From: "Kenneth S. Polonsky, MD, Dean and EVP for Medical Affairs"
<dean@bsd.uchicago.edu>
Subject: HIRO Fee Policy
Date: February 20, 2014 8:52:31 AM CST
To: BSD Faculty <bsdfaculty@bsd.uchicago.edu>

Dear Colleagues:

Important documents are attached from the Department of Radiology regarding new fee schedules for imaging studies in clinical trials. These decisions were made after consultation with Clinical Chairs and other senior management. HIRO plays an important role in clinical research and compliance, which is why we have been subsidizing these services since its inception. The change in the fee schedule is believed to be fair and consistent with peer institutions. Please direct any questions regarding these changes to Drs. Paushter, Sam Armato or Nick Gruszauskas as listed in the attachments.

Kenneth S. Polonsky, MD
Richard T. Crane Distinguished Service Professor
Dean of the Division of the Biological Sciences
and the Pritzker School of Medicine
Executive Vice President of Medical Affairs
The University of Chicago
To: BSD Faculty
From: David M. Paushter, M.D.
Subject: Medical Imaging for Clinical Research/HIRO
Date: February 19, 2014

Clinical trials and other clinical research studies often require medical images to evaluate subject eligibility, disease burden, or response to therapy. These imaging examinations usually are performed on clinical equipment and would seemingly be considered “standard of care;” however, imaging for clinical research almost always requires modifications to the clinical workflow in ways that may be subtle or more substantive. Although these requirements tax the clinical infrastructure and complicate the imaging process, failure to abide by the specifications of these requirements could compromise the integrity of the study and jeopardize University of Chicago Medicine participation. Furthermore, the images that often must be sent off-site to the study sponsor for analysis or archiving contain protected health information electronically embedded in the image files; failure to properly and completely remove these data exposes the University to HIPAA violations. We cannot afford the liability and negative impact associated with either of these breaches of federal law or research compliance.

Over the past four years, the BSD has invested considerable resources in establishing the Human Imaging Research Office (HIRO). The purpose of the HIRO is to assist investigators and research staff with medical imaging performed on human subjects for clinical trials and research purposes. The activities of the HIRO include setting up imaging for clinical trials as well as the analysis, collection, anonymization, and distribution of image data per study protocol in a HIPAA- and IRB-compliant manner. Since its inception, the HIRO has played a role in over 300 clinical studies and has distributed over 89,000 imaging studies in support of research across 28 University of Chicago Medicine sections and departments. The HIRO paradigm has been published in the peer-reviewed literature and has been recognized as a key office for efficiency and compliance unmatched by many of our peer institutions. The HIRO’s infrastructure provides a valuable resource to University researchers and study personnel.

During the first two years of the HIRO’s existence, these valuable services were provided by the HIRO to investigators without charge, with funding provided entirely by the Division; during the
past two years, a modest fee structure was imposed, with Divisional funds heavily subsidizing studies that lacked the ability to pay. Now, however, the BSD must cap the subsidy provided to support the operation of the HIRO, and a new schedule of mandatory fees has been designed to reflect this shift in available support. The expectation is that investigators, working with their grant administrators and contract negotiators, will include the appropriate HIRO fees in their study budgets. Study sponsors should appreciate the contributions of the HIRO to the efficiency, integrity, and compliance of the study. Fees not covered by the study sponsor will be cost-shared with the investigator’s department.

It is imperative that HIRO services be used by all research studies that include an imaging component and that the HIRO be consulted well in advance of study initiation. Any other solution will pose considerable risk to the researcher as well as to the University of Chicago Medicine. You are encouraged to explore the services and other resources on the HIRO’s website hiro.bsd.uchicago.edu and to contact Dr. Sam Armato, Faculty Director, or Dr. Nick Gruszauskas, Technical Director, directly to learn more about the HIRO’s operation and the role that the HIRO may play in facilitating your research.

Sincerely,

David M. Paushter, M.D., FACR
To: Clinical Research Faculty and Staff

From: Samuel G. Armato, III, Ph.D.,
Faculty Director, Human Imaging Research Office

Nick Gruszauskas, Ph.D.
Technical Director, Human Imaging Research Office

Date: February 19, 2014

Re: Human Imaging Research Office Fee Policy

Over the past 11 months, the Human Imaging Research Office (HIRO) has worked with the Office of Shared Research Facilities (OSRF) and the BSD Dean’s Office to evaluate its operation and its cost recovery model. The HIRO is committed to assisting BSD investigators conducting clinical trials and research studies that require medical imaging and to ensuring that all research-related imaging is performed and distributed in compliance with the research protocol, IRB requirements, and HIPAA regulations.

The HIRO is currently providing support for over 300 research studies that are either open or preparing to open for enrollment. Its four full-time staff members are responsible for the majority of its operation: assisting with study initiation and start-up activities, actively monitoring and providing support for research-related imaging procedures, and providing de-identified image data for local research or for submission to a central group. Unfortunately, it has become clear that the HIRO’s current fee structure, which has not changed in two years, is inadequate to support the necessary staff and technology needed to achieve appropriate quality and service needs.

We have therefore agreed on a new HIRO fee policy (see attachment) and rate. This policy replaces the previous policy and becomes effective for all new studies beginning March 1, 2014. Studies currently in progress will be expected to adhere to the new policy by no later than May 1, 2014. The HIRO will also work with the IRB to review all newly submitted studies and assess any HIRO-related needs. We will continue to implement various HIRO quality improvement measures including an upgraded web site featuring new tools based on customer feedback, an automated tracking system to reduce the time between the performance of an imaging procedure and its submission to the study sponsor, and the rollout of a biomedical image repository for use by the entire BSD research community. Although we regret the necessity for increasing the cost of investigational studies to our faculty and sponsors, we believe this will allow the Human Imaging Research Office to continue to provide high quality support to all research that utilizes medical imaging while making the UCM more competitive in the clinical research arena.