



# Are You Thinking About Being in a Research Study?

A guide to research participation.



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## Introduction

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Research discoveries can improve people's health (OHRP 2015). Before deciding to participate in a research study, you should learn about what to expect and where to find more information.

What is Research?	What is Research Involving Human Subjects?
Research is the collection of information and/or biological specimens (like blood, saliva, or tissue) to obtain more knowledge or to answer a specific question about a certain topic. Gathering information or testing an idea in an organized manner is helpful to better understanding a topic. A "researcher" or "investigator" is the person who conducts research. A researcher may get help and support to conduct research from members of a team.	When research calls for obtaining personal information from, or about people, it is research involving human subjects. Researchers may seek to answer questions, such as why people vote in elections, or the good and bad effects of one or many drugs for treating a disease. Researchers may also get information about people without directly speaking to them, or asking them to do things. For example, a study may use personal information from medical records in order to answer a research question.

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## What Are Your Rights as a Human Research Subject?

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One of the most important jobs a researcher has is to protect your rights as a research subject. Before you enter a study, you have the right to be given all the information you need to make an informed decision about participating in the study.

You have the right to receive all this information in an understandable manner and to be given as much time as needed to make a decision about participating in the research. You also have the right to have a detailed conversation about the study with the person asking you to volunteer. This helps with making an informed decision about whether to be in a study, or whether to continue once you have agreed to participate. You may ask as many questions as you like, as many times as you like, to make sure you understand what you are told. The person who is asking you to be in the study may also ask you questions to ensure you fully understand what you have been told.

**Note:** For a glossary of commonly used terms in research, see the appendix at the end of this resource.

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## How do I Decide About Being a Research Subject?

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After you have asked all your questions and you have been told about the research study, you should ask yourself:

- *Could this research help me personally?*
- *Do I still want to be a part of the research study even if the study will not help me personally, but may help others?*
- *Do I understand what the research is about and what is expected of me?*
- *Am I comfortable with what is going to happen to me?*
- *Do I have the time to commit to the research study?*
- *How does my family feel about me being in a research study?*
- *Can I agree to take the chance that the negative things ("risks of harm") might happen to me?*
- *Do I feel confident that the people who are conducting the study respect me, treat me kindly, and will do everything possible to keep me safe during the study?*
- *If I receive standard of care treatment on the study, will my health insurance cover medical expenses that are not covered by the study itself?*

Finally, depending on the type of study, and the amount of time that will be needed, you may want your family to help you make the decision about being in the study.

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## What About People Who Are Not Able to Decide for Themselves About Being a Human Research Subject?

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You can see that it is a very important decision when thinking about becoming a human research subject. There are research studies that require the involvement of:

- *Children, who are not able to make decisions to be in research because they are too young.*
- *Adults who are not able to make decisions because they may be too sick to do so, either mentally or physically.*

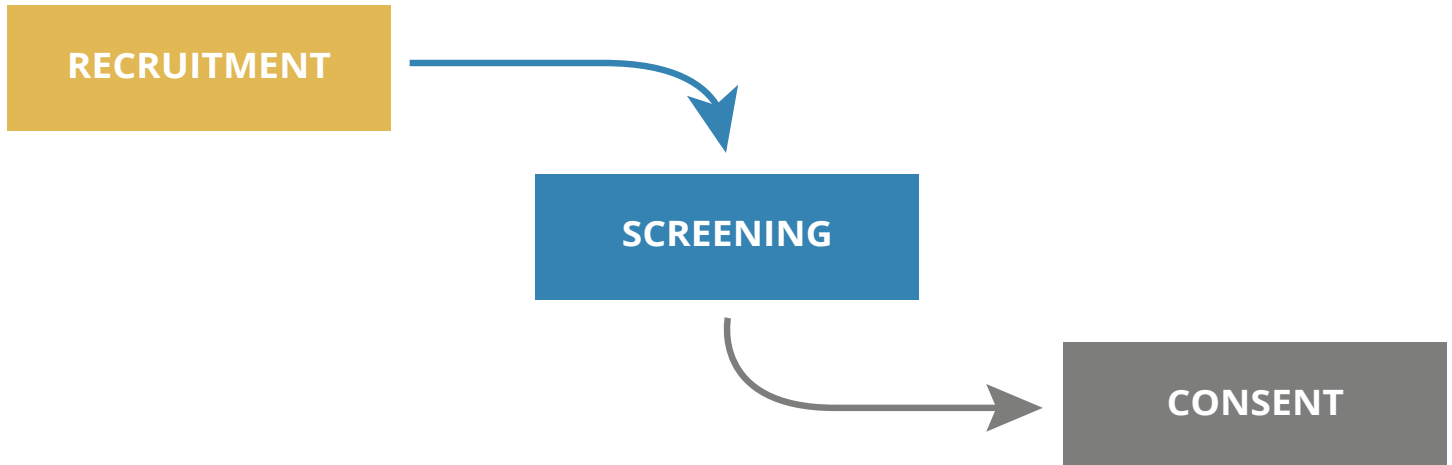
Children are protected when it comes to being in research studies because there are special rules in place that ensure, with very few exceptions, that:

