AAHKS Patient Education Committee

What is Research?

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Not many people know what it means to be a part of a research project. So, don't feel bad if this is new to you. This article intends to provide you with the 'Who', 'What' and 'Why' of clinical research.

Clinical research helps doctors decide how to best treat patients and allows us to advance the field of medicine. Research allows for the development and improvement of medicines, surgeries and tools to treat patients. Most research focuses on new treatments and if they are better than existing treatments. This can include an improvement in safety, changing a treatment so it works better or finding a new medicine to cure disease.

Who becomes involved in research?

All types of people can participate in clinical research. Many research studies involve men and women of all ages, races and backgrounds. This diversity helps your doctors decide if some groups in the population are better suited for a treatment than others. Other studies recruit patients that will be undergoing a specific type of surgery, like joint replacement, while other studies may only include patients who have a rare condition or certain illness.

Why should I participate?

There are many reasons why people agree to participate in research. Many people decide to participate in research to help doctors learn more about their condition or how to best treat it (advancement of medical knowledge). Sometimes, involvement will provide access for future patients to a treatment that might not have otherwise been discovered. In certain cases, research studies provide another option when a standard therapy has failed.

Safety

It is very important to ensure people who participate in research are not harmed by being in the research study. All studies are reviewed and approved by an independent group called an Institutional Review Board (IRB). This group reviews the planned study and identifies any potential ethical or safety concerns in an effort to prevent harm. This stamp of approval must be obtained prior to starting the research study or discussing the research with patients.

Confidentiality

Protecting your personal information during a research project is an important part of the process. The research plan, which ensures protection of your information, is one of the of the components reviewed by the IRB. The information you provide is kept confidential among the research team and is used only for research purposes for which you have consented. Results from a study are usually reported in terms of trends with no information that would allow anyone to identify specific participants.

Informed consent

Informed consent is a document designed to ensure your understanding of the purpose and plan for a research study and how it could impact you. The consent forms can be quite lengthy and thus discussing the pertinent points of the research and how it may impact you with your health care team is important. Your orthopaedic surgeon, and their team, are there to ensure that you understand the process from start to finish.

What questions should I ask?

Before joining a clinical trial, it is important to learn as much as possible. Discuss your questions and concerns with members of the health care team conducting the trial. Your questions should be focused to determine if the research trial is *right for you.* Be sure you understand:

- What happens during the trial?
- How and if your care will be different before, during and after surgery compared with a patient not participating in the research trial?
- Are there any research related costs or money provided to you once you are enrolled in the trial?
- What are the benefits and risks associated with participating?
- How will this research improve patient care?

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This article has been written by W. Trevor North, MD, in collaboration with the AAHKS Patient and Public Relations Committee and peer reviewed by the AAHKS Evidence Based Medicine Committee. Links to these pages or content used from the articles must be given proper citation to the American Association of Hip and Knee Surgeons.