Summary of Informed Consent (IC) Audits Conducted Q4 FY 2019 *(note: numbers in blue italics are from the 2017 IC audit)*		
72 *(80)* protocols reviewed • 32 *(14)* non-IND treatment • 40 *(66)* observational	Random selection of 593 *(628)* participants enrolled between January 1, 2018 – June 30, 2019 • 197 *(95)* enrolled in non-IND treatment protocols • 396 *(533)* enrolled in observational protocols • 28 participants <18 y.o. • 33 participant used short form process	Outcomes • Overall improvement compared to 2017 audit. • QI activities after 2017 audit included: team-based training and development of CCR Informed Consent SOP
Overall Findings	• 14 protocols (19%): no deficiencies found; *2 (2.2%);* Improved • 27 protocols (37.5%): no issues reportable to the IRB; *3 (3.8%);* Improved • 31 protocols (43%): at least one finding was reportable to the IRB; *75 (93.75%);* Improved	
Finding	**Detailed Findings**	
Several findings are ≤ 4%	• Correct version of consent not used (n=5, <1%); *2%;* Improved • IC document not in CRIS (n=1, <1%); *No change* • Investigator signature missing (n=1, <1%); *None* • IC obtain by someone not listed on the KSP or delegated to consent (n=23, 4%); *2%:* worse than previous • Inconsistent dates (n=8, <2%); *4%;* Improved • Not all embedded questions answered if applicable (4 out of 14, <1%); *2%;* Improved • Extraneous marks on IC document (n=18, 3%); *5%;* Improved • No IC note in CRIS (n=24, 4%); *23%;* Improved	
Inadequate documentation of IC process (10%); *13%* - Improved	• Applies to 57 records. • CRIS note doesn't specify that the patient received a copy of the IC document (2%); *1%,* worse than previous • IC process documentation greater than 72 hours (CCR SOP) (8%); *6% when measured at one month* • Missing interpreter name/code in CRIS note (n=3, 9%); *collected with other required note elements* • NIH admin section on short form missing (n=4, 15%); *N/A per policy* • CRIS note missing assent process (n=5, 18%); *>50%;* Improved	
For assent process, missing signature/date on IC document or assent document (11%); *not collected separately*		