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

Nick Gruszauskas, Ph.D.
Technical Director, HIRO

Orientation for new study coordinators

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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)
  - Nuclear Medicine (scintigraphy, SPECT, PET)
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.
HIRO Primary Services

• 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 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.

An example of an imaging questionnaire.

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Medical Imaging in Clinical Trials: The HIRO and You! | 7
Service: Exam Coordination

• Not all scans are created 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.

• 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 group for providing de-identified copies of imaging exams to local teams for research purposes.
  - Usually scans performed here at UCM (including Orland Park and Silver Cross), 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 submit 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.
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.

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.

- 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!
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!
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 exam records from outside hospitals, letting us know that they have had scans performed elsewhere.

✓ Not a great way to get copies of outside scan 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 share the actual scan 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.
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