- *Parents give their permission.*
- *The child assents (agrees).*
- *Only certain types of studies are permitted with children. A committee, called an Institutional Review Board (IRB), makes sure the study is acceptable for children to participate.*



Adults who are too sick to decide to be in research studies or have impaired decision-making abilities are also protected under specific research rules. Only someone (legally authorized representative) who is allowed by law to make decisions for another person can give the researcher permission to include the person in the study. Who is allowed to make decisions on behalf of another person depends on state or local laws (or institutional policy if there is no specific law). If you are asked to give permission on behalf of someone who cannot consent for him or herself, you have to understand as much as possible about the research so that you can make the best decision. Always ask the question: "Would the person want to be a human research subject in this study?"

# What is the Informed Consent Process?



The process that involves receiving important details, and asking and answering questions about the study, is the informed consent process. You may also sign an informed consent form that has all the information you have discussed with the researcher.

You have the right to be given a copy of this form after you have signed it. This is beneficial, because it contains names and phone numbers if you have more questions, and information about the research you can share with your family members or regular doctor.

Participating in a research study is a choice. This means you never have to be in, or continue to be in, a research study. You have the right to say, "No, I don't want to be in this study," or, "I said yes to being in this study, but now I've changed my mind," without having to give a reason, and without any penalties. If you do not want to start, or continue, research procedures you have been asked to do, that is acceptable. If, for example, you are uncomfortable about answering a certain question, or doing a certain task, simply tell the researcher as soon as you can.

Even though you can leave a study if you want to, sometimes the researcher needs to take certain steps so that you can be safely removed from the study. This really matters in studies where it may be dangerous for you to simply stop a study procedure (for example, if you are going to stop taking a study drug). You may need to slowly withdraw from the study, or come back for a safety visit to ensure you are doing well now.

While you are in a study, you have the right to be given any new information that the researcher discovers that might make you change your mind about continuing in the study. For example, during the study:

- *It may be found that there are negative side effects occurring in other subjects that were not known at the time you agreed to be in the study.*
- *Researchers may decide that they want to do an extra test or have you come in for an extra visit.*

## Recruitment

You may learn about a research study in a variety of ways, such as:

- A doctor or researcher
- Advertisements on the television, radio, newspaper, or internet
- Flyer or brochure

Researchers are allowed to advertise to find people who may want to participate in a research study. The IRB must review and approve all materials used by a researcher to potentially recruit subjects.

Recruitment incentives are sometimes offered by researchers to help make up for some of the inconveniences or additional expenses you may incur by participating in a research study. The incentive could include reimbursement for travel expenses, parking, hotels, or other such expenses. Incentives should never be so large as to attract people who otherwise would not consider being part of the research.

## Screening

Screening is a process to ensure you meet all the requirements (eligibility) for a particular research study. For example, if the research requires you to have a normal blood count and you do not, you would be "ineligible" for the research. Screening is an important process to ensure that you are not harmed by participating in research that you do not qualify for, and to ensure that the research results are accurate and meaningful.

