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The Human Imaging Research Office: **An Introduction**

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An overview of the HIRO's services

Road Map

- **What is medical imaging?**
- **What (and why) is the HIRO?**
- **What services does the HIRO provide, and how do they support research?**

Road Map

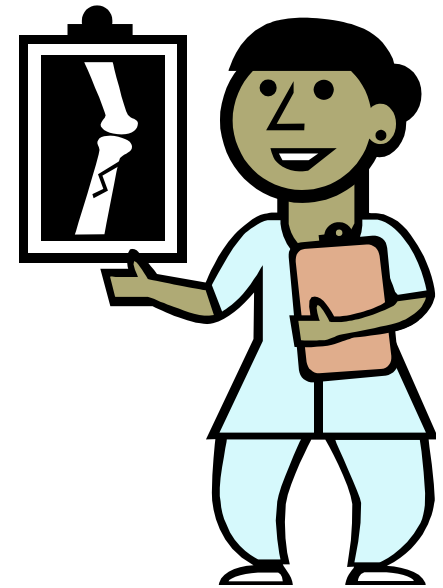
- **What is medical imaging?**
- What (and why) is the HIRO?
- What services does the HIRO provide, and how do they support research?

What is Medical Imaging?

- **Medical imaging** is the use of equipment and techniques to create images of the human body for clinical care and/or scientific research.
- There are a variety of medical imaging techniques that are often used to create images of internal structures and organs.
- Imaging techniques may be **spatial** (highlighting structure and anatomy) or **functional** (highlighting physiology). In some cases, they can be both.

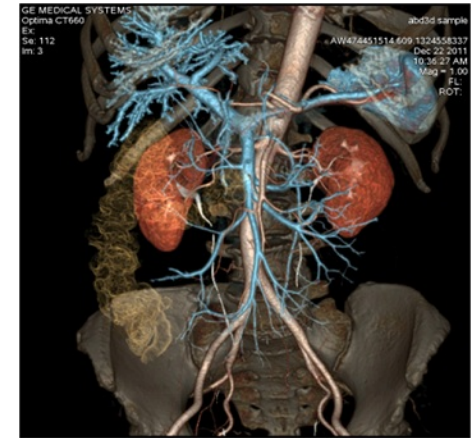
What is Medical Imaging?

- Most modern imaging techniques can create images of internal structures and physiology quickly and in a minimally invasive manner.
- The images can be used to identify abnormalities, diagnose diseases, and guide treatment.
- The images can be stored and archived so anatomy and diseases can be tracked over time.



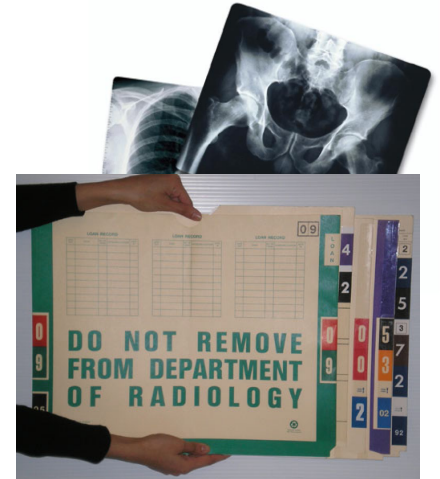
What is Medical Imaging?

- Different types of imaging methods are known as **modalities**.
- The basic imaging modalities are:
 - Radiography (x-ray) and Fluoroscopy
 - Computed Tomography (CT)
 - Magnetic Resonance Imaging (MRI)
 - Ultrasound (general, vascular, echocardiography)
 - Nuclear Medicine (scintigraphy, SPECT, PET)
- Each modality operates on a different principle and has different advantages and disadvantages.



What is Medical Imaging?

- **Film** was the original method of presentation for all modalities.
- Nearly all modern medical images are created and stored as **digital image files**.
- These images are typically stored in a hospital's **Picture Archiving and Communication System (PACS)**, a centralized archive where staff and clinicians can easily store, retrieve and review a patient's imaging examinations.



What is Medical Imaging?

