Radiology Research Services Handbook

(Updated 09/2009)
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Welcome to the Department of Radiology’s Office of Research Administration

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

Contact Information

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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 your full protocol and a Pricing Request Form, to Megan Quinn at mmquinn@vcu.edu, or 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. [If your study involves a specific Technical Manual/Protocol for imaging, please submit with the Pricing Request Form.] Once the Director 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 Megan Quinn, 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.
Radiology Services Pricing Request
(please note: you must submit Protocol along with this form)

Date: _______________  PI: ____________________________
Contact: ____________________________  Department: ____________________________
Address: ____________________________  Phone: ____________________________
Fax: ____________________________

Study Information:
Title: ____________________________
Protocol #: ____________________________
Est. Start Date: ____________________________
Est. End Date: ____________________________
Est. # of Patients: ____________________________

Radiology Studies/Procedures Requested:

________________________________________________________________________

Has this Study received IRB approval?  □ Yes  □ No

Does Your Study Need the Involvement of a Radiologist (i.e., RECIST/WHO reads, reports/forms filled out, protocol oversight)?  □ Yes  □ No
If yes, please explain:
________________________________________________________________________

Does the Sponsor require any of the following:
Site Survey/Questionnaire*  □ Yes  □ No
QC/Test Images to be performed*  □ Yes  □ No
Specific Technical factors for imaging†  □ Yes  □ No
Anonymized CDs to send data to Sponsor  □ Yes  □ No

*Please allow 2-3 weeks for review/completion
†Submit copy of Technical Manual to Radiology
(Updated 4/08)
II) Establishing a Service Agreement

The Service Agreement email will contain 5 important attachments: Service Agreement, VCU Health System Billing Form, MCV Physicians Billing Form, Patient Registration Form, and Monthly Patient Log.

1) The Service Agreement -
   - Includes an 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 Megan Quinn via fax 804.828.6129 or email mmquinn@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.
# Service Agreement

**DATE:**

*Pricing valid until:* 2 years from above date  
Prepared by:

<table>
<thead>
<tr>
<th>Requestor Information</th>
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<tbody>
<tr>
<td><strong>Title of Study:</strong></td>
</tr>
<tr>
<td><strong>Sponsor:</strong></td>
</tr>
<tr>
<td><strong>PI:</strong></td>
</tr>
<tr>
<td><strong>Dept:</strong></td>
</tr>
<tr>
<td><strong>Contact:</strong></td>
</tr>
<tr>
<td><strong>Address:</strong></td>
</tr>
<tr>
<td><strong>Phone:</strong></td>
</tr>
<tr>
<td><strong>Est. # of Patients:</strong></td>
</tr>
<tr>
<td><strong>Comments or special instructions:</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Procedure</th>
<th>CPT Code</th>
<th>Technical</th>
<th>Professional</th>
<th>Costs</th>
</tr>
</thead>
</table>

*Pricing will increase 2.5-3% after each 2 year increment.*

If you have any question concerning this pricing, please contact Megan Quinn at 828-8196 or mmquinn@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](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.**

**Approved:**

---

Megan Quinn, Director  
Research Administration

Sherry C. Elliott, Vice Chair  
Administration and Operations

---

Principal Investigator
2) VCU Health System Billing Form -

This form arranges for billing on technical services for radiology procedures and must be completed once and returned to Megan Quinn via fax at 804.828.6129 or email at mmquinn@vcu.edu.

*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.
VCU HEALTH SYSTEM - RESEARCH ACCOUNT BILLING REQUEST

General Information
Name of Grant/Study: ___________________________ Grant # if applicable: ________________
Contact Person: ___________________________ Phone #: ___________________________
Date Begin: ___________________________ End: ___________________________ Max. Funding if applicable: ___________________________

Billing Information
How will we need to bill this Grant/Study?
{} UB-92 Billing form (3rd Party Insurance)
{} Regular Statement (All Others)

How often will you need billing?
{} For each date of service per patient
{} Weekly Summary
{} Monthly Summary

Billing forward to:
Name Grant/Study: ___________________________
Address: ___________________________
City, State: ___________________________
Zip Code: ___________________________
Attention to: ___________________________

Please indicate in descending order the appropriate payors to be billed for the account
(1=primary, 2=secondary)

_________ Grant
_________ Patient/Patient’s Insurance

Special Billing Requirements: ___________________________

Special Reimbursement Agreement: Begins ___________________________
Expires ___________________________
Explanation: ___________________________

Check the Patient type of the account:

______ Recurring
______ Outpatient (routing)
______ Special Institutional/patient specimen)
______ Inpatient

At what registration site will the patient/specimen be registered?

