life.
2) Level of satisfaction with one's health.
3) Level of satisfaction with one's current level of energy.
4) Level of satisfaction with oneself.
5) Level of satisfaction with one's capacity for work.
6) Level of satisfaction with the availability of information that one needs.

To measure these indicators, the M&E Plan will use the *World Health Organization Quality of Life Survey Abbreviated Version* (WHOQOL – BREF).

Developed in 1991, the WHOQOL was designed to evaluate the quality of life of PLHIV with an international perspective. Quality of life was defined as a "individual's perceptions in the context of their culture and value systems, and their personal goals, standards and concerns" (WHOQOL Group 1994). To design and validate this instrument, the WHO organized a multi-center research study that included 15 countries in a rigorous process. The final result of the process was the WHOQOL-100, an auto-evaluation instrument with 100 questions that take 6 domains into account including physical health, psychological health, level of independence, social relationships, environment, and personal beliefs. The abbreviated version of this instrument to be used by Pact Brasil was developed in 1998 and contemplates the four domains of the physical, psychological, environmental and social relationships. The Portuguese versions were validated and tested by the WHOQOL Center in Brazil located at the Psychiatric and Legal Medical Department at the Federal University of Brazil in Rio Grande do Sul between 1996 and 1997 with patients at the Clinical Hospital of Porto Alegre (Fleck et al 1999).

The present document presents the theoretical, practical and financial basis for the application of the WHOQOL-Abbreviated instrument to monitor the results of the above stated Program. The implementation of the study considers the need for the active participation of the CSOs and other partners of the Program. As such, prior to sending the

complete version of this project to the Ethic's Review board, it was reviewed with all partners and also discussed with the local organizations that will be responsible for implementing it.

2. GENERAL OBJECTIVE:

1. Monitor the results of the health promotion and quality of life improvement activities to be implemented with PLHIV through the application of the WHOQOL-BREF.

3. SPECIFIC OBJECTIVES:

1. Monitor the level of satisfaction of PLHIV reached through the Program in terms of quality of life:
2. Monitor the level of satisfaction of PLHIV reached through the Program in terms of their actual energy:
3. Monitor the level of satisfaction of PLHIV reached through the Program in terms of their health;
4. Monitor the level of satisfaction of PLHIV reached through the Program in terms of their capacity for work;
5. Monitor the level of satisfaction of PLHIV with relation to themselves;
6. Monitor the level of satisfaction of PLHIV reached through the Program in terms of access to information they need.

4. METHODOLOGY:

4.1 STUDY DESIGN

The study includes two cross-sectional studies to monitor the results of the Program to be implemented with the three CSOs. As it is a study to monitor results, it will be implemented in two stages: once at the beginning of the program and at the end of the Program activities. The first application will serve as a baseline. The second cross-sectional study will be applied at the end of the Program to verify if any changes occurred and to serve as a base for future actions for PLHIV to be developed in the area of health promotion, quality of life, and social inclusion.

4.2 SAMPLE POPULATION – INCLUSION CRITERIA

The sample population for the study is PLHIV (men and women) reached by the three organizations. The participants should fit the following three criteria for inclusion: be 18 or older, be sero-positive and receive services from the CSO.

For the baseline, the questionnaire will be applied with the people receiving services from the NGO. In the comparative study, the questionnaire will be applied with people who report having participated in the health promotion and quality of life activities implemented as part of the Program actions.

4.3 SAMPLE DESIGN

The sample was calculated using the program Stat Calc, from Epi Info 3.4.3. The sample was stratified by city, to ensure a representative sample in each location, assuming a standard deviation of p=0.05, a margin of error of ±5% and a 95% confidence interval. The number of people to be included both in the baseline and final evaluation will be: 155 in Sao Paulo, 91 in Salvador, and 59 in Brasilia.

The questionnaire will be applied in the institutions during a three-week period. During this time, all of the people who arrive at the institution who meet the study requirements defined above will be invited to participate.

4.4 INTERVIEWER TRAINING

All of the interviewers and people responsible for the organization and application of the questionnaire will be trained in how to do so before the study is conducted. The training will be one day long and cover the study methodology that was tested and validated by the WHOQOL Center in Brazil. The training will also focus on ethical issues including the

protection of the confidentiality of the participants, how to apply the Consent Forms, confidential ways to archive the data collected in locked cabinets (focusing on the importance of keeping the consent forms separate from the questionnaires), and how to send the data to the study coordination center in Rio de Janeiro a confidential manner.

4.5 Data Collection Procedures

The methodology of this proposal involves the utilization of the WHOQOL-BREF. The instrument will be applied in the CSO offices where they provide services to PLHIV. The instrument will be applied according to the instructions detailed by the WHOQOL Center in Brazil (Centro WHOQOL 2008).

