

The Jean Hailes *Foundation* *for women's health*

Fact Sheet

Understanding Medical Research

What is medical research?

Medical research studies help us to provide information on health or disease, to learn how our bodies work, why we become ill, and what we can do to stay healthy.

Types of medical research

There are several types of medical research. Some studies aim to learn what causes disease, and how to prevent or avoid getting sick; others aim to improve treatment. Specific types of studies include:

1. Observational studies: Follows the same people over a period of time to observe what happens to their health.

2. Epidemiological studies: Looks for patterns of diseases in large groups of people. These studies (1 and 2) cannot prove causes of illness or support specific treatments. But they can make suggestions about causes of illness or potential treatments that then need further intervention studies.

Prevention studies: Looks for ways to keep people from becoming ill. These studies often involve people who are at high risk for a particular disease.

Clinical trials or intervention studies: Are performed to learn the best ways to treat or, sometimes to prevent, disease. This kind of study may test a lifestyle change (e.g. weight loss) or a new drug, vaccine, or medical device. Clinical trials of new medications begin only after results from laboratory and animal studies show that the new treatments are safe and likely to be effective in people. The best types are those that compare treatments to dummies or placebo treatments (randomised control trials). All research contributes to an overall body of evidence on how effective a treatment is and what the side effects are. Of this body there are several levels of evidence, of which randomised control trials are the highest.

Clinical trials are done in stages, which are called 'phases'. If you are thinking about volunteering for a clinical trial, you should know which stage of testing the drug or device is in.

Phase I: Aims to determine the best dosage to be used in further testing, and to measure how quickly the drug is broken down in the body.

Phase II: Aims to find out if the treatment has the desired effect in people, to confirm the best dosage to be used in further testing, and to confirm testing for safety.

Phase III: Aims to measure how well the treatment works and to determine how much of a drug is needed to achieve the best result.

Phase IV: Begin after the results of Phase I–III trials have been given to the government for approval. These trials are done for many reasons – to test different dosages, to determine if the treatment works for other diseases or conditions, or to test different ways of taking the treatment (e.g. tablets, syrups).

Why are women needed for medical research studies?

For many years, researchers did not include women in medical research studies. They just assumed that if a treatment worked for men, it would work the same way for women. Now we know that women and men can react differently to the same treatment, and that some treatments that work for men may not work as well for women and vice versa. In addition, there are many diseases and conditions that only affect women, such as cancer of the uterus or ovaries, pregnancy and menopause.

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Who can participate in medical research?

Nearly every woman can qualify for a medical research study at some time in her life. Even perfectly healthy people may participate in observational studies and Phase I clinical trials. If you are currently healthy but are at risk for a disease, you may qualify for a prevention study. And if you get sick, you may want to consider entering a clinical trial to test a treatment.

Ethics approval

All studies involving animals or humans must be approved by an intensive ethics approval process, where the study is reviewed by a panel of scientists, doctors, lawyers, community representatives and religious leaders. Once a study is approved by an ethics committee it is deemed to be an important study where risk to participants is minimised and the potential benefits to human health are worthwhile.

What will I be told about the study?

All medical research is done with volunteers who participate by their choice. Researchers use a process called informed consent to make sure that volunteers understand what will happen during and after the research study.

During the informed consent process you should learn

- What kind of information the research study is looking for and what you can expect
- What the treatment or intervention is (if any)
- If a clinical trial, is there a chance that you will receive a placebo (inactive treatment)
- What are the chances of being harmed (risks) and chances of being helped (benefits)
- What alternative treatments are available (if any)
- Are there any costs to you or your health insurance company for taking part in the study
- Who will have access to your medical and personal information
- Who is responsible for paying for treatment if you are injured as a result of being in the study
- Who is paying for or sponsoring the study
- Will you be paid or compensated for taking part in the study
- How long will the study last and whom do you contact if you have any questions

What are the risks?

The answer to this question depends on the type of study. Some studies involve little or no risk, while others may be risky. Most studies are somewhere in between. There are two risks that are particularly important for women:

Pregnancy: When a woman is pregnant, any drugs that she takes may have an effect on her foetus. Because the risks of new drugs and other treatments to the foetus are not always known, women who may become pregnant must take these risks into consideration.

Birth control pills and hormone replacement therapy: Can affect how your body handles drugs. It is important to discuss any hormones or other medications you are taking, including bioidentical hormones, herbs and dietary supplements.

How will the research study benefit me?

Benefits of participating in research are mostly indirect - you are helping researchers learn more about health and disease, which may improve the health of others, now or in the future. It is important to understand that participation in medical research is not the same as getting medical care. If you have a disease or condition that requires medical care, you should seek that care from a physician or other healthcare provider.

* Written by the Jean Hailes Foundation for Women's Health in conjunction with www.womenshealthresearch.org

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health tips

Enjoy a wide variety of nutritious foods, by eating plenty of vegetables, legumes, fruit and wholegrain cereals. Include lean meat, fish, poultry and/or alternatives.

Try to include fish 3–5 times a week (this can include canned fish, such as salmon, sardines and tuna).

Take time out just for you.

Make pelvic floor exercises a life-long habit — even if you have no symptoms.

Be active on most, or all, days of the week: you don't have to do a 30 minute walk, 3x10 minutes is just as good!

3 serves of dairy each day for good bone health.