Problem Areas Identified in CQI Assessments
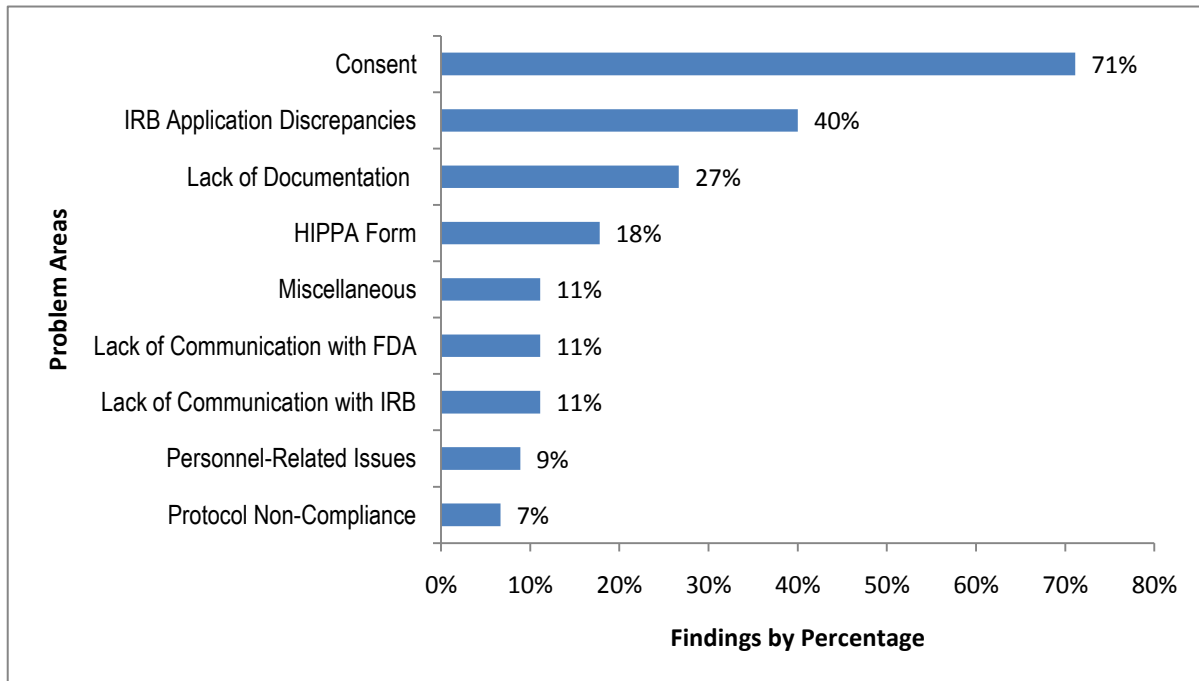

First assessment: 5/2008
To Date: 15 Assessments; 2 required Follow-up (15 investigators; 17 visits)
Total Number of Studies Audited: 49
9 UPC investigators; 8 HSC investigators

Consent: no documentation of consent; use of unapproved/expired consent; missing subject name, signature, or signature date; missing PI signature; stamp used to date consent instead of handwritten date by subject and person obtaining consent; use of one consent for more than on subject

IRB Application Discrepancies: discrepancies between IRB application and study procedures; study team unable to locate approved documents in iStar; study personnel different from those in application; personnel obtaining consent is different from that in application, funding question answered incorrectly

Lack of Documentation: no documentation of subjects meeting inclusion/exclusion criteria; no study or regulatory binder

HIPAA Form: use of wrong HIPAA form; HIPAA form not signed by subjects; required fields not completed in HIPAA form; stamp used to date HIPAA form instead of handwritten date by subject and person obtaining consent

Miscellaneous: potential for subject coercion; funding not distributed to proper channel; personnel obtaining consent not aware of departmental policy

Lack of Communication with FDA: personnel listed on Form 1572 form differs from IRB application; missing information in Form 1572; lack of annual progress report for investigator-initiated studies

Lack of Communication with IRB: done in untimely manner; study closure report not submitted; adverse events reported as Data Safety Monitoring reports, study status incorrectly reported at Continuing review; protocol deviations not reported to IRB

Personnel-Related Issues: lack of GCP training; lack of personnel; lack of personnel oversight; personnel conducting study procedures not designated on IRB application

Protocol Non-Compliance: differences between protocol and study procedures; inclusion/exclusion violations