

## **Good Clinical Practice Q&A: Focus on Exams vs. Assessments**

**Physical exams of study subjects are important in the context of several aspects of clinical studies. Is there a difference between a physical exam and a physical assessment? If so, under what circumstances? Must the protocol state which is required?**

There is a definite difference between a physical exam and a physical assessment. A physical exam is conducted by a physician, a physician’s assistant, or a nurse practitioner. The procedure involves an examination of all or certain body systems (e.g., genito-urinary). The examiner uses auscultation, palpitation and percussion, as well as visual, auditory and olfactory means, to evaluate the individual. In most states, a registered nurse who performs a physical exam is operating outside his or her scope of practice.

On the other hand, a physical assessment is an abbreviated evaluation, typically performed by a registered nurse. Percussion and palpitation are not routinely employed. The examiner may auscultate heart and lungs, measure vital signs, check pupil size and reaction, and assess skin turgor.

The protocol in clinical studies should define which of the two procedures would be required. In many cases, protocols are ambiguous and physical assessments are performed in lieu of physical examinations — sometimes to the surprise of the sponsor. There have been studies in which a physical exam was required, but the physical exam source document forms created for the study were actually titled “Physical Assessments.” Of course, this creates a conflict between the protocol and study source documents. In other studies, the physical exam source document form was correctly titled, but physical assessments were performed.

In simple studies, nursing assessments may suffice and protocols should reflect this specification. For complex studies, the physical exam is an important activity necessary to demonstrate that the patient’s safety is ensured. Unless specified in a protocol, a physical assessment cannot be submitted for a physical exam.

### **Source**

“Good Clinical Practice: A Question & Answer Reference Guide”, Barnett International. The Guide is available at <http://www.barnettinternational.com> in electronic and paper form.