Appendix I
Human Subjects

1. Permission to Use Personal Health Information for Research
2. Informed Consent HIV – Negative Partner
3. Informed Consent HIV – Positive Partner
4. Informed Consent – Staff
5. Adverse Events and Serious Adverse Events
6. Event Report
7. Negative Incident Report – Case File Report
8. Participant Referral Form
9. Protocol Violation Report Form
10. Session Attendance Form
11. Summary Referral Form
12. Visit 3 Checklist – Facilitator Forms – Post Group

1. Permission to Use Personal Health Information for Research

University of California
Permission to Use Personal Health Information for Research

Study Title (or IRB Approval Number if study title may breach subject's privacy):
EBAN II PROJCECT

Sponsor/Funding Agency (if funded):

A. What is the purpose of this form?

State and federal privacy laws protect the use and release of your health information. Under these laws, the University of California or your health care provider cannot release your health information to the research team unless you give your permission. The research team includes the researchers and people hired by the University or the sponsor to do the research. If you decide to give your permission and to participate in the study, you must sign this form as well as the Consent Form. This form describes the different ways that the researcher, research team and research sponsor may use your health information for the research study. The research team will use and protect your information as described in the attached Consent Form. However, once your health information is released it may not be protected by the privacy laws and might be shared with others. If you have questions, ask a member of the research team.

B. What Personal Health Information will be released?

If you give your permission and sign this form, you are allowing _____ [*insert UC campus or name of health care provider(s) releasing medical records]* to release the following *medical records containing your Personal Health Information. Your Personal Health Information* includes health information in your medical records and information that can identify you. For example, Personal Health Information may include your name, address, phone number or social security number.

☐ Entire Medical Record	☐ Laboratory Reports	☐ Emergency Medicine Center Reports
☐ *Health Care Billing* Statements	☐ *Dental Records*	☐ *History & Physical Exams*
☐ Pathology Reports	☐ Operative Reports	☐ Diagnostic Imaging Reports
☐ EKG	☐ Radiology Reports	☐ Consultations
☐ Progress Notes	☐ Radiologic & MR Scans	☐ Outpatient Clinic Records
	☐ *Discharge Summary*	☐ *Psychological Tests*

☐ **Other (describe): Address, Phone Number, E-mail Address, or other contact information only**

C. Do I have to give my permission for certain specific uses?

Yes. The following information will only be released if you give your specific permission by putting your initials on the line(s).

____ I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment.
____ *I agree to the release of HIV/AIDS testing information.*
____ I agree to the release of genetic testing information.
____ **I agree to the release of information as follows:**
Address, Phone Number, E-mail Address, or other contact information only

D. How will my Personal Health Information be used?

Your Personal Health Information may be released to these people for the following purposes:

1. To the research team for the research described in the attached Consent Form;
2. To others at UC who are required by law to review the research;
3. To others who are required by law to review the quality and safety of the research, including: U.S. government agencies, such as the Food and Drug Administration, the research sponsor or the sponsor's representatives, or government agencies in other countries. These organizations and their representatives may see your Personal Health Information. They may not copy or take it from your medical records unless permitted or required by law.

E. How will my Personal Health Information be used in a research report?

If you agree to be in this study, the research team may fill out a research report. (This is sometimes called "a case report".) The research report will **not** include your name, address, or telephone or social security number. The research report may include your date of birth, initials, dates you received medical care, and a tracking code. The research report will also include information the research team collects for the study. The research team and the research sponsor may use the research report and share it with others in the following ways:

1. To keep you informed about your appointments for interviews;
2. Use it to locate you if you have moved from your current address;
3. Use it to contact you about future studies;

F. Does my permission expire?

This permission to release your Personal Health Information expires when the research ends and all required study monitoring is over. Research reports can be used forever.

G. Can I cancel my permission?

You can cancel your permission at any time. You can do this in two ways. You can write to the researcher or you can ask someone on the research team to give you a form to fill out to cancel your permission. If you cancel your permission, you may no longer be in the research study. You may want to ask someone on the research team if canceling will affect your medical treatment. If you cancel, information that was already collected and disclosed about you may continue to be used. Also, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

H. Signature

If you agree to the use and release of your Personal Health Information, please sign below. You will be given a signed copy of this form.

_____

Subject's Name (print)

_____ _____

Subject's Signature Date

H. If the subject is a minor, or an individual signing with an "X", or an adult incapable of giving consent (where IRB approved), the legally authorized representative or witness signs here:

_____	_____
Legally Authorized Representative's Name or Witness to the "X" (print)	Relationship to the Subject
_____	_____
Representative or Witness Signature	Date

H. If the subject is unable to read the authorization, the translator or reader and a witness sign here:

I have accurately and completely read this Authorization to _____ (subject's name) in _____(language), the subject's primary language. **The subject has verbally affirmed his/her Authorization to me and to the witness.**

_____
Translator or Reader's Name (print)

_____ _____
Translator or Reader's Signature Date

_____
Witness Name (print)

_____ _____
Witness Signature Date

2. Informed Consent HIV – Negative Partner

CONSENT TO PARTICIPATE IN RESEARCH

UCLA NEUROPSYCHIATRIC INSTITUTE
DIVISION OF PSYCHIATRY

HIV Negative Partner

Title: HIV/STD Risk Reduction for African American Couples.

Introduction:

You have been asked to participate in a research study conducted by Gail Wyatt, Ph.D. from the Department of Psychiatry and Hector Myers, Ph.D., at the University of California Los Angeles. You have been asked to participate because you and your partner are 18 years or older, you or your partner identify as African American, your partner is HIV positive and you are HIV negative, and both of you have agreed to consider participation in this study. We expect to enroll 200 African American couples at numerous sites throughout California. In these couples, one partner is HIV Positive and one partner is HIV negative. The duration of this study is approximately 6 months. Your participation in this study is entirely voluntary. You should read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate.

Purpose:

The purpose of this study is to understand health risks and risk reduction methods for African Americans and their families, particularly risks for HIV/AIDS. This information may help you make meaningful decisions about your overall physical and sexual health, personal well being, coping with the disease, and strengthening your relationship. This is a study intended to deepen our understanding of how best to help African American couples protect each other from HIV/AIDS. However, we do not know whether the intervention will be effective; this is why studies of this kind are conducted.