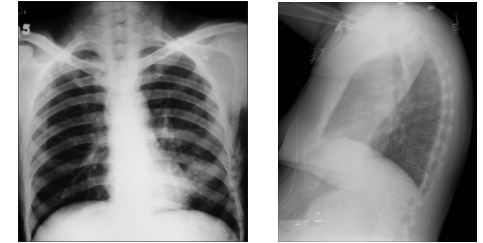
- Digital medical images are usually stored in **DICOM** format (as opposed to formats like jpeg, etc.).
- DICOM is an acronym for **D**igital **I**maging and **C**ommunications in **M**edicine. It is the industry standard format for medical images*.
- DICOM images contain a wide variety of information in their **headers**, including information about the patient and the parameters used to create the image.
 - Information stored in an image header is not necessarily visible when reviewing the image; special software is often required to view header information.

What is Medical Imaging?

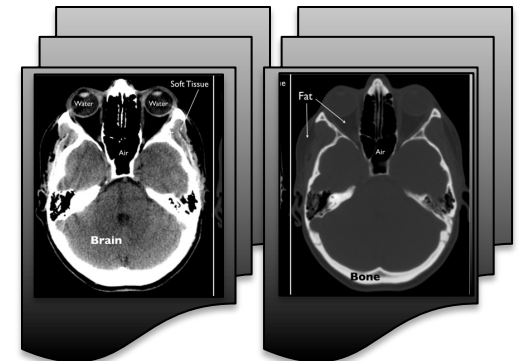
- The terms **exam**, **scan**, and **study** are often used interchangeably to refer to a single imaging examination.
- The number and type of images that are grouped together as a single “exam” vary depending on the modality, facility procedures, and other factors.
- All images that are considered part of the same exam are grouped under a single **accession number** (or scan number) in the patient’s medical record. This number is unique to the exam; no two exams within the same facility will have the same accession number.

What is Medical Imaging?

- For example:
 - A single “chest x-ray” is generally two images - a PA view and a lateral view (sometimes more depending on patient size).
 - A single “head CT scan” may consist of hundreds of images grouped into many different series. Each series may have a different filter applied or a different reconstructed geometry or thickness. From the patient’s perspective, however, they may have been “scanned” only one or two times.



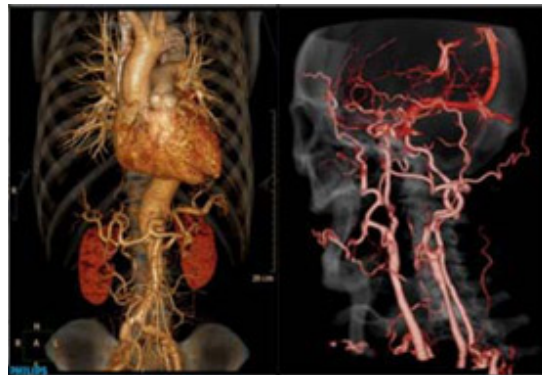
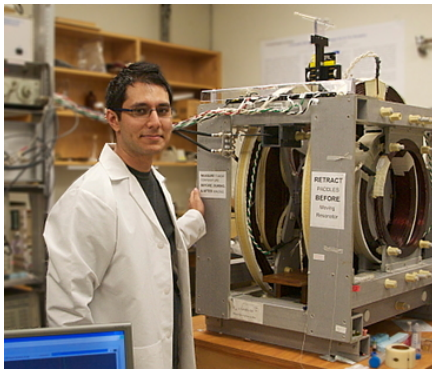
A PA view (left) and lateral view (right) of the chest, comprising a single “chest x-ray” exam.



A soft tissue image stack (left) and bone image stack (right) of the head, comprising a single “CT head” exam.

What is Medical Imaging?

- Within the context of clinical research, the use of medical imaging can usually be divided into two broad categories:
 - **Clinical Trials**
 - **Basic Science**



What is Medical Imaging?

- **Clinical trials** often use imaging to:
 - ✓ Determine patient eligibility.
 - ✓ Measure response to treatment.
 - ✓ Determine if an endpoint has been met.
- To support these goals:
 - Imaging may need to be performed at specific intervals defined by the trial protocol.
 - Imaging may need to be performed using guidelines and parameters specific to the trial.
 - De-identified copies of exams may need to be provided to the trial sponsor or central reviewer.

