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MEDICINE &
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SCIENCES

Medical Imaging in Clinical Trials: The Human Imaging Research Office and You!

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Orientation for new study coordinators

What is Medical Imaging?

- **Medical imaging** is the use of equipment and techniques to create images of the human body for clinical purposes 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 nature. In some cases, they can be both.

What is Medical Imaging?

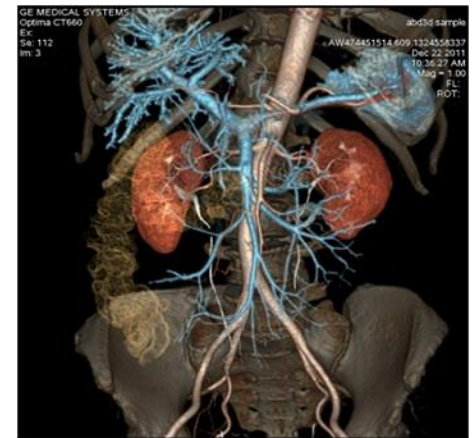
- Most modern imaging techniques can create images of internal structures and physiology quickly and in a minimally invasive manner.
- The images can be used to identify abnormalities, diagnose diseases, and guide treatment.
- The images can be stored and archived so anatomy and diseases can be tracked 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 (US, echo, vascular)
 - Nuclear Medicine (scintigraphy, SPECT, PET, bone scans)
- The HIRO assists with all of these modalities (and more)!



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 routine intervals defined by the trial protocol.
 - Imaging may need to be performed using guidelines and parameters specific to the trial.
 - Copies of exams may need to be provided to the trial sponsor.



- The BSD's **Human Imaging Research Office** (or HIRO) is a core facility that provides local investigators and research staff with a number of services to support the imaging needs of their clinical trials.
 - Site Initiation / Qualification
 - Imaging Exam Coordination and Monitoring
 - Imaging Exam De-identification and Distribution

Service: Site Initiation

- The HIRO assists with the imaging-related 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.

The image shows a screenshot of a 'CT/MRI Site Questionnaire' form. The form is titled 'CT/MRI Site Questionnaire' and has a reference number '(VS 33305)'. It includes a 'Protocol' section with a dropdown menu and a text area. Below this is a 'Please Note' section with a paragraph of text. A 'Completing and Submitting This Form' section provides instructions and contact information. The 'Site Information' section contains fields for 'Principal Investigator', 'Clinical Site Name', and 'Site Number'. The 'CT Scanner' section has checkboxes for 'GE', 'Siemens', 'Philips', and 'Other', along with fields for 'Model' and 'Software Version'. There are also checkboxes for 'Is this a Multi-slice Scanner?' and 'Does your Site use a Power Injector?'. The 'Name of Contrast Agent(s) Used:' section has a dropdown for 'IV:' and a text area for 'Oral:'. The 'CT Imaging Contact:' section has fields for 'Name:', 'Title:', 'Phone:', and 'Email:'. The 'Ship To Address:' section has fields for 'Address:', 'City:', 'Country:', 'State/Province:', and 'Zip/Postal Code:'. The form footer includes 'FORM 001 - v. 2.0 - 04/2014', 'Page 1 of 2', and 'FORM 0002 - v. 1.0 - 04/2014'.

An example of an imaging questionnaire.

- The HIRO also reviews protocols and imaging guidelines.
 - HIRO staff will assess feasibility and create a trial-specific workflow if needed to ensure compliance with a trial's imaging guidelines.

Service: Exam Coordination



- **Not all scans are equal:** the imaging parameters required by a 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.

PAREXEL International
21071 Image Acquisition Guidelines
Version 1.0

MEDICAL IMAGING SERVICES

A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy in Combination with [REDACTED] Adva

Image Acquisition Guidelines

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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 Screening scan.

