

THINKING ABOUT PARTICIPATING IN A RESEARCH STUDY?

Some information to consider



MENTAL HEALTH AND ADDICTIVE DISORDERS
RESEARCH PROGRAM

The Mental Health and Addictive Disorders Research Program

**Department of Psychiatry,
New York University School of Medicine/
Department of Veterans Affairs
New York Harbor Healthcare System**

Research Program Summary

The Mental Health and Addictive Disorders Research Program (MHADRP) is part of both the Department of Psychiatry at New York University School of Medicine and the Department of Veterans Affairs New York Harbor Healthcare System. Our goals are to enhance the understanding of and improve treatment options for psychiatric and addictive disorders. Our emphasis is on addictive disorders, adult attention-deficit hyperactivity disorder, the anxiety and depressive disorders, and schizophrenia.

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The Purpose of Clinical Trials

Though there are currently Food and Drug Administration (FDA) approved medications and effective behavioral therapies for certain mental health and substance use diagnoses, clinical trials are still extremely important. Researchers are working on providing patients with additional treatment options as well as developing medications with fewer side effects and easier treatment regimens. All of these experimental treatments must be tested for safety and effectiveness through either medication or behavioral therapy clinical trials. Without participants in these trials, progress in understanding and treating mental health and addictive disorders is impossible.

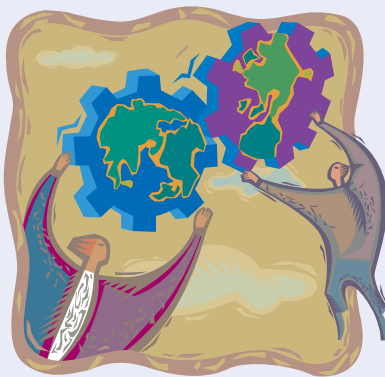
Historically, study participants have been primarily white males. Women, people of various ethnicities and races, as well as other populations have been under-represented in clinical research. In order to better advance treatment, all populations must be represented in clinical trials.

In addition to medication and behavioral trials, our group conducts other types of research. Some treatment studies involve procedures rather than medications or behavioral therapies. We also conduct non-treatment studies such as observational studies, survey studies, and studies that employ a variety of techniques to further our understanding of certain diagnoses.

Medication & Behavioral Clinical Trials

Medication Clinical Trials: In order for any medication to be approved by the FDA and placed on the market, it must be tested on humans in clinical trials. Clinical trials show if a medication is effective in treating and/or reducing symptoms and if it is safe. There are different kinds of medication trials. Some examples are: testing a single experimental medication, evaluating different combinations of approved medications, and examining a combination of approved and experimental medications.

Behavioral Therapy Clinical Trials: Behavioral therapies focus on changing an individual's thoughts, behaviors, or environment to promote a decrease in symptoms, better management of symptoms, or improved quality of life. Clinical trials determine whether behavioral therapies are effective in achieving these goals. There are many different kinds of behavioral treatments (e.g., Cognitive Behavioral Therapy, Community Reinforcement Approach). In addition, sometimes behavioral therapies are added to medication clinical trials to evaluate their combined effects.



Clinical Trial Phases & Stages

When a new medication is developed, the process starts in a test tube and then progresses to animal studies. These early studies give researchers an idea of whether a medication may work and what kind of side effects it might have in humans. In the same way, when developing a new behavioral therapy, procedures delivered in the therapy are tested very early in the process to see if they are helpful. If the results of early studies look promising, clinical trials are conducted to test the medication or behavioral therapy treatment in people. Medication trials are divided into phases. Similarly, behavioral therapy trials are divided into stages.

Take a look at Table 1 in order to see how Phase I, Phase II, and Phase III medication trials break down. When Phases I, II, and III are complete, the information from the trials is submitted to the FDA. The FDA reviews the information, and then may approve, reject, or ask for additional information about the new medication. After a medication is FDA-approved, Phase IV trials may be conducted. Phase IV trials are used to gather long-term safety information. These trials involve thousands of people and can give information about very rare side effects.