The questionnaire is self-applied and will be filled out in a private location reserved specifically for this purpose. Before responding to the questionnaire participants will sign a Consent Form. After signing the Consent Form, a trained interviewer will ask apply a short questionnaire with socio-demographic variables. After finishing this process, the study participant will begin filling out the WHOQOL-BREF.

The participant will have the opportunity to clear up any doubts that may arise while filling out the questionnaire. If the participant does not understand a question, instead of explaining the question with synonyms, the trained interviewee will simply read the question more slowly (in accordance with the WHOQOL guidance). If the participant is unable to finish filling out the questionnaire, due to health or literacy problems, the questionnaire will be read to the participant and the responses transcribed by the interviewer.

As previously described, the questionnaire will be applied during a period of three weeks with PLHIV frequenting the CSO for other activities. As such, Pact Brasil does not anticipate any payment or reimbursement for the participants as only those people who are at the CSO for other reasons will be invited to participate. However, if any costs associated with transportation or food for the study participants are identified, Pact Brasil will cover them.

During the study implementation phase, the participation of the NGOs will be to assist in the organization and identification of participants. The consent forms and completed questionnaires will be completed and stored in locked and isolated cabinets within the NGOs. After finishing the data collection phase, the data will be mailed to Pact Brasil by the consultant responsible. Pact Brasil will coordinate the consolidation and analysis of the data with the assistance of specialized consultants. The envelopes will be sent to the attention of the person responsible for the study at Pact Brasil. This person will be the only person authorized to open and store the Consent Forms.

After arriving at Pact Brasil, all of the empirical documents used in the study, including the questionnaires, database, and consent forms, will be kept in locked cabinets and used exclusively for purposes of the study. These documents will never be sent to any other institution, within or outside Brazil.

4.6 Data Analysis

The WHOQOL-BREF will be analyzed by an external consultant using SPSS 11.0. The consultant will follow the instructions elaborated by the WHOQOL Group in Brazil regarding how to code, verify, clean, and input the final data from the questionnaires.
The analysis will focus on the six indicators agreed upon with NAP and USAID:

1) Level of satisfaction with one's quality of life.
2) Level of satisfaction with one's health.
3) Level of satisfaction with one's current level of energy.
4) Level of satisfaction with oneself.
5) Level of satisfaction with one's capacity for work.
6) Level of satisfaction with the availability of information that one needs.

These indicators were chosen for their relevance to the physical activities, counseling, nutrition workshops, and positive prevention actions that will form the base of the NGO pilot project activities of this Program. A stratified analysis by city will also be conducted to evaluate differences between the participants in the three cities in terms of the indicators mentioned above and their socio-demographic profiles.

The reports of the baseline and one year evaluation will be elaborated and disseminated within one month after the fieldwork ends.

4.7 Ethical Questions

As stated above, all of the participants will sign a Consent Form prior to participating in the study. Participation in the study is completely voluntary and should potential participants refuse participation at any time, they will not be penalized in any way, nor will their refusal bring them any risks. Participants will be able to interrupt their participation at any time, even after their interviews.

The study is confidential and the participants will not be identified at any time. Their names, and those of those who could possibly be cited in the study, will not be released with the study results. The information will be used only for the reasons here stated and the people interviewed will have the liberty to access the results.

As stated above, all of the empirical information used in the study, including the questionnaires applied, database, consent forms (in a separate place from all other data) will be kept in locked cabinets at the Pact Brasil office in Rio de Janeiro.

The data collection instruments and consent forms to be used will be analyzed and approved by the Ethics Review Board of the Municipal Health Department of Sao Paulo and the National Research Ethics Board (CONEP) before they are implemented in the field. Any change in the study during its implementation will be immediately communicated to the respective ethic's boards in Sao Paulo, Salvador, Brasilia, and CONEP.

5. Dissemination of the Results

The dissemination of the results after the one-year evaluation will include all of the partner institutions involved in the Program implementation as well as the ethics committees in the town included in the study. The research team will also send the report with the final results to the coordinator of the WHOQOL Center in Brazil in Porto Alegre, Rio Grande do Sul, who will send the information to the World Health Organization. The final report will include the comparison with the baseline evaluation and serve source of data for future programs for USAID/Brazil, the National AIDS Program, National Network of People Living with HIV, Municipal and State STD/AIDS Programs, and Pact Brasil.

6. Implementation

Pact Brasil will be responsible for the design, execution, monitoring, and analysis of the data produced through this study. As such, the coordination of this evaluation will be the responsibility of the Research and Monitoring and Evaluation area of Pact Brasil and the responsibility of Laura Murray, with the support of the consultants Alessandro Oliveira de Santos, Javier Angonoa e Mario Angelo Silva.

The OSC teams involved will participate in the fieldwork process, but the application of the questionnaire will be coordinated by the external consultants identified above.