Quality assurance of University-sponsored human-interventional studies

**Definition of Quality Assurance:**

Quality assurance (QA for short) is about the University testing for itself the effectiveness of QA systems that are in place within academic departments/schools through the timely execution of independent assessments.

1. **Medium and high risk human-interventional studies**

   With respect to those University-sponsored human-interventional studies which the University categorises as potentially high or medium risk, the University has a meeting with the Chief Investigator (CI) of the study (and, in the case of potentially high risk studies, also reviews the essential documents in the master site file). The purpose of this is to reassure the University that the CI has in place present and effective QA systems for:
   
   a. safeguarding the dignity, rights, safety and well-being of participants in the studies;
   
   b. the validity of the data collected, analysed, recorded and reported in the studies.

   The purpose is not to undertake quality control (QC), which is the CI’s responsibility. QC is the continuous verification of data quality.

2. **Low risk human-interventional studies**

   With respect to those University-sponsored human-interventional studies which the University categorises as potentially low risk, the University has a meeting with the Head of Department (HoD) of the academic department/school within which the CIs of the low risk human-interventional studies are based. The purpose of this is to reassure the University that the HoD is confident that the CIs have in place present and effective systems for:

   a. safeguarding the dignity, rights, safety and well-being of participants in the studies;
   
   b. the validity of the data collected, analysed, recorded and reported in the studies.