Procedures:

If you and your partner volunteer to participate in this study, we would as you to do the following things:

You will attend a health program that lasts for 8 sessions. Couples will attend one of two interventions. Either A) an 8 session Sexual Risk Reduction Program, designed to prevent the spread of sexually transmitted diseases (STDs), including HIV or GAIL WHAT GOES HERE. This is a randomized study. This means that you will have a 1 in 2 chance of being assigned to Group A or Group B. This assignment will be determined by chance, in a process similar to flipping a coin. This means your assignment to Group A or Group B is based on chance rather than a decision made by the study investigator. Since you will be assigned at random, you will not have a choice about which intervention you attend.

First, you and your partner will both be asked to attend a pretest session with a trained staff during which you will each complete a baseline assessment in separate private rooms. During this assessment, you will use a lap top computer on which structured questions will be administered. Both of you will be asked about:

- your general health practices
- your past and current sexual practices,
- use of drugs and alcohol, and related problems
- your physical and mental condition
- your attitudes about HIV and AIDS
- your current and previous experiences with sexually transmitted infections
- a number of psychological measures
- your use of media and services

This assessment will last approximately 90 minutes, and will be repeated three more times over the next 12 months (post-test, 6- and 12-month follow ups). You should understand that there are no right or wrong answers to these questions. You may refuse to answer any questions that you consider too personal.

Proof of HIV Diagnosis

Proof of HIV status is a prerequisite for this study. First, you will be asked to bring in documented proof of HIV status. If a potential participant does not have proof of diagnosis, HIV testing may be accessed at local HIV testing sites referred to by project staff.

Intervention

After completing the first interview, you and your partner will be asked to attend 8 weekly sessions with a team of trained African American group leaders. You will be asked at the end of this form if you will allow the investigators to inform the facilitators of your HIV status. The facilitators will be informed of your HIV status only if both partners have given permission for their status to be provided. Each session will last approximately 2 hours. In Session 1, a group of 4 to 6 couples will be divided by gender and meet in single sex groups with the same-sex member of their assigned co-facilitator team. In Sessions 2-4, each couple will meet separately with the co-facilitator team. In Sessions 5-7, the 4 to 6 couples in the original group will attend group sessions with their co-facilitators. In Session 8, each couple will meet separately with the co-facilitators.

If you are immediately enrolled in, the *Sexual Risk Reduction Program*, the sessions will focus on teaching you communication and decision-making skills to enhance communication and strengthen your relationship, and reduce your risk for STDs and HIV by changing risky sexual behaviors. These sessions will include information on:

- sexual health
- birth control
- sexually transmitted infections
- condom demonstrations using models of body parts.

If you wait 8 months you will also receive the exact same intervention in the "sexual Risk Reduction Program".

Potential Risks and Discomforts:

It is possible that issues may be raised by you or your partner that might cause conflicts between you. It is also possible that your relationship may be adversely affected if you or your partner test positive for an STD. Project staff are trained to help couples deal with issues on which they have disagreements and help them to resolve these issues. If you need additional psychological services, you will be referred to counseling agencies with low fee services, so that you may talk to someone about your problems. However, the study will not pay for the costs for these services.

In this study, you will be asked to answer questions that may make you feel embarrassed or anxious. Some of the topics that will be discussed may sometimes upset you. If this should happen, you will be given referrals for counseling or other assistance.

During group sessions there may be a risk of group members telling other people personal information you share. To reduce this risk, facilitators will explain in the introduction to the group, that participants may not tell information divulged during the group to anyone outside of the group. All women and men asked to participate in groups will be asked to sign a confidentiality agreement stating that they pledge to maintain the confidential nature of the group. Participants who do not sign the form may not participate in the group.

Anticipated Benefits to Subjects:

Participating will give you the opportunity to meet and learn from others who are in relationships that are affected by HIV or have other life challenges. You also may personally benefit from participating in the sessions by learning information and skills that that will help you improve your health and your partner's health. You may also find that you enjoy discussing these topics.

You will also learn whether you have an STD, including HIV, so that you can get the care you need. If you test positive for Chlamydia, Gonorrhea or Trichomoniasis, both you and your partner will receive treatment at no cost to you.

Anticipated Benefits to Society:

By participating in this study you will assist in developing better ways to improve the health of couples and families, including preventing the spread of sexually transmitted diseases and HIV.

Payment for Participation:

Should you agree to participate, you and your partner will be paid $25 for completing the first computerized interview, $10 for each of the 8 sessions completed, $35 for the post-test interview, and $40 for the 3-month follow-up interview. You will also receive $10 each for each sexually transmitted infection verification that you provide, for a maximum of $20. If you complete the study, you may receive a total of $200

Financial Obligation:

You will not be charged for participating in this study.

Emergency Care and Compensation for Injury:

If you are injured as a direct result of research procedures not done primarily for your own benefit, you will receive treatment at no cost to you. The University of California does not provide any other form of compensation for injury.

Privacy and Confidentiality:

The only people who will know that you are a research subject are members of the research team and, if you request, your physicians and nurses. We will do everything we can to protect your privacy and to make sure that information about you, or provided by you during the research, will not be disclosed to others without your written permission.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

Audiotapes will be used during some of the assessment and couples sessions to make sure that study procedures are being followed. These tapes will be used for research purposes only and your identity will not be disclosed. You may use a false name or nickname for purposes of identification in the sessions. You will have the right to review the tapes made as part of the study to determine whether they should be edited or erased in whole or in part. The tapes will be kept for 3 months and then destroyed.

This research is covered by a Certificate of Confidentiality issued by the Department of Health and Human Services (DHHS). This certificate will protect the investigators from being forced to release any research data in which you are identified, even under a court order or subpoena. This protection, however, does not prohibit the investigators from taking action to protect you or someone else from serious harm. For example, if any member of the program staff learns that you or your partner is in danger, or that someone else is in danger (child or elder abuse, threats to harm self or others, domestic abuse or abuse in your home), they will report these incidents. However, we would work with you to help you resolve these problems. You should understand that a

Confidentiality Certificate does not prevent you from voluntarily releasing information associated with medical tests and treatment for STDs, including HIV.

The confidentiality of your responses, your HIV and STD test results will be respected and used for research purposes only. Your records, which are computerized, will be identified only by location of interview and city and participant identification number. Data files will be protected by passwords known only to project staff. No names or any other identifying information will be included in the data file. Data may be released upon request by the Department of Health and Human Services (DHHS) for audit or program evaluation purposes, but this data will only be identified by code number, and will not include your name.

Alternatives to Participation:

The alternative is not to participate. If you do not want to participate in this study, you may be able to access other resources for yourself and your partner such as support groups, couples groups, and HIV related information at local AIDS agencies and health clinics. Study staff can provide you with a list of these resources. Abstinence (not having sex) and the use of condoms are effective in the prevention of HIV and other sexually transmitted diseases.

