Radiology Resource Utilization Committee (RRUC)

Guide for end users (USER)

Version 1

January, 2024

What is the RRUC?

The RRUC is a committee that reviews and approves all research studies that utilize radiology resources. Including, but not limited to:

- Imaging Research Center (IRC)
- Clinical Radiology
- Radiology Informatics
- Staff (analyst, radiologist, and/or physicist support)

RRUC Goals:

- To optimize, facilitate and monitor utilization of Department of Radiology resources pertaining to research.
- To confirm the safety of Radiology related procedures/interventions utilized in research.
- To confirm the feasibility of Radiology related procedures/interventions utilized in research.
- To direct researchers to needed physical and human resources in the Department of Radiology, as appropriate, to optimize imaging research.

What resources are available through the Department of Radiology?

- **Clinical**
  - MRI
    - M1: Philips Ingenia 1.5T
    - M2: Philips Ingenia 1.5T
    - M3: Philips Ingenia 3T
    - M4: GE Architect 3T
    - A6: Philips Ingenia 1.5T
    - NICU: Eyas Ascent 3T*
    - ED MRI: Philips Ingenia 1.5T
    - Kenwood: Philips Ambition 1.5T
    - Green Township: Philips Ambition 1.5T
    - Liberty: Philips Ingenia 1.5T
  - CT
    - CT1: Canon/Toshiba Aquilion
    - CT2: Canon/Toshiba Genesis Edition
    - ED CT: GE APEX
  - X-ray
    - Philips Digital Diagnost
  - PET
    - PET/CT: GE Discovery MI, Gen 2
  - Ultrasound:
    - GE logiq
    - Canon Aplio i800
  - Nuclear Medicine
    - SPECT/CT: GE Discovery 670 Pro
    - SPECT: GE Discovery Nm 630
  - Fluoroscopy
    - Siemens Luminos
  - Interventional Radiology

- Philips Azurion
- Philips Allura

* Scanner not U.S. Food and Drug Administration (FDA) approved – not yet available for clinical *OR* research scanning.

- **Research: Imaging Research Center (IRC)**

MRI Equipment				
MRI Scanner	**Field Strength**	**Human Imaging**	**Animal Imaging**	**Location**
T1: Philips Ingenia	3T	YES	NO	T1
T2: Philips Elition	3T	YES	NO	T1
Philips Ingenia	1.5T	YES	YES	R
Philips Achieva*	3T	YES	YES	R
Bruker	7T	NO	YES	R
ONI	1.5T	NO	YES	R
* IRC 3T-R Achieva scanner will be decommissioned at the end of FY23 (June 28, 2024)				

Ultrasound Equipment			
Ultrasound Scanner	**Human Imaging**	**Animal Imaging**	**Location**
Canon Apilo i800	YES	NO	R or T1*
* If the ultrasound team determines that they would prefer to utilize clinical space for the exam, the clinical pathway (orders, location, etc.) will need to be followed instead of the research pathway.			

IR-TRSL			
Equipment	**Human Imaging**	**Animal Imaging**	**Location**
Philips Allura FD20	NO	YES	R

- **Other**
    - Radiology Informatics tasks/effort
        - Image de-identification (clinical scans only)
        - Image storage
        - Image transfer portal
        - Image CRF creation
        - Image duplication

Systems that can be used		
System	**Task**	**Description**
Compass	Image de-identification	Only utilized for imaging completed utilizing clinical resources.
RRUC SharePoint	Image transfer	After images have been de-identified, study teams can access images via SharePoint for upload to their study-specific portal. 6-month retention for all images on Sharepoint site.
Clinical Ambra	Image transfer	Sending imaging to another site. Typically only utilized for sites/studies that do not have an image sharing platform set-up.