What is Medical Imaging?

- **Basic science research** may include:
 - ✓ The investigation of a new imaging technique, or a novel use of an existing technique.
 - ✓ The investigation of novel image processing and analysis methods.
 - ✓ The investigation of artificial intelligence in disease detection, diagnosis, or clinical decision making.
 - ✓ Epidemiologic investigations or quality improvement investigations.
 - ✓ The investigation of novel radiotracers or contrast agents.
 - ✓ Pre-clinical imaging (small animal imaging, etc.).
- **To support these goals:**
 - Cohorts may need to be identified based on specific criteria, including imaging-centric criteria.
 - Large amounts of de-identified imaging exams may need to be provided to the investigator.

What is Medical Imaging?

- How do investigators properly incorporate medical imaging into their research?
- How do investigators and imaging personnel ensure that imaging exams adhere to research protocols?
- How do investigators obtain the appropriate image data, and how do we ensure it has been properly de-identified?



Road Map

- What is medical imaging?
- **What (and why) is the HIRO?**
- What services does the HIRO provide, and how do they support research?

Why is the HIRO a thing?



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- It is becoming increasingly common for clinical trials to include **imaging manuals**.
- These manuals may include specific scan parameters and paperwork that must be utilized when performing imaging exams on a trial patient.



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Why is the HIRO a thing?

- Improperly de-identified image data carries increasingly significant institutional risks, as evidenced by the 2007 breach of mammography research data at UNC.
 - The database contained image and demographic data, and was breached due to inadequate information security.
 - UNC paid \$250,000 to notify roughly 180,000 patients and set up a call center to field questions about the breach.
 - The principal investigator, a tenured professor, was initially fired, but after appeal was demoted. Concerns were raised regarding the obligation of individual investigators vs. their institutions with regard to data security.
- <https://campustechnology.com/articles/2009/10/09/u-north-carolina-undertakes-review-in-face-of-7-state-data-breach.aspx>
 - <https://www.insidehighered.com/news/2011/01/27/unc-case-highlights-debate-about-data-security-and-accountability-for-hacks>
 - http://www.rsna.org/uploadedFiles/RSNA/Content/News/PDF/2011_RSNA_New_PDF/003%20RSNA_News_March2011.pdf

What is the HIRO?

- The mission of the **Human Imaging Research Office:**

“...to facilitate University of Chicago investigators conducting clinical trials and research studies that require medical imaging, and to ensure that the necessary imaging is performed and distributed in compliance with the research protocol, IRB requirements, and HIPAA regulations.”



What is the HIRO?

- The HIRO is a BSD **Core Facility** under the direction of the Office of Shared Research Facilities (OSRF).
- Oversight of the HIRO is governed by its Faculty Oversight Committee.
- Day-to-day direction and leadership of the HIRO is provided by its Technical Director and Faculty Director.
- The HIRO occupies a single office in Mitchell/Billings.



Photo credit Sara Serritella/UChicago ITM

What is the HIRO?

- The HIRO maintains strong relationships with many BSD departments and sections, including Radiology, Cardiology, and Oncology.
- HIRO staff are members of, or participate in, several clinical research and informatics committees and initiatives, including:
 - ❖ Clinical Trials Review Committee (CTRC)
 - ❖ BSD Cyber Risk Management Group
 - ❖ Clinical Research Data Warehouse committees
 - ❖ BSD Information Security Office committees

What is the HIRO?

- Internally, the HIRO is loosely divided into three operational teams:
 - ❖ **Image Acquisition Team** – responsible for coordinating the initiation, planning and execution of research-related imaging.
 - ❖ **Image Measurement and Analysis Team** – responsible for providing investigators with image-based measurements or analyses for research projects.
 - ❖ **Image Distribution Team** – responsible for providing properly de-identified image data to investigators or trial sponsors, and for assisting in the development of image databases.

What is the HIRO?

