

## **AWARE For All - Clinical Research Education Day Audience Survey Answers**

1. Usually, the longest part of the research process is finding volunteers to participate in clinical trials.
- a. True
  - b. False

**TRUE.** It takes 15 years, on average, for an experimental drug to travel from the laboratory to U.S. consumers. Often the longest part of the process is finding people to participate in each trial phase. With increased public awareness about clinical trials, more people may be willing to participate, and more professionals may refer people into appropriate trials. This awareness ultimately reduces the time it takes for researchers to enroll participants in trials and complete them-and speeds the movement of new drugs or treatments into standard care.

2. Only people who are sick can volunteer for a clinical trial.
- a. True
  - b. False

**FALSE.** Some trials enroll only patients with certain medical problems or diseases, but many clinical trials enroll people who are healthy.

3. One main reason why people do not volunteer for clinical trials is fear or distrust of research.
- a. True
  - b. False

**TRUE.** Sometimes people fear being treated like "guinea pigs" or being "experimented upon," as well as not receiving treatment for their medical problem. People may have a general lack of trust in the medical profession based on past negative experiences or the knowledge of historical abuses of research participants.

4. In all clinical trials, patients receive free care.
- a. True
  - b. False

**FALSE.** The trial sponsor usually pays for the cost of the intervention being studied (for example, any drugs being compared). The sponsor also usually pays for the cost associated with any special testing or extra doctor visits that are required. If you are considering volunteering for a treatment clinical trials, always check with your insurance company and the research team to understand how the costs of your regular medical care will be handled.

5. Participants may leave a clinical trial after signing the consent form.
- a. True
  - b. False

**TRUE.** An important safeguard in a clinical trial is your freedom to leave. You can leave a clinical trial at any time for any reason. The informed consent document that you sign does not force you to remain in a trial. If you do leave a clinical trial, it may be helpful to let the researchers know why you are leaving, although it is not required. This information may help researchers improve the clinical trial experience for other participants and may make the results of the trial more reliable.

**Informed consent is not a contract. Study participants are volunteers and may withdraw from a study at any time. Informed consent is intended to provide the volunteers with information regarding the study intent, design, and procedures, as well as the rights and responsibilities of the study participant.**

6. If not enough people volunteer for clinical trials it....
- a. Takes longer to complete the clinical trial
  - b. Increases the cost of the clinical trial
  - c. It takes longer for researchers to find better treatments
  - d. All of the above

**Answer D: All of the above are true. If enough people don't volunteer, the clinical trial may have to be closed. Or more money will be spent to run the trial longer or to intensify the efforts to find volunteers. Sometimes important clinical trials are not completed due to lack of volunteers.**

7. **To participate in a clinical trial, you must**
- Have health insurance
  - Have tried all other treatment options
  - Be eligible and agree to participate
  - Be able to read English

**Answer C: Be eligible and agree to participate. Each clinical trial has guidelines for who can or cannot participate in the study. These guidelines, called eligibility criteria, describe characteristics that must be shared by all participants. The criteria differ from study to study. They may include age, gender, medical history, and current health status. Enrolling participants with similar characteristics helps to ensure that the results of the trial will be due to what is under study and not other factors. In this way, eligibility criteria help researchers achieve accurate and meaningful results. These criteria also minimize the risk of a person's condition becoming worse by participating in the study.**

**Health insurance is typically not a requirement of the clinical trial, nor is the ability to read English. Often people believe that treatment clinical trials are only for people who have very advanced diseases and don't have any other options, however, many new drugs or devices may be tested in healthy volunteers or people with early stages of disease.**

8. **In "randomized" trials, who assigns participants to a control group or experimental group?**
- An objective panel of scientists
  - The research nurse
  - The doctor
  - The flip of a coin

**ANSWER D: The flip of a coin. Randomization is a method used to prevent bias in research. Participants are assigned to either the investigational group or the control group by chance, via a computer program, much like the random flip of a coin. Randomization ensures that unknown factors do not influence the trial results.**

- The control group is made up of people who will get the most widely accepted treatment (standard treatment) for their cancer.**
- The investigational group is made up of people who will get the new agent or intervention being tested.**

**Anyone who is considering participation in a randomized clinical trial needs to understand that she or he has an equal chance to be assigned to one of the groups. Neither a panel of scientists, the research nurse, nor your doctor can select your treatment in a randomized trial.**

9. **What is "standard treatment"?**
- A placebo or sugar pill
  - Treatment provided through insurance
  - Current approved treatment
  - None of the above

**ANSWER C: Current approved treatment, or the most widely accepted treatment. Phase 3 trials focus on learning how a new treatment compares to standard treatment. Researchers want to learn whether the new treatment is better than, the same as, or worse than the standard treatment.**

10. **Where can you find information about clinical studies?**
- Search the Internet
  - Ask my doctor or nurse
  - Go to the library
  - Call a medical center
  - All of the above

**Answer E: All of the Above.**