Research Ambra	Image storage Image transfer Image CRF creation	Allows multiple sites to upload and store images. Can create image CRF's within the platform, and beneficial when CCHMC is the lead imaging site.
Clinical PACS	Image storage	Image storage for identifiable imaging obtained on clinical resources. Add-on imaging is also automatically stored in clinical PACS.
Research PACS	Image storage	Image storage for de-identified imaging. Imaging obtained in the IRC is automatically sent to research PACS for image storage.
IRC DICOM	Image storage	De-identified imaging can also be stored on IRC DICOM so that study teams can access for upload to their study-specific portal

- Radiology faculty/staff support
  - Post-processing/Image analysis
  - Case report form completion
  - Image protocol creation
  - Study support staff

Internal submissions:

Studies internal to CCHMC are able to utilize all radiology resources and are responsible for ensuring a budget string has been provided to the RRUC in order for the study to begin.

External submissions:
External (including UC) studies are classified into two categories: engaged and non-engaged.

1) *External non-engaged:* When researchers external to CCHMC reach out to only have services be performed at CCHMC, and no CCHMC faculty or staff are further *engaged* in the research. Also known as, fee for service studies.
2) *External engaged:* When faculty or staff at CCHMC are *engaged* in the research through grant funding or providing academic output outside of standard services provided in Radiology.

What categories of imaging are available in CLINICAL Radiology?

1) **Clinical Imaging:**
   - Imaging requirements: Must use CCHMC standard of care (SOC) scan protocols ***without modification***
   - Stored in: Clinical PACS
   - Radiologist review: Clinical read performed and stored in EPIC
2) **Clinical imaging with a research add-on:**
   - Imaging requirements:
     - Clinical imaging must use CCHMC SOC scan protocols ***without modification***

- MRI:
    a. Research imaging protocol and order created to meet study requirements based on room time
        i. 20 minute add-on
            - Has to be same body part as clinical imaging
        ii. 30 minute add-on
            - Different body part of clinical imaging OR > 20 min room time
- Other modalities (ultrasound, CT, PET, etc.)
    a. Research imaging protocol and order created to meet study requirements based on the applicable CPT code and the research review rates.
- Stored in: Clinical PACS as part of clinical exam
- Radiologist review:
    - If same body part, clinical read performed for clinical images and stored in EPIC. No separate review of research images
    - If different body part, review for abnormal findings on research images required

3) **Research only imaging:**
- Imaging requirements: Specific reason for completing research only imaging on clinical equipment – must be approved by RRUC
    - Research imaging protocol and order created to meet study requirements
- Stored in: Research PACS (de-identified)
- Radiologist review:
    - A radiologist will perform a safety review for unexpected findings. Please reference the CCHMC Radiology Department Policy for more information.
        - Study team is responsible for sending image review form to assigned radiologist
        - No clinical read will be performed
        - If a radiologist is funded on the study, that radiologist will perform the review
            - Funded radiologist may also assist with completion of imaging-related CRF
        - If no radiologist is funded, a radiologist will be assigned to perform the safety review

What categories of imaging are available in the IMAGING RESEARCH CENTER (IRC)?

2) **Research only Human imaging**
- Modalities
    - MRI
    - Ultrasound
        - To minimize clinical ultrasound workflow interruption, research only ultrasound imaging is not typically completed in the IRC unless an MRI is also being completed in the IRC at the same time point
- Imaging requirements: Research imaging protocol created to meet study requirements

- Physicist/Technologist effort may be required to develop imaging protocol
- Test scans may be needed to validate imaging protocol

- Stored in: Research PACS (de-identified)
  - Imaging *cannot* be sent to clinical PACS to be included as a part of the electronic medical record
  - Imaging cannot be sent to the participant's doctors even when unexpected findings are present
- Radiologist review:
  - A radiologist will perform a review for unexpected findings. Please reference the CCHMC Radiology Department Policy for more information.
  - Study team is responsible for sending image review form to assigned radiologist
  - No clinical read will be performed
  - PI is responsible for notifying participant of unexpected findings found by radiologist

2) **Research only Animal imaging**
- Modalities
  - MRI
  - IR Translational Lab
    - Cone beam CT
    - Fluoroscopy
    - Ultrasound
- Imaging requirements: Research imaging protocol created to meet study requirements
  - Effort may be required to develop imaging protocol
  - Test scans may be needed to validate imaging protocol
- Stored in: Research PACS
- Radiologist review: N/A
- Billed to: All services (including imaging) billed to research study via Stratocore

What ancillary procedures/services are available in the IRC?