REQUIRED SCAN 1: VOLUMETRIC MDCT SUPINE INSPIRATORY SCAN
REQUIRED SCAN 2: SUPINE EXPIRATION HRCT SCAN
REQUIRED SCAN 3: PRONE INSPIRATION HRCT SCAN

SCAN 1: VOLUMETRIC MDCT 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 direction.
Breathing Instructions	Inspiration Supine: Suspended full inspiration Note: Allow sufficient passes between breath holds to avoid motion artifact. Do not use auto voice; watch subject's respirations. Release the breath holds before acquisition.
Scan locations/coverage	Lung apices to costophrenic recesses
Scanning mode	Helical
Scanning plane	Axial
Dose modulation	GE: HDGE scanner - Auto-mA OFF Philips: 64 scanner - Dose Right (ACS) OFF Siemens: 64 scanner - Care Dose OFF Toshiba: Aquilion 64 - Sure Exp. 3D OFF 64 x 0.625 mm (GE example; varies by make and model)
Detector	64 x 0.5 mm (Toshiba Aquilion 64 example)
Scan and Display FOV	Set scan FOV ("cFOV") to ensure the extent of the patient is encompassed within the FOV while minimizing air space around the patient. For reconstructions, adjust the display FOV to encompass lungs at the largest anatomical location and do not change it throughout the scan.
Contrast kVp	None 120 kVp
mA	GE: HDGE scanner - 100 mA Philips: 64 scanner - 100 mA Siemens: 64 scanner - 100 effective mA Toshiba: Aquilion 64 - 100 mA GE: HDGE scanner - 0.984 Philips: 64 scanner - 0.923 Siemens: 64 scanner - 1.0 Toshiba: Aquilion 64 - 1.484 (Fast Pitch)
Pitch	
Rotation time	0.5 s
Fluorare	1.75 mm
Interval	1 mm
Matrix	512 x 512
Motion Artifact	Repeat all scans which contain motion artifact
Hard Films If Used	6 on 1

TP-FI-MG-WW-008-03 Image Acquisition Guidelines Template
Effective Date: 09 Jun 11
CONFIDENTIAL DOCUMENT Page 7

Example guidelines documents.

- The HIRO may provide a customized workflow for ordering imaging exams. Be sure to keep the HIRO in the loop and utilize this workflow to ensure your exams will meet your trial's requirements!



Service: Exam Distribution

- 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 is the **official UCM team** for providing de-identified copies of imaging exams to local teams for research purposes.
 - Usually scans performed here at UCM (including Orland Park, Silver Cross, and Ingalls), but can also include scans from other places (more on that later).
- Requests for image data are submitted to the HIRO by the research team via its website (<https://hiro.bsd.uchicago.edu>).
 - The HIRO can provide you with the data, or it can often upload the data directly to the trial sponsor/CRO.
 - Note if the *patient* wants copies of their scans, you should contact the Radiology Film Library.

Service: Exam Distribution



- 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 trial in question with the HIRO (or if it is already registered, you must request access to it).
 - To register a trial on behalf of a PI, you must become a **Technical Liaison**.
- Quick tutorials for all of these activities are available on the HIRO's website.

Human Imaging Research Office (HIRO) | THE UNIVERSITY OF CHICAGO

Imaging Research Institute • The University of Chicago

Welcome!

Our goal is to assist University of Chicago investigators and research staff with medical imaging performed on human subjects for research purposes. This includes the acquisition, analysis, collection, anonymization and distribution of image data. We also provide access to and support for the University's Broker Systems, which allow investigators to obtain HIPAA- and IRB-compliant clinical research data. Our website is meant to serve as a complete portal, or "one stop shop," for biomedical researchers to learn about the University's research policies and to provide access to the various resources that researchers can use to obtain compliant clinical data.

