

Department of
Radiology

V i r g i n i a C o m m o n w e a l t h U n i v e r s i t y

VCU Medical Center

*Subspecialty Expertise and Quality
Imaging for Better Patient Care*

Department of Radiology

Ancillary Research Services Handbook

(Updated 10/2013)

TABLE OF CONTENTS

	<u>PAGE</u>
Contact Information	i
I Introduction	1
Getting Started	2
Example Price Request Form	
II Establishing a Service Agreement	4
1 The Service Agreement	4
Example Service Agreement	
2 A Letter to the PI	6
3 Patient Registration Form	6
Example Patient Registration Form	
4 Monthly Patient Log	8
Example Monthly Patient Log	
5 Grants and Clinical Trials Agreement for Institutional Acct Billing Form	10
Example Grants and Clinical Trials Agreement Form	
III Further Guidelines for using Radiology Ancillary Services	13
Studies Requiring Radiology Specific Imaging Protocol	13
Preliminary Test Images / Dummy Scans	13
Imaging Data (CDs)	14
Special Radiologist Reads	15
IV Policies & Procedures Overview for Start Up and During your Study	16
Process Flow Chart	17
Frequently Asked Questions	18

Welcome to the Department of Radiology's Office of Research Administration

www.radiology.vcu.edu/research/index.html

Contact Information

Meagan D. Sok
Clinical Research Administrator

Tel: (804) 828-8196

Fax (804) 828-6129

PO Box 980470

mdsok@vcu.edu

INTRODUCTION

Requesting Radiology Services for Research

The Department of Radiology is committed to upholding the tradition of research excellence known at the VCU Medical Center. With seven full-time research scientists and more than forty faculty radiologists, our research initiatives are multifaceted and cutting-edge. The driving force behind everything we do is simply to provide patients with the best diagnostic and therapeutic medical care possible.

We are also dedicated to facilitating the research of other physicians in the institution or the community who require use of our state-of-the-art equipment, staff and/or faculty. Any researchers wishing to use these facilities must have their protocols reviewed and have a Service Agreement in place through the department's Office of Research Administration. Please involve the Department of Radiology early in the planning process for your research/ clinical trial. We will assist you through each phase of this process: I) Getting Started; II) Establishing a Service Agreement; and III) Policies & Procedures Overview for the Start-up and Duration of Your Study.

We look forward to working with you!

I) Getting Started

The first step in acquiring Radiology services for your study is to submit:

1. A Completed Pricing Request Form
2. Your Full Protocol or Study Plan
3. All Special Imaging Guidelines that must be followed during image acquisition.

You can submit all of the above to Meagan Sok electronically at mdsok@vcu.edu or hard copy to PO Box 980470.

Please allow up to two weeks for evaluation and pricing of your study. For government grants, pricing is based on Medicare rates. For non-government grants, pricing is based on a negotiated percentage of standard charges.*

When completing the Pricing Request Form, be sure to fill in all of the required fields, paying special attention to any specific technical requirements, test images, surveys, reads (RECIST, WHO), or CDs to be sent to the Sponsor. This will enable our office to properly price your Agreement. Once the Research Administrator has reviewed your protocol and Pricing Request, a Service Agreement will be generated and sent to you via email. (For further information, please see the section titled “Establishing a Service Agreement” on page 4.)

* If the quoted price is unacceptable, please send a letter requesting reduced pricing with an explanation of the circumstances necessitating the request to the Radiology Executive Committee, c/o Meagan Sok, PO Box 980470. Include a brief synopsis of your study with a description of the Radiology services requested. The Executive Committee will review the request and notify you of its decision as soon as possible, typically within two to three weeks.