Participation and Withdrawal:

Your participation in this study is voluntary. If you choose not to participate, that will not affect your relationship with UCLA (or the UCLA Medical Center), or your right to health care or other services to which you are otherwise entitled. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without prejudice to your future care at UCLA. However, you and your partner will only be paid for those sessions that you attend.

Withdrawal of Participation by the Investigator:

The investigators may withdraw you from participating in this study if circumstances arise which warrant doing so. You may be asked to drop out if you or your partner experience significant psychiatric distress that prevents you from continuing the study, or if either of you become ill during the study. The Principal Investigator, Dr. Gail Wyatt, will make the decision and let you and your partner know if it is not possible for you to continue. The decision may be made either to protect your health or your partner's health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate, or the investigator determines that you are not appropriate for the study.

If you must drop out because the investigator asks you to, you will only be paid for the sessions that you attended.

New Findings:

During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in the study will be obtained again.

Identification of Investigators:

In the event of a research related injury, or if you experience an adverse reaction, please contact the investigator listed below immediately. If you have any questions about the study, please feel free to contact:

Gail E. Wyatt, Ph.D., *Principal Investigator*
Neuropsychiatric Institute, UCLA
760 Westwood Plaza, Room C8-871
Los Angeles, CA 90024
(310) 825-0193 or (310) 206-9860
24-hour phone line: (310) 825-0511

OR

Kabir Hypolite
Alameda County Public Health Department
Director, Division of Communicable Disease Control & Prevention – OAA
(510) 268-7654
1000 Broadway, Ste 310,
Oakland, CA 94607.

You may also contact the co-investigators, Hector Myers, Ph.D., (310) 825-1813.

Rights of Research Subjects:

You may withdraw your consent at any time and discontinue participating without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this study. If you have any questions regarding your rights as a research subject, you may contact:

Office for Protection of Research Subjects
11000 Kinross Ave
Suite 102, Box 951694
Los Angeles, CA 90095-1694
(310) 825-8714

Signature of Research Subject

I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been give a copy of this form, as well as a copy of the Subject's Bill of Rights.

By signing this form, I willingly agree to participate in the research it describes.

_____
Name of Subject

_____ _____
Signature of Subject Date

Please indicate whether you will allow us to inform the facilitators of your HIV status by checking one of the boxes below:

_____ I give permission to have the facilitators informed of my HIV status. Facilitators will be informed of your HIV status only if both partners give permission.

_____ I do not give permission to have the facilitators informed of my HIV status

Signature of Investigator

I have explained the research to the participant, and answered all of his/her questions. I believe that he/she

understands the information described in this document and freely consents to participate.

_____
Name of Investigator

_____ _____
Signature of Investigator Date

3. Informed Consent HIV – Positive Partner

CONSENT TO PARTICIPATE IN RESEARCH

UCLA NEUROPSYCHIATRIC INSTITUTE
DIVISION OF PSYCHIATRY

HIV Positive Partner

Title: HIV/STD Risk Reduction for African American Couples.

Introduction:

You have been asked to participate in a research study conducted by Gail Wyatt, Ph.D. from the Department of Psychiatry and Hector Myers, Ph.D., at the University of California Los Angeles. You have been asked to participate because you and your partner are 18 years or older, you or your partner identify as African American, your partner is HIV positive and you are HIV negative, and both of you have agreed to consider participation in this study. We expect to enroll 200 African American couples at numerous sites throughout California. In these couples, one partner is HIV Positive and one partner is HIV negative. The duration of this study is approcimately 6 months. Your participation in this study is entirely voluntary. You should read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate.

Purpose:

The purpose of this study is to understand health risks and risk reduction methods for African Americans and their families, particularly risks for HIV/AIDS. This information may help you make meaningful decisions about your overall physical and sexual health, personal well being, coping with the disease, and strengthening your relationship. This is a study intended to deepen our understanding of how best to help African American couples protect each other from HIV/AIDS. However, we do not know whether the intervention will be effective; this is why studies of this kind are conducted.

Procedures:

If you and your partner volunteer to participate in this study, we would as you to do the following things:

You will attend a health program that lasts for 8 sessions. Couples will attend one of two interventions. Either A) an 8 session Sexual Risk Reduction Program, designed to prevent the spread of sexually transmitted diseases (STDs), including HIV. This is a randomized study. This means that you will have a 1 in 2 chance of being assigned to Group A or Group B. This assignment will be determined by chance, in a process similar to flipping a coin. This means your assignment to Group A or Group B is based on chance rather than a decision made by the study investigator. Since you will be assigned at random, you will not have a choice about which intervention you attend.

First, you and your partner will both be asked to attend a pretest session with a trained staff during which you will each complete a baseline assessment in separate private rooms. During this assessment, you will use a lap top computer on which structured questions will be administered. Both of you will be asked about:

- your general health practices
- your past and current sexual practices,
- use of drugs and alcohol, and related problems
- your physical and mental condition
- your attitudes about HIV and AIDS
- your current and previous experiences with sexually transmitted infections
- a number of psychological measures
- your use of media and services

This assessment will last approximately 90 minutes, and will be repeated three more times over the next 12 months (post-test, 6- and 12-month follow ups). You should understand that there are no right or wrong answers

to these questions. You may refuse to answer any questions that you consider too personal.

Proof of HIV Diagnosis

Proof of HIV status is a prerequisite for this study. First, you will be asked to bring in documented proof of HIV status. If a potential participant does not have proof of diagnosis, HIV testing may be accessed at local HIV testing sites referred to by project staff.

Intervention

After completing the first interview, you and your partner will be asked to attend 8 weekly sessions with a team of trained African American group leaders. You will be asked at the end of this form if you will allow the investigators to inform the facilitators of your HIV status. The facilitators will be informed of your HIV status only if both partners have given permission for their status to be provided. Each session will last approximately 2 hours. In Session 1, a group of 4 to 6 couples will be divided by gender and meet in single sex groups with the same-sex member of their assigned co-facilitator team. In Sessions 2-4, each couple will meet separately with the co-facilitator team. In Sessions 5-7, the 4 to 6 couples in the original group will attend group sessions with their co-facilitators. In Session 8, each couple will meet separately with the co-facilitators.

If you are immediately enrolled in, the *Sexual Risk Reduction Program*, the sessions will focus on teaching you communication and decision-making skills to enhance communication and strengthen your relationship, and reduce your risk for STDs and HIV by changing risky sexual behaviors. These sessions will include information on:

- sexual health
- birth control
- sexually transmitted infections
- condom demonstrations using models of body parts.

If you wait 8 months you will also receive the exact same intervention in the "Sexual Risk Reduction Program".

