Research Participant Resources

So, you are considering being a research participant?

This document provides important information to keep in mind.

Who are we?

The Office of Research Integrity (ORI) provides broad oversight, resources and education for integrity and compliance issues relating to the conduct of research at the University of California, Riverside. We strive to promote excellence in research while ensuring compliance with federal and state regulations. The Office of Research Integrity has oversight and responsibility over the research compliance committees on campus. For the purposes of this page, we will be discussing human subjects research.

What is an Institutional Review Board (IRB)?

The Institutional Review Board- Socio-behavioral (IRB-SB) and the Institutional Review Board-Clinical (IRB-Clin) review and approve studies that involve human research participants. These committees are independent from the studies they review. The membership of the committees include faculty, medical personnel, scientists, and people from the community. They review human research to make sure it is well-planned and that the study has a favorable risk-benefit ratio. The IRBs serve to protect your rights and your welfare prior to the initiation of the research. The IRBs may also review studies while they are ongoing to make sure volunteers are protected.

The IRBs do not decide for you nor endorse any particular study. Whether or not you should participate in a research study is a decision for you to make after contemplation of the risks involved. You are encouraged to compile a list of questions and call the study coordinator or principal investigator for answers (see 'What questions should I ask?' below) before enrolling in the research.

If you have questions, concerns, or complaints about your involvement in the research, you should talk to the research team. If the issue is still unresolved or you had an unpleasant experience or have questions about your rights, please contact the IRB at (951) 827 - 4802 or irb@ucr.edu. You can also send a letter to 900 University Ave, UOB 216, Riverside, CA; 92521. Please provide as much information as possible (dates, names, location, study title, etc.).

We will review your comments/concerns/questions and then best determine how to assist you.

Additional general information regarding human participant research protections can be obtained from the U.S. Department of Health and Human Services Office for Human Research Protections,

www.hhs.gov/ohrp
(866) 447-4777
1101 Wootton Parkway, Suite 200
Rockville, MD. 20852
ohrp@osophs.dhhs.gov
fax: (240) 453-6909

(You should contact the IRB, not OHRP, regarding complaints or issues regarding participation in a specific study)

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What is a research study?

A research study collects information to learn more about a problem, answer questions and/or test ideas for the benefit of society. Faculty, students and staff conduct different kinds of studies in various fields. For example, a research study may test whether a treatment is safe and effective, attempt to find out what health care practices work best, or seek the best way to prevent an illness. A research study may use a survey or an interview to understand feelings people have about their health. People might participate in research about things like:

- how or why an illness occurs or spreads
- what treatments work best for an illness
- how people behave or make decisions
- the ways groups and societies are organized
- what people think or believe
- how people learn
- the best ways to provide social services or healthcare

Another type of research study is called a “clinical trial.” That is a name for research about health and illness in people, especially when the research compares treatments or uses experimental drugs or devices. A clinical trial is a research study that will try to decide whether new treatments are safe and effective. In clinical trials, treatments may be compared with placebos to check the effectiveness of those treatments. A placebo is an inactive substance which may resemble an active substance (often it’s a sugar pill that has no value to treat or prevent an illness). Also, a drug or device is called "experimental" when the U.S. Food and Drug Administration (FDA) has not approved it for that particular use or indication. Clinical trials are usually divided into different phases which range from Phase I to Phase IV.

Please be aware that the ORI does not maintain a list of UCR research studies.

Who can be a study participant?

Study participants can be healthy volunteers, or they can be people who have specific diseases or conditions. They may test a drug or treatment, or they may serve as a control population which does not get either the drug or treatment being tested or a placebo. The participant may be compensated or not, depending on the research design.

Children can also participate in research studies. However, there are additional protections for children. For example, the parents or legal guardians must provide permission for the children to participate. In addition, if a child is old enough to understand what the study is about, the child may also be asked to give his/her agreement or assent to participant in the research.

What does a study participant do?

By volunteering to participate in the research, participants help researchers in many different ways. Depending on the goals of the research, participants might be asked to do things like:

- Take part in interviews (sometimes as part of a group)
- Complete questionnaires, tests or special tasks
- Allow access to private information (such as medical records or school records)
- Let researchers observe behavior
- Complete physical, psychological or other kinds of examinations
- Give samples of blood, saliva, urine or other materials
- Take experimental drugs or use experimental medical devices

If anyone asks you to take part in a research study, you always have the right to refuse.

Remember:

- Your decision not to participate will **not** affect how the service providers treat you
- You need to weigh both the risks and the potential benefits of the research study
- It may be helpful to talk with family members, friends, or your health care providers about participating in the study
- If you decide to volunteer for a research study, you **can** change your mind and stop or leave the research study at any time

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How do I start?