## Consent

As part of the informed consent process, a researcher may be required to provide you with an informed consent form. This document will include all the information you should know about the research you are being asked to volunteer for.

Depending on the type of research you are being asked to participate in, the informed consent form should include the following information:

- A statement that the study involves research
- The purpose of the research
- The expected amount of time for your participation
- A statement that participation is voluntary, and that you can withdraw at any time without penalty
- A description of the procedures to be followed and any experimental procedures
- A description of any possible risk of harm or discomforts
- A description of any expected benefits for the subject or others
- Any alternative procedures or courses of treatment
- A description, if any, of how confidentiality will be maintained
- Any compensation that may be included
- Any medical treatments that may/may not be available in the event you are injured during your participation
- Contact information (phone numbers, emails, addresses) of whom to contact if you are injured or if you have questions about the research or your rights

Where Applicable:

- A statement that there may be the risk of harm to the subject, embryo, or fetus that are currently unforeseeable
- Circumstances where a subject's participation may be terminated by the researcher
- Any additional costs to the subjects that may result from their participation
- Any consequences of a subject's decision to withdraw and any procedures for a safe and orderly termination
- A statement that any significant new findings developed during the research that would possibly change a subject's willingness to participate must be provided to the subject
- The approximate number of subjects that will be included in the study

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# What is Expected of You After You Have Said “Yes” to Being a Human Research Subject?

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After saying yes to being in the study, you have to follow the directions given to you by the researcher as best you can. For example, if you have agreed to come in for a study visit at a certain time, you need to show up on the day and time you agreed to.

If you have been asked to provide information about yourself, you need to be sure that you are giving accurate, honest information. If you provide inaccurate information, you may not only hurt the study (that may need certain kinds of people with certain kinds of qualities in order to answer the research question) but you may also put yourself at risk of harm. One of the goals of any study is to keep subjects safe. That is why the types of people who can and cannot be in a study are very carefully looked at and approved before a study starts.

During the study, you must contact the researchers (or their staff) if anything begins to bother you, or if you do not feel well during the study. For example:

- *You are answering questions that are very personal and you start to become upset. You should let the person asking the questions know that you are becoming upset. That person should stop asking the questions, and try to help you feel better.*
- *You are taking a drug and you start to feel sick, you need to inform the researcher as soon as you can. It is more important, however, that at any time you feel the need, you should go to the nearest emergency room, just as you would if you were not in a study.*

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## — Who Protects People Who Agree to be Human Research Subjects? —



Many groups work together to ensure people are protected when they are participating in research studies. The main groups are:

**Researchers** (also called investigators) ensure your rights are protected and that you are kept as safe as possible throughout study participation. Your safety and rights are more important to the researcher than finding out the answer to the research question. Researchers are required to be knowledgeable about how to conduct a research study and how to protect those who have volunteered to participate.

**The Institutional Review Board (IRB) / Research Ethics Board (REB) / Independent Ethics Committee (IEC)** is a group of people that are not a part of the research study team, who are specially trained to review, approve, and watch over studies that involve human subjects. This group can be called different names in different places, (for example, Research Ethics Board), but they all have to follow the same laws to make sure that the amount of protection they give human research subjects is the same.

**In the U.S., the federal government and some state and local governments have enacted laws related to the protection of human research subjects.**

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## Summary

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Before agreeing to participate in research, you should be well informed and understand what may happen. The better you understand the research, the more informed choice you can make to participate.

