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IRB Update

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Imaging Research at National Jewish Health

Douglas Stinson, BS, MCSA, Associate Director, Imaging Research

Imaging requirements for research have been steadily increasing at National Jewish Health. The Department of Radiology, the Institute for Advanced Biomedical Imaging, and the Quantitative Imaging Laboratory formed a working group, along with representatives from the Clinical Research Unit, to develop a registration process for research imaging. The goals of the registration process include the following:

- To develop constructive partnerships involving the imaging groups, investigators, and research staff at National Jewish Health
- To ensure that the imaging studies ordered for research are appropriate to the studies being conducted
- To ensure that informed consent language is consistent with the imaging studies ordered
- To identify the imaging costs associated with a project for proper budgeting and to provide the Affinity charge codes that will apply to each project
- To establish a workflow for each study that includes ordering and scheduling of imaging studies and transfer of images to the sponsor or investigator
- To determine any additional needs such as phantom imaging or study forms to be completed by a radiologist

This newly formed Research Imaging Committee is responsible for managing the registration process. An imaging registration form and checklist will be completed for each study that has imaging requirements to ensure that all needs are addressed. The committee is coordinating this effort with the National Jewish Health IRB to include the checklist with new study protocol applications for studies with imaging requirements. Studies that utilize a central IRB will also require the registration form and checklist, which will be coordinated by the committee and the individuals responsible for the study.

Please contact Will Cook (cookw@njhealth.org), Eric Yager (yagere@njhealth.org) or Doug Stinson (stinsond@njhealth.org) with any questions and to begin the registration process for studies with imaging requirements.

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Update on Right to Restrict Disclosure to Insurance Carriers

Steve Leibold, MSHA, Corporate Compliance Manager and Privacy Officer

In recent years, the IRB and Privacy Offices have been advising that when certain types of medical services performed for research are added to the electronic medical record, these services could be accessible to an insurance carrier who requests past medical records pertinent to a billable service.

Research subjects are advised of the risk of disclosure in the consent form. Below is wording from the IRB consent form template:

> Test results and other medical information gathered in this study will be stored in your medical record*<if applicable>*, research study file, or both*<if applicable>* and will be treated with the same confidentiality as other medical records here at National Jewish Health as required by state and federal regulations. *[Include the following text if stored in the medical record:]* When stored in the medical record, we may receive requests from health insurance providers for copies of this record. Records will be released according to state and federal laws. The release of this information may affect your insurability either now or in the future.

The HIPAA Omnibus Rule now allows individuals to restrict information from being provided to their insurance carrier if they (or a person or an entity who is not an insurance company) pays for a medical service. This new regulation has practical implications for research subjects because most research procedures are paid for with funding provided by a grant or commercial sponsor.

National Jewish Health's *Notice of Privacy Practices* was updated with this privacy provision (for all patients and research subjects), and the IRB's research consent form template will now contain the following additional text:

> You have the right to restrict specific research procedures from being provided to your health insurance provider. Please talk to a study Investigator or a member of his or her staff to learn more about your options.

If a research subject asks you about his or her options, be aware there are some limitations to when the restriction can be requested and what National Jewish Health can restrict. Please note that:

- A restriction must be requested by the patient/research subject on the day the service is performed.
- The individual must complete the *Right to Restrict Disclosure to Insurance Carrier* form (HIP-028), describing restricted services.
- This form must be submitted to the Health Information Management Department on the day of service.

Just because someone requests restriction does not mean that the information will remain restricted. The *Right to Restrict Disclosure to Insurance Carrier* form provides more detail about the possible need for future disclosure of restricted medical information to an insurance carrier to provide a basis for a future billable service.

Because individuals may ask nuanced questions, research subjects can be directed to the Health Information Management Department, where a member of the HIM staff can answer their questions and help them complete the form.

Form HIP-028 is considered an institutional privacy form (used in both clinical and research settings) and does not need to be submitted for IRB review.

Our institution is evaluating ways of communicating this new restriction right to currently-enrolled research subjects. We will provide more information in the near future.

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Research Manager / Team Lead Roundtable Meetings

Wendy Charles, MS, CIP, CCRP, Director, Research Regulatory Affairs

On October 11, 2013, Dr. Greg Downey introduced Research Manager / Team Lead meetings as a new research resource at National Jewish Health.

Why are these meetings being held?

The primary purpose is to educate research managers on topics that impact National Jewish Health researchers. Other goals include:

- Creating a collaborative research community
- Sharing best practices/tools with each other
- Better information = better compliance
- Managers are asked to share information they learn with faculty and research staff

How do these meetings differ from other research meetings currently offered?

These roundtable meetings are largely collaborative and are geared toward empowering researchers in a leadership role. Managers and team leads will receive timely updates about news, NJH operations, and regulations. There will be one or two compliance officials at every meeting to facilitate discussion and answer questions with the focus on best compliance practices.

As examples of recent and upcoming topics:

November 1, 2013: Doug Stinson spoke about how to work with the Radiology Department when a study involves imaging.

Dec 6, 2013: Wendy Charles will talk about IRB Authorization Agreements. These are new documents and processes that will allow the NJH IRB to cede IRB review for some types of research to other academic IRBs.

Jan 10, 2014: Astrid Eder, COMIRB manager, will share COMIRB's new processes and resources.

Feb 7, 2014: Kelé Piper, Children's Hospital Regulatory Compliance Officer, will share how to perform collaborative research with Children's Hospital Colorado.

Future topics will be driven by research managers' requests and/or regulatory updates.

Who should come to these meetings?

These meetings are intended for people who supervise or direct others who conduct clinical research. These individuals need not have a "supervisor" designation through Human Resources, but these individuals typically:

- Have an active role in overseeing clinical research
- Evaluate and modify research operations
- Lead meetings or have an active role in communicating news and regulatory updates
- Train and motivate research staff

Research Manager meetings will typically be held the first Friday of each month from 12 – 1 pm. The next meeting will be held Friday, December 6, 2013 from 12 – 1 pm in J106. The following meeting will be held January 10, 2014 (the 2nd Friday) in J105.

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Research Coordinator Training Sessions

Deb Clayton, MA, IRB Regulatory Affairs Monitor

The IRB is developing a series of seminars and workshops focused on the issues facing IRB Coordinators, Regulatory Specialists, and anyone who submits regulatory documents for review and approval. The series will be held on the third Thursday of month (times and locations to be determined), beginning in December 2013. There be a published theme and objectives for each session with the possibility of guest speakers or outside resources, depending on the session's focus. The IRB Staff will work with Nursing toward the goal of offering contact hours toward various certification requirements for these sessions. Participants are encouraged to bring questions, thoughts and their own solutions to the table. These sessions will last about an hour and will be facilitated by Deb Clayton, IRB Regulatory Affairs Monitor.

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