Study Title:			
IRB Number		**IND/ IDE**	
Sponsor		**NCT Registration**	
Phase		**Expected Enrollment**	
Principal Investigator		**Contract Finalized**	
Lead Study Coordinator		**Budget Finalized**	
Protocol Version/ Date		**BCA Version/ Date**	

Qualifying Clinical Trial Evaluation			
Criteria	**Yes**	**No**	**Comments**
Is the item under investigation for the evaluation of an item or service that falls within a Medicare benefit category?			
Does the clinical trial have therapeutic intent?			
Does the clinical trial enroll subjects with a diagnosed disease (not health volunteers only)?			
Is the trial considered deemed?			
Is this a Qualifying Clinical Trial?			

Informed Consent (ICF) Document	
The benefits section of the ICF states:	
The cost section of the ICF states:	

Guidance Resources:	**Issues of note:**

I, as Principal Investigator, certify that I have reviewed the attached Billing Coverage Analysis along with the Research Finance Coordinator, and have provided my clinical input with regard to standard of care and medical necessity, to the best of my judgment and normal clinical practice guidelines.

Principal Investigator

_____ _____

Signature **Date**

I as Research Finance Coordinator, certify that I have reviewed the attached Billing Coverage Analysis along with the Principal Investigator, and confirm to the above to be in compliance with current Medicare regulations and coverage determinations to the best of my knowledge.

Research Finance Coordinator

_____ _____

Signature **Date**