

Counseling Potential Participants About a Clinical Trial

If you are counseling a potential study participant about a clinical trial, the following questions are a convenient way of organizing the information you want to review.

What is the purpose of this study?

- ◆ Why is the study being done?
- ◆ What medicines are being studied?

What are the risks and benefits of participating?

Risks

- ◆ What are the treatment groups?
- ◆ How is it decided to which treatment group the participant is assigned?
- ◆ What is known about the potential side effects or risks associated with the study medicine? What is known about the side effects and risks of standard treatment?
- ◆ What happens to the participant if he or she experiences side effects during the trial?
- ◆ Is there a placebo group in this study? (What is a placebo treatment?)
- ◆ Will the participant know which treatment he or she is receiving?
- ◆ What happens if the participant's condition worsens during the trial?
- ◆ How will this study affect future treatment options for the participant?

Benefits

- ◆ What is the chance of receiving the study medicine vs. being assigned to a control group?

- ◆ Why do the researchers believe the treatment being studied may be better than the one being used now? Why might it not be any better?
- ◆ What are the potential benefits of the study medicine vs. other treatment?

What are the alternatives?

- ◆ Will the participant be started on HIV treatment during the trial if he or she would otherwise not be advised to start (or change) HIV treatment?
- ◆ What are the alternatives to participating in this trial?
- ◆ How does the study treatment compare with the other available treatments?

What will be required of participants?

- ◆ How often must the study medicine be taken, and what time of day?
- ◆ Who will care for the participant during the trial? Will the participant see the usual health care provider?
- ◆ How often will the participant have to come to the clinic?
- ◆ How long will clinic visits generally take?
- ◆ What tests and exams will be done during these visits?
- ◆ Is there a way to contact someone after clinic hours if the participant has any urgent questions or important concerns about treatment, side effects, or symptoms?
- ◆ How long will the study last?
- ◆ Does the participant have to pay for any of the treatments, tests, or visits?

- ◆ Are there medications or treatments that the participant cannot take during the trial?
- ◆ Are there any restrictions for the participant related to birth control or pregnancy?

What are participants' rights?

- ◆ Who will know that the participant is on the study?
- ◆ Who will see the medical records of the participant during the study?
- ◆ If the participant decides not to participate in the study, or stop participating during the study, will the clinician still care for him or her?

- ◆ What will happen if the participant change his or her mind about participating after the study begins?
- ◆ What happens if new information about the medicine is discovered during the trial?
- ◆ Will the participant be told the results of tests and examinations during the trial?
- ◆ Whom should the participant speak with if questions arise about the study or the rights of the participant?
- ◆ When the study ends, will the participant be told the results?
- ◆ After the study ends, will the participant still receive the medicine if it is effective?

These general statements below focus on the benefits and risks of participating in any study.

Reasons to join a study	Reasons not to join a study
Early access to a new medicine that may be beneficial	May be assigned to the control group and not receive the experimental medicine
Access to free medicine and testing. For some people, a clinical trial may be the only access to HIV treatment.	The clinic may be inconveniently located.
Access to high quality medical care with expert clinicians at leading medical centers	Experimental treatment may have unexpected side effects or may not be effective.
More frequent, intensive monitoring	May require too many clinic visits or longer clinic visits
May get satisfaction from helping others by helping to advance medical knowledge	May require using contraception or a specific type of contraception for the duration of the study