



HUMAN RESEARCH SHOULD I PARTICIPATE?

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What is medical research?

Medical research is an organized way of answering a question or finding particular information that contributes to health improvements.

What is human subjects research?

When research depends on human subjects to find information, it is called human subjects research.

Who is a research participant?

A research participant is anyone who participates in a research study and could be a healthy volunteer or a patient.

What kind of procedures are involved in research?

Procedures involved may include filling surveys and questionnaires, receiving experimental treatments, using experimental devices, or even undergoing surgical procedures. Before you agree to participate in a study, the procedures involved will be thoroughly explained to you by the research team.

Who is in charge of a research study?

The Principle Investigator (PI) is the individual who is in charge of the overall conduct of a research study. He/she is also responsible to ensure safety of the research participants that is more important to him/her than answering the research question.



Who else is present in a research study?

A research team usually assists the Principal Investigator in his/her study and may consist of co-investigators, research assistants, data coordinators, nurses, statisticians and others.

Who approves the research study?

All studies that involve human subjects are reviewed and approved by an Institutional Review Board (IRB) before the research is allowed to begin.

What is an Institutional Review Board (IRB)?

An IRB is a committee of healthcare professionals and non-healthcare related members of the community, usually based in an academic clinical center. It overlooks all human research projects. Its main role as a reviewer of research proposals serves its primary concern to protect the rights and wellbeing of research participants, to ensure privacy and confidentiality in the research and to ascertain the accuracy of the informed consent. The IRB also follows up on any complaints filed by research participants and ensures that possible breaches are spotted and rectified.

Who decides whether you participate?

The decision to participate is entirely up to you. It is not an obligation. However, the study investigators will decide if you are eligible to enroll or not based on preset inclusion and exclusion criteria.

Are there benefits to being in a research study?

The ultimate aim of research is to serve the community. As a research subject, you may not always benefit personally. Sometimes, your taking part in the study will only be of benefit by helping researchers to learn more about a certain disease or condition. The research team will inform you about the benefits of being in the study before you decide whether to participate or not.

Are there risks to participating in a research study?

Research studies may involve some risk; however the research team will inform you about any possible known risks of being in the study before you decide whether or not to participate. Remember that there might be some unanticipated risks as well.

What is the procedure for participation?

If you wish to participate, you are required to sign a consent form known as the "informed consent". It is a vital part of research. It is more than obtaining your signature prior to enrolment in a study. Obtaining an informed consent is a process that needs thorough interaction between you, a potential participant in a study, and the researcher running a study.

What is meant by informed consent?

Informed consent is the process by which you, as a research participant, are given all the necessary information that will help you decide whether you would agree to participate in the research study in question. The person who will provide you with this information will have to tell you the aim of this study, the results from previous similar studies, what is required from you as a research participant, what are the benefits as well as the harms that may ensue as a result of participating in this study. You will be informed about the time you will have to spend in this study. You also need to be told about other alternatives. You will have the chance to ask questions about every aspect of the study.

What are your rights as a research participant?

As a research participant, you have rights. Understand your rights well to make sure they are not violated.

1. The right to make your own decision:

By law, you and only you are the one in charge of deciding whether you want to participate in a study or not. You should not feel obliged even if your physician asks you to do so. You can always refuse and this should not result in any negative influence on you.

2. The right to understand:

You should understand clearly and completely the kind of research you are asked to participate in. The researcher is supposed to meet you and provide you with all the necessary information.

3. The right to ask questions:

You have the right to develop and raise any question at any time before, during or after the completion of a study. The researchers are obliged to address your questions properly.

4. The right to take your time:

For almost all studies, you are not obliged to make an immediate decision. You should be allowed to take the necessary material home, read them thoroughly, and slowly make up your mind.

5. The right to leave the research at any time:

You have the right to withdraw from any research at anytime during the study. No penalty or loss of a benefit to which you were otherwise entitled will ensue. You do not even have to justify the reason. However, sometimes if you were receiving a treatment as part of the study, an abrupt interruption of this treatment may result in hazardous outcomes. Hence, you are always advised to notify the researchers ahead of time.

6. The right of confidentiality:

During research, data is collected from you. You have the right to protection of your data. Your data can only be accessed by the investigators and researchers directly involved in the study, the IRB, and regulatory agencies.

What are your obligations as a research participant?

Just like you have many rights protected by law, as a research participant, you also have certain obligations to ensure that the research is conducted properly and its results will be of reliable value. You must respect the rules of the research and abide by them. Those rules differ for each research but you may be obliged to do tests or interventions at an empty stomach, or take a pill at the same time every day, etc.

Before you participate

It is important to know as much as possible about a research study before you decide to participate. Make sure you ask all the questions you need. No matter how “not important” the question might seem to be, it is still your right to know. Here is a list of questions that might be important for you to check, whether you just signed the consent, or even during the study.

1. Will I benefit from the study?
2. Who is doing the study and what is its purpose?
3. Was this study approved? By whom?
4. How long will the study last and how long will I be committed to it?
5. What tests, procedures or measurements will be done, and are they suitable for me?
6. Who finds out about my participation, who will have access to my information, and what happens to the specimens I give?
7. How will my personal information be protected?
8. Will I be told about the results of the study?
9. Whom do I contact for questions?
10. How do I end my participation if I change my mind?
11. What risks are involved in the study? Does participation affect my daily life?
12. Will I have to pay extra costs for any procedure or medical tests that may not be covered by the research study?
13. Will I be compensated if something goes wrong during the study? If so, how and by whom?

If the research involves any kind of treatment, ask your study staff:

1. Will I miss out on any “normal care” by participating?
2. If I refuse to participate, will there be any other alternative for me?

Can you change your mind about participating?

Of course!

It was **your** decision in the first place!

You can *withdraw* at any point without any penalty.

Be sure to inform the research staff about your decision.

Are there precautions to protect special populations?

Children, pregnant women, and prisoners can all be participants in research studies. However, they are considered potentially “vulnerable populations”. Special rules exist to protect you as a participant if you fall into one of these groups.

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