Potential Risks and Discomforts:

It is possible that issues may be raised by you or your partner that might cause conflicts between you. It is also possible that your relationship may be adversely affected if you or your partner test positive for an STD. Project staff are trained to help couples deal with issues on which they have disagreements and help them to resolve these issues. If you need additional psychological services, you will be referred to counseling agencies with low fee services, so that you may talk to someone about your problems. However, the study will not pay for the costs for these services.

In this study, you will be asked to answer questions that may make you feel embarrassed or anxious. Some of the topics that will be discussed may sometimes upset you. If this should happen, you will be given referrals for counseling or other assistance.

During group sessions there may be a risk of group members telling other people personal information you share. To reduce this risk, facilitators will explain in the introduction to the group, that participants may not tell information divulged during the group to anyone outside of the group. All women and men asked to participate in groups will be asked to sign a confidentiality agreement stating that they pledge to maintain the confidential nature of the group. Participants who do not sign the form may not participate in the group.

Anticipated Benefits to Subjects:

Participating will give you the opportunity to meet and learn from others who are in relationships that are affected by HIV or have other life challenges. You also may personally benefit from participating in the sessions by learning information and skills that that will help you improve your health and your partner's health. You may also find that you enjoy discussing these topics.

Anticipated Benefits to Society:

By participating in this study you will assist in developing better ways to improve the health of couples and families, including preventing the spread of sexually transmitted diseases and HIV.

Payment for Participation: Should you agree to participate, you and your partner will be paid $20 for completing the first computerized interview, $15 for each of the 8 sessions completed, $25 for the post-test interview, and $30 for each follow-up interview. You will also receive $10 each for each urine or vaginal specimen you provide. If you complete the study, you may receive a total of $225.

Financial Obligation:

You will not be charged for participating in this study.

Emergency Care and Compensation for Injury:

If you are injured as a direct result of research procedures not done primarily for your own benefit, you will receive treatment at no cost to you. The University of California does not provide any other form of compensation for injury.

Privacy and Confidentiality:

The only people who will know that you are a research subject are members of the research team and, if you request, your physicians and nurses. We will do everything we can to protect your privacy and to make sure that information about you, or provided by you during the research, will not be disclosed to others without your written permission.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

Audiotapes will be used during some of the assessment and couples sessions to make sure that study procedures are being followed. These tapes will be used for research purposes only and your identity will not be disclosed. You may use a false name or nickname for purposes of identification in the sessions. You will have the right to review the tapes made as part of the study to determine whether they should be edited or erased in whole or in part. The tapes will be kept for 3 months and then destroyed.

This research is covered by a Certificate of Confidentiality issued by the Department of Health and Human Services (DHHS). This certificate will protect the investigators from being forced to release any research data in which you are identified, even under a court order or subpoena. This protection, however, does not prohibit the investigators from taking action to protect you or someone else from serious harm. For example, if any member of the program staff learns that you or your partner is in danger, or that someone else is in danger (child or elder abuse, threats to harm self or others, domestic abuse or abuse in your home), they will report these incidents. However, we would work with you to help you resolve these problems. You should understand that a Confidentiality Certificate does not prevent you from voluntarily releasing information associated with medical tests and treatment for STDs, including HIV.

The confidentiality of your responses, your HIV and STD test results will be respected and used for research purposes only. Your records, which are computerized, will be identified only by location of interview and city and participant identification number. Data files will be protected by passwords known only to project staff. No names or any other identifying information will be included in the data file. Data may be released upon request by the Department of Health and Human Services (DHHS) for audit or program evaluation purposes, but this data

will only be identified by code number, and will not include your name.

Alternatives to Participation:

The alternative is not to participate. If you do not want to participate in this study, you may be able to access other resources for yourself and your partner such as support groups, couples groups, and HIV related information at local AIDS agencies and health clinics. Study staff can provide you with a list of these resources. Abstinence (not having sex) and the use of condoms are effective in the prevention of HIV and other sexually transmitted diseases.

Participation and Withdrawal:

Your participation in this study is voluntary. If you choose not to participate, that will not affect your relationship with UCLA (or the UCLA Medical Center), or your right to health care or other services to which you are otherwise entitled. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without prejudice to your future care at UCLA. However, you and your partner will only be paid for those sessions that you attend.

Withdrawal of Participation by the Investigator:

The investigators may withdraw you from participating in this study if circumstances arise which warrant doing so. You may be asked to drop out if you or your partner experience significant psychiatric distress that prevents you from continuing the study, or if either of you become ill during the study. The Principal Investigator, Dr. Gail Wyatt, will make the decision and let you and your partner know if it is not possible for you to continue. The decision may be made either to protect your health or your partner's health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate, or the investigator determines that you are not appropriate for the study.

If you must drop out because the investigator asks you to, you will only be paid for the sessions that you attended.

New Findings:

During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in the study will be obtained again.

Identification of Investigators:

In the event of a research related injury, or if you experience an adverse reaction, please contact the investigator listed below immediately. If you have any questions about the study, please feel free to contact:

Gail E. Wyatt, Ph.D., Principal Investigator
Neuropsychiatric Institute, UCLA
760 Westwood Plaza, Room C8-871
Los Angeles, CA 90024
(310) 825-0193 or (310) 206-9860
24-hour phone line: (310) 825-0511

OR

Kabir Hypolite
Alameda County Public Health Department
Director, Division of Communicable Disease Control & Prevention – OAA
(510) 268-7654
1000 Broadway, Ste 310,

Oakland, CA 94607.

You may also contact the co-investigators, Hector Myers, Ph.D., (310) 825-1813.

Rights of Research Subjects:

You may withdraw your consent at any time and discontinue participating without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this study. If you have any questions regarding your rights as a research subject, you may contact:

Office for Protection of Research Subjects
11000 Kinross Ave
Suite 102, Box 951694
Los Angeles, CA 90095-1694
(310) 825-8714

Signature of Research Subject

I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been give a copy of this form, as well as a copy of the Subject's Bill of Rights.

By signing this form, I willingly agree to participate in the research it describes.

_____
Name of Subject

_____ _____
Signature of Subject Date

Please indicate whether you will allow us to inform the facilitators of your HIV status by checking one of the boxes below:

_____ I give permission to have the facilitators informed of my HIV status. Facilitators will be informed of your HIV status only if both partners give permission.