Virginia Commonwealth University

Radiology Services Pricing Request
(please note: you must submit Protocol along with this form)

Date: _____

PI: _____

Contact: _____

Department: _____

Address (Box #): _____

Phone: _____

Fax: _____

Study Information:

Title: _____

Sponsor: _____

Protocol #: _____

Est. Start Date: _____

Est. End Date: _____

Est. # of Patients: _____

Department of Radiology
 PO Box 980470
 Richmond, VA 23298
 Phone: 804.828.3993
 Fax: 804.828.6129
 www.radiology.vcu.edu

Radiology Studies/Procedures Requested:

Imaging Location (select all that apply)	<input type="checkbox"/> Main 3 <input type="checkbox"/> Nelson Clinic <input type="checkbox"/> Stony Point <input type="checkbox"/> ACC <input type="checkbox"/> Nuclear Medicine
---	--

Has This Study received IRB approval? Yes No

Does The Study Require the Involvement of a Radiologist (i.e. to provide information not typically found in standard reports, RECIST/WHO reads, CRF completion, protocol oversight)? Yes No

If yes, please explain in detail:

Does the Sponsor/Protocol require any of the following:

- Site Survey/Questionnaire* Yes No
- QC/Test Images to be performed* Yes No
- Specific Technical factors for imaging^Δ Yes No
- Anonymized CDs to send data to Sponsor Yes No

*Please allow two to three weeks for review/completion
^ΔSubmit copy of Technical Manual to Radiology

Version 03/2010

II) Establishing a Service Agreement

The Service Agreement email will contain 5 important attachments:

1. The Service Agreement
2. A letter to the PI
3. Patient Registration Form
4. Monthly Patient Log
5. Grants and Clinical Trials Agreement for Institutional Acct Billing Form

1) The Service Agreement -

Includes an line itemization of all radiology services and associated costs required by your research study/clinical trial. The pricing quoted is valid for 60 days (if the Agreement has not been executed* within 60 days, Radiology reserves the right to review the quote and adjust, if necessary).

-The PI should review and sign the Agreement

-Return the Agreement to Meagan Sok via fax 804.828.6129 or email mdsok@vcu.edu.

***Note:** The Service Agreement is considered “executed” when Radiology Research Administration has received the signed Agreement, completed Billing Forms, and the Banner Index #. Furthermore, if the Service Agreement is not executed at least thirty (30) days prior to any patient enrollment, full radiology charges will be applied.

Department of Radiology

Virginia Commonwealth University Medical Center
 P.O. Box 980470
 Richmond, VA 23298
 Phone (804) 828-8196 Fax (804) 828-6129

Service Agreement

DATE:
Pricing valid until: 1 yr from pricing date
Prepared by: Meagan Sok

Requestor Information				
Title of Study:				
Protocol #:				
Sponsor:				
PI:		Est. Start Date:		
Contact:		Est. End Date:		
Department:		Est. # of Patients:		
Address:				
Phone:				
Fax:				
Comments or special instructions:				
Procedure	CPT Code	Technical	Professional	Charge Per Scan
				\$0.00
				\$0.00
				\$0.00
Start Up Fees				

If you have any questions concerning this pricing, contact Meagan Sok at 828-8196 or mdsok@vcu.edu

The signature of the PI (or his/her designee) constitutes acceptance of this quotation, execution of the formal price agreement for this trial, any requirements set forth on this service agreement, and adherence to Radiology Research Administration's policies and procedures (<http://www.radiology.vcu.edu/research/index.html>). You are further acknowledging that this study is in strict compliance with VCUHS and HIPAA Policies and Procedures on how Protected Health Information can be accessed and used by researchers.

Thank You for Using the Services of The Department of Radiology

Approved:

 Meagan Sok Date
 Research Administration

 Sherry C. Elliott, Vice Chair Date
 Administration and Operations

 Principal Investigator
 0

2) A Letter to the PI -

The letter to the PI acts in two ways. First, it acknowledges the agreement we have entered into with the study team regarding the radiological research services being requested. Second, the letter outlines all the forms associated with the agreement and how to use them during the trial.

3) Patient Registration Form* -

This Form is specifically tailored for each research study/clinical trial. It will include the appropriate registration/scheduling information along with pre-populated research study/clinical trial billing information. One form per subject, per imaging study is required, each time he/she is receiving a radiology test or procedure that is being paid for by a research study/clinical trial.