1) **Oxygen respiratory support**
2) **Adjunctive medication administration**
   - Study team is responsible for coordinating with necessary parties
     - Need to obtain medication from the investigational pharmacy (IP) The medication should be administered by a licensed professional
3) **Intravenous contrast administration (Human scans)**
   - Study team is responsible for coordinating with necessary parties
     - Need to obtain contrast from the investigational pharmacy (IP)
     - Nursing support should place the IV and the contrast should be administered by a licensed professional
     - MD must be present in IRC during scan to monitor for and respond to adverse events (AEs)
4) **Intravenous contrast administration (Animal scans)**

- For large animal studies completed on the 1.5T scanner, the study team is responsible for coordinating with necessary parties
    - Need to obtain contrast from the investigational pharmacy (IP) if internal, or for external users, providing the contrast for the procedure
    - Placing the IV and removal of the IV post procedure
    - Proper dosing and delivering the contrast agent
- For small animal studies completed on the 7T scanner, all animal handling, including contrast administration, is completed by IRC faculty/staff.
- For animal studies completed in the IR-TRSL, all animal handing, including contrast administration, is coordinated between the IR-TRSL and vet services.

5) Anesthesia (Animal scans)

- For large animal studies completed on the 1.5T scanner, the study team is responsible for coordinating with necessary parties.
    - Need to obtain the anesthesia and analgesic drugs required for the imaging session
    - Setting up the anesthesia machine (typically vet services)
    - Listing the required vitals to be monitored during the imaging session, e.g. Heart Rate, SpO2, Respiration, ECG, etc.
    - Sedating the animal before bringing the animal to the MRI suite
    - Assisting in transferring the animal onto and off the tabletop
    - Administering euthanasia drugs to the animal post-imaging session if a non-survival protocol
    - Removing the animal post euthanasia
    - Returning the animal to the vivarium or cage in vet services for survival post imaging session of survival protocols
- For small animal studies completed on the 7T scanner, all animal handling, including anesthesia, is completed by IRC faculty/staff.
- For animal studies completed in the IR-TRSL, all animal handling, including anesthesia and administration of other medications, is coordinated between the IR-TRSL and vet services. All animals are completely sedated prior to arrival in the IR-TRSL.

What ancillary procedures/services are NOT available in the IRC?

1) **Anesthesia (Human scans)**

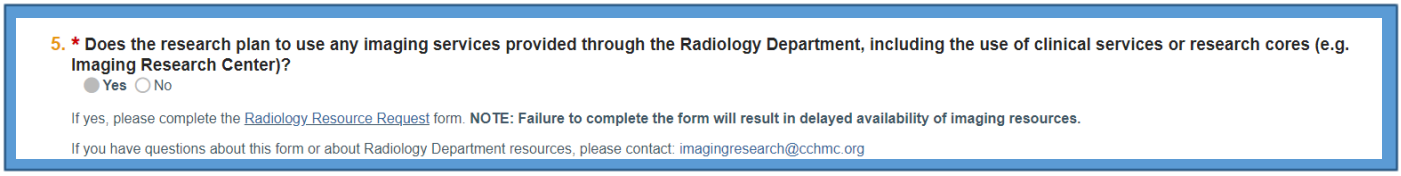
- Anesthesia is not permitted in the IRC for human scanning.

2) **Additional respiratory support**

i. Respiratory support beyond oxygen administered via high-flow nasal cannula is not permitted in the IRC.

What studies should be submitted through the RRUC? How do I submit? Who can I contact with questions?

Any study that involves radiology resources should be submitted and reviewed before resources are requested in the radiology department. The RRUC intake form is available within the HRS IRB submission on Special Locations and/or Services SmartForm page or on the Imaging Research Center Shared Facilities CenterLink Page.