_____ I do not give permission to have the facilitators informed of my HIV status

Signature of Investigator

I have explained the research to the participant, and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

_____
Name of Investigator

_____ _____
Signature of Investigator Date

4. Informed Consent – Staff

INVITATION TO PARTICIPATE

You are asked to participate in a study supported by The University of California, Los Angeles and The Oakland Office of AIDS because you are a staff member working at a participating organization within the State of California Implementation Network (SCIN). All staff members of the SCIN are being asked to participate in this study. You are being asked to participate at certain times, for the duration of the five year study. Your participation in this study is entirely voluntary. You should read the information below, and ask questions about anything you do not understand before deciding whether to participate.

1. PURPOSE OF THE STUDY

The overall purpose of the study is to evaluate implementation effectiveness at community agencies. Specifically, to determine how effective the Eban I1 Intervention is disseminated throughout your agency; how effectively you were trained to implement the Eban I1 Interventions; and how we11 you are able to implement the Eban I1 study where you work in order to decrease HIV risk behavior among sero-discordant African American couples.

2. PROCEDURES

If you volunteer to participate in this study, you will be asked to do the following things:

- You will be asked to fill out a survey 3 times: prior to conducting each group your agency conducts, immediately after the last group your agency conducts, and three months thereafter.

It is likely that you will fill out the survey at your agency. This will involve taking the survey yourself by reading the questions and choosing the best answer on your own. The survey will take about 15 minutes to complete.

The survey will ask questions about what you think about the Eban I1 project. Some of the questions asked might be:

- What impact might this program have on other services that you are required to provide?
- What needs to be improved about how the program was disseminated?
- What do you think about the Eban I1 research project?
- How likely are you to use this program with couples?

3. POTENTIAL RISKS AND DISCOMFORTS

You may experience the following risks and discomforts as a result of participating in this research study:

There are minimal risks to participating in this study. You may find some of the questions uncomfortable. You may skip any question that you do not feel comfortable answering and can stop answering questions at anytime. It is possible that someone who you do not want, like an administrator, might find out the information you provide during the surveys and focus groups, but again this risk is minimal. None of the decisions made about your participation will change your job status where you are employed or change the services you provide there.

4. ANTICIPATED BENEFITS TO SUBJECTS

It is not expected that you will gain any personal benefit from participating in this research.

5. ANTICIPATED BENEFITS TO SOCIETY

Although you may receive no direct benefit from being in the study, your taking part may help others in the future as a result of knowledge gained from the research. For example, it will be learned whether services for serodiscordant couples can be implemented at your organization and this information can be used to improve services for serodiscordant couples at other locations.

6. ALTERNATIVES TO PARTICIPATION

You may choose not to participate in this study for any reason. Your decision will not affect your job at any corresponding organization affiliated with this study.

7. REIMBURSEMENT (PAYMENT) FOR PARTICIPATION

You will not receive financial reimbursement (payment) for your participation in this study.

8. POSSIBLE COMMERCIAL PRODUCTS

This study will not result in the development of any commercial product.

9. FINANCIAL OBLIGATION

You will not be charged for any treatments or procedures that are part of this study. These include the cost of conducting the interviews.

10. EMERGENCY CARE

In the event of a research related injury or if you experience an adverse reaction, please immediately contact your own doctor during the day and 911 after business hours. If you have any study-related concerns, please immediately contact one of the investigators on this study: Dr. Wyatt at 310-825-0193. If you need emergency hospitalization a referral to the nearest hospital will be provided upon request.

11. PRIVACY AND CONFIDENTIALITY

Participation in this study will involve a loss of privacy, but information about you will be handled as confidentially as possible. While the SCDC and the researchers on the team will do everything to prevent any loss of information, in the event that there is a breech of information, you will be contacted by the principal investigator directly.

Identifying information will be collected during the survey. This information will be limited to your name and agency affiliation. This information will be separated from your survey answers by assigning you an ID number that only will be known by the Principal Investigator and Project Director. No individual information collected during the survey will be shared with other person(s) you work with. In addition, when the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. Your information will be combined with information from other people taking part in the study.

We will keep confidential all research records that identify you to the extent allowed by law. However, you should know that there are some circumstances in which we may have to show your information to other people. For example, someone from, the Office of Human Research Protections, the Government Accounting Office, the UCLA Office of Research Oversight, our Institutional Review Board, our Data and Safety Monitoring Board and the sponsor of the study may look at but not copy portions of records that identify you.

In addition, in accordance with California law, confidentiality cannot be guaranteed if the investigator becomes aware that you may be a danger to yourself or to others, or becomes aware that acts of child abuse or elder abuse may have occurred.

You can help make sure that the group discussion and interviews remain confidential. Although all answers to the surveys will be kept confidential by the investigator, after the session is over you should not discuss your answers with other staff members as this could make your answers more identifiable.

12. PARTICIPATION AND WITHDRAWAL

Your participation in this research is voluntary. If you choose to stop participating that will not affect your job with any participating agency.

12a. CONSEQUENCES OF WITHDRAWAL

There are no known consequences of withdrawal from this study.

12b. WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR

The study's principal investigator(s) has the right to end your participation in this study for any of the following reasons: it would be dangerous for you to continue; you do not follow study procedures as directed by the study doctors.

13. NEW FINDINGS

We will tell you about new information that may affect your willingness to stay in the study.

14. IDENTIFICATION OF INVESTIGATORS

In the event of a research related injury or if you experience an adverse reaction (which might include a feeling of stress or anxiety), please immediately contact your physician or treating provider.

If you have any study-related concerns, please immediately contact one of the investigators on this study:

Gail E. Wyatt, Ph.D., Principal Investigator
Neuropsychiatric Institute, UCLA
760 Westwood Plaza, Room C8-871
Los Angeles, CA 90024
(310) 825-0193 or (310) 206-9860
24-hour phone line: (310) 825-0511

OR

Kabir Hypolite
Alameda County Public Health Department
Director, Division of Communicable Disease Control & Prevention – OAA
1000 Broadway, Ste 310,
Oakland, CA 94607.
(510) 268-7654

15. RIGHTS OF RESEARCH SUBJECTS

If you have any concerns regarding the following:

- the legitimacy of this study (whether it is an approved study);
- your rights as a research subject;
- how to express complaints regarding this research study; or
- what will happen in the event of a research-related injury;

you may also contact your Dr. Gail Wyatt at 310-825-0193 or Kabir Hypolite at (510) 268-7654 regarding:

- any of the above issues, and
- to ask any questions about the research.

