WHAT IS RESEARCH?
Research is a way to study the safety and effects of a new medicine, treatment, procedure or a person’s behavioral change. The studies can have several names such as clinical trial, intervention study, clinical research, observational study, or behavioral study. They also can have several phases or steps, such as phase I, II, III, IV. Sometimes a study may just be called a “pilot study,” which is being tried out in a small group before going to a larger group.

In the field of HIV & AIDS we have had the success we see today thanks to the many volunteers who took part in research. But many questions still remain, so learn more and get involved.

You can look around the following website to obtain information about most HIV/AIDS clinical trials currently underway or planned in Florida:
www.clinicaltrials.gov

WHAT YOU SHOULD KNOW BEFORE YOU START

PARTICIPATING IN A RESEARCH STUDY IS ALWAYS VOLUNTARY

YOU CAN WITHDRAW FROM THE STUDY AT ANY TIME WITHOUT ANY PENALTY AND STILL RECEIVE THE CARE FROM YOUR PROVIDER WITHOUT ANY PROBLEM

YOU SHOULD ALWAYS HAVE YOUR QUESTIONS ANSWERED BY THE STUDY TEAM TO YOUR SATISFACTION

BE COMFORTABLE WITH YOUR PARTICIPATION

The AIDS Institute is a national organization that promotes action for social change through research, public policy, advocacy and education.

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WHY IS RESEARCH DONE?
Research looks at different ways to prevent diseases, treat illness, discover new diseases, find cures, and control symptoms. Whenever possible, research on people begins after research has been completed in the lab and/or with animals.

RESEARCH IS IMPORTANT TO MAKE SURE THE NEW DRUG, MEDICAL PROCEDURE OR VACCINE BEING STUDIED:
- work as well as or better than what is currently used
- does not have severe side effects
- promotes a feeling of well-being
- gets the right result
- is safe

Studies also have to be reviewed by an independent human subject protection review board which is called an “institutional review committee” or “Institutional Review Board (IRB),” among other names. These committees help to make sure participant interests are protected, and that they will be safe during the study. The committees are made up of scientists, doctors, nurses, pharmacists, psychologists, clergy, patients, and community volunteers. The US Food and Drug Administration (FDA) also requires additional safety measures for patients in research studies.

In the past, you may have heard of studies where the well-being of the participants was not protected, such as the Tuskegee Experiment. In this experiment, which began 80 years ago, syphilis treatment was not provided to a group of African-American men for many years (at that time, there were not any laws or rules to protect the study participants). Today, this is not the case, and many laws are now in place because of what happened in that study. New Federal guidelines and codes of research ethics were created to protect all research volunteers from harm. One such change is the requirement that an IRB must be involved to assure that participants are fully informed about all aspects of the study, including the risks and benefits.

WHY IT IS IMPORTANT THAT ALL OF US CONSIDER PARTICIPATING IN RESEARCH?
Diseases and treatments may affect all of us differently whether we are African American, Hispanic, or Caucasian - female, male or transgender - young or old. To be sure that medicines are going to work for everyone, we can all help by participating in studies.

WHAT SHOULD YOU CONSIDER BEFORE YOU DECIDE TO PARTICIPATE?
Before saying yes to participate in a research study, you should ask your provider what you can expect, what are the risks and benefits.

**BENEFITS** can include:
- Getting treatment for an illness when none exist
- Getting expert care for your disease
- Getting early access to the medicine/treatment
- Getting medications for free
- Knowing you are helping others with the same condition as you
- Getting someone in person (research nurse) to talk to

**RISKS** can be:
- Not being able to choose your treatment
- Receiving a treatment that may not work as expected
- Having unpleasant or serious side effects

**EXPECTATIONS** can be:
- Attending clinic on specific days and times, often more than usual
- Having tests done that you normally would not have
- Being in regular contact with the research team
- Having to stay in the area throughout the study

MAKING THE DECISION
When talking to the study team about participating in a study, you will be provided with a written informed consent. This document should answer most of your questions and must be signed if you want to participate in the study. You should be given plenty of time to read it and have time to ask questions including taking it home to talk with family and friends. Any study should be discussed with your care provider prior to participation, since the care provider can offer advice and additional information regarding the study and your participation.

SOME QUESTIONS YOU MAY WANT TO ASK BEFORE AGREEING TO PARTICIPATE ARE:
- What is being studied?  
- How many people have been on this treatment?  
- What is known about the treatment?  
- Will I know what treatment I am getting?  
- What do I have to do?  
- Will I have to pay anything?  
- Will I get help with transportation or childcare?  
- Who will know about my participation?  
- How is my personal information protected?  
- What happens if it doesn’t work?  
- If it works, can I still get the medicine when the study ends?  
- Will my medical expenses be paid?  
- Can I still see my own doctor?  
- Do some people not get the drug in the study?  
- How long will I be in the study?  
- What happens if I am injured because of the study?  
- Will my medical expenses be paid?  
- If I don’t want to be on the study, what other options or treatments do I have?  
- Can I quit at any time?  

The answer to the last question above is always YES!