- The HIRO has three full-time staff members:
 - ❖ Technical Director
 - ❖ Research Imaging Coordinator
 - ❖ Image Distribution Specialist
- The HIRO also has four part-time professional staff members:
 - ❖ 3 Software Developers
 - ❖ Research Radiologist

What is the HIRO?



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Road Map

- What is medical imaging?
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HIRO Primary Services

- The HIRO provides investigators and research staff with a number of services to support the imaging needs of their clinical trials and research projects.
 - Site Initiation / Qualification
 - Imaging Exam Coordination and Monitoring
 - Imaging Exam De-identification and Distribution

Service: Site Initiation



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- The HIRO assists with the imaging-related study initiation activities noted below:
 - ✓ **Site surveys** – the completion of imaging surveys and questionnaires.
 - ✓ **Site training** – participation in imaging tele-training and online training sessions.
 - ✓ **Test scans** – performance and submission of test imaging when required.
 - ✓ **SIVs** – participation as imaging personnel in site visits when required.

VIRTUALSCOPICS
Imaging for Clinical Trials

CT/MRI Site Questionnaire
(VS 33305)

Protocol: A [redacted]
[redacted]
assessments will be performed using contrast enhanced CT scans of the chest, abdomen and pelvis or a non-contrast CT scan of the chest and a gadolinium IV contrast enhanced MRI scan of the abdomen and pelvis. Assessments will be performed at Baseline, Week 8 (Cycle 1), Week 16 (Cycle 2), every 8 week cycles thereafter up to Cycle 12, Follow up and Survival Follow up visits. An MRI of the brain will be performed for subjects with a history or symptoms of brain metastasis at Baseline or as clinically indicated.

Please Note: VirtualScopics strongly encourages that the same scanner be used on a subject throughout the study. The use of the same scanner may significantly reduce acquisition and measurement variability. Please contact VirtualScopics if you have any questions or concerns with this.

Completing and Submitting This Form
Please ensure when completing this form that the information is correct and is completed by an authorized site representative. Use N/A for anything not applicable; please do not leave any blanks. Send the completed form to VirtualScopics via one of the following methods:
1. Email to vsSite_Management@virtualscopics.com
2. Fax to +1 585 218 7350

Site Information

Principal Investigator: [redacted]
Clinical Site Name: [redacted]
Site Number: [redacted]

CT Scanner

Manufacturer: ☐ GE ☐ Siemens ☐ Philips ☐ Other: [redacted]
Model: [redacted]
Software Version: [redacted]
Is this a Multi-slice Scanner? ☐ Yes ☐ No **If Yes: Number of Slices:** [redacted]
Does your Site use a Power Injector? ☐ Yes ☐ No **If Yes: Manufacturer:** [redacted]
Name of Contrast Agent(s) Used: IV: [redacted]
Oral: [redacted]

CT Imaging Contact: **Name:** [redacted]
Title: [redacted]
Phone: [redacted]
Email: [redacted]

Ship To Address: **Address:** [redacted]
(for CT Study Materials) **City:** [redacted]
Country: [redacted]
State/Province: [redacted]
Zip/Postal Code: [redacted]

An example of an imaging questionnaire.



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Service: Site Initiation

- The HIRO also reviews protocols and imaging guidelines.
 - ✓ The HIRO reviews most trials that are routed through the **CTRC**.
 - ✓ Investigators can optionally request HIRO review or input on their protocol via the **AURA IRB** system.
 - ✓ The HIRO provides input during a study's **budget** process if requested (for example, by providing guidance to the Dept. of Medicine's CTFG).
 - ✓ HIRO staff will create a trial-specific workflow if needed to ensure compliance with its imaging guidelines.

Service: Exam Coordination



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- The imaging parameters required by a clinical trial may not match UCM's standard parameters.
- The HIRO can determine if trial-specific parameters are needed:
 - ✓ **Exam ordering** – identification of the correct orderables in EPIC and order comments.
 - ✓ **Exam monitoring and assistance** – availability to provide help to coordinators and imaging technologists at the time of an imaging exam.
 - ✓ **Protocol programming** – we can work with the appropriate imaging techs to program trial-specific imaging parameters when needed.

