OREGON HEALTH & SCIENCE UNIVERSITY **RESEARCH RATES REQUEST FORM**
UNIVERSITY HOSPITALS AND CLINICS

The purpose of this form is to: 1) request hospital services for research and 2) request research rates for hospital services.

NOTE: This form is for rate approval and departmental review, but it is the responsibility of the researcher to contact the hospital service departments and apprise them of the details of the protocol if it is complicated or outside of the usual service requirements. Charges relating to your research study will be charged to your Oracle Grants Accounting (OGA) Project Number according to OHSU Hospitals & Clinics Research Rate policy. The RPCNA rates charged to your grant are calculated as a percentage of hospital charges. In instances where the RPCNA rate is greater than 100% of the hospital charge, then your grant is charged the hospital charge. As hospital charges are updated, the amount charged to your grant will be correspondingly updated. As the RPCNA is updated (on an annual basis), the rates will be adjusted accordingly (it is recommended that you budget for an increase of 10% per year of the study).

Form Procedure:

Researcher: Complete items 1-3 on page 1, complete p. 2, and attach IRB lay language protocol, Clinical Study Billing Schedule from the study IRB Initial Review Questionnaire (IRQ), and full research protocol; Discuss requested clinical services with the providing Department Director(s), obtaining Department Director approval signature. **Forward form, IRB Lay Language Summary, and IRQ Clinical Study Billing Schedule to Patient Business Services (PBS) at Fax 4-4546 or mail code L227.**

PBS: Forwards copy of approved Research Rates Request Form to providing Department Director (s). If section 2 is completed, forward a copy to Admitting. Forward Clinical Study Billing Schedule and page 2 to the PBS Governmental Billing Manager.
Note: PBS will not process charges or issue an industrial account number until this form has been completed and the IRB Lay Language Summary and Clinical Study Billing Schedule are received.

1. Planned Hospital Services for Research: (Add additional pages if necessary)

Note: All procedures coded 0000 will not be discounted.

Clinical Department	Dept. No.	Description of Services (Indicate excluded procedures.)	Department Approval		Date of Approval
			Signature:		
			Printed Name:	Ext:	
			Signature:		
			Printed Name:	Ext:	
			Signature:		
			Printed Name:	Ext:	
			Signature:		
			Printed Name:	Ext:	

2. Study Name (30 characters): _____
IRB# : _____
Grant Period From: _____
To: _____
Number of Patients: _____

3. Responsible Party: _____
Lead Contact Person: _____
Ext: _____
Department: _____
Mail Code: _____

OHSU

Checklist of Requirements for Medicare Coverage of Routine Clinical Trials Costs

Study:

PI:

This form assists PBS to determine whether certain services are billable to Medicare under the National Coverage Decision "Routine Costs in Clinical Trials" for Medicare (NCD). The study must meet **all** of the following to be covered under the NCD:

Yes	No	
☐	☐	**1.** The subject or purpose of the trial is the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic tests) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).
☐	☐	**2.** The trial is not be designed exclusively to test toxicity or disease pathophysiology. It must have a therapeutic intent.
☐	☐	**3.** Trials of therapeutic interventions enrolls patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

The study must also be **one** of the following to be covered under the NCD:

Yes	No	
☐	☐	**1.** Is funded by NIH, CDC, AHRQ, HCFA, DOD, and VA.
☐	☐	**2.** Is supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, HCFA, DOD, and VA.
☐	☐	**3.** Is conducted under an investigational new drug application (IND) reviewed by the FDA.
☐	☐	**4.** Is a drug trial that is exempt from having an IND under 21 CFR 312.2(b)(1).
☐	☐	**5.** Is an experimental/investigational (category A) device for use in the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition.[1] (NOTE: Approval must be obtained from Medicare prior to billing services related to devices. Please refer to Use of Devices in Patients and Research Subjects, Adm 05.18 for instructions related to obtaining approval.)

Principal Investigator Signature _____ Date _____

[1] An immediately life-threatening disease or condition is defined as "a stage of a disease in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment." (CMS Transmittal 131, 12/17/04)

Print Name