There are various ways: If you see an advertisement, you can call the number listed, a service provider may tell you that you qualify for a study and ask you to contact the researchers directly, you may hear about the study by word of mouth or you may see a study advertised on social media. These are just a few options.

How do I stop?

You always have the right to stop being a participant. Just tell the researcher you want to stop participating and withdraw from the study. In some cases, you may also ask to have your data withdrawn from the research and in other instances this may not be possible.

You do not have to explain your decision to anyone. You might feel less comfortable than you thought you would, or maybe the research takes up too much of your time. Nobody should pressure you into staying in the research if you do not want to participate.

You do not have to, but you might want to discuss any problems with the researchers before leaving. They might not be able to do anything if the research plan is not flexible, but it might be helpful for them to know why you cannot continue.

If you leave a medical study, you might be asked to come back once or twice for some extra safety tests. This is to make sure that you are not having any problems related to the study. You do not have to come back, but it is often important for your safety.

What is Informed Consent?

Informed consent is the process of learning the key facts about a research study before you decide whether or not to volunteer. Your agreement to volunteer should be based upon knowing what will take place in the research study and how it might affect you. Informed consent begins when the research staff explains the facts to you about the research study. The research staff will go over the "informed consent form" that explains these facts so you can decide whether or not you want to take part in the research study. These facts include details about the research study, tests or procedures you may get as part of the study, the benefits and risks that could result, and your rights as a research volunteer.

While Informed Consent is the default mechanism for securing consent from participants, in rare cases Passive Consent can also be used. Passive consent means participants are informed of the study, and are considered to agree to participate unless they specifically decline to be included in the study. There are some instances where consent can be waived by the IRB.

This is a list of different variations of consent:

Implied consent - Participation in the study is proof of consent. This is acceptable for studies that provide anonymity, such as opinion surveys.

Explicit consent - Participants give consent by answering a specific question about their willingness to participate. This may be done verbally or in writing (consent form).

Active consent - Participants indicate their willingness to participate by agreeing to a specific statement, and then are included in the study. This is the most common, and recommended, form of consent for research.

Written - Participants give their consent by filling out a consent form. Written consent guarantees active and explicit consent, thus offering the highest guarantees to the participants.

Oral/verbal - Oral consent should be considered when obtaining explicit, active consent is essential, but the risk or discomfort involved in the process is too great to make just written consent a valid option. This information is generally provided in conversations with the researcher and in written Consent Forms.

The Consent Form should be written so it can be easily understood. If you don't understand part of it, be sure to ask the researcher, doctor, or other study person to explain it. *Make sure you understand all of the information in the consent form before you agree to be in the study.* See “What questions Should I Ask” below.

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What are the risks and benefits of participating?

Risks – Sometimes research procedures and treatments may cause discomfort and side effects. The questions being asked could make you uncomfortable. The risks and side effects of the research study may not be known completely when you start the research study. The research staff will discuss with you known possible risks so you can decide if you want to volunteer. If you do volunteer, the research staff will tell you about any new risks that they learn about during the research study for as long as you take part in the research study.

Benefits - There may or may not be direct benefits to you if you take part in a research study. For example, your health or a health condition you have may get better as a result of your participation in the research study. It may stay the same. It may get worse. No one can predict what will happen with a research study or how it might affect you. Or the research study may not help you personally but it may provide information that will help others in the future.

Research is not the same as treatment. In medical research, many of the drugs, devices and procedures being tested are experimental. This means that they may have not been proven to work. There may be unknown risks, as well. Although being in a medical study might help you, nobody can guarantee a direct benefit for you. Most often the benefit is to future patients.

What are my rights as a research participant?

It is your decision whether or not you want to participate. In most cases, you do not have to decide right away if you wish to participate. You have the right to make this decision and be informed of the nature and reason for the study. There will not be any negative consequences if you refuse. You do not have to participate in any research offered by your doctor.

To help you make an informed decision, you have the right to receive information about the study. Information will almost always be given to you in writing ("informed consent form" or "study information sheet"). The information should be in a language you can understand. If you do not understand something, the study team must explain it for you in a way that you can understand. You have the right to ask questions at any time, and to have your questions answered. You should be informed regarding what will happen during the study and what risks, benefits or discomforts there may be. If you decide to participate, you will be asked to sign and date the informed consent form.