PARENEX International
21871 Image Acquisition Guidelines
Version 1.0

MEDICAL IMAGING SERVICES

21871 Image Acquisition Guidelines
Version 1.0

perceptive

IMAGE ACQUISITION GUIDELINES
MULTI SLICE HELICAL CT • SINGLE SLICE HELICAL CT

• Once the parameters listed below have been configured, they shall remain consistent throughout the Scanning run.

REQUIRED SCAN 1: VOLUMETRIC MBCT SUPINE INSPIRATORY SCAN
REQUIRED SCAN 2: ST PNE EXPIRATION HBCT SCAN
REQUIRED SCAN 3: PRONE INSPIRATION HBCT SCAN
SCAN 1: VOLUMETRIC MBCT SUPINE INSPIRATORY SCAN

(Parameters for a 64 detector helical CT. If necessary, please adapt the following parameters for your scanner.)

Subject positioning: Supine, ensure no subject movement during acquisition and consistent positioning throughout the study. Make sure patient is well centered in AP and lateral directions.

Breathing Instructions: Note: Allow sufficient pauses between breath holds to avoid motion artifact. Do not use auto voice; watch subject's respirations. Rehearse the breath holds before acquisition.

Scan: Lung apices to costophrenic recesses

Injection/Contrast: None

Scanning mode: Helical

Dose modulation: GE: HDDE scanner - Auto mA OFF
Philips, 64 scanner - Dose Right (ACA) OFF
Siemens, 64 scanner - Care Dose OFF
Toshiba, Aquilion 64 - Sure Exp. 1D OFF

Detector: 64 x 0.625 mm (GE example, varies by make and model)
64 x 0.5 mm (Toshiba, Aquilion 64 example)

Scan and Display FOV: Set scan FOV (C-FOV) to ensure the entire of the patient is encompassed within the FOV while maintaining as much space around the patient. For reconstruction, adjust the display FOV to encompass image at the largest anatomical location and do not change it throughout the scan.

Contrast: None

KVP: 120 kVp

mA: GE: HDDE scanner - 100 mA
Philips, 64 scanner - 100 mA
Siemens, 64 scanner - 100 effective mA
Toshiba, Aquilion 64 - 100 mA

Pitch: GE: HDDE scanner - 1.084
Philips, 64 scanner - 0.923
Siemens, 64 scanner - 1.0
Toshiba, Aquilion 64 - 1.484 (Fast Pitch)

Rotation time: 0.5 s

Thickness: 1.25 mm

Interval: 1 mm

Matrix: 512 x 512

Motion Artifact: Remove All scans which contain motion artifact

Hard Film (If Used): 4 mm

TP-21871-000-01 Image Acquisition Guidelines Template
Effective Date: 02 Jun 11
CONFIDENTIAL DOCUMENT
Page 7

Example guidelines documents.



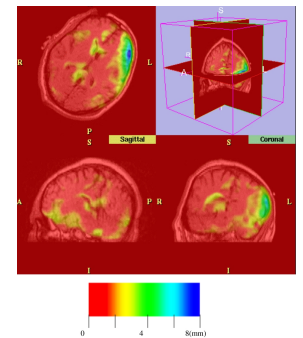
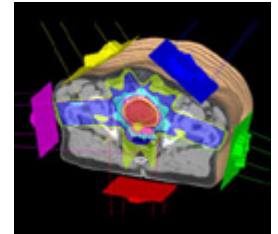
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Service: Exam Coordination

- The HIRO may provide a customized workflow for ordering imaging exams.
- The HIRO leverages existing RIS infrastructure (like the CLI Protocols System) and its own website to provide materials and instructions to technologists.
- The HIRO has also developed tools to monitor the EPIC schedule for imaging exams of particular interest.

Service: Image Analysis

- Some research projects or clinical trials may require specialized **lesion or tumor measurements, volumetric measurements**, or other types of analysis.
- The HIRO can evaluate the feasibility of the desired analysis and in many cases can provide the requested analysis in the form of customized reports.
- The HIRO can also match investigators seeking specific types of image analysis to imaging research groups on campus that may be pursuing similar or relevant topics, fostering collaboration.