Month	Nbr of Exams/Scans Processed
Jan-2016	213
Feb-2016	327
Mar-2016	283
Apr-2016	140

Register IRB Protocol
View Protocols
Submit Image Request
View Image Requests

Submit an image request to the HIRO

Select Scans

Your order cart

Scan List
Your cart is empty
0 scan(s)

Enter scan details

Outside exam

Medical Record Number (MRN) *

Patent name



Service: Exam Distribution



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

Data Transmittal Form

TRANSMITTAL FORM

SUBJECT INFORMATION

Subject Number: [REDACTED] 15 Modality: multi_slic Body Region: Chest Abdomen Pelvis Brain Other

VISIT INFORMATION

Exam Date: [REDACTED] 2016
Time Point: 070_week_45 Unscheduled Visit Description:

COMMENTS

SQC RESULTS

Ensure Slice Thickness for CTs is between 2.5 and 8.0 mm : Pass
Ensure no non-DICOM files : Pass
Ensure no lossy images : Pass
Checking for gaps in images : Fail

Form Completed by: [REDACTED]

MNI PET Acquisition Document

Country ID: 78 Site ID: 28 Subject ID: E7828006
Country ID: [REDACTED] Site ID: 2016
Ligand: AV-1451 Florbetapir FDG Scan Acquisition Date: [REDACTED] DD MON YEAR

Imaging Center Name: University of Chicago Medicine PET Imaging Center
Clinical Site Name: University of Chicago Medicine

Check the appropriate PET scan: AV-1451 Baseline (Scan 1) AV-1451 Week 52 (Scan 2)
 AV-1451 Week 104 (Scan 3) AV-1451 Early Discontinuation (ED Scan)
 Florbetapir Screening (Scan 1) Florbetapir Week 104 (Scan 2) Florbetapir Early Discontinuation (ED Scan)
 FDG Baseline (Scan 1) FDG Week 104 (Scan 2) FDG Early Discontinuation (ED Scan)

Document for QC of Florbetapir or AV-1451 Production Received Prior to Injection? Yes No N/A NOTE: If QC Document has not been received, DO NOT inject subject (if QC document is applicable to your country)

Pre-Injection Information: Weight: 190.000 kg lbs kg

Injection Information:
Initial Activity in Syringe: 1.080 mCi Time Measured (24hr): 12:21
Date of Injection: [REDACTED] 2016 Time of Injection (24hr): 12:24
Residual Activity Post Injection: 0.12 mCi Time Measured (24hr): 12:26

Imaging Protocol Parameters:
Camera: Siemens Biograph mCT
Acquisition Protocol Used (Use protocol created at set-up visit): PETCT_florbetapir_Amaranth_4x5min
Recon Filter Type (e.g. Gaussian, All-pass...): GAUSSIAN Kernel (FWHM): 5 Iterations: 4 Subsets: 12
CT/Transmission Scan Start Time: 13:13 Stop Time: 13:13 (24hr clock)
Emission Scan Start Time: 13:14 Stop Time: 13:34 (24hr clock)

TECHNICAL COMMENTS:

Please fax to MNI at +1-203-401-4303 or email to corelab@mniimaging.com

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Example data transmittal forms.



Service: Exam Distribution

- The HIRO can pull copies of **most** imaging exams that are listed in the patient's EPIC chart (including **echocardiography** and **DXA scans**).
- This includes scans performed at outside hospitals, *as long as* a copy of the scan was forwarded to UCM at some point and loaded into our hospital archive (PACS).
 - If you have a copy of an outside scan on disc, you can bring it directly to the HIRO and we can de-identify & submit it to the sponsor as needed. Note you will still need to submit an image data request in our website!
- The HIRO can also assist in resolving imaging-related queries from the sponsor or CRO.
 - It is not unusual for the CRO to send queries directly to the HIRO. The HIRO may reach out to you for assistance when needed!
 - If you receive a query and you're not sure what it means, please reach out to the HIRO!

Keys to Remember

- The HIRO is here to help you! Here are some keys that will help keep your trial's imaging running smoothly:
 - ✓ **Engage the HIRO with new trials early** – if your new trial will involve imaging, contact the HIRO as soon as possible. This is especially important if the trial will use a central reviewer or requires imaging qualification. Forward any imaging materials you receive to the HIRO, and if you don't receive any, ask the sponsor to provide them!
 - ✓ **Let HIRO help with imaging questionnaires** – if you receive imaging-related questionnaires or surveys, forward them to the HIRO for review and completion. Please don't use answers from old surveys; things change all the time!

