University of Mississippi Medical Center Clinical Studies Charge/Billing Form

Project Title:			IRB#
Principal Investigator:		**Department:**	
Study Coordinator:		**Phone #:**	
Bills will be submitted to: (Please list Study's primary contact for billing)		**Fax#:**	
		Email:	
Contact Information for Person completing Form:			
Sponsor (source of funding):			
Type of Sponsor	☐ **Federal** ☐ **Industry** ☐ **Foundation** ☐ **Internal**		
Expected number of Participants:		**Projected Length of Study:**	
Services will be provided as:	☐ **Inpatient** ☐ **Outpatient** ☐ **Both**		
Will any study-related procedures/services be billed to any third party payer? ☐ **No** ☐ **Yes** **(If Yes, page 4 of this form must be completed)**			
Will a study drug be used: ☐ **No** ☐ **Yes** **(If Yes, Pharmacy IDS Epic Investigational Product Build Form must be completed)**			
Will sponsor request itemized invoice with CPT codes and non-discounted charges? ☐ **No** ☐ **Yes**			
National Clinical Trial (NCT) Number: **This is the 8-digit number assigned by ClinicalTrials.gov**			

List all Hospital Services that will be <u>billed to Sponsor</u>. If additional lines are needed please use additional pages.

Will service also be SOC?	Hospital Services Requested (Procedures, tests, exams, etc.) Please also include anesthesia and recovery room services, etc.	Performed By (MD name, department, etc)	Location(s) of Service (Building and room number or cost center)	UMMC Charge Code or CPT Code	Charge for Service:	Discount % Applied	Discounted Charge for Service
No							
No							
No							
No							
No							
No							
No							
No							
No							
No							
No							

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List all Physician Services to be <u>billed to Sponsor</u>. If additional lines are needed please use additional pages.

Will service also be SOC?	Physician Services Requested (Physical exams, interpretations, fees, etc.)	Performed By (MD name, department, etc)	Location(s) of Service (Building and room number or cost center)	UMMC Charge Code or CPT Code	Charge for Service:	Discount % Applied	Discounted Charge for Service
No							
No							
No							
No							
No							
No							
No							
No							
No							
No							
No							
No							
No							
No							
No							
No							
No							
No							

_____ _____

Principal Investigator Signature **Date**

_____ _____

Hospital Finance Signature **Date**

Project Title:		IRB#

Principal Investigator:		Department:	
Study Coordinator:		Phone #:	

List all non-investigational, non-standard of care medication that will be used during the study

If investigational drug will be used, complete IDS Epic Investigational Product Build Form and Estimated Charge Worksheet

Will medication also be SOC?	Medication Name	Concentration	Strength	Form	Charge for Medication	Discount % Applied	Discounted Charge for Medication
No							
No							
No							
No							
No							
No							
No							
No							
No							
No							
No							
No							
No							
No							
No							
No							
No							

Medicare Coverage Analysis

This form should be completed for all studies that will bill study-related procedures/services to any third party payer.

Project Title:		IRB#

Principal Investigator:		**Department:**	
Study Coordinator:		**Phone #:**	

For help with answering the questions below, please see instructions http://research.umc.edu/private/clinical_research.html or contact: Bessie Greene (601.926.3602) / Bonnie Woods (601.925.6744)

Medicare Part A Provider Inquiries: Novitas Solutions – Office of the Medical Director, Attn: Debra Patterson, M.D., P O Box 890089 Camp Hill, PA 17089-0089

Clinical trials that are deemed to be automatically qualified:			
	Yes	**No**	**Comments**
Is the trial funded by NIH, CDC, AHRQ, CMS, DOD or VA?	☐	☐	
Is the trial supported by centers or cooperative groups that are funded by NIH, CDC, AHRQ, CMS, DOD and VA?	☐	☐	
Is the trial conducted under an investigational new drug application (IND) reviewed by the FDA?	☐	☐	
Is the trial a drug trial that is exempt from having an IND under 21 CFR 312.2(b)(1)?	☐	☐	
Any clinical trial receiving Medicare coverage of routine costs must meet the following three requirements:			
	Yes	**No**	**Comments**
Is the subject or purpose of the trial the evaluation of an item or service that falls within a Medicare benefit category (e.g. physicians services, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g. cosmetic surgery, hearing aids)?	☐	☐	
Does the trial have a therapeutic intent? The trial must not be designed exclusively to test toxicity of disease pathophysiology.	☐	☐	
Does the trial enroll patients with a diagnosed disease rather than healthy volunteers? Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.	☐	☐	
Clinical trials also should have the following desirable characteristics:			
	Yes	**No**	**Comments**
Does the trial to test whether the intervention potentially improves the participants' health outcomes?	☐	☐	
Is the trial well supported by available scientific and medical information or is it intended to clarify or establish the health outcomes of interventions already in common clinical use?	☐	☐	
Does the trial not unjustifiably duplicate existing studies?	☐	☐	
Is the trial design appropriate to answer the research question being asked in the trial?	☐	☐	
Is the trial sponsored by a creditable organization or individual?	☐	☐	
Is the trial in compliance with federal regulations relating to the protection of human subjects?	☐	☐	
Are all aspects of the trial conducted according to appropriate standards of scientific integrity?	☐	☐	
Does the study involve either of the following devices:			
Category A – Device will be used in immediately life-threatening situations. Fiscal Intermediary must approve protocol.	☐	☐	
Category B - requires a coverage determination from the Fiscal Intermediary	☐	☐	