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## References

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- *National Institutes of Health (NIH). 2015. "Glossary of Common Terms." Accessed August 18.*
- *Protection of Human Subjects, 45 CFR § 46 (eCFR current as of March 19, 2020).*
- *U.S. Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP). 2011. "What does it mean to minimize the possibility of coercion or undue influence?" Accessed August 18, 2015.*

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## Additional Resources for Potential Subjects

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- [Office for Human Research Protections \(OHRP\) offers information about research participation.](#)
- [The Multi-Regional Clinical Trials \(MRCT\) Center of Brigham and Women's Hospital and Harvard has resources on health literacy in clinical research.](#)

# Definitions of Commonly Used Terms

Adverse Event	An undesirable or unfavorable incident in a research study. Incidents may include physical or psychological harms.
Anonymous	Not involving a name or any identifiable information that can be linked to a research subject. For example, an anonymous survey would not ask the person filling out the survey for their name or any other identifying information (social security number, address, demographics etc.) when that information (alone or in combination) could identify the subject. Anonymous is not to be confused with confidential (see confidentiality below).
Assent	The agreement to participate in a research study from a child or an adult who is not capable of consenting for themselves.
Clinical Trial	A type of research study where researchers study the effects of experimental drugs, devices, or therapies (also known as medical research).
Coercion	Occurs when an overt or intentional threat of harm is intentionally presented (HHS 2011). This can be when a researcher uses too much or unnecessary influence to encourage an individual to participate in a research study. For example, a researcher tells a subject they will lose access to health services if they do not participate in a study. Undue influence is different from coercion because it occurs through an offer of an excessive or inappropriate reward in order for the person to get what they want from the other person (HHS 2011). For example, a researcher offers a \$100 gift card to subjects for taking a five-minute survey.
Confidentiality	The protection provided by the researcher of a subject's identifiable, private information collected for a study as well as at times, their participation in the research. The researcher keeps such information in a secured, limited access location (for example, a locked file cabinet in a private office), and does not share it with anyone other than those individuals or groups agreed upon by the subject. Confidentiality is not the same thing as anonymity, where the information that is collected is not identifiable, in other words, cannot be linked, to the subject by anyone (see anonymous above).
Control Group	The group in a study that is not assigned to receive the experimental procedure or test article. For example, in a clinical trial that is examining the effects of a new headache medicine; one group (experimental) of research subjects will get the new headache medicine while the other group (control) does not (and may, instead, get a medication that is already available in drug stores or a placebo [like a sugar pill]).
Focus Group	A group of people gathered together where a leader is asking about their attitudes or opinions towards a product, service, concept, or idea, or to just talk about a particular topic.
Human Subject	A living person participating in a research study or experiment. A human subject may also be called a research subject, study participant, or volunteer.
Incidental Finding	Something found in a test report that is not related to the study but may be important clinically to the subject. For example, a researcher conducts a scan of a subject's brain for a memory study, and finds a possible brain tumor (also can be called a secondary finding).
Informed Consent	An individual's decision to participate in a research study after being given all information necessary to be able to make a knowledgeable choice. The informed consent process does not end when the research subject initially agrees to participate. It is ongoing because subjects must be provided with any new information that might affect their willingness to continue participation in the study, and they must be given the opportunity to decide whether or not to continue their participation in light of the new information.
Interview	The process of asking a subject questions.
Investigator	The person who is actually conducting the research study (also known as researcher). There can be more than one investigator for a study.



