

Study Initiation Activities Checklist

Protocol – Abbreviated Title: _____

Protocol #: _____ **PI:** _____

Study Initiation Activity (see SOP for specifics)	Completed on (mark N/A if not applicable)
All contracts and funding agreements fully executed and/or approved	
CCR sponsored-IND, protocol submitted to FDA and activation memo sent by OSRO	
Reliance Agreement for outside investigators/collaborators fully executed	
Genomic Data Sharing (GDS) Plan and Institutional Certificate (IC) Memo approved (or GDS exception granted)	
IRB approval, including approval of Local Context Worksheet, if applicable	
Site initiation visit complete, including Study Start Up for CTEP-sponsored studies	
Communication from CC DTM that cells can be processed	
Communication from research lab that specimens can be processed, etc.	
CCR study database built	
CRIS order sets submitted to DCRI	
Notification from study sponsor that study may be activated at site	
Manufacturer notified that investigational product can be shipped	
Communication from pharmacy that protocol agents are available in pharmacy	
The below activities are for industry-sponsored studies:	
<ul style="list-style-type: none"> • Research Team training on sponsor’s electronic data capture system 	
<ul style="list-style-type: none"> • Study-specific supplies and documents received 	

PI Signature

Date