SIGNATURE OF RESEARCH SUBJECT OR LEGAL REPRESENTATIVE

I have read the information provided in this consent/authorization form. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. If I have questions later, I understand I can contact Dr. Gail Wyatt. As part of this consent process, I will be given a copy of the rights of human subjects in medical experimentation and a copy of this consent form.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

_____ _____
Subject's Signature Date

_____ _____
Signature of Principal Investigator/Research Staff Date

5. Adverse Events and Serious Adverse Events

THE EBAN II PROJECT

Cohort ID: __ __ __ Group ID: ___ Site #:__ __ Date completed: __ __/__ __/__ __ __ __

Staff ID: __ __ __

ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

1. Participants involved:

__ __ __ __ __ __ __ (participant 1) __ __ __ __ __ __ __ (participant 2)
__ __ __ __ __ __ __ (participant 3) __ __ __ __ __ __ __ (participant 4)
__ __ __ __ __ __ __ (participant 5) __ __ __ __ __ __ __ (participant 6)
__ __ __ __ __ __ __ (participant 7) __ __ __ __ __ __ __ (participant 8)
__ __ __ __ __ __ __ (participant 9) __ __ __ __ __ __ __ (participant 10)
__ __ __ __ __ __ __ (participant 11) __ __ __ __ __ __ __ (participant 12)

Adverse Event Code	Date of Event	Duration	Grade	Relationship to Study	Action taken	Referral Given
	mm/dd/yyyy	1 = minutes 2 = hours 3 = days 4 = weeks 5 = months 6 = ongoing 88= unknown	1 = mild 2 = moderate 3 = severe 4 = life threatening	1 = Definitely related 2 = Probably related 3 = Probably not related 4 = Definitely not related		
	__ __/__ __/__ __ __ __				❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No
Brief Description of Event (Please print):						

Principal Investigator's Signature: _____ Date: __ __ / __ __ / __ __ __ __

6. Event Report

THE EBAN II PROJECT

EVENT REPORT

THE PURPOSE OF THIS FORM IS TO REPORT ANY EVENT THAT OCCUR IN GROUP OR THAT OCCUR OUTSIDE OF GROUP AS A RESULT OF PARTICIPATING IN THE EBAN II PROJECT. ANY STAFF INVOLVED SHOULD COMPLETE THIS FORM IMMEDIATELY AFTER THE EVENT AND IT SHOULD BE GIVEN TO THE AGENCY LIAISON AND AGENCY COORDINATOR IMMEDIATELY, AND THE AGENCY LIAISON IS TO FILE ONE COPY AWAY IN THEIR CASE FILE. THESE EVENTS REPORTS WILL BE REVIEWED BY THE PI, IF NEEDED.

Name: _____ Position: _____

Staff ID#: __ __ __

Site #: __ __

Cohort # __ __ __

Intervention: ❑ Risk Reduction ❑ Health Promotion (Check one.)

Today's Date: __ __/__ __/__ __

Date of Incident: __ __/__ __/__ __

Time of Incident:__ __: __ __ pm/ am

Where did incident take place?

_____

_____

1. Participant ID numbers of all participants involved in or affected by incident.

_ _ _ _ _ _ _ (participant 1) _ _ _ _ _ _ _ (participant 2)
_ _ _ _ _ _ _ (participant 3) _ _ _ _ _ _ _ (participant 4)
_ _ _ _ _ _ _ (participant 5) _ _ _ _ _ _ _ (participant 6)
_ _ _ _ _ _ _ (participant 7) _ _ _ _ _ _ _ (participant 8)
_ _ _ _ _ _ _ (participant 9) _ _ _ _ _ _ _ (participant 10)
_ _ _ _ _ _ _ (participant 11 _ _ _ _ _ _ _ (participant 12)

2. Describe incident (Please be as specific as possible and use ID#'s instead of names.)

_____

_____

_____

_____

_____

_____

3. Describe any follow up actions taken by staff in response to incident.

_____

_____

4. List names of any staff or non-participants who witnessed incident.

Witness 1 _____ phone number(s): _____
Witness 2 _____ phone number(s): _____
Witness 3 _____ phone number(s): _____
Witness 4 _____ phone number(s): _____

5. Was this incident captured on audiotape? ❑ YES ❑ NO
If yes, please submit a copy of audiotape with this report to PI.

6. Was incident reported to police or any other authorities? YES/NO
If yes, to whom and when was incident reported?

Signature of Staff making report_____ Date:__ __/__ __/__ __

(To be filled out by Principal Investigator)

Name of Principal Investigator:_____

Assessment of Incident (Please indicate how you reviewed incident and whether or not in your opinion this may constitute an adverse event.)

Disposition of Incident (Check relevant category.)
❑ This incident does not constitute an adverse event, and no further review is needed.
❑ I have reported this incident to UCLA for further review to determine if it is an adverse event of the study on __ __/__ __/__ __ (indicate date of report to UCLA).

Recommended Follow up Actions to Incident:

Signature of Principal Investigator: _____Date: __ __/__ __/__ __

7. Negative Incident Report – Case File Report

THE EBAN II PROJECT

Negative Incident Report
Case File Report

THE PURPOSE OF THIS FORM IS TO REPORT ANY NEGATIVE INCIDENCES THAT OCCUR IN GROUP OR THAT OCCUR OUTSIDE OF GROUP AS A RESULT OF PARTICIPATING IN THE EBAN II PROJECT. ANY STAFF INVOLVED SHOULD COMPLETE THIS FORM IMMEDIATELY AFTER THE NEGATIVE INCIDENT AND IT SHOULD BE GIVEN TO THE AGENCY LIAISON, PI AND AGENCY COORDINATOR AND IMMEDIATELY, AND THE AGENCY LIAISON IS TO FILE ONE COPY AWAY IN THE PARTICIPANT'S FILE. THESE NEGATIVE INCIDENTS REPORTS WILL BE REVIEWED AND REPORTED TO THE DSMB OR IRB, IF NEEDED.

Name: _____
Position: _____
Staff ID#: _____
Site: _____ Cohort/Group ID#_____
Today's Date: _____
_____

Date of Incident: __ __/__ __/__ __

Time of Incident: : pm/ am

Where did incident take place?
_____
_____

First Names and Last Initials of all participants involved in or affected by incident
___ ___ ___ ___ ___(participant 1) ___ ___ ___ ___ ___(participant 2)
___ ___ ___ ___ ___(participant 3) ___ ___ ___ ___ ___(participant 4)
___ ___ ___ ___ ___(participant 5) ___ ___ ___ ___ ___(participant 6)
___ ___ ___ ___ ___(participant 7) ___ ___ ___ ___ ___(participant 8)
___ ___ ___ ___ ___(participant 9) ___ ___ ___ ___ ___(participant 10)
___ ___ ___ ___ ___(participant 11)___ ___ ___ ___ ___(participant 12)

Describe Incident (Please be as specific as possible and use participant first names and last initials only)
_____
_____
_____
_____
_____
_____

Confidential Material

(Agency Coordinator – PLEASE MAKE COPIES OF REPORT AND PLACE IN PARTICIPANT CASE FILES. FILL OUT PAGE 2 WITH PARTICIPANT ID NUMBERS AND SUBMIT TO PI FOR REVIEW).

