VAIL HEALTH

RESEARCH PARTICIPATION

Considering participating in a research study?

Deciding whether to participate in research is your choice. That choice may involve many considerations, whether you are looking to participate yourself, or if your child, friend, or someone for whom you are a caregiver has been asked to participate in research. Here are some resources you may find helpful in making your decision.

WHAT IS RESEARCH?

Research is how scientists and other professionals obtain information to answer questions that they hope will help benefit society. Researchers conducting medical research often ask volunteers to take a medication or complete a task. The research can also involve collecting information about the volunteer. Medical research can lead to discoveries in several areas including new medication to treat cancer patients or improve educational programs. Since researchers use a variety of methods and study a wide range of topics, every research study is different. Some research may benefit you as a volunteer and some research may not benefit you. When considering volunteering for a research study, it is highly recommended that you gather necessary information and understand all the details involved in participating in the research.

TYPES OF RESEARCH

There are different types of research – clinical research, clinical trials, and social, behavior and educational research – and many different procedures used in research. Some of the studies involve medical procedures and multiple visits, while other studies may involve just a one-time survey or questionnaire.

WHAT IS CLINICAL RESEARCH?

The term "clinical research" describes studies to collect new information on human health and disease. Clinical research involves research participants to test new drugs, procedures, or devices, or to better understand how the human body works.

There are several types of clinical research studies:

Genetic studies find the role of genes in different diseases.

Prevention studies test ways to prevent specific diseases.

Behavioral studies test how people act in different situations.

Physiological studies increase understanding of how the human body works.

Clinical trials are studies of a drug, procedure, or medical device used in healthy participants or people who have a specific disease.

Clinical trials of new drugs are done in different phases to answer different questions.

PHASE I
Studies test a new drug for the first time in humans to see if it is safe.

PHASE II
Studies include more people to see if the new drug works.

PHASE III
Studies are done in large groups of people to see if the new drug works better than what is already available.

PHASE IV
Studies are done after the drug is approved by the U.S. Food and Drug Administration (FDA) to find out more information.

RESEARCH PARTICIPANT RIGHTS

If you are considering taking part in a research study, you should be aware of your rights as a research participant:

- To be treated in a caring and polite way.
- To be told what the study is trying to find out.
- To be informed what will happen, and whether any of the procedures (including any drugs, devices, or treatment methods) are different from what would be used in standard medical or psychological/emotional care.

- To be told about possible discomforts, or side effects, that may occur during the study.
- To be told if you can expect any direct benefit from being in the study and, if so, what the benefit might be.
- To be told of other choices for treatment you have, if any, and how the alternative treatment might be better or worse than being in the study.
- To be told what sort of treatment is available if any medical problems arise.
- To be allowed to ask any questions about the study both before agreeing to be involved and during the study.
- To be free from pressure when deciding if you want to be in the study.
- To be told about new information learned during the study that might affect your safety or your willingness to continue to take part in the study.
- To refuse to be in the study, or to change your mind about being in the study after it has started. This decision should not affect your education, your employment, or the care or services you receive from the institution conducting the research.
- To receive a copy of your signed consent form.

QUESTIONS FOR THE RESEARCH TEAM

When considering participation in a research study, below are some of the questions you should ask the research team to help determine if you want to participate.

Why is the study being done?

What will happen if I agree to join?

Could the study help me? Could it help others?

Could I get hurt during the study?

Will I be paid to participate in the study?

Will I have to pay for anything if I am in the study?

How will my personal information be protected?

What happens if I get hurt in the study?

How long will the study last?

Can I leave the study at any time?

Who should I call with questions about the study?

Additionally, the Office for Human Research Protections (OHRP) maintains a useful list of questions you can download, print, and ask a research team before participating in a study.
https://www.hhs.gov/ohrp/education-and-outreach/about-research-participation/questions-to-ask/index.html

HOW AM I PROTECTED IF I PARTICIPATE IN A RESEARCH STUDY?

Researchers design studies that keep the risks to participants as small as possible. There are also laws to protect participants.

- All clinical studies have a very detailed study plan called a "protocol" spelling out how the study will be done.
- A group of doctors, nurses, researchers, and members of the community looks carefully at each protocol. This group is called an Institutional Review Board or IRB. They make sure that the study is conducted fairly, with as little risk for participants as possible.
- When you enroll in a study, you will receive the contact information of the person in charge of the study, along with a phone number of the IRB, for any issues and questions related to safety.
- Some studies that have more risk also include another review group called a Data and Safety Monitoring Board (DSMB). A DSMB is made up of doctors who are not part of the study. They make sure that the risks of participating in the study are as small as possible.

RESEARCH PARTICIPANT RESOURCES

- **OHRP VIDEOS** The Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) videos provide basic information on research participation.

  https://www.hhs.gov/ohrp/education-and-outreach/about-research-participation/informational-videos/index.html

- **NIH.GOV** contains many useful resources, including information on clinical trials taking place in the United States, and all over the world.

  https://www.nih.gov/health-information/nih-clinical-research-trials-you/finding-clinical-trial

- **CISCRP** (Center for Information and Study on Clinical Research Participation) is a nonprofit organization dedicated to educating and informing the public, patients, medical/research communities, the media and policy makers about clinical research and the role each party plays in the process.

  https://www.ciscrp.org/

- **CENTERWATCH** provides information on clinical trials for research participants and professional researchers.

  https://www.centerwatch.com/

- **CLINICALTRIALS.GOV** is a searchable database of active research studies.

  https://www.clinicaltrials.gov/

RESEARCH COMPLAINTS OR CONCERNS

If you have a general question (e.g., where to go for your study visit, when you should expect to receive compensation), concern (e.g., you think you may be experiencing a side effect of the research intervention, you are not sure if you can make your next study visit) or complaint (e.g., it was hard to find the research site, the person at the reception desk wasn't expecting you), you should first contact the research team, and specifically, the principal investigator whose name and phone number is listed on the consent form.

If you have a complaint or concern that you feel should be reported and investigated (e.g., you were not fully informed about what the research involved, you feel as though the consent process was rushed, your questions were not sufficiently answered, you felt as though your rights were violated) please contact the VH IRB Office: irboffice@VailHealth.org

Disclaimer: This material is the work of the New England Research Subject Advocacy Group and Boston University Office of Research.

ABOUT VAIL HEALTH

With a focus on providing access to higher quality, more affordable care, Vail Health is a nonprofit community health care system offering one of the world's most advanced mountain hospitals. Vail Health includes award-winning oncology care and a state-of-the-art cardiac catheterization lab, as well as internationally renowned orthopaedic specialists led by The Steadman Clinic and Vail-Summit Orthopaedics & Neurosurgery. Primary, specialty and behavioral health care are provided through its partner, Colorado Mountain Medical. Vail Health is committed to meeting the growing and ever-changing needs of the diverse region and encouraging wellness and prevention through effective population health management. Vail Health is locally operated and governed by a volunteer board of directors. For more information, visit VailHealth.org.