-Do not use this Form for Standard of Care procedures.

-The Form must be faxed to the listed registration/ scheduling area at least one (1) day before the scheduled procedure.

-The Form should also be given to the patient to take with them when registering for radiology test/procedure.

-The Study Coordinator needs to only fill out the patient name, MR#, Banner Index #, and in some instances, the procedure/service requested.

-The Patient Registration Form is not to be used for RECIST or WHO reads.

* When ordering an exam for an inpatient, the coordinator must specify that the patient is part of a study and ensure that the title of the study appears on the order's comment section. Research Administration must be notified when an in-patient has been scheduled within 48 hours.

- If a specific radiology-related protocol is to be followed (one that differs from our institutional radiology imaging or procedure protocols), the coordinator must communicate directly with the appropriate area of radiology the day of the services (regardless of whether the subject is inpatient or outpatient). When applicable, it is strongly recommended that the coordinator accompanies the subject to radiology. This will ensure that specified protocols are followed and proper billing occurs.

DEPARTMENT OF RADIOLOGY

RESEARCH PATIENT REGISTRATION FORM
GROUP BILLING

❖ Fax this form to the appropriate registration location (see options below) 1 day before the scheduled procedure. This form should only be used for out-patients having radiology service(s) paid for by sponsor/grant.

Registration Location:

- Main 3
 - Fax: 827-0089
 - Contact: Chante Henderson if needed (6-2938)

*Give a copy to the Patient to present to the registrar at time of service

Attention Study Coordinator: Please fill in Patient Name, MR #, Procedure Requested, and Banner Index # (This can be obtained from your Fiscal Administrator). The remainder of the form is for internal Radiology Department use only.

PATIENT NAME	MEDICAL RECORD #
Procedure/Services Requested:	

Attention Registrar:

On the *XP-Reimbursement Responsibility* screen in **IDX Visit Management**, move the patient's insurance information down & **insert the grant billing information (listed below) as the 'primary payor'** to ensure the bill is sent to the grant account for this particular procedure/service.

Click the "**Insurance Code**" tab, and type in Insurance code **0421** which will register as "**Group Billing – Visit Level**", then **Add** this plan and click **OK**. Fill in the following plan detail:

1	ID#	<i>(Banner Index #)</i>
10	Effective date	<i>Type "T" for today's date</i>
11	Expiration date	<i>Leave Blank (unless study/procedure only needed 1 day)</i>
22	Insurance Company Dictionary Entry	<i>Type "10140" which will fill in as "Grant Varies"</i>
23	Insurance Company Name Override	<i>Study Name</i>
24	Insurance Company Address Line 1	<i>Coordinator/Billing Contact Address</i>
25	Insurance Company Address Line 2	Blank
26	Insurance Company City, State	
27	Insurance Company Zip Code	
30	Insurance Company Telephone Number	
5082	Carrier Code	
5083	Eligibility Verified by	Blank
50	Date Eligibility Verified	Blank
5090	Billing Contact	<i>Coordinator or Other</i>
5101	Generate Claim?	<i>Type "Y"</i>
5098	IDX User Initials	<i>Type in your initials</i>
51	Date Added/Updated	<i>Type "T" for today's date</i>

Version: 05/08/2009

4) Monthly Patient Log -

As part of your Service Agreement, we require that you email to Meagan Sok (at mdsok@vcu.edu) a Monthly Patient Log identifying patients who have received radiology services for the previous month. This Log is due on or about the 5th of each subsequent month, and should include Study Name, Patient Name, MR#, Radiology Procedure/Exam, and Exam Date.

Purpose: to help ensure appropriate billing of radiology services.

5) Grants and Clinical Trails Agreement for Institutional Account Billing Form -

This form is of especially high importance. This form ensures that as a institution and health system, we are abiding by the multiple regulations that are outlined with regards to research billing. This form is to be completed and sent in to the individuals on the form, **BEFORE** any patient is enrolled into the trial.

