VCU Clinical Trial Cost Analysis
Device Studies Package

Clinical Trial Device studies must complete the Clinical Trial Device Cost Anaysis Package.

The local Medicare Contractor must make final determination on coverage qualification for the device and other services provided as part of the trial. Investigators must consult with their Medicare contractor of the IDE device trial in order to complete the package. The package must be routed internally with your clinical trial budget. In addition, after the approval letter from the Medicare Contractor is received (regardless of funder), all documentation including the Medicare Contractor's Letter, the Clinical Trial Device Cost Analysis Package, the Grants and Clinical Trials Agreement for Institutional Account Billing must be forwarded to vfowler@mcvh-vcu.edu and mejohnson@mcvh-vcu.edu. If there is not external funding the package must be maintained in your study regulatory binder and forwarded with the Grants and Clinical trials Agreement for Institutional Account Billing to vfowler@mcvh-vcu.edu and mejohnson@mcvh-vcu.edu. When Oncore© is fully functional, these forms will be uploaded into that system. If the required documentation is not included or incomplete, your trial will be returned for coverage-analysis completion.

Study Information

Study Title:	
Sponsor:	**Protocol Number/Reference/Version/Date:**
Principal Investigator Name (Department):	
Study Coordinator Name:	
Study Location:	
Anticipated Start Date:	**Name of person completing form**
Study Type: ☐ Device^:	

		Comments
Does CMS allow coverage of the investigational device	Yes ☐ No ☐	
a. Is the device FDA approved and used on label?	Yes ☐ No ☐	
i. If no, does the device have an investigational device exemption (under 21 CFR 312.2(b)(1)?	Yes ☐ No ☐	
ii. If yes, what is the category for the IDE?	A ☐ B ☐	
1. If Category A, has the contractor determined the device is used for diagnosis, monitoring or treatment of an immediate life-threatening disease condition? Attach documentation	Yes ☐ No ☐	
2. If Category B, has the contractor approved the use of the device? Attach Documentation	Yes ☐ No ☐	
b. If device is investigational and does not have an investigational device exemption (IDE), does the device have a 510K exemption?	Yes ☐ No ☐	
i. If yes, what is the 510 exemption number? Obtain contractor approval before billing for services and attach		

Items not billable to Participant/Medicare/Insurance			
Carve-outs	**Requirement**		**Comments**
	Is the Sponsor reimbursing for <u>all</u> tests, services, and procedures (i.e., nothing is to be billed to Medicare or other payers)? This excludes complications as a result of the study procedures that may qualify for coverage under Medicare	Yes ☐ No ☐	
	• If you answered NO above, continue to the 3 questions below. • If you answered YES above, then STOP (The trial does NOT meet Medicare's requirements for coverage of routine costs).		
	1. Does the study include any items, tests, or services that are provided free of charge or reimbursed by the Sponsor?	Yes ☐ No ☐	
	2. Does the study include any items, tests or services that are not part of routine care	Yes ☐ No ☐	
	3. Does the study include any items, tests, or services that are non-covered by local or national CMS	Yes ☐	

	coverage determinations?*	No ☐	

- If any of the above questions #1-3 were answered YES, then attach an allocation of study procedures table
- If none of the above questions #1-3 were answered YES, then STOP (Completion of Part II is not necessary).

*Medicare Coverage Database: www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx

Final Disposition:

Based on the above documented Coverage Analysis and documents from Medicare (attached), and the study regulatory documents , the trial is a Medicare Qualifying Clinical Trial and meets Medicare's requirements for payment of routine costs. **Yes** ☐ **No** ☐

CERTIFICATION ***(only the PI can provide this certification):***

The Principal Investigator has reviewed the entire protocol and has identified all procedures and/or activities both listed or not listed in the protocol schedule of events/schema. All procedures and/or activities identified from the protocol have been assigned as either: Routine Care (billed to Medicare, insurance, or patient), needs to be included in budget (Sponsor will reimburse VCU), or is Sponsor covered (Sponsor will pay directly). **Yes** ☐ **No** ☐

INVESTIGATOR STATEMENT:

_____ **Principal Investigator Name**	I have reviewed the information within this form and the attached Research Billing Plan (as applicable) and agree that it is complete and accurate to the best of my knowledge. **By:** _____ ***Signature of Principal Investigator*** **Date:** _____
Signature/Date of School/Center Cost Coverage Analysis Designee _____ **Name of Designee/Title** _____	

VCU Clinical Research Costs Analysis
Itemized Research Billing Plan Device and Non Device Clinical Trials and Clinical Studies with Anticipated Participant/Third Party Billing

For Clinical Trials found to be Medicare Qualifying Trials, Part II must be completed and routed with the final internal budget. See sample Itemized Billing Plan Worksheet for tips in worksheet completion. This form must also be completed for any Clinical Research Study in which there is anticipated billing to the participant or a third party.

NOTES:

- *Medicare coverage items definitions are known by Modifiers:*
  - Q0: "investigational clinical service"
  - Q1: "routine clinical service"
- Q1 = RC = Routine Care (Billed to Medicare, patient/patient's insurance); Q0 = SB= Sponsor Billed (must be budgeted); SDP= Sponsor Directly Paid (not in budget)
- Visits that are the same may be listed together as long as the allocation is the same. (Example – title a column visits 1-3, instead of a column for each visit)
- The table should be modified to meet study needs as long as all procedures that are potentially billable are allocated.
- In the comment column please note your rationale for this decision and include which national guidelines for disease treatment were utilized if applicable.
- All procedures and visits must be included.

Billing Plan – Payment Responsibility

		Study Title:
		Sponsor: **Protocol Number/Reference/Version/Date:**
		Principal Investigator Name (Department):
		Study Coordinator Name:
		Study Location:
		Anticipated Start Date: **Name of person completing forms**
		☐ **Clinical Trial Non Device** ☐ **Clinical Trial Device** ☐ **Clinical Study**
		Original: **Revision:** **Date:**

		Revision Checklist: ☐ **Revised Itemized Research Billing Plan** ☐ **This revision/amendment has been revised and:** ☐ **Requires adjustment to the budget/contract** ☐ **Does not require adjustment to the budget/contract** **Signature of PI for Revision: _____**

RC= Routine Care (billed to Medicare, patient/patient's insurance); SB= Sponsor Billed (needs to be budgeted); SDP= Sponsor Directly Paid (not in budget)												
		(Screening Baseline)	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Comments
Procedures													