

Research plays a critical role in helping scientists better understand the causes of and treatments for many diseases, including depression. Clinical research studies or *clinical trials* (studies that require human participation) have improved our understanding of the causes of depression and bipolar disorder. They have also paved the way for every breakthrough in medication, devices, and procedures we rely upon today to help patients manage their symptoms. Research is helping us to discover why some people are more likely than others to experience depressive illnesses. It is also helping us understand how to make depression symptoms less severe and less likely to come back.

Who participates in research?

Thousands of people take part in U-M studies each year – and each person's participation matters! Research studies are conducted with every group of people – from infants to the elderly, men and women of all racial and ethnic backgrounds, and both healthy volunteers and those with serious medical conditions. Each study has specific guidelines about who can participate so that researchers can accurately evaluate how well the treatment they are studying works. If one study isn't a good fit for you, there are probably many others that need your help!



Is clinical research safe?

The safety of participants is the top priority in clinical research studies. Before any clinical study can begin recruiting volunteers, it must be approved by a regulatory group called the Institutional Review Board (or IRB), which is an independent team of doctors, scientific experts in medical ethics, and community members. The IRB evaluates the safety of the study by reviewing all of the tests and procedures planned, as well as the steps that will be taken to protect participants' rights and monitor their health and safety. In addition, the federal government regulates most clinical research.

Should I participate in a research study?

Consider the following factors carefully before determining whether you should participate in research:

Potential advantages:

- The opportunity to access and possibly benefit from new treatments before they are widely available.
- The potential to receive additional medical attention at a reduced cost or no cost.
- The opportunity to help others by contributing to medical research.
- The knowledge that you can decide to stop participating at any time, for any reason.

Potential disadvantages:

- The possibility of testing a drug that does not work, or does not work as well as anticipated.
- The time, energy, and resources involved in meeting all of the requirements for participation in a study.
- The possibility that you may have costs associated with medications or procedures, which may or may not be covered by insurance.
- The possibility that, although you participate fully in a study, there is no guarantee that you will learn the final results of the research.
- The possibility that, for any number of reasons, you may be removed from the study at any time.

What is informed consent?

The “informed consent process” is how a person learns the facts about a research study before deciding whether to participate. The healthcare professionals involved in the study explain all of the details, and provide a document that summarizes the study’s purpose, length, required procedures, known risks and benefits, and key contact people. The informed consent document is not a contract – it simply ensures that all of the relevant study information has been explained. Even after you sign an informed consent document, you may still withdraw from a study at any time.

For more information on studies at U-M, call 1-877-536-4243 or visit www.umclinicalstudies.org

U-M Depression Center ● 800-475-6424 ● www.depressioncenter.org

Please visit the UMDC online toolkit at www.depressiontoolkit.org. This toolkit was made possible by the Friends of the University of Michigan Hospital and Health System.

Disclaimer: This document is for informational purposes only and is not intended to take the place of the care and attention of your personal physician or other professional medical services. Talk with your doctor if you have Questions about individual health concerns or specific treatment options.

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