5. * **Does the research plan to use any imaging services provided through the Radiology Department, including the use of clinical services or research cores (e.g. Imaging Research Center)?**
Yes No

If yes, please complete the Radiology Resource Request form. **NOTE: Failure to complete the form will result in delayed availability of imaging resources.**

If you have questions about this form or about Radiology Department resources, please contact: imagingresearch@cchmc.org

Email imagingresearch@cchmc.org with any study specific questions (to see if you should submit, to ask about study resources necessary, to confirm you're submitting correctly), general questions about radiology processes or work flows, or anything radiology-related.

When are submissions reviewed?

RRUC meets twice a month – 2nd and 4th Friday. The automatic response on the imagingresearch@cchmc.org email will indicate the next meeting date. Any study submitted less than 1 business day prior to the RRUC meeting will be up to the RRUC administrators' discretion as to whether it can be reviewed that week. Rush submissions **ARE NOT** encouraged.

How should I expect the process to work?

The process of what you can expect as an end user is detailed below. If you have questions at any point during the process, please reach out to the RRUC administrators at imagingresearch@cchmc.org for assistance.

STEP 1: Submitting

The RRUC submission consists of several pages. The RRUC will *only* review **complete** submissions. Listed below are the most important items on each page that you should expect to complete.

1. General Info:
   a. Type of equipment –
      - IRC equipment
      - Clinical equipment
   b. Subjects –
      - Humans
      - Animals
      - Phantoms
      - Specimens
   c. Working with a CCHMC Radiology faculty/staff member?

   NOTE: *The remainder of the form is based on accurately completing page 1. If you do not believe page 1 was accurately completed, please reach out to imagingresearch@cchmc.org for assistance.*

2. Approvals:
    a. IRB/IACUC Approval –
        - Study ID
        - Approval date
        - Approved protocol

3. Miscellaneous Services:
    a. Radiology informatics –
        - Image de-identification (for clinically obtained images)
        - Image transfer to a SharePoint site
        - Image storage
    b. Radiology faculty/staff –
        - Protocol development (physicist or technologist)
        - CRF completion
        - Post-processing/image analysis
    c. Specific tech training

4. Financial:
    a. Financial information
        - Appropriate financial contact with accurate email
        - Funding status and source
    b. Clinical imaging only: Insurance/patient or Research study billed

5A. Animal Research:

    a. IRC equipment –
    b. Imaging protocol/plan
    c. Species –
        - Mice
        - Rats
        - Rabbits
        - Sheep
        - Swine
        - Cadavers
    d. Scanning details –
        - Scan length (hours)
        - Number of subjects (total)
        - Scans per subject
        - Subjects per year
        - Number of years
        - Estimated number of practice scans

5C. Clinical Human Research:

    a. Justification for use of clinical equipment –
    b. Clinical Equipment to be used –
        - MRI
        - Ultrasound

- X-Ray
- Interventional Radiology
- CT
- Fluoroscopy
- Nuclear Medicine
- PET

c. Imaging protocol/plan
   - Imaging information you have including specific time points or requirements

d. Ancillary Procedures in Radiology –
   - Nursing
   - Contrast agent during study
   - Anesthesia/sedation
   - Patient monitoring
   - Medication administration

5H. IRC Human Research:

a. IRC equipment –
   - MRI (see table above)
   - Ultrasound

b. Imaging protocol –
   - Imaging information you have. If you have a separate document containing your imaging guidelines email them to imagingresearch@cchmc.org

c. Scanning details –
   - Scan length (hours)
   - Number of subjects (total)
   - Scans per subject
   - Subjects per year
   - Number of years
   - Estimated number of practice scans

6. Done
   a. Submit –

NOTE: Completing 6. Done is important for our team to know that study submission is finalized

STEP 2: RRUC Review

Prior to the RRUC meeting, RRUC administrators complete a pre-review of submissions and look for completeness and try to address questions they are aware will arise based on the submission. This will often involve communication with the study team.

Once questions are addressed during pre-review, completed submissions are added to the bi-weekly agenda and the committee reviews the submissions.