Negative Incident Report

Name: _____

THE EBAN II PROJECT

Position:_____
Staff ID#:_____
Site:_____
Today's Date:_____

_____

Date of Incident: __ __/__ __/__ __

Time of Incident: : pm/ am

Where did incident take place?

_____
_____
_____

PROJECT DIRECTOR FILL OUT NEXT TWO QUESTIONS

1. Study ID numbers of all participants involved in or affected by incident

___ ___ ___ ___ ___(participant 1) ___ ___ ___ ___ ___(participant 2)
___ ___ ___ ___ ___(participant 3) ___ ___ ___ ___ ___(participant 4)
___ ___ ___ ___ ___(participant 5) ___ ___ ___ ___ ___(participant 6)
___ ___ ___ ___ ___(participant 7) ___ ___ ___ ___ ___(participant 8)
___ ___ ___ ___ ___(participant 9) ___ ___ ___ ___ ___(participant 10)
___ ___ ___ ___ ___(participant 11 __ ___ ___ ___ ___(participant 12)

2. Describe Incident (Please be as specific as possible and use IDs# instead of names)

_____
_____
_____
_____
_____
_____
_____
_____
_____

3. Describe any follow up actions taken by staff in response to incident

_____
_____
_____
_____
_____

THE EBAN II PROJECT

Negative Incident Report

4. List names of any staff or non-participants who witnessed incident.

Witness 1 _____ phone number(s):_____
Witness 2 _____ phone number(s):_____
Witness 3 _____ phone number(s):_____
Witness 4 _____ phone number(s):_____

5. Was this incident captured on audiotape? YES/NO
If yes, please submit a copy of audiotape with this report to PI

6. Was incident reported to police or any other authorities? YES/NO
If yes to whom and when was incident reported?

_____
_____
_____

Signature of Staff making report_____Date:__ __/__ __/__ __

(To be filled out by Principal Investigator)

Name of Principal Investigator:_____

Assessment of Incident (Please indicate how you reviewed incident and whether or not in your opinion this may constitute an adverse event)

_____
_____
_____
_____
_____
_____
_____
_____

Disposition of Incident (Check relevant category)
( ) This Incident does not constitute an adverse event and no further review is needed
( ) I have reported this incident to PI, DSMB or IRB for further review to determine if it is an adverse event of the study on __ ___/__ __/___ ___(indicate date of report to PI, DSMB or IRB).

Recommended Follow up Actions to Incident:

_____
_____
_____
_____

Signature of Principal Investigator:_____**Date**: __ __/__ __/__ __

8. Participant Referral Form

THE EBAN II PROJECT

PARTICIPANT REFERRAL FORM

FACILITATORS, AGENCY LIAISONS, AGENCY COORDINATORS: PLEASE COMPLETE THIS FORM WHENEVER AN INDIVIDUAL OR COUPLE IS REFERRED TO ANOTHER SOURCE.

Participant ID #: _ _ _ _ _ _ _

(If Couple referral) Partner ID#: _ _ _ _ _ _ _

Cohort ID# __ __ __

Name of staff making referral: _____ Staff ID#: __ __ __

Today's Date __ __/__ __/__ __ __ __

1. Date of Referral: __ __/__ __/__ __ __ __
2. Briefly describe participant's presenting problem or issue that led to referral:

_____

_____

_____

_____

3. Was referral made as a direct result of distress or negative incident that participant experienced in Eban II Project (Circle)?

   ❑ NO ❑ YES ❑ NOT SURE

   3a. If "Yes" or "Not Sure," please describe circumstances which led to referral.

   _____

   _____

   _____

4. What Agencies/services did you refer participant to? (PLEASE INDICATE ALL REFERRALS)

Name of Agency/Service (REFERRAL 1):_____

Type of services referred for:_____

Address of Agency/Service:_____

Phone Number of Agency/Service: ( ) _____

Name(s) of Contact: _____

Did staff or participant contact Agency/Service?

❑ NO, not yet ❑ YES ❑ NOT SURE

If yes, Services Requested: _____

If yes, Disposition of Referral:

❑ Participant did not receive services
❑ Participant received services
❑ Not sure

THE EBAN II PROJECT

PARTICIPANT REFERRAL FORM

Name of Agency/Service (REFERRAL 2): _____

Type of services referred for: _____

Address of Agency/Service: _____

Phone Number of Agency/Service: ( ) _____

Name(s) of Contact: _____

Did staff or participant contact Agency/Service?

❑ NO, not yet ❑ YES ❑ NOT SURE

If yes, Services Requested: _____

If yes, Disposition of Referral:
- ❑ Participant did not receive services
- ❑ Participant received services
- ❑ Not sure

Name of Agency/Service (REFERRAL 3): _____

Type of services referred for: _____

Address of Agency/Service: _____

Phone Number of Agency/Service: ( ) _____

Name(s) of Contact: _____

Did staff or participant contact Agency/Service?

❑ NO, not yet ❑ YES ❑ NOT SURE

If yes, Services Requested: _____

If yes, Disposition of Referral:
- ❑ Participant did not receive services
- ❑ Participant received services
- ❑ Not sure

9. Protocol Violation Report Form

THE EBAN II PROJECT

PROTOCOL VIOLATION REPORT FORM

AGENCY COORDINATORS AND PI SHOULD FILL OUT THIS FORM IF AND WHEN THEY DETERMINE THERE HAS BEEN A SIGNIFICANT DEVIATION FROM THE INTERVENTION PROTOCOL

Name: _____
Position:_____
Staff ID#:_____
Site:_____
Today's Date:_____
Cohort/Group:_____

1. Study ID numbers of all participants involved in or affected by incident

___ ___ ___ ___ ___(participant 1) ___ ___ ___ ___ ___(participant 2)
___ ___ ___ ___ ___(participant 3) ___ ___ ___ ___ ___(participant 4)
___ ___ ___ ___ ___(participant 5) ___ ___ ___ ___ ___(participant 6)
___ ___ ___ ___ ___(participant 7) ___ ___ ___ ___ ___(participant 8)
___ ___ ___ ___ ___(participant 9) ___ ___ ___ ___ ___(participant 10)
___ ___ ___ ___ ___(participant 11 ___ ___ ___ ___ ___(participant 12)

2. Describe How Protocol was Deviated (Use Participant ID numbers not names when describing incident)

_____

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

3. How long did deviation take? __ ___ __ __ minutes

4. Describe any follow up actions taken by staff in response to incident

5. Was this incident captured on audiotape? YES/NO
If yes, please submit a copy of audiotape with this report to PI

Signature of Staff making report_____ Date:

Name of Principal Investigator:_____

Assessment of Incident where protocol was deviated (Please indicate how you reviewed incident and whether or not in your opinion this may constitute a protocol violation)

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Disposition of Incident (Check relevant category)
( ) This Incident does not constitute a protocol violation.
( ) I have reported this incident to UCLA to be reviewed as protocol violation on __ ___/__ __/___ ___(indicate date of report to UCLA).