Take a look at Table 2 in order to see how Stage I, Stage II, and Stage III psychotherapy trials break down. When information in Stage I is complete, the information may be used to plan later Stage II and Stage III studies. The Mental Health and Addictive Disorders Research Program conducts Phase I, II, III, and IV medication trials and Stage I, II, and III behavioral therapy trials. Sponsors (the organizations that provide financial support of our clinical trials) include the National Institutes of Health, the Department of Veterans Affairs and the pharmaceutical industry.

TABLE 1: Phases of Medication Trials

	Phase I	Phase II	Phase III
Question	Is the treatment safe?	Does the treatment work?	What are the long-term results in lots of people?
Risk	Riskiest First trials in humans	Moderate risk Some safety information about the drug is already known	Lowest Risk More information about safety and effectiveness is known
Purpose	These studies determine safety of a drug in a healthy volunteer	The purpose is to determine the efficacy of a medication	These studies are looking at efficacy and safety in a larger group over a longer period
Length	Shortest - A few weeks to a few months	Medium length - A few months to a year or more	Longest - Often a year or longer
Number of participants	Approximately 20 - 80 participants	Approximately 100 - 300 participants	Approximately 1,000 - 3,000 participants

TABLE 2: Stages of Behavioral Trials

	Stage I	Stage II	Stage III
Question	Does the technique show initial promise and is it safe?	Does this behavioral therapy work?	Can this behavioral therapy be widely used?
Purpose	The purpose is to create the manual for therapists to follow, procedures to evaluate the therapists administering the therapy, and to assess the safety of therapy	The purpose is to determine the efficacy of the behavioral therapy	These studies are looking at efficacy and safety in a larger group over a longer period

Potential Benefits and Risks When Participating in a Clinical Trial

There are many reasons to think about joining a clinical trial. When you are deciding whether or not a trial is right for you, consider some of the benefits and risks.

Some Possible Benefits:

1) Access to medications that are not FDA approved or behavioral treatments that are not broadly used

You may have already tried every available medication or psychotherapy for your condition. The medication or behavioral therapy under investigation may be effective in treating the symptoms or condition you have, though there is no guarantee that you will benefit. If you are already on a medication that you like, it is probably not advisable to switch to a new medication. Discuss your decision to participate in a study with your family and your doctor.

2) Increased Care

You may receive your regular care in a large clinic or see a health care provider with many patients. As a result, you may not have as much one-on-one time with your health-care provider as you would like. When you get involved in a clinical trial, you develop a relationship with the research team (the investigator, study coordinators, therapists and nurses running the trial).

You may benefit from having more health professionals involved in your care. The research team can be a great resource for questions about your diagnosis.



3) Helping Others

Some people decide to join a clinical trial because they want to help others. Joining a clinical trial contributes to the development of new treatments. As a volunteer in a clinical trial, you can help yourself while helping others.

We have come a long way in our understanding of many illnesses thanks to people who join clinical trials. As we continue to move forward, clinical trials will provide answers to many remaining questions about illness. Without participants in clinical trials, we will never have safer and more effective drugs and treatment strategies nor would we have more effective and widely available behavioral treatments.



Some Possible Risks:

1) Safety and Health Concerns

In order to participate in a trial, you may have to stop taking some medications or stop the therapy you are currently attending, which might make your symptoms worse. Additionally, the experimental treatment may cause side effects and the experimental treatment may be less effective than the treatment you are currently receiving. It may not help you at all. However, our study staff will be there to monitor your reaction to the new medication/therapy. It is important that any side effects are reported to study staff immediately.

