



What is Observational and Behavioral Research?

Observational research is a type of research where the researcher observes without interfering in the care of patients.



An opinion study is one way of conducting observational research. This type of research involves designing a study and collecting measurable data. Questionnaires are an effective way of obtaining

opinions or preferences in order to measure the data being collected.

Medical or health record studies are another form of observational research. These studies may include gathering information from medical records and analyzing the data. This is done without participating in the care of patients.



Other studies involve re-viewing already completed clinical trials.



Where can I learn more about research studies or find research studies to participate in?

www.clinicaltrials.gov

This brochure was done in collaboration between the Florida Consortium for HIV/AIDS Research and the University of Florida Center for HIV/AIDS, Research, Education & Service (UF CARES).

www.fchar.org



Questions to Ask Before Agreeing to Participate in a Study:

- What is being studied?
- What are the risks and benefits?
- 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?
- Will my insurance cover the costs?
- Can I still see my own doctor?
- How long will I be in the study?

It is very important that you understand you can change your mind at any time and drop out of the study without any penalty. This is always stated in the consent form.



Behavioral studies usually involve observing a participant's behaviors in certain circumstances. For example, sometimes study participants are divided into two groups, where only one group receives special education about HIV prevention. This way, we can see whether or not the special information leads to safer behaviors.

Why is Research Done?

- To discover ways to prevent disease, illness, or a condition
- To treat disease, illness, or conditions
- To discover new diseases
- To find ways to control symptoms of disease

Why is Research Important?

Observational and behavioral studies are important because they:

- Identify possible long-term effects of living with HIV
- Identify possible long-term side effects of drugs used in the treatment of HIV and/or drugs used to treat co-morbidities, such as, high cholesterol, diabetes, and high blood pressure
- Promote finding answers to scientific questions and apply findings to improve care
- Can lead to more effective HIV prevention measures and improved linkage and adherence to care.



How Long Do Observational or Behavioral Research Studies Last?

The length of time a study can take varies depending on the study and how many participants are needed for the study. For example, some pediatric trials may follow children from birth until 18 years of age. In some studies, participation can take only a few hours time.



Why is it Important That Everyone Considers Participating in Research?

Diseases and treatments may affect us differently depending on our age, race, or ethnic heritage. To be sure that treatments will work for everyone, we can all help by participating in studies. Some other reasons that people volunteer to participate in trials include:

1. To take an active role in their healthcare
2. To gain access to additional labs/tests that may not be available to the public
3. To obtain expert medical care at leading health care facilities during the trial
4. To help others by contributing to a broader scope of knowledge



Participating in a research study is always **voluntary**. Participants can drop out of the study at any time. If the participant withdraws from the study they can still receive care from the provider without any penalty. All personal information is protected and kept confidential. The participant should always have all questions answered by the study team and be comfortable with participation.



Making the Decision:

When talking to the study team about participating in a study, the participant will be provided with a written informed consent. This document should answer most questions and must be signed in order to participate in the study.

The participant should be given plenty of time to read the informed consent and have time to ask questions. Any study should be discussed with the participant's care provider prior to participation, since the care provider can offer advice and additional information regarding the study and participation.



Risks Can Include:

- Discomfort due to lab testing, such as drawing blood
- Feeling that you are not a part of the study if it is a medical record review study
- Not seeing effects of your participation in the study
- Feelings of invasion of privacy
- Small risk of loss of confidentiality, although all personal information is carefully protected

Participant Expectations Can Include:

- Attending clinic on specific days and times, often more than usual
- Additional tests and labs completed
- Contact with a member of the research team on a regular basis
- Staying in the area where the study is conducted throughout the duration of the study



How Safe is Research?

Observational studies are relatively safe since there are no interventions or treatments administered.

All observational and behavioral studies have to be reviewed by an independent human subject protection review board. This board is called an “institutional review committee” or “Institutional Review Board (IRB)”.

These committees protect the participants’ interests who are involved in the study. They also ensure that the participants will remain safe during the study. The committees are made up of scientists, doctors, nurses, pharmacists, psychologists, clergy, patients, and community volunteers.



There are Federal guidelines and codes of research ethics that were created to protect all research participants from harm. One guideline is that an IRB must be involved to assure that participants are fully informed about all aspects of the study, including the risks and benefits.



What is Consent and Who Signs the Consent Form?

Consent is a document signed by participants, which indicates they understand what they are agreeing to by participating in the study. The consent form includes:

- Purpose and duration of the study
- Risks and benefits of the study
- What other treatments or options may be available
- Any diagnostic procedures, labs, and/or behavioral interventions that can be expected in the study
- An explanation that it is alright to drop out of the study at any time without any penalty



The study coordinator/research staff is responsible for going over the consent form with the participant, explaining the study and answering any questions. The participant then signs and dates the consent form. The consent form may also be co-signed by a witness and the principal investigator (PI) or the PI's designee. A copy of the consent form is given to the patient.

In the case of minors, the legal guardian can sign the consent form, and the child signs a simplified version of the form, if he or she is 8 years old or older. This age



What Should You Consider Before Participating in a Research Study?

Before you commit to participating in a research study, you should ask your provider what to expect. Take into consideration:

- Risks and benefits of the study
- Time commitment
- Duration of the study
- Any additional information the provider presents to you



Benefits (depending on the study) Can Include:

- Receiving diagnostic tests, at no cost to you, that might not be covered by insurance
- Receiving expert care for your disease or condition
- Receiving developmental and cognitive testing, for your child, that otherwise might not be ordered
- Knowing you are helping others with the same condition as you
- Having someone, such as a research nurse to talk to about your condition and help coordinate your care