

Medical Imaging in Clinical Trials:

The Human Imaging Research Office and You!

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An overview of the HIRO's services



Road Map



- What is medical imaging?
- Why and What is the HIRO?
- What services does the HIRO provide, and how do they support research?
- Wrapping Up

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What is Medical Imaging?

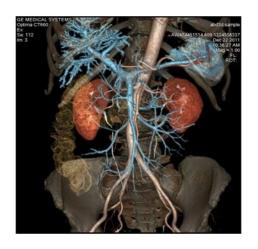


- Medical imaging is the use of equipment and techniques to create images of the human body for clinical purposes and/or scientific research.
- There are a variety of medical imaging techniques that are often used to create images of internal structures and organs.
- Imaging techniques may be spatial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

What is Medical Imaging?



- 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 (SPECT, PET, bone scans, theranostics)
- 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



- 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 images may need to be provided to the trial sponsor.



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- It is 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 participant.
- Investigator-initiated projects may also include specific parameters, which can be cumbersome to execute in a clinical setting.



- Images and related data are increasingly forwarded to external core labs for central review. Some projects may also collect images as part of chart reviews or Al development.
- Improperly de-identified image data carries increasingly significant institutional risks, as evidenced by the 2007 breach of mammography research data an UNC.
- The database contained image & 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 PI, a tenured professor, was initially fired but after appeal was merely demoted. Concerns were raised regarding the obligation of individual investigators vs. their institutions regarding data security and de-identification.
- 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





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The Washington Post

Fumbled project with NIH highlights potential pitfalls of Google's ambitions with sensitive health data.

By Douglas MacMillan and Greg Bensinge November 15, 2019 at 9:00 a.m. ES



Two days before Google was set to publicly post more than 100,000 images of human chest X-rays, the tech giant got a call from the National Institutes of Health, which had provided the images: Some of them still contained details that could be used to identify the patients, a potential privacy and legal violation.

Google abruptly canceled its project with NIH, according to emails reviewed by The Washington Post and an interview with a person familiar with the matter who spoke on the condition of anonymity. But the 2017 incident, which has never been reported, highlights the potential pitfalls of the tech giant's incursions into the world of sensitive



COO

New liability concerns emerge for radiologists who have used patient images in

MANAGEMENT IMAGING TECHNOLOGY VIDEOS CONFERENCES CUSTOM CONTENT SUBSCRIBE

Marty Stempniak | August 21, 2020 | Radiology Business | Imaging Informatics



Recent updates to search engines such as Google and Bing may expose patient imaging data previously thought to be

That's according to an update shared by the American College of Radiology, RSNA and the Society for Imaging Informatics in Medicine on Thursday, Radiologists and other providers often use patient images in educational presentations or online PDFs and, until recently, search engine spiders could not pinpoint any unique patient identifiers However, advances in web-crawling and content processing are increasingly allowing for large-scale info extraction from previously stored files thought to be safe

Physicians and other health professionals must pay special attention to this concern or open themselves up to potential privacy breaches and liability risk, the three groups advised

"Healthcare providers frequently create presentations containing medical imaging for many worthwhile purposes," according to an Aug. 20 ACR news update. "Patient privacy guidance including the Health Insurance Portability and Accountability Act and General Data Protection Regulation may extend to these situations. Providers may be responsible or protecting their patients' privacy in this context just as they are in routine clinical operations

Millions of Americans' medical images and data are available on the Internet Anyone can take a peek. EFF KAO, AND IEFF LARSON, PROPUBLICA - 9/17/2019, 2:21 PM ProPublica is a Pulitzer Prize-winning investigative newsroom. Sign up for The Big Story newsletter to receive stories like this one in your inbox. Medical images and health data belonging to millions of Americans, including X-rays, MRIs, and CT scans, are sitting unprotected on the internet and available to anyone with basic computer expertise. The records cover more than 5 million patients in the United States and millions more around the world. In some cases, a snoop could use free software programs—or just a typical Web browser—to view the images

and private data, an investigation by ProPublica and the German broadcaster Bayerischer Rundfunk fou

BIZ & IT TECH SCIENCE POLICY CARS GAMING & CULTURE STO

- https://www.washingtonpost.com/technology/2019/11/15/google-almost-made-chest-x-rays-public-until-it-realized-personal-data-could-be-exposed
- https://radiologybusiness.com/topics/health-it/enterprise-imaging/imaging-informatics/patient-images-exposed-liability-concerns
- https://arstechnica.com/information-technology/2019/09/millions-of-americans-medical-images-and-data-are-available-on-the-internet/







- https://www.modernhealthcare.com/article/20140627/NEWS/306279933/guest-commentary-more-research-hospitals-need-a-hiro
- https://doi.org/10.1016/j.acra.2019.04.003
- https://chicagoitm.org/human-imaging-resource-office-hiro-accelerates-research-itm-helps-make-it-accessible/



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 of the HIRO is provided by its Director and Faculty Advisor. The HIRO also has two full-time staff and a few part-time professional staff.
- The HIRO occupies a single office in Billings/FMI.