2) Protecting Your Rights

You may be hesitant to join a clinical trial because you are not sure if the researcher or research team can be trusted. In the past, there have been human rights abuses made in the name of scientific research. An example that you may be familiar with is the Tuskegee Syphilis Study. The study was conducted in Alabama by the United States Public Health Service to examine the effects of untreated syphilis. It began in the 1930s and continued until 1972. The African-American men who were recruited for the trial were not told about the purpose of the trial. They were also not told about penicillin when it became the standard treatment for syphilis in 1943.

The Tuskegee Syphilis Study was shut down in 1973. To prevent history from repeating itself, the National Research Act was passed in 1974. This act led to the establishment of Institutional Review Boards (IRBs). IRBs exist to protect the rights of trial participants.

An IRB is a group that consists of people such as doctors, lawyers, community members, and members of the clergy. In order to run a clinical trial at a hospital, clinic, or private doctor's office, the research investigator must submit an application to the IRB at that site or to a central IRB. The application contains detailed information about the trial. The IRB reviews the application to make sure that the trial asks a worthwhile scientific question and that the trial design is ethical. The IRB also reviews the safety monitoring of the trial.

Researchers are required to submit regular reports about the progress of trials and to inform the IRB about any side effects that trial participants experience. The IRB has the authority to shut down a trial if serious unexpected side effects occur or if the trial is not run properly.

Independent Data and Safety Monitoring Boards (DSMBs) may also review trials. When members of a DSMB review the data from a trial, they look for patterns of side effects or treatment benefits. They may suggest changes to the trial design if they find clear benefits or disadvantages to one group in the trial. They might also recommend that a trial be shut down if there are serious safety issues. Additionally, if the trial demonstrates that the research treatment is so effective that it would be unethical to deprive others access to this new treatment, they may work to bring the treatment to practice as quickly as possible.

There are extensive guidelines in place that protect your privacy as a study participant. These will be explained in the informed consent form and by a member of the research team.

Informed Consent

As part of the application to the IRB, researchers submit an informed consent form for review. This form includes complete information about the trial written in easy to understand language. It also contains contact information for the IRB. If you have questions about your rights as a research participant, please speak with the study team. If you still have questions and/or want to report a problem with the trial, please call the IRB.

The first time that you go to a research site to learn about a trial, the research team will review the informed consent form with you in detail. They will make sure that you understand everything about the trial, including any possible risks and the possible benefits.

You will be encouraged to take the informed consent form with you and talk it over with your healthcare provider, friends and family. If you decide to participate in the trial, and you are committed to following the trial procedures (which may include regular clinic visits and possibly laboratory tests), you will sign (or initial) and date each page of the form. You will be given a copy of the informed consent form for your records.

If there are changes to the trial while it is in progress or if there are any additional risks or safety concerns, the consent form will be revised to reflect this information. The changes will be explained to you, and you will be asked to sign a new consent form if you wish to continue in the study.



Basic Parts of Informed Consent

The informed consent form must include the following:

Yes, this is research

- A statement that the study involves research
- An explanation of the purpose of the research
- The expected length of participation in the research
- A description of the research procedures (lab tests, physical exams, other procedures)
- Identification of any procedures that are experimental

There are risks

- A description of risks/discomforts to the participant

And possible benefits

- A description of possible benefits to you or to others

There may be alternatives to participating in this trial

- A description of other procedures/treatments that are options for you if you decide not to participate in the trial