Does a new charge need to be established for the services to be provided?
Yes ______ No ______

VCUMC Patient Accounting will require a monthly list of patients and dates of service to ensure that appropriate identification has been made. As per your agreement with the Department of Radiology, you are requested to furnish this information directly to them.

Patient Accounting Use ONLY:
Contractual Adjustment Code: ___________________________
Out of Funds Code: ___________________________ Date: ___________________________
Group Director Approval: ___________________________ Date: ___________________________
Finance Director Approval: ___________________________ Date: ___________________________
3) MCV Physicians Billing Form -

This form arranges for billing on physician services for radiology procedures and must be completed once and returned to Megan Quinn via fax at 804.828.6129 or email at mmquinn@vcu.edu. [Please note: this form must be signed by the Grants/Fiscal Administrator, or other authorized person from your Department.]

*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.
MCV PHYSICIANS - Agreement for Group Account Billing

A. Type of Group Account: ☐ Grant/Study  ☐ Organizational Billing

Is this a government funded grant/study? YES or NO

B. Group Account Information:

Group Account Name: ____________________________

Billing Address: __________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

Responsible Person Name: ____________________________  Phone Number: ____________________________

C. Additional Information for Grant/Study:

Principal Investigator: ____________________________  Effective Date: ____________________________

Grant Number: ____________________________  Expiration Date: ____________________________

D. Billing Instructions: 

☐ Bill Grant/Study Only  ☐ Bill Organization Only

☐ Bill Patient’s Medical Insurance prior to billing and Grant/Study

☐ Government Funded Grant/Study (Must be billed to Group Account. Can’t bill both patient’s Insurance and grant.)

IMPORTANT NOTE: To properly establish this Group Account, please submit a “contract” providing billing instructions to include explanation of services, list of patients, and choice of monthly itemized statement or individual claim per service.

E. Billing Agreement:

Agreement is made between ____________________________ and MCV Physicians regarding reimbursement for professional services rendered on behalf of the above mentioned organization or Grant/Study. Payment in full to MCV 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, it will be the Principal Investigators responsibility to get the Department’s approval to adjust all outstanding balances.

F. Authorization Signature:

__________________________________________  ____________________________

MCV Physicians  Special Accounts Supervisor  Date

__________________________________________  ____________________________

Clinical Department/Organization Authorization  Title  Date

Should you have questions, please contact Alice Fowler, Special Accounts Supervisor, MCV Physicians, at 358-6100 ext 1249
4) 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.

- Only use this Form for out-patient 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.

* For out-patient use only.
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 a radiologic services paid for by sponsor/grant.

- ACC
  - Fax: 628-0792 (utilize a cover sheet with ATTENTION: ACC Registration)
- Main 3
  - Fax: 827-0089
    - Contact: Sandy Bumbrey if needed (6-2938)
- Nuclear Medicine: 828-4181
  - Point of Contact: Tedra Baskerville
- Walk-in x-ray: 827-0089
  - Point of Contact: Peggy Williams
- CT/MRI/Ultrasound: 628-3593
  - Point of Contact: Linda Turner

*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.

<table>
<thead>
<tr>
<th>PATIENT NAME</th>
<th>MEDICAL RECORD #</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Procedure/Services Requested:

Attention Registrar:
On the XP-Reimbursement Responsibility screen in IDX Visit Management, delete the patient's insurance information, and add the following information to have the above service billed to the appropriate grant or study:

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:

