

COM Research Professional Reading and Interpretations Policy

September 10, 2010

“Reading Exception” refers to no professional reading/interpretation from the department in which the service is performed. This can include exceptions such as:

- a) PI/Investigator is performing the read, or
- b) The technical portion is being sent to a centralized core-lab to perform the read. The results may or may not be provided to the PI.

Reading Exception Policy:

Service Type	Research Only	Clinical Care (including Clinical Care with Research also collecting Data)
Definition	Service done solely for research, not for clinical purposes	Services are required as part of patient’s Standard of Care, data from service also required by study protocol
Payor	Research	Patient/insurance or Research
Reading Exception Allowed?	Yes Individual Ancillary Departments are required to develop, provide and monitor a billing process to ensure proper reading and billing procedures are followed.	No The reading must be performed by that service department and must meet billable service requirements. The results are part of the clinical medical record.
Reading Exception Notification Requirements	The PI will, 1) indicate a reading exception in the RAC submission, 2) notify the IRB through appropriate ICF language, and 3) follow individual service department procedures/processes to ensure proper billing procedures are followed. A liability waiver is no longer required with the Ancillary Department.	N/A
IRB Language Requirement	The ICF will provide the details of the Reading Exception to the study subject and identify each service as applicable. “Tests done only for research purposes will not be evaluated or used to diagnose or treat any of your medical problems. This/these test(s) may need to be repeated if required for your medical care in the future”	N/A

Policy Workgroup written and approved 9/10/10: Workgroup included: Peter lafrate PharmD; David Nelson MD; Marvin Dewar, MD; Carl Pepine, MD; Anthony Mancuso, MD; Michael Clare-Salzler, MD; Susan Collingwood; Dianne Farb; Betsy Miller; Yvonne Brinson