- **Image Data Distribution for Clinical Trials**

- Clinical trials will often require that **de-identified** copies of imaging exams be submitted to a central reviewer or core lab.
- Increasingly, the use of a trial-specific electronic submission system is required.
- The HIRO has been designated as the official group for providing **compliant, de-identified copies** of imaging exams for research purposes.
- The HIRO can tailor its de-identification paradigm to meet the requirements of the specific trial.



Service: Image Data Distribution



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• Image Data Distribution for Clinical Trials

- Some trials may require the completion of **data transmittal forms** with each exam submitted.
- These forms vary in complexity.
- The HIRO is generally able to complete imaging transmittal forms and patient baseline forms, and will do so when submitting exams if required.

The image displays two example data transmittal forms. The left form is a 'TRANSMITTAL FORM' with sections for Subject Information, Visit Information, Comments, and SQC Results. The right form is a 'PET Acquisition Document' with sections for Subject Information, Imaging Information, Pre-Injection Information, Injection Information, Imaging Protocol Parameters, and Technical Comments. Both forms contain various input fields, checkboxes, and dropdown menus for clinical trial data entry.

Example data transmittal forms.



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- **Image Data Distribution for Basic Science**

- The HIRO also provides image data to basic science researchers and investigator-initiated projects.
- The HIRO can provide copies of properly de-identified imaging exams for **retrospective studies**, **chart reviews**, and other types of epidemiologic, analytic, or quality improvement projects.
- The HIRO can assist with cohort identification and build databases of imaging exams based on specific criteria. This may be performed in conjunction with the Clinical Research Data Warehouse team.
- The HIRO also vets access to the UChicago Medicine IT Electronic Honest Broker and iBroker systems for eligible imaging-centric projects.



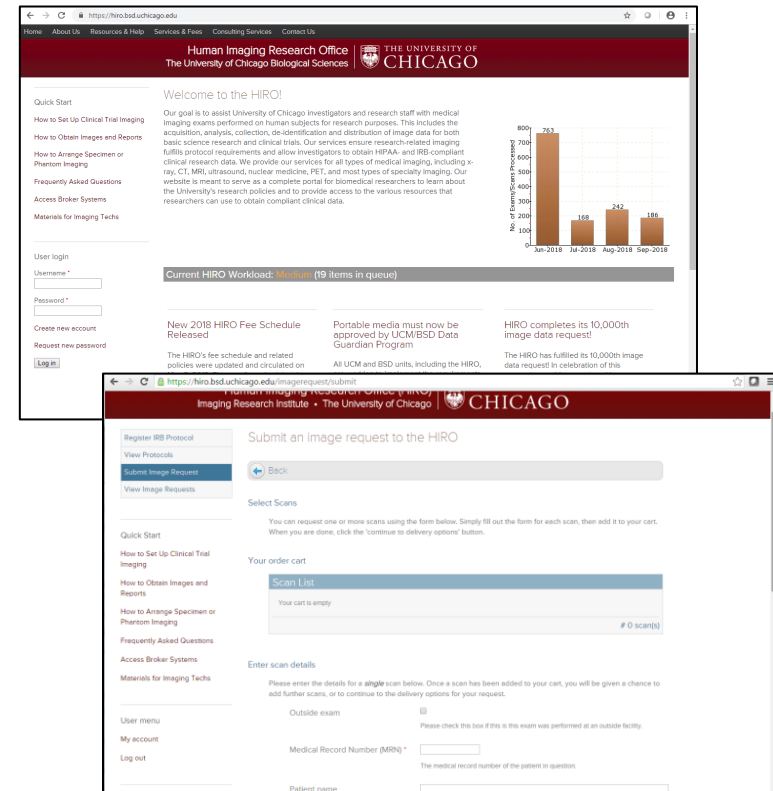
Service: Image Data Distribution



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- Requests for image data must be submitted via the HIRO's website.
- In order to submit requests, you must first create an account in the system.
- You must also register the research study in question with the HIRO (or if it is already registered, you must request access to it).
- Quick tutorials for all of these activities are available on the HIRO's website.