<table>
<thead>
<tr>
<th>1</th>
<th>ID#</th>
<th>(Banner Index #)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Effective date</td>
<td>Type &quot;T&quot; for today's date</td>
</tr>
<tr>
<td>11</td>
<td>Expiration date</td>
<td>Leave Blank (unless study/procedure only needed 1 day)</td>
</tr>
<tr>
<td>22</td>
<td>Insurance Company Dictionary Entry</td>
<td>Type &quot;10140&quot; which will fill in as &quot;Grant Varies&quot;</td>
</tr>
<tr>
<td>12</td>
<td>Insurance Company Name Override</td>
<td>Study Name</td>
</tr>
<tr>
<td>24</td>
<td>Insurance Company Address Line 1</td>
<td>Coordinator</td>
</tr>
<tr>
<td>25</td>
<td>Insurance Company Address Line 2</td>
<td>Blank</td>
</tr>
<tr>
<td>26</td>
<td>Insurance Company City, State</td>
<td>Coordinator address</td>
</tr>
<tr>
<td>27</td>
<td>Insurance Company Zip Code</td>
<td></td>
</tr>
<tr>
<td>30</td>
<td>Insurance Company Telephone Number</td>
<td></td>
</tr>
<tr>
<td>5082</td>
<td>Carrier Code</td>
<td></td>
</tr>
<tr>
<td>5083</td>
<td>Eligibility Verified by</td>
<td>Blank</td>
</tr>
<tr>
<td>50</td>
<td>Date Eligibility Verified</td>
<td>Blank</td>
</tr>
<tr>
<td>5090</td>
<td>Billing Contact</td>
<td>Coordinator or Other</td>
</tr>
<tr>
<td>5101</td>
<td>Generate Claim?</td>
<td>Type &quot;Y&quot;</td>
</tr>
<tr>
<td>5098</td>
<td>IDX User Initials</td>
<td>Type in your initials</td>
</tr>
<tr>
<td>51</td>
<td>Date Added/Updated</td>
<td>Type &quot;T&quot; for today's date</td>
</tr>
</tbody>
</table>

Version: 03/03/2008
5) **Monthly Patient Log -**

As part of your Service Agreement, we require that you email to Emily Klinedinst (at klinedinstea@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.
## Department of Radiology
### Monthly Patient Services Log

<table>
<thead>
<tr>
<th>STUDY</th>
<th>[Study Name]</th>
</tr>
</thead>
<tbody>
<tr>
<td>GRANT/INDEX #</td>
<td>[Index #]</td>
</tr>
<tr>
<td>PRIMARY INVESTIGATOR</td>
<td>[PI name]</td>
</tr>
<tr>
<td>Contact Person:</td>
<td>[contact name/phone]</td>
</tr>
<tr>
<td>MONTH</td>
<td>[month/year]</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Subject Name</th>
<th>Subject #</th>
<th>Date of Service</th>
<th>Procedure</th>
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**Imaging Guidelines**

Please review the following Guidelines for more information on obtaining clinical services for research and clinical trials through the Department of Radiology.

**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 Buzz Willis at 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.
**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).

**Reduction for RECIST & WHO reads**

- If no lesions are found, a charge of $75 will be invoiced (per area of interest).
- Coordinator must provide proof (i.e., send the report, include in patient log) so as not to be billed the full $100.

**Specialty/Research Read Set Up Process**

- RECIST costs are to be included in the Service Agreement.
- The Research Director 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 Emily Klinedinst), please add RECIST reads performed, so that charges are invoiced appropriately.
- Always alert the assigned radiologist of an upcoming specialty read.

* A backup 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.
III) 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 Emily Klinedinst at klinedinstea@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 (Emily Klinedinst) as soon as possible via our Billing Correction Form. This form may be faxed (804.828.6129) or emailed (klinedinstea@vcu.edu).
Billing Correction

Project Title:
Principal Investigator:
Coordinator:

Patient Name:
Patient MR or SSN:
Date of Service:
Study/Procedure:

Description of Error: (double click to check boxes on all that apply)

☐ Procedure/Study billed to Patient/Patient's Insurance
☐ Overcharge for service
☐ Undercharge for service
☐ Invoice not received
☐ Other: "[Click here and type specific error]"

Your request will be reviewed promptly, and someone from the Office of Research Administration will contact you.

PLEASE FAX THIS FORM TO: 804.828-6129
Flow Chart

Process to Obtain Radiology Services

1.) Pricing Request Form ✤

2.) Service Agreement E-mail ✡

Pricing, Billing Forms, Registration Form, & Monthly Log

3.) Executed Service Agreement ✤

Signed by PI, & completed billing forms returned to Radiology

4.) Monthly Logs ✤

Sent at end of every month – even if no patients

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 Megan Quinn (mmquinn@vcu.edu) and attach the full protocol.

How often do I fill out the billing forms? Only one time. The billing forms are to be completed by the requesting department and returned to Megan Quinn 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 Megan Quinn.

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 Emily Klinedinst.

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