Once sent in, a billing account will be set up on the physician and hospital sides. When this account is set up, the study team will receive confirmation of this and the account number that has been assigned to their study. This account number is to be inserted onto the Patient Registration form to ensure that the individual registering the patient for the service, attributes the charges to the correct account.

***Note:** if this Billing Form is not returned appropriately signed and completed at least thirty (30) days prior to any patient enrollment, full radiology charges will be applied.

Grants and Clinical Trials Agreement for Institutional Account Billing

- A. Is this a revision of a prior form for this study? Yes/ No**
- a. **If yes, when will this change become effective?**
- b. **Does this revision effect all participants in the study after the effective date? If not please explain.**

B. Type of Account

	Grant/Study	Clinical Trial	Contract/Other
Government	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Non-Government	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

C. Account Information

VCU IRB#:

NCT#:

Account Name (mnemonic):

Account/Study Alias Name(s):

Billing Department:

Department Billing Contact:

Department Billing Address:

Phone Number: Email:

D. Additional Information for Grant/Study/Trial

Official Protocol Title:

Principal Investigator: Effective Date:

Study Coordinator: Effective Date:

Grant Number: Expiration Date:

PT#:

Sponsor: Site Accrual Goal:

Please attach the completed cost coverage package

E. Billing Instructions

- Please indicate how this study is to be billed. Please choose only one.
- PO #
- Bill Grant/Study Only
- Government Funded Grant/Study (Must be billed to Institutional Account for the same service)

Form version: July 29, 2013

F. Patient Information

Please send the completed table, "Monthly Report of Patient Information for Grants and Clinical Trials" each month to Alice Fowler, Special Accounts Supervisor, vfowler@mcvh-vcu.edu, and Margaret Johnson, Special Billing Supervisor, mejohanson@mcvh-vcu.edu.

G. Departments and Procedures: You must attach a detailed agreement from each ancillary service

- | | | | |
|---|--|---|---|
| <input type="checkbox"/> Anesthesiology | <input type="checkbox"/> Ophthalmology | <input type="checkbox"/> Radiation Oncology | <input type="checkbox"/> Dermatology |
| <input type="checkbox"/> Orthopedics | <input type="checkbox"/> Radiology | <input type="checkbox"/> Emergency Services | <input type="checkbox"/> Otolaryngology |
| <input type="checkbox"/> Surgery | <input type="checkbox"/> Family Medicine | <input type="checkbox"/> Pathology – Lab | <input type="checkbox"/> Human Genetics |
| <input type="checkbox"/> Pediatrics | <input type="checkbox"/> Internal Medicine | <input type="checkbox"/> Physical Med & Rehab | <input type="checkbox"/> Neurology |
| <input type="checkbox"/> OB/GYN | <input type="checkbox"/> Neurosurgery | <input type="checkbox"/> Psychiatry | <input type="checkbox"/> Inv. Pharmacy |
| <input type="checkbox"/> CRSU | <input type="checkbox"/> Other: | <input type="text"/> | |

H. Billing Agreement

Agreement is made between and MCV Hospitals/Physicians regarding reimbursement for professional services rendered on behalf of the above mentioned organization or Grant/Study. Payment in full to MCV Hospitals/Physicians is due upon receipt of our statement. Balances over 45 days old are considered past due. In the event that a grant should expire or funds are dissipated before all outstanding charges have been paid, the PI agrees that MCV Hospitals/Physicians will bill the covering account identified by the PI.

PI Signature Date

Coordinator Signature Date

Should you have any questions about Physician Billing, contact Alice Fowler, Special Accounts Supervisor, MCV Physicians, at 358-6100 ext 1249. Should you have any questions about Hospital Billing, contact Margaret Johnson, Special Billing Supervisor at 828-2841 ext 1099.