<https://hiro.bsd.uchicago.edu>



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Service: Image Data Distribution



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- Although most medical imaging at UCM is performed by the Department of Radiology, several departments and sections perform and maintain their own imaging exams. For example:
 - **Section of Cardiology:** Echocardiography, Cardiac cath procedures
 - **Section of Endocrinology, CRC:** DXA scans
 - **MRI Research Center:** Functional MRI scans, Research MRI scans
 - **Dept. of Ob/Gyn:** Ob/Gyn ultrasound
 - **Dept. of Radiation Oncology:** Therapy planning CT scans
 - **Dept. of Surgery:** Vascular ultrasound, OCT scans



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Service: Image Data Distribution



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- In addition, patient scans are often brought in from outside institutions and facilities, including affiliates (e.g., Silver Cross, Orland Park, etc.).
- This includes scans loaded into the hospital PACS and scans delivered on discs or other media.
- The HIRO is generally able to create de-identified copies of all types of scans, regardless of origin, for research and clinical trial purposes.



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- **Delivery Methods for Clinical Trials**

- The HIRO will generally submit imaging exams directly to the sponsor electronically and has experience using most imaging EDC systems.
- The HIRO can also provide copies of imaging exams on professionally labeled CDs or DVDs for trials that require this format.

- **Delivery Methods for Basic Science**

- The HIRO supports all University cloud storage products.
- The HIRO can also copy data to portable media that meet BSD guidelines.





- **Current Data Processing Methods**

- The HIRO currently utilizes several different open-source and internally developed software tools to build databases and process image data.
- Several of these tools (as well as the HIRO website) are operated on virtual machines hosted by the CRI.

- **Future Data Processing Methods**

- The HIRO is currently working to consolidate its various tools into a single, automated, user-friendly system: the “Assembly Line.”
- The HIRO is also developing a framework for a “Biomedical Image Repository” intended to allow investigators to store and share medical images in a metadata-aware database for both archiving and easy cohort generation.



Service Fees

- The HIRO recovers its costs through a recharge model.
 - ✓ HIRO fees are subject to standard University indirect rates.
 - ✓ The HIRO's invoicing and collections are handled by the OSRF.
- Most industry clinical trials are able to include the HIRO's fees in the trial budget.
- Investigator-initiated projects can include the HIRO's fees in grant budgets and can utilize local funding programs like ITM Core Subsidy awards.
- The HIRO also receives a subsidy from the Cancer Center, and it offers a volume discount for qualifying projects.

The Importance of the HIRO

- The HIRO's primary goal is to ensure that the imaging exams performed for, and distributed to, clinical trials and research projects are compliant with the research protocol, IRB requirements, and HIPAA regulations.
- Failure to properly engage the HIRO's services with your trial may lead to:
 - **Queries and Deviations** – Imaging exams that are not performed according to trial guidelines or properly submitted to the trial sponsor will generate numerous trial queries and may even trigger an official protocol deviation or violation.
 - **Repeat Imaging** – Imaging exams that are not performed according to trial guidelines may need to be repeated at UCM's expense. This may also increase patient radiation exposure and decrease patient satisfaction.

The Importance of the HIRO

- Failure to properly engage the HIRO's services with your trial may lead to:
 - **Patient Removal** – Imaging exams that are not performed according to trial guidelines or properly submitted to the trial sponsor may force the removal of the patient from the trial. This may have an adverse impact on patient care and satisfaction.
 - **FDA Action** – Numerous or repeated deviations or violations may prompt an audit from both the trial sponsor and the FDA. Such audits may lead to the suspension of patient enrollment and trial activities and could jeopardize participation in future trials.
 - **HIPAA Compliance** – Improperly de-identified data may generate protocol deviations or violations and may even trigger federal HIPAA violations and fines to the institution.

Questions?

- The HIRO is always available to help answer any imaging-related questions you might have! If we can't answer them, we will help find the people who can!

❖ **Phone:** 702-9172

❖ **Fax:** 834-6721

❖ **Office:** Billings I-102

❖ **Website:** <https://hiro.bsd.uchicago.edu>

❖ **Email:** hirohelp@bsd.uchicago.edu

❖ **Hours:** 8AM – 4PM, Monday - Friday



Photo credit Sara Serritella/UChicago ITM