Your research record is confidential

- A description of how your confidentiality and privacy will be protected

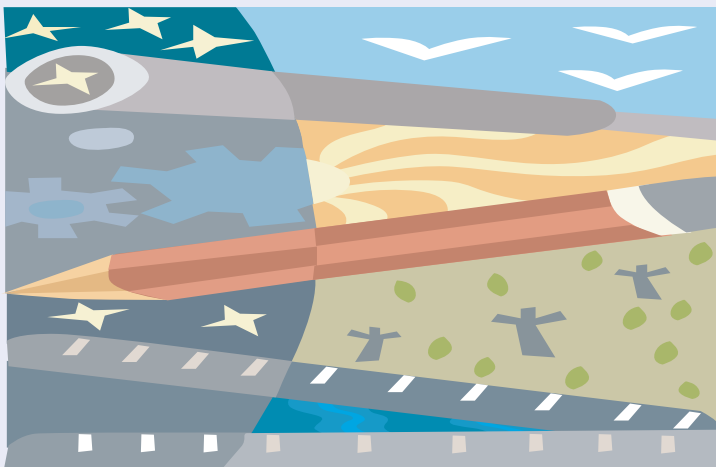
You may get paid

- A description of any compensation for time and travel
- A description of expenses that are covered and who, if anyone, covers those expenses if you are injured in the trial

If you have questions, ASK

- Contact information for questions about the trial and about your rights as a trial participant
- The decision to participate is yours
- Your participation is voluntary
- If you do not wish to participate, there is no penalty, and you will not lose benefits at the site
- You may withdraw from the study at any time

From the Code of Federal Regulations for Protection of Human Subjects



As you review the informed consent form, you may come across some of these terms:

Inclusion and Exclusion Criteria

Inclusion and exclusion criteria are the rules that say who is allowed to join a trial. The rules are different for each trial.

Inclusion criteria are characteristics you must have to be eligible to participate in the trial. Some examples of inclusion criteria may be:

- Between the ages of 18 and 60
- Willing and able to give informed consent

Exclusion criteria are characteristics that you must not have in order to participate in the trial. Some examples of exclusion criteria may be:

- Patients who do not meet criteria for the disorder that is being studied
- Women who are pregnant or breast-feeding

Inclusion and exclusion criteria are used by the researchers to be certain that they are admitting the appropriate persons into the trials. These criteria are also used to protect participants in trials. For example, if a medication is known to cause liver problems, people with liver problems will not be allowed to participate in the trial.

Placebos

A placebo is a substance that looks like a trial medication but does not contain active drug. It is sometimes referred to as a sugar pill. The placebo is a pill if the trial medication is a pill, and it is an injection if the trial medication is an injection.

Placebos may seem unfair or unethical. Why would a doctor give something that does not work to someone who needs treatment? Placebos are used to help determine if an experimental medication works. Some people get the medication, other people get placebo, and the results are compared. That way, researchers can see if the medication being studied really works.

In some studies that use placebos there are two evenly divided groups: those on placebo and those on active study medication. Each participant in the study is assigned by chance to one of the two groups in a process called randomization. Randomization is like flipping a coin to see who gets what, the medication or the placebo. It is used to make sure that there is no bias in the trial.

Trials that use placebos are usually double-blind, which means that neither the research doctor, study coordinator, nor the trial participant knows which medication the participant is taking. If both the research team and the trial participant know which medication is being used, then the trial is open-label.

Not all trials use placebos. But if the informed consent form says that a trial uses a placebo, ask lots of questions. Also, find out if you will eventually have a chance to get the experimental medication as part of your participation in the trial if the drug is shown to work.

Financial Considerations

There should be no financial cost to you as a trial participant. Trial medication should always be free, and the sponsor or research site conducting the trial usually pays for all study specific lab tests. However, some trials expect your private insurance or Medicaid to pay for some lab tests and other medications that might be used. Make sure that you understand how this works before agreeing to join.

Some trials pay participants. There are different reasons for getting paid to participate in a trial. Many of our studies compensate participants for travel expenses.

When a Clinical Trial Ends

As your participation in a trial draws to a close (several weeks or even several years after you started), you will start thinking about how to handle your treatment after the trial ends. If you are receiving an experimental medication as part of the trial, you may be able to continue receiving that medication, especially if it is about to become available by prescription. Members of the research team will work with you and your doctor to determine the best plan for your treatment.

Many trial participants are interested in the results of their trial. The research team will inform you of the results as soon as they become available. Sometimes the results are not available for several months or even years.

Questions To Ask Before Joining a Clinical Trial

How often do I have to visit the study site and how long will each visit take?

