

HPTN 037 INTERVENTION MANUAL

General Overview of the 037 Research

The HPTN 037 research study will test a peer-based educational and counseling program to see if it can reduce the spread of HIV by changing behavior in a substance user population. Half of the study participants will be assigned to a “control group” which will receive the standard HIV and harm reduction counseling. The other half will be assigned to attend special training sessions that facilitators will conduct; this group will also receive the standard HIV counseling that is offered to everyone in the study

This research is taking place in Thailand and Philadelphia, and other locations may join later. *In research, it is crucial that the protocol is followed and study is conducted in a consistent manner across all study sites and over time.* Careful attention to the details will help ensure that the data are valid when the study is completed. We will also be able to provide a clear description of the intervention and how it was delivered in all the study locations.

This manual is intended to guide facilitators in the delivery of the intervention and to ensure that it is delivered and reported accurately.

General Guidelines for Facilitators

- ✔ **Facilitators will use this manual while conducting the sessions for the 037 study.** The site supervisor and an independent reviewer will listen to audiotapes to assess content and quality of the intervention.
- ✔ **It is essential that all of the topics that are listed in the “Overview” be covered during a session.** Information for each session is provided for the facilitators in a script format.
- ✔ **Strict adherence to the script for each session is not required; however, the content must be closely covered.** The facilitator does not have to read the script verbatim, but may until he/she is comfortable with the information. The facilitator should be thoroughly knowledgeable about the content before the session begins. Then, during the session the facilitator can present the information in a less formal manner so that discussion and group participation is encouraged.
- ✔ **Group facilitators are not expected to be able to answer all questions or needs that arise.** The facilitator is expected only to master the content and exercises of this manual. If participants ask for information or services that the facilitator cannot provide, the facilitator should seek advice from their supervisor or study coordinator.
- ✔ **Group facilitators are not therapists.** If personal issues arise for a participant (such as anger about HIV or losing their job), you may want to ask the

study staff for referral information or suggest to the participant that they seek help from a local agency.

☑ **Group sessions are not support groups.** Participants may share many personal things in the groups, and at times, need support for what they have shared. Facilitators may offer praise for willingness to share, but gently and quickly bring the focus back to the group activity. As mentioned above, group leaders are not therapists and can talk to individual participants after sessions and provide them with referrals.

☑ **Confidentiality must be maintained and emphasized.** It is very important to stress the importance of confidentiality during the sessions for both participants and facilitators. Knowing that confidentiality is expected and trusting that it is maintained, helps establish an environment in which people can talk honestly and openly.

Preparing for Each Session

Each session in the Manual contains:

Objectives: the primary tools that participants are expected to develop during each session

Materials in Session: items needed to accomplish the objectives

Overview: topics that must be covered during the session and the estimated time it takes to complete these activities.

Script: detailed procedures that facilitators will use to conduct the session.

There are many activities in each session that are designed to accomplish the objectives. Facilitators have some flexibility in presenting the educational messages, but each activity or discussion that is listed in the “Overview” of each session must be discussed during the course of the session.

☑ **The sessions must be covered in the order presented here in the Manual.** Each session builds on the previous session.

☑ **The activities should be presented in the order presented here in the Manual.** Each activity builds on the previous activity, so it is important to do them in the right order. If you must skip a particular activity, for example, the VCR might not work at Session 2, be sure to write a note about that on an index card and insert into the tape box.

☑ **It is important to start and end on time and watch the time limits of each activity.** Although we encourage participants to engage in conversation and explore the session topics, try to avoid “chats” about personal situations, politics, etc. Group size and dynamics may greatly influence the amount of time spent on a given topic or in a specific activity, but facilitators can help move the activities along so everything gets accomplished during the session.

If a session must end early, the session may be continued at the next scheduled meeting date. However, the next session should NOT be tacked onto the “continued session.”

For example, if the power goes out in the middle of Session 3 on Tuesday, you would complete Session 3 on Thursday (or your next scheduled time). At the end of the session 3 content on Thursday, the group is concluded for the day. The group returns next Tuesday for Session 4. Be sure to write an explanation for this on index cards and include it in the tape boxes; also note this schedule change on the Site Session Content Checklist.


Materials Needed for Each Session

Part of the facilitators’ role is to make the necessary preparations before each session. Making the preparations includes getting any necessary equipment, supplies, and handouts ready, and making sure all the materials are well organized prior to starting the session.

There are samples of the materials facilitators need for each session included in this Manual. These are offered as a convenience to the study staff. Sites may make their own material, but the content must match the content that is presented in this manual.

For example, a site may re-design how the “Injection Risk Ladder” looks as long as the risk behaviors are the same as the samples in this Manual.

Taping Each Session

 **Each intervention session will be audio taped.** The supervisor and an independent reviewer will listen to these tapes to ensure that the Intervention was delivered accurately. Prior to starting each session, the facilitators should remind participants that, if they want to turn the tape off, they may do so. The tape should be re-started when the participants feel comfortable again with the taping. Facilitators will indicate on the Site Session content checklist that the tape was shut off for a specified period of time.

- Position the microphone so it clearly records all voices
- Test tape equipment before starting each session
- At beginning of session, each facilitator will speak their leader number, the date, and the session number into tape recorder.

Example: “This is Facilitator number 123 on Sept. 20, 2003.” The second facilitator also says, “This is Facilitator number 124 on Sept. 20, 2003. This is session 3.” This will be very important to the outside reviewers who will listen to the tapes.

- Tape entire session, making sure to have 2 labeled tapes available if needed
- At end of session, rewind a few minutes and listen to tape to ensure quality

- Prepare labels clearly and accurately as shown below and attach directly to tape

Date ____/____/____	Group #: ____
Facilitator #: ____	Session # ____
Facilitator #: ____	Tape # ____ of ____

- Return tapes and taping equipment to study staff.

If for some reason, the session is not taped or is only partially taped, or if the facilitator would like to explain a special situation, the facilitator should write a note on an index card stating the circumstances. Be sure the card also includes the date and session number. Put the note inside the tape box along with the tape.

Documentation of Session

There are two pieces of documentation required at the end of each session:

The **Site Session Content Checklist**. This form will collect the date of session, the facilitators' ID numbers, and the topics covered in each session. There is also a space for facilitators to write comments. Be sure to use this space to explain an unusual or special circumstance that occurred during the session.

A list of attendees, preferably a sign-in sheet with each participant's signature.

These two documents are to be stored in a secure location at the site and will be checked by monitors who visit the site quarterly.

Finally . . . a note to the facilitators

Remember that HIV/AIDS information changes over time. It is a good idea to stay updated. And many thanks for helping to conduct this very important research!