McLaren HEALTH CARE

Human Research Protection Program

Guidelines to Good Clinical Research Documentation

A	**Attributable** - It should be clear. • Who documented the data? • The person performing clinical trial duties listed on signature/delegation log. • What is the persons' credentials?
L	**Legible –** It should be readable. • Can you identify the signature? • Can you identify the entry? • Changes or corrections should not obscure original entry. • Can you easily understand the information? • Black or blue pen is preferable.
C	**Contemporaneous** – It should be in real time. • The information should be documented in the correct time frame along with the flow of events. • If a clinical observation cannot be entered when made, an addendum should be recorded. • Any delay should be define and justified. **Complete –** There should be no empty blanks without notation. • Complete all entries or document why data not obtained.
O	**Original** • Investigator should have access to the original source document
A	**Accurate** • The information should be accurate, consistent and real representation of the facts. • All blanks filled in. • Errors identified and corrected. • When were corrections made and who made corrections evident.

Adapted from **- FDA - GUIDANCE FOR INDUSTRY - COMPUTERIZED SYSTEMS USED IN CLINICAL TRIALS** - ALCOA http://www.fda.gov/downloads/ICECI/EnforcementActions/BioresearchMonitoring/UCM133749.pdf