Study Initiation Activities Checklist

Protocol – Abbreviated Title: _____

Protocol #: _____ PI: _____

Study Initiation Activity (see SOP for specifics)	**Date Completed** (mark N/A if not applicable)
All contracts and funding agreements fully executed and/or approved	
Clinical Center Protocol Resources Impact Assessment (PRIA) approval	
Reliance Agreement for outside investigators/collaborators fully executed, as applicable	
Data Management and Sharing (DMS) Plan approved (or Genomic Data Sharing (GDS) Plan only, as applicable)	
Institutional Certification (IC) Memo approved, if applicable	
IRB approval, including approval of Local Context Worksheet, if applicable	
Site initiation visit (or Study Start-Up Meeting) complete	
Communication from CC DTM that cells can be processed, if applicable	
Communication from research lab that specimens can be processed, etc.	
All CCR study databases built	
CRIS protocol order sets submitted to DCRI	
Notification from study sponsor that study may be activated at site	
CCR SMC acknowledges safety oversight of the trial (if OSRO SMC/DSMB, no action required)	
Manufacturer notified that investigational product can be shipped	
Communication from pharmacy that protocol agents are available and ready to dispense	
Confirmation that study is registered and posted on www.clinicaltrials.gov (NCT # available)	
The below activities are for industry-sponsored studies:	
• Research Team training on sponsor's electronic data capture system	
• Study-specific supplies and documents received	

_____ _____

PI Signature – checklist completed
(Electronic signature using PIV card acceptable)

Date