# Definitions of Commonly Used Terms

Institutional Review Board (IRB)	A group of individuals (for example, scientists, non-scientists, statisticians, clergy, community members etc.) that review and approve research activities, ensuring that the research study has appropriate protections in place for the rights and welfare of human subjects. Research involving human subjects must always be approved by an IRB before it begins. An ethics committee that reviews and approves research may also be referred to as an Independent Ethics Committee (IEC) or a Research Ethics Board (REB).
Legally Authorized Representative (LAR)	A person authorized under state or federal law, or a legal body (such as a court) to consent (make decisions) on behalf of another individual to participate in research.
Monitor	A person who constantly tracks and reviews the progress of the study and the safety of study subjects.
Participation	The act of being involved in a research study.
Phase - According to the U.S. Food and Drug Administration (FDA)	<p><i>There are four stages of a clinical trial.</i></p> <ul style="list-style-type: none"><li>• Phase I studies consist of testing a new drug in a small group of healthy human subjects aimed at studying the effects and interaction of the drug in the subjects (determines safety and side effects).</li><li>• Phase II studies consist of a larger group of human subjects aimed at studying how effective a drug is in treating the specific condition, disease, ailment it was produced for (determines whether the treatment works).</li><li>• Phase III studies consist of an even larger group of human subjects intended to gather additional information to evaluate the overall effectiveness (risks and benefits) of the drug and is built on the results of the phase I and II trials (determines if it is better than current therapies).</li><li>• Phase IV studies are conducted after the drug has been licensed and marketed to the public and are intended to gather additional information about the drug's risk of harm, benefit, and its best use (determines the long-term safety and effectiveness of a new treatment).</li></ul>
Placebo	An inactive pill, liquid, or powder that has no value or effect on the person taking it. It is also known as a "sugar pill."
Placebo-Controlled Study	A study that has at least two groups; one being the group that receives the placebo and the other group receiving the new treatment. For example, a study examining the effects of a new pain drug will have one group receiving a placebo while the other group receives the new pain drug.
Principal Investigator (PI)	The researcher who is leading the study and responsible for the conduct of the study.
Protocol	The document that describes, in detail, the study plan. This is a detailed explanation of the purpose, procedures, and methods of a research study.
Questionnaire/Survey	A method of obtaining information from subjects by using organized questions. Often this method is used in social-behavioral-educational research.
Randomization	A method of assigning individuals to a group or treatment not using a specific matrix, but a random process (v. randomized). The researcher or subject do not choose the group or treatment. The subject would be assigned to a group or treatment based on chance (like the flip of a coin).
Registry	A registry is used for the collection and maintenance of information on individuals who have a similar condition and who will consent to being contacted for future studies or who agreed to allow their data to be used for future studies in a specific area of research (NIH 2015).

# Definitions of Commonly Used Terms

Repository	A repository is used for the collection and storage of identifiable specimens. By participating in the repository, the subjects consent to be contacted for possible participation in future studies or who agreed (in advance) to allow their data to be used for future studies in a specific area of research.
Research	An organized method, design, or study in which researchers (scientists, physicians, students) attempt to obtain information or answer a question (answering a question is also known as an experiment).
Risk/Benefit Ratio	The method in which risks are compared to the benefits. IRBs use the risk/benefit ratio to evaluate human subject studies to see whether the benefits of the study outweigh the risk of harm.
Screening	The process of evaluating potential subjects for a research study. This occurs before the actual study starts and may consist of a variety of tests or questions in an effort to find the exact type(s) of people appropriate for the study.
Study Population	The people who meet the criteria to be in a study. For example, a study involving experimental methods to reduce stress in senior citizens will have a study population of: male and females, age 55 and over, who are showing signs of suffering from stress.
Therapeutic Misconception	When the subject thinks the research study they are involved in is treatment (will potentially help them) rather than realizing the study is research (which is testing to see the good and bad effects of the drug/device/procedure).
Therapy versus Research	A treatment involves using an approved drug, method, therapy, etc. to help mental or physical disorder, disease, or illness. Research, on the other hand, is the process of obtaining information or answering a question and may involve a treatment. Not all research studies involve treatment.
Unanticipated Problem	An unexpected event that may add additional risk of harm to a research study. For example, if one or more research subjects become very upset that medical intervention is required, and the investigator of the research study only expected that subjects might become mildly upset.

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## What should you be told about the research?

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- *Why the study is being done (what is its purpose)*
- *Your option to withdraw from the study at anytime without penalty and without having to give a reason*
- *What is expected of you during the study*
- *Which procedures are for research, and which ones are not (for example, procedures for clinical purposes)*
- *What are alternatives, if any, to the study*
- *How long you will be in the study*
- *Any bad or good things that may happen to you as a result of being in the study*
- *Whether there is any compensation if you get hurt from the study*
- *Who to contact for questions about the study*
- *What will happen to your information and biomedical samples (blood, saliva, tissue) after the study has been completed*
- *Whether the researchers may profit commercially from your study information and samples, and if you get to share in that profit*
- *Whether clinically relevant results will be returned to you*
- *If the research includes whole genome sequencing (which reveals the complete, unique DNA 'blueprint' of a person).*
- *If there are any special processes to withdrawn to ensure your safety*

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