

In addition to the Phase I through III studies discussed in the previous article, a new medication or treatment may still go through additional testing even after it has been FDA approved and available on the market. There are several reasons why a pharmaceutical company may want to further study a new medication. It may be to compare it to a competitive medication for marketing purposes; to monitor a medication's long-term effectiveness and impact on a patient's quality of life; or to test it on a different ethnicity, gender, or age. These Phase IIIB and IV studies are very common and in fact constitute a significant portion of the studies conducted by Horizons Clinical Research Center, LLC.

During all of the various phases of a research study the safety and protection of the participant's rights are always of prime importance. Research participants have the right to expect that their exposure to risk is minimized. All medical procedures that a participant receives must be consistent with the standards of good research design and not pose any undue risk to the health of the volunteer. Participants have the right to privacy and by law every research site must protect a volunteer's personal information. Participation in a study must also be truly voluntary and every participant must be provided with an Informed Consent statement that presents the details of the study. These include the length of the study, what medical procedures there will be, the medications used, the number and frequency of visits, what will happen at those visits, the potential benefits of the treatment, and possible side effects. The Informed Consent also advises that the participant has the right to withdraw from the study at any time and for any reason. The Consent process assures that volunteers are aware of the study details and have had any and all questions answered to their satisfaction prior to agreeing to participate in a study.

(To be continued)

To learn more about medical research and what studies are currently enrolling participants please visit the website of Horizons Clinical Research Center, LLC www.horizonsrcrc.com or call 303-399-4067.