What should I do if I miss an appointment?

What should I do if I get sick or experience side effects while participating in the study?

Does the informed consent form list all of the risks and benefits?

Can I participate in therapy while I'm in the trial?

Will I get any money for participating in the trial?

Will I need to return to the site once the trial is over?

How can I find out the results of the trial?

What alternative therapies are available?

Can I take nonprescription (over-the-counter) drugs or complementary therapies while I am in this trial?

Can I use prescription drugs while I am in this trial?

Can I take other experimental drugs?

Will the lab tests cost me anything?

Will I get the results of these tests?

Will I get the study drug once the trial is over?

What should I do if I miss a dose of my drug?

What are the possible immediate and long-term side effects of this drug?



Glossary of Terms

Double-Blind - A procedure for assigning treatment regimens which keeps both trial participants and members of the research staff from knowing which participants are on which assigned treatments.

Efficacy - The ability of a drug, procedure or therapy to control or cure a diagnosed disorder or illness.

Institutional Review Board (IRB) - A committee of physicians, statisticians, community advocates, and others which ensures that a clinical trial is ethical and that the rights of the study participants are protected. All clinical trials in the United States must be approved by an IRB before they begin.

Informed Consent - The voluntary consent given by an individual to participate in a trial. The participant must be informed of the trial's purpose, treatment, benefits and risks of participation, and the schedule of required procedures.

Open Label Trial - A trial in which the research staff and the trial participant know to which treatment the participant has been assigned.

Placebo - An inactive agent given as a substitute for an active agent for the purpose of comparison.

Randomization - The process of assigning patients to different treatments by chance.

Side Effects - The action or effect of a drug or therapy beyond what it is supposed to do. The term usually refers to undesired or negative effects, such as headache, skin irritation, or liver damage. Side effects can be expected or unexpected, desired or undesired. Experimental drugs must be evaluated for both immediate and long-term side effects.

Adapted from Glossary of Medical, Statistical, and Clinical Research Terminology by Carlton Hogan, University of Minnesota, for the National AIDS Treatment Advocates Forum (NATAF)

Mental Health and Clinical Trial Information Resources

If you have decided that you would like to learn more about participating in clinical trials, start by talking to your healthcare provider. He or she probably knows about trials in the area.

Where to find information on mental health and substance abuse diagnoses, treatment, and support groups:

American Psychological Association

<http://helping.apa.org/>

American Psychiatric Association

http://www.psych.org/public_info/lets_talk/talk_facts.cfm

National Institute of Mental Health

<http://www.nimh.nih.gov/publicat/index.cfm#disinfo>

National Institute on Drug Abuse

<http://www.nida.nih.gov>

National Alliance for the Mentally Ill

<http://www.nami.org/illness/index.html>

Where to find additional information on clinical trials:

NIDA: Clinical Trials Network (CTN) Current Trials:

http://www.nida.nih.gov/ctn/patient_info.html

NIH: Current Information on Clinical Trials

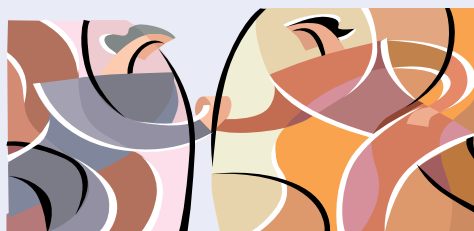
<http://clinicaltrials.gov>

NIMH: Participants Guide to Mental Health Clinical Research

<http://www.nimh.nih.gov/publicat/clinres.cfm>

CenterWatch Clinical Trials Listing Service

<http://www.centerwatch.com>



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With permission, this brochure was adapted from an AIDS-related clinical trials brochure produced by AIDS Community Research Initiative of America (ACRIA).

If you are interested in learning more about clinical trials at the Mental Health and Addictive Disorders Research Program or would like additional information about our program, please e-mail us at mhadrp@med.nyu.edu, call 212.951.6888 or write us at:

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