STEP 3: Estimate creation

Based on the submission, the RRUC review, and inquiries to the study team, RRUC administrators work with the Radiology and IRC business staff to create a charge estimate. Charges and the how billing will occur is dependent on the location of imaging and whether radiologists have allocated effort on the study.

All rates are subject to change each FY. When planning, estimate a 5% increase per FY.

1. Clinical Radiology:

   Charges are based on the applicable CPT code and the research review rates. Accurate estimates can be provided by the RRUC administrators, and are subject to increase each FY. All billing is completed via EPIC.

   1) Clinical Imaging:
      - Imaging must be CCHMC SOC imaging and is billed to the patient/insurance
   2) Clinical Imaging with a research add-on:
      - Clinical imaging is billed to the patient/insurance
      - Research imaging is billed to the study based on clinical imaging rates
      - Billing completed via EPIC
   3) Research only imaging:
      - Research imaging should be billed to the study. Based on clinical imaging rates
      - If a radiologist is funded on a study there will be no charge for the safety read
2. Imaging Research Center:

   Charges are based on IRC hourly rate and whether a radiologist is funded on the study. All billing is completed via Stratocore.

   - Billed in 15-minute intervals
   - If a radiologist is funded on a study they will be only charged for the base rate, not including an incidental read.
3. Faculty/staff effort and required systems:

   Charges are based on faculty and staff effort and required systems. All billing is either completed via divisional billing or through effort reporting.

   - Includes research IT staff and systems.

STEP 4: Approval

Requirements for Approval:

- All RRUC questions answered – including, but not limited to:
  - Imaging protocol/guidelines/manuals (requirements vs. recommendations)
  - Financial coverage
- IRB/IACUC approval shared with RRUC team
- Financial information, including a GL string, completed
- Order finalized (if applicable)
- Reviewing Radiologist assigned (if applicable)
- IT/Radiology Faculty quote finalized (if applicable)

Approval letters will include a study specific estimate and workflow. Letters will come from imagingresearch@cchmc.org and outline what the study team is approved for based on their RRUC submission.

If applicable, approval letters will include CPT and billing codes to cross-reference with the study-specific coverage analysis.

STEP 5: Modifications to initial RRUC submission/approval

If the study protocol or funding stream changes, the RRUC may require an updated submission and re-review with an updated approval letter.

Update to Budget String:

Study teams can reach out to imagingresearch@cchmc.org to update their GL string. If the study bills in EPIC (uses clinical resources) the GL string will also have to be updated in EPIC via RPF.

Update to study other than the budget string:

May require a re-review or new submission. If re-review or new submission is required, study teams must wait until the next RRUC meeting for their study to be reviewed.

1) New submission requirements:
    - Multiple budget strings for the same study
2) Re-review requirements:
    - Imaging requirements changed (including, but not limited to the following situations):
        - Adding administration of intravenous contrast
        - Protocol change requiring additional effort or resources to implement
    - When body part(s) being imaged change
    - Modality change
        - Including adding imaging in clinical/IRC space to an already approved study
    - Requiring additional resources
        - Including, but not limited to faculty/staff effort
3) No review requirements, but may require updates to RRUC submission:
    - Billing changes
    - Workflow changes
    - Scanner change using same workflow (clinical or research)

Updated Approval Letter:

RRUC requirements for a new approval letter to be created are based on the updates to the study and follow the same guidelines for approval as listed above.

If a task is already outlined, and the workflow will not be altered by the study change, no updated approval letter will be established.

STEP 6: Annual check-in

Studies that are active and approved in the RRUC database will receive a request for a study update at the beginning of each FY. Study staff will be responsible for submitting the check-in within 30 days of receiving the request. To ensure that the check-in is shared with accurate study staff, please ensure that you provide PI and/or CRC updates to imagingresearch@cchmc.org.

Study teams wishing to close their study in the RRUC database prior to the annual check-in can do so by reaching out to imagingresearch@cchmc.org, and their team will not receive a notification at the beginning of the FY.