Summary of Informed Consent Audits Conducted June 27, 2016 – April 14, 2017		
80 protocols reviewed • 14 non-IND treatment • 66 observational	Random selection of 628 participants • 95 enrolled in non-IND treatment protocols from start of study • 533 enrolled in observational protocols between 01/01/15-07/31/16	Corrective Action Summary • Deviation, non-compliance reporting to IRB • Informed consent refresher training was conducted with 5 teams. To date, 90 people have undergone training. • Revise CCR SOP PM-2 and post by July 1
Overall Findings	• 2 protocols: no deficiencies found • 3 protocols: no issues reportable to the IRB • 75 protocols (93.75%): at least one finding was reportable to the IRB	
Finding	**Detailed Findings**	**Corrective Actions, *if applicable***
Missing IC documents (ICD)	• Signed ICD missing from CRIS and research chart for 2 protocols (1 consent/protocol)	• Serious non-compliance reported to IRB within 7 days of PI becoming aware of the finding • Teams will maintain a copy of signed ICD until scanned version is uploaded into CRIS
Lack of assent process description per federal regulations and HRPP SOPs	• Majority of protocols enrolling minors lacked description of assent processes or justification for not obtaining assent noted in protocol • IRB lack of documentation for determination of appropriateness of the assent process described in the protocol	• Brought to the attention of the Office of Regulatory Affairs and the Chief of the Pediatric Oncology Branch (fall 2016) o All protocols enrolling minors are being modified • OHSRP notified of IRB's lack of determination o IRB is addressing this issue with each appropriate protocol which is reflected in the minutes
Inadequate or missing documentation of IC process	• No documentation in CRIS (24% of charts reviewed) to support federal regulations and HRPP SOPs requirement that a copy of the consent be given to the person signing the consent document • Note contained inaccurate information (13%) • Note did not contain all the elements described in the CCR SOP for documentation of informed consent process (7%) • Note was completed greater than one month after consent was signed by participant (6%)	• Non-compliance reported to the IRB when regulations and/or HRPP SOPs not followed • Research team training on informed consent and appropriate documentation of IC process

Alteration of IRB-approved ICD (5% of ICDs reviewed)	• IRB-approved ICD was altered with handwritten notes (15 instances) • A paragraph was crossed through with a single line (1 instance) • Information written in English on bottom of non-English short form (1 instance) • "N/A" was handwritten next to embedded questions (5 instances) • Other extraneous underlining and markings (5 instances)	• Non-compliance reported to the IRB when regulations and/or HRPP SOPs not followed • Research team training on informed consent and appropriate documentation of IC process
Expired or incorrect ICD	• Expired version of the ICD used (8 instances) • Incorrect version of ICD used despite availability of correct version on IC website (4 instances) • Consent document used was both expired and incorrect version (2 instances) • ICD for another Institute's protocol for another patient uploaded under NCI protocol in CRIS (1 instance)	• Medical Records was notified of the ICD in wrong patient's chart and the incorrect ICD has been removed • Non-compliance reported to the IRB when HRPP SOPs not followed • Research team training on informed consent and appropriate documentation of IC process
Issues with dates or signatures	• Dates of signatures were inconsistent or absent (8% of ICDs reviewed) • Section C of the ICD signature page "Child's Verbal Assent" not completed and the medical record note did not explain why assent was not obtained (3%) • Child participant signed assent document and parent/guardian signed section C of ICD (2%) • Participants initialed each page of ICD (2%) • Child participant signed ICD (3 instances) • Date of signature of the participant, Investigator obtaining consent and witness appeared to be written by the same person. When compared to another informed consent document signed and dated by the participant, the handwriting of the date is inconsistent. (1 instance) • Two people signed on the Investigator Obtaining Consent line of ICD (1 instance) • Third signature was on a short form IC (1 instance)	• Non-compliance reported to the IRB when HRPP SOPs not followed • Research team training on informed consent and appropriate documentation of IC process

IC obtain by someone not listed on the protocol	• Person obtaining consent was not listed on the protocol as an AI as required by HRPP SOP (2% of ICDs reviewed)	• Non-compliance reported to the IRB when HRPP SOPs not followed • Research team training on informed consent and appropriate documentation of IC process
Inappropriate IC process	• Embedded questions not answered (2% of ICDs reviewed) • Both the English version and translated Spanish long form of the consent were used during the informed consent process (2 instances) • Participant was consented using the long version of the ICD when the medical record note documenting the informed consent process noted that participant cannot read (1 instance) • Participant and investigator obtaining consent and witness "backdated" the ICD. Participant initially consented using an expired version of the ICD. When participant returned to clinic to sign the correct version of the ICD, all signatures on that document were dated for the date consent was originally obtained. (1 instance) • Interpreter not identified as such on ICD as required by HRPP SOP 12 (9 instances) • Research team member served as witness to participant signature when informed consent process occurred via telephone and the ICD was not signed in the presence of the team member (4 instances)	• Non-compliance reported to the IRB when HRPP SOPs not followed • Research team training on informed consent and appropriate documentation of IC process
Randomization procedures conducted prior to patient signing ICD (1 protocol, 9 instances)	• IRB approved protocol allowed for telephone consent followed by a second ICD being signed in person; nine participants randomized prior to the in-person consent being obtained.	• Non-compliance reported to the IRB • Protocol amended to correctly describe the informed consent process when consent obtained via telephone • Research team training on informed consent and appropriate documentation of IC process