You also have the right to leave a study at any time. If you leave the study, your decision will not affect your relationship with University, or any rights or benefits to which you are entitled. You simply need to tell your study doctor or research staff that you have changed your mind. Depending on the study, the study doctor may ask you to come back for a final visit. This information should be included in the consent form or information letter provided to you.

UCR also suggests that the Experimental Subject's Bill of Rights or its Spanish equivalent be made available for all studies conducted at UCR. This document, according to California law, requires that anyone who is asked to be in a research study (specifically those in what are defined as 'medical experiments'), and anyone who is asked to agree for someone else to be in a research study, has the right to be informed regarding their rights in a language in which the person is fluent.

What questions should I ask?

Before you decide to volunteer to take part in a research study, you need to know as much as possible about the research study. If there are any issues that concern you, be sure to ask questions. You might want to write your questions down in advance or take this document with you. The following is a list of sample questions. Not every question will apply to all various research studies out there.

- Who is doing this research study and what question might it answer?
- Will this research study help in understanding my condition? If so, how?
- What tests or procedures will be done?
- Is it possible that I will receive a placebo (inactive substance)?
- Will I have to make extra trips?
- What could happen to me, good and bad, if I take part in the research study?
- How long will this research study last?
- What will happen to any specimens that I give?
- Who has reviewed and approved this research study?
- Could my condition get worse during the research study?
- What will happen if it does?
- What other options or choices do I have if I decide not to take part in this research study?
- Who will be in charge of my care?
- Will I be able to continue to see my own doctor?

- Will I be charged anything or paid anything to be in this research study?
- If I decide to participate in this research study, how will it affect my daily life?
- What will happen to me at the end of the research study?
- Will I be told the results of the research study?
- Who will find out that I am taking part in this research study?
- How do I end my participation in this research study if I change my mind?
- Whom do I contact for questions and information about the research study?
- Whom can I complain to if I feel that I have been mistreated or my rights have been violated?

Remember, if you do not understand the answer to any of your questions, ask again. Ask the person to explain the answer in a way you can understand it. If you forget the answers to the questions during the research study, just ask them again.

What information should the researcher give me?

The research team will explain the research study to you, and they will review any forms including the informed consent form with you. You should take your time during this process. The researchers will usually give you the information listed below. Some of the information below will only be given to you for medical studies.

- Why the research is being done
- Why I am being asked to participate
- How long my participation will last
- What will happen during the research (what you will do, the drugs you will take, etc.)
- How the research is different from your usual medical care (research is not the same as treatment)
- Any expected risks or discomforts that you might experience
- How information about you will be protected
  For example, Your information will be given only to the people who need it, which can include the researchers and staff who carry out the study, the IRB, the company or group funding the study and various government oversight agencies.
- Whether there are any expected direct or indirect benefits
- Whether there are any expected costs to me or my insurance provider
- What you can do instead of participating, such as what treatments you can take that might work for you, and how those treatments compare to the research procedures
- What medical treatment you will get in case of problems
- Who can help you with problems or give you more information about the study or your rights

You can take the information home. You can discuss it with your family, friends, a health care provider, or others before you decide whether or not to take part in the research study. If you decide to take part in the research study, you will be asked to provide your informed consent.

If you are concerned about any issues, or you do not feel like you have enough information, tell the researcher at any time before, during or after the research.

While you are participating, you also have the right to be given any new information that comes up. This information might include changes to what you will be asked to do, new risks or new treatment options. If you are given new information, you will be asked if you are still willing to stay in the research.

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What is the takeaway?

Questions, questions, questions! Make sure you ask questions until you are completely satisfied with the answers, and then ask more if another question comes to mind. There is never a 'dumb question' when you are participating as a research participant/subject. Do not forget that you are a volunteer helping the researchers and their job is to make this experience as comfortable as possible.

The most important thing to do is to take an active role and communicate with the study team before, during and after the research. You should always ask questions if you are not clear about something, if you are curious about something or if it seems like the research plan is different from what you were told. You have a right to have your questions answered!

If you feel uncomfortable with what you are doing, or if you think you might be experiencing changes in your health (whether good or bad), let the study team know so that they can help you.

Always keep in mind that participation in research is voluntary. If you feel like you are being pressured to join or stay in a study, you can always say no. You can leave the research at any time for any reason, and you do not have to explain your decision. You may, however, be asked to have certain procedures performed for you to safely withdraw from medical studies.

The following pages provide additional information.

- List of registered clinical trials around the world
- Precision Medicine Initiative Cohort
- Patient Centered Outcomes Research Institute
- Office for Human Research Protections
- US Food and Drug Administration
- The Belmont Report
- Presidential Commission for Study of Bioethical Issues
- HHS – About Research Participation