Form version: July 29, 2013

III) Further Guidelines for using the Department of Radiology Ancillary Services

Studies Requiring a Radiology Specific Imaging Protocol

-A copy of the imaging protocol must be given Research Administration. The study-specific imaging protocol will be compared to existing Radiology protocols. If it differs greatly and the study is to be read by a staff radiologist, the radiologist must give approval for implementing the protocol as to keep with our department's high quality imaging standards.

***Once approved, the study's coordinator must provide a binder with the following three sections: full protocol, the imaging-specific protocol, and the coordinator contact information along with the PI's information. This binder will be placed in the appropriate Radiology work area that will implement the study specific imaging protocol.

Preliminary Test Images/Dummy Scans

Preliminary test imaging scenarios and requirements:

-If imaging is performed on a human subject, the cost of the exam will be charged.

-If imaging is obtained from a prior study, a fee will be charged for time and effort to collect the images and anonymize the data.

-Labeling and shipping of the CDs will be the responsibility of the study's coordinator.

-All CDs will have patient information anonymized. VCU's name and logo will remain unless a blank CD is provided.

-HIPAA forms "Request for Limited Data Set" and/or "Request for De-Identified Health Information" must be submitted to the Compliance Services Office if a patient's images are used. These forms can be downloaded from the VCU HIPAA Compliance web site and sent electronically. Approval from the Compliance Services Office must be received prior to obtaining the CD.

Imaging Data (CDs)

- Images can be placed onto a CD in Dicom format (except mammograms).
- All CDs should be anonymized (this service is available through the Imaging Resource Center, 804.828.3543). It must be specified that a CD is to be anonymized or the patient's information will remain.
- Labeling and shipping is the study Coordinator's responsibility, as well as downloading all anonymized images to a central reader.

Special Radiologist Reads

RECIST, WHO, or any Non-standard-of-care Radiology Research Read

For each special read, there will be a flat rate fee of \$100 per area-of-interest (i.e., chest, abdomen, pelvis CTs are charged \$100 each for a total of \$300, if all three areas are needed).

Specialty/Research Read Set Up Process

- RECIST costs are to be included in the Service Agreement.
- The Research Administrator facilitates assignment of a radiologist to provide reads.*
- The Coordinator will be notified of the assigned radiologist. Coordinator must contact the radiologist to determine the work flow strategy (i.e., how will the radiologist be alerted to a subject's exam date/time, etc.).
- It is the Coordinator's responsibility to provide CRFs if required.

Duration of the Study

- When scheduling/ordering an exam which requires a RECIST read, be sure to add to the order's comments (must appear on Radiology's PPF form) which radiologist is to perform the read (i.e., "Dr. Halvorsen is to perform RECIST read").
- In the Monthly Patient Log (sent to Meagan Sok), please add RECIST reads performed, so that charges are invoiced appropriately.
- Always alert the assigned radiologist of an upcoming specialty read.

*A back-up radiologist may be provided for emergency scenarios (i.e., assigned radiologist is off for one week and a measurement is needed in 48 hours) upon request of the Coordinator or PI.

IV) Policies & Procedures Overview for the Start-up and Duration of Your Study

Once your study is up and running, you are required to do the following:

-Continue using the Patient Registration Form for all services that are to be billed to the study (for out-patients only).

-Contact Radiology Research Administration when scheduling an in-patient.

-The Service Agreement must be signed within 60 days of the date it was generated (and faxed back to our offices).

-The Service Agreement and Billing Forms must be signed and appropriately completed 30 days prior to any patient enrollment in order for an account to be set up. Otherwise, full radiology prices will be applied.

-All images sent to a Sponsor or Core lab must be anonymized. This service is available through the Imaging Resource Center (804.828.3543). Anonymization must be requested specifically.

-Send the Monthly Patient Log to Meagan Sok at mdsok@vcu.edu in a timely fashion (generally due by the 5th of the following month for which you are reporting).

-Inform us of any protocol adherence problems immediately.

