**OHSU Policy**

A. The monitoring provisions should be tailored to the expected risks of the research, the type of subject population being studied and the nature, size and complexity of the research protocol.

B. Monitoring exists on a continuum and depending on the nature of the study, one of these monitoring entities may be required:
   1. Investigator Monitor
   2. Independent Monitor
   3. Data Safety Monitoring Board (DSMB)/Data Monitoring Committee (DMC)
   4. OHSU Cancer Institute (CI)

C. The monitoring provisions must be described in sufficient detail for the IRB to determine whether they are appropriate for the research.

D. All research requires some level of monitoring and principal investigators are responsible for monitoring their studies. However, the IRB must approve the plan for monitoring data and safety for all research except minimal risk research where OHSU is the only site.

Effective 10/31/07