THE UNIVERSITY OF CHICAGO | Human Imaging Research Office

Phone 773.702.9172 • **Fax** 773.834.6721
Web https://hiro.bsd.uchicago.edu • **Office Location** Billings I-102
E-mail hirohelp@bsd.uchicago.edu

WHY DO YOU NEED A HUMAN IMAGING RESEARCH OFFICE?

Clinical imaging departments are designed to accommodate consistent, standard-of-care imaging examinations. Many research studies and clinical trials, however, have unique imaging constraints that may differ substantially from those for standard clinical purposes and, thus, burden the established infrastructure. These constraints are often present even when imaging is not the focus of the study but is simply being used to asses an endpoint – imaging may be a part of the study merely to help determine if a new treatment or therapy is working, for example, and groups often wish to standardize their study's imaging across all participating sites. These constraints often include:

- **Specialized scan parameters** – the use of specific imaging equipment (i.e., equipment that has passed the sponsor's QA process) and protocols (i.e., slice spacing and thickness, etc.).
- **Unique scan interpretation guidelines** – the use of standard scan assessment paradigms such as RECIST or alternate paradigms such as mRECIST, irRECIST, iwCLL, PCWG2, RANO, etc.
- **Specific image processing and de-identification requirements** – the removal of specific Protected Health Information, the insertion of study-specific identifiers into the DICOM headers of the image files, and the delivery of image data via physical or electronic methods.

The complex infrastructure for standard-of-care clinical imaging is typically stressed by the unique technical, administrative, and compliance needs of a research protocol.

At The University of Chicago Medicine and Biological Sciences there are literally hundreds of clinical trials and research studies in progress simultaneously at any given moment, and many of them involve the use of some form of medical imaging. Ensuring the compliance of scans, their interpretation, and the resulting image data with the appropriate research protocols and all applicable regulations was only becoming more arduous, and leaving these issues to the responsibility of individual investigators was becoming less and less feasible. Consequently, a unified solution to the many imaging demands and challenges presented by clinical research was needed. The **Human Imaging Research Office (HIRO)** was created to directly address these challenges at The University of Chicago.

The HIRO's mission is 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.

SERVICES

The goal of the HIRO is to provide logistical support and ensure the compliance of research-related imaging with all relevant regulations and requirements (HIPAA, IRB, and the research protocol itself). As such, the services of the HIRO include:

- **Assistance with imaging-related site initiation activities** – this may include protocol review, participation in training teleconferences, performance of test scans, etc.
- **Completion of validation forms and data forms** – this includes the completion of site surveys and questionnaires, image data transmittal forms, etc.
- **Imaging protocol review and programming –** this includes a review of the imaging guidelines provided by the study sponsor or CRO and a comparison with UCM standard guidelines, the implementation of any necessary modifications, programming specific parameters into clinical imaging equipment, etc.
- **Assistance with study budgeting and billing**
- **Assistance with exam scheduling**
- **Assistance with image interpretation and analysis** – this may include assistance with research-related measurements and volumetric analysis.
- **Creation of customized image databases** – this includes the collection of large image databases and related metadata for retrospective studies, etc.
- **Distribution of de-identified images to researchers and study sponsors**

FEES

Service	Brief Description	Fee (Direct Cost)
Study Imaging Initiation	Covers all initiation activities and acquisition services for the life of the study.	$3,000
Image De-identification and Distribution	Exam(s) retrieved and de-identified in a HIPAA- and IRB-compliant manner, and distributed to the researcher or study sponsor via media or electronically with any required reports.	$30-60 per exam
Rush Data Requests	Requests for data that must be processed within a compressed time frame.	Addl. $10 per exam

For full details and additional information, please check out the HIRO's website at https://hiro.bsd.uchicago.edu or email hirohelp@bsd.uchicago.edu!