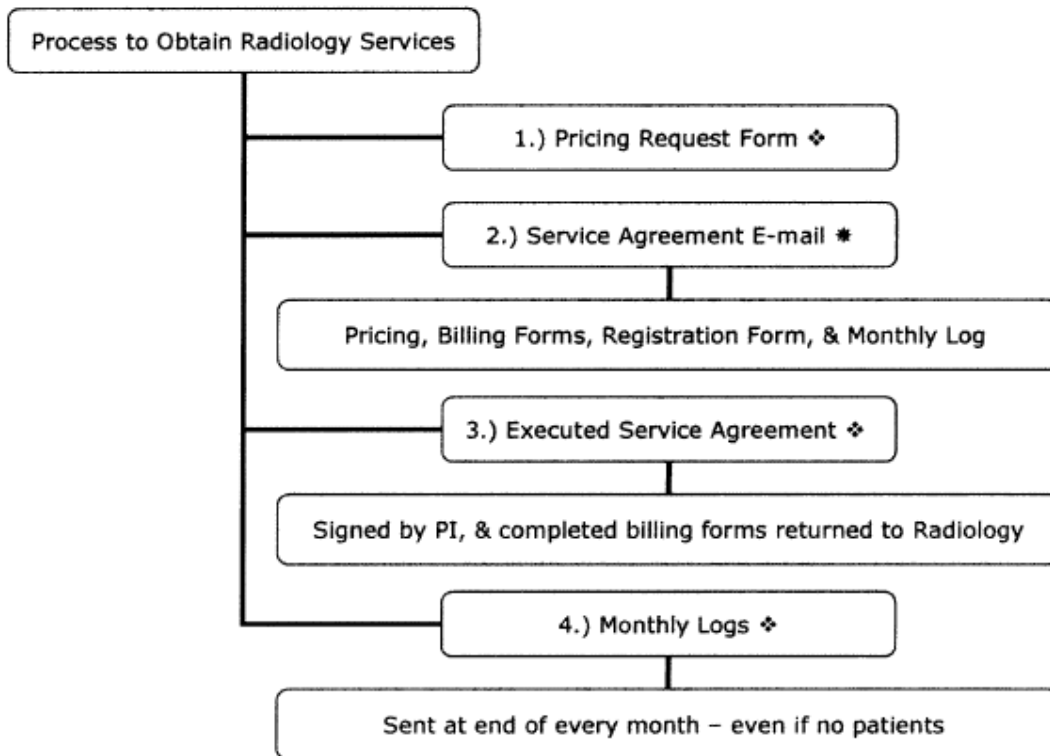
-If you encounter any billing errors while administering your project, please notify our Department (Meagan Sok) as soon as possible via email with the patient's MRN, date of service and service provided.

Flow Chart

Key:

❖ = Coordinator

* = Radiology



Frequently Asked Questions

How is the process started to obtain radiology services for a research study?

E-mail a Pricing Request Form to Meagan Sok (mdsok@vcu.edu) and attach the full protocol along with any special imaging guidelines required.

How often do I fill out the billing form?

Only one time. The billing form is to be completed by the requesting department and returned to Meagan Sok along with the signed Service Agreement. If the completed billing forms are not received by the Radiology Research Administration office 30 days prior to first enrolled patient, full radiology charges will be applied.

When do I use the Radiology Research Registration Form?

Only when research funds are going to pay for a radiology service. One form per patient, per imaging study is required. For example, if a study is paying for a patient to have a chest x-ray and CT, two registration forms are needed. For more guidance, refer to the Registration Form instructions on page 11.

Can I add a service to an existing Service Agreement?

Yes. However, a new Pricing Request Form must be sent. A revised Service Agreement will be returned to the principal investigator for review and signature. The revised and resigned Service Agreement should be sent back to Meagan Sok.

When is the monthly log due? Logs are due at the end of each month and should be received no later than the fifth of the following month. All pertinent information must be included. This should be e-mailed to Meagan Sok.

If you have any additional questions pertaining to requesting radiology research services, please contact the Office of Research Administration at 804.828.8196