Recommended Follow up Actions to Incident:

_____
_____
_____
_____
_____

Signature of Principal Investigator:

_____

Date: __ __/__ __/__ __

Protocol Violation Form

Name: _____
Position:_____
Staff ID#:_____
Site:_____
Today's Date:_____
Cohort/Group:_____

1. Type of Violation
    - o Site Procedures
    - o Biospecimen
    - o Data Collection
2. Describe Violation

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

3. Describe Site Action

The couple was allowed to be randomized and to continue in the intervention.

4. Date Protocol Violation Form sent to UCLA _____.

5. Date reviewed by Steering Committee _____.

6. Action taken by Steering Committee

THE EBAN II PROJECT

Cohort ID: __ __ __ Group ID: ___ Site #:__ __ Date completed: __ __/__ __/__ __ __ __

Session: 1 2 3 4 5 6

1. Facilitator ID# (completing form): __ __ - __ __ __ __- __
2. Co-Facilitator ID#: __ __ - __ __ __ __- __
3. Co-Facilitator's Signature _____
4. Intervention: ❑$_0$ Health Promotion ❑$_1$ Risk Reduction

Instructions for Completing Session Attendance Sheet

:

After each session, including break up and make up sessions, one Co-Facilitator should complete the corresponding column for that session.

The Co-Facilitator who does not complete this form should:

- Enter his or her ID #
- Sign the top of this form to indicate agreement with the reported information.

KEY:

0 = Did Not Attend Session: Participant did not attend the regular session and did not attend any make-up of that session.

1 = Abbreviated Review of a Missed Session: Participant attended a shortened make-up session.

2= Partial Regular Session: Participant attended part of a regular session (e.g., left early, arrived late).

- If a participant misses more than 15 minutes of a regular session without making up the time and information, it is a partial session.

3 = Full Regular Session: Participant attended a complete regular session.

- If a participant misses more than 15 minutes of a regular session, it is not considered a full session.

General Instructions, please indicate:

- Make sure all participants' **first names** and **last initials** are on the sign-in sheet. All participants in the group should be listed, so add those participants who are absent and circle 0. If it is a group session, add in any names of participants who did not attend. Circle "0" if the participant did not attend the session, "1" if the participant attended an abbreviated review of a missed session, "2" if the participant attended a partial regular session, and "3" if the participant attended a full regular session. Circle only one number.
- The date of the session.
- Circle the number of the session being administered.
- Enter cohort ID and Group ID.
- Enter site #

THIS FORM IS TO BE TURNED INTO THE AGENCY LIAISON AFTER EACH SESSION

10. Session Attendance Form

THE EBAN II PROJECT

Cohort ID: __ __ __ Group ID: ___ Site #:__ __ Date completed: __ __/__ __/__ __ __ __

Session: 1 2 3 4 5 6

Please Print Your First Name and Last Initial	Level of Session Completion (Completed by Facilitator)			
1. _____	0	1	2	3
2. _____	0	1	2	3
3. _____	0	1	2	3
4. _____	0	1	2	3
5. _____	0	1	2	3
6. _____	0	1	2	3
7. _____	0	1	2	3
8. _____	0	1	2	3
9. _____	0	1	2	3
10. _____	0	1	2	3
11. _____	0	1	2	3
12. _____	0	1	2	3

11. Summary Referral Form

THE EBAN II PROJECT

Cohort ID: _____ Group ID: __ Site #: _____ Date of Session: ____/____/_____

Participant ID: _____

Summary Referral Form

FACILITATORS, AGENCY LIAISONS, AGENCY COORDINATORS: PLEASE COMPLETE THIS FORM TO SUMMARIZE ANY REFERRALS MADE FOR COUPLES OR INDIVIDUALS THROUGHOUT THE PROGRAM.

1. Was this a couple referral? ❑$_1$ Yes ❑$_0$ No

If Yes, who referred this couple? _____

2. Today's Date: ____/____/_____

Type of Referral Made	Referral result of distress/negative incident from EBAN II?	Did participant receive service?
Department of Health	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't know
VA	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't know
Hospital-based Clinic	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't know
Non-Hospital-based Clinic	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't know
Community Based Organization	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't know
AIDS Service Organization	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't know
Physician Referrel	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't know
Church Services Organization	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't know
Media	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't know
Word-of-Mouth	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't know
Housing Facilities	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't know
Other Research Studies	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't know
Other _____(specify)	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't know

12. Visit 3 Checklist – Facilitator Forms – Post Group

THE EBAN II PROJECT

Couple ID: __ __ __ __ __ __ __ Site #:__ __ Visit #:__ __

Date:__ __/__ __/__ __ __ __ Staff ID: __ __ __

Visit 3 Checklist

ADMINISTRATIVE

The following CRFs and materials will be needed for this visit

- ❑ Couple Eligibility Criteria (COPELIG)
- ❑ Randomization (RAND)
- ❑ Randomization Assignment Envelopes
- ❑ HIV/STD Tracking Form (HIV/STDTRACK)
- ❑ Locator Form (for review)
- ❑ STI referral information
- ❑ Reimbursement form

	Male	**Female**
Are they still eligible?	❑ Yes ❑ No	❑ Yes ❑ No
		If "No" OK to contact in future? ❑Yes ❑ No
Are they still participating?	❑ Yes ❑ No	❑ Yes ❑ No

- ❑ Confirm Couple Eligibility
- ❑ Complete Randomization and record assignment
- ❑ Complete Intervention Session #1
- ❑ Provide HIV/STD Notification Letter (if needed)
- ❑ STI referral for treatment
- ❑ Provide Reimbursement
- ❑ Update couple contact information
- ❑ Assess couple support needs (travel, childcare, etc) _____
- ❑ Schedule Visit 4 (7-10 days) Date:_____
- ❑ Make a reminder call

Notes: _____

_____