Photo credit Sara Serritella/UChicago ITM

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HIRO Primary Services



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

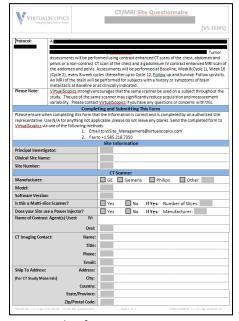
Service: Site Initiation



The HIRO assists with the imaging-related initiation activities

for clinical trials noted below:

- ✓ **Site surveys** the completion of imaging surveys and questionnaires.
- ✓ Site training participation in imaging and online training sessions.
- ✓ Test scans performance and submission of test imaging when required.
- ✓ SIVs participation as imaging personnel in site visits when required.



An example of an imaging questionnaire.

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

Service: Site Initiation

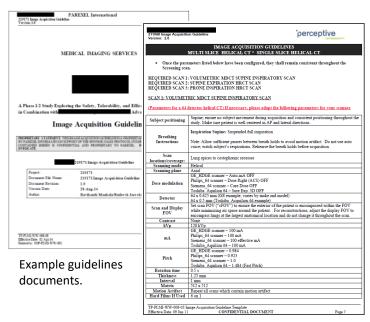


- The HIRO also reviews protocols and imaging guidelines:
 - ✓ The HIRO reviews most trials that are routed through the PRMC (formerly CTRC).
 - ✓ Investigators can optionally request HIRO review or input on their protocol via the AURA IRB system.
 - ✓ The HIRO provides input during a study's budget process if requested (for example, by providing guidance to the CTFG).

Service: Exam Coordination



- Not all scans are equal: the imaging parameters required by a trial may not match UCM's routine clinical 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.



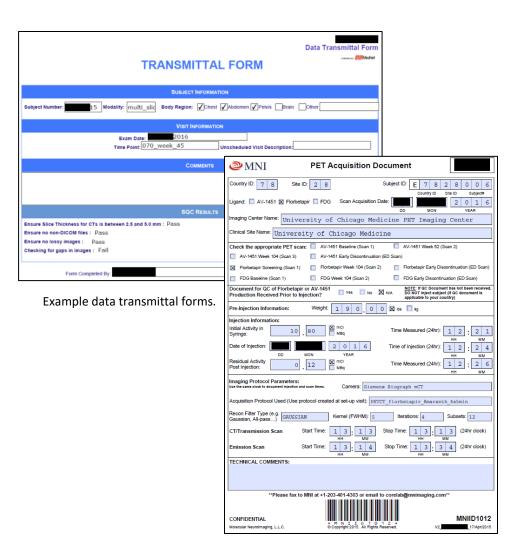
The HIRO may provide a customized workflow for ordering imaging exams. Be sure to keep the HIRO in the loop and utilize this workflow to ensure your scans will meet your trial's requirements!



- Trials will often require that de-identified copies of imaging exams be submitted to a central reviewer or core lab. The use of an imagingspecific electronic submission platform is also often 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, Crown Point and Ingalls) but can also include scans from other places*.
- 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.



- 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 transmittal forms and baseline forms and will do so when submitting exams if required.





- 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!

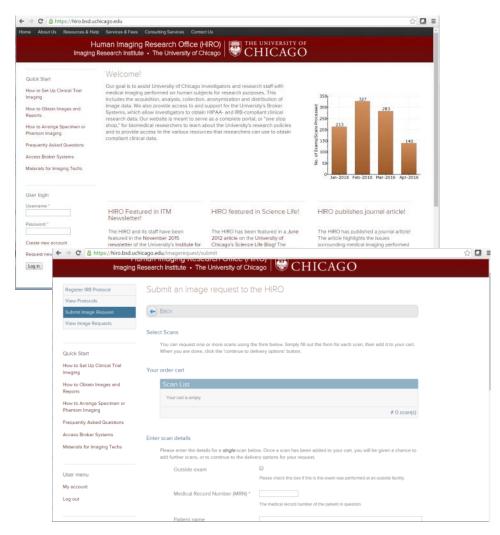


Image Data Distribution for Basic Science

- The HIRO also provides image data to basic science researchers and investigator-initiated projects.
- The HIRO can provide copies of de-identified imaging exams for retrospective studies, chart reviews, and other types of epidemiologic, analytic, machine learning/AI 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.



- 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 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 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 for qualifying projects.

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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.



- 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 site 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!



- 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

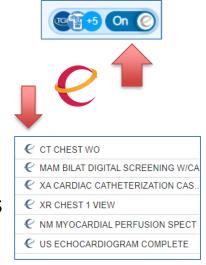


- The HIRO is here to help you! Here are some keys that will help keep your trial's imaging running smoothly:
 - ✓ Submit image data requests as soon as possible most clinical trials require that we submit exams 3-5 days after they are performed. Failure to do so will usually generate queries. The HIRO 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!





- 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: 702-9172

❖ Fax: 834-6721

❖ Office: 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