Keys to Remember

- The HIRO is here to help you! Here are some keys that will help keep your trial's imaging running smoothly:
 - ✓ **Notify the HIRO of upcoming scans as soon as possible** – remember to keep the HIRO in the loop when you schedule imaging appointments! If the HIRO asked to be notified when scans are scheduled, be sure to email the HIRO as soon as possible. This will allow the HIRO to provide the imaging technologists with the resources needed to perform the exam properly.

HIRO Email: hirohelp@bsd.uchicago.edu

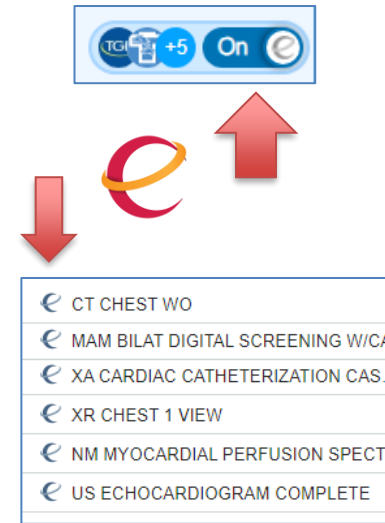
Keys to Remember

- The HIRO is here to help you! Here are some keys that will help keep your trial's imaging running smoothly:
 - ✓ **Submit image data requests as soon as possible** – most trials require that we submit exams 3-5 days after they are performed. Failure to do so will usually generate queries. The HIRO cannot submit an exam without the proper data request, so make sure you submit the necessary requests via the HIRO's website!
 - ✓ You can even submit an image data request for a scan scheduled in the future!



Keys to Remember

- A note about EPIC CareEverywhere:
 - ✓ A great way to see if a patient has outside scans! – the CareEverywhere feature will display a patient’s imaging records from outside hospitals, letting us know that they have had exams performed elsewhere.
 - ✓ Not a great way to get copies of outside images! – unfortunately, CareEverywhere only lets us know that an outside scan was performed (and sometimes it will give us a copy of the report). It does **not** automatically share the actual *images*. If images must be submitted to a sponsor, *you will need to request a copy of the scan on disc from the outside facility*. Once the disc is available, you can submit an image data request via the HIRO’s website and we can use the disc to upload the images to the sponsor.



- The MRI Research Center (Mitchell Q300):
 - ✓ The MRIRC is a core facility that can perform complex MRI scans. If your trial includes MRI scans, the HIRO will review the requirements and determine if their level of complexity requires the MRIRC. The MRI requirements for most trials are relatively routine and do not require the MRIRC. The HIRO will provide you with its assessment during start-up.
 - ✓ If the HIRO assigns your trial's MRI scans to the MRIRC, we will let you know as they have a slightly different start-up and scan scheduling process. *If your trial's MRI scans have been assigned to the MRIRC, they **must** be performed by the MRIRC.*
 - ✓ If you are not sure if your trial has been assigned to the MRIRC, *please check with the HIRO.* The MRIRC cannot perform scans for trials that have not gone through their start-up process.

More Protips!

- If you submit an image data request and ask us to expedite it (“**stat**”), please be available in case there are questions.
- Similarly, please be available for discussion if you submit a large image data request (> 10 scans). Large requests often take longer to process and generate questions.
- If you receive a missing data query for a scan you’ve already requested, or if you’re not sure if a scan has been uploaded, please reach out to the HIRO and ask. Don’t submit a (duplicate) request!
- Double-check the subject numbers and time points in your image data requests (**don’t guess!**).
 - Incorrect subject IDs or time points can lead to multiple queries and require lots of time to untangle. Although the HIRO tries to double-check when possible, we don’t always have all the required information.

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:** 773-702-9172
- ❖ **Fax:** 773-834-6721
- ❖ **Office:** Billings/FMI I-102

- ❖ **Website:** <https://hiro.bsd.uchicago.edu>
- ❖ **Email:** hirohelp@bsd.uchicago.edu
- ❖ **Hours:** 8AM – 4PM, Monday - Friday



Photo credit Sara Serritella/UChicago ITM

