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Clinical Trials Research Why should I participate?

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Research is the cornerstone for advancement of knowledge in medicine. Many of the drugs and devices that we now take for granted would not have been available had it not been for clinical trials research.

Informed consent is essential to performing high-quality research. The investigator should be able to explain to you what the study is about, who is doing it, what are the risks, benefits and alternatives, what the safeguards are, and how your privacy is protected. All quality research is overseen by an institutional review board (IRB) who provides independent oversight to ensure that the work is conducted to the highest ethical standards.

Research is voluntary. It has the potential to provide the participant with some benefits in terms of more diligent care, early access to a new drug or device and free medical evaluations with a specialized team. This is one of the reasons why patients who participate in clinical trials usually do better than patients outside of trials.

In clinical trials there is often a placebo (standard of care) arm. The purpose of this blinded random assignment to active treatment versus placebo is to reduce the possibility of introducing bias regarding the effect of the new intervention. In addition, it is well known that the power of suggestion has a large therapeutic effect and therefore must be balanced.

In cardiology we have learned that when we use drugs or devices, there are often unforeseen consequences. A promising drug that lowers blood sugar ended up having a harmful effect on the heart. Similarly, a drug that raised good cholesterol also raised blood pressure. Another drug that was effective at eliminating skipped beats turned out to cause more severe arrhythmias. We have seen equally surprising benefits. A drug that slows down your heart rate in turn makes you live longer. Only with research did we find that a drug as simple as aspirin used previously for pain control, actually improved survival during a heart attack!

Research is conducted in phases. Phase I studies are the first exposure in humans and carry with them the greatest risk or uncertainty. Phase II studies are small and designed to see if the experimental agent is beneficial. Phase 3 studies are the large clinical trials that determine whether the drug should make it to market. Phase 4 studies take the approved compound and look for new indications for its use and are usually the safest of the trials.

Being involved with research for the past 20 years and working with an outstanding team of nurses and physicians I want to encourage you to consider participating in clinical trials when the opportunity arises. To learn more about trials visit us at ***www.ahsmed.com*** or nationally at ***www.clinicaltrials.gov***.

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